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Abstract

Exercise for depression in care home residents: a randomised controlled trial with cost-effectiveness analysis (OPERA)

M Underwood,* SE Lamb, S Eldridge, B Sheehan, A Slowther, A Spencer, M Thorogood, N Atherton, SA Bremner, A Devine, K Diaz-Ordaz, DR Ellard, R Potter, K Spanjers and SJC Taylor

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Background: Many older people living in care homes (long term residential care or nursing homes) are depressed. Exercise is a promising non-drug intervention for preventing and treating depression in this population.

Objective: To evaluate the impact of a 'whole-home' intervention, consisting of training for residential and nursing home staff backed up with a twice-weekly, physiotherapist-led exercise class on depressive symptoms in care home residents.

Design: A cluster randomised controlled trial with a cost-effectiveness analysis to compare (1) the prevalence of depression in intervention homes with that in control homes in all residents contributing data 12 months after homes were randomised (cross-sectional analysis); (2) the number of depressive symptoms at 6 months between intervention and control homes in residents who were depressed at pre-randomisation baseline assessment (depressed cohort comparison); and (3) the number of depressive symptoms at 12 months between intervention and control homes in all residents who were present at pre-randomisation baseline assessment (cohort comparison).

Setting: Seventy-eight care homes in Coventry and Warwickshire and north-east London.

Participants: Care home residents aged ≥65 years.

Interventions: *Control intervention*: Depression awareness training programme for care home staff. *Active intervention*: A 'whole-home' exercise intervention, consisting of training for care home staff backed up with a twice-weekly, physiotherapist-led exercise group.

Main outcome measures: Geriatric Depression Scale-15, proxy European Quality of Life-5 Dimensions (EQ-5D), cost-effectiveness from an National Health Service perspective, peripheral fractures and death.

Results: We recruited a total of 1054 participants. *Cross-sectional analysis*: We obtained 595 Geriatric Depression Scale-15 scores and 724 proxy EQ-5D scores. For the cohort analyses we obtained 765 baseline Geriatric Depression Scale-15 scores and 776 proxy EQ-5D scores. Of the 781 who we assessed prior to randomisation, 765 provided a Geriatric Depression Scale-15 score. Of these 374 (49%) were depressed

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and constitute our depressed cohort. Resource-use and quality-adjusted life-year data, based on proxy EQ-5D, were available for 798 residents recruited prior to randomisation. We delivered 3191 group exercise sessions with 31,705 person attendances and an average group size of 10 (5.3 study participants and 4.6 non-study participants). On average, our participants attended around half of the possible sessions. No serious adverse events occurred during the group exercise sessions. In the cross-sectional analysis the odds for being depressed were 0.76 [95% confidence interval (CI) 0.53 to 1.09] lower in the intervention group at 12 months. The point estimates for benefit for both the cohort analysis (0.13, 95% CI –0.33 to 0.60) and depressed cohort (0.22, 95% CI –0.52 to 0.95) favoured the control intervention. There was no evidence of differences in fracture rates or mortality (odds ratio 1.07, 95% CI 0.79 to 1.48) between the two groups. There was no evidence of differences in the other outcomes between the two groups. *Economic analysis*: The additional National Health Service cost of the OPERA intervention was £374 per participant (95% CI –£655 to £1404); the mean difference in quality-adjusted life-year was –0.0014 (95% CI –0.0728 to 0.0699). The active intervention was thus dominated by the control intervention, which was more effective and less costly.

Conclusion: The results do not support the use of a whole-home physical activity and moderate-intensity exercise programme to reduce depression in care home residents.

Trial registration: Current Controlled Trials ISRCTN43769277.

Funding: This project was funded by the National Institute for Health Research Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 17, No. 18. See the Health Technology Assessment programme website for further project information.

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Glossary

Assessment data Study data collected directly from participants.

Caldicott Guardian A Caldicott Guardian is a senior person in each National Health Service organisation, who is responsible for the protection and confidentiality of patient and service-user information.

Care homes (with or without nursing) Care homes are residential settings where a number of older people live together and have staff available 24 hours to provide personal care. Care homes with nursing must have a qualified nurse on duty 24 hours to provide additional nursing care for more dependent residents.

Care home data Data collected indirectly from care home records and National Health Service records. This includes data collected from routine care home records (see **Record data**), from staff (see **Proxy data**), and the National Health Service (see **National Health Service data**).

Care Quality Commission The Care Quality Commission (formally Commission for Social Care Inspection) is the independent regulator of health and social care in England. It promotes the rights and interests of people who use services and it has a wide range of enforcement powers to take action on their behalf if services are unacceptably poor.

Case report form A paper or electronic form used to collect research data from each participant or participating site.

Clinical record form A paper form used by the physiotherapists to record each resident's physical performance during each exercise group that they attended.

Cohort population Study participants who were present and provided baseline assessment data prior to randomisation.

Cross-sectional population All study participants irrespective of the time point at which they entered the study who provided data for end of study assessments.

Data Monitoring and Ethics Committee The Data Monitoring and Ethics Committee is an independent committee, the role of which is to safeguard the interests of the study participants, assess the safety and efficacy of the study interview, and monitor the overall conduct of the study.

Dementia specialist homes Care homes where residents must have a diagnosis of dementia to be considered for admission to the home.

Depressed cohort Study participants who provided baseline assessment data prior to randomisation and whose Geriatric Depression Scale-15 scores indicated that they were depressed at baseline.

Group exercise programme Exercise activities that are provided in a group format (and do not include teaching of skills, such as might be taught in an exercise class).

Independent Mental Capacity Advocacy Independent Mental Capacity Advocacy provides an independent advocacy service for people who lack capacity in facing decisions made by the National Health Service or local authorities on serious medical treatment, change of residence, a care review or adult protection issue.

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Mental Capacity Act The Mental Capacity Act (2005) for England and Wales is designed to support and protect people who cannot make decisions for themselves or lack the mental capacity to do so.

National Health Service data Data from the Secondary Uses Services databases held by participating primary care trusts, and the National Health Service Medical Record Information Service.

Nominated consultee If a person who lacks capacity has no personal consultee (see below), a nominated consultee can be proposed. This could be someone from an organisation (church, charity) or a professional (general practitioner, social worker), providing that they have no connection with the research study.

Personal consultee Someone trusted by the person who lacks capacity, such as a family member or friend who is not acting in a professional or paid capacity.

Physical activity assessment Assessment of physical abilities and mobility factors, along with other considerations relating to participation in a moderate-intensity exercise programme.

Primary care trust Primary care trusts receive budgets from the Department of Health to commission and provide primary care and community services across the local area and to commission hospital services for patients.

Process evaluation A process evaluation can assess to what degree a programme was implemented, including what activities were carried out, the degree to which the priority population was reached, and what the barriers were to adoption and implementation of the intervention.

Proxy data Assessments by care home staff of participant's health state and social interaction.

Record data Data collected directly from routine care home records.

Trial Steering Committee The Trial Steering Committee is a committee responsible for the overall supervision and progress of a study ensuring it is conducted in accordance with the principles of Good Clinical Practice and the relevant regulatory requirements.

Whole-home intervention A whole-home, 'ecological' intervention directed at changing the whole-home environment and culture within care homes.

List of abbreviations

A&E	accident and emergency
C&W	Coventry and Warwickshire
CES-D	Center for Epidemiologic Studies Depression Scale
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
DMEC	Data Monitoring and Ethics Committee
EQ-5D	European Quality of Life-5 Dimensions
HDRS	Hamilton Depression Rating Scale
ICD-10	*International Statistical Classification of Diseases and Related Health Problems*, Tenth revision
MADRS	Montgomery–Åsberg Depression Rating Scale
NA	not available
NEL	north-east London
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
NOK	next of kin
NSAID	non-steroidal anti-inflammatory drugs
OR	odds ratio
SD	standard deviation
SSRI	selective serotonin re-uptake inhibitor
WHO	World Health Organization

All abbreviations that have been used in this report are listed here unless the abbreviation is well known, or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

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Executive summary

Background

The population of Britain, as in other countries, is ageing and the residents of care homes are increasingly frail. Many care home residents have depression. Much of this depression is not recognised either by the care home staff or the resident's general practitioner. There is limited evidence that pharmacological treatments are effective for depression in the very elderly and ample evidence for the high incidence of adverse events. The National Institute for Health and Care Excellence guidelines do not recommend drug treatment for mild depression; they suggest that drugs should be used only as part of a more holistic package of care for those with moderate depression. For the elderly, the guidelines recommend that their poor physical state and social isolation should be addressed. Interventions that may address these multiple requirements are therefore needed.

Exercise is a promising non-drug intervention for depression. Exercise may have a central effect on depression through an increase in the release of ß-endorphins, through an increase in the availability of brain neurotransmitters (such as serotonin, dopamine and noradrenaline), or through increases in brain-derived neurotrophic factor. Engaging in exercise may have the capacity to counteract common symptoms of depression, such as negative thought patterns including low self-esteem and anhedonia through distraction, mastery experience, improvements in self-evaluation and a sense of achievement. Further theoretical underpinning comes from the theories of positive psychology, considering the potential of exercise interventions to build on the 'virtues' and 'character strengths' such as love of learning, bravery and hope (expecting the best and working to achieve it). In addition the increased social interaction involved in a group exercise may have positive effects on mood.

Aims and objectives of OPERA

The overall aim of the OPERA study was to evaluate the impact of a 'whole-home' intervention, consisting of training for care home staff backed up with a twice-weekly, physiotherapist-led exercise class on depressive symptoms in care home residents.

Our primary objective was to compare depression levels between intervention and control homes, addressed via three primary analyses that represent different ways of expressing depression levels.

To compare:

- the prevalence of depression in intervention homes with that in control homes in all residents contributing data 12 months after homes were randomised (cross-sectional comparison)
- the number of depressive symptoms at 6 months between intervention and control homes in residents who were depressed at pre-randomisation baseline assessment (depressed cohort comparison)
- the number of depressive symptoms at 12 months between intervention and control homes in all residents who were present at pre-randomisation baseline assessment (cohort comparison).

In parallel with this effectiveness analysis there was a cost-effectiveness analysis, a process evaluation of the study, an ethics study and a post-study evaluation.

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Methods

We recruited care homes from two geographical locations: Coventry and Warwickshire (C&W) and north-east London (NEL).

We approached all apparently eligible care homes within the relevant primary care trust areas with between 16 and 60–70 beds. Interested care homes were visited by a member of the recruitment team to assess their suitability. At this time, homes were excluded if fewer than six residents were likely to be able to take part in the study, more than half of the residents had severe cognitive impairment, the majority of residents were non-English speaking, or after discussion with the study team the home felt they were too busy to participate. In care homes in which the managers consented to join the study we assessed all English-speaking, permanent residents, aged ≥65 years, excluding for potential inclusion in the study those with a terminal illness, those who were too ill to be seen at the time of assessment or who had severe communication problems, or those for whom the care home manager felt the study was not suitable for some other reason. We asked residents to give consent, or their next of kin (NOK) to give agreement, for us to collect data directly from participants, and/or from their care home and National Health Service records. Care homes wrote to the NOK of residents who lacked capacity to consent, seeking agreement for them to take part in the study.

Baseline assessments

At the baseline assessment we collected the Geriatric Depression Scale-15, Mini Mental State Examination, EuroQol 5D (European Quality of Life-5 Dimensions; EQ-5D), fear of falling and current pain, a brief physical assessment, and the Short Physical Performance Battery. We collected demographic data (age, sex, ethnicity, age at leaving full-time education) and data on length of residence and fee status from the care home records. Data on current medication use were obtained directly from residents' Medication Administration Record sheets. The resident's key carer or carer looking after them on the day of data collection was asked to complete a proxy EQ-5D, Barthel Index and Social Engagement Scale.

For our cohort analyses, all baseline data were collected prior to randomisation. For the end-of-study cross-sectional analysis we also included participants recruited after randomisation.

Follow-up

We did four cycles of follow-up data collection in each care home over several visits, usually within 1 week, at around 3, 6, 9 and 12 months after the care home was randomised. We collected Geriatric Depression Scale-15, Mini Mental State Examination, EQ-5D, fear of falling, and current pain at 6 and 12 months. We collected Short Physical Performance Battery at 12 months. We collected care home data on medication use, visits by health-care professionals, proxy EQ-5D and the Social Engagement Scale at 3, 6, 9 and 12 months. At these visits we also sought to recruit any new residents to the study.

Primary outcome measure

Our primary outcome measure was the Geriatric Depression Scale-15. This brief instrument consists of 15 yes/no questions and has been well validated in care home populations. It avoids using potentially somatic features of depression that may be misleading in this age group.

Interventions

Any intervention with a care home that is seeking to maximise physical activity and exercise has to be delivered within the existing organisational structures. A 'whole-home' intervention, using an organisational approach to encourage all residents and staff in efforts to increase the residents' level of physical activity, is more likely to achieve the positive effects sought than simply providing group exercise sessions. We used an active control intervention consisting of a package of depression awareness training for care home staff in all participating homes to ensure that they were aware of current best care for the identification and management of depression in this population.

The OPERA intervention was designed to test the effects of exercise and increased physical activity on depression and other important outcomes. We delivered a 'whole-home' exercise intervention, consisting of training for care home staff backed up with twice-weekly physiotherapist-led exercise groups.

The twice-weekly group exercise programme delivered a structured, standardised and replicable programme of exercise targeted at the physiological, biochemical and psychological mechanisms considered responsible for depressive symptoms in older people, which also accounted for the frailty of residents.

Sample size

The sample size was based on showing an increase in the remission rate for depression over 6 months from 25% to 40% at 5% significance level with 80% power. We assumed we would recruit 16 residents per home and that 40% would have depression (6.4 per home). Allowing for 15% loss to follow-up and an intracluster correlation coefficient of 0.05 mean, we needed to recruit 77 care homes (1232 residents) to cohort analyses.

Randomisation

This was a cluster randomised study, with homes as the unit of randomisation. Care homes were first stratified by location (NEL or C&W) and then minimised into intervention and control arms. Allocation concealment was ensured by using a statistician independent of the study.

Economic evaluation

Our primary economic analysis was a cost–utility analysis over 12 months, examining the cost per quality-adjusted life-year gained for all those residents who were assessed for proxy EQ-5D prior to randomisation.

Process evaluation, ethics study and long-term follow-up

Alongside the main study we carried out a process evaluation and long-term follow-up using both qualitative and quantitative methodologies to explore the process of implementing the study in a care home setting to develop a set of transferable principles regarding both the OPERA depression awareness training and the OPERA 'whole-home' exercise intervention to inform its implementation on a wider scale. We did independent observations of the process of obtaining consent from participants. We did focus groups and interviews with key informants about the process of consent in care home studies.

Results

Recruitment

Between January 2009 and March 2010, 78 homes joined the study. Prior to randomisation, we began the assessment process with 907 residents. Six died before randomisation and are not included as study participants, and for a small minority recruitment was complete only after randomisation. We recruited a further 153 participants after randomisation, making a total of 1054 participants. Of the 781 who we assessed prior to randomisation, 765 provided a Geriatric Depression Scale-15 score. Of these, 374 (49%) were depressed and constitute our depressed cohort. We found that older people participating in research may not necessarily welcome the standard informed consent framework of provision of full information and explicit written consent uninfluenced by others.

Follow-up

No care homes dropped out of the OPERA study. For the cohort analyses we obtained 484 Geriatric Depression Scale-15 scores at 12 months: 62% of those assessed at baseline, 79% of survivors and proxy EQ-5D data on 526 participants; 68% of those present at baseline, 86% of survivors. For the depressed cohort analysis we obtained 259 Geriatric Depression Scale-15 scores at 12 months; 69% of those depressed at baseline, 80% of survivors. For the end of study cross-sectional analysis we assessed 631 residents and obtained care home data from 763 residents.

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Intervention delivery

Both the control and active interventions were well received by the care homes. The activities of the physiotherapists in the homes were appreciated by both staff and residents. However, there was little evidence that we were able to change activity patterns within the intervention homes or to effect long-term changes after the intervention was withdrawn. We delivered 3191 group exercise sessions with 31,705 resident attendances and an average group size of 9.9 (5.3 study participants). On average, our participants attended around half of the possible sessions. No serious adverse events occurred during the group exercise sessions.

Clinical outcomes

There was no evidence of a positive effect from the intervention in any of our primary or secondary analyses. In the end-of-study cross-sectional analysis the odds for being depressed were 0.76 [95% confidence interval (CI) 0.53 to 1.09] lower in the intervention group. The point estimates for benefit from the OPERA intervention on the Geriatric Depression Scale-15 in both the cohort analysis (0.13, 95% CI –0.33 to 0.60) and depressed cohort (0.22, 95% CI –0.52 to 0.95) favoured the control intervention. There was no difference in fractures incidence rate ratio 1.14, 95% CI 0.60 to 1.63 or mortality [odds ratio (OR) 1.07, 95% CI 0.78 to 1.48] between the two groups. There was no evidence of a difference in the other outcomes between the two groups.

Economic analysis

Resource use and quality-adjusted life-year data, based on proxy EQ-5D, were available for 798 residents recruited prior to randomisation. In the base-case analysis, the additional National Health Service cost of the OPERA intervention was £374 (95% CI –£655 to £1404). The mean difference in quality-adjusted life-years was negligible (0.0014) (95% CI –0.0728 to 0.0699) and favoured the control arm. The probability of the intervention being cost-effective at a willingness-to-pay threshold of £20,000 per quality-adjusted life-year was 33% and at a threshold of £30,000 was 37%.

Discussion

The OPERA study was complex and multifaceted. The nature of both the intervention and population being studied means that a simpler study design would not capture all of the active intervention's possible effects (positive or negative) on care home residents. In addition to obtaining data on the effects of the intervention, we have also been able to investigate, in detail, both the process of running the study within care homes and of implementing a complex intervention within care homes. This has generated high-quality data on both how to do research in this environment and how to implement change in this environment.

The overall findings of the study are clear and conclusive. We developed a high-quality intervention that was extremely well received both by staff and residents within the care homes. Uptake of the intervention was very good and was maintained throughout the 12-month intervention period. There was not, however, any benefit on any of our primary or secondary outcome measures. The limit of the 95% confidence for possible benefit from the OPERA intervention (0.33 points on Geriatric Depression Scale-15) is around one-quarter of the minimally clinically important change for an individual and equates to a standardised mean difference of 0.1, effectively excluding any possibility of a beneficial effect on depressive symptoms, as measured on the Geriatric Depression Scale-15, from the OPERA intervention. Furthermore, in our health economic evaluation the OPERA intervention was dominated by the control intervention, i.e. the OPERA intervention cost more and had worse outcomes. These results are particularly disappointing, as nearly half of our residents were depressed and they are still in need of an effective approach to treating their depression.

That there was no difference in the prevalence of depressive symptoms between baseline and follow-up in the control group (mean Geriatric Depression Scale-15 at baseline and follow-up 4.7 and 4.6, respectively)

suggested that the control intervention was also ineffective and it is not the success of depression awareness training that means we failed to find a beneficial effect from the OPERA intervention.

Overall, this is a very robust study, which has obtained a clear answer to the research question set and has helped to develop our understanding both of how to do research in a care home environment and how care is delivered in this environment.

Conclusions

The results of this study do not support the use of a 'whole-home' physical activity and moderate intensity exercise programme, such as the OPERA intervention, to reduce depression in care home residents. Future research should consider evaluating a multifactorial intervention targeted specifically at care home residents with depression.

Trial registration

This trial is registered as ISRCTN43769277.

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Chapter 1 Background

Care homes

The population of Britain, like that of other countries, is ageing. The biggest change for health and social care systems is the expansion in the number of the oldest old (aged ≥85 years). In mid-2010, there were 1,410,700 people aged ≥85 years in the UK[1] – an increase from 600,000 in 1981. Increasing age is associated with increasing disability. This large burden of illness and disability inevitably places huge demands on health and social care services. One consequence of this is an increase in demand for long-term care for the oldest old, which, despite the increased emphasis on community care,[2] will remain a necessary component of health and social care provision.[3,4]

Even the most optimistic projections for increasing quantity and quality of care in the community leave society facing the prospect of greatly increased numbers of older people in care homes.[4] There are 18,000–19,000 care homes in England with a capacity of 450,000–469,000 places; the majority of places are residential, not involving specialist nursing care.[5,6] Nearly 90% of residents in care homes require care because of disability from long-term conditions, 72% have mobility problems, and 62% are described as confused.[7] Concerns exist about the standards of care received by care home residents.[6,8] Care standards introduced by the Care Quality Commission[9] for all care homes in England and Wales in 2011 defined minimum standards of care. These include overriding principles including that residents will be told what is happening to them; that they will receive care and support to meet their needs; that they can expect to be safe; that they will be cared for by qualified staff; and that their care will be constantly checked. The care home business has some inherent instabilities. The Care Quality Commission's 2011 report[6] on the state of health care and adult social care in England identified substantial potential for improving the quality of care homes. Even quite modest improvements in mental and physical health are likely to produce large relative increases in the number of quality-adjusted life-years available to this group, which has an extremely poor baseline level of health and life expectancy.

As much of this long-term care provision is in the private sector, and privately funded, one might question the National Health Service's interest in this area. The financial collapse of the Southern Cross Group in 2011, however, emphasises the over-riding role of the state in sponsoring an ostensibly private sector of the economy; what happens in care homes is everybody's business.[10] Large chains of care homes report that between 40% and 75% of their residents are state funded.[11]

There is a clear need for more high-quality research to identify effective and cost-effective approaches that can improve the quality of life of care home residents. Because of the very large numbers of National Health Service patients in this sector, and their major health problems, it is an appropriate area for health services research.

Care home terminology

At the time this study was designed the terms *residential home* and *nursing home* were used to distinguish between residential facilities that did, or did not, provide nursing care. Since then, the terminology has changed to *care homes with, or without, nursing*. All of our study materials and our protocol papers used the old terminology.[12,13] The results of this study will be interpreted within the current terminology. Henceforth, we will use the terms *care homes with, or without nursing*, in preference to the terms *residential home* and *nursing home* except when the older terms are critical in understanding the work or when we are reporting work by others and use their original terminology.

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Depression in care home residents

Untreated depression is a major cause of morbidity in older people, particularly in those who live in care homes. Up to 40% of care home residents meet criteria for significant depression on validated depression symptom scales.[14,15] Incidence rates for depression in care home residents are typically 6–12% per year for major depression,[16–18] with persistence of depression among people already depressed also a major contributor to the burden of morbidity.[19]

Multiple physical morbidities are expected in care home residents[20] and there is often a lack of social interaction among those living in nursing homes.[21] There is good evidence that both functional impairment and loneliness are risk factors for depression in care home residents.[22]

In many cases depression is not recognised by the care home staff or by the resident's general practitioner[23–25] and, even if recognised, it is often not treated.[26] Using various depression identification methods, only between 15% and 27% of depressed residents were identified by staff in 30 UK care homes.[27] Evidence from the USA, in contrast, suggests substantial increases in the diagnosis of depression among nursing home residents[28] and in the rates of prescription of antidepressants among nursing home residents.[28,29] This matters because depression is an important, independent predictor of adverse outcomes in older people. Among older people living in the community, depression is an independent predictor of both admission to care homes and death.[30–33] Furthermore, in care home residents, it is an independent predictor of more rapid cognitive decline,[34] increased medical service use[35] and death.[18,27] For people with dementia living in care homes, depressive symptoms are the most important single influence on their quality of life.[36] In care homes, the likelihood of persistence of depression has been shown to be between 45%[18] and 63%.[35] Depression is therefore an important target for interventions within care homes.

Approaches to managing depression among care home residents include staff training in detection,[25] multifaceted interventions involving highly qualified specialists,[15] adaptations of cognitive behavioural therapy for care home populations,[37] antidepressant medication and exercise. The evidence that exercise has a beneficial effect on depression in older people with dementia is limited.[38] Antidepressant medication has attractions and there is some evidence of increased use in care homes, especially in the USA.[28,29] Evidence for the efficacy of antidepressants remains modest in this patient group, whereas they have major potential for adverse events due to comorbidity[20] and direct toxicity; for example, there is a twofold increase in falls in those taking tricyclic or selective serotonin re-uptake inhibitor (SSRI) antidepressants.[39] Reducing the burden of depression in care home residents, by using a conventional medical model of diagnosis and drug treatment, is likely to fail, at least in the UK, because of poor recognition, low intervention rates and the toxicity of medications. More generally there is a move away from drug treatment for mild/moderate depression. The National Institute for Health and Care Excellence (NICE) guidelines do not recommend drug treatment for mild depression; they suggest that drugs should be used only as part of a more holistic package of care for those with moderate depression.[40] Specifically for the elderly, the guidelines recommend that their poor physical state and social isolation should be addressed.[40] Interventions that may address these multiple requirements are therefore needed. Exercise shows promise as a non-drug intervention that may be helpful for depression.

Exercise/activity as treatment for depression

Evidence for the use of the structured exercise programme

Physical activity is 'any bodily movement produced by skeletal muscles that results in caloric expenditure'.[41] Exercise is a subcategory of physical activity; it is planned, structured, repetitive and results in improvement or maintenance of one or more facets of physical fitness. There are several types of exercise, including aerobic exercise (submaximal, rhythmic, repetitive exercise of large muscle groups, during which the needed energy is supplied by inspired oxygen) and resistance exercise (any form of active exercise in which a dynamic or static muscular contraction is resisted by an outside force).[42]

The endorphin hypothesis suggests that physical activity and exercise cause an increase in the release of ß-endorphins, believed to be related to a positive mood and an enhanced sense of well-being.[43] Although it was originally thought that these ß-endorphins could not cross the blood–brain barrier,[44] the endogenous release of central opioids with strenuous exercise may directly account for the sensations of euphoria associated with this type of exercise.[45] Some of the endorphin-related effects may be elicited during aerobic physical activity via an increased discharge from the mechanosensitive nerve fibres within contracting skeletal muscles.[46,47] The level of these increases in endorphins also appears to be directly related to the use of more intense resistance exercise.[48]

The monoamine hypothesis suggests that exercise leads to an increase in the availability of brain neurotransmitters (such as serotonin, dopamine and noradrenaline) that are often decreased in depression.[43,47] Exercise also appears to cause increases in levels of monoamines in the blood and urine, and may do so centrally. This theory is based on animal work, and the connection to central increases in monoamines following exercise in humans is as yet unproven.[43]

Neurotrophins, especially brain-derived neurotrophic factor, can counteract the hippocampal atrophy that appears to be associated with the high plasma cortisol levels seen in stress and depression,[49] and may make the brain more resistant to stress. Neurotrophins are a family of closely related proteins that control many aspects of survival, development and function of neurons in both the peripheral and central nervous system.[50] Exercise appears to activate cellular cascades, such as increases in brain-derived neurotrophic factor expression, which may be both time and intensity dependent.[51,52] Moderate intensity aerobic exercise for a period of 12 months may have the capacity to significantly increase hippocampal size in healthy older adults[53] and there appear to be links between resistance exercise and mood changes via the brain-derived neurotrophic factor system,[54] although the evidence for the direct effects of resistance exercise on brain-derived neurotrophic factor levels have so far been inconsistent.[55]

Engaging in exercise may have the capacity to counteract common symptoms of depression, such as negative thought patterns, low self-esteem and anhedonia (the inability to gain pleasure from enjoyable experiences)[56] through distraction, mastery experience,[43,57] improvements in self-evaluation[58,59] and a sense of achievement.[60] A further theoretical underpinning comes from the theories of positive psychology, considering the potential of exercise interventions to build on 'virtues' and 'character strengths', such as love of learning (mastery of new skills), bravery (not shrinking from challenge or difficulty) and hope (expecting the best and working to achieve it).[61]

Based on our literature review we developed a theoretical model for how exercise might reduce depressive symptoms (*Figure 1*).

A systematic review of the evidence for the effects of exercise and physical activity on depression in older people concluded that aerobic and resistance exercise are likely to be the most effective forms of exercise for decreasing depressive symptoms in this group. The review also found that interventions using moderate or high intensities of training appeared to be the most effective, signifying that there may be a dose–response effect.[62] A second review examined the evidence for the effect of physical activity and exercise interventions in older people with dementia and depression. It concluded that although there is no clear indication of effect on depressive symptoms or quality of life, there appears to be good potential for people with dementia to participate in physical activity and group exercise programmes, including the use of strength training and higher exercise intensities.[38]

Exercise participation for older people with dementia

Kitwood's principles of 'positive person work' emphasises the need to understand people with dementia as individuals with very different experiences of life, and different needs, feelings, likes and dislikes[63] (*Box 1*). The features of a person-centred dementia care approach are most likely to support well-being and enable any intervention to create the best possible effects.

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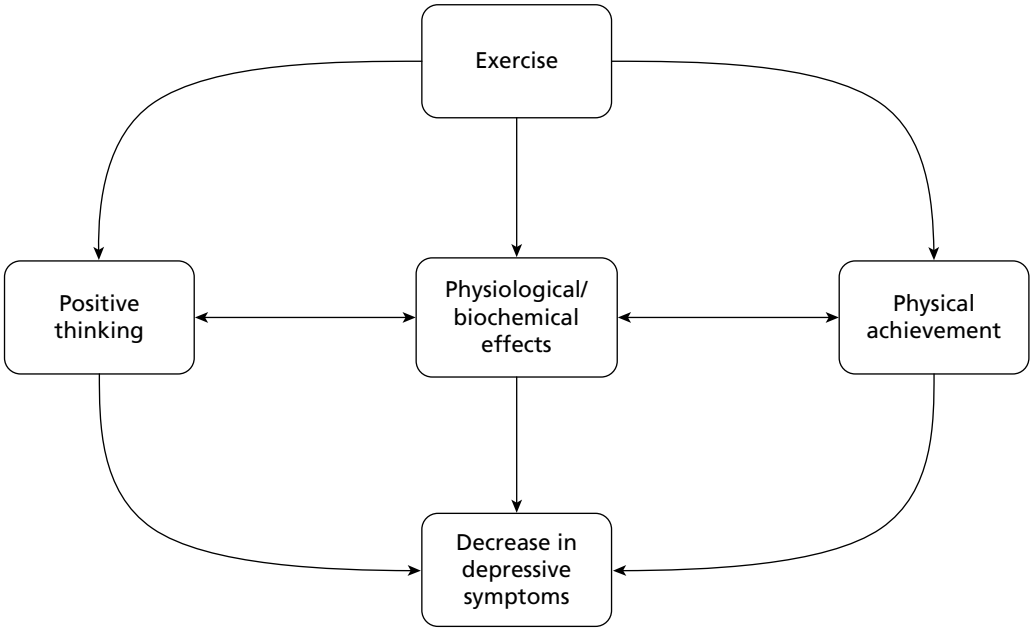

FIGURE 1 Theoretical model of effect of exercise on depressive symptoms.

BOX 1 Principles of Kitwood's 'positive person work'

Recognition To be acknowledged as a person, known by name, unique

Negotiation To be consulted about preferences, desires and needs, skills needed to take into account anxieties and insecurities

Collaboration Align on a shared task, person's own initiative and abilities are involved

Play To encourage development of spontaneity and self-expression

Timalation The use of interactions of which the prime modality is sensory, without the use of complex cognitive strategies, so that it provides contact, reassurance and pleasure while making few demands

Celebration To enable life to be experienced as intrinsically joyful

Relaxation To enable a person to relax in solitude or with others near them (considering that some people with dementia have strong social needs)

Validation To accept someone's subjective truth, and acknowledge that person's emotions and feelings

Holding To provide a safe psychological space, to help 'hold' someone psychologically or physically. This can help the person feel that there is hope that things will get better, and that there is someone who will stay with them however bad things (or they) get

Facilitation Where enabling merges into collaboration, to enable an interaction to get started and to amplify it. This requires great sensitivity to the possible meaning in a person's movements

Neurophysiology of dementia and motor control theory

Motor learning principles can further support maximum participation, success and adherence within both a physical activation programme and exercise groups. A person with dementia can face many challenges in processing visual, auditory, proprioceptive and somatosensory information, indicating the need to provide adequate time to achieve this processing, along with other props that might support their responses, such as the use of rhythm, familiar actions and tasks.[64,65]

Because of the pattern of initial change in declarative or explicit memory and learning (for names and facts) among most people with dementia, the use of procedural or implicit memory stimulation and learning strategies (for processes and routines) can be very useful[66,67] via the use of:

- *Preserved functions*:
  - Brain areas involved in motor learning may be relatively spared in most dementias, such as the basal ganglia and the cerebellum, so these preserved functions can form the basis for motor learning strategies that rely on more automatic, less conscious processes.[68,69]
- *Repetition*:
  - Procedural learning accumulates slowly through much repetition in varying circumstances, where the person (possibly unconsciously) begins to form rules associated with the task.[70]
- *Feedback and demonstration*:
  - The use of targeted feedback and demonstration is linked to classical conditioning and the formation of a predictive relationship between stimuli,[68] which can further support the development of automatic responses to those stimuli.

Associated with these procedural learning strategies are specific training techniques:

- *Errorless learning*:
  - Where multiple cues are provided to prevent errors and so enable success at every stage of a task. This is particularly useful in training people with memory losses, as it avoids the learning of the 'error' that might be encountered in 'trial and error' techniques, and is effective in promoting the mastery experiences mentioned previously.[71]
- *Backward chaining*:
  - Where a task is broken down into small, achievable parts, with assistance provided until the end of the task (e.g. guide each stage of 'turn to sit', but allow person to descend to sitting independently). This is also useful for people with cognitive impairment as it is more likely to promote success and mastery.[72–74]
- *Functional approach*:
  - Owing to the frequent involvement of the parietal cortex and the resultant presence of dyspraxia as a symptom of dementia, the functional approach can be a valuable tool. This employs the use of visual, verbal and physical prompting to support and enhance either the learning of new compensatory strategies or the regaining of previously learned skills.[75]

Music can be used to increase the efficiency of exercise efforts with evidence indicating improved respiratory efficiency associated with the use of synchronous music, and improved running speeds associated with the use of motivational synchronous music.[76] Music may act as a cue to improve performance, especially in neurological conditions,[77] as well as to support memory via the use of classical conditioning.[68] Music may also positively influence adherence via its influences on cerebral areas associated with arousal, emotions and reward,[78,79] as well as the attainment of flow (a state of focused motivation/concentration).[76]

A group format for structured exercise may offer the protective and positive effects associated with social activities on well-being and mental health.[80,81] Delivering exercise in groups is also likely to enhance adherence and may improve the cost-effectiveness of an intervention.[82,83]

Theoretical concepts supporting the use of a whole-home approach

Older adults are more likely than any other age group to lead a sedentary lifestyle despite an awareness of the benefits of being physically active. They cite deterrent factors such as lack of interest, shortness of breath, joint pain, perceived lack of fitness and lack of energy.[84] Frail older adults with multiple comorbidities and high disability levels residing in care homes are even more likely to have very limited physical activity levels.[85,86] To influence the physical activity behaviour of as many residents as possible,

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and maximise exposure to the exercise sessions, any activity/exercise intervention should offer a variety of physical activity opportunities without placing unreasonable demands on care home staff.

A large number of factors create barriers to physical activity within care homes: resource limitations, perceived role boundaries, limited staff training opportunities and restricted access to appropriate health-care providers.[86–92] Hence, any intervention to increase exercise participation should include approaches to create the culture change needed to effectively address these barriers.[92,93]

A whole-home intervention, using an organisational approach to encourage all residents and staff in efforts to increase the residents' level of physical activity, is more likely to achieve the positive effects sought than simply providing group exercise sessions. Such whole-home interventions need to consider the full range of physical, organisational and attitudinal barriers that may be encountered.

Cluster randomised trials in care homes

A systematic review identified 73 cluster randomised trials in residential facilities for the aged, of which 70 were conducted in care homes (*Table 1*).[94] The earliest trial identified was published in 1992. The trials randomised between 3 and 230 homes, and recruited between 49 and 10,558 participants. The review identified variable quality among the trials, with particularly low proportions accounting for clustering in the sample size calculations and reporting the intracluster correlation coefficients for the homes.

Most commonly, the trials focused on falls, use of medications, use of physical restraints or quality of life. Two trials focused on depression. There were 13 trials for which physical exercise formed part of the experimental intervention. Overall, the quality of these trials was varied (based on their potential for recruitment/identification bias of participants, and accounting for clustering in design and analyses). The nature of the exercise interventions was also very varied, ranging from gentle exercises based on activities of daily living (six trials) to balance and resistance exercises (seven trials). The frequency of the exercises ranged from once to thrice weekly (except for one trial on hand motor activity for 30 minutes, 5 days a week, during 6 weeks).

The outcomes of these exercise interventions included physical function, falls, quality of life and depressive symptoms. One trial[95] tested the effect of a moderate-intensity functional exercise programme, of 3 months' duration. There was no evidence of effect of the intervention on depression. This trial,[95] published after OPERA had completed recruitment, was too small, however, to exclude a positive effect from the intervention, particularly in those with depressive symptoms.[95]

Ethical issues

Cluster randomised trials have become increasingly common in health service research for a range of pragmatic and methodological reasons. However, the nature of cluster randomised trials, where randomisation, and often also the intervention, is at the level of the cluster rather than the individual, means that the standard ethical requirement of informed consent from all research participants prior to participation cannot be achieved.

The diverse range of models for cluster randomised trials means that how researchers need to secure appropriate consent, while respecting the rights of research participants, is complex.[96–98] MacRae *et al.*[99] draw on the moral foundations of informed consent and international regulatory guidelines to offer a framework for consent in cluster randomised trials.[99] This includes justificatory reasons for waiver of consent, when consent to randomisation may not be necessary, and the level of information required to be provided following randomisation. When the unit of randomisation in a cluster randomised trial is a care home, the 'cluster guardian', who provides consent for participation in the study, will usually be the care home manager. The manager also acts as a gate keeper, controlling access to individual residents for recruitment. The importance of care home managers and staff in the recruitment of participants to

TABLE 1 Characteristics of the cluster randomised trials in residential facilities for aged residents included in the review

Characteristics	Median	Minimum	Maximum
Year of publication	2006	1992	2010
No. of clusters randomised	15	3	230
Mean cluster size (participants per cluster)	28	2	217
No. of participants recruited	352	49	10,558
Country	No.		
USA	16		
UK	16		
Netherlands	9		
Canada	6		
Sweden	5		
Others	18		
Type of outcome			
Falls	15		
Medication prescription	13		
Quality of life	9		
Mobility	6		
Fractures	5		
Others	22		

research in care home settings has been noted previously.[100] Reasons for excluding access include the views of care home staff on the resident's capacity to consent, the resident's or their next of kin's (NOK's) physical frailty, and the value they place on their privacy. There is a difficult ethical balance to be struck by care home managers in protecting their residents' interests while not denying them the opportunity to participate in research if they wish.

A further difficulty in conducting research in care homes is the substantial number of residents who have a degree of cognitive impairment and who therefore may lack capacity to consent. Cognitive impairment, per se, is not determinative of whether or not a person has capacity to make a specific decision such as consenting or refusing to participate in a research project. There is no direct correlation between Mini Mental State Examination scores and capacity to consent,[101] and there is considerable variability in judgements of the capacity of people with Alzheimer's disease to consent to research, even among experienced psychiatrists.[102] A key message from these studies would appear to be that researchers must take responsibility for assessing capacity of participants for their specific study, and recording the process and reasoning for their assessment. It is not clear from the literature that this is currently regarded as standard research practice. A systematic review of cluster randomised trials in care homes found that of the 46 papers that reported consent processes, three trials relied on the opinion of care home staff to assess capacity and seven assumed lack of capacity in all participants by virtue of being resident in a dementia specialist home.[94]

Some potential research participants in care homes will clearly lack capacity to consent to take part in research. International research ethics guidelines permit research involving participants who lack capacity if specific criteria are met, for example that the risk of harm to the participant should be no more than slightly greater than that of ordinary medical care[103] or that consent is given by a legal representative.[104]

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The Mental Capacity Act 2005[105] requires researchers to consult with either a personal or nominated consultee to seek advice on whether or not the person who lacks capacity would have objected to taking part in the research if they were able to consent. Confusion among research ethics committees and researchers regarding this consultation process has been identified.[106,107] There are also concerns about the impact of this requirement on recruitment of participants who lack capacity to consent. Two UK studies that specified recruitment rates for care home residents through proxies or consultees reported levels of 61% and 41%, respectively.[100,108]

In developing this study we identified several ethical issues:

1. the ethics of cluster randomisation and the role of care home managers as cluster guardians providing consent for participation in the study
2. recruitment and consent of individuals for assessments and data gathering in an institutional setting, including the role of home staff as gatekeepers
3. obtaining valid consent for individual participation in a population that will include a high number of cognitively impaired participants, including assessment of capacity to consent
4. the involvement of personal and nominated consultees in decisions about recruitment of residents who lacked capacity to consent
5. the challenges of fluctuating mental capacity throughout the study.

Process evaluations of complex interventions

The effectiveness of any intervention is only partly determined by the content of the intervention. The context in which it is delivered, including the process of delivery and the physical and social environment, has a major influence and should be considered.[109] Process evaluation involves an examination of the processes by which a programme or intervention is implemented. A number of authors have described the use of process evaluation in complex intervention trials, pointing out the value of being able to place findings into context, understanding both how the intervention was delivered and how the social, political and physical context impacted on its effectiveness.[109–111]

Aims and objectives of OPERA

The overall aim of the OPERA study was to evaluate the impact of a whole-home intervention, consisting of training for residential and nursing home staff backed up with a twice-weekly, physiotherapist-led exercise class on depressive symptoms in care home residents. Specifically, we sought to test the effect of the OPERA intervention on:

1. the prevalence of depression in those able to complete assessments 12 months after their homes were randomised (cross-sectional analysis)
2. the change in number of depressive symptoms 6 months after randomisation in those who were depressed at baseline (cohort analysis)
3. the change in the number of depressive symptoms in all residents 12 months after randomisation (cohort analysis).

In parallel with this effectiveness analysis, there was a cost-effectiveness analysis, a process evaluation of the study, an ethics substudy and a post-study evaluation.

Chapter 2 Methods

Trial design considerations

The focus of OPERA was on testing an intervention that could be implemented as part of routine health/social care. The original brief from the National Institute for Health Research Health Technology Assessment programme called for a cluster randomised trial of the effect of a programme of group exercise on the remission of depression in care home residents. An exercise intervention would be difficult to introduce into normal practice if it is to be available only to those who have been diagnosed with depression. This is because of the need to pre-screen residents for depression. It also may be less likely to be effective if only those who are depressed attend, as positive social interactions and peer modelling of maximal effort may contribute to effectiveness. If a positive approach to increasing exercise in the residents is built into the values of care home staff, the likelihood of a group exercise intervention having a positive effect will be maximised. We, therefore, chose to test a whole-home intervention, consisting of a training programme for care home staff backed up by a twice-weekly, physiotherapist-led exercise class. As all residents were exposed to the OPERA intervention, its effects, positive or negative, on mental and physical health, may affect both those who are depressed and those who are not depressed. Furthermore, there is a high turnover of care home residents, with many new residents also being exposed to the intervention. For these reasons measurement of outcomes on all residents is important. The potential for harm from the intervention meant that it was very important to collect data on all residents, not just those with depression. With an ongoing intervention any effects, positive and negative, will continue to accrue in the long term. Indeed, only if long-term beneficial effects can be demonstrated would it be appropriate to build such a programme into the work of care homes. The outcome of interest then becomes the prevalence of depression in all of those residents in the care home at the end of the study. This includes any new residents who joined the study after randomisation. Thus, our pragmatic primary outcome of interest was the proportion of care home residents who were depressed 12 months after their care home was randomised. Henceforth, we will refer to this as the *cross-sectional analysis*, recognising that this population includes participants who had been in the study for variable lengths of time. The term *cohort analysis* will be used when referring to our more explanatory primary outcomes of change in depressive symptoms, involving those residents who were present in the home, and who had provided data, prior to randomisation. Where appropriate, we refer specifically to the *depressed cohort* of residents, who were classified as depressed on the Geriatric Depression Scale-15.[112] Likewise, the results of secondary analyses are similarly reported as *cross-sectional analysis* and *depressed cohort analysis.*

We collected data from several sources:

- Directly from the participants, henceforth *assessment data.*
- Indirectly from the care homes and the National Health Service, henceforth *care home data.* This includes data collected from routine care home records, henceforth *record data,* and assessments by care home staff of participant's health state and social interaction, henceforth *proxy data,* and data from the Secondary Uses Services databases held by participating primary care trusts, and the National Health Service Medical Record Information Service, henceforth *National Health Service data.*

A participant in the OPERA study is anyone for whom we have consent/agreement to provide data; a resident is anyone living an OPERA home. Some participating residents might not have been present in the home at the time assessments were carried out, for example because they were in hospital. On occasion when referring to the group exercise sessions we refer to exercise group participation which is distinct from study participation.

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Some participants did not complete face-to-face assessments, and thus did not provide assessment data, but they did provide care home data. The reasons for this were either that the relevant permissions (consent/assent) were not obtained to allow face-to face assessments, the participant was not present at the time assessments were done, or that when approached the residents were unable, or unwilling, to engage with the assessment process because they were cognitively impaired. A small number of participants agreed to provide assessment data but not to allow access to care home data.

In addition to those included in the cross-sectional analyses and the cohort analyses there are two further groups of residents who have contributed data to the study. Firstly, there are those who provided individual baseline data after their home was randomised but who did not provide data for the cross-sectional analysis; typically these were people who were only resident in the home for part of the year. This group contribute to the specific data on fracture rates. Secondly, as any harms from the intervention might also affect non-participants we collected some safety data from all residents.

Although the core of this study was a very simple trial to find out if exercise helps depression, there are a number of different populations contributing to the different analyses. Only by including these different populations are we able to give the full picture of how the intervention might affect care home residents. This added overall value to the study.

Pilot study

In the pilot study we tested the recruitment processes and refined the study interventions and process evaluation design prior to the main study.

We recruited three local care homes in Coventry in June/July 2008: two residential care homes and one dementia specialist care home. The residential homes were selected to represent care homes in the locality, and the dementia specialist home to test the assessment procedures and exercise intervention with more cognitively impaired residents. We assessed recruitment flow for the three care homes to allow comparison of recruitment rates between the two residential homes and the dementia specialist home (*Figure 2*).

There were 89 residents in the three care homes at the time of recruitment; staff excluded two residents because they were considered too ill to take part in the study. Half of residents in the two residential care homes were judged to have capacity to consent and one resident in the dementia specialist home. Fifteen residents gave consent to take part in the study assessments and permission for staff to collect data from their home records.

Twenty-three (37%) NOK did not respond to written request for assent and nine NOK did not want their relatives to take part in the study. Assent/agreement was obtained for 31 residents to take part in the study; however, 16 of these, when approached by the recruitment team, were unable to complete study assessments and provided access to care home data only. That 14 of these participants were resident in the dementia specialist home identified initial challenges in collecting assessment data from more cognitively impaired residents.

Following the recruitment phase of the pilot study a number of processes were revised:

1. Permission was approved by the ethics committee to contact NOK by telephone if no reply for assent/agreement had been received 2 weeks after the written request in an attempt to improve response rates.
2. Owing to difficulties experienced in recruiting residents from, and collecting the primary outcomes in, the dementia specialist home, the management team proposed re-evaluating the inclusion of dementia specialist homes in the main study.

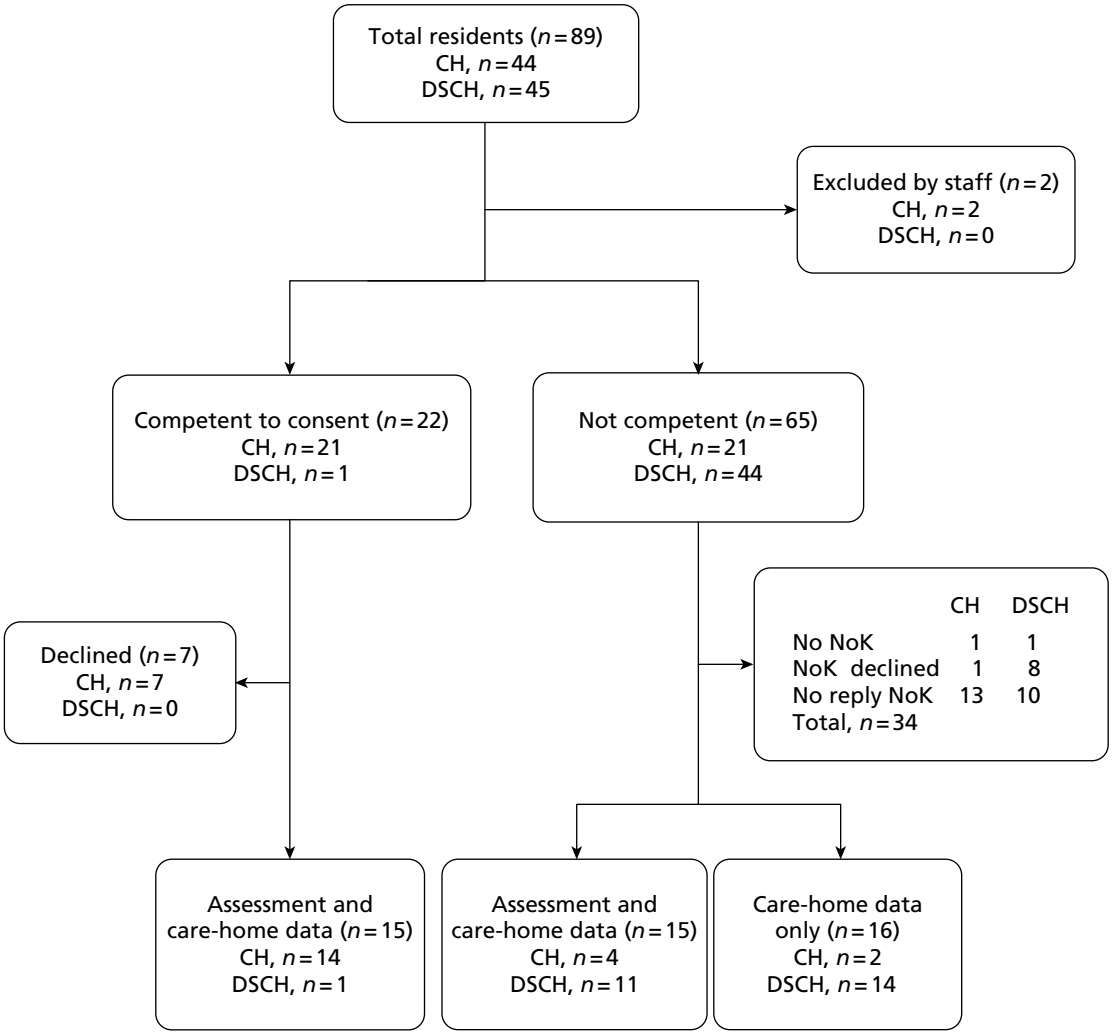

FIGURE 2 Recruitment in pilot homes. CH, care home; DSCH, dementia specialist care home.

Once potential participants were recruited to the pilot, we randomised the two residential care homes: one to the control intervention and one the exercise intervention. The dementia specialist care home was allocated the exercise intervention so that we could evaluate the feasibility of running the exercise groups for residents with moderate to severe cognitive impairment.

The exercise groups were well attended in the residential homes and dementia specialist home, and proved to be appropriate for residents with and without cognitive impairment. Following observation by a member of the process evaluation team and staff delivering the exercise groups, small changes were made to the physiotherapist assessments of residents and the format of the exercise groups.

The pilot study demonstrated that the depression awareness training (a component of both the control and active intervention, which is outlined in detail later) was well received by care home staff, and the format required very little change prior to the start of the main study.

Observation visits to the three care homes helped inform the development of the process evaluation protocol for the main study. The wide range of cognitive and physical abilities observed in the residents in the care homes identified the importance of developing an inclusive approach to recruitment to ensure that findings reflected the experiences of all residents. As a consequence of our observations in the pilot homes we felt that none of the planned outcome measures captured levels of activity or social

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engagement in the homes. We therefore decided to add the Social Engagement Scale as a secondary outcome measure.[113]

Developing the process evaluation

The process evaluation pilot had two main aims: to inform (1) the development and implementation of both the whole-home intervention and the control intervention for the main study, and (2) the design of the process evaluation of the main study. We used a formative approach in the pilot phase to ensure that any problems were identified and addressed in the main study protocols and procedures. As part of the process evaluation of the pilot study, one researcher (DE) spent time in the three pilot study homes observing the research staff activity and talking to staff and residents. Although we aimed to conduct non-participant observation, it proved impossible to maintain non-participant observer status in this setting. The researcher was inevitably drawn into the activities in the home; residents became familiar with him and expected him to interact with them socially. We used both non-participant and participant observation in the main study process evaluation as these approaches are complementary.[114]

Other challenges were identified in the pilot process evaluation[13] and influenced our development of the process evaluation protocol including:

1. We were working with a vulnerable population with varying degrees of cognitive and physical abilities. We had to take care to be inclusive in our approach to ensure that our findings reflected the experiences of the whole population of the care homes.
2. In many homes space to carry out interviews in private was limited. We needed to establish standard operating procedures that as far as possible respected residents' right to privacy.
3. A normal day in a care home is structured with set times for meals, breaks, activities and drug rounds, which can leave little time for a researcher to engage with residents. During the pilot study, we found that there was often a narrow window of opportunity to engage in individual interviews. Residents tended to be more receptive in the mornings (a common finding in populations with a high prevalence of dementia), with many homes running activities at these times for this very reason. This coupled with prearranged interviews being cancelled when the resident was found to be asleep further narrowed the opportunities for carrying out interviews.
4. Observations and feedback from team members revealed that the process of recruiting participants and, in particular, gaining informed consent, took considerably longer than originally envisaged. During the pilot phase, a number of problems with the process of gaining consent were noted, including the content of the consent forms and the difficulties of ensuring that participants had given informed consent.

In a focus group with the recruiting team, to discuss issues in the process of gaining consent, the team reported finding the process challenging, and thought the consent form was too complex for residents. It took up to 20 minutes to complete the process for each individual resident, and some of the residents found the information difficult to understand and to retain. Those study recruitment staff who had carried out the assent/agreement process (with relatives of residents deemed unable to give informed consent) found it easier, with fewer tick boxes, making it simpler to complete. This led to the consent form being shortened to make it easier for residents to complete.

A number of other changes to the conduct of the main study were implemented as a result of the pilot study process evaluation, including changes to data collection forms. Other recommendations arising from the pilot process evaluation are described in *Box 2*.

BOX 2 Actions following pilot study

Ensuring that the intervention homes were aware of what the exercise intervention entailed and the need for support from the staff
A review of the physiotherapist assessment of residents to reduce burden on physiotherapist
A review of the exercise sessions and the use of leg weights in the classes
A review of whether or not dementia specialist homes should be included, given the low numbers or residents who were able to complete the primary outcome measure, the Geriatric Depression Scale-15

As a result of the recommendations from the pilot study, amendments were made to the process evaluation protocol: nursing homes were included as a separate category in the sampling frame for case study homes and two focus groups (one for the recruiting team and one for the physiotherapists) were planned instead of individual interviews

Recruitment

Homes

We recruited homes from two geographical locations: Coventry and Warwickshire (C&W) and north-east London (NEL). The practicalities of delivering the intervention meant that all care homes needed to be within reasonable travelling distance for the physiotherapists delivering the intervention: either Warwick Clinical Trials Unit for C&W or Barking & Dagenham Primary Care Trust's physiotherapy department for NEL. Together, these two locations provided a wide range of populations broadly representative of the social mix within the UK, ranging from prosperous rural South Warwickshire through to deprived multicultural urban communities in Coventry and NEL.

We identified all care homes within the relevant primary care trust areas (Barking & Dagenham, Coventry, Havering, Redbridge, Waltham Forest, Warwickshire and West Essex). Following primary care trust approval we approached all care homes with between 16 and 60 beds, but from 11 February 2009 increased the maximum number of beds to 70. Also, from this date we specified that a minimum of six residents needed to have been assessed to be included in the study; our lower limit for home size was based on being able to recruit a minimum of six participants from each home. We excluded smaller homes to ensure that we could collect, from each home, follow-up data from at least one resident with five or more depressive symptoms at baseline. We excluded larger homes because the reduced statistical power from larger clusters meant the additional time taken in recruitment and delivering the intervention was an inefficient use of available resources. With the agreement of the Trial Steering Committee we decided to exclude homes in which more than half of the beds were registered as dementia specialist beds. We took this decision because recruiting in the first dementia specialist home for the main study confirmed our observation from the pilot study, that too few residents in dementia specialist homes were able to provide data on the primary outcome measure. With the agreement of the Trial Steering Committee we changed our protocol to exclude these homes after the first of them had been randomised.

We approached, by post, all apparently eligible homes, apart from three in C&W included in our pilot study. Interested homes were then visited by a member of the recruitment team to assess their suitability. At this time homes were excluded if fewer than six residents were likely to be able to take part in the study; more than half of the residents had severe cognitive impairment; the majority of residents were non-English speaking; or, after discussion with the study team, the home felt they were too busy to participate. Towards the end of the study some interested homes were unable to participate because we had reached our target for home recruitment.

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Inclusion and exclusion criteria

Inclusion criteria:

- permanent resident in the care home
- aged ≥ 65 years
- English speaker (for assessments).

Exclusion criteria:

- terminal illness or too ill to be seen at the time of assessment
- severe problems communicating (for assessments).

Many care home residents had multiple comorbidities, which meant that they would not be able to provide data for some, or all, of our assessments. The whole-home nature of our intervention meant, however, that all home residents would be exposed to the intervention regardless of their ability to provide data for our primary outcome or to participate in the exercise groups. For this reason we asked residents to give consent, or their NOK to give agreement, for us to collect assessment data directly from participants, and also to collect indirect care home data. Furthermore, any harms relating to the intervention would affect both participants and non-participants. For this reason we collected safety data (fractures and deaths) on all residents.

In some instances NOK had provided assent/agreement for us to assess a resident but upon approaching them the assessment was abandoned due to the resident being uncooperative or too cognitively impaired.

Ethical considerations

Obtaining appropriate valid consent from participants is essential to any research study and there are specific ethical concerns regarding consent in both cluster randomised trials and research conducted in care homes (see *Chapter 1*, *Ethical issues*). Many residents were likely to have substantial cognitive impairment and therefore may have lacked capacity to consent to taking part in a research study, which involves completing a series of assessments and allowing access to their records.

In the OPERA study the clusters were the care homes where the home managers not only acted as gatekeepers to individual residents, or their NOK, for the purposes of consent to the assessments, but were also the cluster guardians for the home giving consent for the home to participate, and actively participated in the whole-home intervention.[96]

To ensure that participants had given valid consent particular attention needed to be paid to assessment of capacity during the information-giving process. We therefore developed a two-stage approach to gaining consent; first assessing capacity and at a second visit obtaining consent (see *Obtaining consent*, below). All of the research nurses and physiotherapists who were part of the recruitment team received specific training in assessment of capacity and taking consent by the study ethicist.

Enrolling participants who are unable to consent into a study is ethically problematic, as it can be difficult to argue that participation is necessarily in their best interests. For those residents who were unable to consent to take part in the assessment component of the study we followed the requirements of The Mental Capacity Act 2005,[105] which provides the legal framework for involving people who lack capacity in medical research. Initially, the NOK was approached as the personal consultee, as defined in the Act, and if no personal consultee could be identified then a nominated consultee, as defined in the Act, was sought.

If the consultee agreed that the resident should take part in the study then the resident was enrolled as a participant. The process of setting up the study and obtaining ethics approval took place very soon after enactment of The Mental Capacity Act 2005, when researchers were still familiarising themselves with the practical implications of its requirements for research. As a result, our documentation referred to assent/

agreement of the consultee to the resident taking part in the research. We are aware that there has been discussion in the literature about the initial failure of researchers and research ethics committees to fully understand the precise intention of the Act in this regard.[106]

There has been a subsequent movement towards seeking a consultee's views about the likely wishes of the individual (the resident) about participating in the research, rather than their agreement on their behalf. Our own research practice has mirrored this development in thinking. However, as our study documentation, which had been subjected to ethical review, included the terms *assent* and *agreement*, we will continue to use these throughout this report to describe this research process.

Residents who lacked capacity to consent to take part in the research may still have been able to give consent, or refuse, to take part in an individual assessment. Therefore, at each assessment their consent or agreement was sought for that particular assessment. If at any time during the assessment a participant indicated that they did not want to take part their wishes were respected, whether or not they had formally consented or agreement had been provided by NOK.

Ethical review for the study was provided by the Joint University College London/University College London Hospital Committees on the Ethics of Human Research (Committee A), now known as Central London REC 4. The REC reference for the study is 07/Q0505/56. The Committee also approved 10 Substantial Amendments for the study.

Obtaining consent

At the first visit to the care home the care home manager, or delegated staff member, was asked to exclude any residents whom they felt it would be inappropriate to approach to take part in the study, for example those with a terminal illness. A specially trained research nurse or physiotherapist approached the remaining residents to tell them about the study and assess their capacity to give consent (stage 1). Those who, in the opinion of the recruitment team, lacked capacity to give consent to participate were not approached further; we did, however, approach their NOK. Residents not interested in taking part in the study were excluded.

Information sheets were given to residents who were considered competent to consent, and left in a prominent place so that they could discuss it with their relatives or friends. Large print or audio versions were available for those with visual impairment. Mutually agreed appointments were made for study assessments within about 1 week of the initial approach, giving residents time to consider taking part in the study.

Residents had the option to consent, or NOK had the option to give assent, either to the assessments, the use of care home data or to both. Residents (or NOK) could also consent (or assent) to the results of assessments being shared with the care home manager and their NOK, and/or their general practitioners being informed of their participation in the study. The research nurse/physiotherapist conducting the recruitment assessment checked that the resident had read, or otherwise availed themselves of, the information sheet and understood the broad nature of the study, and answered any questions that the resident had. In practice, family members were sometimes present for these discussions. Each statement on the consent form was discussed and initialled by the resident; if they were in agreement then the consent form was signed by the resident and witnessed by the research nurse. For those residents with sight impairment a member of the care home staff witnessed the consent process. The process of going through the information sheet and consent form and checking understanding provided a further check on the resident's capacity to consent (stage 2). If at this stage it was clear that the resident lacked capacity then the process was stopped and a personal consultee was approached.

Care homes wrote to the NOK of residents who lacked capacity to consent, enclosing information about the study and an expression-of-interest slip. Residents who were unable to communicate were identified by the care home manager at the initial meeting, and agreement was requested for access to care home

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data only. NOK who expressed an interest in their relative/friend taking part in the study were contacted by telephone to answer any queries and arrange for an assent form to be sent to them by post or to be completed with the research nurse at the care home.

If after 2 weeks there had been no response to the request from the initial letter the relatives were contacted by telephone. It had been anticipated that if a resident had no known NOK then an appropriate nominated person could be contacted as permitted by The Mental Capacity Act 2005.[105]

We consulted with local social services departments and the Independent Mental Capacity Advocacy (IMCA); neither organisation felt able to provide this service. In view of the relatively small numbers of residents involved we decided not to explore other possibilities for a nominated consultee and therefore residents who were unable to give consent and who had no contactable NOK were not recruited.

Baseline data collection

Assessments were carried out in the resident's own room or an alternative quiet location in the care home in which the resident felt most comfortable. Assessment lasted between 30 and 60 minutes and the research nurse/physiotherapist administered the questionnaire instruments; Geriatric Depression Scale-15,[112] Mini Mental State Examination,[115] European Quality of Life-5 Dimensions (EQ-5D),[116] fear of falling and current pain. They also did a brief physical assessment: the Short Physical Performance Battery.[117,118] The results were recorded on paper whilst with the resident, and entered directly on to a laptop computer after the assessment had finished. Assessments were terminated if the resident expressed any distress or desire to withdraw.

Wherever possible all baseline assessments were collected prior to randomisation. For a small number of residents the recruitment process was started prior to randomisation but consent/assent was not obtained until after randomisation. Data collection for these participants was then carried out as soon as possible after randomisation. These participants' data were not included in the cohort analysis but were included in safety analyses, and if present at the end of the study they were included in the cross-sectional analyses.

Where consent/agreement had been given we provided the care home manager with the resident's Geriatric Depression Scale-15 scores and a brief interpretation/suggested action. Residents with Geriatric Depression Scale-15 scores of 0–4 were considered to have no depression. It was suggested that residents with Geriatric Depression Scale-15 scores of between 5 and 10 (moderate depression) were encouraged to take part in activities and be monitored by care home staff. Care home staff were encouraged to refer residents with Geriatric Depression Scale-15 scores of between 11 and 15 (severe depressive symptoms) to their general practitioner or Community Mental Health Team. For those residents who were unable to complete all 15 questions (but did complete ≥ 10) we used an algorithm to calculate and report the score, based on proportion of positive replies from questions answered (see *Appendix 1*).

Residents recruited after randomisation

At the 3- and 6-month visits the care home manager was asked to identify any new permanent residents (see *Follow-up*, below). We did not do this at 9 months to ensure that all those contributing to the cross-sectional analyses had been exposed to the environment within the care home long enough to be exposed to at least 4 months of the environment of that home. If the resident was eligible and interested in taking part in the study, the research nurse/physiotherapist explained the study and assessed their capacity to give informed consent, allowing the resident at least 24 hours to consider taking part in the study. NOK of residents unable to give informed consent were contacted in the same manner as those approached prior to randomisation. All processes for data collection were the same as for participants recruited prior to randomisation (see *Obtaining consent*, above).

Care home data

We collected demographic data (age, sex, ethnicity, social class, age at leaving full-time education), comorbidities (cancer, stroke, dementia, depression, anxiety, osteoporosis, chronic lung disease, urinary incontinence) and data on length of residence from the care home records. Data on current medication use were obtained directly from residents' Medication Administration Record Sheets. The resident's key carer, or carer looking after them on the day of data collection, was asked to complete a proxy EQ-5D, Barthel Index and Social Engagement Scale (*Table 2*).[113,116,119]

Follow-up

We did four cycles of follow-up in each home. Follow-up data were collected over several visits, at around 3, 6, 9 and 12 months after the home was randomised.

Follow-up data collection

At 6 and 12 months we sought to complete follow-up assessments on all residents from whom we had consent or agreement to take part in study assessments. The research nurse/physiotherapist confirmed

TABLE 2 Summary of data collection

	Time recruited			
Data collection	**Baseline**	**3 months**	**6 months**	**9 months**
Before randomisation and immediately post randomisation	Sociodemographic data, comorbidities, GDS-15, MMSE, EQ-5D, SPPB, fear of falling, pain, Barthel Index, proxy EQ-5D, SES, medications			
3 months	Proxy EQ-5D, SES, medications, fractures, deaths	Sociodemographic data, comorbidities, GDS-15, MMSE, EQ-5D, SPPB, fear of falling, pain, Barthel Index, proxy EQ-5D, SES, medications		
6 months	GDS-15, MMSE, EQ-5D, fear of falling, pain, proxy EQ-5D, SES, medications, fractures, deaths	Proxy EQ-5D, SES, medications, fractures, deaths	Sociodemographic data, comorbidities, Barthel Index, GDS-15, MMSE, EQ-5D, SPPB, fear of falling, pain, Barthel Index, proxy EQ-5D, SES, medications	
9 months	Proxy EQ-5D, SES, medications, fractures, deaths	GDS-15, MMSE, EQ-5D, fear of falling, pain, proxy EQ-5D, SES, medications, fractures, deaths	Proxy EQ-5D, SES, medications, fractures, deaths	Sociodemographic data, comorbidities, Barthel Index, GDS-15, MMSE, EQ-5D, SPPB, fear of falling, pain, Barthel Index, proxy EQ-5D, SES, medications
12 months, end of study	GDS-15, MMSE, EQ-5D, SPPB, fear of falling, pain, proxy EQ-5D, SES, medications, fractures, deaths			

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SES, Social Engagement Scale; SPPB, Short Physical Performance Battery.

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with the care home manager that it was an appropriate time to approach the resident. Residents who agreed to take part in follow-up assessment completed the same questionnaire instruments as baseline apart from the physical assessment Short Physical Performance Battery, which was not administered at 6 months.

Residents who were known to have died or had moved from the home were reported to the study team by the care home manager at each visit. At 6 and 12 months residents who were in hospital, or too unwell at the time of assessment, were contacted within 1 month to see if they were now well enough to be assessed. Participants who had moved to another participating care home were contacted and assessed, at the time that assessments were being done in their original home. We were unable to follow-up participants who had moved to a non-participating home.

Care home data were collected for those for whom we had consent/agreement and who were present in the care home at 3, 6, 9 and 12 months. Medication use, visits by health-care professionals, outpatient appointments, accident and emergency (A&E) attendances, and hospital admissions were recorded. The resident's key carer, or carer looking after them on the day of data collection, was asked to complete a proxy EQ-5D and the Social Engagement Scale at the 3-, 6-, 9- and 12-month follow-up visits.

Residents recruited after randomisation

Follow-up assessments were completed in the same manner as those recruited prior to randomisation with an assessment 6 months after they had joined the study. All participating new residents had an end of study assessment when their home came to the end of its 12-month study period. The majority of new residents were identified and recruited at 3- and 6-month follow-up visits to the care homes; a small number requiring assent from NOK were recruited at between 6 and 9 months post randomisation.

Evaluation of recruitment processes

As part of the process evaluation, recruitment processes, including home recruitment and recruitment of individual participants, were evaluated (see *Process evaluation*, below).

Independent observations of the process of consenting participants were carried out by the process evaluation research fellow. This involved shadowing the recruiting staff on a number of occasions and observing the consent and assessment process in different homes. Results of these observations are reported in the quality control section and are mentioned in the consent substudy section (see *Ethics substudy*, below).

Assessment

In light of the poor state of health of many of our study participants we used a parsimonious set of outcome assessments. For the cohort analyses we collected follow-up data, directly from participants, at 6 and 12 months after randomisation. A drug trial for the treatment of depression would expect maximal effect to be seen by 4 months.[40] If exercise were an effective treatment for depression we might expect a response in a similar time. However, there is a time lag between randomisation and participants gaining any benefits from the exercise programme because of the time taken to start changing the attitudes of the care home staff and to establish exercise groups as a regular routine in the care home. Anticipating that the intervention would be fully functional 2 months after randomisation, we did our first assessment 6 months after the home was randomised.

We originally intended to collect 6-month follow-up data just from those with five or more depressive symptoms (or equivalent) at baseline. Early in the study it became clear that the average cluster size was smaller than anticipated. In view of concerns about obtaining sufficient data for any 6-month analysis, and with the agreement of the Trial Steering Committee, we changed to collecting 6-month assessment data from all participants. We did not, however, have sufficient research nurse/physiotherapist capacity to also

collect the Short Physical Performance Battery on all participants at 6 months and therefore did not include the 6-month physical assessment. For the cross-sectional analyses we included residents who had been in an OPERA care home for at least 3 months prior to the end-of-study (12-month) data collection.

At each assessment we started by collecting our primary outcome measure, the Geriatric Depression Scale-15, to maximise response rates in those who might not be able to complete the full assessment.[112] We had originally set an exclusion criterion of a Mini Mental State Examination score of <10 for severe cognitive impairment, as we thought that those with lower scores would be unable to complete the Geriatric Depression Scale-15.[115] Experience in the pilot study was that we were collecting satisfactory Geriatric Depression Scale-15 scores prior to attempted completion of the Mini Mental State Examination. We therefore removed this exclusion criterion from the main study. This concurs with reports of successful completion of the Geriatric Depression Scale-15 in people with severe cognitive impairment.[120]

Primary outcome measure

Our primary outcome measure was the Geriatric Depression Scale-15.[112] This brief instrument consists of 15 yes/no questions and has been well validated in care home populations. It avoids using potentially somatic features of depression that may be misleading in this age group, focusing more on mood and functional symptoms of depression.[121] It is one of the most widely used measures in this field. It is simple to complete, with 97% of cognitively intact nursing home residents producing analysable data, and showed high internal consistency in a large sample of US nursing home residents.[122] The Geriatric Depression Scale-15 can be interpreted as an indication of the presence/absence of depressive mood. A score of ≥5 appears to give the best sensitivity and specificity for presence/absence of depressive mood.[120,123] Nevertheless, the Geriatric Depression Scale-15 is not a substitute for a clinical diagnosis of depression. However, in this report we will refer henceforth to the presence of five or more depressive symptoms, or its equivalent, on the Geriatric Depression Scale-15 as depression (*Table 3*). Some individuals completed fewer than 15 items on the Geriatric Depression Scale. The recommended score indicating depression is '5' when 13 or more items are completed, '4' when 12 or 11 items are completed and '3' when 10 items are completed (see *Table 3*). When nine items or fewer were completed the Geriatric Depression Scale-15 score was set to missing. Henceforth the presence of the appropriate number of positive items is referred to as depression. The Geriatric Depression Scale-15 has been used as a continuous measure in other randomised controlled trials based in care homes.[95,124] We also use the Geriatric Depression Scale-15 as a continuous measure in some of our analyses.

Data collection

For the cohort study we collected Geriatric Depression Scale-15 and the other participant reported outcomes prior to randomisation and then at 6- and 12-month follow-up. For those joining the study

TABLE 3 Geriatric Depression Scale-15 scoring algorithm

Responses to GDS	Score indicating depression
15	≥5
14	≥5
13	≥5
12	≥4
11	≥4
10	≥3

GDS, Geriatric Depression Scale.

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after randomisation we collected these data at study entry, 6 months after study entry and/or at the end of the study.

Other participant reported outcomes

Health-related quality of life

The EQ-5D is a widely-used brief measure of health utility.[125–127] [The EQ-5D and proxy EQ-5D were used with the permission of the EuroQol Executive Office. All copyrights in the EQ-5D, its (digital) representations, and its translations exclusively in the EuroQol Group. The EQ-5D™ is a trade mark of the EuroQol Group.] It measures quality of life using questions in five domains, the EQ-5D, plus the EuroQol Visual Analogue Scale (thermometer). To reduce questionnaire load we used the EQ-5D as our overall measure of health-related quality of life and for our health economic analyses. It has been used satisfactorily in previous studies of nursing home residents.[127]

Cognitive function

We measured cognitive function using the Mini Mental State Examination[115] (The Mini Mental State Examination was used with permission of Psychological Assessment Resources Inc., which retains the copyright). The Mini Mental State Examination is the most widely used measure of cognitive impairment worldwide.[128] It is quick, validated in relevant populations, sensitive to change and allows comparisons to be made with other studies. There is a suggestion that exercise may have a direct effect on preventing cognitive decline.[129] This is therefore an important secondary outcome.

Fear of falling

Although there are grounds for optimism that exercise intervention of the type used in OPERA may reduce both falls and falls injury, there is a justifiable concern that, by encouraging residents to be more active, it might lead to an increase in falls.[130,131] Recording of falls within care homes is likely to be unreliable and within a cluster randomised trial of this nature it is prone to reporting bias. In community studies fear of falling has been shown to be an independent predictor of falls risk.[132] For this study we used a simple yes/no question of fear of falling to make completion easier. Others have found, in similar populations, that many residents are unable to complete a scale for fear of falling.[133]

Pain

The association between pain and depression in older people is well recognised.[134,135] Exercise may have a beneficial effect on pain in this population, independent of the beneficial effects it may have on depression.[33] We ascertained presence or absence of pain from the EQ-5D pain question. For those with pain we then assessed their current level of pain on a five-point ordinal scale, i.e. pain now: no pain, mild pain, moderate pain, severe pain, and pain as bad as it could be. For analysis we collapsed this into three groups: no pain, mild/moderate pain, and pain as severe or as bad as can be.

Physical assessment

Mobility

To assess the effect of the programme on mobility we used the Short Physical Performance Battery, which incorporates three essential aspects of physical function that should be improved by the exercise programme: static balance, lower limb strength and dynamic balance.[117] Because of the central importance of physical function to the ability to thrive, the Short Physical Performance Battery has been used extensively in trials and observational studies of older people. It has well-established and surprisingly strong relationships with a range of important public health outcomes, including onset and progression of disability, mortality and nursing home admission.[136] Testing procedures are standardised and timed.[117,118] A change in the Short Physical Performance Battery would indicate if the OPERA intervention has had an effect on its primary target of improving physical activity.

Data collection

For the cohort study we collected Short Physical Performance Battery prior to randomisation and at the end-of-study assessment. For those joining the study after randomisation, we collected these data at study entry and at the end of the study. In the original protocol we were planning to collect only 6-month outcome data on those who were depressed at baseline. As a sustained effect on mobility was the outcome of interest this was measured at study entry and end-of-study assessments only.

Proxy measures

We collected proxy data on all of those for whom we had permission to collect care home data. Thus, more proxy data are available on participants than data from the participant-completed measures.

Activities of daily living

At baseline only we collected data on activities of daily living in order to provide data on the severity of physical disability in our population. We used the Barthel Index, a widely used measure of activities of daily living.[119]

Health-related quality of life

The use of proxy measures of the EQ-5D, where the proxy is asked to report on how they think the subject feels, is well established.[137] Many of our participants would be unable to satisfactorily complete the EQ-5D. In particular, the use of the EQ-5D Visual Analogue Scale (thermometer) is difficult for those with substantial cognitive impairment or visual impairment. The level of agreement between self-completed and proxy scores varies according to subjects' underlying illnesses and who the proxy is (family member or health-care professional). Agreement is better for the EQ-5D index score than the Visual Analogue Scale but varies across EQ-5D domains. Agreement is reasonable for people living with stroke and better for Parkinson's disease.[138,139] One study in dementia found an intracluster correlation coefficient of 0.42 for the index score between health-care professionals and patients for EQ-5D index score in people suffering from dementia.[140] Whatever the absolute level of agreement between proxy and self-completed EQ-5D might be in individual cases, the proxy values should reliably identify changes in health state.

The calculation of quality-adjusted life-years requires multiple measures at different time points. It is likely that the health of a substantial proportion of participants will deteriorate over 12 months, reducing the proportion who can contribute to the health economic analysis. For this reason we collected proxy EQ-5D at each time point on all participants, even if they had satisfactorily completed an EQ-5D themselves. We asked carers to rate how he/she (the proxy) thought the resident would rate his/her own health-related quality of life if he/she (the resident) was able to communicate it (EQ-5D, proxy version 2).[137]

Social engagement

Improving level of social engagement in care home residents through group activity and increased mobility is an alternate pathway through which the OPERA intervention might affect mood. Collecting data by direct observation across 78 homes would be impractical. For this reason we used the Social Engagement Scale, which is completed by carers to give an indication of the involvement of a resident in activities within a nursing or residential home. (The Social Engagement Scale is part of assessment instruments owned by interRAI, a non-profit corporation with central offices in the USA. However, use of these instruments in the UK is handled by an English affiliate led by Dr Iain Carpenter, University of Kent. Dr Carpenter kindly gave us permission to use this item.) The Social Engagement Scale uses six Minimum Data Set Resident Assessment Instrument items.[141] As part of the Minimum Data Set Resident Assessment Instrument the Social Engagement Scale is normally administered by direct observation of the resident by the researcher as well as asking the residents and care home staff. This was impractical in our study and the Social Engagement Scale was added to proxy measures completed by care staff. The items are scored with yes (1) or no (0) responses indicating the presence or absence of the behaviour in question.[113,142] Scores range from 0 to 6, with a higher score indicating higher levels of social engagement. For the purposes of reporting, individual scores were calculated and then grouped into low (scores of 0 or 1), medium (scores 2–4), and high social engagement (scores of 5 or 6).

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Data collection

For the cohort analyses we collected proxy EQ-5D and proxy Social Engagement Scale prior to randomisation and then at 3-, 6-, 9- and 12-month follow-up. For those joining the study after randomisation we collected these data at study entry, and 3 and 6 months after study entry and/or at the end of the study.

Care home data

Participant characteristics.

We collected demographic data (age, sex, ethnicity, social class and age at leaving full-time education), comorbidities (cancer, stroke, dementia, depression, anxiety, osteoporosis, chronic lung disease, urinary incontinence) and data on length of residence and current medication from the care home records.

Medication

We collected data on all medications used over a 1-week period from the home records. We extracted the exact drug name (as written in care home records), preparation and dose used, plus the number of times any medication was actually administered over a 1-week period. We then used the prescription cost analysis database to attach a code to each unique preparation used.[143] In this way we were able to attach a cost to each individual preparation used, and to estimate total amount used of each individual drug listed in the *British National Formulary*.[144] Using the World Health Organization (WHO)-defined daily dose for each drug we were able to generate number of days of medication used by *British National Formulary* chapter and subchapter.[145]

For some products estimating total usage from care home records was not possible. For example, the amount of topical preparation used at each administration is not recorded, and the degree of variability in recording of appliances and dressing between care homes meant that these data were not reliable.

We collected these care home record data on all of those for whom we had permission to access records. We collected data on medication use prior to randomisation and then at 3-, 6-, 9 and 12-month follow-up. For those joining the study after randomisation we collected these data at study entry, and at 3 and 6 months after study entry and/or at the end of the study. We restricted our collection of medication use to no more than 5 weeks over the study period to ensure the task remained manageable within the available resources.

Safety data

Care home record data

Everyone in the home is exposed to the intervention, including those who are not study participants. Safety monitoring, therefore, needs to include all residents. To get an overall picture for each home we used the routinely collected data that care homes are required to keep on deaths and fractures. Care homes are specifically required to record and report deaths and serious injury, including falls and fractures, under Regulation 37, Part V11 of The Care Home Regulations (2001).[146] These regulations were made under the Care Standards Act (2000).[147]

We extracted pooled anonymous data unlinked to identity for the preceding 3 months from each home for all residents (participants and non-participants) at 3, 6, 9 and 12 months after randomisation (see *Directly attributable diverse events*, below).

National Health Service data fractures

At the end of the study, Hospital Episodes Statistics Secondary Uses Service data were collected from each primary care trust in which the study had been run.[148] Permission to access these data was obtained

from the primary care trusts' respective Caldicott Guardians. Once the relevant permissions had been obtained, the primary care trusts' information analysts provided us with data for each of our participants for whom we had permission to access National Health Service data (a small number of participants who were assessed did not wish their care home data to be used) (see *Economic valuation*, below). This included data for A&E department attendances, hospital admissions, outpatient attendances and use of community services.

Fractures of interest were prespecified as peripheral fractures, defined as fractures not involving the spine. All spinal fractures were excluded, as these are not strongly related to fall injury. We identified all fracture codes in *The International Statistical Classification of Diseases and Related Health Problems*, Tenth revision (ICD-10)[149] and then searched diagnostic descriptions from the inpatient, outpatient and A&E departments for fracture diagnoses.

One fracture event may lead to multiple heath service encounters, for example an A&E department attendance followed by an admission and a subsequent outpatient appointment. We therefore cross-referred between data sets to identify linked episodes that represented a single fracture event. The quality of coding in A&E data was poor; typically, these reported an attendance accompanied by a broad, non-specific diagnostic description of 'dislocation/fracture/joint injury/amputation'. Outpatient data typically reported the clinic attended but not the diagnosis. We were not able to link these to care home records' data on fractures, as these had been provided to us as pooled anonymous data. When a participant had multiple peripheral fractures for one episode of care, this was treated as a single fracture event. We then allocated events to different levels of certainty that there had been a fracture:

- *confirmed fracture* definite fracture code identified, typically an inpatient admission
- *probable fracture* an A&E attendance followed by an orthopaedic outpatient appointment
- *potential fracture* an A&E attendance for an injury in which the term *fracture* appeared (among other diagnostic terms) in the diagnostic description with no further data provided.

National Health Service data deaths

At the end of the study we collected data on date and cause of death for all of the participants for whom we had permission to access medical record data from the Medical Record Information Service.[150]

Health service activity

Care home data

We collected data on all general practitioner and practice nurse consultations from the care home records.

For the cohort study we collected follow-up data on medication use at 3-, 6-, 9- and 12-month follow-up. For those joining the study after randomisation we collected these data at study entry, 3, 6 and 9 months after study entry and/or at the end of the study. We collected these care home data on all of those for whom we had permission to access records.

National Health Service data

As described above, we used routine primary care trust Secondary User Services data on visits by community services, A&E attendances, outpatient appointments and hospital admissions. In addition to the episode statistics, these data included the price of each encounter with secondary care services. We were not able to collect general practitioner consultation data from these records. We collected these data at the end of the study on all those for whom we had permission to access records.

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Interventions

In line with the Medical Research Council's framework[151] we used an active control intervention in all participating care homes to ensure that they are aware of current best care for the identification and management of depression in this population.

- By using current best care as our control, we could ensure that any benefits identified were due specifically to our intervention package rather than to raising awareness of depression within the intervention homes.
- We reduced the risk of 'resentful demoralisation' in the control homes affecting recruitment of new residents after randomisation or even leading to the care home withdrawing from the study.[152]

Control intervention

Our control intervention mirrored as closely as possible a realistic depression intervention which the National Health Service might introduce in care homes that would constitute a best usual care implementable by the National Health Service. The depression awareness training was designed to be short, inexpensive, deliverable by a non-expert clinician, and to address relevant learning objectives for staff in the care home sector. We used a scripted interview that was filmed using a trained simulator (actor) playing a 67-year-old care home resident with clinical depression being visited by a community psychiatric nurse. This video lasted six minutes and was used in the middle part of the depression awareness training session to illustrate key clues to diagnosing depression and possible ways to treat depression.

Each clinician delivering the depression awareness training intervention session in the care homes attended a 120- to 150-minute training session. The session reviewed the definition and epidemiology of depression, the place of depression awareness training in the OPERA study, the care home sector and its staff in the UK, and exercises including role play in delivering the session. Clinicians were able to deliver the depression awareness training only if, after a training session, in the opinion of an experienced training clinician, they had achieved the expertise to deal with this. The implementation of the depression awareness training intervention was studied as part of the process evaluation.

The depression awareness training was delivered to staff in every care home in OPERA. Each session was delivered by a clinically qualified member of the research team (e.g. nurse/physiotherapist/general practitioner) and lasted approximately 30–40 minutes. Staff members at care homes were asked to attend on one occasion. Sessions were designed for 3 to 10 staff. Requirements for the session were a room which could hold the staff group and was quiet, and a session time suitable for the care home staff; this depended on care home arrangements but was typically during the middle part of the day, around staff handovers. A method of delivering a video to staff was needed; either a DVD player and television, or a laptop computer with loudspeakers. In many care homes, more than one session was required to allow as many staff as possible to attend.

The stated aims of the session for staff attending were to be able to:

- say what depression is
- distinguish depression from normal sadness
- name two things that can be done to help people with depression in a care home.

The session was structured as shown below:

- introduction (3–4 minutes)
- talk/discussion on what is depression, supported by written materials (6–8 minutes)
- video of simulated resident/nurse encounter (6–7 minutes)
- case discussion (15–18 minutes).

At the end of each session care home staff completed feedback forms that recorded attendance, satisfaction with the sessions, and suggestions for development.

Active intervention

The OPERA intervention was designed to test the effects of exercise and increased physical activity on depression and other important outcomes (*Figure 3*). Our plan was to deliver a whole-home exercise intervention, consisting of training for care home staff backed up with a twice-weekly physiotherapist-led exercise groups.

Whole-home intervention

The aims of the whole-home intervention were to:

- increase the physical activity levels of care home residents over the length of the study in each home (12 months) using simple approaches
- engage residents' participation in twice-weekly exercise groups delivered by the OPERA physiotherapists.

To promote the effectiveness and sustainability of the OPERA intervention it was envisaged as a whole-home, 'ecological' intervention[153] directed at changing the whole-home environment and the culture within care homes. To this end the intervention adopted the WHO 'settings approach',[154] aiming to strengthen the resources for health in a 'setting of everyday life'. Such systemic interventions have been shown to be effective in significantly changing behaviour within cluster randomised trials in other settings.[155]

The intervention was limited to specific pathways and treatments thought to affect depression. It was not intended to provide physiotherapy more broadly. The approach to safety and risk management was grounded in available evidence, supplemented by pragmatic opinion of professional bodies and internationally respected opinion leaders. The aim was to include and address the problems of as many residents of care homes as possible, including those with dementia.

The whole-home intervention consisted of training for residential and nursing home staff backed up with a twice-weekly physiotherapist-led exercise class. This approach, with the regular exercise groups at its core, was used to ensure that residents had maximum opportunity to engage in the exercise groups and to maintain physical activity outside the formal exercise session.

The development of the whole-home intervention drew on components of both Greenhalgh's 'diffusion of innovations' model[156] and Cialdini's 'model of persuasion and influence'.[157] A dementia/person-centred care approach was robustly promoted within the OPERA intervention along with the use of an 'unconditional positive regard'.[63]

Diffusion of innovations model

The interaction between an innovation, its adopters and the context of the innovation will determine its adoption in service organisations.[156] Greenhalgh *et al*.[156] presented a conceptual model '*intended mainly as a memory aide for considering the different aspects of a complex situation and their many interactions*'.

We took into account the full range of components in this model when considering the design of the whole-home OPERA intervention, for example 'key interactions to help innovations be adopted' listed below:

- *Compatibility – needing to ensure that the innovation is compatible with the adopter's values, norms and perceived needs* Before setting any training, mobility recommendations or exercise groups into action, the physiotherapists ensured that they became familiar with each care home's daily routines and the full range of constraints and opportunities faced by both the management and the care home

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staff, as well as those faced by the residents, in terms of time, equipment, environment, training and available health-care support.

- *Reinvention – the innovation can be adapted, refined or modified* The care home staff were encouraged to raise their concerns and make suggestions about the timing, location of and arrangements for the exercise groups on an ongoing basis; the physiotherapists were encouraged to be open and responsive and to these ideas. The physiotherapists also paid attention to the care home staff's and residents' feedback on the outcome of physical activity recommendations, and disseminated relevant findings to the rest of the physiotherapy team via e-mail networks throughout the study period.
- *Risk – a lower degree of uncertainty of outcome for personal risk* It was essential that the physical activity recommendations for any resident accounted for carers' and home management's safety concerns, while promoting an alternative ethos of positive risk-taking within the home.
- *Task issues – tasks need to be relevant to the performance of users' work and improve task performance* The individualised physical activity recommendations, created through co-operation and discussion with the care home staff, had the potential to increase the efficiency of the carers' working routines when they were able to identify approaches which enabled residents to increase their independent mobility and then take on more of their own care tasks over time.
- *Augmentation/support – innovation supplied as an 'augmented product' with customisation and training* The carer training programme provided care home staff with free on-site health-related training and used simple visual materials designed to be accessible and acceptable to a wide range of care staff in terms of previous training and experience, education and language. The physiotherapists could support this further by providing frequent opportunities for discussion and hands-on training sessions throughout the intervention period.

Persuasion and influence model

Theories relating to the psychology of persuasion and influence can also inform actions aimed at changing both residents' and care home staff's attitudes and behaviours.[157] We used Cialdini's framework of behavioural principles of social influence to develop the OPERA intervention.[158]

We used the following components of this model:

- *Reciprocation* Frequent verbal recognition of, and praise for, care home staff efforts to get residents more active and involved in groups, or rewards for staff, for example evidence for National Vocational Qualification, built up from attending groups or finding ways to increase individual resident's physical activity.
- *Consistency* Aiming to facilitate 'commitment replies' via questions like: 'What do you think would help Mrs X come to the group next time?' or 'Which of the residents do you think might come to the next session?'
- *Concessions* Regular informal discussions took place during care home staff handover periods and more formal (recorded) sessions at least 2-monthly intervals or as/when the need arose. These discussions focused on the constraints that both the physiotherapist and the care home staff faced when encouraging residents to increase their levels of physical activity, with the aim of developing acceptable and appropriate solutions to these constraints, as well as providing opportunities to create increased rapport and feelings of mutual interest.
- *Liking* Developing personal relationships with care home staff though shared 'social' time, demonstrating awareness of their personal strengths and qualities, as well as their particular constraints and obstacles.
- *Authority* Linking the OPERA programme to the importance of activities for Care Quality Commission requirements.
- *Scarcity* Promoting the fact that this might be a chance to have some expert guidance on mobility needs from an 'in-house' physiotherapist, to have a hands-on opportunity to learn how to promote physical activity and develop exercise groups in care homes with the ongoing close support of a health professional, and to be involved in a national level research programme that might influence policy.

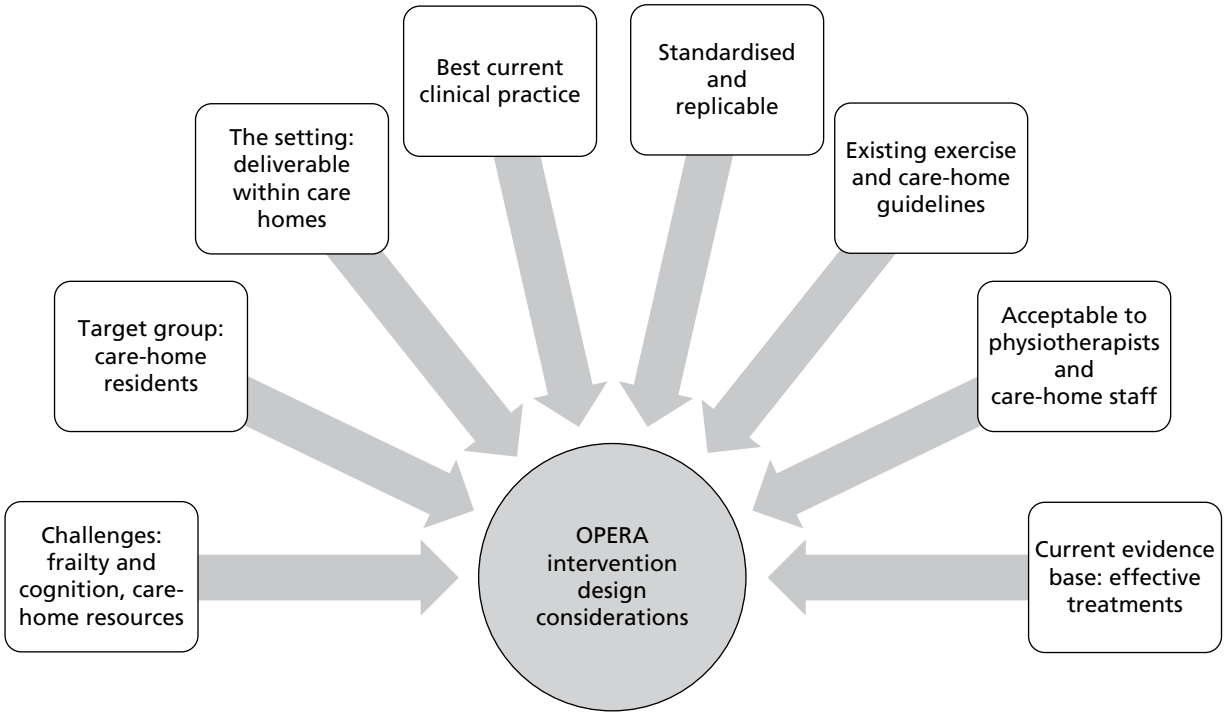

FIGURE 3 Design considerations for OPERA intervention.

The actual intervention design was also based on a number of other principles and considerations (see *Figure 3*). This included the biological rationale for the proposed therapeutic effect and two systematic reviews of randomised trials.[38,62] It was also informed by physical activity guidelines for older adults[159,160] and exercise prescription guidelines,[161–163] with adaptations to account for the high levels of frailty and multiple comorbidities seen in this population.[164] The design followed the principles of person-centred dementia care approaches advocated for use in UK care homes,[165,166] was consistent with the guidelines affecting care home staff such as those specified by the Care Quality Commission, and accounted for the context of UK residential and nursing homes in terms of staffing, time, environment and equipment. Additional expert opinion was gathered in discussion with clinical and exercise specialists in older people's physical and mental health care. We considered the deliverability within care home settings, the frailty of the target group, and the acceptability to physiotherapists and care home staff who would be delivering the intervention. Finally, the design included documentation and training to promote consistency in delivery.

The OPERA intervention

The OPERA study was located in UK care homes in which up to 70% of residents are likely to be living with dementia.[167] A dementia/person-centred care approach was robustly promoted within the OPERA intervention and team members, along with the use of an 'unconditional positive regard'. The intervention was delivered by a physiotherapist who was assigned to work with an individual home for 12 months.

The physiotherapists were allocated two half-days per week to each care home – more in some larger homes in which we ran more exercise groups. There were seven components to the intervention (*Figure 4*).

Initiation and assessment period:

1. Initial meetings with the care home manager and senior care home staff.
2. The identification of a physical activity champion from within the care home staff.
3. Carer training in depression and activity awareness.
4. Physical activity assessments.

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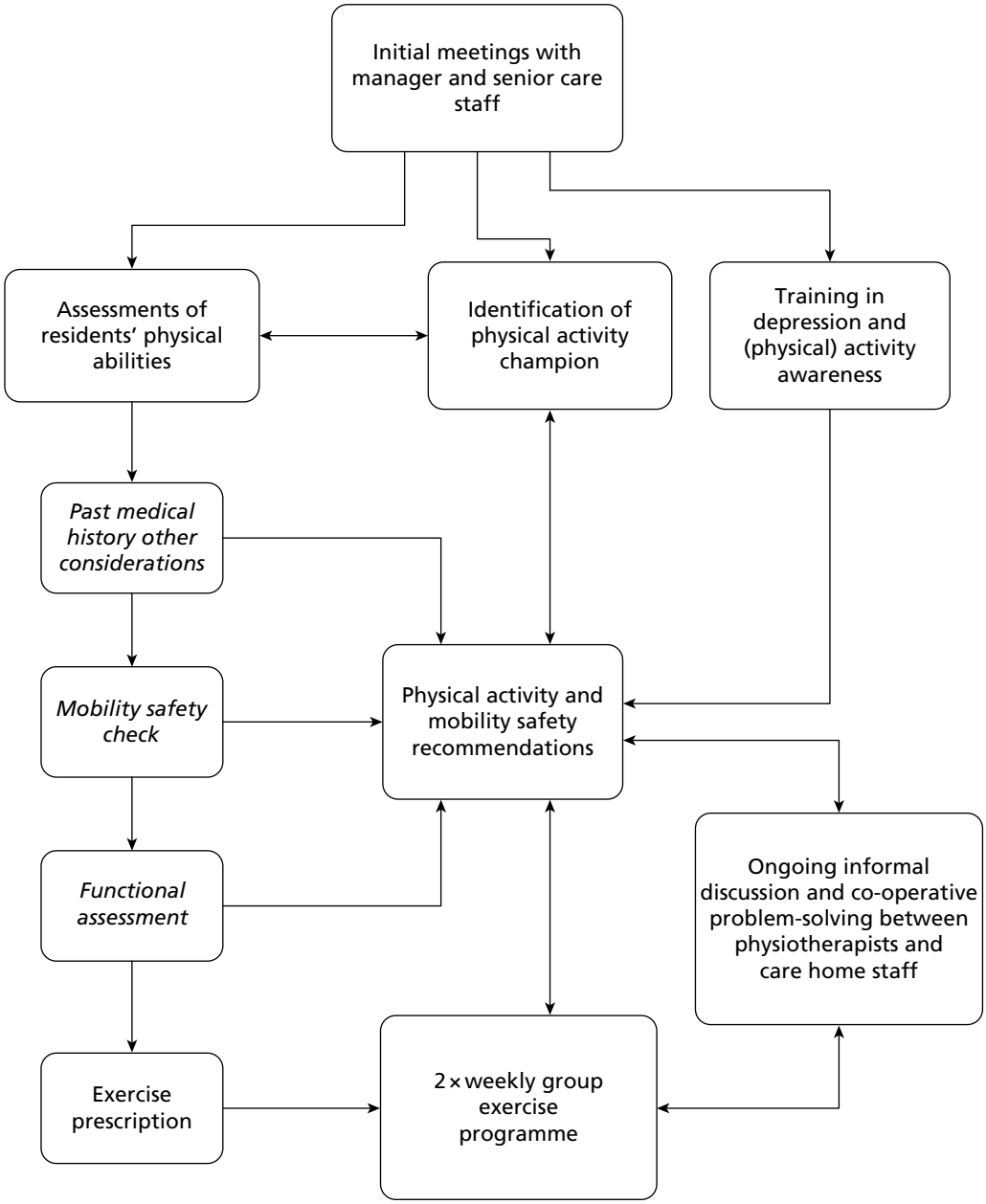

FIGURE 4 OPERA intervention flow chart.

Ongoing physical activity and exercise programme:

5. Physical activity (and mobility safety) recommendations for care home staff.
6. A twice-weekly group exercise programme. The exercise groups were the most resource intensive and most tangible component of the intervention.
7. Ongoing informal discussion and co-operative problem-solving between physiotherapists and care home staff.

Initial meetings with care home manager

The physiotherapist set up an initiation meeting with the care home manager and senior carers aimed at establishing rapport with the care home staff, understanding and agreeing roles within the intervention, and to sort out logistical details such as locations for the exercise groups.

Physical activity champion

A 'champion' (a key individual in an organisation) may assist in the assimilation of an innovation, so we sought to identify a physical activity champion in collaboration with the care home manager and senior care staff to act as a key link within the home. Their role was to assist with planning the exercise groups, and to attend the groups whenever possible, to act as a link between the physiotherapist and home, and to facilitate the implementation of the physical activity recommendations for each resident.

Care home staff depression awareness and activity training

The aims of the care home staff depression awareness and activity training, in addition to the aims of the depression awareness training programme described above, were to:

- highlight the importance of promoting and increasing physical activity to aid the physical and mental health of residents
- establish a collaborative approach towards increasing physical activity within the home
- describe the specific elements of the OPERA intervention and how the staff would be involved.

The session was based on the best current adult pedagogical practice and previous experience of what works in training in care homes. To this end it involved short sessions, used a variety of teaching methods including the depression awareness DVD, and included discussion of cases.

Staff training sessions took about 60 minutes to complete and were repeated when new staff needed to be trained. The training materials used were the same as in the control arm depression awareness training sessions, with the addition of posters illustrating the physical and mental health benefits of physical activity and cycles of activity avoidance related to falls and pain. The training booklets for care home staff had additional pages for copies of these posters plus a mobility safety advice section outlining important enabling techniques and considerations for the care home staff.

Physical activity assessment and recommendations

In consultation with the care home manager all eligible residents were invited to undergo a mobility and physical activity assessment, and received a tailored physical activity recommendation to promote day-to-day activity alongside an invitation to attend the exercise classes. The assessment took place in the resident's room or other locations according to the resident's preference or abilities. The physiotherapist assessed functional capacity, medical history, pain, fear, anxiety, sensory and communication abilities.

On the basis of the assessment the physiotherapist determined a plan of action for the intervention programme elements. The first was a bespoke physical activity programme tailored to each resident and aimed at increasing the level of habitual physical activity, developed in co-operation with the physical activity champion/senior carers. This included the provision of mobility aids, advice on footwear, and manual handling tips to enable mobility. The second was to determine the appropriate level of exercise activities for the group exercise programme.

Group exercise programme

The aim was to provide a structured, standardised and replicable programme of exercise targeted at the physiological, biochemical and psychological mechanisms considered responsible for depressive symptoms in older people, which also accounted for the frailty of residents. This consisted of:

1. An initial adaptive 4-week period utilising shorter exercise times, lower exercise intensity levels, lower numbers of weight lift sets and repetitions, longer repetition durations, and low starting weights set according to functional ability levels.
2. Twice-weekly exercise sessions in a group format, lasting approximately 1 hour each, with at least 45 minutes of expected exercise time per session.

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3. Each session included:
   - a 15-minute section of moderate intensity aerobic exercise
   - an approximately 15-minute section of moderate intensity progressive resistance exercise aiming for two sets of 15 repetitions for each muscle group targeted
   - warm-up and cool-down sections of 5–10 minutes each.

An important concept in exercise therapy is to ensure that the training stimulus is sufficient for each participant to ensure a biological response. Residents' functional status, including their postural stability, was categorised on a three-point scale and the exercise activities used during the class were matched to this. In the first instance the exercise level of the class was set at the level of the least functionally able resident and then progressed on an individual basis in each class.

Screening for exercise safety

All residents were assessed to identify the aspects of their medical history, psychological and physical abilities that would need to be considered in the delivery of moderately intense group exercise activities and screened for absolute contraindications to exercise such as recent operations and severe breathlessness at rest according to New York Heart Association Class IV.[168] This information was drawn from observations, resident's report, care home records or care home staff. Residents who were unable to maintain a seated position while moving their limbs were excluded, and the levels of exercise activities matched to both aerobic/strength capacity and postural stability. Review of resident's health and ability to participate in the exercise and physical activity programme were undertaken by the physiotherapist and care home staff on an ongoing basis in order to ensure safety and progression where changes in functional status were occurring.

The OPERA exercise prescription

We developed three levels of exercise to match the expected levels of functional ability (*Table 4*). These levels were developed to enable the physiotherapists to develop a 'profile' of the likely group participants, both for setting the exercise level for group sessions and as a reminder to increase the exercise challenges for the more physically able residents over time, as well as for ease of communication to physiotherapists providing cover.

After an initial low to moderate intensity start-up phase of several sessions (which varied according to the frailty levels of the residents) group members were encouraged to exercise for up to 45 minutes at moderate intensity. The sessions comprised the following three components.

Progressive resistance exercise

In order to achieve an increase in muscle strength or aerobic conditioning, the demands placed on the musculoskeletal and cardiopulmonary systems must progressively increase over time and stress them beyond their accustomed loads.[169,170] Informed by American College of Sports Medicine[161] and by several existing evidence-based exercise programmes for older people, we aimed to increase general muscle work and strength.

TABLE 4 Levels of functional ability

Level	Functional ability
1	Person able to exercise safely when seated, with lower intensity aerobic and strength challenges
2	Person able to exercise safely when seated and in supported standing, and to work at a moderate level of intensity
3	Person able to exercise more dynamically in sitting and standing with some walking-/dancing-based activities and to work at a sustained moderate to high-intensity aerobic and strength training level

We decided not to use the one repetition maximum to calculate starting weights or progressions, because many of the residents in the pilot study were not able to be accurately tested with free weights or a dynamometer. Instead, our starting weights (*Table 5*) were set according to functional ability level, which could be adapted according to individual preference for acceptability and promotion of adherence.

For the OPERA study we chose to use an observed form of the Borg Scale of Perceived Exertion for resistance exercise.[171–173] It is unlikely that many residents would be able to subjectively report their rate of perceived exertion owing to the high levels of observed cognitive decline observed in residents in the pilot study, and the high prevalence of dementia in the study population as mentioned earlier. We are not aware of any studies that have examined the use of such observed measures in older adults.

Owing to the high levels of frailty common in UK care home residents, it would be likely that few residents could attain or tolerate the higher level of Progressive Resistance Exercise intensity used in previous studies, which demonstrated positive effects on the symptoms of depression.[174–176]

Aerobic exercises

Aerobic exercises are activities that are most likely to increase cardiorespiratory demand, and need to be sustained for 15–20 minutes. Aerobic intensity was monitored by rating perceived exertion using the adapted 10-point Borg rate of perceived exertion scale.[173,177]

Given the frailty of this population, and the setting, the aim was to achieve (the higher end of) a moderate level of intensity, built up over time, using the 'start low, go slow' maxim.[178,179]

Warm-up and cool-down sections

These sections included activities designed to gradually increase or decrease heart/respiratory/circulatory rates as recommended by American College of Sports Medicine.[161]

Progression of exercises In order to ensure and maintain a training effect over time, each resident was progressed within the exercise activities at their starting level or up to next level (*Figures 5* and *6*). Residents could progress between levels on an individual basis by changing their position, for example by standing up in some parts of the aerobic section (level 2). The group could also progress as a whole through the use of changes in music tempo and routines. The exercise progression models were, again, set according to the American College of Sports Medicine Guidelines,[161,162] and informed by several existing evidence-based exercise programmes for older people (see *Figures 5* and *6*).[174,180–182]

OPERA music and equipment

The exercise activities were set within a structured routine, with the target timings matched to selected music tracks for each ability level. The music tracks were carefully selected and arranged to exploit their tempo, themes and psychological appeal.[76,78,183] The choice of music tracks was also based on the likely preferences of older people living in care homes, developed out of experience and expert opinions, and not limited to any musical era in recognition of the potential breadth of musical tastes of this population group. These were provided on a CD [we obtained an annual Limited Manufacture Licence from Mechanical Copyright Protection Society (MCPS) to allow us to disseminate copies of these CDs to all the

TABLE 5 Starting weights for the progressive resistance exercise section

Level	Soft hand weights	Ankle weights
1	Juggling ball (~200 g)	0.5 kg
2	0.5 kg	1.0 kg
3	1.0 kg	1.5 kg

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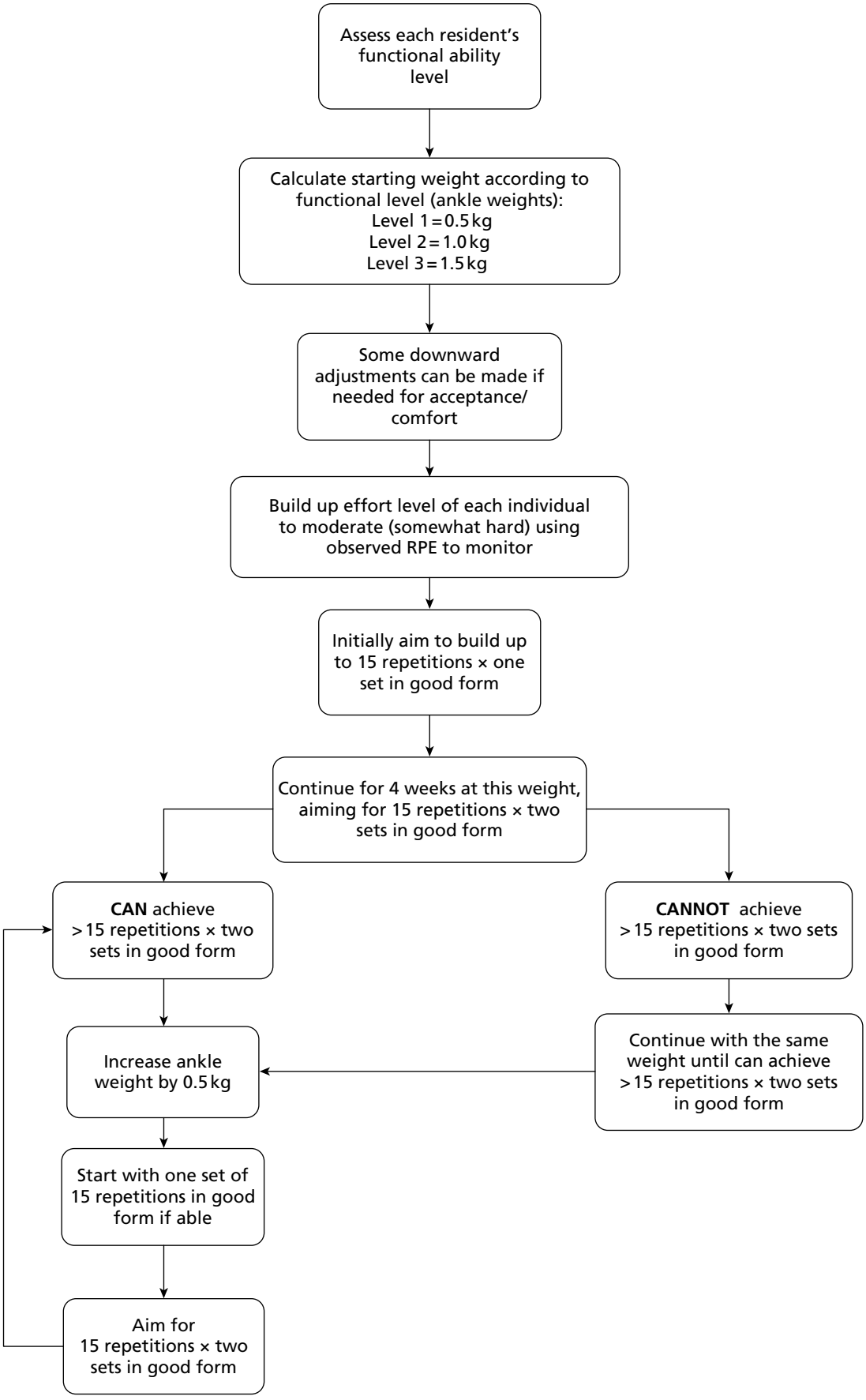

FIGURE 5 Flow chart for the progressive resistance exercise progressions. RPE, rate of perceived exertion.

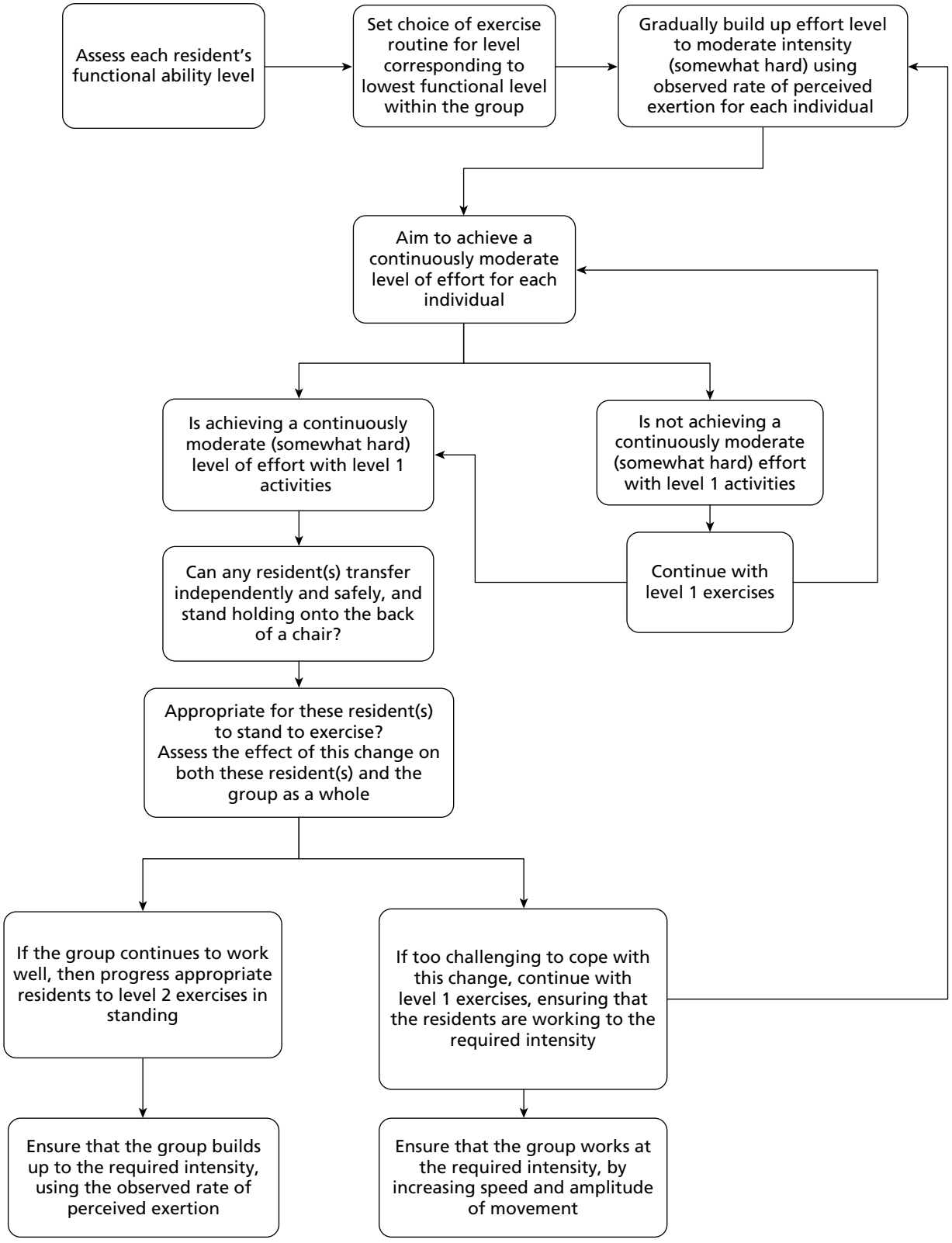

FIGURE 6 Flow chart for progression of aerobic exercise. RPE, rate of perceived exertion.

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OPERA physiotherapists] for levels 1, 2 and 3 to each physiotherapist for easy reference before, and during, the group sessions (see *Appendix 2*).

The exercise equipment comprised small and large soft foam/inflatable footballs (principally for the warm-up period), soft weighted hand balls and ankle weights, plus a 10-metre stretchy velvet band for the aerobic section. This equipment had been chosen for safety reasons (no hard metals or sharp edges), for practicability within UK care home facilities (no space for resistance exercise machines), and for their potential to enable participation, enjoyment, success and so maximise possible adherence for all residents, however frail or cognitively impaired.

Group size and levels of supervision

Although it had initially been planned that group size would be limited to eight residents, because of the numbers of residents in some homes, pragmatically the group size was instead based on the numbers of residents willing and able to attend the exercise sessions. In addition, in many homes the group sessions were run in the main lounge, where residents who expressed a wish not to take part usually sat during the day. These residents remained in their chairs during the sessions, sometimes joining in over time or in a limited manner according to their preference or abilities. Each intervention home was asked to provide a member of the care home staff to help the physiotherapist with running the exercise group sessions.

Logistics of delivering the OPERA intervention

Physiotherapist recruitment and training

The intervention was delivered by chartered physiotherapists registered with the Health Professions Council.

We developed a 2-day training programme to train the physiotherapists, reflecting the typical length of informal training programmes for qualified staff currently available in the UK. The training included a background of the neurophysiology of exercise and depression, exercise prescription guidelines, person-centred dementia care and neurofacilitation techniques relevant to people living with dementia. Physiotherapists were trained in how to deliver the exercise prescription and programme, including practice sessions. The training also covered the assessment of residents, physical activity programme, whole-home approach, carer training package and the logistics of preparing and completing the data collection and clinical record forms. The training was delivered by a physiotherapist with specialist expertise in the management of dementia and mental health, and documented in an extensive training manual (NA).

Physiotherapist support

In addition each physiotherapist received a carer training pack (with cue cards, posters and DVD) and a set of the specially produced OPERA CDs to accompany the exercise routines. Ongoing support was provided to each physiotherapist via e-mail communications and a study day half-way through the 2-year recruitment and delivery period. Clinical supervision and support was provided by local team leaders and supplemented by regular visits from the research team. The frequency of supervisory support visits was between 2- and 6-monthly, depending on the experience and confidence levels of the physiotherapists.

Physiotherapy team

There were two distinct models of physiotherapy delivery in OPERA. These were planned from the outset with oversight of the whole of the intervention delivery being provided by the lead physiotherapist in C&W. In C&W the physiotherapists were employed by the University of Warwick and their main role was OPERA intervention delivery (some on casual or part-time contracts). In NEL the physiotherapists were seconded from Barking & Dagenham Primary Care Trust and generally had a clinical caseload as well as OPERA commitments. At times of peak demand some sessions were delivered by a private physiotherapy service. One primary care trust physiotherapist in NEL acted as the main contact with the primary care trust physiotherapists. Training for physiotherapists at both sites was provided by the lead physiotherapist in C&W.

Consent to exercise

As this was a cluster randomised trial, all residents were exposed to the intervention that included the opportunity to take part in the exercise classes. Formal written consent was not taken for participation in the classes. A more informal approach was taken that reflected best clinical practice. Residents were encouraged to take part in a home activity, which was briefly described during the assessment, with visual/aural clues acting as non-verbal descriptors and reminders during the classes themselves (setting out the equipment, playing the music, demonstrating the exercises). Residents then expressed their implied consent or refusal, by either participating, leaving the room or requesting to leave the room (could be expressed non-verbally), or by not doing the exercises.

Directly attributable adverse events

We defined a directly attributable adverse event as an event needing external medical attention as a consequence of participation in OPERA. This included events occurring during an intervention exercise group, or when participants in the groups were getting to and from the session. Events to be included (but not restricted to) were injurious falls, myocardial infarction, angina, stroke, respiratory distress, musculoskeletal injuries, severe psychological distress or death. For any such events, which were suspected to be a directly attributable adverse event, the treating physiotherapist completed a notification form and notified the study manager. Clinical members of the team then assessed if this event was a directly attributable adverse event. In the event that the home manager became aware of such an event after the physiotherapist had left the home they completed a suspected serious adverse event form and notified the study manager. We used the same system for assessing any suspected adverse events that occurred during study assessments.

Summary

We designed a structured exercise and physical activation programme, within a whole-home approach, to affect the physiological and psychological processes most likely to be able to decrease or prevent depressive symptoms in older people residing in care homes in the UK. The intervention adhered to the principles of exercise prescription, person-centred care and innovation adoption, and was structured with sufficient flexibility to be delivered within a range of different care home settings, to a variety of resident profiles. The training and support package was practical to allow for roll out within the National Health Service if the intervention proved effective.

Methodological considerations

Objectives

Our primary objective was to compare depression levels between intervention and control care homes, addressed via three primary analyses that represent different ways of expressing depression levels:

1. the prevalence of depression (defined as proportion of participants with five or more positive responses to the Geriatric Depression Scale-15 or equivalent) in intervention homes with that in control homes in all residents contributing data 12 months after homes were randomised (*cross-sectional analyses*)
2. the number of depressive symptoms at 6 months between intervention and control homes in residents who were depressed at pre-randomisation baseline assessment (*depressed cohort analyses*)
3. the number of depressive symptoms at 12 months between intervention and control homes in all residents who were assessed prior to randomisation (*cohort analyses*).

In our original proposal we planned to include, as part of our primary analyses, comparisons of the rates of remission from depression at 6 months and the number of depressive symptoms at 12 months in those who were depressed at pre-randomisation baseline. Early in the study it became clear that the average cluster size and follow-up rates would be smaller than originally anticipated and that we would be unlikely

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to obtain sufficient data to produce robust comparisons. We therefore changed our primary analyses with the agreement of the independent Trial Steering Committee, Data Monitoring and Ethics Committee (DMEC) and the funder (see below). Remission of depression became a secondary outcome.

Our secondary objectives were:

1. to compare, between intervention and control arms:
    i. remission of depression
    ii. cognitive function
    iii. health-related quality of life
    iv. mobility and exercise tolerance
    v. pain
    vi. fear of falling
    vii. social engagement
2. to report descriptive statistics on:
    i. the prescribing of antidepressants, hospital admissions
3. to report the following safety outcomes:
    i. injurious falls as indicated by peripheral fractures, mortality rates.

For the depressed cohort we just report a 6-month analysis. For remaining analyses we report on each time point at which we collected data.

Sample size

Unusually, three linked primary analyses were specified for this study. The funder's brief specified a cluster randomised trial with the outcome of interest to be remission of depression. In designing the study, the research team developed a whole-home intervention that would have a long-term impact on all residents. Thus, the outcome of greatest interest to the research team was the difference in the prevalence of depression (as indicated by five or more depressive symptoms or equivalent) at 12 months. (If 15–13 items on the Geriatric Depression Scale-15 have been completed a score of ≥5 is indicative of depression; if 12–11 items on the Geriatric Depression Scale-15 have been completed a score of ≥4 is indicative of depression; if 10 items on the Geriatric Depression Scale-15 have been completed a score of ≥3 is indicative of depression.) For completeness we also considered the long-term effect the intervention may have on the mean level of depressive symptoms at 12 months for all study participants with baseline assessments prior to randomisation.

The remission of depression question originally specified by the funders required the largest number of participating homes; it was therefore this comparison we used to set our original sample size of 77 homes. To reduce treatment costs we planned an unbalanced randomisation of 1 : 1.5 in favour of control.

Original sample size

To show an increase in the remission rate after 6 months from 25% to 40% in those depressed at baseline, with 80% power at the 5% significance level, with this unbalanced randomisation using a simple sample size calculation requires data on 343 subjects. Assuming an average home size of 32 and a 50% recruitment rate to the study the average cluster size at randomisation would be 16. Assuming that 40% of the residents recruited had five or more depressive symptoms and a 15% loss to follow-up at 6 months, the average cluster size for the analysis would be 5.44. Few previous studies were available to allow us to estimate the range of likely values for the intracluster correlation coefficient needed to estimate the inflation factor required for a cluster randomised trial in care homes. We therefore used a conservative value of 0.05 for the intracluster correlation coefficient; towards the upper end of the range seen in previous primary care studies. We inflated our sample size by a factor of 1.22, meaning that we required data on 418 subjects at follow-up for this analysis. This in turn means we needed to recruit 77 homes to achieve this target (*Table 6*).

TABLE 6 Original sample size calculations

ICC = 0.05	A. To show a reduction in the proportion of participating residents depressed (GDS-15 score < 5) at the end of the study from 40% to 25%	B. To show an increase in the remission rate after 6 months from 25% to 40% in those depressed at baseline	C. To show a mean reduction in GDS-15 score of 1.2 after 12 months in those depressed at baseline
Power	80%	80%	80%
Significance	5%	5%	5%
Simple sample size	343	343	280
Mean cluster size at follow-up	15.0	5.4	4.5
Inflation factor	1.7	1.22	1.175
Total no. required at follow-up	With complete assessments: 583	With depression at baseline and complete assessments: 418	With depression at baseline and complete assessments: 330
Care homes required	39	77	74

GDS-15, Geriatric Depression Scale-15; ICC, intracluster correlation coefficient.

The mean change in the Geriatric Depression Scale-15 score in a community sample of people aged >85 years after a major negative life event (e.g. death of partner) is 1.2.[121] This is indicative of a clinically important mean difference in Geriatric Depression Scale-15. In previous studies the standard deviation (SD) of the Geriatric Depression Scale-15 in care home residents was in the range of 3.2–3.6;[120,122,124] for depressed care home residents it was 3.5.[26] We therefore used a minimally important difference of 1.2 and a SD of 3.5 in the sample size calculation for the comparison of depressive symptoms.

Revised sample size

We revisited this sample size, using baseline data, part-way during recruitment because the average cluster size was smaller than anticipated. After we had randomised 47 care homes the mean cluster size at baseline was 10.7, intracluster correlation coefficient = 0.053, 6-month follow-up rate 70%, 46% of our participants had a baseline Geriatric Depression Scale-15 score of ≥5, and the SD of the Geriatric Depression Scale-15 was 2.2 and 3.1 for depressed and all residents, respectively. Reworking our sample size in light of these data showed that we were unlikely to have sufficient statistical power to show our prespecified increase in rate of remission from depression – comparison B (*Table 7*).

With the agreement of the Trial Steering Committee, DMEC and funder we therefore dropped comparison B as one of our primary analyses, replacing this with new comparison C (see *Table 7*), seeking to show a mean difference of 1.2 points in the Geriatric Depression Scale-15 for those depressed at baseline. Consequential upon this change, to avoid making multiple comparisons on the same group, i.e. those depressed at baseline, we changed our third primary analysis to comparing change in depressive symptoms at 12 months in all of those present at baseline – new comparison D (see *Table 7*). In this way we ensured that we had adequate statistical power to test the effect of our intervention on all three overlapping populations of interest: those resident in the homes at the end of 12 months, those who were depressed at baseline and able to provide 6-month data, and all residents present at baseline who were still able to give data at 12 months. To allow for unforeseen events we continued to recruit to our original target of 77 care homes.

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TABLE 7 Revised sample size calculations

ICC = 0.053	A. To show a reduction in the proportion depressed (GDS-15 score < 5) at 12 months from 46.1% to 28.8%[a]	B. To show an increase in the remission rate after 6 months from 25% to 40% in those depressed at baseline[b]	C. To show a mean reduction in GDS-15 score of 1.2 after 6 months in those depressed at baseline: from 7.27 to 6.07 (SD = 2.21)	D. To show a mean reduction in GDS-15 score of 1.2 after 12 months: from 4.5 to 3.3 (SD = 3.12)
Power	80%	80%	80%	80%
Significance	5%	5%	5%	5%
Simple sample size	281[a]	343	112	224[a]
Mean cluster size at follow-up	9.6	3.9	3.9	7.5
Inflation factor	1.46	1.16	1.16	1.34
Total no. required at follow-up	With complete assessments: 409	With depression at baseline and complete assessments: 396	With depression at baseline and complete assessments: 130	With complete assessments: 301
Care homes required	43	101	33	41

GDS-15, Geriatric Depression Scale-15; ICC, intracluster correlation coefficient.

a Using actual data in revised sample size means simple sample sizes changed.

b Analysis dropped as primary analysis because of insufficient statistical power – based on actual data >100 homes needed.

Randomisation

This was a cluster randomised trial with care homes as the unit of randomisation. Care homes were first stratified by location (NEL or C&W) and then minimised into intervention and control arms using the MINIM programme (www-users.york.ac.uk/~mb55/guide/minim.htm). This programme uses minimisation with a random element, allocating care homes to the arm of the study that gives the better balance with a probability of 70%. The minimisation factors were type of home (local authority, voluntary, private and care home, private and nursing home), and size of home (32 beds or fewer, >32 beds). Initially, we had intended to use a third randomisation factor, dementia home or not, but only one dementia home was recruited (see *Homes*, above).

Allocation concealment and identification/recruitment bias

Allocation concealment was ensured by using a statistician who was independent of the study, based at the Pragmatic Clinical Trials Unit, Barts and The London School of Medicine and Dentistry, to carry out the minimisation. Researchers recruiting homes provided details of a recruited home by e-mail directly to the independent statistician. They were always notified, by telephone, of allocation within a week but usually within a few days.

Bias can occur in cluster randomised trials when identifying and recruiting participants is carried out after randomisation. The issues that arise are similar to those arising when allocation is not concealed. This identification/recruitment bias has the potential to be a serious source of bias in these studies.[184–186] This bias is avoided if those identifying and/or recruiting participants do so before randomisation. In OPERA the majority of participants were recruited prior to the care homes being randomised. In addition, the majority of these individuals provided baseline data prior to randomisation thus avoiding the chance of participant responses to the baseline questionnaires being influenced by their knowledge of the intervention they would be receiving. Some baseline data were collected from participants after

randomisation, either from participants who had been approached before randomisation, for whom assent was only obtained after randomisation, or from participants who had been unable to provide a complete data set prior to randomisation, for example if records data were available but the resident was not available for assessment. Data from these participants collected after randomisation were not used in the cohort analyses.

Some participants joined the study because they moved into participating homes after the homes had been randomised. We could not avoid the possibility of identification and/or recruitment bias for those participants; both their likelihood of identification as a potential study participant and their likelihood of participation might have been affected by their knowledge, and knowledge of care home staff, of the intervention in their home.

Baseline comparisons

We compared baseline characteristics of homes and characteristics of participants in the intervention and control arms. We compared the baseline characteristics between intervention and control groups for the cohort and the depressed cohort (these individuals are included in our cohort comparisons). We also compared these characteristics for those participants who joined the study after randomisation.

Analysis

Our full analysis plan is included in *Appendix 3*. In this overview we describe the general principles for our primary and secondary analyses. Safety analyses are described later in this chapter (see *Safety analyses*, below).

We conducted available case analyses using intention-to-treat principles. This meant that, for the cohort analyses, when we were able to obtain data for an individual at a specified outcome point (6 or 12 months), we analysed them in the care home they were recruited to regardless of whether they were still in this care home, had moved to another OPERA care home, or had moved to a home outside OPERA or elsewhere. For the cross-sectional comparisons we analysed data according to which care home they were in at the time data were collected. We did not impute missing values in our clinical analyses.

To account for cluster randomisation, we used mixed-effect models with care home as a random effect, and intervention and minimisation factors as fixed effects. Baseline values of outcome and other covariates were also used as summarised in *Table 8*. All covariates were selected prior to any analyses, as specified in the analysis plan, and all were retained in the analysis, unless there was evidence of multicollinearity. To assess any potential multicollinearity we examined correlations between covariates. If severe multicollinearity was present we dropped one of the collinear covariates, retaining the covariate providing the best fit.

An appropriate link function was used in the analyses depending on the type of outcome:

- *continuous outcomes* an identity link function
- *binary outcomes* a logit link function
- *count outcomes* a Poisson link function
- *ordinal outcomes* cumulative logit link function.

We used model diagnostics to check distributions of residuals and homoscedasticity as appropriate.

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TABLE 8 Covariates at home and individual level

Outcome	Covariates at home level	Covariates at individual level
All outcomes	Location (C&W or NEL) Home size Home type (voluntary and local authority; private and care home; private and nursing home) Proportion of residents in home with MMSE score of <20	Sex Whether or not individual on antidepressants when recruited SPPB when recruited
Cross-sectional outcomes only	Mean outcome measure in home at baseline (except for MMSE)	Age at study end
Cohort outcomes only		Baseline value of outcome Baseline value of GDS-15 Age at baseline

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination.

Populations of interest

The nature of OPERA study design is that there are several populations of interest, each being relevant to different comparisons. On each occasion our analyses refer to the individuals in that population of interest.

- *Cohort analyses, assessment data* All of those who provided one or more outcome at an assessment prior to randomisation and who were alive the day before their care home was randomised.
- *Cohort analyses, care home data* All those for whom we had consent/assent to collect data prior to randomisation and who were alive the day before their care home was randomised.
- *Depressed cohort analyses* Assessment data and care home data; all of those with a Geriatric Depression Scale-15 score of ≥5 (or its equivalent) completed prior to randomisation and who were alive the day before their care home was randomised.
- *Cross-sectional analysis, assessment data* All those for whom we had consent/agreement to collect assessment data and who were present in an OPERA home at the time of the end-of study assessment for that care home.
- *Cross-sectional analysis, care home data* All of those for whom we had consent/agreement to collect care home data and who were present in an OPERA home at the time of the end-of study assessment for that care home.
- *Safety analysis* All residents in OPERA homes at any time during the study period for that care home.

Cross-sectional analyses were performed for outcomes only at 12 months. In these analyses we included all residents who had been resident in the home for at least 3 months. This included all of those who had been resident prior to randomisation regardless of whether they had provided baseline data before or after randomisation, plus residents who were recruited to the study after randomisation. In our reporting we assumed that those assessed within 6 weeks of randomisation were present at randomisation; those assessed between 6 weeks and 4.5 months post recruitment moved into homes within 3 months of randomisation and were recruited at a 3-month follow-up visit; those assessed between 4.5 and 7.5 months were recruited at a 6-month follow-up visit; and those assessed between 7.5 and 9 months were recruited at a 9-month visit.

Cohort analyses were conducted for outcomes at both 6 and 12 months. In these analyses, we included only those who had provided the outcome of interest prior to randomisation and who also provided the same outcome at the specified outcome point. Thus, our cohort comparisons were always smaller than our equivalent cross-sectional comparisons.

All analyses were undertaken in Stata release 11 (StataCorp LP, College Station, TX, USA), using xtmixed and xtmelogit commands, with the exception of ordinal outcomes, for which SAS 9.2 (SAS Institute Inc.,

Cary, NC, USA) proc glimmix was used. We report intracluster correlation coefficients for all outcomes. For linear and Poisson models, intracluster correlation coefficients were produced directly from the models. For logistic models, intracluster correlation coefficients were produced on the logistic scale. These were converted on to the linear scale using a method.[187] For the glimmix routines in SAS we used the ordinal scales for pain and social engagement. Intracluster correlation coefficients were obtained using intracluster correlation coefficient $= \sigma_u/(\sigma_u + \pi^2)/3$ and are on the logistic scale. There is currently no straightforward way of converting these on to a linear scale for ordered logistic regression but the intracluster correlation coefficients are likely to be slightly smaller on the linear scale.

Primary analyses

1. To compare the prevalence of depression in intervention homes with that in control homes (cross-sectional comparison) we used a mixed model with a logit link. We included those who had been in the study for >3 months at the 12-month outcome point. To assess the effect of recruitment post randomisation when there was a chance of identification/recruitment bias, we conducted a sensitivity analysis that excluded those whose baseline assessments occurred after randomisation of the home into which they were originally recruited.
2. To compare (1) the number of depressive symptoms at 6 months between intervention and control homes in participants who were depressed when assessed prior to randomisation and (2) the number of depressive symptoms at 12 months in all participants assessed prior to randomisation (cohort comparisons), we used mixed models with an identity link and with the number of depressive symptoms at baseline as a covariate. Those recruited post randomisation were not included in the primary analyses because the effects on these individuals was likely to be less given that they had been resident in the homes for a shorter period and there was potential for identification/recruitment bias among these individuals.

Note that we hypothesised a reduction in depression score and prevalence of depression as a result of our intervention, thus negative mean difference or an odds ratio (OR) of <1 favours the intervention.

Secondary analyses

Secondary analyses used the same principles as the analyses of primary outcomes. Note that we hypothesised that our intervention would increase the score or prevalence for most outcomes, thus in general positive mean differences and ORs of >1 favour the intervention. The only exceptions are the outcomes levels of depression, pain and fear of falling, all of which were hypothesised to reduce as a result of our intervention.

TABLE 9 Summary of primary analyses

Outcome	Measurement[a]	Population of interest[b]	Source of data[b]	Model, programme and command	Effect and interpretation
Prevalence of depression	Proportion of those depressed as measured by GDS-15	Cross-sectional at 12 months	Assessment	Mixed model, logit link Stata xtmelogit	OR <1 favours intervention
Level of depression	No. of depressive symptoms as measured by GDS-15	Cohort at 12 months Depressed cohort at 6 months	Assessment	Mixed model, identity link Stata xtmixed	Negative mean difference favours intervention

GDS-15, Geriatric Depression Scale-15.

a See *Residents recruited after randomisation*, earlier in this chapter.

b See *Trial design considerations*, earlier in this chapter.

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TABLE 10 Summary of secondary analyses

Outcome	Measurement	Populations of interest[a]	Source of data[a]	Model, programme and command	Effect and interpretation
Secondary analyses of GDS-15					
Remission of depression	Proportion not depressed as measured by GDS-15	Depressed cohort at 6 months	Assessment	Logistic-mixed model, logit link Stata xtmelogit	OR > 1 favours intervention
Level of depression	No. of depressive symptoms as measured by GDS-15	Cross-sectional at 12 months	Assessment	Linear-mixed model, identity link Stata xtmixed	Negative mean difference favours intervention
Other outcome measures					
Health-related quality of life	Self-assessed EQ-5D score	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Assessment	Linear-mixed model, identity link Stata xtmixed	Positive mean difference favours intervention
Cognitive function	MMSE score	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Assessment	Linear-mixed model, identity link Stata xtmixed	Positive mean difference favours intervention
Fear of falling	Yes/no question	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Assessment	Logistic-mixed model, logit link Stata xtmelogit	OR < 1 favours intervention
Pain	Ordinal five-point scale reduced to three points for analysis	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Assessment	Ordinal logistic-mixed model, cumulative logit link SAS glimmix	Proportional OR < 1 favours intervention
Mobility	SPPB	Cohort at 12 months Cross-sectional at 12 months	Physical assessment	Linear-mixed model, identity link Stata xtmixed	Positive mean difference favours intervention
Health-related quality of life	Proxy EQ-5D	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Care home, proxy	Linear-mixed model, identity link Stata xtmixed	Positive mean difference favours intervention
Social engagement	SES, six binary items reduced to three-point scale for analysis	Cohort at 6 months Cohort at 12 months Cross-sectional at 12 months	Care home, proxy	Ordinal logistic-mixed model, cumulative logit link SAS glimmix	Proportional OR > 1 favours intervention

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SES, Social Engagement Scale; SPPB, Short Physical Performance Battery.

a See *Trial design considerations*, earlier in this chapter.

TABLE 11 Summary of safety analyses

Outcome	Measurement	Populations of interest[a]	Source of data[b]	Model, programme and command	Effect and interpretation
Aggregated fracture rate	No. of fractures at home level	All residents of the home over the year following randomisation, regardless of whether or not they were participants in the study	Care home records	Poisson mixed model in SAS[c] Stata xtmepoisson	OR < 1 favours intervention
Fracture rate	Fracture or not	Study participants over the year following randomisation	NHS data	Logistic-mixed effects model, logit link Stata melogit	OR < 1 favours intervention
Mortality	Death	Study participants over the year following randomisation	NHS data	Logistic-mixed effects model, logit link Stata melogit	OR < 1 favours intervention

NHS, National Health Service.

a See *Populations of interest* for definitions.

b See *Trial design considerations* for definitions.

c Poisson mixed model in SAS (with offset for total number of residents in a year assuming constant exposure).

Safety analyses

Two of our safety analyses (on fracture and death rates) were based on data relating to study participants and conducted in a similar fashion to our primary (*Table 9*) and secondary analyses (*Table 10*), using mixed-effects logistic models. The third analysis (*Table 11*) was of fractures among all care home residents (aggregated fracture level). These fractures could not be attributed to individuals so we used a Poisson model at the care home level, adjusting for clustering with a random effect, and home location, home size, home type, mean age of home participants at pre-randomisation baseline, proportion female, percentage on antidepressants at pre-randomisation baseline, proportion of residents with moderate or severe cognitive impairment at pre-randomisation baseline assessment.

Descriptive analyses

We collected data on medication use. We present descriptive data on use of medications most relevant to our study hypotheses: hypnotics and anxiolytics, antipsychotics, antidepressants, tricyclic antidepressants, SSRIs, analgesics and non-steroidal anti-inflammatory drugs (NSAIDs).

Blinding

As described above (see *Allocation concealment and identification/recruitment bias*), new residents joining the study after randomisation could not be blinded to their care home's allocation status prior to recruitment. Identification/recruitment bias was possible for these participants because all care home staff and study staff visiting the care homes were aware of the care home's allocation. Indeed, one marker of success for the programme would be achieving this obvious level of awareness. Additionally, recruitment and treatment visits might coincide.

We protected against this by asking care homes to notify us of all new residents and monitored reasons for exclusion from the study and considered basing our analysis of the proportion of residents depressed at the end of the study only on those residents who joined the study before randomisation and who were present at the end of the study if there were baseline differences between intervention and control homes in characteristics of those who joined the study after randomisation.

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Members of the research team collecting follow-up data were aware of the care homes' randomisation status leading to possible bias in data collection. We would anticipate more potential for bias in the physical function assessment – the Short Physical Performance Battery – than for patient-completed outcomes. As part of staff training we emphasised the importance of consistency of approach in the two arms of the study. Results from proxy outcomes, collected from care home staff, might be more likely to be prone to bias than those collected by the research team.

The routine data collected were less prone to bias. Drug-use data were extracted from routine care home records; data on fractures and deaths collected under Regulation 37, Part V11[188] are unlikely to be biased because this recording by care homes is a statutory obligation. Routine National Health Service data used for deaths, fractures in study participants and other health service activity (except general practitioner consultations) would not be prone to bias. Where coding of these data was required (fracture-related deaths), this was undertaken by a study team member blind to allocation. Our overall mortality data are not prone to bias.

Economic evaluation

The whole-home aspect of the intervention means that those residents who did not wish to participate in the study were also exposed to the intervention. This was a result of the training given to the care home staff who looked after them and, in the intervention homes, due to the ability of residents who were not participating in the evaluation to participate in the exercise groups. The economic evaluation was designed to capture the costs associated with these changes. Our aim was to examine the cost–utility of the whole-home exercise intervention to alleviate depression among care home residents aged ≥ 65 years, as compared with current best practice for the identification and management of depression in this population from the National Health Service provider perspective.

Data collection

Data for the economic evaluation covered a 12-month time period from when the home was randomised. We collected data needed to calculate costs at the individual-level through the care home records at 3, 6, 9 and 12 months and from routine primary care trust data provided after the study was finished (*Table 12*).

We used the EQ-5D to measure gains in quality-adjusted life-years. The research team collected proxy EQ-5D data on all participants at baseline, and 3, 6, 9 and 12 months after randomisation. Additionally, we collected self-completed EQ-5D scores at baseline and 6- and 12-month assessments on participants able to complete these. They are not reported here but will be used to look at a secondary analysis of the relationship between EQ-5D and proxy EQ-5D.

For residents joining the study after their care home was randomised, we collected data in the same way but participation in the study is deemed to start from the time they were first assessed, i.e. 3, 6 or 9 months after randomisation (see *Table 12*). These participants were included only in our secondary analysis.

Costs

Individual-level resource use was combined with unit costs to calculate the total health-care cost for each resident. The data received from the primary care trusts on inpatient services, outpatient services and A&E visits included diagnostic related groups and associated tariffs. These costs included staff costs, consumables and procedure costs. For those A&E attendances that recorded arrival 'via ambulance or air ambulance', the primary care trusts confirmed that most, or indeed all, arrivals were via road and the cost for a road ambulance journey[188] was added to the tariff for the visit. For resource use coming from care home records and community data provided by primary care trusts, we obtained unit costs for the UK from published sources.[189,190] Unit costs are inclusive of ancillary staff costs, overheads and training

TABLE 12 Summary of health care use collected and associated unit costs

Item	Unit	Unit cost (£)	Source of resource use collection
A&E	Investigation	Variable	PCT data extract
Community visits	Visit	47	PCT data extract
GP home visit	Visit	120	Care home records
GP surgery visit	Visit	36	Care home records
Inpatient service	Dominant episode	Variable	PCT data extract
Medications			
Tablets	Tablet	Variable	Care home records
Liquid medicines	ml	Variable	Care home records
Patches	Patch	Variable	Care home records
Suppositories	Suppository	Variable	Care home records
Metered-dose inhalers	Dose	Variable	Care home records
Mental health team	Visit	108	Care home records
Outpatient service	Visit	Variable	PCT data extract
Practice nurse	Visit	12	Care home records
Transport to A&E via ambulance	Trip	246	PCT data extract

PCT, primary care trust.

costs. We used unit costs for the year 2010, actualising unit costs for inflation using the Healthcare Price Index when necessary.[189] *Table 12* shows all unit costs derived from published sources. We were unable to procure data on diagnostic tests.

Unit costs for medications were obtained from the Prescription Cost Analysis database for 2010.[190] We included all medication costs where reliable data could be collected, as there were unlikely to be many health costs that could not plausibly be related to the intervention. We obtained details for medications that were being taken by study participants over the 1-week time period that preceded the data collection visit (see *Health service activity*, above). We calculated the total medication costs using the average cost per dose for each product obtained from the database, and the mean quantity taken per day of each product during the 7 days prior to data collection. These costs were extrapolated for the 91 days prior to the follow-up visits at 3, 6, 9 and 12 months. If the daily drug cost was missing for a time point then we used the midpoint of the adjacent time points.

Where a dose range is cited as 'as required', we coded it as the midpoint of that range. For common analgesics such as paracetamol and co-codamol, the dose was considered to be two tablets unless another dose was clearly specified. If the dose of the drug had not been recorded, the standard dose for that drug was assumed. If the quantity was not recorded, the standard quantity for that drug was assumed. Good data were available for tablets, liquid medicines, patches, suppositories and metered-dose inhalers. Owing to inconsistencies in the way dosing was recorded within care homes, the following items were excluded from our analyses: all wound dressings (including bandages), creams and lotions, sprays, eye drops, ear drops, injections (including insulin), glucose strips and lancets, catheters and catheter solutions and appliances.

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Active control and intervention costs

Control home costs included the cost of training a nurse to deliver the depression awareness intervention, the costs of the nurse's time and travel to deliver the intervention at the care homes, and the materials for the training sessions. In the control homes, the total cost of implementing 'best practice' for diagnosis of depression was divided by all residents in the home to arrive at the unit cost.

Intervention care home costs included the training of physiotherapy staff, the delivery of the depression awareness training, the implementation of the exercise regime, physiotherapists' time and travel expenses for organising and running the exercise class, and equipment used both for the exercise programme and to aid resident mobility. Data on the National Health Service costs of providing equipment resulting from mobility assessments with the physiotherapists were not easily available. The likely differences between the market purchase price and National Health Service costs, including a discount, would be small for most items, as items were of relatively low cost. These items were estimated by study staff at the aggregate level for residents in the intervention homes and this cost was attributed to the total cost of the intervention.

Deciding how to attribute the cost of intervention delivery to study participants, and hence arrive at unit cost for the intervention was not straightforward. This was because non-study participants are also exposed to the intervention and a proportion of the cost could also be attributable them.

We considered four different ways of attributing costs to study participants:

1. *Cost per study participant* The fixed cost is divided by number of study participants to develop a cost of delivery of the intervention package to each study participant; however, this may overestimate the costs to study participants, as many non-study participants were exposed. Furthermore, some study participants did not attend any exercise groups.
2. *Cost per session attendance* The fixed cost (TC) is divided by the number of attendances at the exercise intervention sessions, regardless of whether or not the attendee was a study participant, to estimate a cost per session attendance, i.e. $TC/(a_p + a_{np})$ (where a_p equals the number of attendances to exercise classes by study participants and a_{np} equals the number of attendances to exercise classes by non-study participants). This cost per session attendance can then be applied at an individual study participant based on the number of sessions attended by each study participant. This method ignores the whole-home aspect of the intervention as residents who did not attend any sessions could still benefit from the intervention through the mobility assessments and general changes to the atmosphere of the care home.
3. *Cost per resident* The fixed cost is divided by the number of residents to develop a cost of delivery of the intervention package to each resident. This may underestimate the cost to participants as some non-participants, for example those with severe disability or cognitive impairment, will not have had substantial exposure to the intervention.
4. *Weighted cost per resident* The fixed cost is divided by the overall percentage of residents assessed for eligibility to participate in the exercise sessions. This method has the advantage of reflecting the whole-home aspect of the intervention while removing the cost burden from those residents who were unlikely to receive much benefit from the programme due to communication difficulties or serious illness.

We chose to use option 4, the weighted cost per resident, to attribute costs to study participants. In addition, for those leaving the care homes or dying, the costs were truncated at the point of leaving or death.

Quality-adjusted life years

The proxy EQ-5D is a well-accepted measure that has been used for stroke patients.[138,191] Responses from proxy EQ-5D questionnaires were transformed into quality of life weights (utility) derived from at UK general population sample using an algorithm developed by Dolan *et al.*[192] We specified a priori that we

would use proxy EQ-5D data rather than self-completed EQ-5D. This was because of an anticipated poor completion rate and to avoid problems with participants whose health deteriorated making them unable to complete the EQ-5D at follow-up time points. In practice, the proxy EQ-5D was completed for a larger proportion of participants than the self-reported EQ-5D.

In order to ensure that quality-adjusted life-year calculations were as accurate as possible, we chose to use multiple imputation to guard against any bias that may result from missing proxy EQ-5D scores. As the study was cluster randomised rather than individual randomised, the data were multilevel. To adjust for this characteristic of the data, a multiple imputation model that accounted for clustering (by means of a random cluster effect) by care home was used to generate the missing proxy EQ-5D scores at each of the five time points (baseline and 3, 6, 9 and 12 months). The imputation model was multivariate for the five EQ-5D scores at each time point, and used the auxiliary variables home size, baseline age of resident and proxy EQ-5D scores at all five time points. Five imputed data sets were created in this way.

The EQ-5D scores, including those scores that were generated by the multiple imputation, were then used to calculate five quality-adjusted life-years, one for each imputed data set. We calculated the total utility for each participant from point estimates at baseline, 3, 6, 9 and 12 months, using the 'area under the curve'. To estimate the total utility, we assumed that utility for each person followed a linear trend line between these point estimates.[193] We then added up these utility estimates. As many study participants died over the course of the study, we assumed a linear relationship from last proxy EQ-5D measurement to death.

Analyses

Our primary analysis was a cost–utility analysis over 12 months examining the cost per quality-adjusted life-year gained for all participants, who were assessed for proxy EQ-5D prior to randomisation and had primary care trust data extracts. Importantly, the health economics criteria for inclusion were slightly more restrictive than those for the statistical analysis. The clinical effectiveness analysis included residents with and without primary care trust data extracts, whereas the health economic analysis included only those residents with primary care trust data extracts. This should not be confused with the notion of complete or missing data, as all participants with a primary care trust data extract were included irrespective of the completeness of their records. This analysis included those who were not depressed as well as those who were depressed. This was a more meaningful analysis than the alternative of only examining those who were depressed at baseline, as the costs and any potential benefits were related to all of those exposed to the intervention. In order to be aligned with the clinical effectiveness analysis, we included only those who provided the primary outcome, in this case proxy EQ-5D, prior to the home being randomised. Unlike the clinical effectiveness analysis, we included those residents with partially incomplete proxy EQ-5D scores, as these scores could be imputed for our analyses. In line with an intention-to-treat principle, any participants who moved between care homes during the study were analysed as if they had remained in their original care home.

For each cost category, we multiplied the number of items, or contacts with each type of health-care service, by their unit cost. We calculated the mean total costs per participant from an National Health Service provider perspective adding the cost of consultations, admissions, equipment, rehabilitation and physiotherapy services, prescriptions and applicable intervention costs.

As the outpatient data had a large proportion of missing costs, and these missing data were more frequent with some primary care trusts than with others, we imputed these data using the same methodology as we did for the missing EQ-5D scores before calculating the total outpatient cost. We log-transformed costs before imputing, to make the assumption of normality more plausible. The imputation model also accounted for clustering using random home effects and used the auxiliary variables home size, baseline age of resident and the specialty code provided by the primary care trust. Five data sets with imputed data were created. From these sets, the total outpatient cost per resident was calculated and

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added to the total cost from the other cost categories to produce five total cost data sets, which were used in the baseline analysis.

To compare differences in mean resource use and mean costs between participants in the intervention and control arms of the study, a univariate linear-mixed model was used. To aid in the comparison of costs between the two groups for the outpatient data and total costs, the univariate linear-mixed model was applied to one of the data sets generated by multiple imputation.

Base-case analysis

The correlation between individual costs and outcomes needs to be considered in the cost-effectiveness analysis. In order to acknowledge this correlation when estimating mean incremental costs and mean incremental quality-adjusted life-years, we used bivariate normal mixed models with cluster random effect to obtain maximum likelihood estimates.[194] Originally, we planned to use seemingly unrelated regression, but this method does not strictly recognise the hierarchical nature of our data and so multilevel models have been reported instead.[194] The hierarchical multiple imputation of EQ-5D and outpatient data resulted in five sets of total costs and five sets of EQ-5D scores from which we calculated total costs and total quality-adjusted life-years. Rubin's rules were used to combine these estimates of incremental costs and incremental quality-adjusted life-years with multiple imputation standard errors.[195] Intracluster correlation coefficients were calculated using a mixed model without adjusting for any covariates.

We plotted the spread of incremental cost-effectiveness ratio across the four quadrants of cost-effectiveness, but calculated a mean incremental cost-effectiveness ratio only if it would be informative. For example, with data that show an insignificant quality-adjusted life-year gain, it was more informative to report disaggregated data on costs and effects than report a mean incremental cost-effectiveness ratio. As a definite threshold has proven difficult to set empirically, we planned to assess the cost–utility of the intervention using willingness-to-pay thresholds ranging between £0 and £40,000.[196] The probability that the intervention was cost-effective at willingness-to-pay thresholds was calculated based on the incremental net benefit, which was assumed to be normally distributed, with both mean and SD equal to their multiple imputation estimates.

Sensitivity analyses

To assess the robustness of the analysis to changes of key input values and assumptions, we conducted the cost-effectiveness analysis using alternative scenarios for some cost items. The following were considered:

1. *Excluding high cost individuals* This analysis excluded those individuals who were above the 95th percentile of total cost of care including intervention costs at 12 months.
2. *Including costs from the societal perspective* This perspective includes the cost of care home staff time lost to training and gained by having the residents in the physiotherapy sessions. For the societal perspective, we included the costs of the exercise programme to care homes in terms of time taken to set up and monitor the exercise routines, or to implement the control intervention, as estimated by study staff.

Secondary analysis

A secondary analysis was conducted to include the costs and quality-adjusted life-years for all those participants who joined after the homes were randomised. These individuals provide cost and proxy EQ-5D for the period following their first EQ-5D at a home follow-up visit until the end of the study for the home in which they were recruited.

Process evaluation

Alongside the main study we carried out a process evaluation, using both qualitative and quantitative methodologies, to explore the process of implementing the study in a care home setting, to develop a

set of transferable principles, regarding both the OPERA depression awareness training and the OPERA whole-home exercise intervention, and to inform its implementation on a wider scale.

No data from the process evaluation of the main study were provided to the research team until after the intervention phase was complete. A full process evaluation report was completed and submitted to the chief investigator before any analyses of outcome data were performed (September 2011). This ensured that this assessment was conducted blind to the outcomes of the study.

We used the Theory of Change[197] to identify the important processes to consider in the process evaluation.[109] The Theory of Change identifies the causal processes through which change comes about as a result of a programme's strategies and action.[197] It relates to how practitioners believe individual, intergroup, and social/systemic change happens and how, specifically, their actions will produce positive results.

Figure 7 is a representation of the Theory of Change in relation to the active whole-home intervention in the OPERA study. In this model the primary outcomes (on the right) are brought about by a series of 'changes' as a result of introducing the intervention into the care.

The process evaluation followed the key components of process evaluation proposed by Steckler and Linnan:[198] context, reach, dose delivered, dose received, fidelity and recruitment (*Box 3*). We omitted implementation ('a composite score that indicates the extent to which an intervention has been implemented as planned'). Additionally, we sought the views of participants, including residents, care workers and members of the research team. Their experiences, their attitudes to the intervention and their suggestions for improving the intervention have a significant role in interpreting the study outcomes and informing policy development.

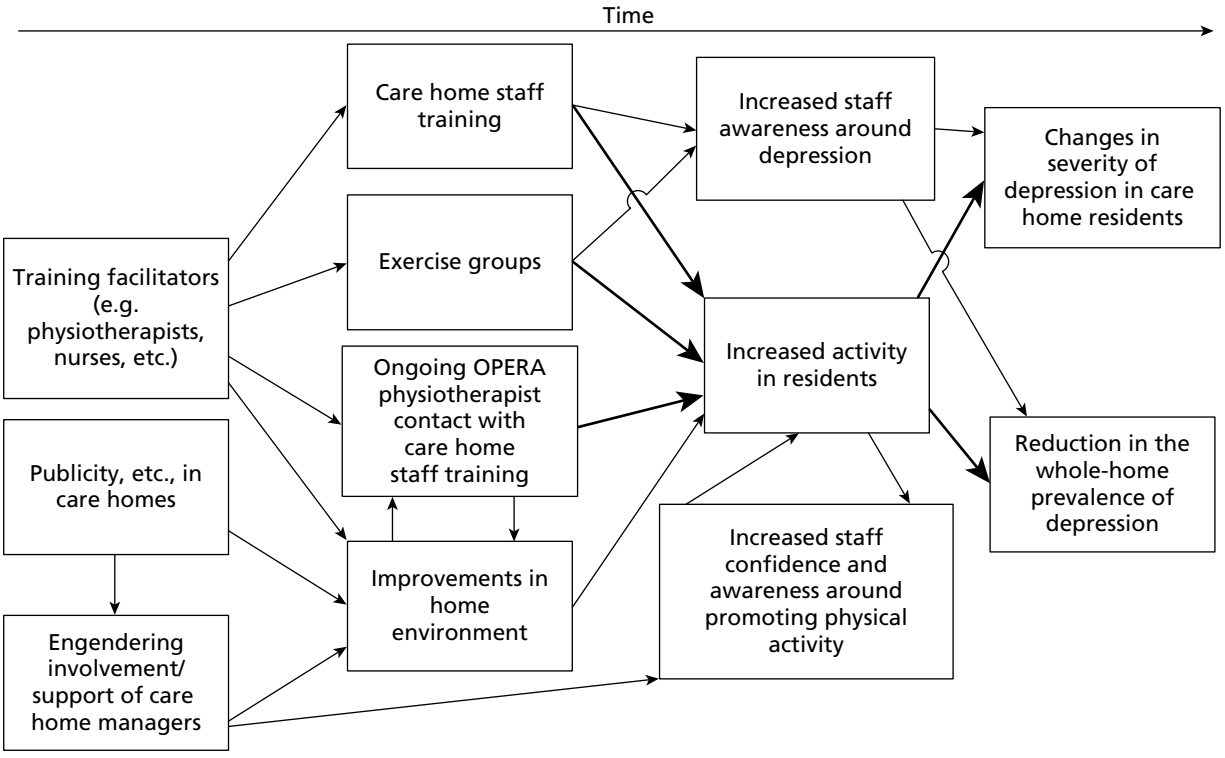

FIGURE 7 Theory of change model for how the OPERA 'active intervention' might work. The bold arrows depict the main direction in which we believe OPERA will have an impact.

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BOX 3 Key process evaluation components, adapted from Steckler and Linnan[198]

Component	Definition
Context	Aspects of the larger social political and economic environment that may influence implementation
Reach	The proportion of the intended target audience that participates in the intervention
Dose delivered	The number or amount of intended units of each intervention or each component delivered or provided
Dose received	The extent to which participants actively engage, and interact, with the recommended resources
Fidelity	The extent to which the intervention was delivered as planned
Recruitment	Procedures used to approach and attract participants

We used a mixed-methods approach, combining quantitative and qualitative data[199,200] to facilitate exploration of apparent discrepancies between findings.[109,201] Integrating quantitative and qualitative methodologies into a single study requires careful planning.[202] Considerations include the priority given to a particular methodological approach and how other methods will complement this. In this process evaluation the principal data collection method was quantitative, while the qualitative data, which complemented and illuminated the quantitative data, were collected from only a small sample of care homes.

Aims and objectives

The aims of the process evaluation were to

- assist in the interpretation of the results of the main effectiveness study
- develop a set of transferable principles regarding the whole-home intervention to inform its implementation on a wider scale.

The objectives were to

- collect quantitative data on the delivery of the intervention in both intervention and control care homes
- observe the exercise programme delivery and the depression awareness training (see *Interventions*, above)
- document the care home environment in case study care homes and document any changes observed
- carry out in-depth interviews with care home managers, care home staff, patients and carers in a purposive sample of the care homes
- collate and interpret the resulting data.

Methods

All of the OPERA care homes contributed quantitative data to the process evaluation; eight purposively sampled care homes (six intervention and two control) were selected as case study care homes where additional quantitative and qualitative data collection took place.

Data were collected from all care homes using specially designed case report forms and from other sources, including the Commission for Social Care Inspection reports for the care homes (i.e. data from the last published report prior to randomisation), and the records of exercise classes kept by the

BOX 4 Summary of quantitative data collected

Care homes

No. of homes overall

Size of home (including number beds and actual occupancy)

Type of home (i.e. registered as a dementia specialist home or not)

Type of home in terms of funding (i.e. independent, charity, group or local authority/run)

Pre-existing reported level of opportunity for physical activity already within home (e.g. groups, trips out)

Facilities available within the home, such as an accessible garden

Residents

Nos. approached

Type of consent [personal or third party (assent)]

Nos. agreeing to take part

Dropouts, adverse events or other attrition

Attendance at the exercise groups

Care staff

No. of staff (day and night), grade, vacancies, qualifications and number and type of ancillary staff

No. of OPERA control or active intervention care home staff training sessions conducted

No. of care staff trained

Satisfaction with the training programmes

physiotherapists. *Box 4* shows the data that were collected from each participating care home and from the residents and staff within each care home.

All staff in the care homes (control and intervention) were invited to participate in a brief training session on depression awareness. Staff in the intervention homes received additional information about promoting and increasing physical activity amongst residents. Key elements included staff response to these sessions, how confident the presenter was in engaging/adapting to residents' needs, the environment used for the training, timing, and the level of interest of participants.

In addition to observing some sessions, feedback on the value and quality of the training package was sought from attendees using an evaluation form distributed immediately after the session. A follow-up questionnaire with a return envelope was mailed to care home staff 4 weeks later exploring how useful the training had been and if it had been put into practice.

Case study homes

Recruitment of case study homes took place after randomisation, and was staggered through the first 6 months of randomisation of homes into the study. All care homes at the point of recruitment were informed about the process evaluation and the possibility that they may be asked to take part. No more than two homes and no more than one intervention home were recruited in any 4-week period. The main sampling criterion was ownership of the care homes and a secondary criterion in the intervention homes was which physiotherapist would be leading intervention delivery. Research carried out in the case

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study homes was predominantly ethnographic and consisted of semistructured interviews and repeated observation with field notes.[203]

In each case study home we invited for interview the care home managers, care home staff, care home residents, residents' relatives/NOK, and the physiotherapists who were involved in the delivery of the intervention in that home.

The inclusion criteria for residents were:

- ability to understand and communicate in spoken English
- provision of consent to participate in OPERA.

We did baseline interviews after randomisation and before the OPERA interventions were implemented. Semistructured, face-to-face interviews were conducted at a time and place to suit participants, were digitally recorded, transcribed verbatim and anonymised. Baseline interviews explored life in the home and the current levels of activity, staff/resident interactions and the process of consent to the OPERA study. We did follow-up interviews with a few of the key informants, where possible, at 6 months and again at the end of the study. Potential interviewees were invited to give written informed consent to participate in the interview.

These interviews explored in more depth perceptions about the care home and its levels of activity and in intervention homes, perceptions of the activity programme and its impact. Follow-up interviews also explored feelings about the withdrawal of OPERA involvement in the home at the end of the study. Topic guides for interviews are shown in *Appendix 5*.

Additional information was sought from the care home managers about their reasons for taking part in OPERA, their feelings about the whole-home intervention and their beliefs about potential long-term changes in the care home as a result of the intervention.

Field observation

Observation of the case study homes was carried out by DE. He spent at least 4 days in each home at baseline and at least 3 days at each follow-up. Observation spells were typically spread over a period of 2 weeks and involved observation of the home environment, the delivery of the depression awareness training in control homes, the depression awareness/activity training in intervention homes and delivery of the exercise groups. At each visit, DE wrote field notes, noting time of day, what residents were doing, any home activity sessions and staff resident interactions.

To quantify the kind of activity that was taking place in the care homes, we did a series of observational sweeps of all the public spaces at baseline and follow-ups. We adapted the observational instrument of activity and well-being Behaviour Category Codes.[204,205] This involved the researcher completing a checklist of where residents were and what they were doing (including interactions with staff and others) at regular intervals in the day (*Box 5*). Observational data sweeps occurred every 15 minutes for a 90-minute period (i.e. six sweeps in 90 minutes). The sweeps recorded the number of residents within each public area exhibiting a particular behaviour. Observations were carried out starting at different times but covering a whole day over a number of visits. The recommended time periods were 1000–1130, 1200–1330, 1400–1530, 1600–1730 and 1800–1930 but we stopped doing observations for the period 1800–1930 as most residents had retired to their bedrooms by then. We collected data at baseline and at follow-up near to the end of the study (12 months). To preserve the privacy and rights of non-participants in the OPERA study no individuals were identified in written records and no researcher entered a resident's bedroom (unless invited by the resident).

BOX 5 Brief explanation of the Behaviour Category Codes

The seven categories used are based on the Behavioural Category Code observational instrument of activity and well-being Behaviour Category Codes,[204,205] which has 10 categories. [Four categories were not used: *communicating with no response*, *other*, *receiving care* (as this mostly took place away from observation) and *unavailable for observation* (not relevant as we were not mapping individuals)]

Active social interaction	Interacting with others verbally or otherwise
Eating/drinking	Meals, snacks or drinks
Recreational activity (not exercise)	Participating in a game, craft activities, using intellectual abilities, performing work or pseudo-work, engaging with media (e.g. 'actively watching TV or listening to radio') or participating in religious activity
Sport or exercise	Exercise (this was separated from the recreational activity category, as we were specifically interested in knowing if exercise took place)
Passive social interaction	Being socially involved but passively, for example sits quietly but aware of what is going on and contributes if needed
Socially inactive	Being socially uninvolved, withdrawn, sleeping, dozing
Walking/wandering	

When coding, the observer, where possible, noted specific interactions with others. For example, if a resident was talking to another resident then this was marked as 'active social interaction' [with ST, RE or OT to indicate whether the interaction was primarily with a STaff member or REsident, or OTher (e.g. relative)]. This was repeated for all categories in which an interaction could be taking place. The results of these individual interactions are not reported here. For the purposes of the results these different interactions were collapsed into the overall category.

Observations included how the exercise classes fitted into the day; how the residents reacted; how the physiotherapist interacted with the residents; the involvement of the staff/home; and what happened at the end of the exercise group.

Quantitative data analyses

Quantitative data were analysed using the statistical package SPSS version 18 (SPSS Inc., Chicago, IL, USA) and reported in descriptive tables. Charts, presenting average monthly attendances at exercise groups, were based on the month the first group was delivered. For each calendar month all attendance register data (see *Box 4*) were pooled and an average attendance calculated. Although this was a 12-month intervention, several homes did, using this method, cover 13 months due to them starting late in the first calendar month.

Data from the activity sweeps described above were summarised in a 100% stacked bar chart, each bar within the chart representing a home displaying the means of 12–14 individual activity sweeps. Activities were grouped into one of seven categorises, elaborated in *Box 5*.

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Data collected from OPERA staff

We ran focus groups to explore the experiences of both the recruiting team and the physiotherapists. These were carried out as the study was drawing to a close. Both of these groups were day-long events and involved a facilitator (DE) and a scribe.

The recruitment team focus group discussions included asking about experiences and thoughts on OPERA in respect to

- recruitment of homes
- recruitment of participants including consent/assent process
- assessments
- follow-ups
- general points about involvement and experiences (e.g. questions on questionnaires, working with care homes and care home staff, interactions with OPERA office).

The physiotherapy team focus group discussions included exploration of the following topics:

- initial meetings with care homes
- assessment of residents
- training of care home staff
- the exercise intervention
- delivery of the sessions
- paperwork
- 'whole–home' interactions
- interactions with care home staff/management
- closing of care homes.

In these sessions topics were discussed and then main points were brought together and agreed by the group and the scribe produced a summary result on each topic. The results of these groups are interlaced in the process evaluation results and the results presented in the ethics substudy section (see *Chapter 3*, *Ethics*).

Qualitative data analyses

The analysis was thematic and we adopted the framework method described by Ritchie and Spencer[206] and Pope *et al.*,[207] which involved the following:

- *Data familiarisation* Repeated reading of interview transcripts and field notes and listening to original audio-recordings.
- *Identifying a thematic framework* Key issues, concepts and themes were identified and an index of codes developed.
- *Indexing* The index generated through identification of the thematic framework was applied to all data.
- *Charting* A summary of each passage of text was transferred into a table to allow more overall and abstract consideration of index codes across the data set.
- *Mapping and interpretation* Understanding the meaning of key themes, dimensions and broad overall picture of the data, and identifying and understanding the typical associations between themes and dimensions.

Researcher bias was minimised through regular cross-checking of data and findings by the members of research team. In addition, transcripts were returned to participants (where appropriate) providing them with the opportunity to check the transcripts for accuracy and authenticity, and to offer any subsequent reflections. Quotes are used as exemplars of key themes.

Ethics substudy

In order to explore some of the ethical issues around recruitment and consent for research involving people who are vulnerable because of either their situation (in this case residents in care homes) or a degree of cognitive impairment, we nested an ethics substudy within the OPERA study.

The aims of the ethics substudy were to

- describe the process of obtaining consent to participate in a complex intervention research study involving people who lack capacity
- consider this in relation to current legislation and international ethical guidelines for the conduct of medical research
- explore the views of older people and key stakeholders on consent to research involving older people who lack capacity.

The study used a combination of the following research methods:

1. Observation of the recruitment and consent process (part of the process evaluation study reported in *Quality control*, below).
2. Interviews with care home staff, residents and NOK of participants in the study (see *Case study homes*, above).
3. Focus group with recruitment staff (see *Data collected from OPERA staff*, above).
4. Focus groups with older people not currently in a care home to elicit their views on research in general and research with people who are unable to consent in particular.
5. Interviews with key professional informants, including researchers, ethicists, academics, health professionals, representative of a national care provider, and representatives of elderly care-related voluntary organisations.

Data collection

Data collection methods for items 1–3 are described in the above sections *Case study homes* and *Data collected from OPERA staff*, respectively.

We conducted three focus groups with elderly people who were not currently living in a care home. Initial attempts at recruitment using advertising through local contact with two national, elderly care-related voluntary organisations were unsuccessful. Final recruitment was through local support groups providing day care or activities for the elderly. The managers of centres within C&W were contacted by the research team via telephone and asked if they would be interested in participating. The first two centres contacted expressed an interest and were sent information and posters about the study. Centre managers spoke with different groups within their centres, using posters and participant information sheets provided by the study team. Three groups from two centres agreed to participate and members of these groups were given copies of the participant information sheet and a consent form. Focus groups were organised on days and times specified by the centre managers to coincide with regular timetabled group meetings and were carried out by two researchers: a lead and a scribe (note taker). All participants provided written informed consent on the day of the meeting. As an introduction to the focus group topic the researcher opened the group discussion with a question about the process of consent that the participants had just experienced. A schedule of open questions followed by prompts where necessary guided the main discussion. Questions focused on experiences, perceptions or feelings about the involvement of elderly people in research, particularly about how decisions to take part in research are made (a copy of the schedule can be found in *Appendix 6*). All focus groups were audio-recorded and field notes were taken. Key points were identified on a flip chart and fed back to participants to check that we had accurately captured their views.

We conducted interviews with key informants, who were purposively selected to provide a range of points of view from different stakeholder and professional groups. We initially contacted 40 potential

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participants by e-mail with an invitation to participate in the study. Following an expression of interest we sent an information sheet and consent form to complete and return to us. Interviews took place either face to face or by telephone, according to the participant's preference. All interviews were audio-recorded and transcribed.

Interviews were structured around a topic guide that focused on their views about health research in elderly or care home populations. Specific prompts were given, where necessary, regarding potential difficulties in conducting research in these populations and on the question of consent. Finally, participants were asked whether or not they would be prepared to be involved in a consent process for research involving a relative who lacked capacity to consent, and who if anyone would they wish to be involved in such a process for them. Personal involvement in this kind of research, for example as a researcher, was explored. (A copy of the interview schedule can be found in *Appendix 7.*)

Analysis

All interviews were recorded, transcribed and analysed using NVivo 7 software (QSR International, Southport, UK). Focus group field notes and flip chart records were used as the basis of analysis with reference to the recordings for clarification of points and illustrative quotes. We used a thematic content analysis based on the framework approach and matching that we used in the process evaluation (see *Process and evaluation*, above). We analysed the process evaluation interview data separately looking for any factors or themes relating to the process of recruitment and consent. We then compared themes emerging from all sources of data (key informant interviews, focus groups, process evaluation interviews and observations) to look for congruence and areas of divergence. In identifying and mapping themes across the data we framed our analysis within the theoretical foundation of informed consent to research and current policy and regulatory frameworks on research ethics. Using a process of reflective equilibrium between empirical data and ethical theory as described by Ives and Draper,[208] we were able to achieve a contextual understanding of the ethical requirement of informed consent to research in older people in care homes.

OPERA end-of-study feedback

At the end of the study, all care homes were sent an end-of-study questionnaire. Two versions were developed: one for intervention homes and one for the control (copies of these can be found in *Appendices 8* and *9*). Both versions included questions about the recruitment process, raising awareness of depression in the home, staff training (i.e. OPERA Depression Awareness or Depression Awareness and Activity Training), interactions with the research team and any contacts made with the OPERA office staff. The intervention version also included questions about interactions with the physiotherapists and the exercise groups. Most of the questions were statements that required a box to be ticked on a four-point scale ('totally agree', 'agree', 'disagree' or 'totally disagree'); some questions required a 'yes' or 'no' answer. Space was provided for free-text comments.

Responses from the questionnaires were collated on a study database and summary statistics generated (i.e. number of particular responses to each question).

Quality control

Recruitment (consent and assessments) and data security (in homes)

As part of the process evaluation a researcher (DE) included quality control assessments as part of the work within the eight case study homes (five in NEL and three in C&W). The researcher observed the consenting of residents; the initial Short Physical Performance Battery; and the completion of baseline outcome measures (e.g. Mini Mental State Examination and Geriatric Depression Scale-15). A formal check was also made that OPERA data/files were being maintained and stored correctly within the care home.

Depression awareness training (control intervention)

Observations were carried out during training sessions. Checklists were completed to ensure training was delivered as per protocol. Interactions with the care home staff during the training were also noted.

Intervention delivery

Although the lead physiotherapist assessed the fidelity of the delivery of the exercise intervention in terms of the individuals (physiotherapists) delivering it [see *Intervention fidelity (physiotherapist)*, below], independent observations were also carried out by the process evaluation research fellow. Observation at these times included how the session fitted into the day, how the residents were reacting, how the physiotherapist was interacting with the residents, staff/home involvement and what happened when it ended.

Data security and data collection accuracy at base

All of the electronic OPERA data are stored on the OPERA web application. The OPERA web application is a secure, password-protected, ASP.net web application developed by the Warwick Clinical Trials Unit programming team. The OPERA web application is hosted on the Warwick University Clinical Trials Unit SQL Server 2005 Enterprise edition database. Full back-ups of the OPERA database are completed once every 24 hours.

Baseline and follow-up data were collected on laptops or on paper case report forms. Data entered on to laptops were directly uploaded on to the OPERA web application. Paper case report forms were returned to the study office. Case report forms received, which had not been inputted on to the online database by the recruitment team, were then inputted directly by a data entry clerk, after having been checked by the study manager. The OPERA web application was equipped with computerised validation criteria to minimise data entry errors. These validations placed limitations and checks on data fields to ensure that only the expected responses could be inputted. The database would flag up unexpected responses, prompting the data entry clerk to investigate the query and to correct it. The programmer produced a regular report to identify any possible anomalies on the database in order that they may be investigated in a timely fashion. After data entry had been completed, a 100% data check was conducted on the primary outcome measure (Geriatric Depression Scale-15). This involved checking all of the data points on all of the Geriatric Depression Scale-15 case report forms. For all other outcomes a random 10% check was carried out. This involved checking all of the data points on a randomly selected 10% of the case report forms that contained secondary outcome data. The data checks revealed an error rate lower than the pre-set maximum error rate of one error in 1000 data points. All data management and quality control checks were in line with the standard operating procedures of the Warwick Clinical Trials Unit.

Intervention fidelity (physiotherapist)

The quality and fidelity of the intervention delivery was checked via a site visit to each physiotherapist at one of their assigned care homes on at least two occasions – at least at 6 weeks and at 6 months after the intervention started in that home. These visits were made by the lead (C&W) physiotherapist, or during annual leave an assigned deputy. The delivery of the exercise group and use of the whole-home approach was assessed by observation, and sample of the intervention case report forms and registers were checked. If any major issues were identified, in which case all were checked, that physiotherapist was then visited again within the next few weeks.

In-depth discussions with individual physiotherapists around strategies to maintain and improve treatment fidelity were held on each visit whenever possible, but particularly whenever an area of concern was observed, especially if that difficulty persisted on later visits. The intervention session content and skills demonstrated by their physiotherapist were assessed using a checklist that included items on administration, group locations, resources, self-assessment, progress of participants, working with the care home and mobility safety.

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Long-term follow-up

Culture within an organisation is constructed from commonly held and relatively stable beliefs and attitudes, and is realised through behaviours and working practices. In OPERA we provided the opportunity for care homes to adopt practices (i.e. increasing activity and safe mobility of residents) that it was hoped would become embedded in the culture of the care home and be sustained over time.

The experience of research team and interim data from the process evaluation indicated that the OPERA intervention was popular in the care homes and that we were producing the desired culture change. Any longer term effects that OPERA had on the culture of homes is a further facet of understanding the effects of the study. We were provided with additional funding by the Health Technology Assessment in the latter part of 2010 to explore this issue further.

Research questions

Primary question:

- Do any beneficial changes brought about by having participated in the OPERA intervention appear to be persistent?

Secondary questions:

- What factors appear to support sustained beneficial changes?
- Are there any sustained effects from having participated in the research in control homes?

Methods

We planned to recruit all 35 of the OPERA intervention homes and a sample of 18 of the control homes. Within this sample we planned to invite all eight case study homes from the process evaluation (six intervention and two control) to take part in both the interview and the observational parts of this follow-up.

This follow-up study followed homes as they reached approximately 6 months after the end of their participation in OPERA. However, as a few of the homes would not reach this 6-month milestone until October 2011, some were approached at about 4 months to ensure their inclusion.

Interviews with care home managers or their delegates were carried out either face to face (in case study homes or some local homes in C&W) or via telephone. Questions explored reflections on the care homes' experiences of OPERA (e.g. interaction with OPERA team, depression awareness training, exercise groups, what went well and what we could have done differently/better), the impact of OPERA interventions on the home during the period of the study and since its end (e.g. awareness of depression, continued use of information, continuation of OPERA-type exercise interventions or other activities), and the impact of the withdrawal of the physiotherapist and the exercise intervention (intervention homes only) (see *Appendix 10*). Analysis was grounded on contemporaneous notes taken during interviews, with transcripts and original recordings available, when needed, for clarification.

We repeated the ethnographic observations that we carried out in process evaluation case study homes during the OPERA intervention period. The method for the activity sweeps carried out during these observations is explained fully in the process evaluation section above (see *Methods*).

Chapter 3 Results

Recruitment

Recruitment of homes

There were 323 care homes across the two localities. Of these, 180 met our inclusion criteria and were sent letters inviting them to take part in the study (*Figure 8*). Around half of these (98, 54%) expressed an interest in participating; 17 of these were excluded after a visit by the study team because they had too few residents at the time of recruitment, were too busy, had too many residents with severe cognitive impairment, had too few residents aged ≥65 years or the residents were too frail/disabled. After having completed service-level agreements and consent processes, we recruited 78 of the 81 eligible homes to the study between January 2009 and March 2010; follow-up was completed 1 year later (see *Figure 8*).

Home characteristics

We recruited equal numbers of care homes from C&W and NEL, and 18 (23%) were care homes with nursing. One residential home was a dementia specialist home, 61 (78%) were privately owned (*Table 13*), 16 (21%) were voluntary or charity owned and one (1%) was owned by the local authority. Fifty-one of the privately run homes were in independent (small company) ownership. Most homes had a large number of residents with cognitive impairment; 22 were registered for dementia care.[209] Most of the participating care homes were rated as good (54/78, 69%) or excellent (11/78, 14%) in the last reported Commission for Social Care Inspection data (*Table 14*).[209]

Care homes ranged in size from 17 to 65 beds across the study; 2140 of the 2450 (87%) of beds were occupied when recruitment started (*Table 15*). Three-quarters of participating homes (60/78) were classed as residential, 15 were classified as nursing and a further three homes were mixed nursing/residential homes (see *Table 13*). Most of the care homes (67/78, 86%) also offered (temporary) respite care.

These results suggest that the care homes in OPERA were broadly representative of care homes in England, with respect to home ownership, and Commission for Social Care Inspection rating. Local authority-run homes were, however, under-represented in our sample, with only one home included (local authority homes represented 10% of care homes in England in 2010),[209] and no very large homes were included. The allocation to intervention and control homes was appropriately balanced in terms of size and location (see *Tables 13–15*).

On average there was one member of staff for every four home residents during the morning and one for every five in the afternoon. At night there was on average of one member of staff for every 10 residents. Few nurses were employed by homes. We are unable to report the different staff types within the homes, as the self-reported data from the homes did not differentiate type of staff and reported numbers may include ancillary staff, thus staff–resident ratios are likely to be overestimates.

Exercise groups at baseline

Nearly all of the care homes reported that they offered established exercise classes, with two-thirds reporting running a class at least once per week (*Table 16*). About half of the classes were reported as being run by members of the care home staff and around half by external fitness instructors but only two care homes reported external physiotherapist-led exercise classes. Reported attendance at these groups ranged from 3 to 25, with a median of 10, but many care home managers (22) failed to give an estimated attendance. However, observations carried out in the case study care homes (see below) and anecdotal reports by the field staff suggest that exercise groups outside the OPERA intervention were, in fact, uncommon. Observations showed that care homes commonly advertised activities on weekly calendars but that these did not always take place.

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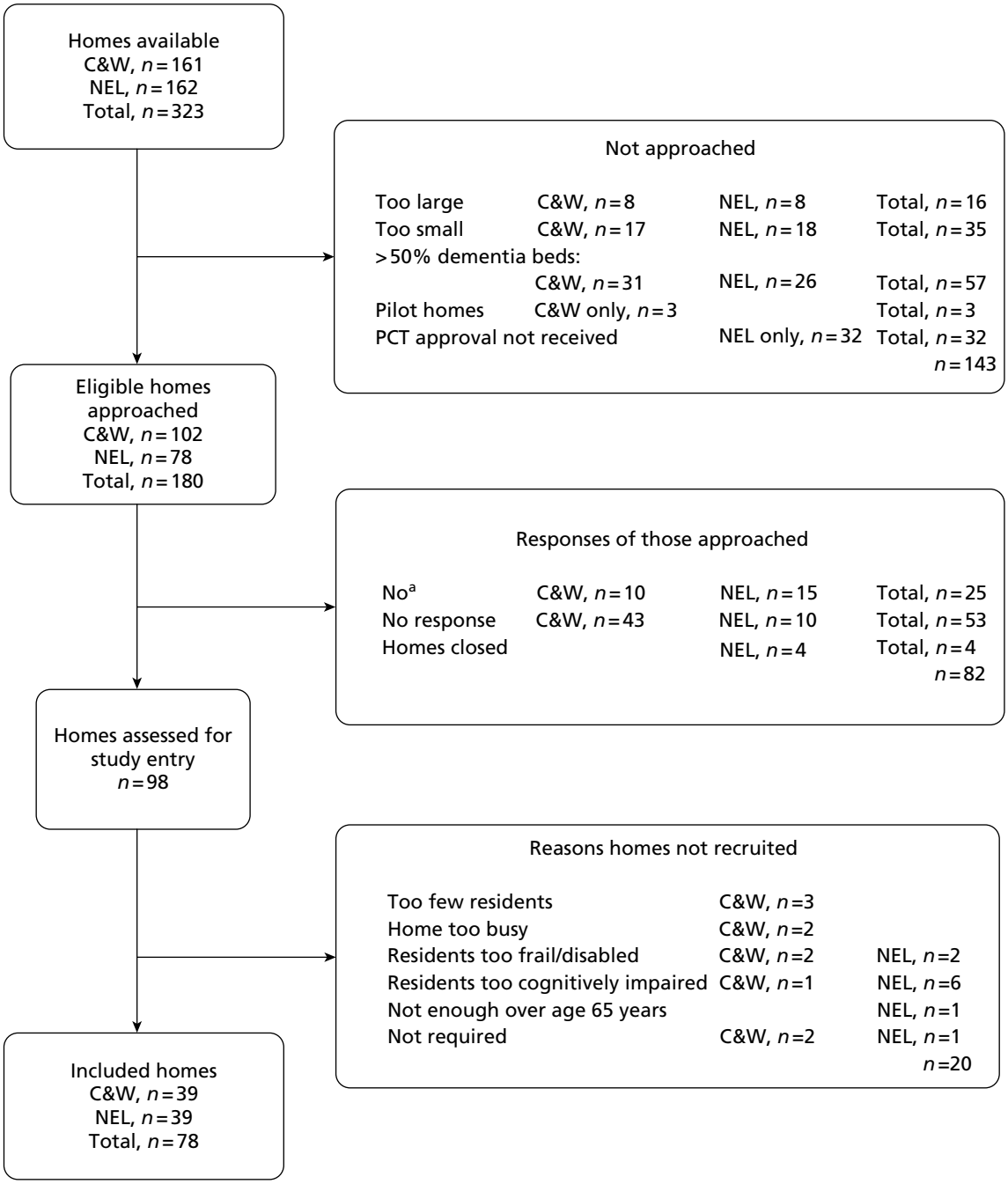

FIGURE 8 Recruitment of homes. a, Did not want to take part.

Individual recruitment

When we started individual recruitment in the care homes we identified 2133 residents. This is slightly different to the number of residents who were present at the time homes were recruited (2140) because of resident turnover. Fifty-five residents (3%) were not eligible as there were aged <65 years or were not permanent residents. We screened the remaining 2078 for study entry. Some residents were excluded because the care home manager felt it was inappropriate to approach them or they were too ill (245 and 279, respectively) (*Figure 9*). We obtained consent from 607 residents and assent from the NOK of 300 (*Table 17*). Ninety-four per cent (853) agreed to both assessment and use of care home data, 50 to use of care home data only and four to assessments only. Of the 907 residents screened and providing consent or

TABLE 13 Home characteristics

Characteristic	All care homes	OPERA care homes
No. of homes	323	78
Type of home (n, %)		
Nursing	81 (25)	18 (23)
Residential	242 (75)	60 (77)
Ownership (n, %)		
Private	262 (81)	61 (78)
Voluntary/charity	36 (11)	16 (21)
Local authority	25 (8)	1 (1)
No. of beds		
Average	36	32
Range	3–121	17–65
Location		
C&W	161	39
NEL	162	39

TABLE 14 Commission for Social Care Inspection rating[a]

Rating	Intervention	Control	Total (no. of homes)
Poor (no stars)	2	0	2
Adequate (one star)	6	5	11
Good (two stars)	23	31	54
Excellent (three stars)	4	7	11
Total	35	43	78

a In June 2010 the Commission for Social Care Inspection became the Care Quality Commission and star ratings were stopped. Ratings presented here are based on the last report produced for these homes.

assent before randomisation, six died prior to randomisation (five of whom had provided some assessment or proxy/care home data), baseline data collection was completed on a further six within 6 weeks of randomisation, one did not complete assessments until 3 months and one completed assessments around 6 months. A further two residents did not provide outcome assessment or proxy/care home data at any point. In total, 897/2078 (43%) of residents screened provided some baseline outcome data prior to randomisation. After excluding the six who died before randomisation, it is the remaining 891 who form our population of interest for the cohort analyses. For a few care homes the number of residents providing a baseline Geriatric Depression Scale-15 prior to randomisation was five rather than six. This was because the lower cluster size criterion for study entry applied to the number of assessments completed rather than the number of baseline Geriatric Depression Scale-15 scores obtained (see *Table 17*). Proportionally more participants in C&W had given assent than in NEL. This was because care homes in NEL had proportionally fewer cognitively impaired residents and some time constraints for the NEL research team limiting time to obtain assent.

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TABLE 15 OPERA self-reported characteristics of care homes at baseline

Characteristics			Intervention			Control			Combined
			C&W	NEL	Total	C&W	NEL	Total	
No. of beds		Median	26	33	28	32	26	31	30
		Range	17–47	18–62	17–62	19–65	17–61	17–65	17–65
Total			479	625	1104	737	609	1346	2450
Reported occupancy		*n*	408	565	973	617	550	1167	2140
% occupancy at baseline		Mean	85	90	88	84	90	87	87
Respite services available		No. of homes	13	17	30	21	16	37	67
Reported staff–resident ratio[a]	Morning	Mean (SD)	0.24 (0.22)	0.29 (0.23)	0.26 (0.11)	0.28 (0.26)	0.23 (0.21)	0.25 (0.10)	0.26 (0.10)
	Afternoon	Mean (SD)	0.19 (0.05)	0.21 (0.07)	0.20 (0.06)	0.21 (0.09)	0.18 (0.05)	0.20 (0.07)	0.20 (0.03)
	Night	Mean (SD)	0.10 (0.03)	0.10 (0.02)	0.10 (0.02)	0.10 (0.04)	0.11 (0.03)	0.11 (0.04)	0.11 (0.03)
Homes with qualified nurse	One nurse employed	*n*	2	2	4	2	1	3	7
	Two or more nurses employed	*n*	1	2	3	2	3	5	8

a Staff/residents based on figures supplied by homes and does not differentiate staff types (e.g. carer or domestic).

Individual characteristics

We had consent/agreement to directly assess 857/907 of the residents who consented or assented to join the study prior to randomisation (see *Table 17*). We assessed 783 (91%) of these. Two died between assessment and the day the home was randomised. (We do not have data on time of death. Some deaths may have occurred on the day of randomisation and prior to the time randomisation was performed.) It is the remaining 781 residents who constitute our population of interest for participant-reported outcomes. We obtained a Geriatric Depression Scale-15 score from 765 (98%) of this population at baseline. Overall we recruited an elderly (age range 65–107 years), predominantly (76%) female sample. Of the 781 individuals included in the analyses for patient-reported outcomes, 94–98% responded to each item of measurement at baseline except for self-assessed EQ-5D for which the response rate was only 81%. We anticipated this low response rate prior to the study and consequently also collected proxy EQ-5D. The majority of residents were not in pain, but almost half were afraid of falling and almost one-third were on antidepressants. Baseline characteristics of those who provided data prior to randomisation were similar in the intervention and control groups (*Tables 18–21*).

Prior to randomisation, we had consent/agreement to obtain care home data on 903/907 residents. Six of these died between consent/agreement being obtained and the day the care home was randomised, and a further 16 had no care home data collected prior to randomisation. It is the remaining 887 participants who constitute our population of interest for care home data. We obtained proxy EQ-5D and Social Engagement Scale data on 88% of these participants.

The prevalence of comorbidities was high and similar in the intervention and control groups (see *Table 19*).

TABLE 16 Care home manager reported data: activities co-ordinators and exercise groups at baseline

Item	Intervention	Control	Total
Activities co-ordinator employed by home?	24/35	29/43	53/78
No. of homes reporting exercise classes being delivered	31	42	73
Frequency of exercise classes			
Less than once per week	9	16	25
Once per week	10	12	22
Twice per week	9	7	16
Three times per week	2	3	5
More than three times per week	1	4	5
Who runs these classes?			
Home staff	16	21	37
External fitness instructor	13	19	32
External physiotherapist	2	0	2
Not reported	0	2	2
How long have these exercise classes been running?			
0–6 months	3	4	7
7–11 months	3	4	7
12–24 months	5	13	18
>24 months	20	19	39
Not reported	0	2	2
Homes providing average attendance figures	23	33	56
Reported average attendance to exercise groups: median (range)	10 (5–25)	12 (3–23)	22 (3–25)

Depressed cohort baseline characteristics

Forty-nine per cent (374/765) of those who provided GDS-15 data at baseline were classified as depressed (GDS-15 score of ≥5 or equivalent) (*Table 22*). It is these participants who are our population of interest for all the depressed cohort analyses. For participants in the depressed cohort, GDS-15 scores were inevitably higher (mean = 7.5), but other baseline characteristics, including the proportion on antidepressants, were broadly similar to those in the overall cohort (*Tables 23–25*). Baseline characteristics of the depressed cohort were also similar in the intervention and control groups. Of those in the depressed cohort, 25% (92/365) had been diagnosed with depression according to care home records and 30% (112/371) were taking antidepressants (see *Table 22*).

The prevalence of comorbidities was high and similar in the intervention and control groups. Prevalence of comorbidities was similar to that observed in the overall cohort (*Table 26*).

Participants joining study after randomisation

A further 163 residents provided baseline data after randomisation; of these 150 provided assessment data and care home data, and 13 provided just care home data. Ten were screened for eligibility prior to randomisation but the recruitment and/or baseline data collection processes were completed only

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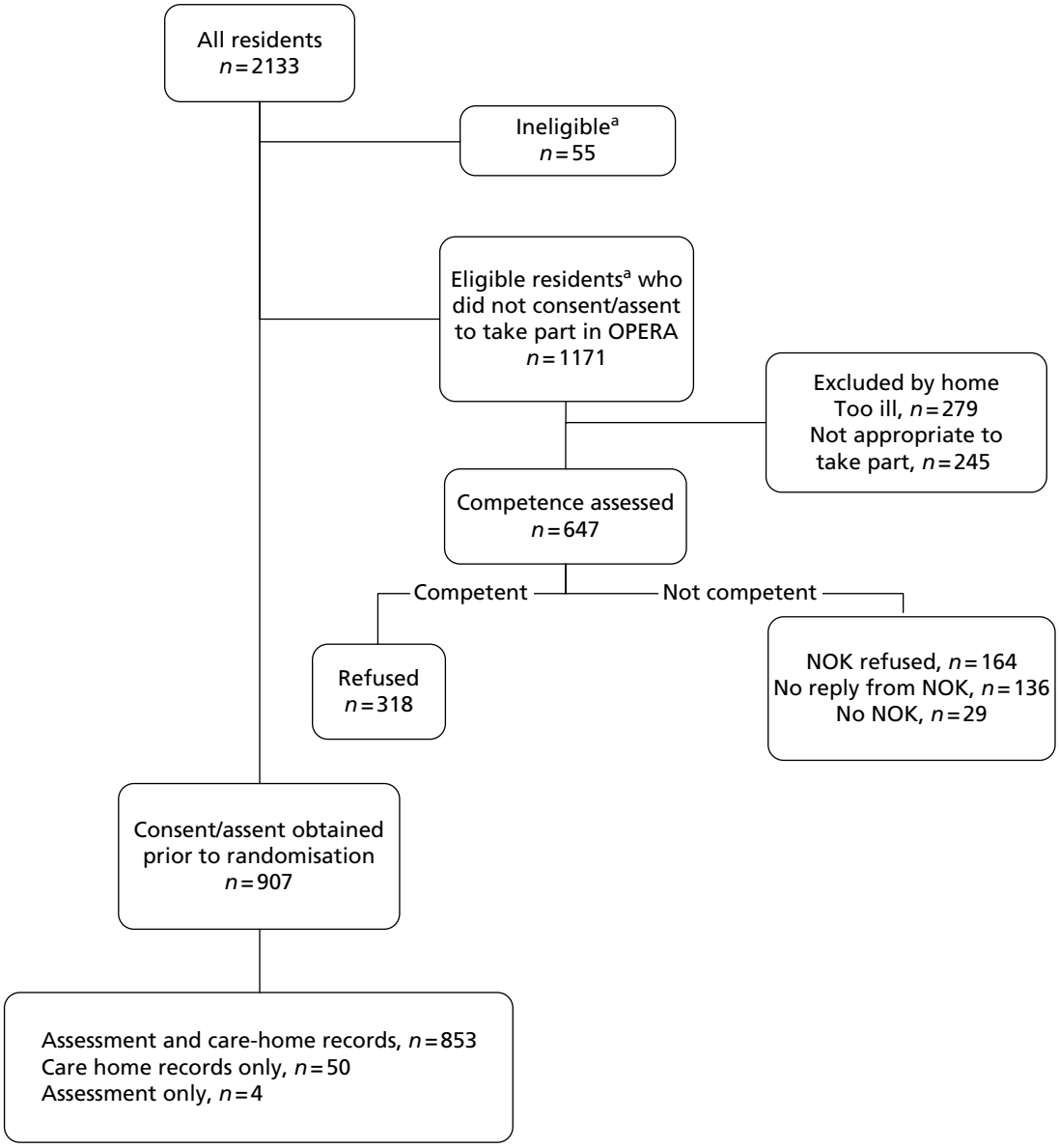

FIGURE 9 Reasons for being unable to gain consent/assent prior to randomisation. a, Eligible residents were ≥ 65 years of age and were permanent residents within the home.

after randomisation (six by 6 weeks, one around 3 months and one around 6 months). Fifty-seven were residents who were already living in the homes (26 recruited around 3 months, 19 around 6 months and 4 around 9 months), 45 were new residents recruited at the 3-month data collection visits, 59 were recruited at the 6-month visits; the remaining two were recruited at the 9-month visits (*Table 27*). In total, 127 of the 163 were present at the end of the study. Of these, 107 contributed direct assessment data and 126 contributed proxy data to the cross-sectional analyses.

The baseline characteristics of participants included in the cross-sectional analyses who were first assessed after randomisation were similar to those recruited before randomisation. Characteristics of intervention and control groups were similar, although larger numbers were recruited in the intervention than in the control arm (*Tables 28–30*).

TABLE 17 Participants recruited prior to randomisation, consent status and level of participation ($N = 907$)

Site	Recruited			
	Assessment and care home data	Care home data only	Assessment only	Total
C&W				
Consented	284	1	1	286
Assented	174	31	2	207
NEL				
Consented	319	1	1	321
Assented	76	17	0	93
Total	853	50	4	907

Includes those who died prior to randomisation.

TABLE 18 Demographics: individual baseline characteristics for all cohort participants ($N = 891$)

Characteristics	Group	
	Intervention ($n = 398$)	Control ($n = 493$)
Female	294/398, 74%	383/493, 78%
White	385/393, 98%	480/488, 98%
Age, mean (SD)	86.7 (7.2)	86.3 (7.5)
Age left full-time education: mean (SD)	15.0 (1.8)	14.9 (1.9)
≤14 years of age	178/304, 59%	207/348, 59%
14–16 years of age	89/304, 29%	90/348, 26%
> 16 years of age	37/304, 12%	51/348, 15%
Length of stay in home	392	488
Years, mean (SD)	2.4 (2.6)	2.5 (2.6)
Interquartile range	0.7–3.3	0.8–3.4
On antidepressants	110/397, 28%	156/490, 32%

This table includes 696 individuals who had direct assessment, proxy and drugs data prior to randomisation, 84 who had proxy and drugs data, 66 who had direct assessment and drugs data, 23 who had drugs data only, 15 who had direct assessment and proxy data, four who had assessment data only and three who had proxy data only.

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TABLE 19 Comorbidities in cohort participants ($n = 887$)[a]

	Group			
	Intervention ($n = 397$)		Control ($n = 490$)	
Comorbidities	*n*	%	*n*	%
Cancer	28/389	7	40/485	8
Stroke	97/392	25	109/488	22
Dementia	113/393	29	134/488	27
Depression	84/392	21	96/486	20
Anxiety	67/391	17	84/485	17
Osteoporosis	45/392	11	50/486	10
Chronic lung disease	47/391	12	56/489	11
Urinary incontinence	214/393	54	286/489	58

a Four out of 891 did not consent or assent to data collection from medical records.

TABLE 20 Self-report: individual baseline characteristics for cohort participants ($n = 781$)

	Group					
	Intervention ($n = 355$)			Control ($n = 426$)		
Characteristics	*n*	Mean	SD	*n*	Mean	SD
GDS-15 (0–15, 0 being the best score)	345	4.8	3.3	420	4.8	3.3
MMSE (0–30, 30 being the best score)	346	18.7	6.9	404	18.1	6.6
SPPB (0–12, 12 being the best score)	348	1.9	2.2	413	1.8	2.0
EQ-5D (–0.594 to 1, 1 being the best score)	297	0.54	0.39	335	0.59	0.37
'Pain now' rating	***n* = 335**		**%**	***n* = 397**		**%**
No pain	221		66	264		66
Mild/moderate pain	107		32	116		30
Severe	7		2	17		4
Fear of falling	***n* = 341**		**%**	***n* = 405**		**%**
Yes	141		41	189		47
No	200		59	216		53

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.

TABLE 21 Proxy: individual baseline characteristics for cohort participants ($n = 798$)

Characteristics		Group					
		Intervention ($n = 352$)			Control ($n = 446$)		
		n	Mean	SD	*n*	Mean	SD
Barthel Index (0–100, 100 being the best score)		337	54.5	29.4	417	54.0	27.8
Proxy EQ-5D (–0.594 to 1, 1 being the best score)		345	0.44	0.35	431	0.46	0.34
		***n* = 342**		**%**	***n* = 435**		**%**
Social engagement	Low	34		10	43		10
	Medium	97		28	133		31
	High	211		62	259		60

TABLE 22 Geriatric Depression Scale score-15 at baseline and whether or not residents have a prescription for antidepressants or a diagnosis of depression ($n = 765$)

Status	GDS-15 score ≥5, $N = 374$: *n* (%)	GDS-15 score <5, $N = 391$: *n* (%)
On antidepressants	112 (30)	102 (26)
Not on antidepressants	259 (70)	288 (74)
Diagnosed depression	92 (25)	60 (16)
Not diagnosed depression	273 (75)	327 (84)

GDS-15, Geriatric Depression Scale-15.

TABLE 23 Demographics: individual baseline characteristics for depressed cohort participants ($n = 374$)

Characteristics	Intervention group ($n = 174$)		Control group ($n = 200$)	
Female: *n* (%)	130/174	75	148/200	74
White	167/169	99	192/197	98
Age, years (SD)	86.6	(7.4)	86.7	(7.8)
Age left full-time education, years: mean (SD)	14.8	(1.6)	15.0	(2.1)
≤14 years of age	101/156	65	100/166	60
14–16 years of age	40/156	26	42/166	25
>16 years of age	15/156	10	24/166	14
Length of stay in home (*n*)	169		197	
Years: mean (SD)	2.4	(2.7)	2.2	(2.7)
On antidepressants	49/173	28	63/198	32

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TABLE 24 Self-report: individual baseline characteristics for depressed cohort participants ($n = 374$)

	Group					
	Intervention ($n = 174$)			Control ($n = 200$)		
Characteristics	*n*	Mean	SD	*n*	Mean	SD
GDS-15 (0–15, 0 being the best score)	174	7.4	2.4	200	7.6	2.4
MMSE (0–30, 30 being the best score)	170	19.4	6.7	186	18.5	6.4
SPPB (0–12, 12 being the best score)	171	1.6	2.2	190	1.3	1.7
EQ-5D (–0.594 to 1, 1 being the best score)	143	0.38	0.40	148	0.43	0.36
'Pain now' rating		%			%	
No pain	84	51		109	59	
Mild/moderate pain	73	45		65	36	
Severe	7	4		10	5	
Fear of falling		%			%	
Yes	97	57		104	56	
No	72	43		83	44	

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.

TABLE 25 Proxy: individual baseline characteristics for depressed cohort participants ($n = 374$)

	Intervention ($n = 174$)			Control ($n = 200$)		
Characteristics	*n*	Mean	SD	*n*	Mean	SD
Barthel Index (0–100, 100 being the best score)	164	56.0	27.7	180	53.5	25.9
Proxy EQ-5D (–0.594 to 1, 1 being the best score)	168	0.42	0.34	190	0.44	0.32
Social engagement		%			%	
Low	16	10		16	8	
Medium	42	25		63	33	
High	107	65		111	58	

TABLE 26 Comorbidities in depressed cohort participants ($n = 374$)

	Group			
	Intervention ($n = 174$)		Control ($n = 200$)	
Comorbidities	*n*	%	*n*	%
Cancer	7/169	4	20/195	10
Stroke	43/169	25	50/197	25
Dementia	37/169	22	42/197	21
Depression	45/169	27	47/196	24
Anxiety	34/169	20	39/195	20
Osteoporosis	14/169	8	18/195	9
Chronic lung disease	22/168	13	19/197	10
Urinary incontinence	99/169	59	111/197	56

TABLE 27 All participants by type of consent/assent and time of individual baseline data collection ($n = 1054$)

	Time of baseline data collection						
Type	0[a]	By 6 weeks[b]	Around 3 months[c]	Around 6 months[d]	Around 9 months	No assessed data[e]	*n*
Consent							
Assessment and care home data	599[f]	0	51	51	1	1[f]	703
Assessment only	2[f]	0	0	0	0	0	2
Care home data only	2	0	0	0	0	0	2
Assent							
Assessment and care home data	242[f]	4[f]	17	22	2	1[f]	288
Assessment only	2[f]	0	0	0	0	0	2
Care home data only	44	2	3	5	3	0	57
Total	891	6	71	78	6	2	1054

a Excludes residents with consent/agreement who died prior to randomisation ($n = 6$).

b Includes four participants recruited prior to randomisation but first assessed/proxy data collected by 6 weeks.

c Includes one participant recruited prior to randomisation but first assessed/proxy data collected at around 3 months.

d Includes one participant recruited prior to randomisation but first proxy data collected at around 6 months.

e Recruited prior to randomisation but no direct or proxy assessed data collected at any time point.

f These participants plus one participant who was first directly assessed at 3 months and the five pre-randomisation deaths in those consenting/assenting to direct assessments are the 857 residents in *Figure 10*.

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TABLE 28 Demographics: individual baseline characteristics for all participants joining the study after randomisation and present at the end of the study ($n = 127$)

	Intervention ($n = 76$)			Control ($n = 51$)		
Characteristic	*n*	Mean/%	SD	*n*	Mean/%	SD
Age (years)	76	86.9	8.0	51	86.9	7.2
Females	59/76	78%		41/51	80%	
White	74/76	97%		50/51	98%	
Age when left full-time education (years)	63	14.7	2.0	39	15.4	2.0
≤14 years of age	39	62%		19	49%	
14–16 years of age	18	29%		13	33%	
> 16 years of age	6	9%		7	18%	
On antidepressants	18/76 (24%)			13/51 (25%)		

TABLE 29 Self-report: individual baseline characteristics for all participants with consent/assent for direct assessment joining the study after randomisation and present at the end of the study ($n = 122$)

	Intervention ($n = 73$)			Control ($n = 49$)		
Characteristic	*n*	Mean	SD	*n*	Mean	SD
GDS-15 (0–15, 0 being the best score)	71	5.4	3.2	44	5.4	3.2
MMSE (0–30, 30 being the best score)	69	19.1	6.4	42	18.3	7.0
SPPB (0–12, 12 being the best score)	69	1.9	2.2	43	1.9	2.3
EQ-5D (self) (–0.594 to 1, 1 being the best score)	58	0.51	0.37	36	0.49	0.40
	Intervention total: *n* (%)			**Control total: *n* (%)**		
'Pain now' rating						
	No pain	**Mild/ moderate**	**Severe**	**No pain**	**Mild/ moderate**	**Severe pain**
	50 (72)	16 (23)	3 (4)	27 (64)	14 (33)	1 (2)
Fear of falling						
	Yes	**No**		**Yes**	**No**	
	33 (48)	36 (52)		15 (35)	28 (65)	

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.

TABLE 30 Proxy: individual baseline characteristics for all participants joining the study after randomisation and present at the end of the study ($n = 127$)

	Intervention ($n = 76$)			Control ($n = 51$)		
Characteristic	*n*	Mean	SD	*n*	Mean	SD
EQ-5D (proxy) (–0.594 to 1, 1 being the best score)	72	0.55	0.32	48	0.50	0.35
	Intervention total: *n* (%)			**Control total: *n* (%)**		
Social engagement[a]	**Low**	**Medium**	**High**	**Low**	**Medium**	**High**
	8 (11)	15 (21)	49 (68)	1 (2)	11 (23)	35 (75)

a Six-point scale collapsed into three for analysis: 0 or 1 = low; 2, 3 or 4, = medium; 5 or 6 = high.

Follow-up

Two different types of analyses were conducted in this study: (1) cohort analyses, in which study participants were included only if they had baseline assessments conducted prior to randomisation, and (2) cross-sectional analyses, in which study participants were included if they were present in the care home 12 months after randomisation (end-of-study assessment) regardless of when they were recruited and assessed.

In addition, data were collected either from direct assessment of participants or using care home data collected either from home staff or from records. We therefore present three different Consolidated Standards of Reporting Trials (CONSORT) charts. A CONSORT checklist is included as *Appendix 11*.

1. cohort, assessment data (*Figure 10*)
2. cohort, care home data (*Figure 11*)
3. depressed cohort, assessment data (*Figure 12*).

No care homes dropped out of the OPERA study and so no clusters were lost to follow-up. One home, in the intervention arm, was unable to provide proxy data at the follow-up assessments. All other data were collected as normal in this care home. The therapy team found in one care home, randomised to the intervention arm, that the residents were too disabled to participate in the exercise groups and no intervention was delivered. We collected follow-up data in this care home and their data are included in the relevant analyses.

At each time point we were unable to collect assessment data on some participants. There was a small but consistent trend, to collect more outcomes within each assessment in the intervention care homes than the control homes (*Tables 31* and *32*).

Overall, however, considering the poor state of health of our participants, we achieved good follow-up rates for our primary outcomes. We obtained Geriatric Depression Scale-15 data from 81% of survivors in the cohort analysis at 12 months and 79% of survivors in the depressed cohort analysis at 6 months.

We collected drug use data prior to randomisation on 869/887 (98%) of the proxy/care home data cohort participants who had agreed to provide care home data. At 3, 6, 9 and 12 months we collected data on 786/804 (98%), 730/758, (96%), 670/704 (95%) and 615/660 (93%), respectively, of those alive at each time point.

For the cross-sectional analyses of assessment data, 722 participants were present in OPERA homes at the time that end-of-study assessments were made, which constitute our population of interest for these analyses. For the cross-sectional analyses of care home data there were 749 participants resident in OPERA homes at the time that end-of-study assessments were made, which constitute our population of interest for these analyses. For our cross-sectional analysis of Geriatric Depression Scale, we obtained responses from 595/722 (82%) of these participants (*Tables 33* and *34*).

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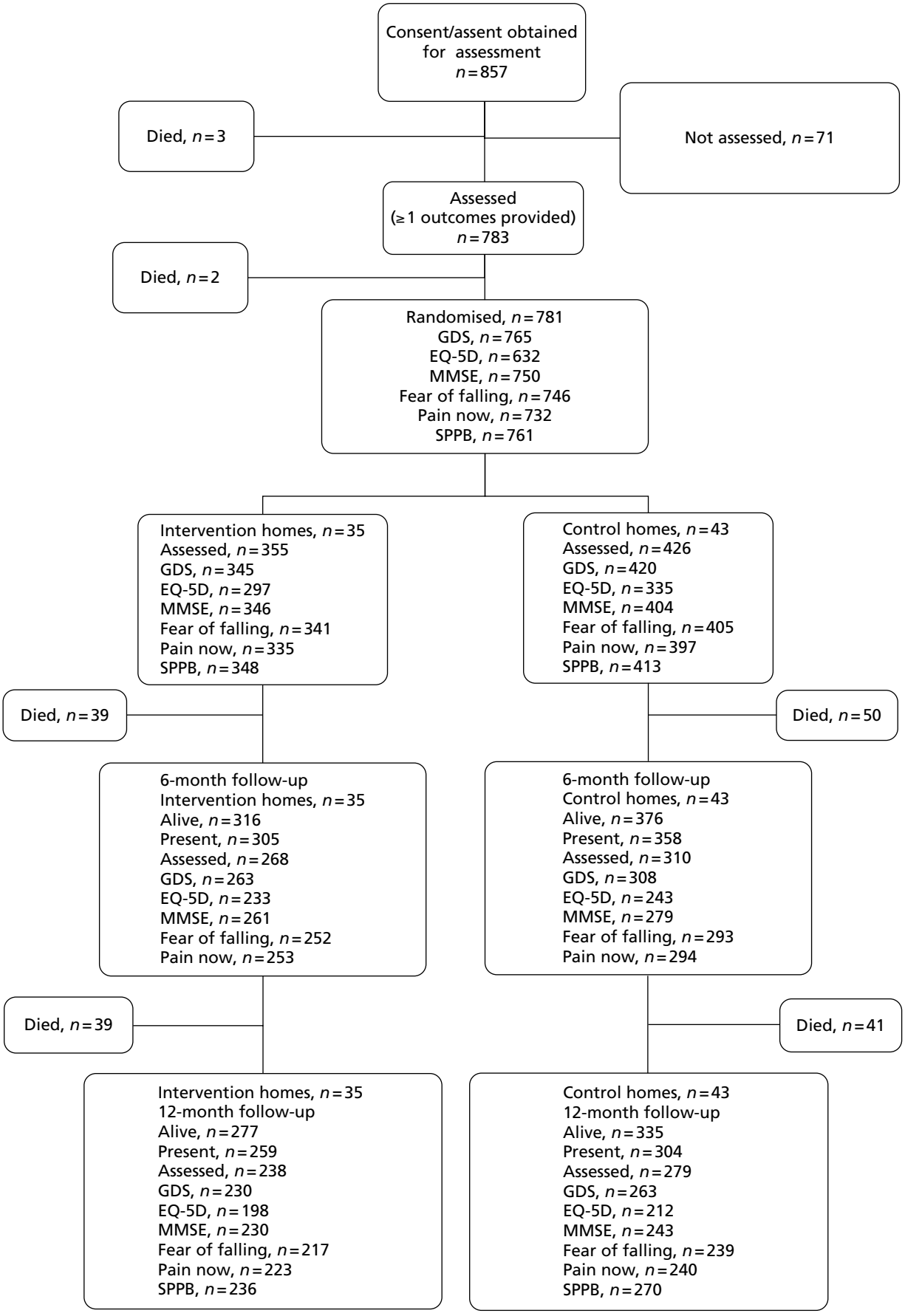

FIGURE 10 Consolidated Standards of Reporting Trials diagram: cohort assessment. GDS, Geriatric Depression Scale; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.

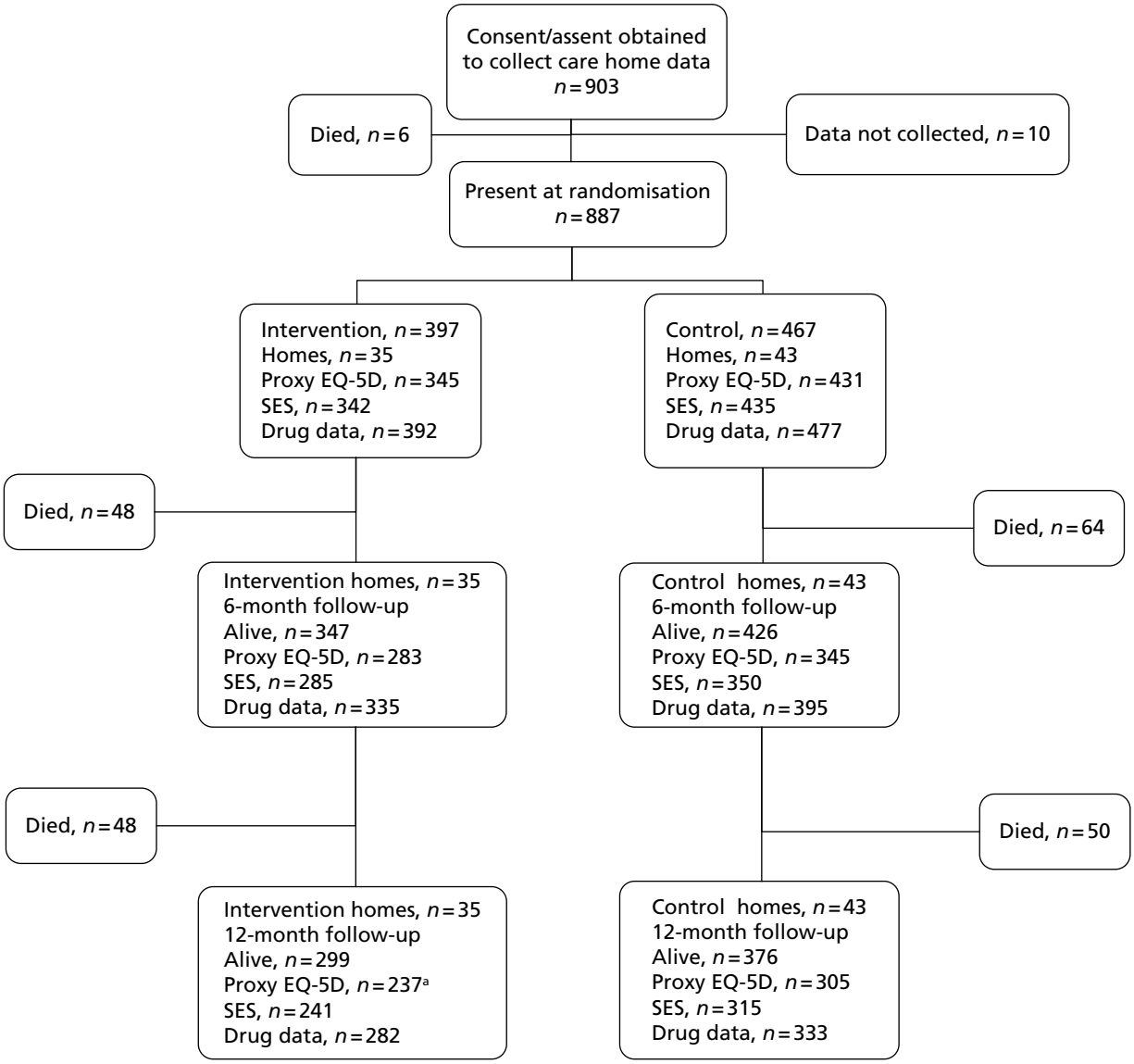

FIGURE 11 Consolidated Standards of Reporting Trials diagram; cohort, care home data. a, One home did not provide proxy EQ-5D or SES data during follow-up. SES, Social Engagement Scale.

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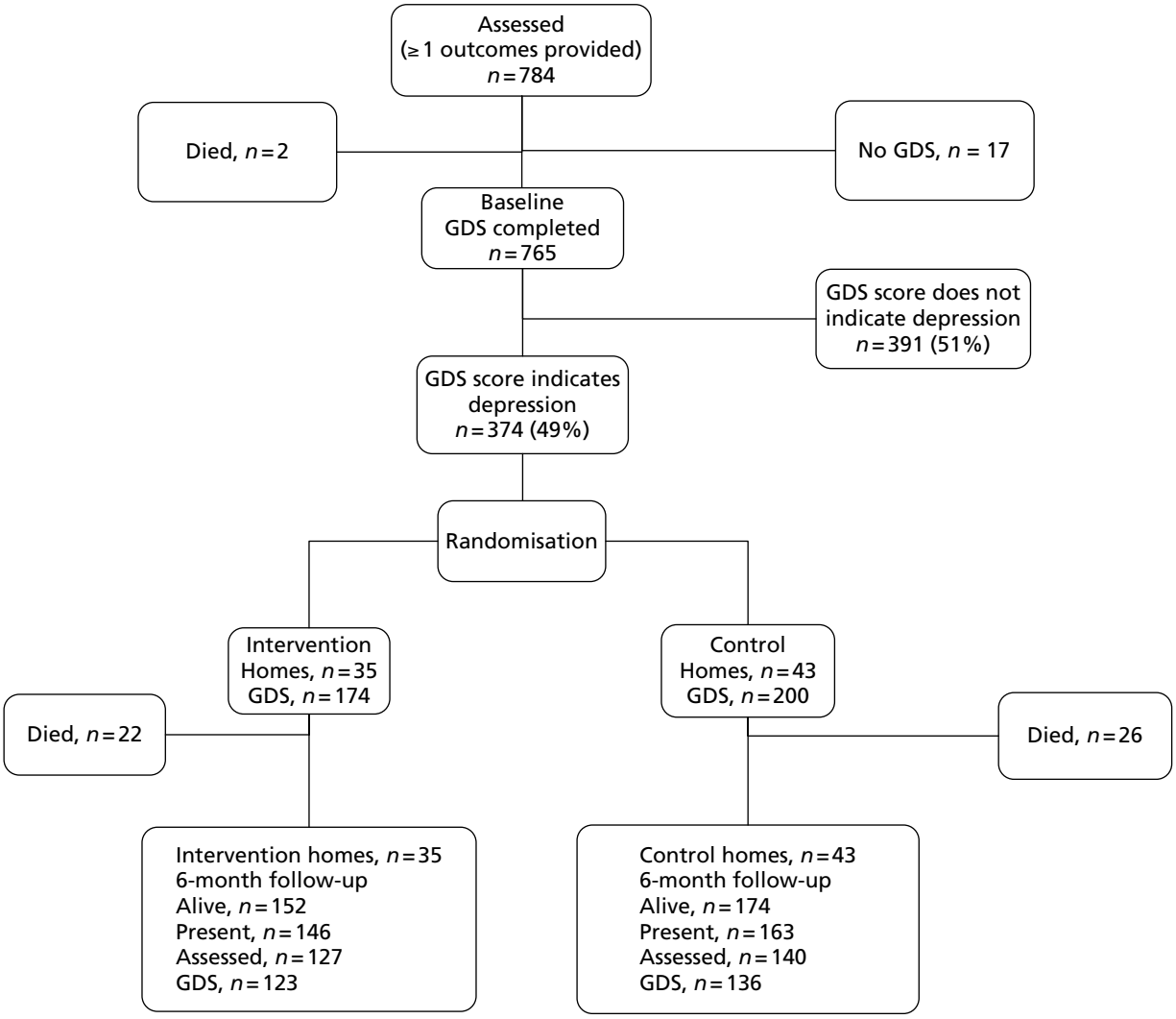

FIGURE 12 Consolidated Standards of Reporting Trials diagram; depressed cohort. GDS, Geriatric Depression Scale.

TABLE 31 Summary of overall follow-up, assessment data, for cohort analyses ($n = 781$ assessed at baseline)

	Outcome					
	Cohort, 6 months		Cohort, 12 months		Depressed cohort, 6 months	
Analysis	Intervention	Control	Intervention	Control	Intervention	Control
No. of homes	35	43	35	43	35	43
Present at randomisation	387	465	387	465	174	200
Assessed at baseline	355	426	355	426	174	200
GDS-15 at randomisation	345	420	345	420		
EQ-5D at randomisation	297	335	297	335		
MMSE at randomisation	346	404	346	404		
Fear of falling at randomisation	341	405	341	405		
Pain now at randomisation	335	397	335	397		
SPPB at randomisation			348	413		
Died randomisation date	39	50	78	91	22	26
Alive at end point *n* (% of all)	316 (89)	376 (88)	277 (78)	335 (79)	152 (87)	174 (86)
Present at end point	305	358	259	304	146	163
Assessed at end point (% of all, % of alive, % of present)	268 (75, 85, 88)	310 (73, 82, 87)	238 (67, 86, 92)	279 (65, 83, 92)	127 (73, 84, 87)	140 (70, 80, 86)
GDS-15 at end point (% of all, % of alive)	263 (74, 83)	310 (73, 82)	230 (65, 83)	263 (62, 79)	123 (71, 81)	136 (68, 78)
EQ-5D at end point (% of all, % of alive)	233 (66, 74)	243 (57, 65)	198 (56, 71)	212 (50, 63)		
MMSE at end point (% of all, % of alive)	261 (74, 83)	279 (65, 74)	230 (65, 83)	243 (57,73)		
Fear of falling at end point (% of all, % of alive)	252 (71, 80)	293 (69, 78)	217 (61, 78)	239 (56, 71)		
Pain now at end point (% of all, % of alive)	253 (71, 80)	293 (69, 78)	223 (64, 81)	240 (56, 72)		
SPPB at end point (% of all, % of alive)			236 (66, 85)	270 (63, 81)		

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery. % of alive, percentage of all those who were alive at the end point; % of all, percentage of those assessed at baseline.

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TABLE 32 Summary of overall follow-up: care home data for cohort analyses ($n = 887$)

Analysis	Outcome	
	Intervention ($n = 397$)	Control ($n = 490$)
No. of homes	35[a]	43
Proxy EQ-5D at randomisation	345	431
SES at randomisation	342	435
Drug data at randomisation	392	477
Alive at 6 months (%)	347 (87)	426 (87)
Proxy EQ-5D at 6 months (% of all, % of alive)	283 (71, 82)	345 (70, 81)
SES at 6 months (% of all, % of alive)	285 (72, 82)	350 (71, 82)
Drug data at 6 months (% of all, % of alive)	335 (84, 97)	395 (81, 93)
Alive at 12 months (%)	299 (75)	376 (77)
Proxy EQ-5D at 12 months (% of all, % of alive)	237 (60, 68)	305 (62, 72)
SES at 12 months (% of all, % of alive)	241 (61, 81)	315 (64, 84)
Drug data at 12 months (% of all, % of alive)	282 (71, 94)	333 (68, 89)

SES, Social Engagement Scale.
% of alive, percentage of all those who were alive at the end point; % of all, percentage of those assessed at baseline.
a One home did not provide proxy data after baseline.

TABLE 33 Summary of assessments cross-sectional analysis ($n = 730$)

Analysis	Outcome	
	Intervention	Control
No. of homes	35	43
Recruited before randomisation	258	305
Recruited after randomisation	97	70
Total present at end of study	355	375
Assessed at end of study	303	328
GDS-15, *n* (% of present)	288 (82)	307 (80)
MMSE, *n* (% of present)	284 (81)	285 (74)
EQ-5D, *n* (% of present)	251 (71)	245 (64)
Pain now, *n* (% of present)	278 (79)	281 (73)
Fear of falling, *n* (% of present)	273(78)	280 (73)
SPPB, *n* (% of present)	296 (84)	315 (82)

GDS-15, Geriatric Depression Scale-15; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.
Two residents moved from intervention to control homes during the study and one from a control home to an intervention home. They are included here according to their home at the time the assessment was made.

TABLE 34 Summary of proxy data cross-sectional analysis ($n = 749$)

Analysis	Outcome	
	Intervention	Control
No. of homes	35	43
Recruited before randomisation	243	321
Recruited after randomisation	112	73
Total resident at end of study	355	394
EQ-5D at end point,[a] *n* (% of participating residents)	346 (95)	378 (92)
SES at end point,[a] *n* (% of participating residents)	349 (96)	386 (94)

SES, Social Engagement Scale.

a One home did not provide EQ-5D or SES data at end point.

Two residents moved from intervention to control homes during the study and one from a control home to an intervention home. They are included here according to their home at the time the assessment was made.

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Primary outcomes: Geriatric Depression Scale-15

In this section we present results for our three co-primary outcomes: (1) prevalence of depression at 12 months; (2) number of depressive symptoms at 6 months in those depressed prior to randomisation; and (3) number of depressive symptoms at 12 months of all those with Geriatric Depression Scale data prior to randomisation.

In the 12-month cross-sectional analysis, 595 participants provided Geriatric Depression Scale-15 data. Forty-eight per cent in the control group and 43% in the intervention group were depressed (Geriatric Depression Scale score of ≥5 or equivalent) (*Table 35*). In a mixed effects logistic regression model adjusting for clustering (with a random effect) and for site (C&W/NEL), home type, number of beds, mean Geriatric Depression Scale-15 score and proportion moderately to severely cognitively impaired in the care home prior to randomisation, whether or not on antidepressants and Short Physical Performance Battery at participant baseline assessment (whether before or after randomisation), age and sex, the odds for being depressed were 0.76 [95% confidence interval (CI) 0.53 to 1.09] lower in the intervention group (see *Table 35*); this effect was not statistically significant ($p = 0.130$). The model included 576 participants who had complete data on all covariates. Our pre-planned sensitivity analysis excluding those who provided baseline data after randomisation did not materially alter our results.

We included 484 participants with baseline and follow-up Geriatric Depression Scale-15 in the 12-month cohort analysis. There was a mean increase in the number of depressive symptoms of 0.05 in the intervention group and a decrease of 0.03 in the control group between baseline and 12 months. In a mixed-effects linear regression model adjusting for clustering (with a random effect) for site (C&W/NEL), home type, number of beds, proportion moderately to severely cognitively impaired in the home prior to randomisation, whether or not a participant was on antidepressants and Short Physical Performance Battery and Geriatric Depression Scale-15 scores at baseline, age and sex, the mean Geriatric Depression Scale-15 was 0.13 points higher in the intervention group (95% CI –0.33 to 0.60); this effect was not statistically significant ($p = 0.576$). The model included 475 participants who had complete data on all covariates.

Of the 374 individuals who were depressed prior to randomisation, 259 had Geriatric Depression Scale measurements at 6 months and were included in the depressed cohort analysis. For these individuals, Geriatric Depression Scale-15 scores decreased slightly at 6 months in both groups. In a mixed-effects model similar to that used for number of depressive symptoms, the estimated decrease in Geriatric Depression Scale was 0.22 points greater in the intervention group (95% CI –0.52 to 0.95); this effect was not statistically significant ($p = 0.566$). The model included 253 participants who had complete data on all covariates.

TABLE 35 Effect estimates and CIs from multivariable models for three co-primary outcomes

Outcome	Population	Intervention		Control				
		Mean (SD) or *n* (%)	n	Mean (SD) or *n* (%)	n	Effect estimate	95% CI	ICC
Prevalence of depression at 12 months[a]	All with GDS at 12 months	≥5: 124 (43%) <5: 164 (57%)	288	≥5: 149 (49%) <5: 158 (51%)	307	0.76[b] (OR for presence of depression)	0.53 to 1.09	0
GDS-15 score at 12 months	GDS at 0 and 12 months	At 0 months: 4.5 (3.2) At 12 months: 4.6 (3.3)	224	At 0 months: 4.7 (3.2) At 12 months: 4.6 (3.3)	260	0.13[c] (mean difference)	–0.33 to 0.60	0
GDS-15 score at 6 months (depressed cohort)	Depressed at 0 months, with GDS at 6 months	At 0 months: 7.3 (2.2) At 6 months: 6.3 (3.1)	123	At 0 months: 7.4 (2.4) At 6 months: 6.5 (3.0)	136	0.22[d] (mean difference)	–0.52 to 0.95	0.03

GDS, Geriatric Depression Scale; GDS-15, Geriatric Depression Scale-15; ICC, intracluster correlation coefficient.

a GDS-15 ≥5 or equivalent if <15 but >10 GDS-15 items completed.

b Seven intervention and 12 control residents excluded owing to missing values in covariates. Adjusted for mean of baseline GDS in the home and age at 12 months.

c Two intervention and seven control residents excluded owing to missing values in covariates. Adjusted for individual baseline GDS and age at baseline.

d One intervention and five control residents excluded owing to missing values in covariates. Adjusted for individual baseline GDS and age at baseline.

Note

Each model adjusted for place (CW/NEL), home type, number of beds, proportion moderately to severely cognitively impaired in the home at baseline, sex, on antidepressants at baseline (Y/N), SPPB at baseline and includes a random intercept for home. OR of <1.0 or negative mean difference favours intervention.

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Secondary outcomes: cohort analyses

We present results for our secondary outcomes in two sections. In this section we present results from analyses conducted on those individuals who provided data on the relevant outcomes prior to randomisation, as well as at the appropriate follow-up time (cohort analyses); thus in these analyses those who were recruited post randomisation are excluded. In the following section we present results from analyses conducted on all individuals who provided outcome data at the end of study in each home, irrespective of when they were recruited.

Among those who were depressed prior to randomisation and had Geriatric Depression Scale-15 scores at 6 months ($n = 259$), 29% were no longer depressed at 6 months. In a mixed-effects logistic regression adjusting for covariates (remission of depression at 6 months for those depressed prior to randomisation) and for clustering, there were very slightly greater odds of those in the intervention group having remission from depression at this stage (30% vs 27%), but the difference between groups was not statistically significant ($p = 0.820$) (*Table 36*).

For those with data prior to randomisation for the relevant outcome, there was little change in mean proxy and self-assessed EQ-5D, Mini Mental State Examination and mean Short Physical Performance Battery scores over the study period or in the odds of being fearful of falling (*Tables 37–40*), although we were not able to collect data on all of those for proxy EQ-5D at each time point. For those who provided data on the relevant outcome at baseline and 6 months there was no evidence of differential change between the intervention and control groups, and this was also true for the change from baseline to 12 months.

Prior to randomisation, 330/746 (44%) of participants were afraid of falling; 527 (71%) provided data on this outcome at 6 months and 439 (59%) at 12 months. The proportions afraid of falling were 43% at 6 months and 39% at 12 months. There was no evidence of a difference in the proportions fearing falling in the two intervention groups at either 6 or 12 months (see *Table 40*).

Mean Short Physical Performance Battery scores at baseline were low (2.2 ± 2.4 intervention and 2.0 ± 2.1 control) indicating poor levels of lower limb function. These had slightly worsened by the end of the study (1.9 ± 2.4 intervention and 1.6 ± 2.1 control). No significant difference is found (*Table 41*).

Sixty per cent (470/777) of participants had high social engagement prior to randomisation. This outcome measure was completed for 616 (79%) of individuals at 6 months and 541 (70%) at 12 months. The proportions with high social engagement at 6 and 12 months were 56% and 54%, respectively. Among those who had values for social engagement at all three time points, the proportions with high social engagement were 64% at baseline, 59% at 6 months and 54% at 12 months. Thus social engagement

TABLE 36 Remission of depression at 6 months for depressed cohort

Outcome	Intervention (6 months)	Control (6 months)	OR[a] (for remission of depression)	95% CI	ICC
GDS < 5 (not depressed)	37	37	1.07[b]	0.59 to 1.95	0
GDS ≥ 5 (depressed)	86	99			

GDS, Geriatric Depression Scale; SPPB, Short Physical Performance Battery; ICC, intracluster correlation coefficient.

a Adjusted for baseline GDS (GDS), place (CW/NEL), home type, number of beds, proportion moderately to severely cognitively impaired in the home at baseline, age, sex, on antidepressants at baseline (Y/N), SPPB at baseline and includes a random intercept for home.

b One intervention and five control residents excluded owing to missing values in covariates.

OR < 1.0 favours control.

appears to have diminished over time among these participants. There was no evidence of a difference between intervention and control groups in terms of their social engagement (*Table 42*).

Of those providing data on their experiences of pain prior to randomisation, 485/732 (66%) experienced no pain. 523 (71%) provided data on their experience of pain at 6 months and 443 (61%) at 12 months. The proportions experiencing no pain rose from 66% prior to randomisation to 70% at 6 months and 73% at 12 months. Nevertheless, the absolute numbers experiencing no pain fell. Thus the rise in proportion experiencing no pain may reflect a greater loss to follow-up among those with moderate and severe pain prior to randomisation rather than a general decrease in pain felt by residents over the study period. There was no evidence of a difference in the experience of pain between intervention and control groups at either 6 or 12 months (*Table 43*).

We calculated intracluster correlation coefficients for all outcomes. These were near zero for outcomes reflecting mental and emotional well-being and quality of life, and considerably higher for outcomes reflecting physical functioning, pain and social engagement (these factors may vary more between care homes because of the type of care provided by the home and the type of residents that homes look after).

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TABLE 37 Difference in mean self-completed health-related quality of life (at 6 and 12 months)

Outcome	Time point (months)	Total	Intervention at baseline	Control at baseline	Intervention at end point	Control at end point	Effect estimate	95% CI	ICC
Self-assessed EQ-5D	6	*n*	214	201	214	201	0.03[a]	–0.02 to 0.08	0
		Mean	0.58 (0.38)	0.60 (0.36)	0.59 (0.36)	0.57 (0.37)			
	12	*n*	184	182	184	182	0.01[b]	–0.05 to 0.06	0.02
		Mean	0.56 (0.39)	0.60 (0.36)	0.56 (0.40)	0.58 (0.38)			

ICC, intracluster correlation coefficient; SPPB, Short Physical Performance Battery.

a One intervention and one control resident excluded owing to missing values in covariates.

b Zero intervention and two control residents excluded owing to missing values in covariates.

Notes

Each model adjusted for place (C&W/NEL), home type, number of beds, age, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, SPPB at baseline, individual baseline self-assessed EuroQol (EQ-5D), and includes a random intercept for home.

Positive difference favours intervention.

TABLE 38 Difference in mean proxy rated health-related quality of life (at 6 and 12 months)

Outcome	Time point (months)	Total	Intervention at baseline	Control at baseline	Intervention at end point	Control at end point	Effect estimate	95% CI	ICC
Proxy EQ-5D	6	*n*	278	336	278	336	0.05[a]	–0.01 to 0.11	0.10
		Mean	0.44 (0.34)	0.47 (0.33)	0.45 (0.35)	0.44 (0.35)			
	12	*n*	232	294	232	294	0.01[b]	–0.06 to 0.08	0.17
		Mean	0.46 (0.35)	0.49 (0.33)	0.43 (0.36)	0.45 (0.35)			

ICC, intracluster correlation coefficient.

a Zero intervention and two control residents excluded due to missing values in covariates.

b Six intervention and two control residents excluded due to missing values in covariates.

Notes

Each model adjusted for place (C&W/NEL), home type, number of beds, age, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, individual baseline proxy EuroQol (EQ-5D), and includes a random intercept for home.

Positive difference favours intervention.

TABLE 39 Difference in mean cognitive function (at 6 and 12 months) for cohort

Outcome	Time point (months)		Intervention	Control	Effect estimate	95% CI	ICC
MMSE	6	*n*	257	269	–0.53[a]	–0.16 to 1.22	0.02
		Mean at baseline	19.5 (6.4)	19.1 (6.1)			
		Mean at 6 months	18.8 (7.0)	17.8 (6.6)			
	12	*n*	227	234	0.02[b]	–0.78 to 0.83	0.03
		Mean at baseline	19.6 (6.4)	19.0 (6.3)			
		Mean at 12 months	18.2 (7.5)	17.3 (6.9)			

MMSE, Mini Mental State Examination; ICC, intracluster correlation coefficient; SPPB, Short Physical Performance Battery.

a One intervention and three control residents excluded due to missing values in covariates.

b Three control residents excluded due to missing values in covariates.

Notes

Each model adjusted for place (CW/NEL), home type, number of beds, age, sex, on antidepressants at baseline (Y/N), SPPB at baseline, individual baseline MMSE, and includes a random intercept for home.

Positive mean difference favours intervention.

TABLE 40 Fear of falling (at 6 and 12 months)

Time point (months)	Fear of falling	Total	Intervention	Control	OR (intervention/control)[a]	95% CI	ICC[b]
6	Yes	229	93	136	0.76[c]	0.51 to 1.15	0
	No	298	153	145			
12	Yes	171	76	95	1.07[d]	0.68 to 1.67	0
	No	268	135	133			

ICC, intracluster correlation coefficient.

a Reference category is not afraid of falling.

b Intracluster correlation coefficient is in the logistic scale.

c Five intervention and 11 control residents excluded owing to missing values in covariates.

d Three intervention and 12 control residents excluded owing to missing values in covariates.

Notes

Each model adjusted for place (C&W/NEL), home type, number of beds, age, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, SPPB at baseline, individual baseline fear of falling, and includes a random intercept for home.

OR < 1.0 favours intervention.

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TABLE 41 Mobility and lower limb function at 12 months

Outcome	Time point	Total	Intervention at baseline	Control at baseline	Intervention at end point	Control at end point	Effect estimate	95% CI	ICC
SPPB	12 months	*n*	231	261	231	261	0.30[a]	–0.05 to 0.64	0.09
		Mean	2.2 (2.4)	2.0 (2.1)	1.9 (2.4)	1.6 (1.9)			

ICC, intracluster correlation coefficient; SPPB, Short Physical Performance Battery.

a Zero intervention and one control residents excluded owing to missing values in covariates favours intervention.

Notes

Model adjusted for place (C&W/NEL), home type, number of beds, age at baseline, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, individual baseline SPPB, and includes a random intercept for home.

Positive difference favours intervention

TABLE 42 Social engagement (at 6 and 12 months)

Time point (months)	Social engagement	Total	Intervention	Control	OR[a]	95% CI	ICC[b]
6	Low	90	43	47	1.11	(0.73 to 1.69)	0.06
	Moderate	184	72	112			
	High	343	161	182			
12	Low	73	27	46	1.08	(0.64 to 1.83)	0.14
	Moderate	177	80	97			
	High	291	128	163			

ICC, intracluster correlation coefficient.

a This model is a proportional odds model. The interpretation of these ORs is similar to that for ORs from a binary logistic regression. In particular, for social engagement at 6 months, the odds of high social engagement compared with the combined middle and low categories are 1.15 greater in the intervention than in the control group, adjusting for all the other variables in the model. Likewise, the odds of the combined middle and high categories compared with low is 1.15 times greater in the intervention compared with the control, i.e. 15% higher odds.

b Intracluster correlation coefficient obtained using ICC $= \sigma_u/(\sigma_u + \pi^2/3)$ and are on the logistic scale.

Notes

Each model adjusted for place (CW/NEL), home type, number of beds, age at baseline, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, individual baseline social engagement, and includes a random intercept for home.

OR < 1.0 favours intervention.

TABLE 43 Proportional ORs of reporting pain at 6 and 12 months

Time point (months)	Pain now?	Total	Intervention	Control	OR[a]	95% CI	ICC[b]
6	No pain	364	168	196	1.08	0.70 to 1.66	0.03
	Moderate pain	141	69	72			
	Severe pain	18	8	10			
12	No pain	322	155	167	1.07	0.67 to 1.72	<0.0001
	Moderate pain	105	51	54			
	Severe pain	16	10	6			

ICC, intracluster correlation coefficient; SPPB, Short Physical Performance Battery.

a Estimates are proportional ORs, i.e. the ORs are assumed to be the same across the different comparisons; for example the odds of experiencing severe pain at 6 months compared with the combined moderate and no pain categories are 19% smaller in the intervention than in the control group, adjusting for all the other variables in the model. Likewise, the odds of experiencing moderate or high pain compared with no pain is 19% smaller in the intervention than in the control.

b Intracluster correlation coefficient obtained using ICC $= \sigma^2/(\sigma^2 + \pi^2/3)$ and are in the logistic scale.

Notes

Each model adjusted for place (C&W/NEL), home type, number of beds, age at baseline, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, SPPB at baseline, individual baseline pain and includes a random intercept for home. Twenty participants in the control group and 9 in the intervention were not included in the analysis at 6 months because of missing covariates. The numbers were 15 in the control and 7 in the intervention for the 12-month end point.

OR < 1.0 favours intervention.

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Cross-sectional analyses

Secondary outcomes: cross-sectional analyses

As for the cohort analyses (see *Follow-up* and *Primary outcomes: Geriatric Depression Scale-15*, above), cross-sectional analyses including all those resident in the home at 12 months do not provide any evidence of an effect of the intervention on any secondary outcomes (*Tables 44* and *45*).

Medication use

We obtained baseline drug use data on 869/887 (98%) of participants in the care home data cohort. We obtained data on progressively fewer residents at each time point falling to 615 at 12 months. We obtained data on 91% of those who were alive at 12 months. A large proportion of these were taking psychoactive drugs; with one in six taking hypnotics or anxiolytics, one in three taking antidepressants, and one in nine taking antipsychotic drugs. There were no differences in the number of participants using these drugs, over time or between the intervention and control (*Tables 46–48*).

There was no evidence of a change in participants' use of psychoactive drugs during the lifetime of the study. Few residents either started or stopped these medications, and there was no suggestion of a difference in the pattern of change between intervention and control homes (see *Table 47*).

Only a minority of residents used any medication from each of the three selected groups of psychoactive drugs. The mean number of defined daily doses taken was small for antipsychotics, larger for hypnotics and anxiolytics and largest for antidepressants. There was no evidence of a difference in amount of these drugs used between intervention and control homes (see *Table 48*).

TABLE 44 Cross-sectional outcomes, continuous measures at 12 months

Outcome	Intervention	Control	Effect estimate	95% CI	ICC
GDS-15					
n = 595	288	307	0.03[a] (mean difference) (*positive change favours control*)	–0.54 to 0.61	0
Mean age (years)	87.3	87.1			
% female	75	78			
Mean (SD)	4.67 (3.39)	4.74 (3.29)			
EQ-5D self-completed					
n = 496	251	245	0.00[b] (mean difference) (*positive change favours intervention*)	–0.06 to 0.06	0
Mean age (years)	87.0	86.9			
% female	73	77			
Mean (SD)	0.55 (0.39)	0.57 (0.38)			
MMSE					
n = 569	284	285	0.68[c] (mean difference) (*positive change favours intervention*)	–0.46 to 1.82	0
Mean age (years)	87.2	87.0			
% female	74	77			
Mean (SD)	18.6 (7.3)	17.7 (6.9)			
SPPB					
n = 611	296	315	0.20[d] (mean difference) (*positive change favours intervention*)	–0.14 to 0.53	0
Mean age (years)	87.3	86.9			
% female	74	78			
Mean (SD)	1.9 (2.4)	1.5 (1.9)			
Proxy EQ-5D					
n = 724	346	378	0.02[e] (mean difference) (*positive change favours intervention*)	–0.05 to 0.08	0.09
Mean age (years)	87.6	87.1			
% female	75	79			
Mean (SD)	0.45 (0.37)	0.44 (0.36)			

GDS-15, Geriatric Depression Scale-15; ICC, intracluster correlation coefficient; MMSE, Mini Mental State Examination; SPPB, Short Physical Performance Battery.

a Twelve participants in the control and seven in the intervention were not included in the analysis owing to missing covariates.

b Six in the control and two in the intervention were not included in the analysis owing to missing covariates.

c Eight participants in the control arm and three in the intervention were not included in analysis owing to missing covariates.

d One participant in the control was not included in the analysis owing to missing covariates.

e Two participants in the control arm and six in the intervention were not included in analysis owing to missing covariates.

Notes

Each model adjusted for place (C&W/NEL), home type, number of beds, age at 12 months, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline (except when the outcome is MMSE), SPPB at baseline (except when the outcome is SPPB), mean of individual baseline level of outcome and includes a random intercept for home.

Mean age in this table is mean age at the 12-month follow-up.

See footnotes in the corresponding cohort tables for further information on directionality of the outcome (i.e. whether it favours control or intervention).

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TABLE 45 Cross-sectional outcomes, categorical measures at 12 months

Outcome		Intervention	Control	Effect estimate	95% CI	ICC
Fear of falling						
No	*n* = 340	170	170	1.16[a] (OR)	0.79 to 1.71	0
	Mean age	86.9	87.2	(*positive change favours control*)		
	% female	71	75			
Yes	*n* = 213	103	110			
	Mean age	87.9	86.6			
	% female	82	88			
Pain now						
No pain	*n* = 411	198	213	1.39[b]	0.92 to 2.08	0
	Mean age	87.4	87.5	(*OR < 1 favours intervention*)		
	% female	73	78			
Moderate	*n* = 131	70	61			
	Mean age	87.0	85.9			
	% female	76	69			
Severe	*n* = 17	10	7			
	Mean age	84.4	81.2			
	% female	70	100			
Social engagement						
Low	*n* = 100	49	51	0.89[c]	0.57 to 1.38	0.12
	Mean age	87.6	87.1	(*OR < 1 favours control*)		
	% female	80	82			
Moderate	*n* = 233	108	125			
	Mean age	87.7	86.8			
	% female	69	78			
High	*n* = 402	192	210			
	Mean age	87.3	87.0			
	% female	77	80			

ICC, intracluster correlation coefficient; SPPB, Short Physical Performance Battery.

a Ten participants in the control arm and three in the intervention were not included in analysis owing to missing covariates.

b Twenty-one participants in the control arm and 17 in the intervention were not included in analysis owing to missing covariates.

c Two participants in the control and six in the intervention were not included in the analysis owing to missing covariates.

Notes

Each model adjusted for place (CW/NEL), home type, number of beds, age at 12 months, sex, on antidepressants at baseline (Y/N), proportion moderately to severely cognitively impaired in the home at baseline, SPPB at baseline, mean of individual baseline level of outcome and includes a random intercept for home.

Mean age in this table is mean age at the 12-month follow-up.

See footnotes in the corresponding cohort tables for further information on directionality of the outcome (i.e. whether it favours control or intervention).

TABLE 46 Numbers of cohort participants using medications for selected drug groups

BNF chapter	Time point	*n*/total (%)	Intervention *n*/*N* (%)	Control *n*/*N* (%)
4.1 Hypnotics and anxiolytics	Baseline	139/869 (16)	53/392 (14)	86/477 (18)
	3 months	126/786 (16)	45/359 (13)	81/427 (19)
	6 months	112/730 (15)	42/335 (13)	70/395 (18)
	9 months	107/670 (16)	43/306 (14)	64/364 (18)
	12 months	98/615 (16)	40/282 (14)	58/333 (17)
4.2 Antipsychotics	Baseline	100/869 (12)	40/392 (10)	60/477 (13)
	3 months	88/786 (11)	38/359 (11)	50/427 (12)
	6 months	80/730 (11)	35/335 (10)	45/395 (11)
	9 months	81/670 (12)	35/306 (11)	46/364 (13)
	12 months	74/615 (12)	32/382 (11)	42/333 (13)
4.3 Any antidepressants	Baseline	260/869 (30)	110/392 (28)	150/477 (31)
	3 months	231/786 (29)	100/359 (28)	131/427 (31)
	6 months	221/730 (30)	97/335 (29)	124/395 (31)
	9 months	193/670 (29)	88/306 (29)	105/364 (29)
	12 months	186/615 (30)	83/282 (29)	103/333 (31)
4.3.1 Tricyclic antidepressants	Baseline	54/869 (6)	18/392 (5)	36/477 (8)
	3 months	46/786 (6)	16/359 (4)	30/427 (7)
	6 months	48/730 (6)	15/335 (4)	28/395 (7)
	9 months	40/670 (6)	13/306 (4)	27/364 (7)
	12 months	36/615 (6)	13/282 (5)	23/333 (7)
4.3.3 Selective serotonin re-uptake inhibitors	Baseline	189/869 (22)	86/392 (22)	103/477 (22)
	3 months	177/786 (23)	82/359 (23)	95/427 (22)
	6 months	171/730 (23)	79/335 (24)	93/395 (23)
	9 months	147/670 (22)	70/306 (23)	77/364 (21)
	12 months	144/615 (23)	65/282 (23)	79/333 (24)
4.3.4 Other antidepressants	Baseline	46/869 (5)	17/392 (4)	29/477 (6)
	3 months	39/786 (5)	14/359 (4)	25/427 (5)
	6 months	32/730 (4)	12/335 (4)	20/395 (5)
	9 months	29/670 (4)	12/306 (4)	17/364 (5)
	12 months	27/615 (4)	12/282 (4)	15/333 (5)
4.7 Analgesics	Baseline	420/869 (48)	166/392 (42)	254/477 (53)
	3 months	344/786 (44)	141/359 (39)	203/427 (48)
	6 months	345/730 (47)	137/335 (41)	208/395 (53)
	9 months	316/670 (47)	132/306 (43)	184/364 (51)
	12 months	289/615 (47)	117/282 (41)	172/333 (52)

continued

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TABLE 46 Numbers of cohort participants using medications for selected drug groups (*continued*)

BNF chapter	Time point	*n*/total (%)	Intervention *n*/*N* (%)	Control *n*/*N* (%)
10.1.1 Non-steroidal anti-inflammatory drugs	Baseline	31/869 (3)	12/392 (3)	19/477 (4)
	3 months	29/786 (4)	14/359 (4)	15/427 (4)
	6 months	26/730 (4)	9/335 (3)	17/395 (4)
	9 months	22/670 (3)	9/306 (3)	13/364 (4)
	12 months	19/615 (3)	9/282 (3)	10/333 (3)

BNF, *British National Formulary*.
A few participants were taking antidepressant from more than one group.

TABLE 47 Changes in prescribing of selected drug groups from baseline to the end of the study ($n = 615$)[a]

	Intervention		Control	
BNF chapter	n	%	n	%
Total	282		333	
4.1 Hypnotics and anxiolytics				
On drug beginning and end	29	10	47	14
On drug only at end	11	4	11	3
On drug only at beginning	5	2	9	3
Never on drug	237	84	266	80
4.2 Antipsychotics				
On drug beginning and end	24	9	37	11
On drug only at end	8	3	5	2
On drug only at beginning	7	2	5	2
Never on drug	245	87	284	85
4.3 Antidepressants				
On drug beginning and end	73	26	84	25
On drug only at end	10	4	19	6
On drug only at beginning	10	4	11	3
Never on drug	189	67	219	66

BNF, *British National Formulary*.
a Includes participants alive at end of study and resident in a home from same randomised group.

TABLE 48 Estimated mean total number of defined daily dose for selected *British National Formulary* chapters

BNF chapter	Mean total number of DDDs over whole resident follow-up in cohort			
	N = 869	Intervention (*n* = 392)	Control (*n* = 477)	Mann–Whitney *U*-test: *p*-value
	Mean total (SD), 90th centile	Mean total (SD), 90th centile	Mean total (SD), 90th centile	
4.1 Hypnotics and anxiolytics	23 (69), 111	17 (52), 56	29 (80), 139	0.131
4.2 Antipsychotics	6 (39), 5	7 (48), 2	6 (29), 5	0.630
4.3 Antidepressants	68 (151), 277	59 (123), 242	76 (171), 282	0.168

BNF, *British National Formulary*; DDD, defined daily dose.

Number of DDDs in a given period for a specific drug = concentration × quantity consumed in period/DDD.

The 10th centile is zero for each of these BNF chapters.

Number of DDDs used in 7 days were calculated from medical records data and interpolated forwards and backwards, in multiples of seven, to the midpoint date between each data collection visit to the homes. For residents who died, the interpolation value was scaled by the proportion of the time interval survived if this was less than a half. Otherwise a half was used, as was the case for residents who moved away from OPERA homes. For residents not taking any of the psychoactive drugs in a time interval, their number of DDDs was set to zero for that interval.

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Adverse events

Indirectly attributable adverse events

There was a total of 90 fractures identified from home records over the study period; these occurred in both study participants and in non-participants. There was no evidence of a differential fracture rate between intervention and control homes (*Table 49*).

Among those who had provided consent or assent to have their data examined, there were 56 definite fractures, eight probable fractures and nine possible fractures. Again, there was no evidence of a difference in fracture rate between the intervention and control homes (*Table 50*). Of the definite fractures, i.e. those requiring hospital admission, 39/56 (70%) were fractures of the femur.

There were 241 deaths among the 1054 study participants: 119 in the intervention group and 122 in the control group. There was no evidence of differential death rates between intervention and control groups (*Table 51*).

Directly attributable adverse events

Five residents in intervention homes, including one resident who was not a study participant, experienced adverse events during the exercise groups or when preparing for the groups; none was serious (*Table 52*). Although two residents fell in the lounge of their care home this was before the group started and no injuries were sustained. Two residents had other health problems that became apparent during the groups and one suffered a minor injury, not requiring treatment. Thus incidence of directly attributable serious adverse events was < 1 : 30,000 attendances.

TABLE 49 Incidence rate ratio of peripheral fracture: care home data (all residents)

Outcome		Total no. of fractures	No. of fractures		Estimate[a]	95% CI	ICC
			Intervention	Control			
Peripheral fractures	Aggregated	90	48	42	IRR = 1.14	0.80 to 1.63	0.03

ICC, intracluster correlation coefficient.

a IRR, incidence rate ratio. Adjusted for baseline covariates at aggregated at home level: age, proportion of females, proportion of residents on antidepressants and proportion of residents with moderate to severe cognitive impairment, as well as cluster covariates size, place and type of home.

TABLE 50 Total peripheral fractures: National Health Service data (all participants)

Type	Total no. of fractures	No. of fractures	
		Intervention	Control
Definite	56	29	27
Probable	8	1	7
Possible	9	5	4
Total	75	35	38

Chi-squared test: *p*-value 0.765.

TABLE 51 Deaths

Deaths	Total	Intervention	Control
All-cause mortality	241/1054[a] (23%)	119/501 (24%)	122/553 (22%)

a Includes all participants present at any time after randomisation. This includes those who moved in after randomisation and had moved out or died before the end of study assessments.

Notes

Everybody (1054) [OR = 1.07 (95% CI 0.78 to 1.48), $p = 0.673$, ICC = 0.02].

Only those present at randomisation (901) [OR = 1.08 (95% CI 0.79 to 1.50), $p = 0.620$, ICC = 0].

Adjusted for age at baseline, sex, antidepressant use at baseline, proportion of residents moderately to severely cognitively impaired at baseline in the home, home type, location (NEL or C & W) and size of home.

TABLE 52 Directly attributable adverse events

Resident	Study participant?	Nature of event	Consequences	Serious adverse event?
1	Yes	Fall in lounge before exercise group session	No injury, no medical intervention needed	No
2	Yes	Fresh graze on lower leg noted after removal of soft ankle weight	Seen by community nurse, no medical intervention needed	No
3	Yes	Unwell during exercise, low haemoglobin level, started on treatment for Parkinson's disease	Returned to care home after overnight admission	No
4	Yes	Increased hip and knee pain after joining exercise group sessions, radiograph showed acetabular erosion associated with hemiarthroplasty, change since previous film 4 years earlier	Referred to orthopaedics	No
5	No	Fall in lounge before exercise group session	No injury, no medical intervention needed	No

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Economic evaluation

Resource use and quality-adjusted life-year data were available for 798 participants recruited prior to randomisation. The economic analysis includes those participants who consented or assented to us collecting data from their medical records and the collection of proxy EQ-5D scores. As self-completed questionnaire data were not required for this analysis, the economic evaluation includes two participants who were not included in the analysis of primary outcomes. As the economic analysis required a National Health Service number to get primary care trust data extracts, the economic evaluation excluded two participants who were included in the cohort analysis of effectiveness.

Costs

Resource use was broadly comparable between the control and intervention homes (*Table 53*). Participants were frequent users of community services and general practitioner home visits. Use of general practitioner surgery visits, mental health team visits and practice nurse visits was infrequent. Using the univariate linear-mixed model, no significant differences were seen between the two arms of the study. All event types were more frequent in the intervention arm.

The inpatient and A&E cost data collected from the primary care trusts had some missing data. For the outpatient attendance cost data, 36% of attendances had missing cost values, and 96% of these missing values came from two of the primary care trust data sets. Consequently, the outpatient costs were calculated using data for missing values that had been generated by multiple imputation. Outpatient attendances, however, constitute only a small proportion of the total costs.

The distribution of costs was skewed, as is typical for health-care costs (*Figure 13*).

As with the resource use, no significant differences were found (*Table 54*). For the costs associated with medications, the intervention arm had lower costs. For all other categories, the mean cost of the control arm was lower. The mean National Health Service cost per individual in the intervention arm over 12 months was £4639, whereas the cost per participant in the active control arm was £4251 (mean difference = £388, 95% CI –£604 to £1380).

TABLE 53 Resource use for participants at 12 months expressed as mean events per participant

Contact type	Unit	Intervention mean	Control mean	Mean difference	95% CI of the difference
A&E attendances	Investigations	0.94	0.91	0.03	–0.23 to 0.30
Community visit	Visit	7.03	5.25	1.77	–1.43 to 11.92
GP home visit	Visit	5.23	4.97	0.26	–1.42 to 1.94
GP surgery visit	Visit	0.31	0.29	0.02	–0.23 to 0.27
Inpatient service	Dominant episode	0.87	0.74	0.13	–0.09 to 0.35
Mental health team visit	Visit	0.17	0.15	0.02	–0.10 to 0.14
Outpatient service	Visit	1.56	1.27	0.29	–0.16 to 0.73
Practice nurse visit	Visit	0.14	0.10	0.03	–0.05 to 0.12

Note
Positive differences favour the active control.

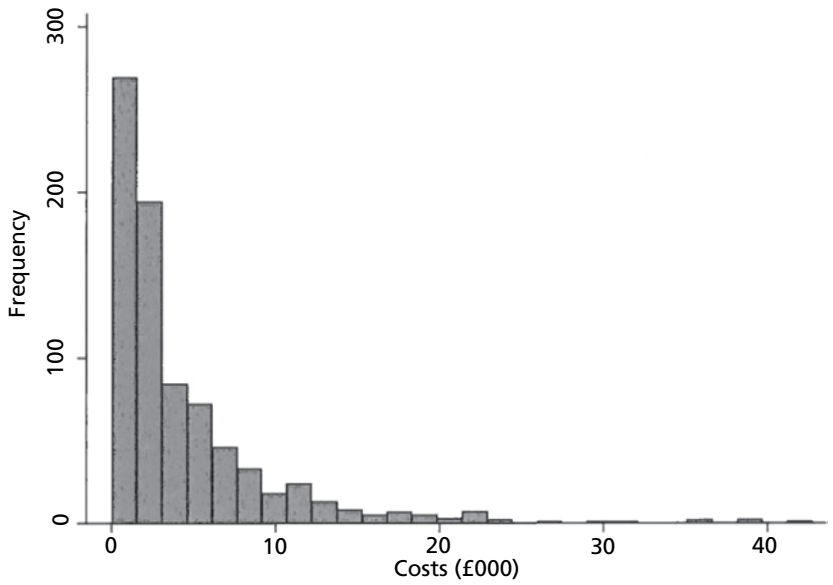

FIGURE 13 Distribution of participants' costs at 12 months, across all homes. (The outpatient costs used in this figure were derived by taking the mean cost of the five data sets generated by multiple imputation.)

TABLE 54 Mean costs (£) for participants at 12 months: active control vs intervention

Cost category	Intervention mean	Control mean	Mean difference	95% CI of the difference
A&E attendances	319	306	13	–79 to 105
Community visit	330	247	83	–393 to 560
GP home visit	628	597	31	–170 to 232
GP surgery visit	11.2	10.5	0.7	–8.2 to 9.6
Inpatient services	2319	2264	55	–688 to 797
Medications	525	626	–101	–268 to 67
Mental health team contacts	19	17	2	–11 to 15
Outpatient visits[a]	450	379	71	–24 to 166
Practice nurse contacts	1.6	1.2	0.4	–0.6 to 1.4
Total costs[a]	4639	4251	388	–604 to 1380

a These data are from one of the five data sets generated by multiple imputation.

Note

Positive differences favour the active control.

Active control and intervention costs

The time and materials needed to deliver both the depression awareness training and the intervention programme were collected alongside the study. Unless otherwise noted, all costs associated with delivering the active control and intervention programmes were taken from the study records (*Tables 55* and *56*). In the control arm the cost of depression awareness training sessions was the highest cost, followed by the materials. For the intervention arm, the cost of the exercise sessions was the highest cost, followed by the mobility assessments.

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TABLE 55 Cost breakdown (£) for depression awareness training in the active control arms of the study

Item	NHS cost	Societal cost	Notes
Depression awareness training sessions	5111	5111	Nursing/physiotherapy staff time to deliver the intervention, including travel
Materials for depression awareness training sessions	1294	1294	Included pack for trainers and booklets for home staff
Nurse/physiotherapist training	166	166	Nursing/physiotherapy staff time being trained to deliver the sessions, including travel
Trainer costs	508	508	Based on £127 per hour for a psychiatric consultant[189]
Home staff carers' time in training		2147	Based on £6 per hour for a care worker[188]
Home staff nurses' time in training		302	Based on £22 per hour for Agenda for Change Band 6[189]
Home staff managers' time in training		405	Based on £17 per hour for a registered manager[188]
Total	7078	9932	
Cost per home	165	231	
Cost per participant	5	7	Weighted cost per participant: assumes that 87% of residents in homes are eligible to participate (see *Table 64*)

The weighted cost per participant in the intervention homes was £322. For participants in the active control homes, it was £5. The societal cost per participant in the intervention home was £314 and for the participants in the control home it was £7. The lower societal cost in the intervention care homes was due to home staff time saved by the assistance and occupation of the physiotherapists while in the home, which outweighed the care home staff time spent training. The higher societal cost in the control care homes was due to the staff time spent in depression awareness training.

Quality-adjusted life-years

The level of missing data ranged from 4% to 16% per time point for the proxy EQ-5D scores; consequently, the quality-adjusted life-years for the primary analyses were calculated from the five data sets (one for each time point) with missing values replaced by values generated by multiple imputation.

Analyses

All reported incremental costs and quality-adjusted life-years are from multilevel models to recognise clustering.

Base-case analysis

In the control arm the multiple imputation averaged correlation between total cost and quality-adjusted life-year is –0.13, whereas in the intervention this correlation is –0.05.

Each of the five sets of total costs and quality-adjusted life-years were analysed using multilevel models to account for clustering. These produced an incremental cost of £374 (SE = £525, 95% CI –£655 to £1404). The incremental quality-adjusted life-year gain was –0.0014 (SE = 0.036, 95%CI –0.0727 to 0.0699). The intracluster correlation coefficient for the total costs was 0.07, and the intracluster correlation coefficient for the quality-adjusted life-years was 0.14.

To obtain a graphical representation of the uncertainty of the cost-effectiveness estimates, we used bootstrapping. We sampled at random with replacement each of our five cost-effectiveness sets including the imputed data, producing 2000 incremental cost and incremental quality-adjusted life-years estimates

TABLE 56 Cost breakdown (£) for the delivery of the intervention

Item	NHS cost	Societal cost	Notes
Training of physiotherapists	13,014	13,014	Includes physiotherapists' time spent being trained to deliver the intervention, travel, materials and lunches. Excludes room hire. Based on £25 per hour for a community physiotherapist[189]
Training of care home staff	3842	3842	Physiotherapists' time to deliver the training to care home staff and associated travel costs. Based on £25 per hour for a community physiotherapist[189]
Mobility assessments	32,425	32,425	Physiotherapists' time to conduct mobility assessments for participants and associated travel costs. Based on £25 per hour for a community physiotherapist[189]
Exercise sessions	287,403	287,403	Physiotherapists' time to deliver the exercise sessions and travel costs. Based on £25 per hour for a community physiotherapist[189]
Equipment for exercise sessions	12,511	12,511	Includes items such as, leg weights and balls
Materials for home staff training	1747	1747	Includes pack for trainers and booklets for home staff
Mobility equipment	1566	1566	Items requested by physiotherapist to aid mobility
Trainer costs	7771	7771	Trainer time spent with physiotherapists, travel and accommodation. Based on £127 per hour for a psychiatric consultant and £21 per hour for a Band 6 physiotherapist[189]
Home staff carers' time in training		2292	Based on £6 per hour for a care worker[210]
Home staff nurses' time in training		381	Based on £22 per hour for Agenda for Change Band 6[189]
Home staff managers' time in training		539	Based on £17 per hour for a registered manager[210]
Carer time assisting with mobility assessments		1185	Based on £6 per hour mean cost assuming a ratio of 9 : 1 carers to senior carers[210]
Carer time in informal 1 : 1 training with physiotherapists		3634	Based on £7 per hour mean cost assuming a ratio of 7 : 13 ratio of carers to senior carers[210]
Carer time saved by physiotherapists transporting participants		–17,111	Based on £6 per hour mean cost assuming a ratio of 9 : 1 carers to senior carers.[210] Gain of 5 minutes per participant attendance at exercise session
Total	360,278	351,199	
Cost per home	10,294	10,034	
Cost per participant	322	314	Weighted cost per participant: assumes that 87% of participants in homes are eligible to participant (see *Table 64*)

for each data set. These estimates were plotted in a cost-effectiveness plane. *Figure 14* shows one of these graphs. The graph of bootstrapped estimates provides a graphical description of the distribution of the incremental costs and quality-adjusted life-years and the uncertainty surrounding these values. From *Figure 14*, it is apparent that more points lie above the *x*-axis, indicating that the intervention is more costly, and that more points are to the left of the *y*-axis, indicating that the intervention produces fewer quality-adjusted life-years. This also displays how other combinations of costs and quality-adjusted life-years that were consistent with the data produced sample means in all four quadrants.

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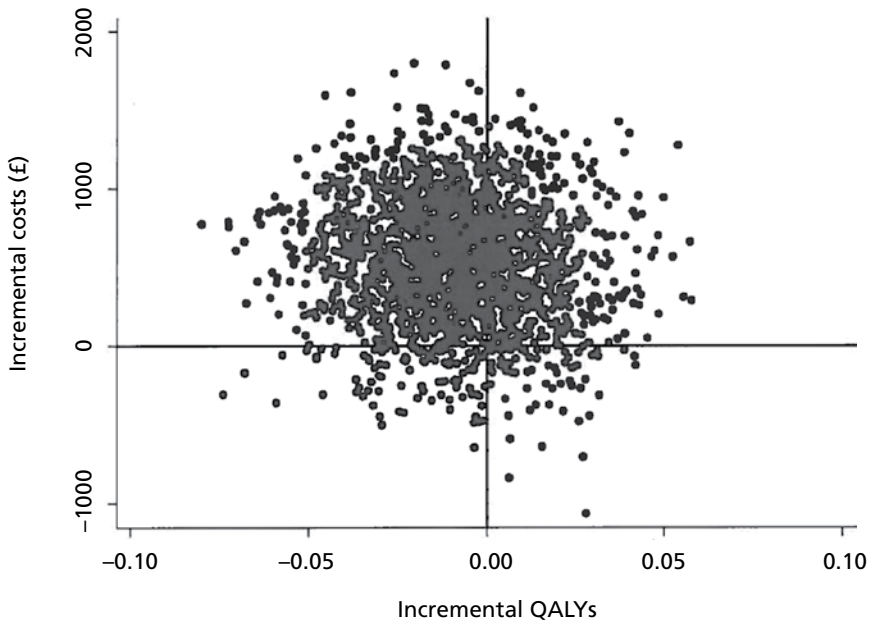

FIGURE 14 Cost-effectiveness plane generated from bootstrapped mean cost and quality-adjusted life-year differences for residents over 12 months (positive values indicate that the intervention was more costly or more effective).

The incremental cost-effectiveness ratio was not calculated as the intervention was more expensive with a net reduction in quality-adjusted life-years. Under these circumstances, disaggregated data on costs and effects are considered to be more informative. The probability of the intervention being cost-effective at a willingness-to-pay threshold of £20,000 per quality-adjusted life-year was 33% and at a threshold of £30,000 was 37%.

Sensitivity analyses

For the sensitivity analysis excluding participants with high costs, the 39 participants with the top 5% of costs were dropped. This resulted in an incremental cost of £402 (SE = £319, 95% CI –£224 to £1028). The incremental gains in quality-adjusted life-years remained negative and very small at –0.0023 (SE = 0.0380, 95% CI –0.076 to 0.072).

The second sensitivity analysis expanded our analysis to the societal perspective. This analysis accounted for the training time of home staff, the time saved by carers in the intervention homes owing to the physiotherapists assisting with participant transport and the time lost by carers owing to mobility assessments and informal training. The incremental societal cost was £366 (SE = £525, 95% CI –£664 to £1396). The quality-adjusted life-year gain was unaltered from the base-case analysis.

For both sensitivity analyses, the mean cost per participant in the intervention arm was higher, and the mean difference in quality-adjusted life-year value was very small and favoured the control arm (*Table 57*).

Secondary analysis

For the secondary analysis including participants recruited after the randomisation of the homes, the analysis included 1025 residents. Of these, 798 were from the baseline cohort and 291 had been recruited at 3, 6 or 9 months. This resulted in an incremental cost of –£176 (SE = £319, 95% CI –£450 to £802). The incremental quality-adjusted life-years were –0.0340 (SE = 0.0193, 95% CI –0.0717 to 0.0037). In this analysis the mean cost per participant in the intervention arm was lower and the mean difference in quality-adjusted life-year was small (see *Table 57*). The CIs for the incremental costs remained very large and overlapped zero, indicating that this finding is not significant. Care is needed in interpreting these results as there is some evidence of differential recruitment in those who joined the study after randomisation and we may not have been able to fully control for differences in length of follow-up between the treatment and control groups.

TABLE 57 Mean outcomes and mean outcome differences from the multilevel models for the baseline and sensitivity and secondary analyses

Analysis	Mean difference	95% CI
Base-case analysis		
Total costs, £	374	–655 to 1404
QALY	–0.0014	–0.0728 to 0.0699
Excluding high-cost participants		
Total costs, £	402	–224 to 1028
QALY	–0.0023	–0.076 to 0.072
Societal perspective		
Total costs, £	366	–664 to 1396
QALY	–0.0014	–0.0728 to 0.0699
Secondary analysis		
Total costs, £	–176	–450 to 802
QALY	–0.0340	–0.0717 to 0.0037

Process evaluation results

The case study care homes

We recruited four homes each from NEL and C&W. In each area one home was a control home and three intervention homes. The three intervention homes were selected so that one was an independent home (where the owner owned fewer than 10 homes), one was part of a larger chain, and one was designated as a nursing home (*Table 58*). All of the case study care homes were located in residential areas – several with local shops and amenities within a short walking distance, and several had access to nearby parkland. They all had gardens, usually well maintained, although one was poorly tended with very limited access. Smokers (staff and residents) were the main users of the outside space.

Of the four homes in NEL, one was a purpose-built home (which in the past was in local authority control) and had two floors. Two were converted houses, while the remaining home was a converted block of flats. With one exception, public areas (e.g. lounges and dining rooms) were all on the ground floor. The purpose-built home had an additional little-used small lounge on the first floor (used as a store room). All care homes had ground floor bedrooms and had lifts to the upper floors. Two of the homes had separate dining rooms next to the kitchen, while in the other two food was served either in the main lounge or an area used during the day as a 'quiet' room for reading or craft activities. Three of the homes had multiple areas for residents to sit and/or become involved in activities, while the other had a large multiuse room.

In C&W, there was one purpose-built home, one converted hospital building and two converted houses. Two of these homes had public areas on each of the floors. There were residents' rooms on all floors and all of the homes had lifts to all floors. In the purpose-built home there were also small kitchen/dining rooms in each of the three wings. One of the converted houses had one large central space divided into three areas: a dining area, a lounge for activities and a TV lounge, with no physical dividers between the areas.

Interviews undertaken

The process evaluation fellow (DE) carried out 48 interviews with 35 people; 21 were from NEL and 14 were from C&W (eight care home managers, six carers, three senior carers, four activities co-ordinators, eleven residents and three NOK). Where direct quotations are used to illustrate themes, an assigned

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TABLE 58 Overview of case study care homes

Home	Intervention/control	Area	Ownership	No. beds	CSCI rating
1	Control	NEL	Independent < 10[a]	39	3 star
2	Intervention	NEL	Independent, nursing	28	2 star
3	Intervention	NEL	Independent, part of chain	40	3 star
4	Intervention	NEL	Independent < 10[a]	24	2 star
5	Control	C&W	Voluntary	28	2 star
6	Intervention	C&W	Voluntary	45	2 star
7	Intervention	C&W	Independent < 10[a]	21	2 star
8	Intervention	C&W	Private/nursing	30	2 star

CSCI, Commission for Social Care Inspection.
a Small company (1–10 homes).

code identifies the respondent and time point within the study. A full table of the interviewees and their corresponding codes is given in *Appendix 12*.

We could not complete as many interviews as we had planned. Care home managers and staff were very busy and often had to cancel interviews. We could interview residents only if they had, themselves, consented to the OPERA study, which restricted the number of potential interviewees. These numbers reduced further as people left the home, were in hospital or died. We also found that participants were reluctant to be formally interviewed. It was particularly difficult to arrange interviews with NOK as we had no access to their contact details.

Evaluation of recruitment processes

Home recruitment

A focus group with the research staff involved in recruiting the homes revealed that the main reasons given by care home managers for not wanting to take part in the study were that the care home already had exercise classes or provided some sort of depression training or dementia training, or the timing of the study was inconvenient. The recruiting team found if the care home manager agreed to a meeting they generally agreed to the home taking part. Early challenges included clarifying the inclusion criteria for homes. Recruiting staff adopted a policy of checking the inclusion criteria by phone before visiting the care homes. The team all noted that information about the care homes obtained from the Commission for Social Care Inspection (now Care Quality Commission) reports was not always accurate.

At baseline interview some care home managers expressed a preference for which arm of the study they might be randomised to. Many managers were interested in the opportunity for regular exercise groups but some preferred the control intervention. Care home staff training in depression was limited and care home managers felt that such training would be an advantage.

> *At first we were really 'Oh I hope we get the [exercise] sessions', but then as we were looking at it and we've got more and more to learn more about it, we were like we actually want the training.*
>
> *5 manager*

> *If we'd have got the staff trained then fine, but I made it perfectly clear what really would have been the massive carrot for me and luckily, we got it (the intervention).*
>
> *16 manager*

I could not influence anything. Of course I could not, but I was really hoping it was going to be a physiotherapist, rather than the training.

19 manager

Recruiting individual participants

We include here data gathered from observations, interviews and a reflective focus group held with the recruiting staff at the end of the study recruitment period.

Care home managers were asked to help identify any residents who were too ill or not eligible for the study for other reasons. The recruitment team found that some care home managers were also excluding people they felt would not want to take part in the study, and the recruiting team made strenuous efforts to ensure that this did not happen.

The recruitment team felt it would have been useful to be able to present the study to the care home staff and residents prior to recruitment but the tight recruitment schedule prevented this. Managers were asked to inform the staff and residents about the study before recruitment started, but this did not always happen. When it did, residents were more interested. Some managers put up notices they had designed themselves to inform staff and relatives about the study.

Assessing capacity to consent in all residents in the care home could mean assessing up to 50 residents; this was time consuming and challenging despite help from care home managers in identifying residents who would definitely not have capacity to consent. Time pressure on the recruiting staff, especially at the peak of recruitment, meant they may have missed a few eligible participants. In some cases the family of a resident who had consented would also ask for information about the study, and some residents with capacity to consent wanted one of their relatives to sign the consent form on their behalf. One resident went to great lengths to report her experience of the physical assessment carried out by the research team after she gave consent to participate.

Well, when she came I amazed myself because I think it was about an hour and a half. It was a mental test . . . And doing it without being warned I was going to do it, I would not have thought I could but I did . . . And she was surprised herself! I mean I still do not know how I did it, she was surprised and when it came to walking she had a white line over there . . . She asked me to walk over there and stand upright and leave that, so my standing is not quite good but she was there. She said 'You will not fall.' . . . She timed me on how long I could stand without holding that.

11 resident

Care home managers who were interviewed were positive about the process of resident recruitment:

No, no problems at all. No, none whatsoever. I mean he's been here – [Name] on . . . I think he's been here about four times in total, four or so times, and he's been good . . . It was very good, yes. Nobody was put under any pressure to participate.

37 manager

Additional data on the use and administration of the outcome measures are summarised in *Appendix 13*.

Impact of recruitment on the care homes

In addition to being asked about their interactions with the physiotherapists, care home managers and carers were also asked about interactions with the OPERA team (including the recruitment/assessment staff, research fellows and contact with the study office). All managers and a number of the care staff commented that the visiting OPERA team, although sometimes viewed warily at the start, became welcome in the home. Care home managers noted that appointments were made for visits and the team were no burden on the homes' residents or staff. Several reported good outcomes from problems that were raised.

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I think it was excellent. There wasn't any problem at all. I mean the residents, they [the OPERA team] did not impose. They knew which residents were not able to make the decision and so they contacted relatives. I think it was done very well – no problem.

19 manager

And it was a pleasure having [Names] here. I mean all of you . . . I've never had any problems. You've actually fitted in and people have accepted you.

20 manager

Even when you did the interviews here, we did not have any problems. Everybody was just so respectful and kind and just nice people – just a nice bunch of people.

32 senior carer

Delivery of care home staff training

We delivered at least 142 depression awareness training sessions to at least 902 care home staff; eight of these training sessions were observed (five intervention and three control) (*Table 59*). Registers are missing from one home where at least one training session was delivered. One home had six sessions delivered covering most of the staff. Overall less than half of the care homes' staff were exposed to the training. OPERA research staff in both arms of the study reported difficulties at times in organising the training sessions. On at least 15 occasions no care home staff attended a booked training session. It proved to be particularly difficult to deliver training in some care homes, and after several failed attempts training was abandoned in one home in the control arm.

We received 916 completed feedback forms at the end of the training sessions (this included 14 forms from the care home with a missing register); 174 (19%) participants had worked in a care home setting for <1 year, while 421 (46%) had worked in such a setting for >5 years. Ethnographic observations in the case study care homes and interviews suggested that a majority of care staff have been working in the sector for many years. We observed cases of a changing staff population but there was a large core of staff with long-term experience.

Specific observations of the delivery of the training revealed some of the challenges faced by the research team delivering the session. Quiet space within homes for staff to attend training was not always available

TABLE 59 Depression awareness training and depression awareness and activity training

Item	Intervention: depression awareness and activity training	Control: depression awareness training	Total
No. homes (*n*)	35	43	78
No. of staff	884	1126	2010
Training sessions delivered (*n*)	69	73	142
Total attendance	406	496	902
Mean attendance	5.9	6.8	6.4
Percentage of staff trained	46%	44%	45%
No training delivered	0	1	1
One session delivered (*n* homes)	8	21	29
Two sessions delivered (*n* homes)	18	15	33
Three or more sessions delivered (*n* homes)	8	6	14
Missing data (*n* homes)	1	0	1

and the attendance varied. Some of the care home managements did not pay staff for time spent in training with the result that there was little incentive to attend, especially if staff had a day off or if training took place outside their shift hours. A number of staff attended the training during their normal shift but in some cases this resulted in them being called away from the training to carry out a caring task. Some home managers actively encouraged all staff to attend (including ancillary staff and night staff) but this was not universal.

Observations during the training sessions generally supported the results of the feedback questionnaire described below (*Table 60*). Care home staff appeared to enjoy the DVD and it generated discussion. The levels of engagement with the training were variable – some got involved and asked questions or made comments, while others said very little.

The immediate participant feedback questionnaires suggested that the training was felt to be relevant and provided new information. However, the response rate to the mailed, 3-month questionnaire was very poor (15%). Investigation suggests that there was no monitoring of returns and no reminders were sent. Those who did respond provided interesting feedback, more detail of which is provided in *Appendices 14* and *15*; in summary it suggested that:

- the training was well liked
- the materials were useful
- the training sensitised people to be aware of low mood and depression
- the training changed people's perceptions of what to look for in a resident.

However, there was not much evidence in the feedback that the training changed the way people did their jobs. Most respondents said they would have liked more training.

Interviews with care home staff and home managers support the findings of the training feedback. Most of the managers had attended the training themselves and several had received positive feedback from their staff. Although the training was seen as a good thing there were comments about the level of the training.

> *. . . to be honest, most of it I felt like I already knew really*
>
> *28 activity co-ordinator*

> *I thought it was very basic and I would have liked something more sophisticated because I think basically what she said, we already knew and we really needed the next level up.*
>
> *23 manager*

TABLE 60 Depression awareness training and depression awareness and activity training post session feedback

Statement	*n*	Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly agree
The session was relevant to my job	888	16 (2%)	6 (1%)	25 (3%)	296 (33%)	545 (61%)
I learned something new from this session	891	19 (2%)	17 (2%)	48 (5%)	421 (47%)	386 (43%)
I am glad I attended this session	889	14 (2%)	7 (1%)	24 (3%)	371 (42%)	473 (53%)
The session was just the right length	881	19 (2%)	34 (4%)	36 (4%)	397 (45%)	395 (45%)

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Equally, there were positive comments such as:

> *I think it was an eye-opener. There was the DVD she brought with her as well. I think it did get people questioning and there was a lot of interacting going on in that session.*
>
> *20 manager*

> *Yes, I mean the whole thing that [Name] and [Name] did was good. It wasn't too technical and it wasn't talking down to people. It wasn't talking under people. It wasn't too complex, too simple, too fussy, too thin or whatever.*
>
> *25 manager*

Many of the research staff who delivered the care home staff training reported that managers and staff would have liked more than just a one-off depression awareness session, and some care homes would have liked the training to be in more depth, supporting the findings from the interviews. One care home requested additional depression training for staff after follow-up was completed (post OPERA). Several physiotherapists were aware that the training helped the home fulfil its requirements for the Care Quality Commission supported by the certificates provided to attendees.

Set-up of the exercise groups

Thirty-five homes were randomised to the 'whole-home' intervention: 18 in NEL and 17 in C&W. After randomisation to the active arm of the study, one care home in NEL was found to be unsuitable for the intervention during the physiotherapist assessments of residents and no exercise groups were delivered in this home. Thus the following data, for the delivery of exercise classes, are from 17 homes in each area. Data presented in this section include all residents within the care homes and are split by those who are study participants and those who are not. There was considerable variation in the time taken getting the intervention started (between 3 and 14 weeks) (*Table 61*). There was a shorter average set-up time in C&W and hence a longer period of actual intervention delivery.

Before the exercise intervention started, there were some anxieties among staff of the homes. Both care home managers and carers anticipated a number of potential barriers, including difficulties in fitting into the care homes' routines and sustaining the participation of residents.

> *Well, one thing that could stop you from doing it is if none of the residents joined in, obviously . . . but other than that, I do not really think there is anything that would stop you from doing it.*
>
> *1 manager*

> *It's a bit of hard question because they might say 'yes' and when it comes to it, they'll probably change their minds – the residents, because they like doing that to us. I mean one or two might do it.*
>
> *12 carer*

TABLE 61 Time in weeks between key milestones: intervention homes

	Time (weeks)		
Time frame	C&W: median (range)	NEL: median (range)	Overall: median (range)
Period from randomisation to first exercise group	5 (3–10)	6 (3–14)	6 (3–14)
Intervention delivery period	48 (39–51)	45 (37–50)	48 (37–51)
Period from randomisation to last exercise group	54 (49–56)	52 (47–55)	53 (47–56)

Well, I think some barriers have probably already come across and that is . . . and I said this from the start, that some residents . . . You know, they're having it twice a week – the exercises and some residents, they may want to be totally committed one week but then the next week they cannot be bothered, and this happens.

19 manager

There were also some reported problems arising from differences in expectations, although these were all resolved relatively quickly.

With regards to myself and the staff, I think she's just a little bit overpowering and I do not think they understood that she would have such an active part that it would be twice a week and it would be so intense, and she would want so much from the other staff. We did not expect that, so I think that's been a bit of a learning curve really.

44 manager

Well, I think it's a bit over the top with [Name] occasionally. You know . . . all I can do as a manager is just put it to the company and it's not my decision. It's the company's decision whether we change things.

19 manager

The residents interviewed at baseline could see no barriers to the research team delivering OPERA into the home and in general thought it was a good idea although two residents doubted that people would participate:

But people will not join in, will they?

11 resident

Yes, that would be good [the exercise groups]. They do not always join in anything here.

34 resident

Dose delivered

In one of the 35 intervention homes the dose delivered was zero because residents were too disabled to participate. We report here on activity in the remaining 34 homes. Delivery of two exercise groups per week over 12 months (allowing for set-up time and key public holidays) gives a potential 100% dose delivered of 92 groups in a home (*Table 62*). The study achieved a 90% dose delivered: 90% in C&W and 89% in NEL. Four homes were so big, or laid out in such a way, that they required more than one pair of exercise classes per week. Some planned exercise classes failed to happen. The physiotherapist team reported a number of reasons for this including infection control issues (e.g. outbreaks of diarrhoea and vomiting, norovirus and the influenza H1N1 epidemic), and adverse weather conditions (e.g. snow and ice, or days that were too hot for residents to exercise).

The 34 intervention homes had a total resident population of 1439 (based on study registers during the period of the intervention delivery); of these, 494 (34%) were study participants. Not all residents were judged by the physiotherapists to be fit enough to participate in the exercise groups. There were around 1256 (87%) residents who were eligible to attend groups of whom 478 (38%) were study participants.

During the study physiotherapists delivered 3191 exercise groups in 34 homes. In total 65,196 person sessions were made available, calculated by summing the number of groups each of the 1256 eligible residents would be able to attend (i.e. excluding sessions for which they were ineligible or when they were not at that point a resident in the home). On average residents attended about half of the available sessions (31,705). An average group size of 10 (5.3 study participants and 4.6 non-study participants) was calculated by dividing the total number of person attendances (31,705) by the total number of groups

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TABLE 62 Dose of intervention delivered

Area	*n* homes	Sets delivered[a]	Median *n* of sessions delivered	Percentiles			Dose delivered: median, % (range)[b]
				25	50	75	
C&W	17	19	83	80	83	91	90% (76–118)
NEL	17	19	82	72	82	88	89% (73–116)
Totals	34	38	82	76	83	89	90% (73–118)

a Owing to the size and layout of the homes in both areas two care homes provided two sets of groups per week (delivered four rather than two groups per week).

b Based on assumption that 100% dose would be 92 sessions (i.e. 52 weeks in a year, minus 4 weeks to set up, minus 2 weeks, Xmas, etc. = 46 weeks, two sessions per week = 92).

delivered (3191) (*Table 63*). *Figure 15* groups study participants into the number of groups they attended. The reasons for not attending the available sessions are discussed in more detail below.

The most cited reason for non-attendance was the unwillingness of participants. Unwillingness to attend appears to be consistently higher in the NEL homes at 31% compared with 21% in C&W. We observed 21 exercise groups in case study care homes; seven in the early stages of their introduction (five homes once and one home twice), six at about the midpoint (once in each of six homes) and eight at the end of the 12-months (four homes once and two homes twice).

During the interviews little was said about why residents attended or did not attend. However, a care home manager and an activities co-ordinator noted that the time of day could have an impact on attendance.

> *The only thing we actually found was that someone could not come in the morning, but wanted to come in the afternoon and they were not having none of it (the residents) … They know their own mind … And no, they're all tired and they've had lunch and no, and it's really funny but that day none of them wanted to do it.*
>
> *31 manager*

> *… what I've found is the best time for me to do it, like you've seen I come in the mornings and I do it straight off in the morning, because the best time is to get them in the morning because they do it before their lunch, they're sitting there, they're tired, they do not … if you allow them to, they'll sit and they'll smoke away in the chairs and be relaxed and just listen to the television or watch the television. Get them up and moving, and then it's easier to get them more involved in other activities later on in the day, where if I do other activities and then just put the exercise at the end of the day, they're normally you've got less of a chance to get them to participate in the afternoon, as you would in the morning.*
>
> *50 activity co-ordinator*

Home observation suggested that some residents preferred groups in the morning and some in the afternoon.

A priori we set the threshold for the minimum effective dose as attending 51 sessions, an average of one per week; 36% of our participants achieved this. Nine per cent of our study participants attended no groups, 20% attended 10 groups or fewer (*Table 64*).

Overall, there was little attrition in the attendance at groups over the year (*Figures 16–18* and *Table 65*).

TABLE 63 Number of exercise groups, total attendances and reasons for non-attendance

Item	*n* or %	Study participant	Non-study participant	Total
Residents (all)	*n*	494	945	1439
Residents eligible to attend groups[a]	*n*	478	778	1256
No. of groups delivered[b]	*n*			3191
No. of eligible groups available[c]	*n*	31,330	33,866	65,196
Total attendances[d]	*n*	16,986	14,719	31,705
Percentage of maximum possible	%	54	43	49
Average attendance[e]	*n*	5.32	4.61	9.94
Reasons for non-attendance				
Out	*n*	382	1067	1449
	%	1	3	2
In hospital	*n*	719	937	1656
	%	2	3	3
Unwell	*n*	1670	1497	3167
	%	5	4	5
Visitors	*n*	369	396	765
	%	1	1	1
Unwilling	*n*	8339	11,930	20,269
	%	27	35	31
Other	*n*	2865	3320	6185
	%	9	10	9

a Eligible residents are those assessed as able to participate in the group exercise session (by the physiotherapist).

b The total number of groups delivered in the 34 intervention homes.

c Based on the number of groups eligible residents could have attended: calculated by summing the number of groups that each of the 1256 eligible residents would be able to attend (i.e. excluding sessions for which they were ineligible or when they were not at that point a resident in the home).

d Total number of person attendances at the available groups.

e Average attendance: 'd' divided by 'b'.

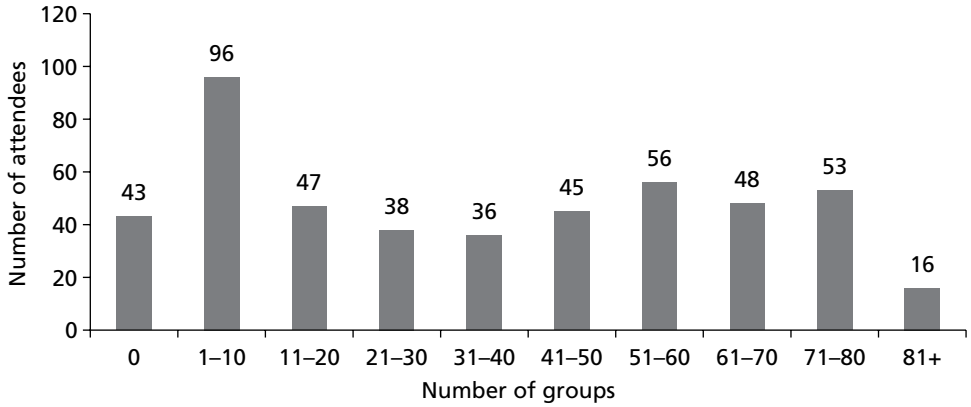

FIGURE 15 Study participants: number of groups attended.

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TABLE 64 Residents' attendance at exercise groups

Area	*n* or %	Total residents	Total eligible residents[a]	No. of groups									
				0	1–10	11–20	21–30	31–40	41–50	51–60	61–70	71–80	81+
Total study participants	*n*	494	478	43	96	47	38	36	45	56	48	53	16
	%		97	9	20	10	8	8	9	12	10	11	3
Total overall[b]	*n*	1439	1256	187	384	132	103	83	85	96	80	81	25
	%		87	15	31	11	8	7	7	8	6	6	2

a Eligible residents are those assessed as able to participate in the group exercise session (by the physiotherapist) and includes those recruited post randomisation.

b All residents in the intervention homes (including all study and non-study participants).

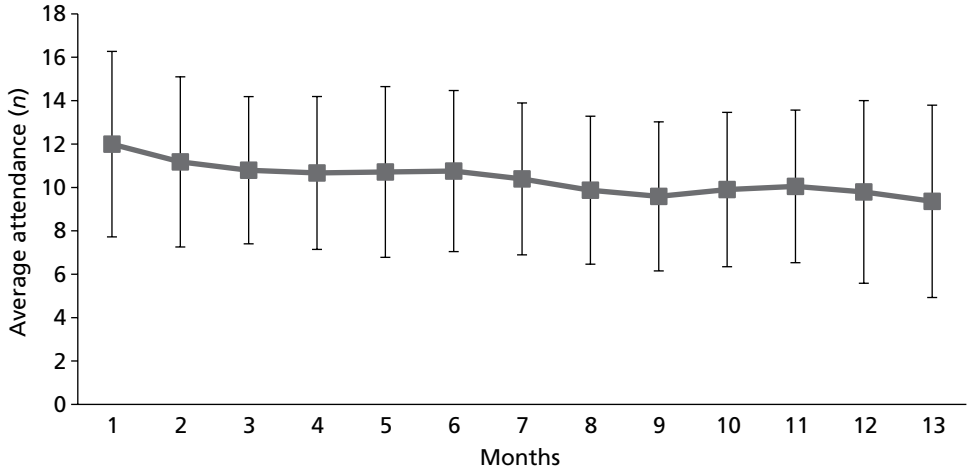

FIGURE 16 Average monthly attendance to exercise groups: all homes (± SD).

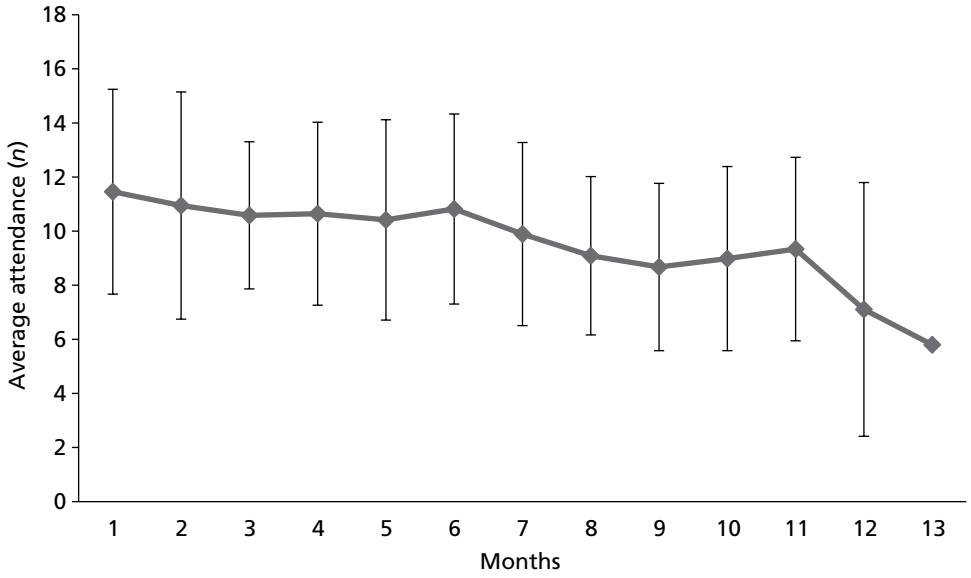

FIGURE 17 Average monthly attendance to exercise groups: NEL homes (± SD).

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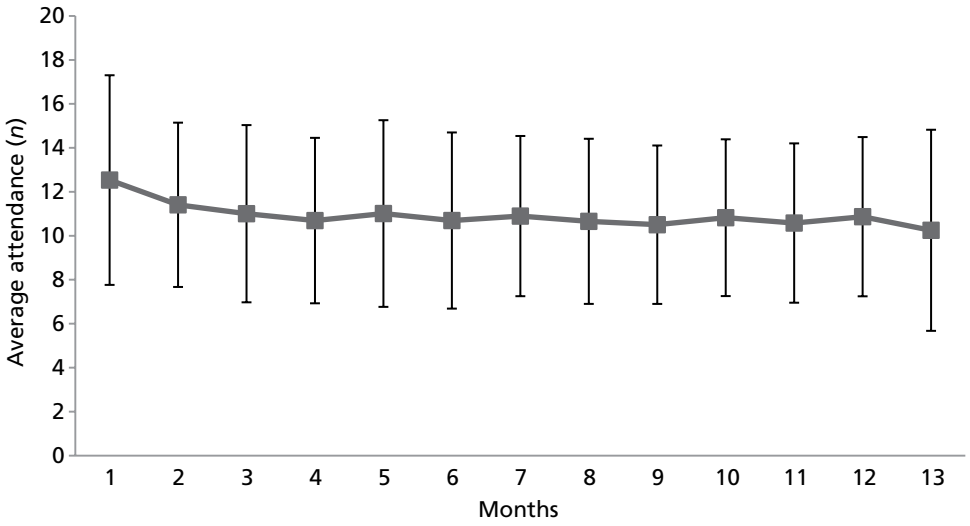

FIGURE 18 Average monthly attendance to exercise groups: C&W homes (± SD).

TABLE 65 Summary table of average monthly attendance at exercise groups

	NEL			C&W			Overall		
Month	*n* (homes)	Mean	SD	*n* (homes)	Mean	SD	*n* (homes)	Mean	SD
1	17	11	4	17	13	5	34	12	4
2	17	11	4	17	11	4	34	11	4
3	17	11	3	17	11	4	34	11	3
4	17	11	3	17	11	4	34	11	4
5	17	10	4	17	11	4	34	11	4
6	17	11	4	17	11	4	34	11	4
7	17	10	3	17	11	4	34	11	4
8	17	9	3	17	11	4	34	10	3
9	17	9	3	17	11	4	34	10	3
10	17	9	3	17	11	4	34	10	4
11	12	9	3	16	11	4	28	10	4
12	6	7	5	15	11	4	21	10	4
13	1	6	NA	4	10	5	5	9	4

NA, not applicable.

Dose received by those providing primary outcome

In a post hoc analysis we examined the attendance at the exercise groups by just those participants who provided the primary outcome for our two cohort analyses (*Table 66*). This shows that over half of our participants contributing to these analyses had attended over half of the group exercise sessions, with around three-quarters attending at least one-quarter of the sessions over a 12-month period. This indicates that an adequate dose was received by a larger proportion of those contributing to our primary analyses.

Perceptions of exercise groups

Interviews at the end of the study illustrate the impact that the groups had on the residents and care home staff. Most were positive about the planning and execution of the groups, noting that the regular and consistent time slots were appreciated and that the physiotherapist liaised well with the care home managers. Care home staff also appreciated having a professional in charge of the exercise class.

> *I mean it's very good because it's always Monday and Wednesday . . .*
>
> *29 manager*

> *. . . and [Name] was very good. You know they would come in and tell us what they were doing and how they were going to do it and what was going to happen so the communication even from them to us was very very good.*
>
> *51 manager*

> *You know, at first even when I used to do my little five minutes and workouts or we'd do a daily dance, it could be quite worrying; 'Oh my legs hurt so I'm not going to do anything', whereas because they've got a professional guiding them, using the weights and even telling her what weights to use . . . You know, there's a sudden interest in their own well-being.*
>
> *27 activities co-ordinator*

The physiotherapists reported that residents, care home staff and visiting relatives enjoyed the exercise groups. Physiotherapists felt that they gained increased confidence in running a group, job satisfaction, and liked being involved in research. The practicalities of running a group raised issues relating to variation in the amount of care home staff input. Examples were given where there was no-one to help get people to the group or help with running it. This was therefore more time-consuming especially if there was little flexibility in time allocated to OPERA. For the physiotherapists, having an activity co-ordinator or member of staff designated to assist was a great help, and they felt that continuity in the staffing was important, and that the bond and understanding of the residents' idiosyncrasies made it easier to gauge the group. However, some of the care home staff felt that the group was a time during which they could 'do other things' (sometimes a highly appreciated aspect of the intervention).

TABLE 66 Cohort sample exercise group attendance and dose received

		Attendance at exercise groups		> 50% dose received[a]	
Cohort	n	Median (range)	Interquartile range	n	%
Depressed cohort[b] (6 months)	123	37 (0 to 82)	7 to 62	66	54
Cohort (12 months)[a,c]	224	55 (0 to 91)	23 to 72	124	51

a Based on an average attendance at one group or more (over 6 months ≥25 groups for 12 months ≥51 groups)
b Depressed cohort with valid GDS score at 6 months.
c Main cohort with valid GDS at baseline and 12 months.

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Interviews with physiotherapists, care home managers, care home staff and residents revealed that the delivery of the group worked well and was easy to follow. Equipment was considered appropriate and the music an important part. Some explanations for the positive impact of music were that it helped to establish a routine, increased enjoyment, promoted activity, encouraged singing, which helped lung function, and promoted discussion about the music and artist.

The positive impact of the exercise groups was mentioned by many interviewees, talking about changes in residents' mood and physical ability and about the changes they have seen in residents' attitude towards exercise:

> *They have become happier in their mood and I think it has achieved what it set out to do. Certainly towards the end of the programme once everyone got into the swing of it, it really picked up.*
>
> *48 manager*

> *I'd often walk by and see them and they were always smiling. There was always . . . a good rapport in there. There was always laughter in there. The music would be going and you would see them all doing this [gesture] and I never saw anybody sitting there sort of looking glum.*
>
> *32 senior carer*

> *You know it has been wonderful, it has been good for our residents, it has been excellent in their development; you know they are happier.*
>
> *51 manager*

> *I just feel a lot better. I mean I can . . . (shows me he can stand) I can (So is that better than it was?) Oh yes (note: was very reliant on wheelchair at start of study).*
>
> *39 resident*

During observation of the exercise groups the challenges faced by the team and the general enjoyment of the residents were noted. As a relationship developed between the physiotherapists and the residents the groups appeared easier but there were still some residents who were reluctant to be involved and others with challenging behaviour. During the groups there was laughter and smiles, and at times the groups became competitive. The music was well liked and residents often sang along, and indeed knew which exercise they should be doing with a particular tune. It was clear in the homes that there were a number of residents who looked forward to the groups.

The physiotherapists running the groups noted that the exercise involving a velvet rope promoted inclusion and involvement, and gave a tactile experience. They also noted that the use of equipment (e.g. balls and weights) promoted activity, especially in the cognitively impaired, but could be problematic. Some of the physiotherapists found the weights hard work and some residents were initially resistant and said that the weights, for example, 'looked like manacles'. In some cases, weights and the weighted balls created some competition between residents, with banter about how much they had done that day in the session.

There were some issues around safety, for example, when throwing and kicking balls, or the potential to wrap the rope around one's neck. Space, temperature, arguments over seats or routines, and group disruptions were also challenges that had to be faced.

The whole-home intervention and role of the physiotherapist

The aim of the intervention was to achieve a change in the whole culture of the home, so that the importance of helping residents to be active was embedded permanently. Home champions were intended to be part of this intervention and it was planned that these would be identified early on. However, this did not happen in all homes. Some of the activity co-ordinators in homes became involved but not all felt it was in their remit. Again, some carers were identified as 'champions' but problems with shifts, time

or enthusiasm limited their effectiveness. It seems that the role of home champion was unrealistically demanding for most staff in most homes.

The physiotherapists felt that it was sometimes difficult to explain their remit to care home staff and that some staff were very wary of them. Nevertheless, the physiotherapists reported that clinical assessments of the residents gave opportunities to meet residents and staff, to build a rapport and increase the understanding of the importance of physical activity and lay good foundations within the home. Several care home staff commented on how staff were encouraging residents to walk more.

> *She said 'Wheelchair' and I said 'No, you can walk.' She said 'Oh I don't know whether I could' and I said 'But you can because you used to walk all the way up there.' She said 'Oh yes, I did' and she walked down there fine. She was slow but she walked there fine because everybody keeps sticking her in the wheelchair to take her to bed, but she can actually walk and I think if she can walk then for G**'s sake, let her walk.*
>
> *1 Carer*

> *But generally, sort of one of the ladies downstairs, she was having the wheelchair quite a lot and then they said 'Well, maybe if we encourage her to walk little bits at a time and then a bit more and a bit more' and it's worked really well and she's walking everywhere now.*
>
> *2 Senior carer*

Physiotherapists reported seeing their suggestions being acted upon, as for example, where residents were seen to be walking instead of using a wheelchair. The physiotherapists also felt that they had reinforced good principles of manual handling and promoting activity, and had broken down barriers to mobility. Physiotherapists encouraged exercise progression by setting individual goals and helping care home staff to recognise and reinforce these.

Care home managers were generally happy to have a physiotherapist working in the home, and communication and understanding increased as the intervention progressed, although not all staff were receptive to the physiotherapists' advice.

> *The staff definitely do not feel that (the physiotherapist is an imposition) and as time has gone on with [Name], they've really got to know [Name] and she sits and has her lunch with them – not for long, but she does and they look forward to her coming in, to be honest*
>
> *19 manager*

> *Yes, because I think that gave us a sort of opening as well to actually think, 'Well, I'll do . . . this person can actually do more than what they're actually saying that they can actually do', so they brought a sort of . . . they brought a lot of that out*
>
> *31 manager*

> *The hardest part I think for me was trying to get the staff on board to realise what this was about, who it was for and how people would benefit.*
>
> *32 senior carer*

One manager noted the challenge she faced in trying to increase mobility.

> *It is a collective protective culture and that's why they come into care. They think people should be protected, but I think in this situation because we deal with people who have very high dependency needs that it sometimes is that we de-skill them, rather than enhance them because it's a protective mechanism.*
>
> *44 manager*

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And another talked about the challenge in bringing about changes to thinking:

> *Yes, that's what I say to the staff because I mean when people talk about activities I think it's still there – the old belief that it is about doing the art work, doing bingo and you need to get away from that because that's not what it's about.*
>
> *20 manager*

Two interviewees reported that OPERA has had a positive impact on external views of the home. One home found the study mentioned approvingly in a Care Quality Commission report and in another home a social workers' report highlighted the positive effect of OPERA.

> *Yes, she'd actually heard of it (Care Quality Commission inspector). She must have gone to another home before she came in here and we actually saw the file and she said it was a very good study and she actually had feedback from another home.*
>
> *32 senior carer*

> *Social Services, they have to have regular reviews and one of the residents who's involved in this study, she had her review and they . . . The reviewing officer always sends me a copy of the review . . . and I read it yesterday and I was so proud of, you know . . . Her and her family could not thank the home enough but also, OPERA was mentioned in that review . . . and about how she's enjoying it and that's recorded.*
>
> *19 manager*

By 6 months and at the end of the study interviewees were positive about the intervention. Most commented on how the relationship developed between the care home (the manager, residents, staff and sometimes relatives) and the physiotherapist and in all cases the physiotherapist became seen as 'members of staff', 'members of the team' or 'one of us'.

> *Brilliant and that's never petered off. In fact, it's just got more positive. They're brilliant with her. They trust her with everything and that in itself is a feat.*
>
> *40 manager*

> *I think the staff . . . well, certainly we will miss her and they really will. The residents . . . my G** they'll miss her.*
>
> *43 manager*

One senior carer felt that the number of falls had reduced and attributed some of this to OPERA physiotherapist input.

> *There was one resident here with a walking stick, 'Where's his stick?' and he kept falling. We had a terrible history of falling with him. With a lot of perseverance, [Name] got the frame and now he actually walks with a frame very well. He's reduced his risk of falls. We've had hardly any falls with this man and he doesn't mention his stick any more . . . Yes, so we have seen some good results . . . (falls). They have been reduced, I'd say definitely . . . And I think if you've got the right aids – and a lot of them didn't have, it has minimised the falls. They now use the proper things they should be using.*
>
> *32 senior carer*

The professional conduct of the physiotherapist was seen as very important, as was having the same physiotherapist over time.

Well that's very important, yes because the residents get used to that person coming in and they build up . . . They kind of bond with them don't they?

28 activities co-ordinator

. . . yes and I think it definitely makes a difference what physio you use because I think it depends on the person they send down as well. I mean [Name] is very . . . She's sort of a bubbly character. She's not afraid to motivate them to join in.

29 manager

It doesn't matter what sector you come from, whether it's general practitioner, physio or district nurse, (continuity) is really important because each time a new person comes in you're starting from the beginning again.

40 manager

However, despite the intervention lasting for a 12-month period physiotherapists felt there was little time to facilitate a change in staff behaviour around encouraging residents' mobility. The barriers to facilitating change included staff turnover, staff attitudes towards manual handling, staff morale and time constraints.

The key facilitators were the physiotherapists and several care home managers saw this as an important benefit for the residents. Physiotherapists were seen as supplying both practical advice on mobility aids and more general advice on navigating the services available.

That time when we'd got a problem with . . . oh that lady who passed away eventually. We were really struggling with the doctors and the mental health team. It was evident that she needed something and [Name] just came and said, 'You can refer her online to the mental health team' and we didn't even know that did we, and because she's a professional, we got somebody here the same day.

43 manager

Yes, that was another asset I think that [Name] and the team brought in, which was yes, we have people walking with the walking aids and the frames and the walking sticks, but the good thing is that for me to get everybody checked here . . . It would be crazy of us. [Name] came in and [Name] and they assessed each person . . .

20 manager

[Name] was excellent there. We were using the wrong aids and we still had walking sticks on the premises we shouldn't have had. [Name] was brilliant that way and that saved us a lot of time I think, referring them from the general practitioner to a physio, for them to come in and then now, the (National Health Service) physios don't actually come on the premises.

32 senior carer

The importance that care home managers placed on having access to a physiotherapist was no doubt influenced by the difficulties they reported in accessing routinely available physiotherapy services and mobility aids.

There are the initial referrals – especially via the general practitioner. Sometimes you get some of the district nurses that um and aah and all the rest of it and then eventually do and I said to [S] last week, I'm finding it quite hard to understand why she's put in her referrals and the equipment had come within a couple of days. If you go via the other channels we've waited an age.

16 manager

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Activity in case study care homes

A total of 109 activity sweeps were carried out: 53 at baseline and 56 at follow-up, with 12 to 14 observations in each home at each time point. Across the case study care homes a substantial amount of residents' time was spent in activities associated with eating and drinking with active social interaction only amounting to between 5% and 15% of daily activity. The proportion of time spent in recreational activity, passive social interaction and being socially inactive appeared to vary across the homes. With only one exception (home 4), no exercise groups or 'exercise' activities were observed (*Figure 19*).

In contrast with the different patterns of activity and inactivity seen between the homes, within homes the patterns of activity were remarkably consistent between baseline and follow-up. None of these data was analysed until all data were collected, so it is unlikely that the researcher was influenced at follow-up by the findings at baseline (see *Figure 19*).

The observation sweeps do not show any major changes in activity within the homes; two homes had some increase in recreational activity and one a decrease, and in one social interaction increased. These may be chance differences because of the large number of comparisons made. General observation in the homes supported the conclusion that there was little change in overall activity levels within the homes.

Ending the intervention

When the intervention was coming to an end, staff in the homes expressed some concern about what would happen when the study was finished. Without exception all interviewees expressed a feeling of sadness, and in some cases concern, about the withdrawal of the exercise groups and the physiotherapist.

> *Oh yes they will miss it as well. They used to come to the exercise class as well so. Yes they will miss it. And I think it is a shame that it has come to an end but everything has to come to an end, and hopefully when all the powers that be have done their research and they have got all of their figures and everything together maybe . . .*
>
> *48 manager*

> *No, I'm just hoping that something can be done for them when this course is over and done with. I just don't like to see them be let down. I've seen it too often and it can actually damage them – and I have seen it, so . . . and if you can do anything for the staff that would be fantastic. We need to be de-stressed.*
>
> *17 carer*

> *Yes, they love it. They really love it and it's actually a shame if it actually stops, because it's something that they've got there that they have every week. You know, it is a shame . . .*
>
> *31 manager*

Many of the care homes brought gifts for the physiotherapists and had celebrations at the end of OPERA and there were tears and sadness on both sides. Several of the physiotherapists have stayed in contact with some of the homes and residents. Some physiotherapists felt unprepared, as the closing process was not in original paperwork. Some homes have kept exercises classes going in a modified form, some have purchased some physiotherapist input, and other homes have no funds to continue.

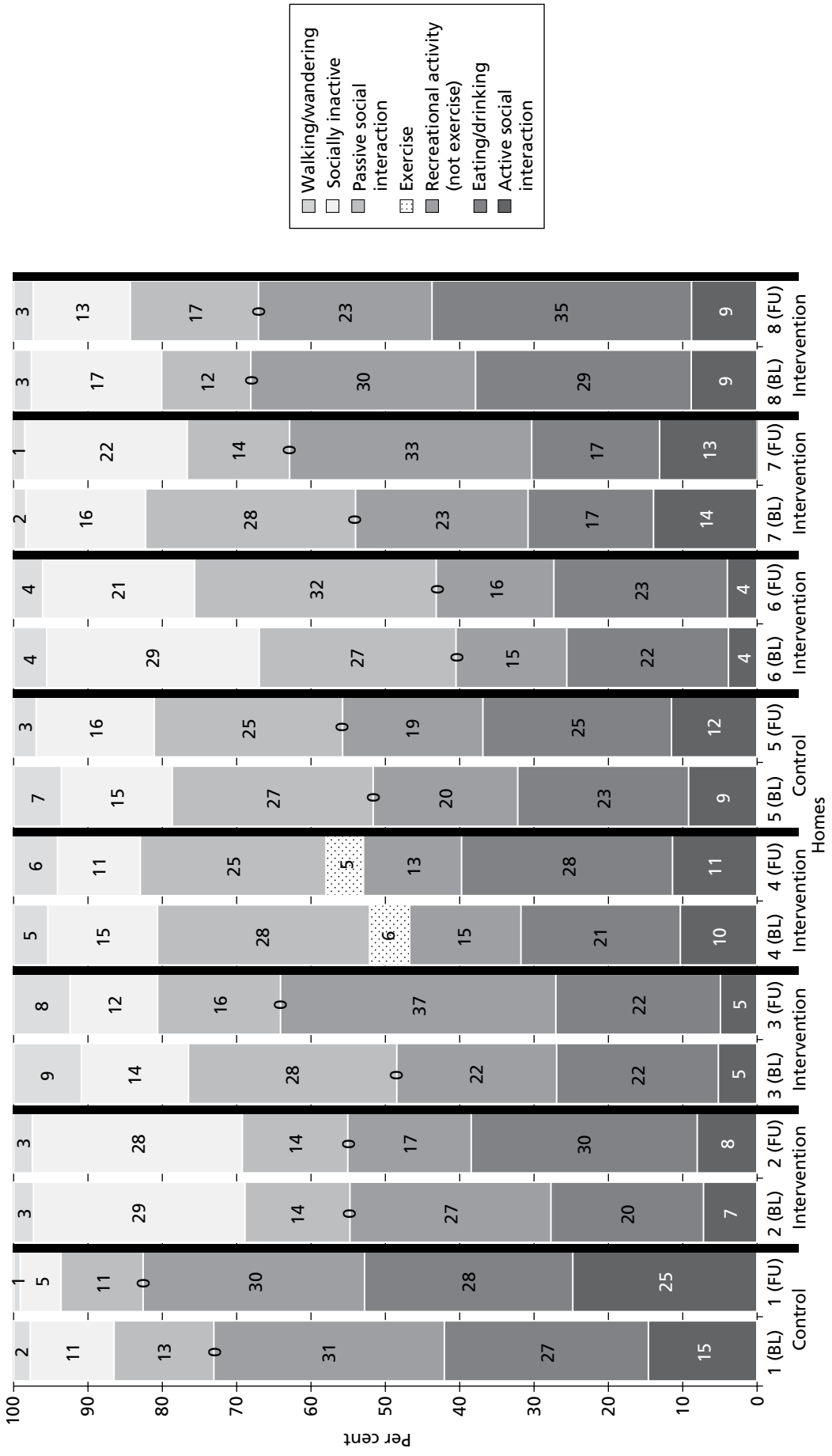

FIGURE 19 Summary of day-time activity in homes, baseline vs follow-up. BL, baseline; FU, follow-up.

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Ethics

The ethics substudy focused on issues relating to recruitment and consent to research of older, vulnerable adults. Data were drawn from the OPERA process evaluation study and a separate qualitative study of key informants' interviews and three focus groups of older people. Key informants included four senior researchers working in elderly care research, three research commissioners/funders of elderly care research including age-related charities, a director of services for an age-related charity, a director of public health, an acute National Health Service Trust chief executive, and a professor of medical ethics. The focus groups were based on groups attending a range of day care or activity-related services for older people. The number of participants ranged from seven to nine in each group and the majority were female (only three males).

Analysis of the observation and interview data from the process evaluation study relating to recruitment and consent identified three broad themes that framed the experience for those involved (participants, care home managers and research staff).

Experience within the OPERA study

The care home manager as gatekeeper and facilitator

Care home managers who were interviewed expressed no concerns about their role as consent giver for the home to take part in the study. They perceived themselves as decision-makers for the home, with a responsibility for improving resident well-being and staff training, and therefore a decision to participate in OPERA was not qualitatively different from other decisions about home activities and processes.

> *The possibility from a selfish point of view for the home; that we could potentially get something out of it and I made it clear right from the very beginning what my interest would be, more for the service users . . . and it was for them more so than the staffing and the home. If we'd have got the staff trained then fine, but I made it perfectly clear what really would have been the massive carrot for me and luckily, we got it.*
>
> *16 manager*

One or two managers commented on the importance of doing research on these issues but this was not the main consideration in deciding to participate.

Managers, and recruiting staff, also identified a gatekeeper role in allowing access to individual residents for participation in the assessment processes, a role recognised and utilised by the recruiting staff. Access to residents for recruitment was negotiated with managers who identified residents whom they considered too ill or frail to be approached, as well as residents who were unable to communicate, thus protecting residents from unnecessary intrusion or distress. Managers also identified residents who, in the manager's opinion, would not want to take part or who might not understand sufficiently to give consent. In line with the legal and ethical requirement that adults with capacity should make their own decisions, and that capacity is decision specific, the study protocol stipulated that trained recruiting staff should assess all residents for capacity to consent following exclusion of those too ill or frail to participate. Thus there was a potential tension between recruiting staff's aims and managers' perceived gate-keeping role. In practice, recruiting staff learned through dialogue with managers to develop a shared understanding of a threshold level at which managers would predict a resident's lack of capacity to make a decision regarding participation, triggering an approach to a personal consultee, which facilitated the effective running of the recruitment process while minimising the risk of a resident being excluded from a decision that they had capacity to make.

The negotiated process between recruiters and care home managers demonstrates a further facet of the manager's role, that of facilitator of the research. In identifying residents who clearly could not consent they assisted in the efficient roll-out of the study, as well as protecting residents from unnecessary

intrusion. Some managers also adopted a facilitation role in individual resident recruitment by being present during the interview, and so acting as a reassuring presence and guarantor of the legitimacy of the study for residents who might feel concerned at a stranger coming to talk to them.

> *. . . and I think we find that the residents are quite wary of new people and I think it's one of the things that sometimes means they say no . . . I sat in on it, you know. . . to let them know we know what's going on. We're not trying to trick them and there's nothing strange about it.*
>
> *16 manager*

The challenge of assessing capacity and validity of consent

Assessing capacity to consent was seen as the most difficult and challenging part of the recruitment process by recruitment staff. Two particular difficulties that were identified related to the understanding and retention requirements for capacity set out in The Mental Capacity Act 2005.[105] Recruiting staff felt that the information sheet and consent form were too lengthy and difficult for participants to understand. However, despite recruiting staff's concerns in this regard, observation of the consent process confirmed that with careful explanation of each section of the information sheet and consent form by the recruiting staff the participants were able to understand what was required of them and provided valid consent. This highlights the particular importance of the recruiting staff's role in promoting participants' capacity.

The question of how long someone must retain relevant information in order to have capacity to make a decision based on that information is particularly pertinent for consent to research where the usual requirement is for at least 24 hours between provision of information and taking of consent. In OPERA none of the residents whose consent process was observed, and who had been assessed as having capacity to consent to participate the previous day, remembered what the study was about. This problem with retention was confirmed in the interviews with residents, most of whom could not recall that they had given consent although they remembered meeting the recruiting staff member. The Mental Capacity Act 2005 does not specify a required time for fulfilment of this element of the capacity assessment although section 3(3) states that '*the fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision*'.

Goodman has used the concept of capacity to consent 'in the moment' with retention only necessary for the period of the conversation with the researcher.[100] In effect this was the standard used by recruiting staff in OPERA as failure to remember information given to them 24 hours previously was not seen as a bar to consenting if the resident was able to understand the information and retain it during the discussion prior to signing the consent form.

Some recruiting staff suggested that the efficiency of recruitment would be increased if the initial step of assessing capacity by talking through the study with potential participants could be dropped, and capacity assessment combined with consent using an 'in the moment' test for retention of information. However, two reasons for retaining this step emerged. First, although the residents did not recall the specific information about the study they had been given previously, some did have vague recollections of discussing it beforehand with the researcher, and repeating the information during the consent process may have acted as a reminder helping to consolidate understanding and reduce concern. Recruiting staff in OPERA also identified the 24-hour period between providing information and consent as an opportunity for staff, or the resident's family, to discuss the study with them. In addition to the importance of beginning the process of consolidating information, the initial visit by the recruiting team member marked the development of a relationship between the recruiter and the resident, the first step in a process of information giving, consent checking and engagement that was to continue throughout the study. Observations of the consent process noted that despite having no recollection of the patient information sheet or the details of the study, residents remembered the researcher and were pleased to see them, appearing relaxed in their presence and happy to discuss the study. Given that care home managers had expressed concern that some residents might be unwilling to speak to a stranger, the building of a positive

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relationship between recruiter and resident could be seen as an important factor in facilitating recruitment in this kind of study.

The creation of a relationship between recruiter and resident, however transitory, does, however, raise potential concerns regarding the voluntariness of the resident's consent to participate in the study. Making these fine judgements about capacity, and validity of consent, in the context of the knowledge that there was a need to recruit posed ongoing challenges for all recruiting staff.

> *We also had the added pressure of needing to recruit numbers, we all felt obliged to make the recruitment work so all tended to give resident's the 'benefit of the doubt' when capacity seemed difficult to assess.*
>
> *Focus Group, recruiting staff*

The importance of relationships

The relationship between recruiter and participant is one of a number of relationships impacting on the process of recruitment and consent identified in the qualitative data from the process evaluation study. The relationship between care home staff and resident has already been noted in the role of the care home manager as gatekeeper and facilitator. Recruiting staff also identified the importance of their relationship with the care home manager for gaining access to residents and, where necessary, their NOK, and also facilitating the consent process. The other key set of relationships involved the families of the residents. The importance of recognising the nature of the relationship between a resident and his or her family was identified by both recruiting staff and care home managers. Some families were heavily involved in their relative's care and expected to be involved in any decision-making process, even if their relative was competent to make their own decisions about care or, in this case, research participation. Recruiting staff noted that this was an unanticipated step in the recruitment process. The notification of families of residents who had capacity to consent seems at odds with the concept of respecting individual autonomy and is contrary to practice in other research contexts. However, involvement of the family in this way was endorsed by at least some residents in the study who, although being assessed as having capacity to consent for themselves, expressed a wish that a relative sign the consent form on their behalf. Care home managers also placed importance on their own relationship with residents' families, emphasising the need to maintain families' trust that the care home would act in their relative's best interests and respect their privacy.

> *. . . you know, I was happier personally signing them myself because then I could honestly say to any relative who said anything that no details had been given, 'No one has been given your address and I've done it' . . .*
>
> *25 manager*

Data external to OPERA

The ethical challenges of recruitment and consent to participation in research studies involving adults who may lack capacity were further explored through analysis of data from the focus groups and key informant interviews. There was a consensus that conducting research with elderly participants was important and focus group participants were prepared to consider participation in a wide range of research studies. Key informants considered that excluding people because of frailty, comorbidities or cognitive impairment was discriminatory. They identified a number of practical and ethical difficulties in organising and conducting research in this population, including protectiveness of research ethics committees or research governance processes stopping research proceeding, the need to minimise the burden on frail and/or ill people in the research design, the demands placed on care home staff in facilitating research, and the difficulty of assessing capacity and obtaining valid consent. Two key themes emerged from the analysis, identified by both focus group participants and key informants from their different perspectives. These were (a) difficulties with the standard consent process, and (b) the importance of trust.

Difficulties with the standard consent process

Focus group participants considered study information sheets too long winded and complicated and were particularly likely to ignore information sheets sent in the post. One participant had withdrawn from a previous research study because of 'too much paperwork'. Generally the participants considered the study paperwork as protection for the researchers rather than protection for them as participants. Verbal communication was valued over written and this was linked to the importance given to a trusted person providing the information and obtaining consent. Several participants expressed a reluctance to sign a consent form for a research study (two participants refused to sign a consent form for the focus group but were happy to give verbal consent). The idea of a son or daughter signing on their behalf, or advising on whether or not to sign, was raised by some participants. One commented that she never signed anything without her daughter. A reluctance of older people to sign consent forms was also noted by researcher key informants.

> *So my feeling would be if there was some way of making the consent process less scary. I mean especially people in care homes they sometimes feel they're signing away their house or something.*
>
> *31 key informant*

One researcher described a study where verbal consent was used specifically to overcome this reluctance to sign a formal document for a stranger.

> *I think when you're working with the older population that you may need to have that sort of flexibility.*
>
> *32 key informant*

The importance of trust

Both focus group participants and key informants identified trust as an essential feature of the process of gaining consent and of making a decision for someone who cannot give consent. Although focus group participants wanted clear and simple information sheets, the determinative factor in whether or not they would agree to take part in a study was whether or not they trusted the person who provided the information. So approaches from someone who knew them, such as their general practitioner or hospital consultant, were likely to be considered, whereas cold call approaches from research groups were likely to be ignored or 'binned'. Similarly, the person providing the information and taking consent was crucial. Given participants' concerns about their own ability to understand the written information, a verbal explanation by someone they trusted as having their interests at heart was seen as providing reassurance and confidence in the study. The importance of trust was also identified by key informants.

> *. . . so when we're trying to reach out to people in their homes where there isn't the level of contact with services – the older person might not have a trusting relationship with a health worker – we're going through the voluntary sector because they have – and we're going through peer systems to help them trust what we are doing.*
>
> *39 key informant*

A trustworthy individual was also required for making decisions for a person who was unable to consent. Most focus group participants and key informants considered that if they lacked capacity to consent then close family members would be most appropriate either as proxy decision-makers or as providing advice on what the person would have wished, although it was noted that some families are estranged or may have different views from the person who lacks capacity. Important criteria for family members, and other proxies/advisors, were knowledge of the person's views about research, ability to assess the value of the research, and an understanding of the risks of the research for the participant. Although participants in general were prepared to trust the relevant individual to make decisions about their participation in a range of research, when asked to imagine taking on this role for a family member who lacked capacity participants expressed some concern about the burden of this responsibility and were more reluctant to

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agree to drug trials compared with other less risky interventions. Research advance directives were seen as potentially helpful in this regard.

> *Yeah, I'm sure I would give an indication to my family, I mean especially with how we're thinking now with The Mental Capacity Act, so I would probably indicate that I would be wanting to be involved in research … But again I'd probably want somebody with an understanding of research to at least look at the protocols and to have an idea of the sort of quality of the research.*
>
> *32 key informant*

The difficulties with the formal consent process and the importance of trust in the researcher were strong themes in the observational and interview data in the OPERA process evaluation. The importance of relationships, particularly family relationships, for older people participating in research was also experienced in OPERA. Our data suggest that older people participating in research may think and act in ways that are not necessarily congruent with the accepted model of individual autonomy underpinning the standard informed consent framework of provision of full information and explicit written consent uninfluenced by others.

OPERA end-of study feedback

We obtained responses from 56 of our 78 homes (72%). Without exception, across all of the responses, answers to the statements that had the four anchor points ('totally agree', 'agree', 'disagree' or 'totally disagree') were either 'agree' or 'totally agree'.

Eighty-nine per cent of respondents found the information about a resident's baseline Geriatric Depression Scale-15 score useful (*Table 67*). Control homes seem to have appreciated this information more than intervention homes. When asked how they had used this information the most popular responses were to encourage the residents (80%) and to monitor the residents (75%). Over half had contacted a general practitioner and about one-third had contacted the mental health team; other health professionals who were contacted in relation to this included community occupational therapy and district nurses. Some respondents reported that they had discussed the information with families and encouraged their involvement.

Responses to questions related to training provided to the care staff in depression awareness and questions about any potential burden placed on the home by the OPERA research team when carrying out follow-up visits were again universally 100% positive (*Table 68*). Twenty-three respondents reported they had needed to contact the OPERA office for one reason or another. Twenty-two of these reported a very positive experience and outcome; the one negative comment relates to changes in study staff and issues not being passed on.

We also obtained 100% positive feedback on the interactions with physiotherapists (*Table 69*) with respondents reporting that the physiotherapists worked well with the care homes and provided useful advice and information. Exercise groups too fitted well into the homes, were run as expected, the residents liked them and the home enjoyed having them twice a week.

Thirty-nine of the follow-up respondents included comments about OPERA. A small selection of these are presented below:

- *We are grateful for having had the opportunity to participate in this study. The training that you supplied was helpful and the time that your trained nurse spent with the chosen residents was appreciated. I think that this study will be of value in the future.*
- *Thank you all very much for allowing my home to participate in this study. We will now continue to maintain exercise groups with our residents because of the positive impact it has had.*
- *Smiley faces and sad faces were extremely helpful. Doctor professional of medical issues were brought in and medication change, some up, some came off medication all together, now they all have smiley faces.*
- *The staff and residents appreciated the visits by professionals.*
- *OPERA took into account the need and well-being of our residents. A friendship was built up between residents, members of staff and management with all who came to our home involved with OPERA. Our residents will be carrying on with the exercise plan.*

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TABLE 67 Results from OPERA end-of-study feedback questionnaire: recruitment processes and raising awareness of depression

Item		Intervention		Control		Total	
Returns (from 78 homes mailed)		**22 (63%)**		**34 (79%)**		**56 (72%)**	
Paraphrased questions from end-of-study questionnaire[a]							
Recruitment processes							
		n	**%**	***n***	**%**	***n***	**%**
Study was fully explained	Agree	3	14	7	21	10	18
	Totally agree	19	86	27	79	46	82
Mutually agreeable times (for assessments, etc.)	Agree	3	14	8	23	11	20
	Totally agree	19	86	26	77	45	80
Easily able to provide information required	Agree	3	14	5	15	8	14
	Totally agree	19	86	29	85	48	86
Identifying eligible residents (not burdensome)	Agree	4	18	10	30	14	25
	Totally agree	18	82	24	70	42	75
Raising awareness of depression							
Depression score useful? (smiley faces)	Yes	22	100	50	84	72	89
How the depression information/score was used							
Monitor resident		18	82	24	71	42	75
Encourage resident		19	86	26	79	45	80
Contact GP		14	64	17	50	31	55
Contacted mental health team		6	27	12	35	18	32
Contacted other health professional		4	18	6	18	10	18
Other		5	23	4	12	9	16

GP, general practitioner.

a Actual questions can be found in the 'end-of-study' questionnaires included in *Appendix 8*.

TABLE 68 Results from OPERA end-of-study feedback questionnaire: staff training, follow-up visits from OPERA team and interactions with OPERA office

Item		Intervention		Control		Total	
Returns (from 78 homes mailed)		22 (63%)		34 (79%)		56 (72%)	
Paraphrased questions from end-of-study questionnaire[a]							
Staff training							
		n	**%**	***n***	**%**	***n***	**%**
(Staff training) times mutually agreed?	Agree	6	27	12	35	18	32
	Totally agree	16	73	22	65	38	68
Staff responded well (to training)?	Agree	7	32	13	38	20	36
	Totally agree	15	68	21	62	36	64
Staff found training useful?	Agree	7	32	10	29	17	30
	Totally agree	15	68	24	71	39	70
Follow-up visits (3, 6, 9 and 12 months)							
Follow-up visits not burdensome on the home?	Agree	8	36	8	24	16	29
	Totally agree	14	64	26	76	40	71
Follow-up visits not burdensome on the residents?	Agree	8	36	9	26	17	30
	Totally agree	14	64	25	74	39	70
Records easily available for review (at follow-up)?	Agree	5	23	9	26	14	25
	Totally agree	17	77	25	74	42	75
Contact with OPERA office/team							
Did you need to contact the OPERA office?	Yes ($n =$)	10		13		23	
Were concerns dealt with satisfactorily?	Yes	9/10		13/13		22/23	

a Actual questions can be found in the 'end-of-study' questionnaires included in *Appendix 8*.

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TABLE 69 Results from OPERA end-of-study feedback questionnaire: physiotherapist involvement in the home and exercise groups (intervention homes only)

Item		Total
Returns (35 intervention homes mailed)		**22 (63%)**
Paraphrased questions from end-of-study questionnaire[a]		
		%
Physiotherapist assessments (of residents)		
Mutually agreeable times arranged?	Agree	18
	Totally agree	82
Usefulness of the physiotherapist (to the home)		
Helping in solving mobility issues?	Agree	18
	Totally agree	82
Advice increasing physical activity?	Agree	23
	Totally agree	77
Exercise groups		
Fitted well into the home?	Agree	5
	Totally agree	95
Ran as regularly as expected?	Agree	5
	Totally agree	95
Residents liked going?	Agree	18
	Totally agree	82
We enjoyed twice-weekly groups?	Agree	5
	Totally agree	95

Quality control

The recruitment process and baseline assessments of participants were observed on a 13 occasions; this included observing the process of consent when this is being given by a third party owing to the cognitive impairment of the participant (one occasion).

The recruiting staff who were observed were all seen to adhere to the study procedures and there were no significant deviations from protocol (*Table 70*).

During these observations, the challenges that recruiting staff face with this population in this setting have been noted. For example, these include:

- the higher levels of cognitive impairment and frailty of the population
- fitting in to a home's timetable (limited window of opportunity to carry out recruitment activities)
- space to carry out assessment (often limited space and not very private).

On visits to the care homes above to carry out the recruitment checks and also on the numerous visits to the eight case study care homes the OPERA sites files were checked. It was found that data were being updated within care home files (e.g. new residents added or deaths/movements recorded) and storage of these files was generally secure within home managers' offices and were easily accessible to OPERA research staff if needed.

Depression awareness training (control intervention)

Research staff who were delivering the control intervention were observed on several occasions. These observations have shown that staff were delivering the intervention as the protocol stated and there were no significant problems. However, it has been noted that these research staff faced a number of challenges when carrying out this work. For example:

- difficulties with some care homes making appointments for training
- trainer turning up and care home staff not being there or aware
- presentation equipment being a little small for large groups (laptops and speakers).

TABLE 70 Consent, assessment and data security

Item	C&W	NEL
No. of recruitment staff	3	2
No. of recruitment staff assessed	3	2
No. of observations	5	8
Percentage of QC assessments where no significant action needed to assure adherence to procedures	100	100
Percentage of QC assessments where minor action needed to assure adherence to procedures	0	0
Maintenance/updating of OPERA files (in homes): percentage of QC assessments where no significant action needed to assure adherence to procedures	100	100
OPERA files security (in homes): percentage of QC assessments where no significant action needed to assure adherence to procedures	100	100

QC, quality control.

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Intervention delivery

Although the lead physiotherapist measured the fidelity of the delivery of the exercise intervention, in terms of the individuals (physiotherapists) delivering it (see below), independent observations were also carried out by the process evaluation research fellow. Twenty-one of the exercise classes in the case study care homes were observed; seven in the early stages of their introduction (five homes once and one home twice), six at about the mid-point (once in each home) and eight at the end of the 12 months (four homes once and two homes twice). Observation at these times included how the session fitted into the day, how the residents were reacting, how the physiotherapist was interacting with the residents, care staff/home involvement and what happened when it ended. These observations proved to be very positive, with groups being delivered as per protocol. Comments from interviews and notes from these field observations can be found within the process evaluation results section (see *Chapter 2*, *Process evaluation*).

Data security and data collection accuracy at base

All data were stored as per protocol and were secure. Although laptops proved to be difficult to use with this population for direct entry of data, there were no problems with the security of downloading of information from remote sites. All participant data were accounted for and entered. Problems were encountered because of the complexity of the study. These related to linking tables for participants who might have very different trajectories in the study and also related to the large amount of data on the intervention delivery. Following internal audits these were resolved by the study team.

Intervention physiotherapists

The lead physiotherapist trained a total of 26 physiotherapists to deliver the OPERA intervention, 24 of whom went on to deliver the intervention on a regular basis (owing to changes in personal circumstances two left before delivering any groups). The 24 physiotherapists who delivered the intervention had an average of 10 years' post-qualification experience (range 0–42 years) and their banding levels ranged between 5 and 7, with 67% of the physiotherapists having previously run therapeutic exercise groups and/or worked in a care home setting (*Table 71*).

TABLE 71 Characteristics of physiotherapists who delivered the OPERA intervention

Characteristics	C&W	NEL	Total
No. of physiotherapists	8	16	24
Employer (*n*)			
University of Warwick	8	2	10
NHS	0	12	12
Private	0	2	2
Band on entry[a] (*n*)			
Band 7	6	3	9
Band 6	1	0	1
Band 5	2	12	14
Years qualified on entry: median (range)	18 (1–32)	7 (0–42)	10 (0–42)[b]
No. of months working in OPERA homes: median (range)	16.5 (4–27)	6 (0–18)	9 (0–27)
No. of homes assigned: median (range)	3 (1–5)	2 (0–5)	2 (0–5)

NHS, National Health Service.

a Band provides the level at which the physiotherapist is working within the NHS (equivalent given for private practitioners), with increasing levels of responsibility. The starting grade for a qualified chartered physiotherapist is 5, with the highest grade in the NHS being 8a.

b Zero (0) years means < 1 year since qualification.

Satisfaction with training

All physiotherapists were asked to provide anonymous feedback in a questionnaire completed after the initial training days; 55% of the physiotherapists who completed the evaluation forms rated the training as 'very good', with the remaining 45% rating it as 'good' or 'average'. The physiotherapists rated themselves as 'very confident' or 'fairly confident' to deliver 87% of the intervention elements and 'a little confident' to deliver 13% of the intervention elements. None of the physiotherapists rated themselves as not at all confident to deliver any of the intervention elements.

Intervention fidelity (physiotherapist)

The quality and fidelity of the intervention delivery was checked via a site visit made to each physiotherapist at one of their assigned care homes on at least two occasions: at 6 weeks and at 6 months after the intervention started in that home. The delivery of the exercise group and use of the whole-home approach were assessed by observation, and a sample of each of the intervention data collection and clinical record forms and registers was checked (unless any major issues were identified, in which case all were checked). The results of these quality assurance visits were documented, with the results shown in *Table 72*.

TABLE 72 Quality assurance tool with percentage achieved during visits

Item	Not achieved: *n* (% of total)	Partially achieved: *n* (% of total)	Satisfactorily achieved: *n* (% of total)
Administration/record-keeping (completion of all forms/ registers)	3 (7)	8 (20)	30 (73)
Preparation for group (room, residents, resources, staffing)	0 (0)	0 (0)	41 (100)
Storage and organisation of equipment	0 (0)	1 (3)	40 (97)
Personal performance in running group (use of communication, music, facilitation)	0 (0)	6 (15)	35 (85)
Content of group exercise session (intensity, progression, equipment use)	0 (0)	8 (20)	33 (80)
Whole-home approach activities/communication/ cooperation/support to care staff, mobility recommendations, equipment procurement	0 (0)	18 (44)	23 (56)

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Long-term follow-up

Sample

We invited all 78 care homes to participate in the follow-up study (postal invitation with telephone follow-up). Thirty declined, a high proportion of which were control homes ($n = 26$). Thirty of the 35 intervention homes completed interviews (including five of the six case study care homes), one care home had closed down and four others declined. Seventeen interviews were completed with control homes (including one of the two case study care homes; the other home declined) (*Table 73*). Observations were undertaken in the six case study care homes that consented.

Quotations used in this section are illustrative of the themes within the heading. These quotes will include reference to their source, including the role of the interviewee and a number to indicate a home/origin (homes numbers 1–30 are intervention homes and numbers 31–47 are control homes).

Table 73 shows that 86% of the intervention homes took part in the follow-up substudy and for control homes 94% of the planned sample participated.

Activities co-ordinators and exercise groups

We asked specific questions about the homes having activities co-ordinators and the running of regular exercise groups (*Table 74*). With the exception of three cases, the role of activities co-ordinator was to promote 'activity' in the care homes. The three exceptions were that two were also the manager of the home and one was also a care assistant. When asked if the role had changed over the last 2 years most gave a positive answer. Some talked about how it had developed.

> *It has developed. Before started no activities co-ordinator and it has grown over time.*
>
> *Home 7, activities co-ordinator*

> *We have become more proactive at getting them active.*
>
> *Home 12, manager*

> *Yes, adapted to changing needs of residents.*
>
> *Home 47, manager*

Interviewees also commented on how OPERA had influenced their decisions to employ an activities co-ordinator:

> *We didn't have an activities co-ordinator when OPERA started but OPERA showed us what could be done. We employed someone who was very good. And as OPERA ended she was able to continue*

TABLE 73 Breakdown of follow-up study sample

Item	Intervention total	Control total	Total
All OPERA homes	35	43	78
Sample required (for follow-up)	35	18	53
Homes approached	35	43	78
Refused	4	26	30
Closed down	1	0	1
Total included	30	17	47
% of required sample recruited	86	94	89

TABLE 74 Summary of responses to questions about activities co-ordinators and group exercise

Question/response		Intervention total	Control total	Total
Someone responsible for 'activity'?	Yes	21	10	31
	No	9	7	16
Activity co-ordinator working hours?	Full-time	12	4	16
	Part-time	9	7	16
Has role changed over the last 2 years?	Yes	18	9	27
	No	3	9	12
Does the home run regular exercise classes?	No	7	4	11
	Yes			
	External or staff run	6	13	19
	OPERA type	17	N/A	17
How often are exercise classes run?	Daily	1	0	1
	Once a week	8	5	13
	Twice a week	8	4	12
	Once a fortnight	5	4	9

with the groups. Sadly she had to leave us and we are currently looking for a replacement. It is OPERA that have given us this will to have someone.

Home 18, manager

Yes, when OPERA started we did have an activities co-ordinator but he was ineffective and after a short time left. Did not employ anyone during OPERA as OPERA were in twice a week; employed new person post OPERA.

Home 1, manager

Yes, got activities co-ordinator after OPERA as realised that resident well-being improved (made them happier).

Home 27, manager

Three homes reported having vacancies for activities co-ordinators, which they hoped would be filled soon.

Thirty-six of the 47 homes interviewed reported that they ran regular exercise groups. When asked when the last of these groups took place, most indicated that they had held exercise groups within the last week. Seventeen of the intervention care homes (around 50% of the total intervention care homes) had adopted versions of the OPERA exercise groups. Most of these were delivered by the care home staff (usually the activities co-ordinator); some took place twice a week, others just once. Several care homes had negotiated privately with the physiotherapist who either went in to deliver groups or went in to support the activities co-ordinator by doing regular assessments of the residents and providing advice and support. Two other intervention care homes were using OPERA-type groups but they have had to stop due to staffing problems in the homes and organisational changes (a number of our homes were part of the 'Southern Cross' chain, which went into receivership post OPERA). Another home was going to be starting OPERA-type groups again after residents at a residents meeting had asked for them to be reinstated.

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Motivation went a bit and we stopped (after a number of deaths in the home). However, at a residents meeting a month ago a resident raised the issue and as a result we are reinstating it (OPERA groups); not yet started.

Home 22, manager

Awareness of depression and activity in the home

We asked specific questions about depression awareness and levels of activity within the homes. From those who responded to the question asking if they are 'more aware of depression', many linked this to the care home staff training we provided early in the project (*Table 75*). Many stated that they already knew about depression and were acting upon it. Others felt that they were more aware since OPERA, and several felt that they were seeing less depression.

Saw a big change in staff; more aware of problems now and will report/refer.

Home 5, manager

Yes it has changed their mood they were much happier and more social.

Home 27, manager

Definitely noticed less depression.

Home 12, manager

We asked if their approach to encouraging residents to be active had changed; 17 of the interviewees said no. Within intervention homes the most reported change was the introduction of OPERA-type groups. There were also reports of more activities in general taking place in some care homes and the introduction of activity co-ordinators in others.

Yes, getting the residents going, lots organised including gardening.

Home 21, manager

Yes, we run regular OPERA-type groups now.

Home 2, activities co-ordinator

TABLE 75 Summary of responses to questions about depression awareness and 'activity'

Question/response		Intervention total	Control total	Total
Do you think you are more aware of depression/low mood in residents since OPERA?	Knew already	7	4	11
	It was a good reminder	2	0	2
	Noticed less depression	3	0	3
	More aware	9	8	17
	No	1	3	4
Has your approach to encouraging residents to be active changed?	No	5	12	17
	Yes			
	Activities co-ordinator now	3	0	3
	Run OPERA groups	9	0	9
	Do more activities	12	4	16
Would you recommend changing the depression awareness training in any way?	No	11	13	24
	More sessions or a follow-up	19	4	23

OPERA has changed us and we are now getting an activity co-ordinator.

Home 18, manager

Yes I have seen what the OPERA intervention can do for residents.

Home 30, manager

We do more with them now. Cooking, games puzzles arts and crafts floor games.

Home 10, manager

When asked about the staff training (depression awareness training in control homes and depression awareness and activity training in intervention homes), just under half of the interviewees reported that they would have liked the training to be either longer (with more sessions or a follow-up) or more in-depth (noted by some as too basic).

We asked two specific questions. The first was about the involvement of physiotherapists in the care home (and was asked only in intervention homes). The second asked about observed changes in the care home during OPERA (which was asked in both intervention and control homes) (*Table 76*). Control homes reported no OPERA-related changes in the home during the study. Without exception, all of the intervention homes placed high value on having access to a physiotherapist for 12 months and noted that this was not just owing to having them deliver the exercise groups; there were other benefits also. The most cited of these was the help, advice and support provided.

Advice and support . . . Staff, families and residents asked for advice from physio . . . Physio services very difficult to get in care home.

Home 30, manager

This theme was expanded to include the support and help given about equipment and aids which many homes found invaluable.

TABLE 76 Summary of responses to questions about physiotherapists' involvement in the homes and impact of OPERA (intervention homes only)

Intervention homes	Total
What else did you get from having a physiotherapist on site twice a week?	
Help/advice/support	29
Equipment and aids	10
Freed up staff time	4
Increased resident social circle	1
Did you see changes in the home during OPERA?	
Residents	
More awake	3
Mobilise easier/more mobile	16
Increased mental alertness	4
Improved mood	9
Happier	9
Physically improved	7

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Physio really nice with residents, helped with equipment and advice.

Home 21, manager

Source of encouragement and information. Helpful to needs of residents. Aids, grab rails. Residents trusted her.

Home 24, manager

Noticed things, gave advice, aids (Zimmers, height of) helped staff.

Home 19, manager

Two care home managers commented that having the physiotherapist in the home twice a week freed up time for staff to do other things. One manager noted that the physiotherapist, and indeed the whole OPERA team, provided added social interaction for the residents, as we were someone different for them to talk to.

The most reported change observed in the intervention homes was that residents seemed more mobile. Some noted improvements in alertness and mood with some describing their residents as 'happier'.

Yes, moods were better. One resident much more mobile. Physio spent time helping residents.

Home 11, activities co-ordinator

A lot of enjoyment in residents and staff . . . mobility improved. Mood (of residents) got better.

Home 12, manager

Yes definitely some physical and mental changes improvements. They were happier.

Home 6, manager

Residents were more awake some changes physically (able to mobilise easier) and mentally more alert.

Home 1, manager

More mobility and happiness.

Home 23, manager and carer

When asked if they would change the exercise groups in any way most said 'no'; however, several did make some suggestions. These included sessions being a little longer, changes to the music ('more jolly'), need to consider the residents with dementia, and, finally, perhaps breaking the sessions up with other activities.

Hard to get services some rehabilitation services but not a lot.

Home 16, manager

Difficult to get physio services in the home.

Home 28, manager

Many felt that if they were to pay for an OPERA-type service it would have to be reduced to perhaps once a week again due to cost. All stated that if the service were provided free of charge they would welcome it with open arms.

Over the moon.

Home 20, manager

Bring it ON.

Home 1, manager

Would grab with both hands.

Home 26, manager

Yes with open arms, such a good thing.

Home 15, manager

Asked if they would pay for an OPERA-type service for the care home all agreed that it would be nice if it were available. However, cost would be a huge issue as homes have limited or no budgets for these things. Some fund external activities via fundraising (e.g. raffles, garden parties) while other homes have small 'activities' budgets that have to be prioritised (e.g. how can the money be used to benefit the most residents).

Cost an issue may be able to pay about £50 but would have to come out of fundraising and residents fund.

Home 7, activities co-ordinator

Cost an issue have no funding for it. We pay up to £70 (for an entertainer) but this would not be every week.

Home 16, manager

£50/h (price they put on it) not feasible twice a week.

Home 11, manager

All felt that OPERA provided a valuable service to the care homes, a service that most found very hard to get. With a few exceptions, care home managers reported that access to physiotherapy services was very difficult. Most were required to 'refer' via the general practitioner and services could take weeks or months to appear and in some cases never appeared.

Asked about the overall experience of having OPERA in the home, all interviewees, from both control and intervention homes, reported this was a very positive experience. Intervention homes again referred back to the exercise groups and the role of the physiotherapist within the home and interviewees from control homes and intervention homes were very positive about day-to-day interactions with the OPERA team, stating that the team were always polite, made mutually agreeable appointments and were never a burden on the home, its residents and staff.

Really nice people, forms easy to complete not a burden, appointments always made.

Home 39, manager

Very motivating really enjoyed the experience.

Home 21, manager

Blended in . . . part of Team . . . all fitted into home really well

Home 23, manager and carer

Very positive, everyone was very professional and not a burden on the home staff or its residents. You placed no pressure on us.

Home 36, manager

Residents liked seeing the kind OPERA staff. It was easy for us and not a burden.

Home 38, manager

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Asked at the end of the interviews if they had any more comments about OPERA, the most persistent comments were from interviews with intervention homes who expressed their sadness at OPERA ending and wishing it could continue.

> *Fantastic, sorry it has gone.*
>
> *Home 10, activities co-ordinator*

> *Drawback was it was only 12 months.*
>
> *Home 2, activities co-ordinator*

> *It was wonderful and we all miss it greatly it has left a big hole.*
>
> *Home 6, manager*

Observations and activity sweeps (case study care homes)

Six of the eight case study care homes (from the process evaluation) agreed to participate in this follow-up. Of the two which did not, one of the control homes had major staff changes and current staff could not comment on OPERA while the other (intervention home) had gone through ownership and managerial changes; thus both declined to take part.

Figure 20 represents an average of activity sweeps in each of the homes (at least eight sweeps of 90 minutes in each home over several days). These were compared with those undertaken at the end of the study (*Table 77*). Observation visits and these activity sweeps revealed that generally little had changed within the care homes since OPERA finished. In the five intervention homes, three carried on the OPERA groups at least once a week using their staff, one stated that they were unable to afford to run groups and the other did not as they had staffing problems. Comparison of the activity (see *Table 77*) shows that home 4 maintained a fairly good level of activity despite the fact that they recently lost their activities co-ordinator. Home 3 showed a reduction in recreational activities and this too was observed during visits. The care home manager reported she was struggling to motivate staff at present and this was clearly having an impact.

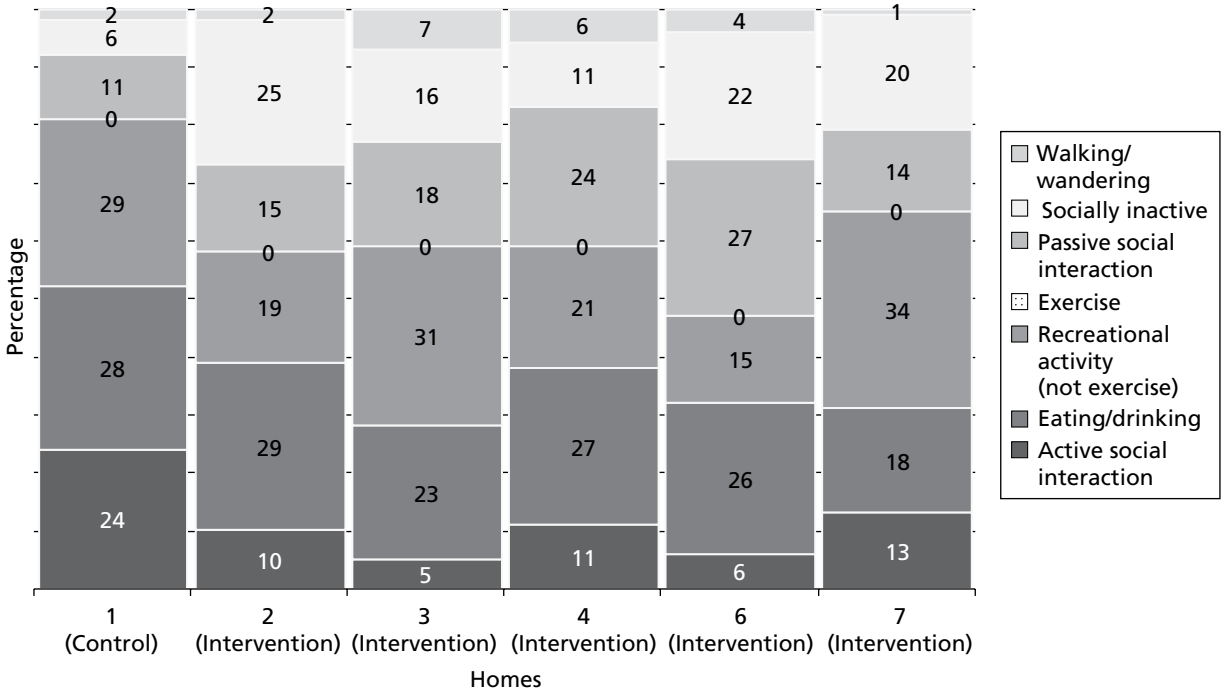

FIGURE 20 Summary of daytime activity in six of the case study homes at post-OPERA follow-up.

TABLE 77 Percentage of residents observed in each activity in case study care homes (comparing end of study[a] with 6 months post OPERA)

		Activity codes[b]						
Home	Time points/change	1	2	3	4	5	6	7
Home 1	a. Trial end	25	28	30	0	11	5	1
	b. Follow-up	24	28	29	0	11	6	2
	c. Change (b–a)	–1	0	–1	0	0	1	1
Home 2	a. Trial end	8	30	17	0	14	28	3
	b. Follow-up	10	29	19	0	15	25	2
	c. Change (b–a)	2	–1	2	0	1	–3	–1
Home 3	a. Trial end	5	22	37	0	16	12	8
	b. Follow-up	5	23	31	0	18	16	7
	c. Change (b–a)	0	1	–6	0	–2	4	–1
Home 4	a. Trial end	12	28	13	5	25	11	6
	b. Follow-up	11	27	21	0	24	11	6
	c. Change (b–a)	–1	–1	8	–5	–1	0	0
Home 6	a. Trial end	4	23	16	0	32	21	4
	b. Follow-up	6	26	15	0	27	22	4
	c. Change (b–a)	2	3	–1	0	–5	1	0
Home 7	a. Trial end	13	17	33	0	14	22	1
	b. Follow-up	13	18	34	0	14	20	1
	c. Change (b–a)	0	1	1	0	0	–2	0

a End-of-study data taken from process evaluation results.

b Activity codes: 1. Active social interaction, 2. Eating/drinking, 3. Recreational activity (not exercise), 4. Exercise, 5. Passive social interaction, 6. Socially inactive, 7. Walking/wandering.

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Chapter 4 Discussion

Overview

OPERA was a complex multifaceted study. The nature of both the intervention being studied and the population studied means that a simpler study design would not capture all of the active intervention's possible effects (positive or negative) on care home residents. In addition to obtaining data on the effects of the intervention we have also been able to investigate, in detail, both the process of running the study and of implementing a complex intervention within care homes. This has generated high-quality data on how to do research and on change implementation in this environment.

At the time we started OPERA we had serious concerns regarding whether or not the study was feasible. In particular there were concerns that care homes, which are often unfamiliar with research, might be reluctant to participate. Contrary to expectations, over half of the care homes we approached were interested in participating. Furthermore, no homes dropped out of the study after randomisation, meaning that we were able to collect ample follow-up data for our cohort analyses and for our end-of-study cross-sectional analysis we had a full complement of homes. Care homes and residents maintained their commitment to the study through what, for some, were difficult times or after many care home staff changes. For example, one care home needed to close during the study because of safety issues and residents were moved to other homes. We were able to follow up most of these residents in their temporary care homes, and after building work was completed, the home re-opened and residents returned, and we were able to complete our 12-month study assessments as planned.

The number of participants per care home was fewer than anticipated at the study design stage. This was partly because of the surprisingly high number of vacant beds in our homes and also the high proportion of residents who were too ill or too cognitively impaired to complete study assessments. For this reason, during the study we changed one of our primary outcomes to ensure that we had adequate statistical power, while still recruiting the originally planned number of homes. Our original sample size estimates were inflated to allow for clustering effects. One of the striking findings was that the intracluster correlation coefficients for participant assessments were very small or zero. These factors meant that although we recruited substantially fewer participants than originally planned (765 vs 1231, with a Geriatric Depression Scale-15 prior to randomisation) the effective number of participants contributing to our three primary analyses is substantially greater than specified in our revised sample size calculation. This means that all of our main effect estimates are much more precise than planned, giving reassurance that our findings are robust.

The overall findings of the study are clear and conclusive. We developed a high-quality intervention that was received extremely well both by staff and residents within the care homes. Uptake of the intervention was very good and was maintained throughout the 12-month intervention period. We have some evidence that homes welcomed, and were supportive of, the intervention package. There was not, however, any benefit on any of our primary or secondary outcome measures. The OR for residents being depressed at the end of the study was 0.75 (95% CI 0.52 to 1.08), the mean difference in Geriatric Depression Scale-15 in the cohort analysis at 12 months was 0.14 (95% CI –0.33 to 0.60) and for the depressed cohort at 6 months this was 0.23 (95% CI –0.50 to 0.96) (*Table 35*). The limits of the 95% CIs for the mean differences are less than the minimally clinically important difference specified for the study (1.2 points in the Geriatric Depression Scale-15), effectively excluding the possibility that the OPERA intervention has a meaningful effect on depressive symptoms as measured by the Geriatric Depression Scale-15. Furthermore, in our health economic evaluation the OPERA intervention was both more costly and less effective than the control intervention. We conclude that the OPERA intervention cannot be recommended as a means of reducing the burden of depression in care home residents.

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OPERA care homes

The OPERA care homes were broadly representative of care homes in the two localities, except that we excluded larger homes and we recruited only one local authority-run home. Local authority homes have also been under-represented in previous studies.[86] It is unlikely that the process of implementing the intervention in large or local authority-run homes would be so different from that in our included homes that the intervention would be substantially more effective. Our findings are generalisable to residents in these homes.

We included only one dementia specialist home. This was because of practical difficulties in obtaining our primary outcome data from residents in these homes. We observed substantial differences in approach to activity between dementia specialist units within OPERA care homes and the rest of the homes; these units were generally more proactive in encouraging activity. This is a difference we would expect to be seen also in dementia specialist homes. It is possible that within a dementia specialist home improved adherence to the exercise regimen might produce beneficial outcomes. Thus, although a large proportion of our participants had substantial cognitive impairment our findings are not necessarily applicable to dementia specialist homes.

OPERA participants

Recruitment

The number of participating residents per care home was fewer than originally planned; the number of eligible residents per home was 28 rather than the anticipated 32. Only 37% of eligible residents provided a baseline Geriatric Depression Scale-15 score and only 43% agreed to provide care home data. This is similar to the proportion of residents recruited to another recent UK care home study of a physiotherapy intervention, targeted just at those with mobility limitations.[86]

Substantial numbers of residents were excluded (524/2078, 25%) (either because their health was too poor or because the care home manager felt that it was inappropriate to approach that individual for another reason). Those residents with poor health would have been unlikely to be able to participate in the exercise groups and would be unlikely to benefit from the intervention.

The baseline characteristics of those recruited prior to randomisation were broadly similar to population values. The baseline Geriatric Depression Scale-15 scores for our population (mean Geriatric Depression Scale-15 score 4.8, SD 3.3) (*Table 19*) are very close to those reported for care home populations in the UK (mean Geriatric Depression Scale-15 score 5.4, SD 3.2)[120] and in the USA (mean Geriatric Depression Scale-15 score 4.8, SD 3.5).[122] This mean Geriatric Depression Scale-15 score also supports reports that a cut-off of 4/5 on Geriatric Depression Scale-15 has good sensitivity and specificity for detecting clinically significant depression among older people, with an expected prevalence of significant depression of 40% in a care home population.

Around half of our participants were depressed, with a mean Geriatric Depression Scale score of 4.8 (SD 3.3). Of the 374 participants depressed at baseline, only 92 (25%) had a recorded diagnosis of depression and only 126 (34%) were taking antidepressants (*Table 22*). This is indicative of substantial under-recognition and undertreatment of depression in care homes and concurs with findings in previous studies.[24,26]

The mean Mini Mental State Examination score of 18.4 indicates that our participants had substantial levels of cognitive impairment and that our findings are applicable to the many care home residents with cognitive impairment. The mean EQ-5D scores of 0.57 (self-report) and 0.45 (proxy) attest to the overall poor quality of life of our participants. UK norms for people in the community aged ≥75 years were 0.73

(SD 0.27).[211] This is consistent with findings from previous studies. Of participants recruited in intervention homes, 16 (3%) were considered ineligible for the group sessions by the study physiotherapists. Our participants overall state of health was, as anticipated, very poor and representative of our target population of care home residents able to participate in exercise sessions.

The mean baseline Short Physical Performance Battery scores indicate poor levels of lower limb function. To our knowledge we are the first study to administer the Short Physical Performance Battery among a care home-dwelling population in the UK. Some studies in the USA have used the Short Physical Performance Battery in assisted living populations;[212–214] however, it is not apparent that assisted living facilities in the USA are comparable with care homes within the UK. The floor effect, demonstrated in the baseline Short Physical Performance Battery scores, limits the ability of the Short Physical Performance Battery to detect deterioration in scores at the follow-up time points. Furthermore, as the Short Physical Performance Battery was designed for community-dwelling older adults, it may not be sufficiently sensitive to detect changes in lower limb function of the OPERA participants who are considerably more frail than older people living in the community.

Baseline social engagement shows a high percentage of residents reported as being highly socially engaged (i.e. interacting with others, very involved in activities, not withdrawn) in both the intervention and control groups (62% and 60%, respectively). In contrast, an international study of nursing home residents in five countries (Denmark, Iceland, Italy, Japan and USA) reported at most 30% of residents reporting high scores. In a large sample in the USA with high social engagement, residents also had high levels of cognitive function and high levels of activity of daily living.[142] This difference in apparent social activity may be related to how we used the measure. As originally designed, it was based on direct observation. For this study we used carer report, which might be subject to bias in measurement of absolute score. We would, however, expect it still to be sensitive to change.

Unusually in the OPERA study we also recruited participants after care homes were randomised to ensure that for our end-of-study cross-sectional analyses we were studying a representative population rather than just relatively healthy survivors. This analysis tells us the likely long-term effect of implementing the OPERA intervention on overall prevalence of depressive symptoms in care home residents. Again this population was broadly representative of the population of care home residents overall, ensuring that our findings are generalisable.

Follow-up

Overall we obtained good follow-up rates. As expected there was a lot of attrition due to death but loss to follow-up arising from residents moving out of an OPERA home was higher than expected. Thus although we were able to obtain a Geriatric Depression Scale-15 on around 90% of participants present in an OPERA home at each end point this represents only 61% of our population of interest for individual assessment data in the cohort analysis at 12 months in the control homes. Nevertheless, our follow-up rate was always in excess of three-quarters of those who were alive for the primary outcome – ensuring that our conclusions in the cohort analysis are robust. There was a consistent trend for more follow-up data to be collected in the intervention homes than in the control homes. Our findings did not, however, change materially in a sensitivity analysis in which missing data were imputed or when an extreme scenario sensitivity analysis was conducted (data not presented). As the study had a much more visible presence in the intervention homes it is not surprising that there was some differential follow-up. The process evaluation has identified how warmly the intervention was received in the homes. It is likely that this was translated into an extra willingness on the part of the care home staff to help follow-up assessments and, of course, an increased interest in assisting in data collection from residents and providing data on residents. The difference is small, however, and any bias introduced by this differential follow-up would be very unlikely to change our conclusions.

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In this study we have made use of Secondary Uses Service data from primary care trusts to collect most health service activity. We are extremely grateful to the primary care trusts who kindly collated these data for us during a difficult time of organisational change within the National Health Service. These data became available just 12 weeks after the end of the study period. Although these data may not be as clean as a final Hospital Episodes Statistics data set, available 6 months after the end of the financial year in which the activity accrued, this has provided a very timely resource for monitoring health service costs in a standardised manner. This data set does, however, have some limitations for collecting causes of A&E attendances and outpatient appointments. Although we cannot be certain that any attendance for injury at an A&E department or at a fracture clinic is the result of a fracture, these are likely to be indicative of a significant injury and are a good marker for the safety of the OPERA intervention.

Clinical effectiveness

This is one of the larger intervention studies run in a care home environment. Surprisingly, for many of the participant-reported outcomes the intracluster correlation coefficient was zero, or close to zero. This is in contrast with findings in some other UK-based cluster randomised care home studies, which have found intracluster correlation coefficients in the range 0.37 to 0.49 for some outcome measures.[86,215] These intracluster correlation coefficients were, however, for measures such as the Barthel Index and the Rivermead Mobility Index, which were collected by independent assessors rather than directly from residents. Our largest intracluster correlation coefficient for assessment data, collected directly from residents, was 0.09 for the Short Physical Performance Battery; a larger intracluster correlation coefficient for measuring an outcome that is dependent on environmental and, possibly, assessor factors is not surprising.

We collected our proxy data from care home staff. Although the intracluster correlation coefficients were large enough to affect our statistical power (0.17 for proxy EQ-5D and 0.16 for Social Engagement Scale at 12 months) they were, surprisingly, much smaller than those found by others.

As a consequence of these small intracluster correlation coefficients we have sufficient data to make quite precise estimates for most of our primary and secondary analyses for between-group differences. Although we have conducted a large number of primary and secondary analyses we have failed to show any statistically significant differences in any of our outcome measures. The large numbers of participants means that we can be confident that these are true-negative effects.

Geriatric Depression Scale-15

Surprisingly, the point estimates for benefit from the OPERA intervention on the Geriatric Depression Scale-15 in both the cohort analysis (0.14, 95% CI –0.33 to 0.60) and depressed cohort (0.23, 95% CI –0.50 to 0.96) favour the control intervention (*Table 35*). We originally set the clinically important difference on the Geriatric Depression Scale-15 score as 1.2. It could be argued that this was based upon a minimally clinically important change for an individual, equivalent to the effect of loss of a spouse, rather than a minimally important change for a population and that we should have chosen a smaller mean difference as clinically important.[216] The limit of the 95% confidence for possible benefit from the OPERA intervention is around one-quarter of the minimally clinically important change for an individual and equates to a standardised mean difference of 0.1 (lower limit 95% CI 0.33, SD at baseline = 3.3), effectively excluding any possibility of a beneficial effect on depressive symptoms, as measured on the Geriatric Depression Scale-15, from the OPERA intervention. For the original research question set by the funders, the proportion of residents with depressive symptoms at baseline who experienced remission of depression (at 6 months), we had data on 259 participants. This is fewer than the 343 participants specified in the simple sample size from our original application, justifying our a priori decision not to consider this as a primary analysis. In this case the direction of change was in favour of the OPERA intervention. This might suggest a possibility that we are overlooking a true effect. However, this would seem unlikely, given that the direction of change for mean scores in the cohort analysis favours the control intervention.

That there was no difference in the prevalence of depressive symptoms between baseline and follow-up in the control group (mean Geriatric Depression Scale-15 at baseline and follow-up 4.7 and 4.6, respectively) (*Table 35*) suggests the control intervention was also ineffective and it is not the success of depression awareness training that means we failed to find a beneficial effect from the OPERA intervention. There was not a significant difference in the rates of antidepressant use between the intervention and control homes at any time point (*Tables 46* and *47*). Neither was there any suggestion of a difference in how many participants started or stopped antidepressants. It is therefore unlikely that changes in medication use, for example increased use of antidepressants in the control arm, masked a beneficial effect from the OPERA intervention.

We are aware of one other cluster randomised trial that has reported the effect of a reasonably similar exercise programme on Geriatric Depression Scale-15 scores delivered to a reasonably similar population in residential accommodation. Conradsson *et al*.[95] tested a moderate intensity functional exercise, delivered 29 times over 3 months, which did not include a whole-home approach. They found no benefit on the Geriatric Depression Scale-15 score at either 3 months (mean difference 0.09, 95% CI –0.55 to 0.74) or 6 months ($n = 191$)[95] for all participants, or for those with a Geriatric Depression Scale-15 score of >4 at baseline (mean difference –0.59, 95% CI −1.66 to 0.48 at 3 months; mean difference, 0.12 95% CI –1.12 to 1.37 at 6 months). Meta-analysis of these data and the OPERA data, for the main cohort and the depressed cohort, provide further support for the notion that such exercise interventions are unlikely to be effective in this population (*Figures 21* and *22*). For these analyses we have used Conradsson's 3-month data, which was at the end of the intervention period rather than 6-month follow-up, as it is at this time that any positive effect was most likely to be evident (the direction of change does favour the intervention in one of Conradsson's analyses), and pooled this with data from our primary analyses for these two populations.

Other outcomes

The absence of any statistically significant difference in any of our other outcomes is notable. Only for the Short Physical Performance Battery does the difference approach statistical significance; this is the case on both the cohort analysis (0.30, 95% –0.05 to 0.64) (*Table 41*) and the cross-sectional analysis (0.24, 95% CI –0.1 to 0.57) (*Tables 44* and *45*). A change of 0.5 points on the Short Physical Performance Battery is considered a small but meaningful change, and 1.0 points a substantial change.[217,218] We have effectively excluded the possibility that the OPERA intervention will have a substantial effect on mobility and lower

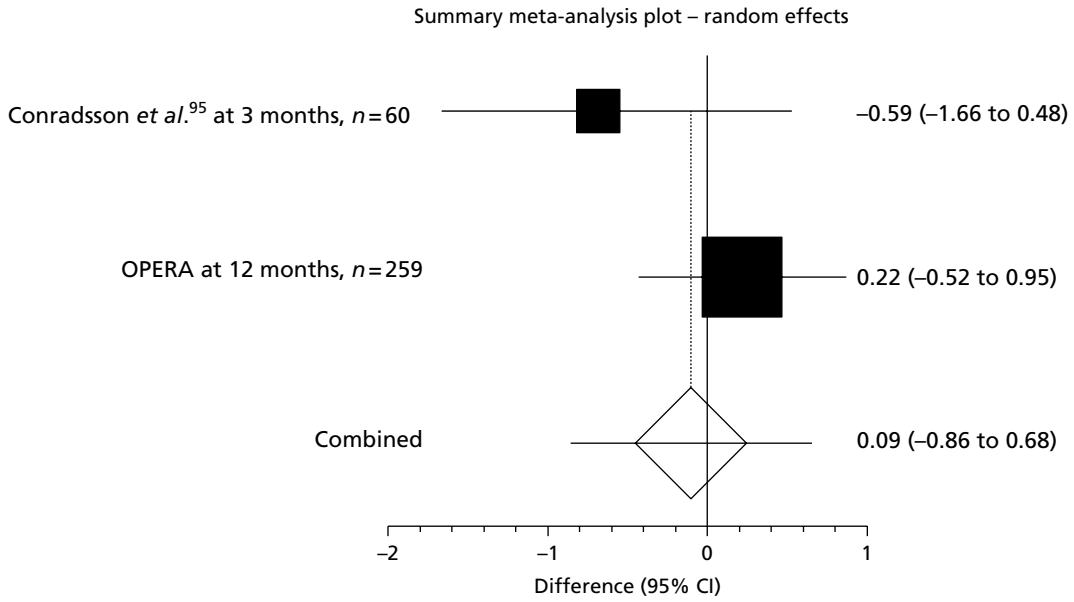

FIGURE 21 Meta-analysis of mean difference on Geriatric Depression Scale-15 in those with depressive symptoms at baseline.

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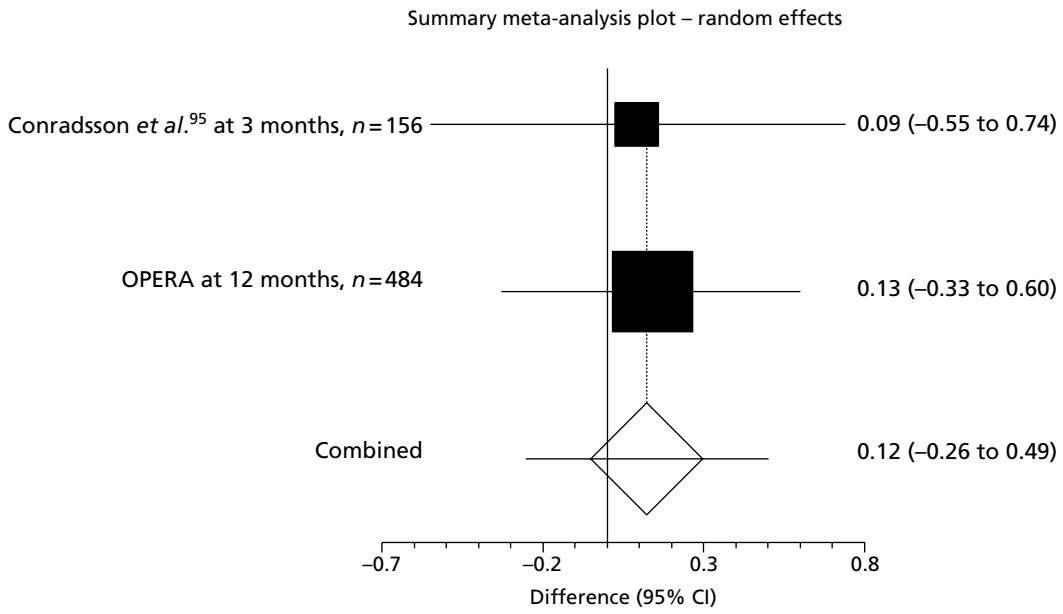

FIGURE 22 Meta-analysis of mean difference on Geriatric Depression Scale-15 in all participants.

limb function. We have not excluded the possibility that the OPERA intervention might have a small but meaningful effect on mobility and lower limb function.

Failing to show a positive effect on the Short Physical Performance Battery may not be a surprising result given that the structured exercise activities needed to be performed largely seated due to the poor physical health and abilities of the exercise group participants, and so were less likely to positively affect the abilities measured by the Short Physical Performance Battery. Although the whole-home intervention included efforts to increase the amount of safe walking for all residents, it appears that the main effect of this approach was improved attendance and adherence to the structured exercise programme offered by participation in the exercise groups.

There is also an emerging literature suggesting that many very frail elderly people, such as those included in OPERA, may be unable to exercise at levels sufficient to fully participate in exercise activities and exercise intensities that might activate the physiological processes hypothesised to ameliorate depressive symptoms.[178,219–221]

Our overall measure of health-related quality of life was the EQ-5D, self-reported and proxy. A priori we decided to use the proxy values, as we were anticipating a large amount of missing data, in particular for completion of the EuroQol thermometer. Although this was the case, fewer participants satisfactorily completed this at baseline and follow-up and the difference in intracluster correlation coefficients between the self-assessed EQ-5D (0.02) (*Table 37*) and the proxy EQ-5D (0.17) (*Table 38*) mean that the precision for the estimate is similar for both proxy and self-completed EQ-5D. Neither shows any significant benefit from the intervention in any of our analyses, with point estimates at, or very close to, zero; effectively ruling out any meaningful benefit on overall health-related quality of life from the OPERA intervention.

Safety

At the time we started OPERA there were significant concerns that we might have been exposing residents to some risk of harm. This was both around the time of the group exercise sessions and at other times when mobility was being encouraged. No directly attributable serious adverse events occurred during over 30,000 individual attendances at the exercise sessions by a very frail elderly population, which is a tribute

to the professionalism of the physiotherapy team. Ascertainment of fractures in the population exposed to the intervention is important. We were able to collect medical record data only on study participants and so we needed to rely on pooled data from the care homes to ascertain overall fracture rates among all residents. Because there is a statutory duty to record these they should be a complete record but they do not give us data on person-years of exposure or identify those with multiple fractures at different times. There was, however, no suggestion of a difference here. The use of routine National Health Service statistics to identify fractures has the potential to provide confirmatory information on fracture rates, based on years of exposure. For inpatient events the data are of high quality but the quality of reporting in routine data sets of events in A&E departments and fracture clinics does not allow for definite diagnosis of fractures. Notwithstanding this problem the data clearly do not show any increased risk of injury fracture in the intervention group. Thus the OPERA intervention is very safe to deliver.

Cost-effectiveness

The results show that the exercise intervention made no significant difference in the number of quality-adjusted life-years accrued by residents while increasing overall costs due to the cost of delivery of the intervention. A high cost of implementation (£322 per resident) was expected for such an intensive intervention. This cost was not offset through decreases in health services use during the 12 months of the study. The intervention did not contribute to an increase in health service use. The findings of no significant difference in mean costs between residents in the intervention and control arms were consistent across all types of health-care visits. Consequently, the incremental cost of the intervention from an National Health Service perspective was £374 (95% CI –£655 to £1404) and £366 (95% CI –£664 to £1396) from a societal perspective.

The base-case analysis found the incremental quality-adjusted life-year figure to favour the control arm of the study; the difference was negligible (0.0014) with a wide CI (–0.0728 to 0.0699). The wide CI means that we cannot formally conclude equivalence in quality-adjusted life-years, as the limits of the 95% CI include values where we might have concluded that the intervention was cost-effective. The sensitivity and secondary analyses showed similar results. In light of the small negative effect from the intervention in all analyses, the economic evaluation does not support the use of the OPERA intervention. The low probability of the OPERA intervention being cost-effective at a willingness-to-pay of £20,000 and £30,000 demonstrates fairly conclusively that this is not a cost-effective intervention.

In such an elderly and frail population, it can be difficult to influence EQ-5D scores because there may be limited potential to achieve the relatively large changes in states within a domain (e.g. from confined to bed to some problems walking about). Often interventions in these populations are only able to slow the deterioration in quality of life rather than improve it. Furthermore, quality-adjusted life-years using the EQ-5D may not be an appropriate outcome for those receiving palliative care.[222] Twenty-three per cent of the residents included in the economic evaluation died during the 12-month follow-up period, indicating that many residents were effectively receiving palliative care at some point during the study. No better method currently exists to measure health utility for those at the end of life.

If there was a measure of health utility that was more suitable for use in this population, and that was more sensitive to change than the EQ-5D, then it might be easier to demonstrate cost-effectiveness of interventions in care homes. As the incremental cost of delivering the OPERA intervention is £374 per resident per year it would still need to show a net quality-adjusted life-year gain of at least 0.012 to be considered as cost-effective at a willingness to pay of £30,000 per quality-adjusted life-year.

Proxy EQ-5D data was chosen a priori for this analysis as it was more complete and collected more frequently, allowing for more residents to be included in our analysis. Over 25% of the self-reported EQ-5D data were missing at each time point. Some residents were unable to fill out the self-completed surveys because they were too unwell or cognitively impaired. Proxy data, however, has some shortcomings, as

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demonstrated by studies that compare self-completed quality-of-life surveys with those completed by a proxy.[138–140] In some homes, these surveys were completed by the care home manager due to language or literacy barriers or time constraints among the care workers working with the residents on a day-to-day basis. Although these care workers may have found it more difficult to complete the survey, they may have had a more comprehensive understanding of what life entailed for the residents. The care home managers, paradoxically, may have had a better understanding of the survey but may have had less interaction with the residents, which might have affected their interpretation of the residents' quality of life, although, particularly in smaller homes, the managers had a great deal of contact with their residents.

Process evaluation of the study

The process evaluation had some limitations. The number and spread of interviews carried out was smaller than planned, particularly with residents in the care homes. Relatives were also difficult to approach as we had no access to their contact information. Here we consider our finding under the different components of our process evaluation.

Context: aspects of the larger social political and economic environment that may influence implementation[198]

Our quantitative and qualitative data clearly illustrate the frailty of care home residents. A 2011 report from the British Geriatric Society concluded:[223]

> *Care homes and the residents they support have changed. They are no longer housing options for frail and financially insecure older people, as might be inferred from reading the National Assistance Act (1948) which set out in Part III the duty of local authorities to provide accommodation. They are now a major component of the welfare system's provision of care for vulnerable and clinically unstable older people. Many are now providing highly specialised services, for instance for older people with dementia.*

The frailty of the residents and the high prevalence of cognitive impairment seen (see *Chapter 3*, *Individual characteristics*) led some care home managers to be pessimistic about the prospects of residents' participation at the start of the study, and doubtless impacted on the implementation of the OPERA intervention. Nevertheless, the principal message from our process evaluation is that, even in this challenging population, it was possible to recruit participants and to implement a complex, multicomponent intervention which made considerable demands on care home staff and residents.

Providing seamless health-care provision for residents in care homes within the independent sector has been identified as an important problem. For example, the OPERA physiotherapists succeeded in obtaining simple, relatively low-cost mobility aids that care homes had been either unaware of or unable to access.

The OPERA study took place across a period of increasing economic uncertainty and, latterly, in an evolving economic recession. The majority of UK care homes are part of the independent sector and one of the largest groups in the UK, Southern Cross, announced it was closing down just after the end of the study;[224] four care homes from the chain took part in OPERA. Even at baseline the mean occupancy was 87% and the recruitment team reported that the number of vacant beds increased during the study. Observation and interviews in the care homes suggested that care home staff often have to work very hard and some resource-stretched care homes may have little spare capacity to engage in cultural shifts that might consume more carer time, such as promoting physical activity among frail elderly residents. Overall in England in 2009 about one-third of adult social care workers had been in their post for <3 years, and one-third for 3–7 years (see *State of the Adult Social Care Workforce 2010*, Skills for Care, p. 11[210]).

One interesting finding from this evaluation is the difference between care homes within the OPERA study. The activity sweeps show patterns of activity that appear to be relatively consistent across time within

the homes, but very different between homes, suggesting that there are huge differences across the care home sector. We do not fully understand why the culture around physical activity appears to differ so much between care homes and it seems unlikely that these differences could be completely explained by a difference in the mix of residents. The process evaluation identified some of the very different physical environments provided by different care homes but it is not fully understood how these environmental differences may impact on residents and care staff. The stability of patterns of activity across 12 months within the case study care homes suggests that changing the culture of homes, at least with regard to patterns of activity among residents, might be difficult.

Reach: the proportion of the intended target audience that participates in the intervention[198]

The OPERA study succeeded in recruiting a representative sample of care homes and the process evaluation suggests that care home managers and staff were enthusiastic about the intervention (even if they did initially express doubts about attendance). The evaluation suggests that it would be possible to introduce the intervention across the care home sector and it would prove popular with most homes.

The cluster randomised design meant that residents within participating homes were exposed to the intervention whether or not they participated in the evaluation of OPERA. Some residents who had neither consented nor been assented into the OPERA evaluation choose to participate in the exercise classes. Unfortunately, because we cannot collect outcome data on these residents we will not be able to measure any potential benefits or disbenefits and in this regard the true magnitude of the effect of the OPERA intervention remains partly unknown.

Dose delivered: the number or amount of intended units of each intervention or each component delivered or provided[198]

All 35 intervention homes and 42 out of 43 control homes received the depression awareness training session, although it was very difficult to arrange, and required considerable persistence, in a few homes. In one intervention home we were unable to deliver the intervention because the residents were too disabled to participate in the exercise group. The physiotherapists assessed all residents for eligibility and safety before they attended the exercise classes and fed this information back to the care home staff. Assessments also provided the opportunity to consider the aids a resident was using, and where necessary to make adjustments or indeed obtain suitable mobility aids/equipment. Across the intervention homes the physiotherapists delivered on average 90% of the maximum dose of exercise classes (*Table 61*).

We are not able to quantify the dose delivered of one aspect of this whole-home intervention, ongoing support and advice from the visiting physiotherapist to the care home staff, but it seems likely from the process evaluation that this aspect of the intervention may have differed between the two geographical locations of the study because of the different ways the physiotherapists delivering the OPERA intervention were employed at the two sites. If the intervention were to be rolled out across the care sector it is more likely that the model seen in NEL, where physiotherapists were seconded from the National Health Service to provide the intervention, would be followed. Our evaluation suggests that this model makes this aspect of the intervention more difficult to deliver.

Dose received: the extent to which participants actively engage with and interact with the recommended resources[198]

Just over one-third of participants attended 51 classes, our predefined estimate of an effective dose, with nearly 10% attending 41–50 classes (*Table 63*). In particular, attendance was good in those who contributed to our primary analyses. Attendance at the class does not, of course, mean that residents exercised to their set target level. There was little evidence of fall off in the numbers attending exercise groups across time, suggesting that ongoing group-based exercise in care home settings is viable. Only 9% of participating individuals attended no classes. This slightly disappointing attendance rate should be seen in the context of the very frail, sedentary, elderly population in the care homes and attendance rates at

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other exercise or other self-management interventions in community settings, which commonly have low attendance rates.

Vectors for change

Alongside the components of a process evaluation[198] this evaluation was underpinned by the theory of change[197] which we outlined in *Chapter 2* (see *Process evaluation*). We identified four vectors through which activity among residents in the homes might be increased: care home staff training, exercise groups, physiotherapist contact with care home staff and improvements in the home environment.

Care home staff training took place and was positively received by those who participated. However, only around 39% of staff in intervention homes in C&W and 54% of staff in intervention homes in NEL actually attended the training. Initial feedback from both the intervention and control training suggests that there was some increase in care home staff's awareness of depression and how to deal with it, and there was some indication that intervention home staff were, with the help of the physiotherapist, more confident in promoting physical activity. However, in the very small proportion who returned a 3-month follow-up evaluation questionnaire, there was little evidence that attendance at the training had changed their practice. In contrast, interview and focus group data strongly suggested that, at least in some cases, the training of care home staff made a real difference to their awareness, ability and practice around promoting increased physical activity in residents. There was less evidence from qualitative sources that the training had influenced the awareness and recognition of depression in practice among care home staff.

The exercise groups were delivered as planned and information from the focus groups and interviews identified many positive effects of the groups and almost universal enthusiasm from the care home staff and residents for the groups, which only appeared to increase across the duration of the study.

Measuring the effect of the physiotherapists' contact with care home staff proved more difficult, and we have relied mainly on data from the observations, interviews and focus groups. Most of the comments about the physiotherapists, especially later in the study, were very positive, making it clear that they had come to be regarded as one of the team and would be sorely missed. However, it was clear that continuity was important. In cases where there were changes of physiotherapist, there were comments about the difficulties this raised. Care home managers and carers also valued the access to professional advice from the physiotherapists about their residents, which they seemed otherwise to find almost impossible to access. A further unexpected benefit of the visits of the physiotherapists was their role as an advisor or guide for care home staff negotiating access to other National Health Service services, including particularly the provision of appropriate mobility aids, but also, for example, providing advice on accessing mental health services.

Measuring changes in the home environment also proved challenging. The activity sweeps that we carried out in the case study care homes provided some insight into the variation between homes in patterns of activity (or inactivity), but failed to provide any evidence of change in activity over the duration of the intervention. Several care homes reported having regular exercise sessions at baseline but there was little evidence of such sessions in either control or intervention homes during the study. Indeed, some homes were seen to struggle to maintain a full activity programme, most commonly due to shortage of staff. Some care homes had activities co-ordinators appointed, but their effectiveness varied. Some were successful in promoting social interaction and activity, but others had many competing demands on their time (e.g. being a carer, errands) and were less effective as activities co-ordinators. Reported staff–resident ratio seems low across the day and in some cases it does seem that there were staff shortages.

There were two models of physiotherapist delivery: one used by the team in C&W and one used by the team in NEL. In C&W, the physiotherapists were employed directly by the University of Warwick to carry out the groups and usually had no other clinical commitments. This resulted in more continuity in provision and may also have meant that physiotherapists were less rushed and more likely to spend

time talking to the staff in the care homes. In NEL, there was a contract with the local National Health Service physiotherapy service to deliver the groups; this resulted in less continuity and, because the physiotherapists had many other clinical commitments, may have meant that they were less able to linger to talk to staff in the care homes.

Hypotheses derived from the process evaluation

One very striking finding from all the observational work was the very large variation between homes in culture, daily activity and staffing level (*Tables 15* and *16*). At the time the process evaluation was being completed and before seeing the final results of the study, we hypothesised that the magnitude of any effect from the OPERA intervention is likely to vary considerably between care homes and this variability will lessen any overall effect size. This is because there is enormous variation between the care homes in the level of engagement of care home staff with the residents, and in the opportunities for activity within the care homes (including the opportunity for trips and activities outside the homes). We also hypothesised that there would be a dose effect, such that the intervention will have a greater effect on those attending a greater number of group exercise sessions. A caveat is that such a dose effect may be hard to detect if it should be found that the absence of depression is a key determinant of whether or not residents were frequent attendees at exercise classes.

Long-term follow-up

The aim of this follow-up was to explore if any beneficial changes in culture within homes brought about by having participated in the OPERA intervention appear to be persistent. It is clear that OPERA was well liked by the care homes and it also seems that it has had a lasting impact. Some care homes have adopted versions of the OPERA intervention and in some cases are still getting input from OPERA-trained physiotherapists (privately). It seems that OPERA has impacted on outcomes far beyond those measured, with reports of 'happier' residents and services beyond those normally available in care homes. There is some evidence that staff have benefited from the training and interactions with the OPERA team but little evidence that OPERA has changed practice other than promoting some homes to employ an activities co-ordinator and inspiring some activities co-ordinators to do more.

In terms of the factors that support beneficial change it is hard to be conclusive. Care homes that have adopted OPERA have probably increased 'activity' and social interaction in their homes, which should benefit the residents. Staffing and funding are barriers to sustainability of programmes such as this, as homes have to prioritise limited budgets. In light of the ineffectiveness of the OPERA intervention on depressive symptoms, it is unlikely to be prioritised by care homes for funding.

Little change was seen in control homes. Staff who were interviewed were complimentary about the training and interactions with the OPERA team. As with the intervention homes, there were control homes with lots of activities for residents and some with very few.

Ethics

Cluster randomised trials and care home managers as gatekeepers for research in care homes

Cluster randomised trials raise particular ethical considerations due to lack of individual consent from all participants in the clusters for at least some aspects of the study. National and international ethics guidelines allow for waiver of consent in specific circumstances and cluster randomised trials are recognised as one potential justification for not obtaining explicit individual consent from all research participants.[225] However, the ethical justification for this must include strong scientific, practical or economic reasons as to why a cluster randomised design is necessary for the research question to be answered. This should include an explanation of the importance of the benefit of the research to the community in which the research takes place (and the individuals in that community), and that the potential harm to individuals within the cluster as a result of the research will be minimal. In addition,

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researchers should endeavour to seek individual consent whenever possible within the research project, and take steps to ensure appropriate cluster representation mechanisms to protect the interests of the cluster.[225] The OPERA intervention was a whole-home intervention and therefore individual consent for the intervention was not possible. Individual consent (or use of a personal consultee) was obtained for data collection at the individual level, although some pooled anonymous data on fracture rates were also collected at a home level without consent. The whole-home intervention, however, included a physiotherapist-led group exercise class that was offered to individual residents. All residents, whether or not they had consented to participate in data collection, were encouraged to attend the exercise classes but a refusal to attend, or a resident's request to leave during the class, was respected in line with normal clinical or home practice for group activities. Thus agreement to participate was obtained but there was no formal research consent process for participation in the intervention. Clinical records were kept for residents attending the exercise classes in line with Good Clinical Practice but these were kept separate from the research data for residents who had not consented to data collection. The complexity of the different levels of consent and arrangements for data confidentiality in OPERA reflects the endeavours of the research team to comply with guidance on cluster randomised trials and illustrates the need for researchers to consider the ethical and practical issues of consent carefully in relation to the specifics of the particular cluster randomised trial being conducted, as recommended by Eldridge *et al*.[98]

The care home managers in OPERA had a key role as both cluster guardians, providing consent for randomisation and implementation of the interventions, and gatekeepers to individual residents for recruitment for the assessments. The literature on cluster randomised trials emphasises the role of cluster guardians in protecting the interests of cluster members. Our interview data from care home managers suggest that they took this role very seriously, choosing to participate in OPERA because they considered that the intervention was likely to benefit their residents but also monitoring the researchers and controlling access to residents and relatives. The importance of care home managers and staff in the recruitment of participants to research in care home settings has been noted previously.[100] Reasons for excluding access varied and included the care home staff's views on a resident's capacity to consent, a resident's or their NOK's physical frailty, and the value they placed on their privacy. We found similar reasons in OPERA. There is a difficult ethical balance to be struck by care home managers in protecting their residents' interests while not denying them the opportunity to participate in research if they wish. Some home managers in OPERA were surprised when residents made decisions that were different to those they had predicted. On the other hand enthusiasm and a sense of ownership of the study could lead to care home staff putting implicit pressure on residents to take part, either in the intervention or the assessments. The care home staff we interviewed were aware of their position as trusted intermediary between residents and their families, and the research team, reassuring residents about the study but respecting their right to say no.

Assessment of capacity and the process of consent

A major challenge identified by the recruitment team in OPERA was the process of assessing capacity and gaining consent from individual residents for the assessments and access to medical records. The difficulty of obtaining valid consent when a substantial number of the relevant population have cognitive impairment was also identified by key informants in the ethics substudy. Notwithstanding that many OPERA participants had substantial cognitive impairment, 67% of participants were assessed as having capacity and gave consent. A similar mismatch between Mini Mental State Examination scores and capacity to consent was found by Warner *et al*.[101] Cognitive impairment, per se, is clearly not determinative of whether or not a person has capacity to make a specific decision such as consenting or refusing to participate in a research project. This poses serious challenges for recruitment staff, placing on them the burden of assessing capacity, ensuring that potential participants have the opportunity to exercise their autonomous wishes but not accepting agreement where there is no understanding. Assessing capacity in people with cognitive impairment is not straightforward, even when using standardised capacity assessment tools. Kim *et al*.[102] found marked variability in judgements of capacity of people with Alzheimer's disease to consent to research or to appoint a research proxy by experienced psychiatrists, including both between expert and within expert variability. An added difficulty is that capacity may

fluctuate, not only over the course of a longitudinal study, which is well recognised, but also from day to day, for example between assessment of capacity and taking of consent. Given the above difficulties it may need to be accepted that judgement of capacity to consent to research in this population may have to be different to those judgements in other populations.

The Mental Capacity Act 2005 specifies retention of relevant information as a component of the capacity test but does not require indefinite retention.[105] Usual practice for the research consent process is to provide participants with at least 24 hours between provision of information and obtaining consent to allow the person to consider the information at greater length and to minimise any likelihood of implicit coercion. This raises the question of whether or not the participant must retain the information over this period for them to be assessed as having capacity. There is no consensus on this issue among researchers or the research ethics community. Goodman *et al*.[100] have described conflicting views on retention by care home managers directly affecting their recruitment of residents with dementia into a research study. The experience in OPERA was that retention for 24 hours was often not achieved but that provision of information some time before the consent process was useful as a first step in the process of information consolidation and in the establishment of a relationship between the researcher and resident.

The importance of a relationship of trust between researcher and participant for the success of the consent process was a key finding of the ethics substudy. Older people are more likely to consent to take part in research if they know and trust the person giving them the information about the study. This will be particularly true for residents of care homes who have less independence and may have cognitive impairment, contributing to feelings of vulnerability. The presence of care home staff or relatives to support, reassure and advise residents can be seen as facilitating autonomous decision making, although the risk of implicit coercion must be borne in mind. However, the idea that the trustworthiness and familiarity of the researcher encourages consent, perhaps even when understanding of the research by the participant is limited, requires further exploration. Difficulties with the formality and complexity of research paperwork and a reluctance of older people to sign documents, or preferring a relative to sign on their behalf, raise further issues for researchers in developing an appropriate consent process that respects older people's preferences and experience.

Recruiting participants who lack capacity

Many research participants in care homes lack capacity to consent to take part in the research (33% of participants in OPERA). Prior to the implementation of The Mental Capacity Act 2005,[105] the legal position regarding research with adults who lacked capacity to consent was unclear for studies not covered by the Medicines for Human Use (Clinical Trials) Regulations (2004).[226] The Mental Capacity Act 2005[105] sets out the criteria under which such research may be lawful, which includes a requirement that researchers consult with either a personal or nominated consultee to seek advice on whether or not the person who lacks capacity would have objected to taking part in the research if they were able to consent. OPERA commenced in 2007, shortly after implementation of The Mental Capacity Act 2005,[105] when there was still some confusion among researchers and research ethics committees regarding the process of involving personal and nominated consultees for people who lacked capacity to consent to research.[106,107] Our recruiting staff found the process of identifying and approaching personal consultees straightforward but very time-consuming, an experience shared by other researchers. The recruitment rate through personal consultees was disappointing (48%), with 23% not responding to letters of invitation. In addition, we were unable to identify anyone willing to be a nominated consultee when no personal consultee was identified. The difficulty in engaging both personal and nominated consultees for conducting research will pose a challenge for future research. A substantial proportion of the relevant population could be excluded from participation in research studies. This could potentially affect generalisability of results, although the nature of the OPERA results is such that this would be unlikely in this case.

The difficulties of identifying appropriate proxy decision-makers for consent to research in the emergency setting has led to the recognition of waiver of consent for this type of research in some research ethics guidelines.[103] However, in non-emergency settings the argument of urgency does not hold and the

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requirements of the relevant legislation (clinical trials regulations or The Mental Capacity Act 2005[105]) must be fulfilled. In many settings identification of a personal consultee will be straightforward as they are likely to be living with the person or in close contact. Care home residents, however, may not have a readily identifiable person to consult, for example if they have no close family or friends and their designated NOK is not in regular contact. Two UK studies that specified recruitment rates for care home residents through proxies or consultees reported levels of 61% and 41%, respectively.[100,108] Recruitment of research participants who lack capacity by using consultees or proxy decision-makers raises a range of legal, ethical and practical issues that may be context dependent and that require further exploration.

The OPERA study met the criteria for waiver of consent in that (1) it had appropriate approval from a multicentre research ethics committee; (2) the intervention was a whole-home intervention, with the exercise classes including people who had cognitive impairment that may have affected their capacity; (3) it was not possible to provide the intervention selectively to residents with capacity and all residents had the potential to benefit without a disproportionate burden of taking part; (4) residents in the control homes, and those taking part in the assessments, were at negligible risk of harm; and (5) the research provided knowledge of the effect of the intervention on depression in residents of care homes, a condition that either affected or had the potential to affect all participants.

Strengths and weaknesses

Particular strengths of this study are that we have recruited a large sample of residents from a representative sample of care homes. This indicates that these findings are generalisable to UK care homes. Although we recruited a smaller proportion of residents than planned (38% vs 50%), the results will be applicable to the overall care home population; as the intervention was ineffective in the more capable and motivated residents who joined the study it is unlikely that it would have any positive effect on those who were too ill to participate. We achieved good follow-up rates. Within the limitations of the outcome measures used we have achieved very precise estimates of the possible effect of the OPERA intervention. However, the study is limited by the sensitivity of the measures used and it might be that other, more sensitive, outcome measures might have shown a benefit, particularly on health-related quality of life.

Any outcome measure measuring depression in a trial focusing on depression in a frail population such as ours should ideally be short, sensitive to change, have face validity, have a relative lack of directly or indirectly somatic items that are likely to be affected by physical health problems, and should have concurrent validity against a gold standard measure (expert clinician judgement). The Geriatric Depression Scale-15 has been shown to be sensitive to change.[121] The full Geriatric Depression Scale–30, from which the shorter 15-item version is drawn, has been shown to demonstrate significant change in intervention among a very similar population of Australian care home residents.[15] It has been used as a primary outcome measure in trials of interventions for depression among older people.[95,124,227–229] In Conradsson *et al*.[95] the Geriatric Depression Scale-15 was used as the primary outcome measure in a trial of a reasonably similar intervention (exercise) and setting (residential care homes) and range of cognitive impairment. At the core of depressive disorders are low mood, reduced energy and reduced enjoyment; the Geriatric Depression Scale–15 items have demonstrated ability to distinguish older people with depressive disorder from those without and despite the atypical situation of care home residents, we believe that any intervention with antidepressant effect should be able to show a reduction on Geriatric Depression Scale-15 symptoms.

Potential alternative outcome measures for trials among people with depression include The Montgomery–Åsberg Depression Rating Scale (MADRS),[230] the Hamilton Depression Rating Scale (HDRS),[231] Center for Epidemiologic Studies Depression Scale (CES-D)[232] and the Cornell Scale.[233] Importantly, very similar outcomes have been found for the Geriatric Depression Scale-15 against alternative established measures of depression, including MADRS and CES-D,[229] and against clinician ICD-10 diagnosis[149] of depressive disorder.[227]

Against other potential measures the Geriatric Depression Scale-15 is significantly shorter than the MADRS,[230] the HDRS,[231] CES-D[232] and the Cornell Scale.[149] Of these scales, the Cornell Scale[149] includes 3/19 items that are indirectly affected by physical disorder (appetite loss, weight loss and lack of energy), the MADRS[230] includes items on lack of sleep and reduced appetite, the HDRS includes – within its 17 symptom areas – three directly somatic items including gastrointestinal, genitourinary and general somatic symptoms, while the CES-D[232] includes one item on lack of appetite.

What was perhaps surprising in the OPERA study was the degree of frailty and cognitive impairment among potential participants, which limited the pool of potential participants who were able to complete the primary outcome measure. Nevertheless, with the substantial numbers in the analyses with full data on Geriatric Depression Scale-15, the choice of instrument was appropriate for this population and the findings are robust.

The primary hypothesis for this study was that promoting physical activity might reduce depressive symptoms. Depression rating scales are, however, only one way of measuring low mood. Since we designed this study there has been a developing interest in well-being as a health outcome. The observational work in our process evaluation suggests that although we did not change any of our objective outcomes, the OPERA intervention did effect some changes within the care homes and we had good participation in the group exercise sessions. It may be that if we had measured well-being instead of either depression or health-related quality of life we might have had a positive impact. Although measures are becoming established for the measurement of well-being in the general population, for example the Warwick–Edinburgh Mental Well-being Scale (WEMWBS),[234] these are not yet well established in care home residents. The social well-being of nursing home residents (SWON-scale) is a candidate that was developed during the lifetime of the OPERA study and might be a suitable measure.[235] Furthermore, we have not measured the effect that our intervention may have had on the care home staff. It was clear from our observations in the homes that the level of interest in the work and training of care home staff was greater than that which they normally experienced. The staff also particularly valued the contact with the OPERA physiotherapists. We have not been able to measure, and account for, these effects in our analyses.

We were unable to collect Short Physical Performance Battery data at the 6-month follow-up data when we changed to collecting 6-month outcomes on all participants rather than just those with depression. This was because much of this was a particularly time-consuming test taking around 15 minutes per participant; this was substantially greater than anticipated at the time we designed the study. With the help of research nurses from the primary care and mental health research networks we were able to collect these data at baseline and 12 months but adding in 6-month data would have increased the workload above capacity at a time when we were at our maximal home recruitment rate. This does mean, however, that we are not able to examine if changes in Short Physical Performance Battery at 6 months mediate any possible changes in depressive symptoms at 12 months.

We have developed a high-quality, theoretically informed intervention that was popular with care homes. We were able to deliver this satisfactorily within homes without any related serious adverse events.

Overall we believe this is a very robust study that has obtained a clear answer to the research question set and has helped to develop our understanding both of how to undertake research in a care home environment and how care is delivered in this environment.

Conclusions

Implications for health care

There is a high prevalence of depressive symptoms in those living in care homes; much of this is unrecognised. There is a clear need for research to reduce the burden of depression in this group, many of whom are extremely frail and have a very limited life expectancy. It is possible to recruit care home

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residents with substantial cognitive impairment to studies; however, there remain some structural problems for obtaining agreement from those whose NOK cannot be contacted to take part in research. The OPERA intervention, targeted at improving physical fitness and social interaction, could be delivered safely and to a high standard over a prolonged period. Both residents and care home staff valued participation in the study, and also the activities of the physiotherapists in promoting physical activity within the homes. There was less evidence of achieving a cultural shift in the attitude towards physical activity in care homes. In some homes, however, we were able to achieve some sustained changes that were maintained after the end of the study. The OPERA intervention had no positive effect on any of our primary or secondary outcome measures and it was dominated by the control intervention in the health economic analysis. This evidence does not support the use of moderate-intensity functional exercise programmes, such as the OPERA intervention, to reduce depression in care home residents.

Recommendations for future research

1. A cluster randomised trial of care home staff training in basic psychological/behavioural techniques may include cognitive approaches (positive thinking/installing hope) and behavioural approaches (suggesting positive activities). This could also include case finding followed by referral for advice on optimisation of drug regimen.
2. Development and evaluation of measures of wellness and health utility that are specific for care home populations, suitable for completion either by residents or by proxies on their behalf.
3. Observational studies to identify modifiable factors that impact on the wellness of care home residents.
4. Work to further develop the evidence base of best practice for recruitment of those who lack capacity, in a variety of clinical situations, to take part in clinical trials, informed both by ethical and legal analysis and empirical data from key stakeholders including trial participants or their NOK.

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Contribution of authors

Martin Underwood (Professor of Primary Care Research, University of Warwick) was the lead applicant and chief investigator for the OPERA trial. Substantial contributions were made to the overall design of the study, the statistical analysis plan, and the writing of the background, methods, results and discussion sections of the report.

Sallie E Lamb (Professor of Rehabilitation and Director of CTU, University of Warwick) was a co-applicant, led the design of the OPERA exercise intervention and contributed to the writing of the background and methods sections of the report.

Sandra Eldridge (Professor of Biostatistics, Queen Mary, University of London) was a co-applicant, lead trial statistician, contributed to the statistical analysis plan and writing of the results section of the report.

Bart Sheehan (Associate Clinical Professor of Old Age Psychiatry, University of Warwick) was a co-applicant, designed the depression awareness component of the OPERA trial intervention and contributed to the writing of the background, methods and discussion sections of the report.

Anne Slowther (Associate Professor of Clinical Ethics, University of Warwick) was a co-applicant, designed the ethics substudy and contributed to the writing of the methods and discussion sections of the report.

Anne Spencer (Co-applicant, Queen Mary, University of London) was a co-applicant and health economics lead. She contributed to the health economic analysis plan and commented on final draft of the report.

Margaret Thorogood (Professor of Epidemiology, University of Warwick) was a co-applicant and a joint process evaluation lead, and contributed the writing of the background, methods, results and discussion section of the report.

Nicky Atherton (Clinical Research Fellow, University of Warwick) designed, led and delivered the OPERA exercise intervention, and contributed to the writing of the background, methods and results section.

Stephen A Bremner (Lecturer in Medical Statistics, Queen Mary, University of London) made a major contribution to the statistical analysis plan, undertook the analysis of the trial data and the writing of the results section of the report.

Angela Devine (Health Economist, Queen Mary, University of London) produced the health economics analysis plan, undertook the health economics analysis and wrote the health economics section of the report.

Karla Diaz-Ordaz (Research Fellow, Medical Statistics, Queen Mary, University of London) contributed to the statistical analysis plan and the health economic analysis plans, and assisted in the analysis of the trial and health economic data and the writing of the results section of the report.

David R Ellard (Senior Research Fellow, University of Warwick) contributed to the design of the process evaluation, collected the process evaluation data, undertook the qualitative and quantitative analyses of the process evaluation, and contributed to the writing of the background, methods, results and discussion sections of the report.

Rachel Potter (Research Nurse, University of Warwick) led the recruitment of care homes and participants for the trial and contributed to the writing of the methods and results sections of the report.

Katie Spanjers (Research Associate, University of Warwick) assisted in the delivery of the OPERA intervention, made a minor contribution to the statistics analysis plan, arranged the collection and undertook the analyses of the Secondary Uses Services data and contributed to the writing of the methods, results and discussion section.

Stephanie JC Taylor (Professor of Public Health and Primary Care, Queen Mary, University of London) was a co-applicant and Principal Investigator for London, designed the whole-home approach of the OPERA trial, was joint lead for process evaluation and contributed to the writing of the background, methods, results and discussion sections of the report.

Other members of the trial team

Amy Campbell (Trainee Clinical Trial Manager, University of Warwick) provided administrative support to the OPERA team, and was responsible for the collation and formatting of the report. Sarah Duggan (Warwick Clinical Trials Unit Manager, University of Warwick) co-ordinated the provision of administrative support for the OPERA team members based at the Warwick Clinical Trial Unit, and proofread the report. Suzanne Parsons (Research Fellow, Queen Mary, University of London) was a co-applicant and contributed to early design of the process evaluation. Emma Withers (Clinical Trial Manager, University of Warwick), Maryam Zare (Clinical Trial Manager, University of Warwick), Jenny Exton (Trainee Clinical Trial Manager, University of Warwick) and Nilu Ahmed (Research Fellow, Queen Mary, University of London) undertook the initial set-up of the trial.

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OPERA intervention team

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1. Atherton N. Could exercise combat depression in nursing and residential homes? *J Dement Care* 2008;**39**.
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Appendix 1 Scoring and algorithm for Geriatric Depression Scale-15

GDS scores for home staff

Item	☺	😐	☹
15	0–4	5–10	11–15
14	0–4	5–10	11–14
13	0–4	5–9	10–13
12	0–3	4–8	9–12
11	0–3	4–7	8–11
10	0–2	3–6	7–10

Answer <10 not given to staff

☺	No response needed
😐	Encourage the resident to take part in activities – monitor and refer to GP if does not improve
☹	Consider referral to GP or Community Mental Health Team for further assessment

GDS, Geriatric Depression Scale; GP, general practitioner.

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Appendix 2 Level 1 OPERA exercise routine with links to music

Section	Song title	Artist	Duration	Activity
Warm-up: tracks 1–3 (7 minutes)				
1	'Memories are made of this'	Dean Martin	2.16	Toe tapping, alternate feet forwards and to side, plus heel lifts, bilateral, gentle kicks – whatever combination suits
2	'I whistle a happy tune'	Bing Crosby	2.45	Alternate shoulder girdle movements, slow neck movements, gentle alternate arm stretches
3	'Swinging on a star'	Bing Crosby	2.30	Kicking large ball/passing football around group, throwing and catching ball
Progressive resistance exercise: tracks 4 – 12 (15 minutes)				
4–12	Mixed instrumental tracks	Practice tap	15.82	Hand squeezes with one weight Single elbow bends – set on one side, change to other hand and repeat Alternate arm upwards with elbow bent – weight use as above Alternate or single sets of knee extension – weight on each leg Alternate or single sets of knee lifts – weight on each leg
Aerobic: tracks 13–17 (15 minutes)				
13	'King of the road'	Roger Miller	2.29	Soft elastic – cycling forwards and backwards, slow and fast, larger circles
14	'Green, green grass of home'	Tom Jones	3.06	Soft elastic – arms up and down (no more than 10 reps), reaching down to floor in unison
15	'Don't fence me in'	Bing Crosby	3.07	Soft elastic – passing elastic round one way then the other, rowing
16	'The great pretender'	The Platters	2.40	Arm swings as walking then with trunk movements
17	'Living doll'	Cliff Richard	2.37	Marching on the spot, kicking (seated can-can!)
Cool down: tracks 18–21 (8 minutes)				
18	'I'm into something good'	Herman's Hermits	2.34	Toe tapping, slow knee straightening with ankle/foot circles
19	'What a wonderful world'	Louis Armstrong	2.22	Seated slow upward side stretch, then down to sides
20	'You need hands'	Max Bygraves	2.41	Hand and arm twists, hands open and close
21	*Canon in D*	Pachelbel	4.53	Seated slump and straighten, some deep breaths to end

Participants seated for all sections.

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Appendix 3 Statistical analysis plan

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Barts and The London School of Medicine and Dentistry

Pragmatic Clinical Trials Unit

OPERA

Statistical Analysis Plan

Approved Version 1.1: 15/09/11
Version 1.0: 11/07/2011

Approved by:
Signature: _____ Date: ___/___/_____
Approved by:
Signature : _____ Date: ___/___/_____

Trial Statisticians: Stephen Bremner, Sandra Eldridge, Karla Diaz-Ordaz

This document was created based on the Mental Health & Neuroscience Clinical Trials Unit (MH&N CTU) Analysis Strategy template (version 1.5; 13/02/2008) based on an earlier version developed by Rebecca Walwyn and Sally Lee.

PCTU

A randomised trial of an exercise intervention for older people in residential and nursing accommodation

Contents

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PCTU

1 INTRODUCTION

1.1 Purpose of statistical analysis plan

The purpose of this document is to provide details of the statistical analyses and presentation of results to be reported within the principal paper(s) of the OPERA trial. Subsequent papers of a more exploratory nature (including those involving baseline data only) will not be bound by this strategy but will be expected to follow the broad principles laid down in it. Any exploratory, post-hoc or unplanned analyses will be clearly identified in the respective study analysis report.

The structure and content of this document provides sufficient detail to meet the requirements identified by the International Conference on Harmonisation (ICH) and the PCTU SOP (PCTU/07).

The following were reviewed in preparation for writing this document:
Trial application submitted *15th March 2006*
ICH Harmonised Tripartite Guideline: Statistical Principles for Clinical Trials
ICH E9 Guidance on statistical principles for clinical trials
ICH E3 Structure and content of clinical study reports
CONSORT guidelines for the reporting of randomised trials, including extensions to cluster-randomised trials and trials of non-pharmacological treatments

1.2 Members of the writing committee

Stephen Bremner, Karla Diaz-Ordaz, Sandra Eldridge and Martin Underwood were primarily responsible for writing the Statistical Analysis Strategy with Stephen Bremner responsible for writing the computer code implementing the analysis strategy, and implementing the strategy at the point of analysis. A senior statistician (Richard Hooper) within the Pragmatic Clinical Trials Unit (PCTU) also reviewed and signed off the analysis strategy prior to a final check by the TSC statistician, Sally Kerry. If decisions are required during the course of the analysis they will be discussed with a statistician within the PCTU, independent of the trial.

This document has been developed prior to examination of trial data and will not be implemented prior to final approval. Much of it is derived from the research protocol (Underwood, 2010).

1.3 Summary

Exercise is a promising non-medical approach to the management of depression. Plausible mechanisms for its possible effect include improved social contact, a diversion from negative thoughts, and the physiological effects on neurotransmitters such as monoamines and endorphins. In this trial we are testing a pragmatic intervention, reflective of current best practice, consisting of training for residential or nursing home (RNH) staff to support the building of safe physical activity into the RNHs' normal routine; and a twice-weekly formal exercise class led by a specially trained physiotherapist.

This is a cluster-randomised trial, with the RNH as the unit of randomisation and residents as the unit of assessment, to study the impact of a whole RNH intervention to increase exercise on the prevalence of depression and the remission of existing depression.

1.4 Changes from planned analysis in the protocol

We will use mixed models rather than generalised estimating equations (GEEs) for the analysis. One motivation for this is the less strict assumption about missing data made (i.e. data missing at random rather than missing completely at random).
One of the co-primary outcomes was changed to a secondary outcome with approval of the TSC [See TSC minutes from 22/09/2009]. Following an early decision [See TMG minutes from 01/04/2009] part-way through the trial to exclude dementia homes, only one dementia home was included.

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There was therefore only one dementia-specialist home in the study, and though strictly speaking, dementia-specialist status was included in the minimisation algorithm, it effectively had no influence in the randomisation schedule (as there was no adjustment done on "dementia specialist" status homes between the two arms). As such, we need not adjust for it.
Exclusion criteria for homes were also modified from protocol (minutes 11/02/2009) though this should not affect planned analyses.

2 STUDY OBJECTIVES AND ENDPOINTS

2.1 Study objectives

2.1.1 Primary objectives

Our primary objective is to compare depression levels between intervention and control homes. See Section 2.2.1 for the definition of depression used in this study. Three comparisons will be made:

(a) Compare the prevalence of depression in intervention homes with that in control homes in all residents contributing data twelve months after homes were randomised and who had also been resident by time of the home's nine month assessment **(cross-sectional comparison)**.
(b) Compare the change in number of depressive symptoms at 6 months in residents who were depressed at baseline **(cohort comparison)**.
(c) Compare the change in number of depressive symptoms in residents who were present at baseline and at twelve months after randomisation. **(cohort comparison)**

We distinguish between the **cross-sectional analysis,** required for objective (a), and **cohort analysis** required for the objectives (b) and (c).

For the **cross-sectional analysis,** outcome data have been collected on the majority of residents in the homes at 12 months. Those residents who had entered a home after a pre-specified cut-off date have been excluded on the grounds that they would not have experienced a sufficient dose of the intervention. This cut-off date was around three months prior to the outcome data collection in most homes but between two and three months prior to outcome data collection in seven homes in which final outcome data collection occurred during the 12th month rather than at the end of the 12th month.

In the **cohort analyses**, a different, but overlapping set of residents (those who had baseline data collected pre-randomisation) provide baseline data. In the cohort analysis those who provide outcome data are the same individuals who provide baseline data prior to randomisation.

This distinction, between cross-sectional and cohort analyses, also applies to secondary outcome analysis and we describe analyses more fully later in this document.

2.1.2 Secondary objectives

To compare the following between intervention and control arms:

- remission of depression by 6 months,
- number of depressive symptoms at 12 months

- cognitive function (at 6 and 12 months),
- health-related quality of life (at 6 and 12 months),
- mobility and exercise tolerance (at 12 months),
- chronic pain (at 6 and 12 months),
- fear of falling (at 6 and 12 months),
- social engagement (at 6 and 12 months).

For all residents with consent/assent to examine the medical and care home records:
Present descriptive statistics on the prescribing of antidepressants
Present descriptive statistics by arm on hospital admissions.
Apart from remission of depression, the primary endpoint will be 12 months for each of these secondary outcomes.

2.1.3 Safety Objectives

To compare the following between intervention and control arms:
(a) Summarise incidence of injurious falls as indicated by peripheral fractures, summarised by home
(b) Compare mortality rates in intervention and control homes.

2.1.4 Exploratory objectives

Whilst listed here, these will not be dealt with in this analysis plan and will be considered in a separate analysis plan to be written after the main analysis outlined in this plan has been completed.
To assess the effect of dose of exercise intervention classes on outcomes.
To assess whether social engagement and prescribed antidepressants (DDD) mediate the effect of exercise on depression and cognition.

2.2 Outcome measures

The following table (table 1) details the primary outcome measure (GDS) and various secondary outcome measures, their data types, and at which end-points they apply.

Table 1: outcomes, end-points and data types

	Outcome measure	At 12 months in all present at end of study	Change at 6 and 12 months in all present at baseline	Change at 6 months in those depressed and present at baseline	Remission of depression at 6m in those depressed at baseline	All residents who provided consent at any time
primary	GDS	dichotomous	continuous (12 months)	continuous		
secondary	GDS	continuous			dichotomous	
	MMSE	continuous	continuous			
	EQ-5D *	continuous	continuous			
	SPPB	continuous	continuous**			
	Pain rating today	ordinal (5 points)	ordinal (5 points)			
	Social engagement	ordinal (6 points)	ordinal (6 points)			
	Fear of falling	dichotomous	dichotomous			
safety	Peripheral fractures					rate
	All-cause mortality					rate

* both proxy and self-completed
** at 12 months only

2.2.1 Primary outcomes

The primary outcome measure is the Geriatric Depression Scale 15 (GDS-15). This brief scale/score consists of 15 simple yes/no questions and has been well

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validated in residential situations. It avoids using potentially somatic features of depression which may be misleading in this age group, focusing more on mood and functional symptoms of depression.

The GDS-15 can be interpreted as an indication of the presence/absence of depressive mood, though this is not a substitute for proper clinical diagnosis. A score of five or above appears to give the best sensitivity and specificity.

- Binary outcome: For the purpose of these analyses, we class a resident as 'depressed' if they have a GDS-15 score of five or above when answering at least 13 items. For those who answered less than 13 items but at least 10, we apply the following rules:
  "Depressed"=Yes if GDS≥4 if they answered 11 or 12 items.
  "Depressed"=Yes if GDS≥3 if they answered 10 items.
  GDS-15 scores are not valid if less than 10 items are answered, in which case they are set to missing.

- Continuous outcome: GDS-15 for the second and third co-primary outcomes
  2nd: change in depressive symptoms* at 6 months in those residents depressed at baseline.
  3rd: change in depressive symptoms* at 12 months in those residents present at baseline.
  * Each item is a depressive symptom (either present (scores 1) or absent (scores 0)).
  If the number of items completed, n is such that 9<n<15, the total score is to be rescaled i.e. GDS' = 15*GDS/n

2.2.2 Secondary outcomes

All of these have both 12-month (primary) (except remission of depression) and 6-month endpoints.

- Remission of depression at 6 months in those depressed at baseline (measured using GDS-15).

- Depressive symptoms at 12 months (measured using GDS-15)

- Cognitive function: measured using the Mini Mental State Examination (MMSE) (treated as a continuous variable). *NB if 15 or more items are missing, the total score should be set to missing.*

- Mobility: the effect of the programme on mobility is assessed using the Short Physical Performance Battery (SPPB) as a continuous variable.

- Falls:
  a) Fear of falling by asking participants "Are you afraid of falling?" requiring only a simple yes/no response from participants.
  b) Rate of peripheral fractures as a marker for injurious falls identified from both RNH (aggregated at the home level) and Primary Care Trust records (at patient-level).

- Pain: Pain today, on a five-point numerical rating scale.

- Health-related quality of life as measured by (a) self-reported EQ-5D (b) proxy EQ-5D

- Social engagement, measured by the Social Engagement Scale designed for use in nursing and residential home care gives an indication of the involvement of a resident in activities within a nursing or residential home. The Social Engagement Scale uses six items from the Minimum Data Set residential assessment instrument (MDS-RAI).

  The following outcomes will be described but will not be subject to formal statistical modelling.

- Medication use: regular medications data collected from RNH records at baseline, three, six, and nine months after randomisation/study entry, and at the end of the study. For anti-depressants, other psychoactive drugs, NSAIDs and other analgesics, we will convert these into the number of defined daily doses (DDD) used over one year (http://www.whocc.no).

- Hospital admissions: we will extract data on cause and duration of any hospital admissions during the study period from participants' hospital records. We will code these admissions into Diagnosis Related Groups (DRGs) or Health Resource Groups (HRGs) as appropriate to identify any fractures, and for the economic analysis (see separate health economics analysis plan).

2.2.3 Safety outcomes

Deaths

Records of all those from whom we obtained consent/assent to examine were flagged at the Medical Research Information Service (MRIS), and assessed in order to identify any differences in mortality between the two groups. For those who died in their RNH we asked the home for a brief description of how they died; for those who died in hospital we extracted this information from their hospital records. Medical members of the study team, blind to participants' allocation, assessed these reports. In the event that any death was deemed to be exercise-related on the basis of these brief reports, we made a detailed assessment as to whether it was related to our programme.

Peripheral fractures

Data on these were collected from two sources (i) aggregated at home level and events counted in all residents, not only those who consented/assented to their data being used. (ii) at the individual level in all residents who provided consent/assent at any time for their medical records (held by the PCT) to be accessed.

3 STUDY METHODS

3.1 Overall study design and plan

Target for randomisation:	77 RNHs (78 actual)
Date of first randomisation:	19th February 2009
Date of last randomisation:	30th April 2010
Trial design:	cluster randomised, parallel group
Blinding:	Clinical researchers were blinded to allocation to interpret records on deaths.

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Randomised Interventions: exercise programme + depression awareness programme vs. control intervention (Depression awareness programme)
Planned allocation ratio: 2 intervention homes : 3 control homes

3.2 Selection of study population

3.2.1. Selection of individuals
Inclusion criteria for residents:

- Permanent resident in RNH
- Aged 65 or over
- Consent/assent to be assessed
- Consent or assent to participate in baseline assessment or to provide medical record data
- We are including non-depressed residents in the exercise programme

Exclusion criteria for residents:

- Problems communicating by any means
- Non-English speakers for whom a translator is not available
- Terminal or other serious illness
- Those with a very limited life expectancy

3.2.2. Selection of clusters (i.e. homes):
All RNHs in outer NE London (Barking & Dagenham, Havering & Redbridge and Waltham Forest), NHS Coventry, NHS Warwickshire, and Coventry & Warwickshire Partnership Trust were invited to participate. There are over 80 RNHs in Barking & Dagenham and neighbouring Havering. There are around 135 RNHs in Coventry & Warwickshire Partnership Trust's locality. One home in Essex was also included.

Inclusion criteria:

- Initially homes with more than 15 beds, but 70 or fewer beds; during the study (TMG minutes 01/04/2009) this was revised to 20-60 grounded at the lower end by our recruitment experience and at the upper limit by practicalities of delivering the intervention in large homes.

Exclusion criteria:

- Homes catering mostly to non English-speaking residents.
- Any homes with fewer than 16 beds (25 homes, of which none are dementia homes).
- Any dementia homes with fewer than 50 beds. However, given the time and cost involved in assessing dementia-specialist home residents, and delivering the intervention, only one such home was recruited.

3.3 Method of treatment assignment and randomisation

Randomisation was stratified on centre (i.e. London or Warwick) and RNHs (clusters) were allocated using minimisation with a random element (70% probability that home will be allocated to group that minimises the imbalance. We minimised by size and type of home (local authority/voluntary/private & care home/private & nursing home)

Table 2 Design variables

factor	Number of categories	Details of Categories
Centre	2	London or Warwick
Home type	4	Local authority, voluntary, private & care home, private & nursing
Size	2	≤32, >32 beds

The randomisation was carried out by an independent statistician at the PCTU using the Minim programme written by Stephen Evans, Simon Day and Patrick Royston available from http://www-users.york.ac.uk/~mb55/guide/minim.htm.
Research nurses provided details of a home to be randomised by email directly to the independent statistician. Once the home was randomised, the research nurse was notified by e-mail within a week of their request.

3.4 Treatment masking (blinding)

All baseline assessments for the cohort comparison were collected blind to treatment allocation. Our primary measure, GDS-15, and other questionnaire data at follow-up were collected by research nurses not blinded to the RNH's allocation status. Our interpretation of cause of death data was blind to allocation.

For new residents joining the study after randomisation allocation concealment was impossible because all RNH staff and study staff visiting the RNHs were aware of the home's allocation. We tried to protect against recruitment bias resulting from lack of allocation concealment by ensuring that we were aware of all new residents and reasons for exclusion from the study were monitored.

We will compare, descriptively or by graphical methods, the GDS-15, MMSE and SPPB scores of residents recruited into the study post randomisation with those recruited pre-randomisation, by arms, for evidence that (a) residents recruited post-randomisation differ between arms and (b) the ratio of participants assenting to those consenting changes over time. We hypothesise that less effort may be made to recruit residents at 9 months than at 6 months, than at 3 months, than pre-baseline. Assent requires more effort to attain than consent and so this ratio may decrease over time.

3.5 Sample size determination

Because few RNH residents were thought to move out of residential accommodation we anticipated good follow-up rates. This population has a high mortality, up to 34% per year (Rothera, 2002); additionally, for some, their health will deteriorate so that they are no longer able to complete some, if not all, of the follow-up assessments.
All of our sample size estimates included an inflation factor to account for clustering effects of residents within RNHs.
A conservative value of 0.05 for the ICCs for the different outcomes was used. The inflation factor also depends on the average cluster size and the variation in cluster size. Our average cluster size is different for our three outcomes relevant for the original sample size calculations outlined in table 3.

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Table 3 Sample size calculations in the original protocol

	A) To show a reduction in the proportion of participating residents depressed (GDS-15 ≥ 5) at the end of the study from 40% to 25%	B) To show an increase in the remission rate after six months from 25% to 40% in those depressed at baseline	C). To show a mean reduction in GDS-15 score of 1.2 after twelve months in those depressed at baseline
Power	80%	80%	80%
Significance	5%	5%	5%
Simple sample size	343	343	280
Mean cluster size at follow-up	15.0	5.4	4.5
Inflation factor	1.7	1.22	1.175
Total number required at follow-up	583 with complete assessments	418 with depression at baseline & complete assessments	330 with depression at baseline & complete assessments
RNHs required	39	77	74

An interim sample size calculation revealed that we had a smaller than anticipated cluster size and in order to be sufficiently powered for outcome B, we would require an additional 24 RNHs (see Table 4). The HTA was not willing to fund an extension. With the agreement of the TSC, we changed outcome B to be a secondary outcome. We also added outcome C (table 4) which is similar to outcome C (table 3), but measured at 6 months rather than 12 months, to compensate for the smaller than expected cluster size, and the greater loss to follow-up than anticipated. Note, outcome C in table 3 becomes outcome D in table 4.

Table 4. Revised sample size calculations

ICC = 0.053	A) To show a reduction in the proportion of participating residents depressed (GDS-15≥5) at 12 months from 46.1% to 28.8%	B) To show an increase in the remission rate after six months from 25% to 40% in those depressed at baseline	C) To show a mean reduction in GDS-15 score of 1.2 after 6 months in those depressed at baseline: from 7.27 to 6.07 (SD=2.21)	D) To show a mean reduction in GDS-15 score of 1.2 after 12 months in all participating residents: from 4.5 to 3.3 (SD = 3.12)
Power	80%	80%	80%	80%
Significance	5%	5%	5%	5%
Simple sample size	281	342	112	224
Anticipated loss to follow-up	10%, 30%	20%	20%	30%
Mean cluster size at follow-up	9.6, 7.5	3.9	3.9	7.5
Inflation factor	1.46, 1.34	1.16	1.16	1.34
Total number required at follow-up	409 (378) with complete assessments	396 with depression at baseline & complete assessments	130	301
RNHs required	43	101	33	41

4 DATA COLLECTION

4.1 Baseline

The following measures are assessed by asking the resident directly: GDS-15, EQ5D, MMSE, fear of falling, current pain, and a brief physical assessment (SPPB).

The following measures are assessed by asking the carer:
Barthel Index, (proxy) EQ-5D, Social Engagement Scale

We collected demographic data (age, sex, ethnicity, age left school (proxy for social class)) and data on length of residence, fee status and current medication from the RNH records for all those for whom we have consent/assent to access their records.

4.2 Follow-up

See the individual case report forms for a full list of all variables which were measured.
The complete list of case report forms is as follows (grey titles irrelevant for this analysis plan):

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Home Data Collection
Randomisation Record
Next of Kin Expression of Interest Form
Initial Assessment
Consent Form (Resident)
Assent Form
Assent Form (Routine Data Only)
Baseline Data Collection Form 1 (Medical Records)
Baseline Data Collection Form 2 (Carers)
Event Notification
Study Register
Follow-Up Data Collection (6 months)
Follow-Up Data Collection (12 months) [Different format to the other follow-up forms (contains a field for the resident's NHS number)]
Follow-Up Data Collection Form 2 (Carers) (at 3, 6, 9 and 12 months)
Follow-Up Record Examination Data Collection
Physical Activity Assessment
Assessment Register
Group Profile (Baseline)
Group Profile (Handover)
Recommendation Form
Supporting Information for OPERA Research Physiotherapist's referral recommendations
Group Attendance Register
Clinical Record Form
Depression Awareness Training Follow-Up
Carer Training Attendance Sheet
Depression Awareness and Activity Training Follow-Up
Depression Awareness Training Feedback (same form for intervention and control)
Physiotherapist Recording Form
Depression Score Notification

4.3 Timing of data collection

Residents, recruited between January 2009 and May 2010, underwent baseline assessments by the recruitment team to establish eligibility and once all had consented/assented/refused, the whole home was randomised to either the exercise intervention or depression awareness training. Follow-up visits were made to all homes at 3, 6, 9 and 12 months post-randomisation. Repeated attempts within one month of the assessment date were made as necessary by the recruitment team to obtain data from participants who were unavailable for assessment at the fixed follow-up points (i.e. at 3, 6, 9 or 12 months). At these fixed follow-up points (except 12 months), residents new to the home since the last visit were invited to participate, baseline assessments were performed and consent/assent was sought. NB this does not include existing study participants who had moved into the home during this time. Furthermore, residents that had previously refused consent/assent could change their mind and become study participants subject to a satisfactory baseline assessment and consent/assent being given.

5 GENERAL ISSUES FOR STATISTICAL ANALYSIS

All analyses will be conducted two-sided and significance interpreted at the 5% level.

5.1 Blinding of the statistical analysis

The study statistician (SB) was not blinded in this study because of (a) the allocation ratio making obvious which group was which and (b) SB handling data to produce the DMC reports.

5.2 Analysis populations

We are conducting three distinct types of statistical analyses within this trial: **cross-sectional** analyses, **cohort** analyses and analyses on **safety** outcomes. Here we define the populations pertaining to each. We define an Intention to Treat Population (ITT) although no strict ITT analysis is planned as part of the main analysis of this trial. We do not describe a per protocol population – no per protocol analyses are planned.

5.2.1 Intent-to-treat analysis population

For each effectiveness outcome, populations for the cross-sectional and cohort analyses are defined as follows:

(a) Cross-sectional analyses –
A strict intention to treat population is difficult to define in a cluster randomised trial, as our intention was to treat all those resident in the home, but we can only include those who agree to participate. For the **cross-sectional analysis,** outcome data have been collected on the majority of residents in the homes at 12 months. Those residents who had entered a home after a pre-specified cut-off date i.e. after 9 months post-randomisation, have been excluded on the grounds that they would not have experienced a sufficient dose of the intervention. This cut-off date was around three months prior to the final outcome data collection in most homes but between two and three months prior to outcome data collection in seven homes in which final outcome data collection occurred during the 12th month rather than at the end of the 12th month. The intention-to-treat population comprises all those resident in the home who consented to intervention (or data collection) at or prior to the cut-off assessment date at their home. Residents that moved will be considered in the home that they have moved to providing that they have been resident there prior to the cut-off date. If they were not resident in the home prior to the cut-off date they will be analysed as if they were still resident in the home in which they originally gave consent.

(b) Cohort analyses –
The intention to treat population is those who provided data at baseline. For those residents that move, they will be assigned to the home in which they started out. For most outcomes the ITT population is all participants who provided the outcome measure of interest prior to randomisation but for the outcome 'remission of depression' it is residents depressed at baseline.

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5.2.2 Available-case analysis population

By the nature of the participants included in the study, many will not be able to provide complete data at each time point. For each outcome the available case population will be defined by the number of people able to provide data for that outcome, thus the population will be different for each outcome.

(a) Cross sectional analyses-
Therefore, for this type of outcome, we use intention to treat principles, and include all those residents in the home who consented to intervention (or data collection) at or prior to the 9 month assessment date at their respective home and who have a valid outcome measure at the end of the study (12 months) (i.e. complete case following the ITT principle). Residents who switch homes will be included in the analysis with the home in which they move to if they have been resident in this home prior to the 9 month cut off. Otherwise they will be analysed as if they were still in the home in which they were originally randomised as long as there is an outcome measure collected within 2 months either side of the point 12 months from randomisation.

(b) For cohort analyses-
We will include all those who gave consent/assent, with a valid baseline measure of outcome before randomisation, resident in a participating home and with a valid outcome measure at the relevant time point (either 6m or 12m). Residents who move to another trial home and are therefore still followed up will be analysed according to their original allocation (i.e. either intervention or control, ITT principle) in the home as if they were in the home in which they first resided. For remission of depression this includes only those who had symptoms of depression at baseline.

5.2.3 Per protocol analysis population

We have not defined a per protocol population; it is unclear what such a population would be.

5.2.4 Safety population

For the safety analyses the population is defined as all those in the home at any time during the intervention period with exposure given by the length of time within the home during the intervention period i.e. person months of exposure, which will form the denominator

The safety outcomes are deaths and peripheral fractures, both classified as serious adverse events (SAEs). For deaths the study population is all residents present in the home during the intervention period.
Data on peripheral fractures will be collected in two ways and different populations are defined for each

a. Events in study participants (data available at the level of the individual)
b. Events in all residents (data available aggregated at the level of home).

For deaths and for peripheral fractures where the event is measured on all participants the denominator is person years of exposure. This allows us to include residents who were neither present at the beginning nor the end of the study.

5.2.5 Other populations

Unconventional movements of some residents through the trial need to be accommodated in the analysis.

(i) All residents in one home got moved temporarily to another home in the opposite trial arm and were moved back to their original home before the end of follow-up. They will be analysed in the home where they resided at the outset.

(ii) Residents who move to another study home part way through will have two follow-up reference points. E.g. study participant X had been living in home A since pre-randomisation. In month 8, X moves to home B (which may or may not be in the same trial arm as home A) which had been randomised only 5 months previously. Therefore, when home B is due for its 6-month assessment visits, resident X will be due a 9 month assessment. Follow-up (12 months) would be due to end for participant X at the 9 month assessment of home B. However, for the cross-sectional analysis, assuming resident X is still present, they may have additional follow-ups and their latest follow-up will be the one that is included in the 12 month assessment of home B. Resident X, in the cohort analysis, would be analysed as belonging to home A, not B. In the cross-sectional analysis, X is treated as residing in B unless they have been in B for a relatively short time (see sections 5.2.2 and 5.2.3).

5.3 Database

5.3.1 Description

Questionnaires were completed on paper with the resident. Data were entered directly onto a study laptop after the assessment time with the resident by the recruitment team.
The database is stored in Microsoft Access 2007 as a series of separate tables.

5.3.2 Data quality

Quality assurance checks will be undertaken by Warwick CTU to ensure the integrity of randomisation, data entry procedures and data collection.

A 10% random sample will be checked against paper records to identify data entry errors. At the level of the home, the records of 8 homes will be checked. Should the error rate exceed 0.1% of all data items recorded, a further sample of 8 homes will be checked.
At the level of the resident, a 10% random sample of residents' records will be selected across all homes. Data entered on the GDS-15 will be checked at item level. Should the error rate exceed 0.1%, a further 10% sample will be drawn for checking.
For the other outcome measures and covariates, we will also tolerate an error rate of 0.1%.

We will fit linear regression models of the primary outcome measure (GDS-15) and main secondary outcome measure, MMSE, to see if there is any association with data input clerk (coded using dummy variables). This could reveal to us if any clerks have a tendency to input consistently high or low values for these outcomes or if there is a preponderance of missing values or zeros.

5.3.3 Database freeze

The statistician responsible for the analysis will conduct or oversee additional data checks. These include range checks, logical and consistency checks which may not be

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picked up by checks performed at the individual patient level by the research staff that collect and enter the data.

Once all 12 month follow-up data have been checked and errors corrected, the database will be frozen in compliance with PCTU SOP 09c (data freeze, handover and lock).

5.4 Analysis software

The analysis will be carried out using mainly Stata version 10.1 or 11 (StataCorp. 2009). However, some analyses may be carried out using MLwiN, a specialist programme for handling multilevel data.

5.5 Methods for withdrawals, loss to follow-up and missing data

Numbers lost to follow up and withdrawal from the study will be described by arm to try and establish if there is difference in attrition rates.
Cross-sectional: N/A
Cohort analyses: as all cohort analyses will be modelled using maximum likelihood methods, outcomes will not be imputed as we do not, at this stage, wish to assume that measurements are missing at random (MAR).

5.6 Method for handling centre effects

The two recruiting centres (London and Warwickshire) will be distinguished in the analysis by a dummy variable.

5.7 Method for handling randomisation stratification or minimisation factors

All analyses will include the minimisation factors and the location stratification variable (i.e. centre (see 5.6)), which are categorical and defined at cluster level. Dementia specialist care home status (Yes/No) will not be included as there was, by design, only one such home.

5.8 Method for handling clustering effects

We will use mixed effects models with a random effect for RNH.

It is possible that there may be additional clustering effects in intervention homes only, because the exercise classes are group activities and there may be therapist effects. However, exactly who delivered each class in not recorded, though each home's activities are overseen by a primary therapist who has the most influence on how the classes are run. It is not possible to disentangle these effects, if they exist, as physiotherapists on annual or sick leave were replaced temporarily by other physiotherapists.
Therefore, we will simply quantify and describe the clustering for each outcome overall by study arm and present 95% confidence intervals for these to check if there is substantially greater clustering in the intervention arm than in the control arm.

5.9 Method for selecting other variables that will be adjusted for

The variables to be included in the model for each outcome are specified in table 5.

Variables that were considered by the trial team, *a priori*, to be related to the outcome will be included. The most important one (for the cohort analyses) is likely to be the **baseline level of the outcome.** In addition, the following will be included:

Cross-sectional analyses

Cluster-level variables

Location of home (stratification variable)
Size of home (minimisation variable)
Type of home (minimisation variable)
Proportion with MMSE<20 in home at the time point at which the cross-sectional analysis is being done, as a measure of dementia in the home at that time
Baseline level of outcome for those in home and consented prior to randomisation

Individual level variables

Age at the analysis time point
Sex
Physical condition: Short Physical Performance Battery (SPPB) (at individual's baseline)
On antidepressants (Yes/No) (at individual's baseline)

Cohort analyses

Cluster-level variables

Location of home (stratification variable)
Size of home (minimisation variable)
Type of home (minimisation variable)
Proportion with MMSE<20 in home at baseline (strictly only those in the home and who provided a measure prior to randomisation as a measure of home baseline status)

Individual level variables

Baseline level of outcome
Age at home's baseline
Sex
Physical condition: Short Physical Performance Battery (SPPB)
On antidepressants (Yes/No) at baseline

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Table 5: Model specifications for the different outcomes

					Covariates*											
					stratification (F)		*minimization (F)*		*allocation (F)*	*demographic (F)(I)*		*clinical (F)*	*clinical (F)*			*offset/ exposure*
Data type	Subtype	Outcome	Note	Classification#	Home location	Home ID	Home size	Home type	Int./Con.	age**	sex	baseline ***	antidepressants * (I)	Prop. MMSE<20 (A)	SPPB at baseline (I)	
Continuous		(b)	C	primary	✓	(R)	✓	✓	✓	✓	✓	GDS-15 (I)	✓	✓	✓	
		(c)	C	primary	✓	(R)	✓	✓	✓	✓	✓	GDS-15 (I)	✓	✓	✓	
		(r)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	GDS-15 (A)	✓	✓	✓	
		(e)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	MMSE (A)	✓		✓	
		(f)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	MMSE (I)	✓		✓	
		(g)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	SPPB (A)	✓	✓		
		(h)	C	secondary**	✓	(R)	✓	✓	✓	✓	✓	SPPB (I)	✓	✓		
		(m)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	EQ-5D (A)	✓	✓	✓	
		(n)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	EQ-5D (I)	✓	✓	✓	
Categorical	binary	(a)	E	primary	✓	(R)	✓	✓	✓	✓	✓	GDS-15 (A)	✓	✓	✓	
	binary	(d)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	GDS-15 (I)	✓	✓	✓	
	binary	(i)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	Fear of falling (A)	✓	✓	✓	
	binary	(j)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	Fear of falling (I)	✓	✓	✓	
	ordinal	(k)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	Pain rating (A)	✓	✓	✓	
	ordinal	(l)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	Pain rating (I)	✓	✓	✓	
	ordinal	(o)	E	secondary	✓	(R)	✓	✓	✓	✓	✓	Social engage. (A)	✓	✓	✓	
	ordinal	(p)	C	secondary	✓	(R)	✓	✓	✓	✓	✓	Social engage. (I)	✓	✓	✓	
Rate		(q)	E	secondary	✓	(R)	✓	✓	✓	✓ (A)	✓ (A)		✓ (A)	✓	✓(A)	✓

* Key: (F) = fixed effect; (R) = random effect; (I) = individual level, (A) = aggregated at home level

** not measured at 6 months

*** name of baseline measure of outcome. For end-of-study outcomes, mean in home at baseline will be covariate, except proportion that feared falling.

* on antidepressants at baseline (Yes vs. No)

** for cross-sectional analysis, use age at end of study. For cohort analysis, use age at baseline.

all change secondary outcomes will be analysed first for 6m endpoints and then for 12m endpoints.

Note: E is for end of study i.e. all residents present at the end of the study. C is for change and so is restricted to residents present at both baseline and end of study.

Outcomes

(a) Presence of depression at 12m: whether or not resident is depressed on the basis of a GDS-15 score of five or above

(b) Change in depressive symptoms at 12 months in those residents present at baseline

(c) Change in depressive symptoms at 6 months in those residents depressed at baseline.

(d) Remission of depression at 6 months in those depressed at baseline.

(e) & (f) Cognitive function, measured using the MMSE

(g) & (h) Mobility: assessed using the Short Physical Performance Battery (SPPB) as a continuous variable.

(i) & (j) Fear of falling

(k) & (l) Pain: Participants were asked to rate their current level of pain, i.e. pain today, on a five-point numerical rating scale at 6 and 12 months

(m) & (n) Health-related quality of life (self-report & proxy)

(o) & (p) Social engagement scale

(q) Rate of peripheral fractures as a marker for (un)safe falls

(r) Number of depressive symptoms at 12 months (added in since version 1.0)

5.10 Multiple comparisons and multiplicity

None.

5.11 Method for handling non-adherence

There is no minimum attendance requirement at exercise classes. The reasons for absences have been documented. Homes are included in the analysis in the arm they were allocated to, regardless of adherence.

5.12 Method for handling time-varying interventions

Not applicable .

5.13 Method for handling outliers

Continuous data will be plotted prior to any modelling to assess potential data errors. These will be followed up with WCTU staff. After the model is fitted, appropriate regression diagnostics will be assessed.

5.14 Derived and computed variables

The primary outcome measure GDS-15 will define the variable 'depressed' if GDS15≥ 5.
For those who answer less than 13 items but at least 10, we apply the following rules:
depressed=Yes if GDS≥ 4 if they answered at least 11 or 12 questions.
depressed=Yes if GDS≥3 if they answered 10 items
Each item is a depressive symptom (either present (scores 1) or absent (scores 0).
If the number of items completed, n is such that: 9<n<15, the total score is to be rescaled i.e. GDS' = 15*GDS/n
MMSE (moderate-severe impairment) is defined by a total score of <20/30. If fewer than 15 items have been completed, a total score will not be computed. If between 16 and 29 items have been completed, MMSE' = 30*MMSE/n for n: 15<n<30.
Social engagement scale: if fewer than 4 items have been completed, a total score is not computed. If 4 or 5 items have been completed, SES'=6*SES/n for n = 4 or 5.
Pain now. There should only be a response to this question if the participant scored 2 or 3 on the EQ-5D pain question, otherwise set to missing. If the participant has a score of 1 on the EQ-5D pain item but 'pain now' is missing, set to 'pain now' to 0 (No).

6 DESCRIPTIVE ANALYSES

6.1 Participant flow

For the co-primary outcomes, both cluster and participant throughput will be summarised in CONSORT diagrams specific to the outcome of interest. The four main CONSORT diagrams are (a) directly assessed outcomes (cross-sectional), (b) directly assessed outcomes (cohort), (c) indirectly assessed outcomes (cross-sectional) and (d) indirectly assessed outcomes (cohort).

6.2 Representativeness of sample

N/A

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6.3 Baseline comparability of randomised groups

To assess the adequacy of our randomisation process in achieving balanced groups we will compare the characteristics of RNHs (location, type and size of home) and individuals (age, sex, baseline assessment scores) in our intervention and control arms using simple descriptive statistics without recourse to hypothesis testing.

6.3.1 Demographics

Age, sex, ethnicity, age at which left school (proxy for social class) and length of residence in home will be checked descriptively.

6.3.2 Prior and concurrent medications

On antidepressants (yes/no)

6.3.3 Baseline and screening conditions

GDS-15, EQ-5D (self-report and proxy), MMSE, Barthel Index, fear of falling, current pain

6.3.4 Baseline medical history

Terminal or other serious illness are exclusion criteria

6.3.5 Baseline physical exam

Consented/assented residents were given a physical assessment (SPPB)

6.3.6 Cluster characteristics

Type (a combination of ownership and services), and size (number of beds) of RNH
Number of beds and occupancy (see table 2)

6.3.7 Characteristics of care providers where applicable

Type of RNH: local authority/voluntary/private & care/private & nursing/dementia specialist

6.4 Comparison of losses to follow-up

Proportion followed up at 6 months and at 12 months in each arm with detail presented on reasons for loss to follow-up presented in CONSORT diagrams.

6.5 Comparison of compliance to treatment and protocol

Not applicable

6.6 Emergency or accidental unblinding of randomised treatment

Not applicable

7 INTERIM ANALYSES AND SAFETY MONITORING ANALYSES

7.1 Purpose of interim analyses

To assess original sample size for adequacy.

7.2 Monitoring plan

None

7.3 Stopping rules

None

7.4 Measures taken to minimise bias

N/A

7.5 Adjustment for p-values

N/A

7.6 Interim analysis for sample size adjustment

Using data from recruitment up to November 2009, baseline data was analysed to re-estimate the power of the study. The intracluster correlation coefficient (ICC) of GDS-15 at baseline was estimated (pooled across Warwick and London). Mean cluster size was ascertained and the sample size rechecked for adequacy. See tables 3 and 4 for details.

8 ANALYSIS OF CO-PRIMARY OUTCOMES

8.1 Definition of outcome measures

i. Difference in proportion of residents depressed (defined in 2.2.1.) at 12 months between intervention and control homes.
ii. Change in number of depressive symptoms at 6 months in all those who were considered depressed at baseline, according to their GDS-15 score.
iii. Change in number of depressive symptoms at 12 months in all those who were present at baseline.

8.2 Descriptive statistics for outcome measure

By study arm, count and percentage of all participating residents depressed at 12 months, of residents present and depressed at baseline and at 12 months, and of residents present and depressed at baseline and at 6 months.

8.3 Primary analysis

To assess the difference in proportions depressed at 12 months between intervention and control homes we will use mixed effects modelling (with a random effect to account for clustering by RNH) with a binomial family and a logit link function (to handle the binary outcome) in Stata (*xtmelogit* command).

To assess the change in severity of depressive symptoms at 6 and 12 months between intervention and control homes we will use mixed effects modelling (with a random effect to account for clustering by RNH) with a Gaussian family and the identity link function in Stata (*xtmixed* command).

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Each model will include the baseline measure of the outcome (except for MMSE), as well as the minimisation variables home type, home size and the stratification variable location. In addition, we will include individual baseline SPPB score and whether or not the resident was on antidepressants (cohort analyses only). We will also include, at the home level, the proportion of residents with moderate to severe cognitive impairment at baseline (i.e. with an MMSE<20).

We will examine the correlations between the covariates to assess any potential multicollinearity problem. This will be done by fitting a linear regression model and requesting the variance inflation factors (VIFs). A VIF>10 indicates severe multicollinearity. VIFs between 5 and 10 indicate some problem.

For the outcomes which indicate a change in severity of depression for those depressed at baseline, we will use a similar strategy, but measurements at baseline and outcome will be on the same individual. We will therefore introduce baseline levels of depression severity as a covariate at the individual level.

All covariates listed in section 5.9 will be entered into the model at the same time and none will be removed unless there is evidence of multicollinearity, in which case, the collinear covariate providing the best fit will be retained.

The regression coefficient for continuous outcomes, odds ratio for binary outcomes, proportional odds ratio for ordered outcomes and incidence rate ratio for rate outcomes, of the treatment (intervention vs. control) variable, and its 95% confidence interval, will be reported along with the p-value.

8.4 Assumption checks

Appropriate model diagnostics will be checked: e.g. normality (continuous outcomes only) and homoscedasticity of residuals and normality of random effects.

8.5 Other analysis supporting the primary (inc. sensitivity analyses)

Residents joining post-randomisation

There are two groups of residents to consider here. By far the largest group is new residents who join the study at 3, 6 or 9 months post-randomisation. The second group comprises a small number of residents who were present in the home at baseline and for whom some data were collected soon after their home was randomised. For example, proxy EQ-5D just before randomisation and a self-completed one just after randomisation.

In the cross-sectional analysis inclusion criteria will be based on length of time resident in home; thus individuals from these two groups may be included in the main analysis. A sensitivity analysis will exclude these individuals.

In the cohort analyses these two groups will not be included in the main analysis. They will be included in a sensitivity analysis providing that they have been resident in the home prior to pre-determined cut-offs set at about 3 months prior to each outcome end point. Their baseline will be the earliest time point at which they are assessed. The cohort analysis has endpoints at 6 and 12 months. This will provide an analysis population that is comparable to that in the health economics analysis.

Missing values
For cohort study outcomes:
Assuming that the linear predictor is correct, the mixed models will provide efficient and unbiased effect estimates despite missing values in covariates, assuming that the missingness mechanism is missing at random (MAR).

After the analyses set out in this plan have been carried out, KDO will perform analyses under various missing data assumptions, to be detailed in a separate analysis plan.

9 ANALYSIS OF SECONDARY OUTCOMES

9.1 Definition of outcome measures

- The proportion of depressed residents, with 'depression' measured prior to randomisation, that experience remission from their 'depression' six months after their home was randomised.
- Cognitive function: Mini Mental State Examination as a continuous variable
- EQ-5D as a continuous variable: proxy and self-reported
- Mobility: Short Physical Performance Battery (SPPB) as a continuous variable.
- Falls:

  (a) Binary fear of falling: "Are you afraid of falling" yes/no response from participants.
  (b) Rate of peripheral fractures as a marker for injurious falls. We will identify these from the RNH (home aggregate level) and hospital records (individual level).
- Pain: ordinal 5-point rating scale at each follow-up.
- The Social Engagement Scale uses six items from the Minimum Data Set residential assessment instrument (MDS-RAI).
- Medication use: For antidepressants, other psychoactive drugs, analgesics and NSAIDs we will convert these into the number of defined daily doses (DDD) used over one year (http://www.whocc.no).
- Hospital admissions: cause and duration of any hospital admissions during the study period from participants' hospital records. We will code these admissions into Diagnosis Related Groups to identify any peripheral fractures.

9.2 Descriptive statistics for outcome measure

Continuous outcome: n, mean, SD, median, 10^{th} and 90^{th} centiles, by arm.
Dichotomous outcome: n (%), by arm.

9.3 Secondary analysis

The analysis strategy is the same as for the co-primary outcomes.

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- Remission of depression: reduction in proportion of participants depressed in the intervention arm. A mixed effects logistic model will be defined. This will be fitted using the *xtmelogit* command.

- Cognitive function Mini Mental State: We will compare the rate of change in MMSE cluster mean at baseline and at end of intervention in exercise and control homes. We could construct linear mixed effects models with MMSE at 0, 6, and 12 months, with random effects for RNH. This will be fitted using the *xtmixed* command.

- EQ-5D: we will use linear mixed models, with RNH as a random effect. This will be fitted using the *xtmixed* command.

- Mobility: (SPPB) we will use linear mixed models, with RNH as a random effect. This will be fitted using the *xtmixed* command.

- Falls
  Binary fear of falling: reduction in proportion of participants declaring fear of falling in the intervention arm. A mixed effects logistic model will be defined. This will be fitted using the *xtmelogit* command.

- Pain: 5-point scale. Ordinal mixed effects logistic regression (either in Stata using the *gllamm* command or in MLWiN.)

- The Social Engagement Scale uses six items from the Minimum Data Set residential assessment instrument (MDS-RAI). Ordinal mixed effects logistic regression (either in Stata using the *gllamm* command or in MLWiN.)

  The following outcomes will not be modelled. However, medication use and hospital admissions are important for the health economic analysis (see separate analysis plan).

- Medication use (descriptive statistics only)
- Hospital admissions (descriptive statistics only)
- All-cause mortality.

9.4 Assumption checks

Appropriate model diagnostics will be checked: normality (continuous outcomes) and homoscedasticity of residuals, normality of random effects.

9.5 Other analysis supporting the secondary (inc. sensitivity analyses)

See section 8.5 for details.

10 SAFETY AND TOLERABILITY ANALYSES

10.1 Drug exposure

N/A

10.2 Adverse events

Data on adverse events was not collected.

10.3 All adverse events

N/A

10.4 Adverse events leading to withdrawal

N/A

10.5 Serious adverse events

According to the 'adverse event reporting protocol', an SAE is any untoward or medical occurrence that: results in death or is life threatening *or* requires hospitalisation *or* results in persistent disability of incapacity *or* requires medical intervention to prevent one of these (or is otherwise considered medically significant by the investigator).

SAEs can be classified as directly attributable (i.e. occur during a study assessment or getting to or from or occur during a group-activity session), or indirectly attributable (i.e. at any other time between randomisation and end of follow-up).

Table 6 Classification of anonymised fracture-related deaths, and fractures data.

Deaths* and Fractures (indivdiual level data)	Attribution of SAE	
	direct	indirect
study participant (intervention)	A, E	otherwise
non study participant (partaking in exercise)	E	otherwise
study particpant (control)	A	otherwise

A = during study assessment
E = during exercise
otherwise = not (A or E)
* fracture-related deaths (ICD10 chapter S)

Difference in rates of peripheral fractures between intervention and control homes (mixed effects Poisson model with resident-time in study as the exposure variable). This will be fitted using the *xtmepoisson* command.

Reporting of cause of death data

All deaths in residents will be reported and documented. We will have data on deaths amongst all residents from all homes. This will not provide accurate dates of death and characteristics of residents. We will conduct a simple comparison of total death rate in the two trial arms. For those who have consented/assented to have their data used, we will have exact date of death from death certification data, plus age and gender and all the other baseline variables. For this group we will construct Kaplan-Meier plots and carry out log-rank tests to see if there is any difference in all cause mortality over time. We will also consider using Cox's proportional hazards models (*streg* command) or logistic regression to allow for covariates depending on the number of deaths.

All cause of death data will be based on ICD10 coding provided by MRIS. These deaths data are provided as the underlying cause of death and also as the factors contributing to death.

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This is a safety analysis that will be presented for all subjects contributing data to the study.

We will present the number of deaths for which any injury, i.e. any underlying of contributory cause of death includes an ICD10 code that starts with an 'S', has contributed to the cause of death. We will present these as fracture-related deaths per year of exposure. We will estimate difference in fracture related death rate within a 95% confidence interval.

For the primary cause of death outcome the underlying cause of death from the MRIS data will be used. This will presented as number of deaths during study period, subdivided by ICD chapters; i.e. the first character in the ICD code, between each group. No statistical analyses will be presented.

10.6 Clinical laboratory evaluations

N/A

11 SUBGROUP ANALYSES

11.1 Definition of outcome measure

N/A

11.2 Definition of subgroups

N/A

11.3 Sample size justification for the subgroup analysis

N/A

11.4 Descriptive analysis for subgroups

N/A

11.5 Method of analysis

N/A

12 AMENDMENTS TO VERSION 1.0

Barthel Index replaced by SPPB as a measure of physical function because Barthel Index was missing for all residents in one home at baseline.
If one or two items are missing in the Social Engagement Scale, the score will be pro-rated according to the rule written in 5.14.
To avoid having a category with only one member, local authority homes and voluntary homes will be collapsed into one category for the purpose fitting the 'home type' design variable in the analysis.

13 REFERENCES

Rothera IC, Jones R, Harwood R, Avery AJ, Waite J. Survival in a cohort of social services placements in nursing and residential homes: factors associated with life expectancy and mortality. Public Health 2002;116:160-5.

Underwood M, Eldridge S, Lamb S, et al. The OPERA trial: protocol for a randomised trial of an exercise intervention for older people in residential and nursing accommodation *Trials* 2011, 12:27 doi:10.1186/1745-6215-12-27

14 APPENDIX

Where scoring of questionnaires is required for the analysis they should be attached here

PCTU

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Appendix 4 Notes on statistical analysis plan v1.1 for OPERA

Section in analysis plan	Action/change	Note/comment
Errors in original text of analysis plan		
2.2.2	No analysis of SPPB at 6 months has been undertaken	A 6-month analysis was never envisaged
5.9	GDS-15 baseline value was used as a covariate in models rather than whether or not individuals were on antidepressants	GDS-15 is correctly specified in table 5 of the analysis plan but the text refers to antidepressants. The text is in error; the agreed plan was to use GDS-15
Changes to plan		
5.2.4	We did not use exposure (length of residence in home) in safety analyses	We do not have length of stay in home for residents who did not take part in the OPERA study. Fractures and death outcomes were on all residents. Exposure could potentially be approximated based on size of home and bed occupancy but this will be time-consuming
5.4	SAS was used for a handful of analyses but is not mentioned as a software package that will be used	For ordinal mixed effects models SAS was suitable and the statistician conducting these analyses was more familiar with using SAS in this context
8.5	No sensitivity analysis has been undertaken for the cohort analyses	The difficulty in interpreting such an analysis given the different time points at which individuals entered the study, the small number of individuals who would be added to the analysis, and the possibility of identification/recruitment bias
9.1	Pain and social engagement were converted to three-point scales for analysis	Social engagement had seven categories. Some categories had very low numbers. For ordinal categorical data, the proportional odds assumption is strong and likely to be violated if there are many categories
Analyses not in the HTA report		
2.1.4	No analysis of hospital admissions has been undertaken	Complicated data, not considered a priority for HTA report given other demands
2.2.2	Medication use has not been converted to defined daily doses	Problems with the medications database have meant that this will be far more time-consuming than originally envisaged
3.4	Cause of death data have not yet been examined	Not considered a priority for HTA report
5.8	Clustering (ICC) is not presented by arm in order to ascertain whether or not there is greater clustering in the intervention arm due to physiotherapist clustering effects	Not considered a priority for HTA report
6.4	Detailed reasons for loss to follow-up have not been presented	Not considered a priority given the complicated nature of the data and competing demands on time
9.2	Medians and centiles have not been presented for all outcomes	Not considered a priority for HTA report, given space available
10.5	Kaplan–Meier plots and log-rank tests were not used for mortality data	It was not possible to complete the manipulation of date-of-death data to produce these analyses in time for the submission of the report

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Appendix 5 Process evaluation interview topic guides

Care home manager: baseline*

(*Could use a description of the programme as a stimulus for these interviews.)

- Ask about the home and what activities are currently available.
- Experiences of being approached by the trial team, for example initial approach, information provided by research team about the study.
- Influences on the decision to take part.
- Process of consent (home, individuals and assent).
- Beliefs about the benefits of taking part.
- Explore current home practices (activities, games).
- Expectations of what the programme can achieve within the home.
- Beliefs about the feasibility of introducing the programme into their home – likely facilitators and likely challenges to this (what aspects do they think will work or not work?).
- Beliefs about acceptability of the programme to care home staff and to residents.
- Beliefs about the likely impact on the home of taking part, for example in terms of how the home runs and on individual staff and residents.
- Beliefs about the usefulness of the programme to them, staff and residents.

Care home manager: follow-up

- Experiences of the various elements of the programme, for example depression awareness training, exercise groups, whole-home intervention.
- Challenges to implementing the programme into the home.
- Beliefs about the acceptability of the programme to care home staff and to residents.
- Beliefs about the extent to which the programme fits into the overall work of the home.
- Beliefs about the impact of the programme on the home overall, on care home staff and on care home residents – short- and long-term impacts of the programme.
- Beliefs about the sustainability of the intervention.
- Suggestions about how the programme might be improved to make it easier to introduce.

Care home staff: baseline*

(*Could use a description of the programme as a stimulus for these interviews.)

- Experience as a care assistant – length of time worked as a care assistant overall, length of time worked in particular home.
- Impressions of life in the home (interactions with residents, activities, workload).

In intervention homes will explore the implementation of the OPERA programme:

- experiences of having the programme explained to them and their role (if any) within helping the implement the programme

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- beliefs about the feasibility of introducing the programme into their home – likely facilitators and likely challenges to this
- beliefs about the impact on the intervention on the home overall, on fellow care staff and residents
- beliefs about the usefulness of the programme received, to them and to residents.

Care home staff: follow-up

- Experiences of the various elements of the programmes – depression awareness training, exercise groups, whole-home intervention (for control homes just the depression awareness training).
- Usefulness of training, did they learn anything that they have been able to use in their everyday work.
- Ease of attending training, did they have enough time off to attend the training, attitudes of other members of staff to the training.
- Beliefs about the impact of the training on the home overall and on residents (if any), potential short- and long-term impacts.
- Have staff acted on information received during training?

Within intervention homes will also explore how the exercise groups have been received:

- beliefs about the sustainability of such a programme
- suggestions about how the programme might be improved.

Care home residents: baseline

(Adapted slightly for NOK, e.g. what are your experiences of the home in which you have a relative?)

- Discuss life within the home, what they do, activities, staff interactions.
- Explore recollections of consenting to be part of main study.
- Did they feel that they had enough information given to them about the study?

In intervention, homes will also discuss:

- expectations of the programme – benefits and challenges of taking part
- beliefs about the impact of the programme on residents.

Care home residents: follow-up

(Adapted slightly for NOK, e.g. have you noticed any changes? If intervention, has your relative talked about the classes?)

- Discuss life within the home, what they do, activities, staff interactions, any recent changes.

In intervention homes will also discuss:

- experiences of taking part in the programme – experiences of attending the activity class
- impact of the programme on usual life in the home
- ease of getting to classes – enough support to take part
- beliefs about the likely impact of the programme on them
- beliefs about how to make the class better.

Physiotherapists (focus group)

- Experiences of learning about OPERA.
- Thoughts on training given to deliver OPERA.
- Experiences of recruiting participants and doing baseline assessments.
- Expectations (and later realities) of carrying out a programme like this.
- Likes and dislikes (possible changes).
- Delivering the depression awareness and exercise interventions.
- Beliefs about the impact of the programme on residents.
- Practicalities of collecting and reporting (OPERA forms).
- Impact on homes (follow-up).
- Any changes noticed (follow-up).

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Appendix 6 Ethics substudy: focus group guide

Pre-meeting

Prepare flip chart/visual aid that outlines the different types of research (generic examples).

- drug trials
- observation studies
- interview studies
- intervention studies
  - therapeutic (none drug) surgery, manipulation, etc.
  - exercise type/behaviour change
  - emergency care
  - disease/condition specific (covers all of the above)
- mixed (intervention and observation and/or interviews).

Introduction

Overview of research, why people may want to include older people in research, what and why we are interested in research with older people and why we are doing this FG (plus explain how we are going to run the FG).

How would you feel (as an older person) about being invited to participate in these types of research projects?

- explore using the heading from the visual aid
- explain about informed consent and research.

What information would help you make a decision to become involved in research?

- use example information sheet to explore.

Some older people are not able decisions for themselves (due to various reasons for example dementia). How can we ensure that we give these people an equal opportunity to participate in research? How can we protect them from exploitation by researchers?

Who do you feel can make a decision for this person? And why?

- list all advocates if needed: husband, wife, children, siblings, friends, solicitor, care home manager, social worker, GP, etc.

If this was you whom would you want to make decision? And why?

Do you think that research participation should be part of advance directives?

- explain.

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Would you be prepared to make a decision for a family member to be involved in research?

What additional information would you want to help you make a decision for a family member?

Appendix 7 OPERA ethics substudy: key informant topic guide

Key informants

Group informant is in researcher/research governance or ethics/care home manager/owner/officer of patient/carer organisation.

Introductory statement

It is well recognised that we now have an increasingly elderly population and these elderly people are now major consumers of health care. Historically older people have been excluded from health research, often due to the complexities of getting old. However, it is our belief that, if we want to ensure that the physical and psychological needs of the elderly are addressed to ensure a good quality of life into old age; then research should be inclusive of this population.

- To what extent do you agree/disagree with this statement and why do you feel this way?
  - How important do you think it is for research aimed at benefiting the health of our elderly to be inclusive of elderly people?
- If you agree that health research for the elderly should be inclusive what is your opinion of this research being carried out in the different setting in which this population can be found? (e.g. hospitals, residential/nursing homes care homes, sheltered accommodation or own home/community) [*note*: expand and explore the different settings]
- What, if any, has been your personal involvement in research with the elderly?
  - Participant, consultee, researcher, ethics advisor, hosting research.
- What do you think are the main difficulties in conducting this type of research?
- What do you think are the ethical difficulties in conducting this type of research?
- Many people in residential accommodation, and some people living in their own homes have cognitive impairment and some may lack capacity to give consent to take part in the research or find it difficult to understand the study information. How do you think researchers should approach this problem?
  - Reference to the law/The Mental Capacity Act.
  - Reference to proxy decision-makers or advisors on capacity.
  - Tailoring the consent process, information sheets, time for considering, involving others in the process, formal assessments of capacity, acting in their best interests.

Cluster randomised trials involve testing an intervention at a group level so individual consent is not required but consent from a 'keyholder', such as the manager of a residential home or a GP practice.

- Do you think this type of research raises particular concerns? If so can you elaborate?
- Does it make a difference if the population concerned includes individuals who are cognitively impaired/lack capacity?

Researchers/academics

- What challenges have you faced as a researcher working with this population?
- How have you handled the recruitment and consent processes with an elderly population?

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- In your opinion how (if at all) could the systems/processes of consent be improved for the involvement of the elderly in research?

General questions

- If you were the relative of person unable to decide for themselves and were asked to advise whether they should be included in some sort of health research project how would you feel about this?
  - How would you make a decision?
  - Would the type of study influence your decision? (e.g. drug trial, exercise/fitness intervention)
  - Would you act with or without consulting your relative?

- Consider that you are an elderly resident in a residential home and you have been approached by a researcher from a university who is carrying out a research study that it is hoped will improve elderly care in the future.
  - What would you want to know to help you make a decision?
  - Would you want your family to be involved in this decision? Or indeed to make the decision for you?

- If in the future you were unable to make decisions for yourself how would you feel about participating in research?
  - Are there types of research you would want to take part in?
  - Are there types of research you would not want to take part in?
  - Who would you want to make the decision for you?

Appendix 8 End-of-study questionnaire: intervention

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OPERA

OLDER PEOPLE'S EXERCISE IN RESIDENTIAL ACCOMMODATION

End of Study Feedback

The OPERA Study team are very interested in receiving feedback about your experiences of OPERA. We would specially like to know how you felt about the study from when the home first entered the study to when the study ended in your home. We would be very pleased if you could take a few minutes to complete this questionnaire and return it to us in the pre-paid envelope provided.

Thank you for your time.

If you have any questions or queries please contact Maryam Zare the OPERA Study Manager on 024 7615 1130 or email Maryam.zare@warwick.ac.uk

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Barts and The London
School of Medicine and Dentistry

Please read each question carefully and indicate how much you agree with the statement by ticking one of the boxes. Some of the questions require a yes or no answer please tick the one box that applies.
We would also welcome your comments and space has been made available for this. Thank you.

	Totally agree	Agree	disagree	Totally disagree
Recruitment				
The study was fully explained to me by the research nurse	☐	☐	☐	☐
The research nurse arranged mutually agreeable times to carry out assessments with the residents	☐	☐	☐	☐
We were easily able to provide all of the information about the home and residents that was required	☐	☐	☐	☐
Helping the recruitment nurses identifying eligible residents was not too burdensome.	☐	☐	☐	☐

Raising the Awareness of Depression in Homes

	Yes*	No
The feedback information about residents' depression scores (the smiley faces) was very useful?	☐	☐

* **If yes** how did you use the information (tick all that apply)

Monitor resident	☐
Encourage resident to become more involved	☐
Contact GP	☐
Contacted community mental health team	☐
Contacted other health professional	☐
Other (please state below)	☐

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	Totally agree	Agree	Disagree	Totally disagree
Staff Training				
Staff training sessions were arranged at mutually agreeable times?	☐	☐	☐	☐
In general staff responded well to the training	☐	☐	☐	☐
The training session was useful	☐	☐	☐	☐

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	Totally agree	Agree	Disagree	Totally disagree
Follow-up visits (3, 6, 9 and 12 months)				
Follow-up visits were not burdensome on the home.	☐	☐	☐	☐
Follow-up visits were not burdensome on the residents.	☐	☐	☐	☐
All required information (records) was easily available in the home for review.	☐	☐	☐	☐

Contact with OPERA office

	Yes*	No
During the project have you been contacted by or had need to contact the OPERA office? (please circle your response)	☐	☐
***If yes** Were your concerns dealt with satisfactorily?	Yes ☐	No ☐

Comments: (please feel free to provide other comments about OPERA in the space below.

	Totally agree	Agree	disagree	Totally disagree
Physiotherapist assessments				
The physiotherapist arranged mutually agreeable times to carry out assessments with the residents	☐	☐	☐	☐
The physiotherapists were useful in helping to solve mobility issues	☐	☐	☐	☐
The physiotherapist has been a useful source of advice, on increasing physical activity	☐	☐	☐	☐

	Totally agree	Agree	disagree	Totally disagree
Exercise Groups				
	☐	☐	☐	☐
The exercise groups have fitted well into the home.				
The exercise group were run as regularly as expected.	☐	☐	☐	☐
The residents, in general, liked going to the exercise groups.	☐	☐	☐	☐
We have enjoyed having twice weekly sessions.	☐	☐	☐	☐

What, if anything, would you change about the content and/or the running of the exercise sessions? **(please state below)**

	Yes*	No
In your opinion has the OPERA exercise intervention helped to improve the mobility of residents?	☐	☐

***If yes how?** (please state)

	Yes*	No
In your opinion has the OPERA exercise intervention helped to improve the mood of residents?	☐	☐

***If yes how?** (please state)

Comments: (please feel free to provide other comments about OPERA exercise intervention in the space below and overleaf)

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Thank you for your time

Appendix 9 End-of-study questionnaire: control

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OPERA

OLDER PEOPLE'S EXERCISE IN RESIDENTIAL ACCOMMODATION

End of Study Feedback

The OPERA Study team are very interested in receiving feedback about your experiences of OPERA. We would specially like to know how you felt about the study from when the home first entered the study to when the study ended in your home. We would be very pleased if you could take a few minutes to complete this questionnaire and return it to us in the pre-paid envelope provided.

Thank you for your time.

If you have any questions or queries please contact Maryam Zare the OPERA study manager on 024 7615 1130 or email Maryam.zare@warwick.ac.uk

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Please read each question carefully and indicate how much you agree with the statement by ticking one of the boxes. Some of the questions require a yes or no answer please tick the box that applies. We would also welcome your comments and space has been made available for this. Thank you.

	Totally agree	Agree	disagree	Totally disagree
Recruitment				
The study was fully explained to me by the research nurse	☐	☐	☐	☐
The research nurse arranged mutually agreeable times to carry out assessments with the residents	☐	☐	☐	☐
We were easily able to provide all of the information about the home and residents that was required	☐	☐	☐	☐
Helping the recruitment nurses identifying eligible residents was not too burdensome.	☐	☐	☐	☐

Raising the Awareness of Depression in Homes

	Yes*	No
The feedback information about residents' depression scores (the smiley faces) was very useful?	☐	☐

*** If yes** how did you use the information **(tick all that apply)**

Monitor resident	☐
Encourage resident to become more involved	☐
Contact GP	☐
Contacted community mental health team	☐
Contacted other health professional	☐
Other (please state below)	☐

.....

.....

	Totally agree	Agree	Disagree	Totally disagree
Staff Training				
Staff training sessions were arranged at mutually agreeable times?	☐	☐	☐	☐
In general staff responded well to the training	☐	☐	☐	☐

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The training session was useful	☐	☐	☐	☐
	Totally agree	**Agree**	**Disagree**	**Totally disagree**
Follow-up visits (3, 6, 9 and 12 months)				
Follow-up visits were not burdensome on the home.	☐	☐	☐	☐
Follow-up visits were not burdensome on the residents.	☐	☐	☐	☐
All required information (records) was easily available in the home for review.	☐	☐	☐	☐

Contact with OPERA office

During the project have you been contacted by or had need to contact the OPERA office? (please circle your response)	Yes* ☐	No ☐
If Yes* Were your concerns dealt with satisfactorily?	Yes ☐	No ☐

Comments (please feel free to provide other comments about OPERA in the space below and overleaf)

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Thank you for your time

Appendix 10 Six-month post-OPERA follow-up interview schedule*

*Intervention homes, all questions; control homes, questions in italic text excluded.

1	Does the home have anybody who takes responsibility for 'activity'?
	If so:
	Who is this?
	How many hours per week do they work?
	What training if any do they have for this role?
	How long have they been in this post?
	Is the primary role of this person to promote activity within the home (i.e. they are not just a carer)?
	Has this 'activity' person's role changed over the last 2 years?
	If so:
	In what way?
2	Does the home run regular exercise classes for the residents?
	If so:
	How often?
	Approximately how many residents attend?
	When was the last one?
	Who runs it?
	How is it funded?
3	Do you think you are more aware of depression/low mood in residents since OPERA?
4	*Has your approach to encouraging residents to be active changed?*
	If so:
	How?
5	*On average the physiotherapists delivered the exercise groups twice a week in the home:*
	How did you find this?
	What else if anything did you get from having a physiotherapist on site twice a week?
6	Have you (over the last year) brought in any additional physiotherapist time other than that currently provided by the NHS?
	If so:
	What are they doing?
	How often?
7	*If you were buying this service (OPERA type of exercise groups) in for home, what sort of service would you buy?*
8	*If the OPERA service was provided to your home indefinitely and at no cost would it be acceptable to you?*

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9	*Has your knowledge of what physiotherapist do changed?*
	If so:
	How?
10	*Do you think your home does more to encourage residents to be active than it did 2 years ago?*
	How?
11	Do you think taking part in OPERA changed the home in any way?
	How?
12	We all learn from new experiences. Do you feel that you can share this new knowledge with other staff?
	If so:
	How do you share knowledge with each other?
13	Did you see changes in the home during OPERA?
	If so:
	How?
14	Did OPERA make a difference to your:
	Residents?
	Staff?
15	Would you recommend changing the depression training in any way?
16	*Would you recommend changing the exercise classes in any way?*
17	Overall how would you describe the experience of having OPERA in the home?
	Why?
18	Would you participate in a similar trial if you had the chance?
	Why?
19	Is there anything else you would like to share with us about OPERA?

Appendix 11 Consolidated Standards of Reporting Trials checklist

Consolidated Standards of Reporting Trials 2010 checklist of information to include when reporting a randomised trial*

Section/topic	Item no.	Checklist item	Reported on page no.
Title and abstract			
	1a	Identification as a randomised trial in the title	i
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Separate doc.
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	1–10
	2b	Specific objectives or hypotheses	10, 43, 44
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial), including allocation ratio	11 and 44–6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	44–6
Participants	4a	Eligibility criteria for participants	16
	4b	Settings and locations where the data were collected	16–17
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	29–43
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	24–9
	6b	Any changes to trial outcomes after the trial commenced, with reasons	44–6
Sample size	7a	How sample size was determined	44–6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA

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Section/topic	Item no.	Checklist item	Reported on page no.
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	47
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	47
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	47
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	47
Blinding	11a	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how	54
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	47–54
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	52
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment and were analysed for the primary outcome	90
	13b	For each group, losses and exclusions after randomisation, together with reasons	92, 93, 123
Recruitment	14a	Dates defining the periods of recruitment and follow-up	73
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	81–5
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	92–3
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)	95–108
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	NA
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	107–8
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	171–3
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	164–5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	155–73

Section/topic	Item no.	Checklist item	Reported on page no.
Other information			
Registration	23	Registration number and name of trial registry	i
Protocol	24	Where the full trial protocol can be accessed, if available	i
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	NA

NA, not applicable.

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all of the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references that are relevant to this checklist see www.consort-statement.org.

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Appendix 12 Process evaluation interviewees: basic characteristics and data source codes

			Data source codes[a]		
Role	Sex	Age (years)	Baseline	6 months	End
Home managers	Female	N/A	16	41	40
		N/A	19		43
		N/A	23		52
		N/A	25		53
		N/A	20	29	31
		N/A	37		51
		N/A	5		42
		N/A	44		48
Carers	Female	N/A	1		
		N/A	12		
		N/A	17		
		N/A	35		
		N/A	8		
		N/A	9		
Senior carers	Female	N/A	2		
		N/A	36		
		N/A			32
Activity co-ordinators	Female	N/A	26	27	
		N/A	54	28	
		N/A			49
		N?A			50

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APPENDIX 12

Role	Sex	Age (years)	Data source codes[a]		
			Baseline	6 months	End
Residents	Female	74	10		
		84	11		
		85	13		
	Male	82	18		39
	Female	79	21		
		91	24		
		78	3		
		88	33		
		71	34		
		83	4		
		75			38
NOK		N/A	22		
		N/A	6		
		N/A			55

N/A, not available.

a These codes are used alongside quotations to indicate respondent.

Appendix 13 Feedback notes on recruitment and assessments (from recruiting team)

The process of assessments

Geriatric Depression Score

- Not always an easy measure to start with, it could be a difficult start to the assessment asking some sensitive questions, for example 'Do you feel pretty worthless the way you are now?'. It was particularly difficult if the resident was depressed.

European Quality of Life-5 Dimensions

- Probably the 'friendliest' measure to administer and was occasionally used first if the resident was very anxious or needed encouragement to respond. Some of the questions don't work very well, for example Mobility – either response allows 'some problems walking about' or 'confined to bed' – nothing in between.

Mini Mental State Examination

- We all felt the measure needed to be administered sensitively; some residents got concerned that they couldn't answer questions, so we all wanted to make residents feel as comfortable as possible.

Short Physical Performance Battery

- It could be difficult to assess balance for those residents who had leg deformities – they needed to get feet together, and some found this very difficult.
- Chairs in homes were all different heights so we generally tried to find dining style chairs with no arms but sometimes this was not possible and we had to make do with what chairs were available.
- Occasionally difficult to find four metres of clear floor to use for the timed walk; it may have meant the resident walking through a door frame or needing to turn.

Confidentiality issues

- It was sometimes very difficult to get residents into private areas for assessments owing to their immobility, or because they didn't want to move from where they were. We always checked that they were happy to be assessed in a communal area but it sometimes felt inappropriate.

Carers' forms

- Generally, carers were very happy completing the carers' forms. The wording of the questions could be difficult for some carers, especially the Social Engagement Scale.
- In some homes one person completed all of the forms and other homes several different carers completed them. Occasionally, we had to go back for forms because staff were too busy to complete them.
- We all appreciated the very difficult role carers have both physically and emotionally.

Follow-up

- There was some discussion on the accuracy of the health professional visit data, not always clearly documented in care home notes. This is now being double checked by the primary care trust, and concerns raised that we may have spent a lot of time collecting useless data.
- It was very time challenging following up homes when new homes were still being recruited.

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Appendix 14 Example responses from training feedback

	Themes (*n*)	Themes (*n*)
1. Which parts did you find the most useful?	DVD/video (2) Scenarios (3) Explanations of depression and how it can be treated (14) All! (25) Most of it (5) The signs to look for (13) The booklet and the delivery (6) Revisiting knowledge (1) Improved knowledge (2)	DVD/video (1) Learning about depression and the signs to look for (22) All (19) How we can help (2) How exercise can help (6) Learning in groups (1) Booklet (3)
2. Which part is the least useful?	Nothing (28) DVD/video and its stereotyped picture of old people (3) A little basic/nothing new (6) Focus is residential rather than nursing home (1) Antidepressant topic (1)	Nothing (28) Not enough information on treatments and dealing with depression (1) Information needed on how to encourage participation (1) 'A lot I knew already' (1)
3. Can you give an example of how you have applied the information on depression in your work since the training session?	Discussing more at handover/cascading (3) More attentive to residents more aware and able to recognise problems (16) Increased ability to recognise depression and to cope with residents who may have it (21) More confident to talk to colleagues about depression and to report cases observed (6) Encouraged activities; talking to residents (interacting) (7)	Being more patient (2) Not a carer but training has helped me recognise low mood in residents (4) Recognising signs (17) Encouraging residents to join in (4) 'none, it is down to the manager' (1) Interacting more (6) Promoting the benefits of physical activity (6) Discussing with the GP (1)
4. Since attending the training have you become more or less aware of the levels of depression in the residents? (If possible give an example.)	Involved GP more (1) Increased interactions with residents (e.g. activities) (7) More aware; know now what to look for (36) Same as before (5)	More aware; know now what to look for (34) Noticed a more happy time during exercise groups (3)

GP, general practitioner.

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Appendix 15 Training follow-up: exemplars of themes

Themes	Control homes (depression awareness training)	Intervention homes (depression awareness and activity training)
Useful	'Explanation of depression How OPERA will help residents and staff' 'I found all of it useful and taught our group a lot also it has made us more aware of the signs to bring attention to their own GP and of great benefit to my job role which I have found I can use more confidently' 'The examples given on how to approach some-one suffering from depression and the different techniques that can be use to comfort individuals' 'What to watch out for if you think someone might be depressed' 'The whole session was useful'	'Signs and symptoms of depression and changes in activity and mood in residents The training was very useful (awareness excellent)' 'Signs and Symptoms of Depression booklet was very useful as a reference guide and reinforced everything discussed during training session' 'Watching out for changes in activity and mood' 'Most information was quite useful although I had studied depression in the past' 'Realising exercise is vital to mental well-being' 'The signs of symptoms of depression the benefits of physical activity to depression'
Not useful	'I didn't find any of it less useful' 'Poor-quality videotape' 'The rather stereotypical pictures of older people' 'Did not increase my knowledge'	'Need more information about how to treat and deal with depression' 'None – whole booklet has been a useful source of information'
Example of applying information	'Since the training I have learned how to cope with resident who feel depressed by giving them more time and try to understand how they feel' 'I feel that I am more likely to report my concerns if I thought that a service user was suffering from depression' 'Discussed their condition with experienced staff members and refer to a community mental health team' 'Recognised some signs of depression and used appropriate approach'	'If I feel a resident seems quiet and low I try to make them more active by taking them for a walk or playing a game' 'The information doesn't really apply to my role in the work place but I have become more aware of the residents' moods' 'I have sat in on an exercise session helping residence to participate and noticed they have found it fun, given them something to achieve and look forward to' 'Discussed with GP regarding patients whom I fell may be depressed' 'One of our residents seems to be responding very well to the exercises. I am encouraging her to attend and she is physically and mentally flourishing'
More or less aware	'More – better at spotting signs' 'I have being able to identify a lot of depressive symptoms with the clients I took after at my work while before I would rather relate these symptoms to tiredness or dementia' 'Neither at present as I know all my residents and would notice any changes in them'	'I have become more aware and watchful with residents' 'I have become more aware and two residents in particular are withdrawn off their food sleeping a lot and not wanting to mix with others' 'Yes I have become more aware I didn't realise how much depression affects a person's everyday life' 'I did. I gained more knowledge and skills to understand depression' 'Informing multidisciplinary team to as well as GP to review cases'

GP, general practitioner.

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Appendix 16 OPERA protocol v3

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Older People's Exercise intervention in Residential and nursing Accommodation (OPERA)

Contents

Background

Untreated depression is a major cause of morbidity in older people, particularly in those who live in residential and nursing homes (RNHs). Up to 40% of RNH residents are depressed.[1;2] In many cases this is not recognised by the RNH staff or by the resident's general practitioner.[3;4] Modest improvements in mental and physical health are likely to produce large relative increases in the number of quality adjusted life years available to this group, which has an extremely poor baseline level of health and life expectancy. Antidepressants are a common first line treatment for depression. In a care home setting, a controlled trial suggested that tricyclic agents are effective but poorly tolerated,[5] whilst more modern drugs are well tolerated but are less well researched in this setting.[6;7] The use of drugs as the primary

approach to managing depression in these patients presents three specific problems: firstly the failure to recognise mild/moderate depression, secondly the absence of evidence for their effectiveness in the very elderly (aged > 80),[8] and thirdly the potential for serious adverse events related to their use, in particular because of the multiple medications commonly taken by RNH residents. Typically RNH residents are on 6-8 different medications, with most receiving at least one psychotropic medication.[9-11] The BNF cautions against the use of tricyclic antidepressants in the elderly because they may cause specific problems with drowsiness, urinary retention and hyponatraemia; and against the use of selective serotonin reuptake inhibitors (SSRIs) in patients with cardiac disease, diabetes, and renal impairment, three conditions which are highly prevalent in RNH residents (32%, 20% & 4% respectively).[12;13] Falls are a major cause of morbidity and mortality in older people.

Antidepressant drugs, both tricyclics and SSRIs are associated with a two-fold increase in falls in care home residents.[14] Reducing the burden of depression in RNH residents by using a conventional medical model of diagnosis and drug treatment are likely to fail, because of poor recognition, low intervention rates and the toxicity of medications. More generally there is a move away from drug treatment for mild/moderate depression. NICE guidelines do not recommend drug treatment for mild depression; they suggest that drugs should be used only as part of a more holistic package of care for those with moderate depression.[15] Specifically for the elderly, the guidelines recommend that their poor physical state and social isolation should be addressed. Multiple physical morbidities are expected in RNH residents[16] and even lack of social interaction has been shown to be common in observational research in residential settings.[17] There is good evidence that both functional impairment and loneliness are risk factors for depression in RNH residents.[18]

In RNH residents who are not depressed at baseline, the annual incidence of depression is around 12%, with depression resolving after a year in only about half of them.[19] Looking more widely at interventions to reduce morbidity in the frail elderly, there is a growing recognition that addressing single outcomes such as falls, cardiovascular disease or depression as isolated problems inadequately addresses the needs of this group.[20] Physical health problems are independently associated with mental health outcomes in older people, thus an intervention that addresses both has intuitive appeal. To maximise the impact on the outcome of interest, in this case depression, interventions should ideally address patients' general health. Depression in RNH residents is undoubtedly an important health problem, but it is difficult to obtain new resources for its treatment from Primary Care Trusts given the

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competing demands for high-cost, life-saving treatment for younger people. Yet depression is a viable target for public health interventions as physical health and costs of care are significantly higher for older people with depression.[21;22]

Thus, an ideal strategy to reduce the burden of depression in RNH residents should:

- not be based primarily on drug treatment,
- not be dependent on a health professional establishing a clinical diagnosis of depression,
- address both the treatment of established depression and the prevention of incident depression, thus reducing the overall prevalence of depression in RNHs,
- improve social interactions,
- be expected to have beneficial effects on multiple systems,
- be economical to deliver.

Exercise is a promising non-medical approach to the management of depression. Plausible mechanisms for its possible effect include improved social contact, a diversion from negative thoughts, and the physiological effects on neurotransmitters such as monoamines & endorphins.[23] A number of systematic reviews which pooled data from different study designs found that exercise improved depression.[24;25] A review of 14 randomised controlled trials suggested that exercise might be efficacious in reducing symptoms of depression in the short term, although all of these studies had significant limitations. Compared with 'no treatment' (usually including an attentional control), the pooled standardised mean difference in effect size was -1.1 (95% CI -1.5, -0.6), indicating a modest reduction in depressive symptoms in favour of exercise. The samples in these studies were diagnostically heterogeneous, ranging from mild depressive symptoms through dysthymia to major depression. Only six studies compared exercise with standard treatments for depression, of which four included cognitive behaviour therapy and only one included antidepressant medication. None of these studies found a statistically significant effect of exercise. Nearly all of the exercise interventions in studies covered by this review took the form of regular sessions of vigorous aerobic exercise, such as running for 20 minutes two or three times per week, supervised by an exercise therapist or personal trainer either individually or in groups. No statistically significant differences were found between aerobic and anaerobic exercise regimens.[26] NICE guidelines recommend exercise as a first line treatment for mild depression.[27] A recent systematic review of the effects of exercise on depression in older people concluded that it might be efficient at reducing depressive symptoms in the short term but that there were insufficient data on its

long-term effect.[28] It identified five RCTs of exercise regimens in older people, all of which were supervised group exercise programmes (mean number of participants 64, range 14-156). Four of these RCTs reported positive results. However, their methodological standard was poor and the longest duration of intervention was just 16 weeks. None of these studies was performed in residential accommodation; and all of them used 2-3 exercise sessions per week. None of them sought to change participants' approach to exercise throughout the week.

Maximising psychological and physiological effects from an exercise regimen requires that increased exercise is built into residents' usual routine. However active residents may be during brief formal exercise sessions, these will occupy only a small percentage of their time. Engineering a system change within RNHs so that increased exercise is both facilitated and actively encouraged will ensure that residents are regularly exposed to the intervention throughout the week.

In this trial we are testing a pragmatic intervention, reflective of current best practice, consisting of training for RNH staff to support the building of safe physical activity into the RNHs' normal routine; and a twice-weekly formal exercise class led by a specially trained physiotherapist. This is a 'whole RNH' intervention; all residents without an absolute contraindication to exercise will be invited to attend the class and to increase physical activity generally. This will allow depressed residents to benefit from interaction with non-depressed residents; and reflects how such a programme, if effective, might be implemented in RNHs by NHS physiotherapists. Furthermore, it may: avoid the use of drug treatment; demedicalise mild/moderate depression; confer wider health benefits; improve social interactions within RNHs; and have beneficial effects on all residents.

This is a cluster-randomised trial with the RNH as the unit of randomisation and residents as the unit of assessment to assess the impact of a whole RNH intervention to increase exercise on the prevalence of depression and the remission of existing depression.

Research objectives

Our objectives within this cluster-randomised trial are to evaluate the impact of a 'whole home' intervention, consisting of training for residential and nursing home staff backed up with a twice-weekly physiotherapist-led exercise class, on:

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- Prevalence of depression in those able to complete assessments twelve months after their homes are randomised (our primary outcome).
- The proportion of residents depressed at baseline that experience remission from their depression six months after their home is randomised.
- Change in the severity of depressive symptoms in depressed residential and nursing home residents twelve months after their home is randomised.

We will also examine the following secondary outcomes:

For all residents participating in assessments

- Health related quality of life
- Mobility & exercise tolerance
- 'Fear of falling'
- Cognitive function
- Chronic pain

For all residents with consent/assent to examine the medical and care home records

- Incidence of injurious falls as indicated by peripheral fractures
- Mortality
- Hospital admissions
- Prescribing costs

In addition, we will assess the cost-effectiveness of the exercise programme from both a societal and an NHS perspective.

Methods

Our focus is on testing an intervention, which if shown to be effective, could be implemented as part of routine health/social care. An exercise intervention as part of routine care in RNHs will be difficult to introduce into normal practice if it is to be available only to those who have been diagnosed with depression because of the need formally to identify those entitled to attend; and it is less likely to be effective if only those who are depressed attend. If a positive approach to increasing exercise in the residents is built into the values of RNH staff, the likelihood of an exercise intervention having a positive effect will be maximised. For these reasons we are testing a whole-home intervention consisting of a training programme for RNH staff, supported by a twice-weekly physiotherapist-led exercise class. Since all residents will be exposed to the intervention its effects, positive or negative, on mental and physical health may affect both those who are depressed and those who are not depressed. It therefore makes sense to seek outcomes for all RNH residents. Indeed, it would be difficult to justify excluding the non-depressed population from an assessment of possible harm from the intervention. With an ongoing intervention these effects, positive and negative, will continue to accrue in the long term. Thus our pragmatic primary outcome of interest is the proportion of RNH residents who are depressed one year after randomisation. Our more explanatory primary outcomes are remission of depression after six months, and reduction in the severity of depressive symptoms after one year, in those who were depressed at randomisation.

Conceptually this is a very simple trial to find out if exercise helps depression. However, we are proposing a complex intervention that involves all residents and staff in participating homes. Thus we need to do additional work to understand how the intervention works in practice and to explore any barriers to implementation; and we need to measure its effect on both depressed and non-depressed residents. Only by measuring its effect on the health related quality of life of all residents can we carry out a robust health economic analysis, and it is essential that we measure any potential harms from the intervention in all those who are exposed to it.

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Planned Interventions

Control intervention (Depression awareness programme)

In line with the MRC's Good Clinical Practice Guidelines there is an active control intervention in all participating RNHs to ensure that they are aware of current best care for the identification and management of depression in this population.

- By using current best care as our control, we can ensure that any benefits identified are due specifically to our intervention package rather than to raising awareness of depression within the intervention RNHs.
- We will reduce the risk of 'resentful demoralisation' in the control homes affecting recruitment of new residents after randomisation or even leading to the RNH withdrawing from the study.[29]

We have developed a depression awareness programme for RNH staff. This consists of brief in-service training for RNH staff backed up with a DVD on recognizing depression, information leaflets/posters and regular contact with study team members. As an addition to best usual care we inform the RNHs of all participating residents' GDS-15 scores. In the control homes our research nurses deliver this intervention soon after randomisation and when they visit the homes for recruitment and follow-up.

In the active intervention RNHs the depression awareness training delivered by the research physiotherapists as part of the overall intervention package.

Active intervention package (exercise programme)

There are two inter-linked components to the intervention:

- physical activation programme, and
- group-based exercise

We anticipate that our intervention, as well as improving mood should also improve functional abilities, reduce falls, and improve mobility.

Physical Activation Programme

The physical activation programme promotes a commitment to encouraging safe physical activity for residents of the home. Evidence suggest that for a complex intervention of this nature to be effective it

needs to be 'normalised'; that is, it should be seen as part of the organisation's normal functioning rather than as an optional extra.[30] Although there is no direct evidence to inform the content of our strategy, evidence from other nursing homes projects is informative (see below). The physiotherapists are asked to do the following:

- Implement a depression awareness programme (see above).
- Improve knowledge and awareness of the benefits of physical activity in the staff, residents and relatives.
- Provide an individualised review of mobility safety. Ensure that appropriate and safe walking aids (including grab rails where needed), and footwear are available to each individual, and reinforce the need for use.[31]
- Provide advice on activation strategies for individual clients, including the level/type of assistance/supervision needed, and support the staff and residents in their implementation.
- With the Director of Nursing/Home Manager, review the policies and strategies in place to promote physical activity.
- Where appropriate, involve volunteers and families in the supervision and promotion of physical activity.
- Identify a physical activity 'champion' within the home who will serve as the main point of contact with the therapist and undertake regular review of the organisation's progress. The main activity that will be targeted in the physical activation programme will be safe walking. This is a realistic aim.[32]

Group-based exercise

All residents are invited to attend twice-weekly group exercise sessions in the communal space of the homes. This is a rolling programme; all new residents are encouraged to enter the groups as they enter the home. The groups are led by physiotherapists experienced in managing frail older people. Timing of the sessions seeks to facilitate maximal likelihood of attendance. The sessions use mixed training stimuli, combining aerobic conditioning, progressive strength and balance training. The programme utilises music and rhythmic, simple movement patterns. The group sizes are do not normally exceed eight participants, and last 40 minutes to an hour depending on the tolerance and ability of the group. Prior to the groups, the physiotherapists give each participant a brief risk assessment; determining any absolute contra-indications to exercise[33], and the optimal exercise intensity for each participant. The physiotherapist may have a group with a range of abilities, and thus intensity is set to

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ensure safety of all participants. In larger homes, where there may be a need for several groups, physiotherapists will group together participants with similar levels of ability, and set the intensity of exercise accordingly. It is challenging to gain engagement and attendance from depressed individuals, but maximising participation is essential to demonstrating effectiveness of the technology. Consent/assent to study assessments does not indicate consent to participate in the exercise class on any particular day. Best clinical practice for consent to physiotherapy treatment is complied with to obtain agreement from individuals for participation in the exercise class. The physiotherapists work with staff to gain participants' trust and acceptance of the programme. All residents will have an activation prescription in addition to the exercise classes (see below).

Rationale for the programme-The design of the programme has been informed by an extensive literature search and the practical experience of the team. In summary, there are three main hypotheses suggesting how exercise can alleviate depression, and a limited amount of experimental evidence. Aerobic activity may affect circulating corticosterone, or hippocampal brain neurotrophic factors, or correct dysregulated monoaminergic neurotransmission, all of which are implicated in the origins of depression.[34-36] Improved self-esteem and self-efficacy, distraction from negative emotion and behavioural activation are also thought to alleviate depression.[37] Experimental evidence also supports progressive strength training as a method of reducing depression.[38] We have therefore proposed a mixed exercise programme. Therapists attend a two-day course to be trained in the intervention. The intervention is documented and standardised, but allows therapists a range of options to adapt the content to the needs of the groups/settings. This approach has been successful in previous studies we have conducted with physiotherapists; therapists are happy that the approach reflects their practice and, importantly, it is possible to document the concept and method with the precision necessary for replication and dissemination.[39] This approach utilises recognised methods of selecting baseline exercise intensity, and progressing exercise,[40] modified for frail older people. Exercise that utilises rhythmic movement and reflex motor activation is effective in people with cognitive impairment.[41] The intervention seeks to minimise unwanted side-effects including an increase in falls and pain.

We are including non-depressed residents in the exercise programme because:

- Non-depressed adults will stimulate those who are depressed to participate,
- It is difficult to predict who will develop incident depression, or outside the trial situation to identify those with mild/moderate depression; thus an inclusive approach is needed for both prevention and treatment,
- Pragmatically, this is how classes would be/are run. Strength training is important for a range of geriatric syndromes which overlap with depression, and residents are likely to have multiple health problems. It would be inconceivable that multiple classes would be set up to target falls and depression separately.

Effecting organisational change- A growing body of evidence on diffusion of innovation and implementation of research/guidelines into clinical practice has highlighted the importance of organisational context as a key factor in effecting change in practice.[42;43] Successful implementation is more likely if the intervention/guideline resonates with the experience of those being asked to embrace it.[44;45] Embedding the exercise intervention within a whole-home strategy that actively engages with the organisational context in which the intervention is delivered should enhance the effectiveness of implementation. There is no guidance for implementation of physical activity programmes in nursing homes, but research on the implementation of clinical practice guidelines has demonstrated that a number of issues need to be addressed. These include:

- Perceived or real workload issues
- Poor communication with nursing/therapy staff
- Insufficient knowledge or education
- Large staff turnover.[46]

We have adopted a range of strategies (see above) based on our knowledge of working with homes and informed by best available evidence.[47;48]

Safety and grade of staff - Several studies have shown that low intensity and poorly implemented physical activation programmes may increase falling[49;50] and pose a threat to the safety of older people living in nursing homes. We consider it essential to the safety of participants that experienced therapists implement the intervention. They need to have the essential awareness of the multiple health problems facing older people in care settings, of exercise prescription in frail older adults, and of promoting safe mobility. If successful, future studies would consider whether fitness instructors could deliver the

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intervention, or components of it, and what level of additional training and supervision they would require. We will undertake an assessment of the competencies and skills required to deliver the intervention. In the event that any participants suffer an injury during the exercise class we will do a critical event analysis.

RNH recruitment-We will recruit roughly equal numbers of RNHs in two localities, North East London and the West Midlands. We have agreement from two local NHS Trusts (Barking & Dagenham Primary Care Trust (PCT), NHS Coventry, NHS Warwickshire, and Coventry & Warwickshire Partnership Trust,) to support this project and, in some cases, to host the service delivery components of the study. We will initially approach all RNHs in these Trust's localities and then approach RNHs in neighbouring PCTs' localities. There are over 80 RNHs in Barking & Dagenham and the neighbouring Havering. There are around 135 RNHs in Coventry & Warwickshire Partnership Trust's locality. These two localities have diverse populations that are representative of the social and ethnic mix of the UK as a whole. We decided against recruiting RNHs that cater exclusively for none-white residence as such RNHs are scarce and there would be difficulties in delivering the intervention and measuring outcomes in non-English speakers; there would also be problems appropriately randomising such atypical RNHs. We are seeking to recruit RNHs with a range of characteristics (large / small, independent/chain, local authority / private / charitable, purpose-built / traditional, nursing / residential, dementia specialism / not).

Participant recruitment- Residents may participate in the study in three ways:

a) completing the baseline and follow-up assessments
b) allowing their routine data to be accessed by the study team
c) participating in the exercise programme

We consider 'a' and 'b' here; 'c' will be considered separately under the intervention. Once the RNHs have consented to join the study we will consider all permanent residents for inclusion in the study:

1. The RNH identifies those residents whom it would be inappropriate to approach for consent/assent either directly or via their next of kin, for example those with a very limited life expectancy.
2. A specially trained research nurse briefly assesses each remaining individual to explain the study and to assess his/her competence to give consent and to participate in the research assessments. Residents are given information about the study in a suitable format (e.g. large print or audio). The RNH and research nurse identify those residents who will clearly be unable to participate in any

assessments but who nevertheless may be able to give consent to the use of their routine data. This group might include those unable for any reason to communicate in English sufficiently well to participate in the assessments.

3. Competent residents have the opportunity to reflect on whether they wish to join the study prior to giving consent to the assessments and/or the use of their medical records. At this stage we will also seek consent from residents to contact their next of kin to collect data for the health economic analysis at the end of the study.
4. The next of kin of those deemed not competent to consent to the study assessments are approached for their assent for the resident to take part in the assessments and/or the use of their medical records. If no next of kin can be contacted we will, as suggested by the 2005 Mental Capacity Act s32(3), nominate an appropriate person, e.g. Age Concern Advocate or GP, to give assent (http://www.opsi.gov.uk/acts/acts2005/20050009.htm).

We will repeat this process for any new permanent resident moving into participating RHNs upto nine months following that RNHs randomisation.

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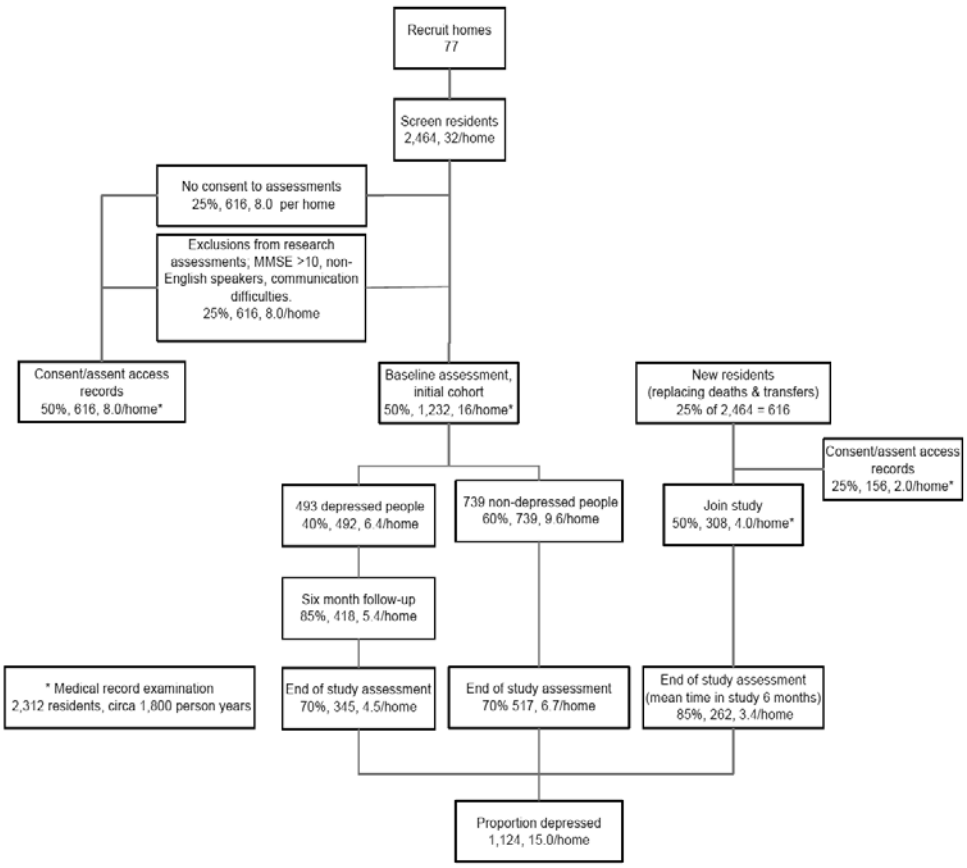
Figure 1
Overall study design



Baseline assessments-

The baseline assessment takes place after consent/assent has been obtained. At this assessment, we confirm eligibility, specifically excluding those with severe cognitive impairment who are not able to complete the GDS-15. In the original protocol we specified a that people with a Mini Mental State Score of ≤10 would be excluded.[51] Experience in the pilot study indicated that even people with quite severe cognitive impairment could complete the MMSE, and some whith an MMSE score <10 were unable to complete this. We have therefore removed this entry criterion.

The assessment lasts around 30-60 minutes, the research nurse administers our questionnaire instruments (GDS-15, Euroqol MMSE, Barthel Index, fear of falling, current pain) and a brief physical

assessment (SPPB) verbally, and complete on paper whilst with the resident and will then enter the data directly onto a study laptop after the assessment time with the resident.

We collect demographic data (age, sex, ethnicity, social class – age left school) and data on length of residence, fee status and current medication from the RNH records for all those for whom we have consent/assent to access their records.

The diagnosis of depression is commonly overlooked in RNH residents.[52] It would be inappropriate, once we have identified depression, to prevent these residents from accessing appropriate conventional health care. We therefore provide the RNH staff with participants' Geriatric Depression Score (GDS-15) scores, and an interpretation of their meaning, prior to randomisation. If the GDS score is 10 or more we encourage the home to discuss this result with the resident's general practitioner.

Randomisation and protection from bias- Randomisation takes place after we have collected all the baseline data in the individual RNH. This ensures allocation concealment for existing residents at the start of the study. For each location, we will minimise by size and type of home (local authority/voluntary/private/residential/private nursing/dementia specialist (>50% dementia beds)). A statistician separate from the rest of the study team is responsible for the randomisation. For new residents joining the study after randomisation allocation concealment will be impossible because all RNH staff and study staff visiting the RNHs will be aware of the home's allocation. Indeed, one marker of success for the programme will be achieving this obvious level of awareness. Lack of allocation concealment may bias recruitment for this minority of residents joining the study after randomisation.[53;54] We will protect against this by ensuring that we are aware of all new residents and monitoring reasons for exclusion from the study. In the event that there are differences in the baseline characteristics between intervention and control RNHs in those who join the study after randomisation, we will consider basing our analysis of the proportion of residents depressed at the end of the study only on those residents who joined the study before randomisation and who were present at the end of the study. We will have sufficient power for this analysis.

Our primary effectiveness outcome, the GDS-15, and other questionnaire data will be collected by our research nurses, who will be aware of the RNH's randomisation status, directly onto a study laptop. We will use linear regression modelling to explore outcome data for individual data entry bias. More

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potential for bias exists in the physical function assessment; this is unavoidable. Our overall mortality data will be not be prone to bias; our interpretation of cause of death data will be blind to allocation.

Table 1, Inclusion/exclusion criteria

Inclusion Criteria	Exclusion criteria
Assessments	
• Permanent resident in RNH • Aged 65 or over • Consent/assent to assessment • Able to participate in baseline assessment • GDS-15 score ≥5 for baseline depression[55]	• Severe cognitive impairment (MMSE <10) • Problems communicating by any means • Terminal or other serious illness • Non-English speakers for who a translator is not available
Record examination	
• Consent/assent to record examination	
Exercise class	
• Able to transfer (with assistance from one person) from a wheelchair to a chair	

Initial phase of study - The intervention is grounded in previous work on group exercise programmes and studies involving RNHs and their residents.[56;56;57] All of the components build on existing work; however these have not been tested together. Informed by the MRC framework for testing complex interventions, and specifically our previous work on modelling a complex intervention for falls prevention, we decided on the final components of the intervention in the pilot stage.[58;59] We will piloted our recruitment processes in three homes during the six months before the main study started. In two of these we piloted the active intervention and in the third we will piloted the control intervention. This will allow us to test all our recruitment, intervention and follow-up processes.

Follow-up- Follow-up assessments for all consenting/assented residents are one year after the home is randomised. In addition those participants who were depressed at baseline have an assessment six months after randomisation. If any of those who were depressed at baseline have moved to another RNH in the locality, or if they are in a local hospital when their assessments are due, we will endeavour to carry out their assessments in these alternative locations.

Sample size

Because few RNH residents move out of residential accommodation we anticipate good follow-up rates. This population has a high mortality, up to 34% per year;[60] additionally, for some, their health will deteriorate so that they are no longer able to complete some, if not all, of the follow-up assessments. However, those residents with the poorest health will be less likely to join the study, so that we can anticipate a smaller attrition rate. The nearest equivalent study collected data on 169/220 depressed residents after 9.5 months (77%)[61], equivalent to 71% at one year. We therefore anticipate a loss to follow-up rate of 30%, made up of those who have died and those no longer willing or able to complete the assessments.

Table 2, Sample size calculations

	A) To show a reduction in the proportion of participating residents depressed (GDS-15 <5) at the end of the study from 40% to 25%	B) To show an increase in the remission rate after six months from 25% to 40% in those depressed at baseline	C). To show a mean reduction in GDS-15 score of 1.2 after twelve months in those depressed at baseline
Power	80%	80%	80%
Significance	5%	5%	5%
Simple sample size	343	343	280
Mean cluster size at follow-up	15.0	5.4	4.5
Inflation factor	1.7	1.22	1.175
Total number required at follow-up	583 with complete assessments	418 with depression at baseline & complete assessments	330
RNHs required	39	77	74

All of our sample size estimates include an inflation factor to account for clustering effects. Few previous studies are available to allow us to estimate the range of likely values for the intra-cluster correlation (ICC) needed to estimate this. We have therefore used a conservative value of 0.05 for the ICCs for the different outcomes, towards the upper end of the range seen in previous primary care studies. The inflation factor also depends on the average cluster size and the variation in cluster size. Our average cluster size is different for our three outcomes relevant for sample size calculations (table 2 and figure 1). Data on variation in cluster size are not available, but we expect any effect on our sample size

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to be modest[62] and that our conservative estimate of ICC will to some extent allow for this. To reduce NHS treatment costs we are using an unbalanced randomisation:- 1 intervention home:1.5 control homes. All our estimates are based on this unbalanced randomisation. The mean change in the GDS-15 score in a community sample of people aged over 85 after a major negative life event (death of partner) is 1.2.[63] This is indicative of a clinically important mean difference in GDS-15. The standard deviation of the GDS-15 nursing home residents is in the range 3.2 -3.6.[64-67]; for depressed residents it is 3.5[68] We have used a standard deviation of 3.5 in the sample size calculation for comparison 'C' (table 2). Comparison 'B' needs the largest number of homes. We will therefore recruit 77 RNHs to the study at the rate of 3.5/location/month for 11 months in year two of the study, plus three pilot RNHs in year one of the study.

Power for primary analysis

Our primary analysis will be a comparison of the difference in proportion of depressed residents at the end of the study. Recruiting participants from 77 RNHs gives more than 97% power to detect this at the 5% significance level, even if we need to exclude residents recruited post-randomisation from this comparison. It also means that, for our primary analysis, we have sufficient power to allow for likely variation in cluster sizes even if our ICC is as high as 0.05 (expected increase in sample size required ~15%) and can also allow for physiotherapist effects; a single physiotherapist will carry out the exercise programme in more than one RNH, and clustering effects due to physiotherapist may therefore occur.

Process evaluation of implementing the intervention- To help to optimise our intervention and gain general information on effecting organisational change in RNHs are studying the process of implementation in the pilot RNHs. This evaluation consists of in-depth interviews with RNH managers and a purposive sample of care staff, patients and their carers, to explore their experiences of the programme, their beliefs about the facilitators and barriers to involvement, and their views on the process of consent for participation in the study. Interviews with RNH managers will also cover their reasons for taking part, their feelings about the study, and their beliefs about the potential for long-term changes in the home as a result of the intervention. All interviews are audio-taped and transcribed for analysis using the Framework method.[69] We will use participant observation of the in-home training sessions on depression and the exercise classes, and collect process data including the number of patients enrolled, number of drop-outs, number of patients giving individual consent, and number of patients requiring carer's assent. Data from the interviews, observational work and process data has

been triangulated and fed back to the research team to assist them in optimising the intervention prior to the main trial. Data will also be fed back to the home staff, patients and carers to enable them to participate in the refinement of the intervention. A full protocol for the process evaluation has been developed from the results of pilot work and is available separately.

Ethical arrangements

This study is a complex intervention within a cluster-randomised trial involving a potentially vulnerable participant population, some of whom will be unable to give consent. Thus raises a number of ethical issues, including consent to cluster randomisation, individual consent to the exercise component of the intervention, participation in research assessments and access to records. Specific measures have been incorporated into the study to address these issues, drawing on recommendations for good practice as well as legal and regulatory frameworks. These include:

- Involvement of local relevant user groups as part of gaining consent for cluster randomisation.[70-73]
- Specific training for research nurses in assessing competence for consent to assessment and access to records*
- Next of kin assent for those residents not competent to consent*
- Best clinical practice protocol for obtaining agreement of residents to participate in exercise classes. We are not aware of any published guidance on this point. We will work with relevant user groups to develop these for use in this study
- Information leaflets available in the home for residents, families and staff providing basic information about the study

(*Compliance with Mental Capacity Act 2005 sections 3, 30-34. http://www.opsi.gov.uk/acts/acts2005/20050009.htm)

To explore these issues further we will, hold two focus groups to explore the views of key informants in the wider community (representatives from local and national user groups) about carrying out this study in nursing and residential homes and the process of consent for such research. This will inform detailed ethical analysis of our proposed approach to recruitment and consent.

Research Governance

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This is a relatively high-risk study that will require regular monitoring of peripheral fracture rates and mortality; a well- functioning DMEC and TSC are essential. There would be particular concern if any exercise-related deaths were identified. There is a rigorous programme of quality control. We will employ a second research fellow based at Warwick who will be responsible for the process evaluation and qualitative aspects of the study. Part of his/her duties are to ensure adherence to the study protocols within the RNHs. To achieve this s/he will periodically observe the consent/assent process and baseline and follow-up assessments. In the pilot study a senior member of the study team (ASl) will also observe the consent process in a sample of cases. The clinical research fellow and the process evaluation research fellow based at Warwick will share responsibility for quality control of the interventions. The clinical research fellow will periodically make quality control visits to observe the group exercise sessions; the process evaluator will ensure quality control for the implementation of organisational change and for the control intervention. Quality assurance checks will be undertaken by the WCTU to ensure the integrity of randomisation, study entry procedures and data collection.

Adverse Event Monitoring

We have prepared a protocol for monitoring and reporting adverse events (V1.3_13 10 08). The protocol covers the specific requirements for recording and reporting adverse events in a cluster randomised trial where adverse events are expected to be high due to the age and frailty of the participants. The protocol distinguishes between adverse events that are directly attributable to the study interventions, and the monitoring of peripheral fractures and deaths indirectly attributable to the study.

Data analysis

Outcome measures - Because of the poor state of health of many of our study participants. We are using a parsimonious set of outcome assessments. We will collect these at one year on all participants and additionally at six months on those who were depressed at baseline. We have selected six months for our primary analysis of remission of depression. Within drug trials we would expect maximal effect to be seen by four months. If exercise were an effective treatment for depression in this group we would expect a response in a similar time. However, there will be a time lag between randomisation and participants gaining any benefits from the exercise programme because of the time taken to start

changing the attitudes of the RNH staff and to establish the class as a regular routine in the RNH. We anticipate that the intervention should be fully functional two months after randomisation; and our first assessment will be after six months. In addition to the patient-centred outcomes we will run a detailed process evaluation alongside the study to develop an understanding of how to interpret our findings and to inform implementation strategies if we demonstrate a positive treatment effect.

Primary outcome – Depression

The primary outcome measure is the geriatric depression scale 15 (GDS-15).[74] This brief scale/score consists of 15 simple yes/no questions and has been well validated in residential situations. It avoids using potentially somatic features of depression which may be misleading in this age group, focusing more on mood and functional symptoms of depression.[75] It is one of the most widely used measures in this field.[66] It is simple to complete, with 97% of cognitively intact nursing home residents producing analysable data, and it has good internal consistency (0.8) in this population.[66] The GDS-15 can be interpreted as an indication of the presence/absence of depressive mood. A score of five or above appears to give the best sensitivity and specificity.[67;76] The GDS-15 has also been used as a continuous measure in at least one RCT based in a nursing home.[77]

Notwithstanding the good previous validation work on the GDS-15 we will assess its performance in our pilot homes before starting the main study. In particular we will compare the performance of the GDS-15 with the GDS-12R, a infrequently used measure, that excludes some items in the GDS-15 that may be redundant for those in residential care.[67]

Secondary outcomes

1. Quality of life- The EuroQol is a widely-used brief measure of health utility.[78;79] It measures quality of life using questions in five domains, the EQ-5D, plus the EuroQol thermometer. To reduce questionnaire load we will use the EuroQol as our overall measure of health-related quality of life and for our health economic analyses. It has been used satisfactorily in nursing home residents.[80] Previous work suggests that it is better at picking up serious illness and has fewer floor effects in groups like this than other measures, such as the SF-6D.[81;82]

   We have some concerns about the completion of the EQ5-D by some of our cognitively impaired participants. In particular completion of the "Euroqol Thermometer" may be difficult for some residents. Wherever possible we will use participant self report – however for some cognitively

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impaired participants this may not be possible and we will use proxy values based on the judgment of their carers within the home. To avoid the possibility of introducing bias if a carer provides a proxy value at follow-up assessment when the participant's health had deteriorated during the study we will collect proxy values for all participants at each time point. When participant self report is not available at all assessments we will use the proxy values for that participant.

2. Mobility - The effect of the programme on mobility is assessed using the Short Physical Performance Battery (SPPB), which incorporates three essential aspects of mobility that should be improved by the exercise programme; balance, chair rise and walking ability. The SPPB has been used extensively in trials and observational studies of older people. Because of the central importance of physical function to the ability to thrive, has well established and surprisingly strong relationships with a range of important public health outcomes, including onset and progression of disability; mortality and nursing home admission.[83;84] The SPPB is particularly well suited to frail elderly populations. Testing procedures are standardised and timed. A change of 0.5/12 points is considered a small but meaningful change, and 1.0/12 points for more substantial changes. Our sample size is more than adequate to detect differences of this magnitude in the context of published estimates of the expected standard deviation of the score.[85]
3. Falls- There is evidence to support the use of multi-factorial interventions in falls prevention in nursing homes.[20] What is less clear is whether all elements of these interventions are needed and whether the interventions reduce injurious falls. Indeed one RCT of a low intensity exercise intervention found an increase in falls in the intervention group (43% vs. 56%),[86] whilst a more intensive intervention succeeded in reducing both falls (OR 0.49, 95%CI 0.37-0.65) and hip fractures (OR 0.23, 95%CI 0.06-0.94)[87]. Whilst we are optimistic that our intervention will reduce both falls and falls injury, there is a justifiable concern that, by encouraging residents to be more active, it might lead to an increase in falls. This is a potential barrier to implementation. Collecting reliable data on actual falls in an RNH environment is problematic, and it is not the primary focus for this study. Furthermore, the cluster randomised nature of this study means that RNH staff may be prone to bias in reporting falls. We will therefore address this outcome in two ways:
   a) We will ask participants about their fear of falling by asking "Are you afraid of falling" requiring only a simple yes/no response from participants.
   b) Rather than measuring falls, most of which do not cause injury, we will measure the rate of peripheral fractures as a marker for injurious falls. We will identify these from the RNH and hospital records. Since all residents will be exposed to the intervention, its positive or negative

effects on fear of falling and injurious falls will affect all residents. It is important that all residents, not just those who are depressed, are included in this outcome assessment. We collect these data on all residents for whom we have permission to examine their medical record.

4. Cognitive function - We will measure this using the mini Mental State Examination.[89] This scale, which measures the key domains of cognition, is easily the most widely used measure of cognitive impairment worldwide. It is quick, validated in relevant populations, sensitive to change and allows comparisons to be made with other studies. There is a suggestion that exercise may have a direct effect on preventing cognitive decline.[90] This is therefore an important secondary outcome. One issue that may arise is the possibility of people initially screening positive for depression (on GDS-15) and cognitive impairment (on MMSE). It is well known that some older people, when treated for depression improve cognitively; in the most marked case this can unveil a misdiagnosis often known as 'pseudodementia'. Initial interest in this situation was stimulated by reports that it was common.[91] Subsequent careful neuropsychological evaluation of people with depressive symptoms indicates that cognitive dysfunction found in depression tends not to normalize after treatment of depression and may in fact be a marker of high risk of development of dementia.[92-94] Co-morbidity between dementia and depression is very common in the care home population and both depressive symptoms and cognition are outcomes in this study. Irrespective of significant cognitive improvement (likely to be rare), the primary analysis will be of resolution of depressive 'caseness' (GDS-15 >5); cognitive improvement will be an independent secondary outcome. Such cases will not require reclassification in statistical analyses.
5. Pain - The association between pain and depression in older people is well recognised.[95;96]Exercise may have a beneficial effect on pain in this population, independent of the beneficial effects it may have on depression.[97] We will ask participants to rate their current level of pain, i.e. pain today, on a ten-point numerical rating scale at each follow-up.
6. Social Engagement We have included a social engagement measure to allow us to measure interactions with other residents, staff and family and friends. Increased social interactions could be an important benefit both from changing the homes approach to exercise and from the group exercise sessions. The social Engagement Scale designed for use in nursing and residential home care gives an indication of the involvement of a resident in activities within a nursing or residential home. The Social Engagement Scale uses six items from the Minimum Data Set residential assessment instrument (MDS-RAI).

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7. Medication use- We will estimate participants' medication use over the follow-up period using data on their regular medications collected at baseline line, three, six, and nine months after randomisation/study entry, and at the end of the study. We will use these data to estimate their total use of medication over the study period. For anti-depressants, other psychoactive drugs, analgesics and NSAIDs we will convert these into the number of defined daily doses used over one year (http://www.whocc.no). We will estimate total cost of prescription medication using the prescribing and cost analysis database (http://www.ic.nhs.uk/pubs/prescostanalysis2005). We have used this general approach successfully in a previous HTA-funded study. We will collect these data on all of those from whom we obtain consent/assent to examine their records.
8. Hospital admissions -We will extract data on cause and duration of any hospital admissions during the study period from participants' hospital records. We will code these admissions into Diagnosis Related Groups to identify any fractures and for the economic analysis. Since our participating RNHs are in defined localities we will need to visit only a small number of hospitals. Because of the large health service cost associated with hospital admission we will collect these data on all of those from whom we obtain consent/assent to examine their records.
9. Death - Records of all those from whom we obtain consent/assent to examine their records to be flagged at NHS central registry. This will allow us to identify any differences in mortality between the two groups at an early stage. For those who die within the RNH we will ask the home for a brief description of how they died; for those who die in hospital we will extract this information from their hospital records. Medical members of the study team, blind to participants' allocation, will assess these reports. In the event that any death is deemed to be exercise- related on the basis of these brief reports, we will make a detailed assessment as to whether it was related to our programme.

Statistical analysis

To assess the adequacy of our randomisation process in achieving balanced groups we will compare the characteristics of RNHs (location, type and size of home) and individuals (age, sex, baseline assessment scores) in our intervention and control arms using simple descriptive statistics. To assess whether there is clustering by physiotherapist we will summarise outcome measures by RNH and, in the intervention arm, physiotherapist, and use computer software that can measure the extent of clustering at two levels to estimate clustering parameters. To assess the difference in proportions depressed at 12 months between intervention and control homes we will initially use generalised estimating equations (to account for clustering by RNH) with a logit link (to allow for a binary outcome) in Stata. We will

include co-variates in our analysis. Ideally these should be chosen on the basis of predictive value. As far as possible we will assess evidence from the previous literature to identify potential co-variates. However, the strategy of choosing co-variates based on predictive value arises from work pertaining to individually randomised trials and application to cluster randomised trials is more complicated, particularly for individual level co-variates and binary outcomes.[98-100] In addition, the previous literature from which we can identify cluster-level co-variates is not extensive. We therefore propose the following strategies for co-variate identification:

For our primary outcome, the proportion of residents depressed at the end of the study, we will consider the following cluster-level variables for incorporation as co-variates in our models:

(1) location of home (our stratification variable).
(2) measurable characteristics of care homes and residents identified from previous literature as related to the prevalence of depression;
(3) baseline level of depression in care home (based on empirical evidence that baseline levels of outcome are often important co-variates);
(4) other measurable characteristics of care homes or residents within care homes hypothesised by the study team as being related to outcome.

The co-variates to be included will be finalised in a statistical analysis plan prior to analysts becoming unblinded to randomisation group.

For other outcomes which indicate a change in severity of depression for those depressed at baseline, remission rate and geriatric depression score-15 score we will use a similar strategy, but for these outcomes measurements at baseline and outcome will be of the same individual. We will therefore introduce baseline levels of depression severity as co-variates at the individual, rather than the cluster, level.

If our preliminary analyses indicate the presence of additional clustering by physiotherapist, we will need to incorporate this in our analyses of outcomes. This will be done using WinBUGs software which allows the building of flexible mixed-effect models such as that needed to incorporate clustering by physiotherapist which, if it exists, will exist in only one arm of our trial.

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Health economic analysis

We will perform two health economic analyses. Our primary analysis will be a cost utility analysis examining the cost per quality adjusted life year gained for all those residents we have assessed. This is a more meaningful analysis than the alternative analysis that just examines those who were depressed at baseline since the costs, and any potential benefits, will be related to all of those exposed to the intervention. However we will not have health utility data on those who did not participate in the assessments. These residents will also have been exposed to the intervention. We will therefore do a secondary costs and consequences analysis to assess the impact of our programme on the prescribing and other health care costs for all residents where we have consent/assent to examine their records.

The variations around the 'average' resource used in the different homes will be used to inform the sensitivity analysis around the results, to check whether the cost utility result will be drastically altered under different estimates. Building on our previous work modelling the impact of implementing falls guidelines[59] during the pilot phase, we will monitor the recruitment and retention of the exercise programme and take note of how these change over time. This will allow us to assess the impacts these may have upon the cost-effectiveness of the programme and to discover whether there are ways of optimising the cost-effectiveness of the intervention for the main study, and of implementation strategies if the intervention is shown to be effective.

Costs will be obtained at a micro-level by recording units of resources used in intervention and control groups; local and/or national cost tariffs will be applied to the resources used. Care will be taken to measure the variations around the 'average' resource used, to allow for sensitivity analysis around the results. The intervention home costs will include physiotherapists' time for organising and running the exercise class, the training of RNH staff to implement the exercise regime, and the RNH staff time to set up and monitor the exercise programme for individual residents. In the control homes we will record the time spent by the research nurse implementing 'best practice' for diagnosis and management of depression. The costs of the exercise programme to RNHs, in terms of time taken to set up and monitor the exercise routines, or to implement the control intervention, will be estimated from data provided by participating RNHs. Other important resource units to capture are prescription costs; GP and, for residential homes, community nurse consultations; attendance at hospital A&E and outpatients; and hospital bed-days. These health service usage data will be collected from RNH and hospital medical records.

Where possible any data on further costs to the residents, or there next of kin, will be collected from participants at the end of study assessment; these may include additional travel and medications. Many of our participants will be unable to provide these data themselves, in which case we will collect them from their next of kin. In both cases we will seek to validate these data against the RNH records. We will explore developing a tariff for the 'opportunity cost' for the elderly participants' time used taking part in the exercise class based on the views of a subset of participants using techniques such as contingent valuation or conjoint analysis.

We assign a value to the EuroQol states using the tariff of values developed by Dolan et al and use these values as our benefit measure in the cost utility analyses. Where there are incomplete (censored) benefit or cost data due to loss to follow-up we will use non-parametric methods to infer cumulative costs and benefits.[101;102] We will calculate the incremental cost effectiveness ratio (ICER) of the programme by dividing the additional costs of the intervention by the additional benefits of the programme. Given the unknown nature of the ICER sampling distribution, we will use a non-parametric bootstrapping approach to estimate the confidence interval around the incremental cost effectiveness ratio.

Process evaluation - In tandem with the main study we will conduct a process evaluation using both qualitative methods and quantitative data collection to explore the process of implementing a whole-home intervention across a range of nursing and residential homes in the main study. The ultimate outcome of the process evaluation will be to develop a set of transferable principles regarding the whole-home intervention to inform its implementation on a wider scale. We will do case studies in a purposive sample of up to eight RNHs, informed by home size, whether local authority or privately run, and client base. Homes will be sampled from those who begin participating during the initial six months of the main study. A mixture of interviews and observational work will be undertaken, to explore the process of implementing the intervention across a range of homes. Purposive samples of home care managers and staff, patients and their carers will be interviewed just after randomisation, in the middle of the intervention period and at the end of the intervention period, to explore their beliefs about the programme and its effectiveness, their experiences of taking part, and the barriers and facilitators to their involvement. The final interviews will focus particularly on the impact of the programme on the home and of the programme being withdrawn at the end of the study. The data will be managed in the

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first instance by mapping key concepts (charting) and extracting emergent themes from the transcripts. Transcripts will be analysed iteratively and emergent themes and concepts will be revisited and refined. Particular attention will be paid to discordant voices or dissonant cases, i.e. elements of the transcript that do not readily accommodate a theme but which are notable for future analysis. The emergent themes will form the basis of the analytical interpretation.[69]

We will collect quantitative process data in all of the study homes. These data will include: number of care staff trained, number of repeat care staff training sessions required, number of patients approached, number of patients agreeing to take part, number of drop-outs, number of physiotherapists involved in delivering the programme, number of falls/injuries sustained during classes.

Follow-up Study (Six-months post OPERA)

Background

The OPERA trial aims to establish whether exercise is effective in reducing the prevalence of depression among older residential and nursing home residents. Intervention homes in OPERA receive twice weekly exercise groups for 1 year, plus a whole-home activity programme. The trial objectives include bringing about a change in the 'culture' of the homes over the one-year intervention period, this change aims to safely increase mobility and activity among residents. Recruitment of homes to OPERA has been very successful; we randomised our 78th and final home on 5th May 2010; 35 of which are intervention homes. OPERA includes two interventions. An experimental condition that includes staff training in depression awareness and how increasing activity/mobility (DA&AC) can help to reduce depression and twice weekly exercise groups for a year. There is also a control intervention that included staff training in depression awareness (DA). It would be wrong in any follow-up to ignore the control condition homes for a number of reasons. An active intervention was delivered in these homes and whilst it was a one-off training session it is important to know if the information provided and the training given is still being used by the staff in the homes and what impact this training has had on the homes if at all. The OPERA research team (physiotherapists and research nurses) have delivered DA&AC training to 377 staff in the 35 intervention homes. They have also delivered DA training (the control intervention) to 497 staff in the 43 control homes. To date the physiotherapists have delivered over 1,400 exercise groups across the 35 intervention homes with an average attendance at each group of ten residents. By the end of the study we will have delivered over 3000 groups.

As part of the project we have an existing process evaluation which aims, among other things, to evaluate the extent to which a culture change has been achieved. The protocol for the process evaluation has been submitted for publication. The aim of this follow-up is to establish to what extent the culture changes brought about by the OPERA intervention persists after the 12 month intervention period.

Culture within an organisation is constructed from commonly-held and relatively stable beliefs and attitudes and is realised through behaviours and working practices. In OPERA we are providing the opportunity for homes to adopt practices (i.e. increasing activity and safe mobility of residents) that it is hoped will become embedded in the culture of the home and be sustained over time. It is the longer term effects of the OPERA intervention on the culture in the homes which is the subject of this extension proposal.

Our process evaluation, so far, indicates that the OPERA intervention is popular in the homes and that we are producing the desired culture change. Results from the primary efficacy analyses will be available in late 2011. The care homes randomised earliest to the OPERA intervention are now finishing the 12 month intervention; withdrawal of study staff raises the question of subsequent persistence of culture change within the homes.

The intervention costs £12,000 per home, per year, to deliver to one home - £400 per resident. Rolling out this intervention nationwide will have substantial resource implications It is therefore important to know whether the OPERA intervention has generated a sustained change in culture within the participating homes. This follow up study will explore OPERA homes 6 months after the end of the intervention period of the trial.

Research questions

Primary question

- Do any beneficial changes brought about by having participated in the OPERA intervention appear to be persistent?

Secondary questions

- What factors support sustained beneficial changes?
- Are there any sustained effects from having participated in the research in control homes?

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Sample

We will recruit all of the OPERA intervention homes and a purposive sample of control intervention homes (Total 53 homes, 35 intervention homes & 18 control homes). During the main OPERA process evaluation eight homes were invited to provide more information about their involvement with OPERA. In these 'case-study' homes the process evaluation research fellow carried out interviews with staff and residents and observations of 'activity' within the home. We will invite all eight case study homes (6 intervention homes and 2 Control), the last of which was randomised in February 2010, to take part in both the interview and the observational parts of this follow-up.

A package of information will be sent to the manager of the homes as they near the six-month post OPERA milestone. The package will include an invitation letter outlining briefly the follow up study, information sheet/s, consent form/s and a reply paid envelope. There are two slightly different sets of information to be sent out. Firstly, for non case study homes, the package will include information sheets and consent forms about the interviews. At least two interviews from each home are planned, which are: the home manager or a delegate of the manager who was working at the home at the time of the OPERA trial and either an activities coordinator or carer who was also working at the home at the time of the OPERA trial. The information will ask the manager to identify these potential participants and to pass the information to them.

Secondly, the package for case study homes will include an information sheet and consent form about the observations within the homes. This includes information about approaching key staff and inviting them for an interview during the observation visits.

Approximately one week after this mail shot the study researcher will contact the home and ask if the information was received and answer any questions. The researcher will establish if the home is interested in participating in the follow up study. In non-case study homes it will be established if there are two potential interviewees; if so they will be asked to return the signed consent forms in the envelope provided. Once these are received further contact will establish times and dates for interviews. These will generally be via telephone but can be arranged face-to-face. In case study homes the manager will asked if they consent to the observation visits; if so they will be asked to return a signed copy of the consent form in the envelope provided. Times and days for observation visits will be agreed once consent is returned. Payments of £25 will be made to the home amenity fund for completing the interview study and an addition £25 will be paid to case study homes for the observations.

Interviews – all participating homes

We will do recorded interviews with home managers or their delegates plus a member of staff who was working in the home at the time of the OPERA intervention (this may be a carer or an activities coordinator). Our interview schedule will be developed through discussions with the OPERA management team, research staff (research fellows, recruitment staff and physiotherapists) and lay representative. Questions will be designed to explore reflection on the homes' experiences of OPERA (e.g. interaction with OPERA team, depression awareness training, exercise groups, what went well and what we could have done differently/better), the impact of OPERA interventions on the home during the period of the trial and since its end (e.g. awareness of depression, continued use of information, continuation of OPERA type exercise interventions or other activities), and the impact of the withdrawal of the physiotherapist and the exercise intervention (intervention homes only). Much of the interview will be based on pre-defined questions (i.e. a form of questionnaire) although some free responses will also be possible where further information is volunteered our where clarification is requested. Analysis will be grounded on contemporaneous notes taken during interviews with transcripts and original recordings available, when needed, for clarification.

In the eight case study homes interviews will be arranged with key staff during the observation visits. Potential participants (e.g. home manager care worker or activities coordinator) will be provided with an information sheet and invited to give an interview. Interviews will only take place with written consent from participants.

Observations – OPERA case study homes

We will repeat the ethnographic observations we have carried out in our eight case study homes during the OPERA intervention period (subject to the consent of homes). In ethnographic terms the research fellow will take an etic (outsider's) view of the homes providing a unique opportunity to become immersed in the 'cultural' norms of the individual homes and observe similarities and differences in culture across the sample. Although commonly thought of as cultural research, ethnography seeks an improved understanding of a unique group of people.[103] Observations will mirror those undertaken in the main OPERA process evaluation and are described briefly below.

The research fellow will arrange suitable days to visit the home where he will act as both a participant (interacting with residents and staff) and non-participant observer (observing activity, interactions and the environment). A minimum of three visits will be undertaken in each home and **will**

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cover the period from rising in the morning to retiring in the evening. Visits will include the research fellow carrying out both participant and non-participant observations.

Observations will also include the level of 'activity' in the homes (e.g. movement around the home and other activities), staff/resident interactions and the ambience of the home. These will be recorded in field notes. Structured activity sweeps using the observational instrument of activity and well-being Behaviour Category Codes (BCC) [104-105] will be used in observation sweeps of all homes as used in the main OPERA process evaluation. Briefly, the observations will be carried out in the following way:

1. Observational data sweeps should occur every fifteen minutes, for a 90 minute period;
2. No more than three hours of observation should occur in any one day;
3. Observation periods should reflect the daily life in the home: Recommended time periods: 10am-11.30am, 12pm-1.30pm, 2pm-3.30pm, 4pm-5.30pm, 6pm-7.30pm (7.5 hours total). During the 3 days of visits all of these time periods will be covered.

Sweeps will only register the ratio of residents within each public area exhibiting a particular behaviour; no individuals will be identified. Data from this measure will be analysed quantitatively and used descriptively. A comparison with the same data analysis conducted for OPERA will provide a unique opportunity to explore how enduring the patterns of activity seen are and the similarities and differences between homes.

Data Analysis

Qualitative data (open responses from interviews and field notes from observations) will be subjected to thematic content analysis. Anonymised quotations will be used to exemplify themes. Data from the telephone questionnaire questions will provide the opportunity to generate some descriptive statistics and these will be presented in appropriate tables or graphs.

Funding

Funding for this follow-up study was agreed by the HTA on 26th August 2010.

Project timetable and milestones:

The project will take three-and-a-half years. Our proposed study milestones are:

- Month 9 Complete participant recruitment in three pilot homes
- Month 12 Fully functioning exercise programme running in two pilot homes
- Month 12 Agreement from majority of main study homes to participate
- Months 14 - 24 Recruit individual participants and randomise main study homes at rate of seven per month
- Month 18 Submit protocol, and description of the intervention for publication
- Month 24 All main study homes randomised
- Month 36 End of follow-up
- Month 39 Closure of all databases
- Month 42 Submission of draft report and draft papers

Table 2 Project timetable

	Year 1				Year 2				Year 3				Year 4	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Set-up & recruit homes	■	■	■	■										
Start pilot homes			■											
Follow up pilot homes				■	■	■	■							
Start main study homes					■	■	■	■						
Follow up main study						■	■	■	■	■	■	■		
6-month post OPERA follow-up										■	■	■	■	
Analysis and write-up											■	■	■	■

Role of Service Users

By the nature of this study, user involvement is essential. As detailed in our method, we will convene user group meetings in each locality as part of our consent process for the cluster-randomised trials and, during the pilot study, we will organise separate focus groups to explore attitudes to our consent processes. During the pilot phase we will consult with RNH staff, residents and their next of kin to ensure that the intervention has been optimised. Apart from PCT commitments, we already have a commitment from a panel of users/experts including older people's social services, trainers of care home staff, those involved in exercise delivery in care homes and those with experience of relative/residents charities facilitating resident/relative groups in RNHs. We will, of course, have RNH and lay representation on the TSC. An important theme of this work is obtaining user views on the implementation of the project. We will in addition convene a user group, with representatives from relevant charities and RNH organisations that will meet periodically during the study to advise on its conduct. Towards the end of

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the study, when the provisional results are available, we will use the expertise and contacts of our panel of commissioners/trainers/users' representatives to form focus groups to assist in the understanding and dissemination of findings.

Research staff

This is a joint project between the University of Warwick, Warwick Medical School Clinical Trials Unit (Warwick) and The Centre for Health Sciences at Barts and the London School of Medicine and Dentistry (Barts). Staff for this study will be split between Warwick and Bart and the London. The Warwick team will be responsible for overall study management, delivering the interventions, process management and analysis.. Each institution will be responsible for recruitment on its own locality. At Warwick we will employ a study manager who will be responsible for overall management of the study and London recruitment; plus a second research fellow who will be responsible for the process evaluation and qualitative aspects of the study. In addition, this second research fellow will assist in observational data collection and assist in extracting health and social care record information, and be responsible for running our user groups, as part of our quality control processes we will also tape record a number of participants assessment. At Warwick we have a full-time clinical research fellow (physiotherapist) who will be responsible for development and quality control of the intervention packages. This individual will also be responsible for delivering the intervention in the pilot phase.

We have R&D agreement from Barking and Dagenham PCT, Redbridge PCT, Havering PCT, Waltham Forest PCT, Barts and The London School of Medicine and Dentistry and Coventry & Warwickshire Partnership Trust to host this work.

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