Appendix 9

Data extractions for full papers for included studies in cost-effectiveness review

Reference

The Counterweight Programme, 2010[87]

Research question

What are the stated objectives of the evaluation?

To estimate the economic effectiveness of the Counterweight Programme

Funding source

Roche Products Ltd

Study population

What definition was used for (condition)?

Obese and overweight adults

What are the characteristics of the baseline cohort for the evaluation?

1906 adult patients (aged 18–75) in 65 UK general practitioner (GP) practices with BMI $\geq 30\,kg/m^2$ or $\geq 28\,kg/m^2$ with obesity-related comorbidities. Mean age 49.4 years, 77% female. Mean BMI $37.1\,kg/m^2$. Diabetes present 13.5%. Cardiovascular disease 8%

Interventions and comparators

What interventions/strategies were included?

Diet, exercise and behaviour intervention

Was a no treatment/supportive care strategy included?

Compared with no active intervention. Note: economic evaluation was based on a cohort study, rather than a randomised controlled trial (RCT)

Describe interventions/strategies

First line interventions were a prescribed-eating plan, a goal-setting approach, or a group intervention. These were all aimed at achieving an energy deficit of ≥ 500 kcal/day. Patients were asked to commit to nine appointments in 12 months, including six individual appointments (10–30 minutes) and six group sessions (I hour each) over a 3-month period and then follow-up at 6, 9, 12 and 24 months. In addition to dietary component, physical activity and behaviour management components were also included. The physical activity component consisted of encouraging patients to take more than 30 minutes moderate physical activities on most days by incorporating activity into daily living, for example through walking more, and referral to existing exercise schemes. Patients who did not achieve more than 5% weight loss at 3 months were eligible for pharmacotherapy. Antiobesity medication was prescribed to approximately 8% of patients during the first 12 months

Analytical perspective

What is the perspective adopted for the evaluation (health service, health and personal social services, third party payer, societal (i.e. including costs borne by individuals and lost productivity)?

UK NHS

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

Cost–utility

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Primary care

Country/currency

Has a country setting been provided for the evaluation? What currency are costs expressed in and does the publication give the base year to which those costs relate?

UK £. 2001–3 for intervention and 2005 for model

Effectiveness

Were the effectiveness data derived from: a single study, a review/synthesis of previous studies or expert opinion?

A single study (the Counterweight Programme)

Give the definition of treatment effect used in the evaluation

Mean weight change

Give the size of the treatment effect used in the evaluation

Mean weight change (kg) at 12 months ($n = 642$) was −3.0 (95% CI −3.5 to −2.4) and at 24 months ($n = 357$) was −2.3 kg (95% CI −3.2 to −1.4). Untreated patients are assumed to gain 1 kg weight per year

Intervention costs

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

A single study (the Counterweight Programme)

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Costs of the intervention are described in another article (*J Health Serv Res Policy* 2008)[36]

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

The cost was estimated for all practices in the UK having access to it over a 5-year period. Costs included remuneration for all clinicians time required for the intervention – training, GPs time for clinical and motivational assessment, practice nurse time for assessment, motivation, delivery of advice and review. Costs for the Counterweight Programme team, training resources and patient information materials were also included in the analysis. Costs for the intervention were based on the optimal attendance rate of at least six visits in 12 months. In addition the costs of weight management medications prescribed according to protocol were incorporated. Around 20% of patients followed up at 12 months or around 9% of the total intervention group were prescribed weight management drugs

Costs shown in Appendices 3 and 4 of prescribing article. However there are some discrepancies between the appendices

Summary of costs:

In year 0 there is a one-off cost of £1.9M to recruit and train the Weight Management Advisors (WMAs). In year 1 the costs are as follows:

National co-ordination costs £120,000

WMA teams cost £7.8M

Meetings with local staff cost £368,000

Costs to practices of the first wave of audit and training are £1.4M

Costs of the intervention in the first-wave practices are £23M

The total cost in year 1 is £33M, two-thirds of which is the practice nurse time and resources for the intervention

Costs in year 2 are similar but it is assumed that first wave practices recruit a further cohort of patients, so the total cost is higher at £45M. Similarly in year 3 first- and second-wave practices recruit further cohorts of patients so total costs are £56M, with costs in years 4 and 5 being £68M and £80M, respectively

The total cost over this period (including set-up) is £196M. In this time 2400 practices will have recruited five cohorts of 92 patients, 2400 practices will have recruited four cohorts, 2400 will have recruited three cohorts, and so on. In total 3.3 million people will have been recruited. The average cost per person recruited is thus £56.60 per patient

Indicate the source for individual cost values (if appropriate)

Other direct costs (costs incurred directly in treating patients)

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Taken from published studies

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used

Yearly costs per year included for medical conditions such as CHD (£1637), diabetes (£653) and colon cancer (£7320), based on (Ara and Brennan, 2005) and (O'leary, 2004)

Indicate the source for individual cost values (if appropriate)

Indirect costs (costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included?

Not included

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

N/A

Indicate the source for individual cost values (if appropriate)

Health state valuations/utilities (if study uses quality of life adjustments to outcomes)

Were the utility data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion. Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Several studies

List the utility values used in the evaluation

Utility values from the general population (Macran and colleagues[88]) were adjusted to obtain QALYs for individuals with any of the comorbidities, such as diabetes and CHD. The multipliers for diabetes and CHD were provided by Ara and Brennan (0.8661 and 0.8670, respectively). Individuals with colon cancer had a 5% lower QALY based on Lewis and colleagues[129]

TABLE 24 Quality of life by BMI and gender

BMI (kg/m^2)	Male	Female
<21	0.86	0.85
21–25	0.87	0.87
26–30	0.86	0.82
31–39	0.82	0.78
>39	0.88	0.75

As such, a man with a BMI of 31–39 who also has CHD, diabetes and colon cancer would have a utility value of 0.58 compared with the 0.82 reported in *Table 24* for an individual with no comorbidities

Indicate the source for individual cost values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation). Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original

A patient-level simulation model was used which was originally developed to provide input to the UK national guidance on obesity. (NICE, 2006)

What was the purpose of the model (i.e. why was a model required in this evaluation)?

To estimate lifetime outcome of a model cohort reflective of UK adult population

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported? (List them if reported)

The model works by randomly selecting an individual whose characteristics are based on those of the population (for example, BMI, age and gender) and following their healthcare costs and outcomes until death. The model assesses people over 6-month cycles. Each cycle each individual will experience a change in BMI (increase, decrease or no change). The individual can develop diabetes, CHD, or colon cancer depending on the prevalence of each disease at the BMI they are currently experiencing. There is a QALY associated with each health state. Patients are at increased risk of death if they experience one of these conditions

Patients are assumed to regain all 4 kg weight difference effect in two years following removal of the programme

Extract transition probabilities for (natural history/disease progression) model and show sources (or refer to table in text)

Prevalence of diabetes based on BMI level from Gregg and colleagues.[130] Prevalence of CHD based on Framingham equation as set out by Brindle and colleagues depending on age, smoking, blood pressure (BP), cholesterol, diabetes. Prevalence of colon cancer was derived from a study by Giovannucci and colleagues[131]

What is the model time horizon?

Lifetime

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

3.5%

Results/analysis

What measure(s) of benefit were reported in the evaluation?

QALY gain

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

For no active intervention, lifetime QALYs are 28.32, for baseline intervention lifetime QALYs are 28.38. QALY gain is 0.056

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation

The lifetime cost to the NHS of no active intervention is £1884 and for the baseline intervention is £1857

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results

The ICER is –£473 per QALY gained, i.e. cost saving

Give results of any statistical analysis of the results of the evaluation

N/A

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc.) or probabilistic]

One-way sensitivity analysis performed

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

No sensitivity analyses for structural, methodological or assumptions

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base case analysis? If so, what were the suggested causes?

Sensitivity analyses were conducted for background weight change for the untreated population. For background weight change of 0.5 kg/year and 0.3 kg/year the ICER was £2017 and £2651 respectively

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

Even based on very limited estimates of the costs of obesity, the Counterweight Programme is highly cost-effective and will provide cost savings in the medium to long term

What are the implications of the evaluation for practice?

Counterweight represents a highly efficient use of health-care resources

Reference

Roux and colleagues 2006[86]

Research question

What are the stated objectives of the evaluation?

To conduct a clinical and economic evaluation of outpatient weight loss strategies in overweight and obese adult US women

Funding source

Not stated

Study population

What definition was used for (condition)?

Overweight and obesity defined as BMI > 24.9 kg/m^2

What are the characteristics of the baseline cohort for the evaluation?

Hypothetical cohort of 10,000 healthy, non-pregnant 35-year-old overweight and obese women with original BMI > 24.9 kg/m^2 and free from known CHD

Interventions and comparators

What interventions/strategies were included?

Each strategy consisted of a 6-month weight loss intervention followed by a 6-month maintenance programme

Diet only

Diet and pharmacotherapy

Diet and exercise

Diet, exercise and behavioural modification

Women unable to lose weight or maintain successful weight loss were assumed to remain at their age-adjusted original BMI

Was a no treatment/supportive care strategy included?

Routine care (not defined)

Describe interventions/strategies

Diet: reduction in caloric intake necessary to achieve a 10% weight loss under the supervision of a dietitian, in accordance with the American Heart Association guidelines

Pharmacotherapy: 120 mg orlistat three times per day for 6 months, then half this dose per day for 6 months maintenance phase

Exercise: three 45-minute structured exercise sessions per week of moderate intensity, led by a certified instructor, and two sessions per month to review clinical progress with an exercise therapist

Behavioural modification: 1 hour cognitive therapy counselling session led by a psychologist every other week

Analytical perspective

What is the perspective adopted for the evaluation (health service, health and personal social services, third party payer, societal (i.e. including costs borne by individuals and lost productivity)?

Societal

Study type

Cost-effectiveness/cost–utility/cost–benefit analysis?

Cost-effectiveness and cost–utility

Institutional setting

Where is/are the intervention(s) being evaluated usually provided?

Outpatient setting? Single urban setting (p. 1103)

Country/currency

Has a country setting been provided for the evaluation? What currency are costs expressed in and does the publication give the base year to which those costs relate?

Canada. Currency US$. Base year 2001

Effectiveness

Were the effectiveness data derived from: a single study, a review/synthesis of previous studies or expert opinion?

Review (methods not clear) of published literature to identify RCTs from which four studies were selected for estimating efficacy (only referenced in online appendix, not accessible)

Give the definition of treatment effect used in the evaluation

10% BMI reduction after 6-month weight loss programme

Short-term success defined as maintenance of reduced BMI postintervention for at least 6 months

Long-term success defined as maintenance of reduced BMI for at least 5 years after intervention

Give the size of the treatment effect used in the evaluation

Change in BMI postintervention:

Routine care 0.26

Diet only –1.98

Diet and exercise –2.55

Diet and pharmacotherapy –4.55

Diet, exercise and behavioural modification –3.11

Intervention costs

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Not clear

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Not enough information

List the direct intervention costs used in the evaluation – include resource estimates (and sources for these estimates, if appropriate) as well as sources for unit costs used

	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Direct non-medical costs and time-related per participant programme costs (6-month, US$)	0	120	630	120	630
Direct medical per participant programme costs (6 month) US$ (referenced overall but not individually, *Table 1*)	700	2150	2750	2820	3040

Indicate the source for individual cost values (if appropriate)

Other direct costs (costs incurred directly in treating patients)

Were the cost data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion?

Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

Micro-costing techniques used to estimate resource use

Direct costs based on published data and valued using Medicare reimbursement rates

(Includes consultations, laboratory tests, chest X-rays, electrocardiogram and exercise stress test, and educational materials)

Unit costs and quantities not reported separately

Obesity-related morbidity and mortality, such as diabetes and CHD, used annual age and sex-specific treatment related costs (referenced)

Age-specific costs associated with CHD for women represented a published weighted average of the expected management costs of a non-fatal myocardial infarction, cardiac arrest and angina pectoris (referenced)

Annual age-specific direct health-care costs not specific to obesity-related morbidity were included (referenced)

List the costs used in the evaluation – if quantities of resource use are reported separately from cost values, show sources for the resource estimates as well as sources for unit costs used

	Costs
Cost of drug per pill (US$) (published data)	1.32
6-month maintenance per-participant programme costs (US$)	Programme incorporating any combination of diet, exercise and behaviour modification: 150
	Programme incorporating pharmacotherapy: 360
	Routine care: 0
Annual comorbidity treatment cost (US$)	Hypertension: 616.62
	Hypercholesterolemia: 176.34
	Type 2 diabetes age-specific
	CHD first year: 10,850
	CHD subsequent years: 1710
	CHD fatal: 3665

Indicate the source for individual cost values (if appropriate)

Indirect costs (costs due to lost productivity, unpaid inputs to patient care)

Were indirect costs included?

Yes (dietary changes, exercise equipment, fitness monitoring devices, fitness apparel, and transportation and time costs)

Describe how indirect costs were estimated (e.g. how days of lost productivity were estimated and how those days were valued)

Primary data collected from a survey of a community sample ($n = 100$) of female weight management programme participants. The survey elicited demographic information and cost information using modified version of a previously described generic UK cost and use survey (referenced). Direct non-medical resources were valued using self-reported items prices. Self-reported mileage travelled to and from classes and associated physician visits to estimate travel costs. Total annual distance travelled in miles was valued per participant, based on published estimates. These per-person annual travel costs were totalled and averaged across all participants. Time costs estimated using survey data; time was valued by applying wage rates specific to their occupation. Time lost from work was valued using US national average wage rate. Wage rates for domestic child care and light cleaning services were used to wage time lost from performing household duties

Indicate the source for individual cost values (if appropriate)

Health state valuations/utilities (if study uses quality of life adjustments to outcomes)

Were the utility data derived from: a single (observational) study, a review/synthesis of previous studies expert opinion. Were the methods for deriving these data adequately described (give sources if using data from other published studies)?

General age-specific quality weights were derived from the Beaver Dam Health Outcomes study[91] and applied for women > 45 years of age. This was a longitudinal cohort study of health status and health-related quality of life for a random sample of adults (mean 64.1, range 45–89 years) in a community population. Four measures were used: Short-Form questionnaire-36 items, Quality of Well-being index, self-reported health status on a five point scale from 'excellent' to 'poor' and evaluation of current health using time trade-offs. These results were adjusted to reflect weight loss using quality weights derived from the study sample and comorbid diseases using a multiplicative function (and an additive function in sensitivity analyses). No further details given

Quality of life for the reduction in weight loss estimated from community sample with average per cent reductions in life expectancy that subjects were willing to give up through treatment with a single pill, free of charge and side effects but which would not prevent or cure health problems or incur survival benefit, to achieve sustained BMI reduction to the average weight for their height (0.87) and for 10% reduction in BMI (0.93). Quality weights rescaled to economic uses between death (0) and perfect health (1) using previously described methods (referenced)

Temporary decrements in QoL attributable to the interventions were assumed to be related to the intensity of effort required to participate in a particular programme from primary data analysis and were assigned for a 6-month period: QoL = 1 for routine care; QoL = 0.91 for diet, exercise, behavioural modification programme. Other programs of intermediate intensity were assigned values between 0.91 and 1

List the utility values used in the evaluation

Disease-specific quality weights:

Obesity = 0.87

10% reduction weight loss = 0.93

CHD = 0.75 (age-adjusted)

Type 2 diabetes = 0.75 (age-adjusted)

Indicate the source for individual cost values (if appropriate)

Modelling

If a model was used, describe the type of model used (e.g. Markov state transition model, discrete event simulation). Was this a newly developed model or was it adapted from a previously reported model? If an adaptation, give the source of the original

First-order Monte Carlo simulation

What was the purpose of the model (i.e. why was a model required in this evaluation)?

Decision analytic techniques can be used to estimate effectiveness and cost-effectiveness of a number of alternative strategies to reduce BMI in overweight and obese women, taking into account best available data and future uncertainties in costs and benefits

What are the main components of the model (e.g. health states within a Markov model)? Are sources for assumptions over model structure (e.g. allowable transitions) reported? (List them if reported)

The model uses a state-transition framework with the natural history of obesity in a cohort of hypothetical women characterised as a sequence of annual transitions from one health state to another

Women enter the model aged 35 years free from known CHD. Each year a woman's BMI predicts the risk of developing hypertension, Type 2 diabetes or hypercholesterolemia, which predicts her risk of CHD and CHD death (diagram given)

Extract transition probabilities for (natural history/disease progression) model and show sources (or refer to table in text)

From *Table 1*[86]	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Probability of programme compliance	1	0.84	0.86	0.69	0.90
Probability 10% weight loss at 6 months	0.05	0.26	0.68	0.96	0.95
Probability of weight loss maintenance at 1 year	0.5	0.15	0.55	0.37	0.67
Probability of weight loss maintenance at 5 years	Programmes without lifestyle modification: 0.1				0.2

What is the model time horizon?

Lifetime horizon

What, if any, discount rates have been applied in the model? Same rate for costs and outcomes?

3% discount rate for costs and benefits

Results/analysis

What measure(s) of benefit were reported in the evaluation?

Life years and QALYs

Provide a summary of the clinical outcome/benefits estimated for each intervention/strategy assessed in the evaluation

From *Table 2*[86]	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Discounted life expectancy (weeks)	24.119	24.120	24.129	24.128	24.170
Discounted QALY? (months)	18.183	18.169	18.255	18.248	18.426

Provide a summary of the costs estimated for each intervention/strategy assessed in the evaluation

From *Table 2*	Routine care	Diet only	Diet and exercise	Diet and pharmacotherapy	Diet, exercise, behavioural modification
Discounted lifetime costs US$	121,120	122,440	123,240	122,660	124,200

Synthesis of costs and benefits – are the costs and outcomes reported together (e.g. as cost-effectiveness ratios)? If so, provide a summary of the results

Diet, exercise and behavioural modification was the dominant strategy. The ICER was US$60,390 per life-year gained and US$12,640 per QALY when compared with routine care

Give results of any statistical analysis of the results of the evaluation

N/A

Was any sensitivity analysis performed – if yes, what type(s) [i.e. deterministic (one-way, two-way etc.) or probabilistic]

Deterministic (one-way) sensitivity analysis performed

What scenarios were tested in the sensitivity analysis? How do these relate to structural uncertainty (testing assumptions over model structure such as relationships between health states), methodological uncertainty (such as choices of discount rate or inclusion of indirect costs) or parameter uncertainty (assumptions over values of parameters in the model, such as costs, quality of life or disease progression rates)?

Discount rate (methodological)

6-month programme costs (parameter)

Probability of compliance with 6-month intervention (parameter)

Mortality rates for CHD (parameter)

Comorbidity QoL (parameter)

Drug costs (parameter)

Give a summary of the results of the sensitivity analysis – did they differ substantially from the base case analysis? If so, what were the suggested causes?

Results were most sensitive to variation in the obesity-related effects on QoL and the likelihood of long-term weight loss maintenance. (Hard to tell which parameters had most effect on results as axis on the graph not labelled properly)

Conclusions/implications

Give a brief summary of the author's conclusions from their analysis

Authors concluded that a multidisciplinary weight management programme of diet, exercise and behavioural modification for overweight and obese women may represent good value for money

What are the implications of the evaluation for practice?

Authors concluded also that although a three-component strategy appears to provide reasonable return on resources invested, the 'worthwhileness' of such a programme would depend on the resources displaced to fund it

Authors recommend that future research should aim to confirm the impacts of such combined programmes on QoL and the likelihood of long-term weight loss maintenance. Investments that improve long-term maintenance, even if costly, may provide good return in terms of population health gain for resources invested