Design		Participants		Arms		Outcomes	
Author and year	Brett and Austoker 2001[59]	**Inclusion criteria**	Women invited for routine screening by mammography, already participating in the study at 5 months	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	PCQ, satisfaction with the breast screening service
Study design	Prospective cohort	**Exclusion criteria**	Aged >65 years, symptomatic referral, in another study, developed cancer	***N***	$n = 375$	**Screening attendance**	Intention to reattend and actual reattendance
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	$n = 505$	**Control**	Routine screening by mammography with a normal result		
No. of centres	13			***N***	$n = 130$		
Length of follow-up	35 months						
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign						
Conflicts of interest	None reported						
Notes							
Definition of false-positive	Women, who after attending breast screening units and undergoing further investigations, were not diagnosed with cancer						
Aim	(1) Are women who had a false-positive screening result still having adverse PCs prior to their next routine screen 3 years later? (2) If yes, is the extent of their distress dependent on the processes used in their assessment (e.g. FNA)? (3) If women do experience false-positive adverse psychological effects, does this affect their reattendance?						
	This is the latest publication from a longitudinal study going back to 1995 (see Brett *et al*. 1998[103] and Ong *et al*. 1997[104])						

Methodological issues			
Allocation to groups	NA		
Data analysis	Pearson's chi-squared test for dichotomous data between groups, McNemar's chi-squared test for differences within groups. RRs with CIs were also calculated and Spearman's bivariate correlation for tests of associations between variables. Logistic regression was used to adjust for possible confounding factors. SPSS (SPSS Inc., Chicago, IL, USA) with a two-tailed significance level at $p<0.05$ was used for all calculations		
Handling missing data	Not reported	**Ethics approval**	Yes
Power calculation	Not reported		
Subgroup analysis	Yes		
Demographics			
	n/N	**%**	
Married	305/377	81	
Home owner	330/376	88	
Higher or further education	125/376	33	
Results			
Adverse PCs (PCQ) 1 month before next screening (35 months after last appointment)			
Last breast screening results group (1995)	**% PC score >12 (*n/N*) 1998–9**	**RR (95% CI)**	**Significant difference vs clear after mammography**
Clear after mammography (reference group)	25 (25/99)	Baseline	Baseline
Clear after further mammography and CE	32 (30/93)	1.28 (0.82 to 2.00)	NS
Clear after assessment with FNA	45 (30/66)	1.80 (1.17 to 2.77)	$p = 0.007$
Clear after early recall	46 (46/100)	1.78 (1.19 to 2.66)	$p = 0.002$
Clear after surgical biopsy	52 (11/21)	2.07 (1.22 to 3.52)	$p = 0.014$

Comparison of PCs 1 month after last breast screening appointment and 1 month before the next one

Last breast screening results group (1995)	% PC score >12 (*n*/*N*) 1995	% PC score >12 (*n*/*N*) 1998/9	Significant difference
Clear after mammography (reference group)	26 (26/99)	25 (25/99)	NS
Clear after further mammography and CE	51 (47/93)	32 (30/93)	$p = 0.014$
Clear after assessment with FNA	55 (36/66)	45 (30/66)	$p = 0.015$
Clear after early recall	62 (62/100)	46 (46/100)	$p = 0.034$
Clear after surgical biopsy	71 (15/21)	52 (11/21)	$p = 0.024$

Correlation between PCs at 1 month before returning for next routine breast screening and dissatisfaction with past routine breast screening

Statements about last screening appointment	False-positive screen	
	Coefficient	*p*-value
The amount of time spent for verbal communication at assessment	0.240	0.001
Difficulties with taking in verbal information at breast screening appointment because of anxiety	0.288	0.001
Women's understanding of test result	0.205	0.001
Quality of verbal communication	0.206	0.001
Opportunity to talk to somebody after the breast screening appointment	0.352	0.001
Perceived performance of health workers	0.267	0.001
Verbal communication: chance to say what is on one's mind	0.233	0.001
Amount of information provided in advance	0.179	0.003
Amount of written information	0.279	0.001

Intention to reattend: external factors influencing attitudes and anxiety about attending the next routine breast screening in women with a previous false-positive mammogram

Item	% (95% CI)	*n/N*	Cause worry (%)	Cause worry RR (95% CI)	*p*-value
Magazine or newspaper article	29 (24 to 34)	83/288	11	1.18 (1.07 to 1.30)	<0.001
Television programme	25 (20 to 30)	72/288	9	1.13 (1.04 to 1.23)	<0.002
Poster or leaflet	17 (13 to 22)	50/288	_	_	NA
Radio programme	13 (9 to 17)	37/288	_	_	NA
GP attitude to screening	24 (19 to 29)	69/288	_	_	NA
Friend	21 (16 to 26)	60/288	_	_	NA
Family	16 (12 to 20)	(47/288)	_	_	NA

Actual reattendance: Numbers of women attending their next routine screening (3 years)

Previous false-positive mammography		**Previous normal mammography**	
%	***n/N***	**%**	***n/N***
85	319/375	92	120/130

CE, clinical examination; CRC, Cancer Research Campaign; NA, not applicable; NS, not significant; PC, psychological consequence.

Design		Participants		Arms		Outcomes	
Author and year	Brett *et al*. 1998[103]	**Inclusion criteria**	Women invited for routine screening by mammography, already participating in the study at 1 month	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	PCQ
Study design	Prospective cohort	**Exclusion criteria**	Aged >65 years, symptomatic referral, in another study, developed cancer	***N***	Women placed on early recall ($n = 23$); further mammography assessment ($n = 51$); FNA ($n = 41$); biopsy ($n = 45$)	**Screening attendance**	Intention to reattend
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	$n = 284$	**Control**	Routine screening by mammography with a normal result		
No. of centres	12			***N***	$n = 52$		
Length of follow-up	5 months						
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign						
Conflicts of interest	None reported						

Notes			
Definition of false-positive	Women who after attending breast screening units and undergoing further investigations were not diagnosed with cancer		
Aim	To find out if (a) women who have a false-positive result after routine screening have adverse psychological consequences 5 months later and (b) if yes, is the extent of their suffering dependent on the process of the further assessment This study is a follow-up from Ong *et al*. 1997[104] and prior to Brett and Austoker 2001.[59] For women on early recall this study was 1 month before their next appointment Sixty-nine (24%) women chose not to return the questionnaire		
Methodological issues			
Allocation to groups	NA		
Data analysis	The Wilcoxon signed-rank test was used to investigate differences between PCs at 1 and 5 months. The Mann–Whitney *U*-test was used to test for differences between PCs in the different categories of false-positive outcome. Spearman's bivariate correlation tested for associations between PCs and experiences of breast screening. Logistic regression was used to explore variables relating to women's breast screening experience. SPSS with a two-tailed significance level at $p<0.05$ was used for all calculations		
Handling missing data	Not reported	**Ethics approval**	Not reported
Power calculation	Sample size based on responders to phase 1 of the study		
Subgroup analysis	Yes		
Demographics			
Not reported			

Results

Adverse PCs (PCQ) 5 months after their last screening appointment

False-positive subgroup	% PC (*n*/*N*)	Significant difference vs routine recall after mammography	RR (95% CI)
NR after screening	10 (5/52)	Baseline	
NR after assessment without FNA	45 (23/51)	$p<0.0001$	4.7 (1.93 to 11.38)
NR after assessment with FNA	44 (18/41)	$p<0.0001$	4.6 (1.85 to 11.26)
NR after benign biopsy	60 (27/45)	$p<0.00001$	5.11 (2.13 to 12.26)
Early recall (6 months)	61 (14/23)	$p<0.00001$	6.33 (2.59 to 15.50)

Comparison of adverse PCs 1 month and 5 months after last breast screening appointment

False-positive subgroup	% PC (*n*/*N*) 1 month after last appointment	% PC (*n*/*N*) 5 months after last appointment	Significant difference
NR after screening	17 (9/52)	10 (5/52)	NS
NR after assessment without FNA	57 (29/51)	45 (23/51)	$p<0.001$
NR after assessment with FNA	63 (26/41)	44 (18/41)	$p<0.001$
NR after benign biopsy	91 (21/23)	61 (14/23)	$p<0.001$
Early recall (6 months)	70 (32/46)	59 (27/46)	NS

Logistic regression: variables related to PCs at 5 months after the last breast screening appointment

Variable	OR	95% CI	Significance
PCs at 1 month	5.82	2.70 to 12.56	$p<0.001$
Age of women	1.00	0.98 to 1.03	NS
Result group (type of investigation)	4.4	1.35 to 14.35	$p<0.01$
Likelihood of attending future breast screening	0.61	0.03 to 11.93	NS
Greater perceived likelihood of ever getting breast cancer compared with the average woman	0.91	0.35 to 2.34	NS
Apprehensiveness about attending	0.92	0.80 to 1.07	NS
Need to discuss breast screening with someone	0.5	0.24 to 1.02	NS

CRC, Cancer Research Campaign; NA, not applicable; NR, normal recall (3 years); NS, not significant; PC, psychological consequence.

Design		Participants		Arms		Outcomes	
Author and year	Ong *et al*. 1997[104]	**Inclusion criteria**	Women invited for routine screening by mammography who were recalled for assessment	**Intervention**	Women placed on ER (<3 years), *n* = 182	**Psychological**	PCQ
Study design	Cross section	**Exclusion criteria**	Not reported	***N***	*n* = 182	**Screening attendance**	_
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	*n* = 877	**Control**	Women placed on RR		
No. of centres	13			***N***	RR: after mammography (*n* = 173); further mammography assessment (*n* = 166); FNA (*n* = 109); biopsy (*n* = 31)		
Length of follow-up	Measures taken 1 month after assessment			**Notes**			
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign, NHSBSP						
Conflicts of interest	None reported						
Notes							
Definition of false-positive	Not defined						
Aim	To find out if women suffered adverse psychological consequences from being put on ER following a false-positive mammogram and to suggest solutions to reduce them This study was primarily about the effects of early recall on women who had been called back for assessment after their mammogram						

Methodological issues			
Allocation to groups	NA		
Data analysis	Differences between groups were calculated with chi-squared tests, bivariate testing, logistic and multivariate linear regression were used to calculate the influence of single PCQ variables. SPSS with a two-tailed significance level at $p<0.05$ was used for all calculations		
Handling missing data	Median scores were used per item on the PCQ. Those not responding to any items were coded as missing values and excluded from the analysis	**Ethics approval**	Not reported
Power calculation	Yes		
Subgroup analysis	Yes		
Demographics			
Not reported			
Results			
Adverse PCs (PCQ) 1 month after further assessment			

Outcome of last screening visit	**% reporting adverse PCs**	***n/N***	**Significance compared with women placed on RR after mammography**	**Significance compared with women placed on RR after assessment**
RR after mammography	29	38/130		
RR after assessment	50	64/128	$p<0.0005$	
RR after FNA	58	61/106	$p<0.00001$	NS
ER after assessment	63	81/130	$p<0.00001$	$p<0.05$
RR after biopsy	87	26/30	$p<0.00001$	$p<0.0005$

CRC, Cancer Research Campaign; ER, early recall; NA, not applicable; PC, psychological consequences; RR, routine recall.

Design		Participants		Arms		Outcomes	
Author and year	Sutton *et al*. 1995[55]	**Inclusion criteria**	Women invited for routine screening by mammography who were recalled for assessment	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	Ad hoc anxiety questionnaire with a three-point scale
Study design	Retrospective cohort	**Exclusion criteria**	None reported	***N***	*N* = 24	**Screening attendance**	_
Study centre	Institute of Psychiatry, London	***N***	*N* = 1021	**Control**	Routine screening by mammography with a normal result		
No. of centres	1			***N***	*N* = 671		
Length of follow up	9 months after pre-screening baseline						
Setting	NHSBSP mobile screening unit						
Funding	Imperial Cancer Research Fund						
Conflicts of interest	None reported						
Notes							
Definition of false-positive	Women who are recalled for investigation after a positive breast screen but subsequently receive a normal result						
Aim	To find out if mammography raises anxiety in routinely screened women who have a negative result						
Methodological issues							
Allocation to groups	NA						
Data analysis	These included product-moment correlations, independent and paired *t*-tests and repeated measures ANOVA. Only unadjusted results are reported. SPSS with two-tailed significance at 0.05 was used for all calculations						
Handling missing data	Not reported	**Ethics approval**	Not reported				
Power calculation	Not reported						
Subgroup analysis	Yes						

Demographics

Measured for the whole sample but data only reported for approximately 40% of sample. It is unknown who these 40% were

Results

Retrospective anxiety at 9 months after baseline pre-screening: three-point scale (1 = not anxious, 2 = a bit anxious, 3 = very anxious)

Outcome of last screening visit	Stage 1: receive screening invitation, mean (SD)	Stage 2: while waiting for the mammogram, mean (SD)	Stage 3: at the clinic after the mammogram, mean (SD)	Stage 4: after screening and before receiving the results, mean (SD)	Stage 5: after reading the results letter, mean (SD)	Stage 6: now (9 months after baseline), mean (SD)
False-positive	Not reported	Not reported	1.60 (0.68)	1.95 (0.09)	2.85 (0.37)	Not reported
Normal mammogram	Not reported	Not reported	1.36 (0.52)	1.70 (0.57)	1.16 (0.36)	Not reported
Statistical significance of the difference between the groups			$p<0.05$	$p=0.054$	$p<0.001$	

ANOVA, analysis of variance; NA, not applicable.

Comment: only some of the results were reported numerically. Other scores were reported graphically in such a way that it is difficult to accurately read the scores.

Design		Participants		Arms		Outcomes	
Author and year	Bull and Campbell 1991[106]	**Inclusion criteria**	Women invited for routine screening by mammography who were recalled for assessment	**Intervention**	Women invited for routine screening by mammography who were recalled for assessment	**Psychological**	Ad hoc questionnaire including frequency of breast self-examination HADS
Study design	Prospective cohort	**Exclusion criteria**	Not reported	***N***	Group A: invitation ($n = 541$); group B: normal mammogram ($n = 331$); group C: assessment with mammogram, ultrasound, FNA ($n = 204$); group D: assessment with surgical biopsy ($n = 49$)	**Screening attendance**	–
Study centre	Salisbury and Southampton Health District	***N***	$n = 541$	**Control**	NA		
No. of centres	1			***N***	–		
Length of follow-up	Measures taken 6 weeks after the 'all-clear'						
Setting	Salisbury and Southampton Health District mammography screening programme						
Funding	Not reported						
Conflicts of interest	Not reported						

Notes				
Definition of false-positive	Not reported			
Aim	To assess the psychological effects on well women of participating in the screening programme			
	It is not known if the women had previously had cancer or were in a high-risk group			
Methodological issues				
Allocation to groups	NA			
Data analysis	A paired comparison of women in groups A and B used a paired *t*-test or Wilcoxon rank-sum test. Independent groups were compared using ANOVA or Kruskal–Wallis test			
Handling missing data	Not reported	**Ethics approval**	Not reported	
Power calculation	Yes			
Subgroup analysis	No			
Demographics				
Age (years)	**Group A, *n* (%)**	**Group B, *n* (%)**	**Group C, *n* (%)**	**Group D, *n* (%)**
50–54	122 (22.6)	76 (22.9)	66 (32.3)	10 (20.4)
55–59	154 (28.5)	113 (34.1)	54 (26.5)	18 (36.7)
60–64	185 (34.2)	105 (31.7)	54 (26.5)	16 (32.7)
65–70	40 (7.4)	26 (7.9)	15 (7.4)	4 (8.2)

Results

Frequency of breast self-examination by group	**Group A invite to screening, *n* (%)**	**Group B normal mammogram, *n* (%)**	**Group C false-positive (not biopsy), *n* (%)**	**Group D false-positive (biopsy), *n* (%)**	
Never	56 (18)	22 (22)	24 (12)	7 (14)	
Less than once a month	155 (50)	23 (23)	34 (17)	7 (14)	
Once a month	69 (22)	47 (46)	97 (48)	18 (37)	
Once a week	25 (8)	10 (10)	41 (20)	12 (25)	
More than once a week	6 (2)	0	8 (4)	5 (10)	
No response	1 (0)	0	0	0	
HADS	**Group A**	**Group B**	**Group C**	**Group D**	***p*-value**
Depression scale, mean (range)	5.0 (0–19)	4.23 (0–15)	4.25 (0–16)	3.82 (0–18)	0.0003
Anxiety scale, mean (range)	4.97 (0–20)	4.43 (0–17)	4.32 (0–15)	4.27 (0–14)	0.014
HADS severity of score by group	**Group A invite to screening, *n* (%)**	**Group B normal mammogram, *n* (%)**	**Group C false-positive (not biopsy), *n* (%)**	**Group D false-positive (biopsy), *n* (%)**	***p*-value**
Depression					
Normal (0–7)	232 (75)	95 (91)	168 (83)	43 (88)	NS
Borderline (8–10)	52 (17)	7 (7)	25 (12)	3 (6)	NS
Abnormal (>10)	26 (8)	2 (2)	9 (4)	3 (6)	NS
Anxiety					
Normal (0–7)	253 (81)	91 (88)	174 (86)	42 (86)	NS
Borderline (8–10)	40 (13)	10 (10)	24 (12)	4 (8)	NS
Abnormal (>10)	20 (6)	2 (2)	4 (2)	3 (6)	NS

ANOVA, analysis of variance; NA, not applicable; NS, not significant.

Design		Participants		Arms		Outcomes	
Author and year	Ellman *et al*. 1989[105]	**Inclusion criteria**	Women invited for routine mammography screening, those recalled for further assessment and those with symptoms being further investigated	**Intervention**	Group B: routine screening by mammography with a false-positive result	**Psychological**	GHQ-28, ad hoc questionnaire
Study design	Prospective cohort	**Exclusion criteria**	Not reported	***N***	$n = 271$	**Screening attendance**	_
Study centre	Institute of Cancer Research, Sutton, Surrey	***N***	$n = 752$	**Control**	Routine screening by mammography with a normal result, symptomatic women who did not have cancer, symptomatic or recalled screened women who did have cancer, history of breast cancer with or without symptoms		
No. of centres	1			***N***	Group A: routine screening by mammography with a normal result ($n = 295$); *group C: symptomatic women who did not have cancer* ($n = 134$); *group D: symptomatic or recalled screened women who did have cancer* ($n = 38$); *group E: history of breast cancer with or without symptoms* ($n = 14$)		
Length of follow-up	3 months after clinic attendance			**Notes**	Participants also received clinical examination. *Symptomatic women do not meet the inclusion criteria for this review and are not included. Those with a history of breast cancer are also excluded in this case because those with and without symptoms were aggregated*		

Design	Participants	Arms	Outcomes
Setting	South West Surrey Health District breast screening programme		
Funding	DHSS Research Management Division		
Conflicts of interest	None reported		
Notes			
Definition of false-positive	Women who attended breast cancer screening clinics who were recalled for further investigation which showed no cancer		
Aim	To find out the immediate and persistent psychiatric morbidity in women recalled for further assessment following mammography screening		
Methodological issues			
Allocation to groups	NA		
Data analysis	Groups' scores were compared with a score of at least 5 to indicate probable psychiatric morbidity, using chi-squared. Change scores were analysed with the Wilcoxon test and between-groups' scores with the Mann–Whitney *U*-test. All tests were two-tailed with significance at $p<0.05$		
Handling missing data	Not reported	**Ethics approval**	Not reported
Power calculation	Not reported		
Subgroup analysis	No		
Participant characteristics			
	Group A normal mammogram	**Group B false-positive**	
Total recruited	295	271	
No. completing both questionnaires (%)	287 (97.3)	266 (98.2)	
Mean age (+– SD)	53.9 (6.8)	54.5 (7.4)	
First screening %	18.3	20.7	

Results

Proportion of GHQ scores of at least 5 at the screening clinic and 3 months later

	Group A normal mammogram	**Group B false-positive**	***p*-value**
Screening visit (95% CI)	24.0% (20% to 30%)	30.1% (24% to 36%)	NS
3 months later (95% CI)	19.2% (15% to 24%)	18.8% (14% to 24%)	NS

Distribution of GHQ scores

	Group A normal mammogram, no. (%)	**Group B false-positive, no. (%)**
Screening visit score		
0	118 (40.0)	111 (41.0)
1–4	104 (35.3)	78 (28.8)
5–9	49 (16.6)	48 (17.7)
10–28	24 (8.1)	34 (12.5)
Total	295 (100)	271 (100)
3 months later score		
0	150 (52.3)	157 (59.0)
1–4	82 (28.6)	59 (22.2)
5–9	31 (10.8)	23 (8.6)
10–28	24 (8.4)	27 (10.2)
Total	287 (100)	266 (100)

Distribution of GHQ subscale scores				
Symptom subscale	**Group A normal mammogram, no. (%)**		**Group B false-positive, no. (%)**	
	Screening visit (*n* = 295)	**3 months later (*n* = 287)**	**Screening visit (*n* = 271)**	**3 months later (*n* = 266)**
Somatic	113 (38)	98 (34)	108 (40)	69 (26)
Anxiety	104 (35)	75 (26)	119 (44)	77 (29)
Social dysfunction	104 (35)	86 (30)	89 (33)	77 (29)
Depression	42 (14)	29 (10)	38 (14)	27 (10)
Ad hoc questionnaire: opinions about the breast screening clinic				
	Groups A and B			
Criticism of communication	40 (7%)			

NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Brain *et al*. 2008[102]	**Inclusion criteria**	Women aged 35–49 years invited for routine annual screening by mammography with a FHBC	**Intervention**	Routine annual screening by mammography with a false-positive result	**Psychological**	Questionnaire including: CWS-R, cognitive appraisal, brief COPE, perceived risk of breast cancer, dispositional optimism
Study design	Prospective cohort	**Exclusion criteria**	Previous history of breast cancer or family history of ovarian cancer	***N***	$n = 112$	**Screening attendance**	_
Study centre	Institute of Medical Genetics, University of Cardiff PIMMS Management Group	***N***	$n = 1250$	**Control**	Routine annual screening by mammography with a normal result		
No. of centres	21			***N***	$n = 1174$		
Length of follow-up	6 months' measures taken at T1 1 month before screening, T2 1 month, and T3 6 months after the 'all-clear'						
Setting	NHS screening clinics for women with FHBC						
Funding	Cancer Research UK						
Conflicts of interest	Not reported						

Notes			
Definition of false-positive	Women who attend screening and are recalled for further investigations before being given the 'all-clear'		
Aim	This study aimed to find pre-screening variables that predicted cancer-specific distress 1 and 6 months after screening		
Methodological issues			
Allocation to groups	NA		
Data analysis	Changes in scores were compared with paired *t*-tests. Preliminary associations were tested with partial correlations. Hierarchical multiple regression explored the contributions of independent variables		
Handling missing data	Not reported	**Ethics approval**	Yes
Power calculation	In related paper Tyndel *et al*. 2007[101]		
Subgroup analysis	No		

Demographics

Participant characteristics from Tyndel et al*. 2007*[101]

Item	**Recall result (*n* = 112)**	**Normal result (*n* = 1174)**
	No. (%)	**No. (%)**
Age, mean (SD)	43.2 (3.52)	43.2 (3.44)
Ethnic group – white	109 (97.3)	1157 (98.6)
Married or partner	109 (97.3)	1158 (98.6)
Higher education	108 (96.4)	1155 (98.3)
Have biological children	109 (97.3)	1158 (98.6)

Results

Multiple regression showing predictive associations between independent baseline variables and cancer worry scores at 1 and 6 months

T1 variable (1 month before screening)	T2 (1 month after screening) CWS-R	*p*-value	T3 (6 months after screening) CWS-R	*p*-value
T1 cancer worry	0.543	<0.001	0.581	<0.001
High perceived lifetime risk of breast cancer	0.092	<0.001	0.075	<0.01
Relative died of breast cancer in the last year	–	–	0.050	<0.05
Belief in increased risk due to family history	0.091	<0.001	0.082	<0.001
First attendance at the screening programme	–0.067	<0.001	–0.044	<0.05
Being recalled for further tests	0.061	<0.05	–	–
Low emotion focused coping potential	–0.055	<0.05	–0.053	<0.05
Use of religion as a coping strategy	0.050	<0.01	–	–
Dispositional optimism	–0.045	<0.05	–0.003	NS
Low challenge appraisal	–0.043	<0.05	–0.019	NS
Substance use for coping	0.042	<0.05	–	–

NA, not applicable.

Design		Participants		Outcomes	
Author and year	Clements *et al*. 2008[107]	**Inclusion criteria**	Women aged 35–50 years invited for routine annual screening by mammography with a FHBC	**Psychological**	The value women placed on being on a FHBC annual screening programme and their reactions to either having an initial all-clear result after screening or only have this result after further investigation (false-positive)
Study design	Interview	**Exclusion criteria**	Previous history of breast cancer or family history of ovarian cancer		
Theoretical framework	Not reported	***N***	$n = 58$: normal result $n = 36$; false-positive $n = 22$		
Study centre	Primary Care Education Research Group, University of Oxford PIMMS Management Group				
Time from 'all-clear'	Not reported				
Setting	NHS screening clinics for women with FHBC				
Funding	Cancer Research UK				
Conflicts of interest	Not reported				

Notes	
This research has only been published as a summary of a poster. It is only included because it is a nested study in Tyndel *et al*. 2007[101]	
Definition of false-positive	Women who were recalled for further tests prior to an all-clear result
Aim	To explore the value women placed on being part of a screening programme and to understand the reactions of women who had false-positive results
Methodological issues	
Sampling strategy	Women who were participants in the Tyndel *et al*. 2007 study[101]
Data analysis	Thematic
All a priori outcomes reported	Yes
Demographics	
Note reported	
Results	
These were only briefly summarised: Women believed that participating in screening would enable cancer to be detected at an early stage leading to a positive outcome Women had greater faith in mammography than themselves to detect early cancer An all-clear result gave a high degree of reassurance that they did not have cancer Women with a false-positive result were initially distressed, the all-clear gave increased feelings of reassurance and security and a greater faith in screening than those with an initial all-clear result Being recalled was given a positive interpretation as proof that screening worked Fear of breast cancer was relieved by being part of the breast screening programme and made the women feel more in control of their family history	

Design		Participants		Arms		Outcomes	
Author and year	Tyndel *et al*. 2007[101]	**Inclusion criteria**	Women aged 35–49 years invited for routine annual screening by mammography with a FHBC	**Intervention**	Routine annual screening by mammography with a false-positive result	**Psychological**	CWS-R, PCQ
Study design	Prospective cohort	**Exclusion criteria**	Previous history of breast cancer or family history of ovarian cancer	***N***	$n = 166$	**Screening attendance**	_
Study centre	Primary Care Education Research Group, University of Oxford PIMMS Management Group			**Control**	Routine annual screening by mammography with a normal result		
No. of centres	21			***N***	$n = 2084$		
Length of follow-up	6 months measures taken at 1 month before screening and 1 and 6 months after the 'all-clear'						
Setting	NHS screening clinics for women with FHBC						
Funding	Cancer Research UK						
Conflicts of interest	None						

Notes				
Definition of false-positive	Not reported			
Aim	To test the hypothesis that in the short and long term women who receive an immediate all-clear result gain psychological benefit from screening, whereas women who are recalled for additional tests before an all-clear result experience increased cancer-specific distress			
Methodological issues				
Allocation to groups	NA			
Data analysis	Between-group categorical characteristics were compared with chi-squared and continuous variables with the Mann–Whitney *U*-test. Negative psychological effects at follow-up were analysed with linear regression with a preliminary analysis using the Mann–Whitney *U*-test			
Handling missing data	Not reported	**Ethics approval**	Yes	
Power calculation	Yes			
Subgroup analysis	No			
Demographics				
Participant characteristics				
Item	**Recall result (*n* = 112)**	**Normal result (*N* = 1174)**	**Mann–Whitney *U*-test and chi-squared test**	***p*-value**
	No. (%)	**No. (%)**		
Age, mean (SD)	43.2 (3.52)	43.2 (3.44)	65,468	NS
Ethnic group – white	109 (97.3)	1157 (98.6)	1.595	NS
Married or partner	109 (97.3)	1158 (98.6)	0.018	NS
Higher education	108 (96.4)	1155 (98.3)	0.305	NS
Have biological children	109 (97.3)	1158 (98.6)	4.896	0.027
High familial risk	109 (97.3)	1166 (99.3)	4.417	0.036
Hospital attendance for recall assessment	112 (100)	1167 (99.4)	56.850	0.000

Results

Within group comparison of distress at T1 (1 month before screening), T2 (1 month after screening) and T3 (6 months after screening)

Questionnaire	**False-positive result**	**Within false-positive result**		**Normal result**	**Within normal result**	
	Mean (SD)	**Paired *t*-test**	***p*-value**	**Mean (SD)**	**Paired *t*-test**	***p*-value**
CWS-R						
T1 ($n = 111, 1171$)	11.61 (2.90)	–	–	10.99 (2.91)	–	–
T2 ($n = 111, 1171$)	11.68 (2.89)	–	–	10.56 (2.60)	–	–
T3 ($n = 111, 1159$)	10.35 (2.65)	–	–	10.12 (2.49)	–	–
Difference T1–T2		–0.298	NS	-	7.537	<0.01
Difference T2–T3		6.372	<0.01	-	8.633	<0.01
PCQ						
T1 ($n = 110, 1167$)	7.32 (7.66)	–	–	5.06 (6.71)	–	–
T2 ($n = 110, 1167$)	7.1 (7.44)	–	–	4.18 (6.19)	–	–
T3 ($n = 110, 1169$)	4.61 (6.42)	–	–	3.84 (6.00)	–	–
Difference T1–T2	–	–0.051	NS	–	6.935	<0.01
Difference T2–T3	–	5.752	<0.01	–	3.183	<0.01

Between-group impact of false-positive result on positive outcomes at T2 and T3

Outcome	False-positive result	Normal result	Mann–Whitney *U*-test	95% CI	*p*-value
Positive PCQ at T2	–	–	51,561		0.002
Mean (SD)	13.02 (7.6)	10.81 (6.9)	–	–	–
Positive PCQ at T3	–	–	–	–	–
Mean (SD)	12.65 (8.9)	11.16 (7.0)	59,169		NS
			OR		
Benefits of screening more positive at T2	–	–	3.168	2.138 to 4.696	0.00
No. (%)	112 (55)	1164 (27)	–	–	–
Benefits of screening more positive at T3					
No. (%)	105 (35)	1085 (19)	2.35	1.531 to 3.606	0.00

NA, not applicable; NS, not significant.

Design		Participants		Arms		Outcomes	
Author and year	McCann *et al*. 2002[61]	**Inclusion criteria**	Women aged 49–63 years invited for routine breast screening by mammography	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	_
Study design	Retrospective cohort	**Exclusion criteria**	Women who were aged >63 years at follow-up	***N***	*n* = 4792	**Screening attendance**	Subsequent attendance at routine screening after a false-positive result and rate of interval cancer – from records
Study centre	Cancer Intelligence Unit, University of Cambridge	***N***	*n* = 140,387	**Control**	Routine screening by mammography with a normal result	**Quality of life**	_
No. of centres	Not reported			***N***	*n* = 108,617		
Length of follow-up	3.5 years						
Setting	NHSBSP in East Anglia						
Funding	NHS Executive Eastern Region						
Conflicts of interest	Not reported						

Notes			
Definition of false-positive	Any woman who is recalled for assessment on the basis on mammographic findings and in whom cancer is not diagnosed		
Aim	To find out if false-positive mammography affects reattendance in East Anglia, to quantify the increased risk of interval cancer and to determine if the risk of cancer detection at second screening is increased		
Methodological issues			
Allocation to groups	NA		
Data analysis	Not reported		
Handling missing data	Not reported	**Ethics approval**	NA
Power calculation	NA		
Subgroup analysis	Yes		
Demographics			
	False-positive, mean (SD)	**Normal, mean (SD)**	
Age	56.1 (3.5)	55.8 (3.5)	

Results

Likelihood of reattendance at second round cancer screening (3 years later)

Study group	*n* (%)	95% CI	OR (95% CI)
All groups			
All	97,062 (85.6)	85.4 to 85.8	
With interval cancer	72 (19.2)	15.2 to 23.2	
Without interval cancer	96,990 (85.8)	85.6 to 86.0	
Normal result			
All	93,081 (85.7)	85.5 to 85.9	1
With interval cancer	69 (21.0)	16.6 to 25.4	
Without interval cancer	93,012 (85.9)	68.1 to 85.7	
False-positive – no biopsy			
All	3572 (83.5)	82.4 to 84.6	0.84 (0.78 to 0.92)
With interval cancer	3 (7.1)	0 to 14.9	
Without interval cancer	3569 (84.3)	83.2 to 85.4	
False-positive – biopsy			
All	409 (79.6)	76.1 to 83.1	0.65 (0.52 to 0.81)
With interval cancer	0	0	
Without interval cancer	409 (80.2)	76.7 to 83.7	
False-positive – all			
All	3981 (83.1)	82.0 to 84.4	0.82 (0.76 to 0.89)
With interval cancer	3 (6.5)	0 to 13.7	
Without interval cancer	3978 (83.8)	82.8 to 84.9	

NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	O'Sullivan *et al*. 2001[108]	**Inclusion criteria**	Women invited for mammography screening for the second or subsequent time	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	_
Study design	Retrospective cohort	**Exclusion criteria**	Women invited for the first time and women who had been previously invited but had never attended	***N***	*n* = 248	**Screening attendance**	Subsequent attendance at routine screening after a false-positive result – from records
Study centre	Department of Psychology, University of Essex	***N***	*n* = 5649	**Control**	Routine screening by mammography with a normal result	**Quality of life**	_
No. of centres	Not reported			***N***	*n* = 5401		
Length of follow-up	Not reported						
Setting	East London and City of London Health Districts						
Funding	Cancer Research Campaign						
Conflicts of interest	Not reported						
Notes							
Definition of false-positive	Women who have previously experienced an abnormal breast screening result, which after further assessment was concluded to be negative for malignancy						
Aim	Effects of a false-positive result on reattendance for those on early recall and routine recall						

Methodological issues			
Allocation to groups	NA		
Data analysis	Not reported		
Handling missing data	NA	**Ethics approval**	NA
Power calculation	NA		
Subgroup analysis	No		
Demographics			
Not reported			
Results			
Attendance at second screening			

Result at initial screening	**Attend second screen, *N* (%)**	**Do not attend second screen, *N* (%)**	**Total**
Normal	3841 (71)	1560 (29)	5401
False-positive – all	175 (70.6)	73 (29.4)	248
False-positive – routine recall	119 (73.5)	43 (26.5)	162
False-positive – early recall	56 (65)	30 (35)	86
Total	4016	1633	5649

NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Meldrum *et al*. 1994[115]	**No. randomised**	3083	**Intervention**	Tailored invitation accounting for screening history for second round mammography screening	**Psychological**	–
Study design	RCT	**Inclusion criteria**	All women invited for second round routine mammography screening	***N***	False-positive $n = 115$; normal $n = 800$	**Screening attendance**	Subsequent attendance at routine screening and effect of a tailored invitation on subgroups
Study centre	Department Public Health, Glasgow Royal Maternity Hospital	**Exclusion criteria**	Women with breast cancer and those whose screening history was not available	**Control**	Standard invitation for second round mammography screening	**Quality of life**	–
No. of centres	1			***N***	False-positive; $n = 112$; normal $n = 791$		
Length of follow-up	Not reported						
Registered	Pre-dates registration						
Setting	North West Glasgow Breast Screening Centre						
Funding	Scottish Office Home and Health Department						
Conflicts of interest	Not reported						

Notes	
Definition of false-positive	Women who attended and were recalled for further tests before they were given an all-clear result
Aim	To determine if attendance at second-round screening (3 years later) could be improved by the use of invitation letters tailored to the outcome of the previous screening round
Methodological issues	
Randomisation and allocation	Random number tables were used. Randomisation was within-study group (false-positive or normal) to intervention or control. It is unclear if the participants were aware that they were in a trial. It appears that they were sent one of two letters from the screening centre; it is unclear whether or not the assessors knew which group women were in
Data analysis	Between-group differences were tested by chi-squared. Analysis was by intention to treat
Missing data	Not reported
Power calculation	Yes
Subgroup analysis	No
All a priori outcomes reported	Unknown
Baseline characteristics	
Not reported	

Results

Second-round screening attendance: comparing standard vs tailored letters within groups

	Previously false-positive			Previously all clear		
	Standard letter	**Tailored letter**	**% difference (95% CI), *p*-value**	**Standard letter**	**Tailored letter**	**% difference (95% CI), *p*-value**
Invited, *N*	112	115		791	800	
Attended, *N*	78	94		583	594	
Attended, % (95% CI)	70 (61 to 78)	82 (75 to 89)	12.1 (1.03 to 23.2), 0.03	74 (71 to 77)	74 (71 to 77)	0.5 (–3.8 to 4.9), 0.8

Second-round screening attendance: comparing standard vs tailored letters between groups

	Standard letter			Tailored letter		
	Previously false-positive	**Previously all clear**	**% difference (95% CI)**	**Previously false-positive**	**Previously all clear**	**% difference (95% CI)**
Invited, *N*	112	791		115	800	
Attended, *N*	78	583		94	594	
Attended, % (95% CI)	70 (61 to 78)	74 (71 to 77)	–0.04 (–0.13 to 0.05)	82 (75 to 89)	74 (71 to 77)	0.08 (0.003 to 0.157)

Meldrum *et al*. 1994[115]

Section/topic	Item No.	Compliant	Checklist item
Title and abstract			
	1a	Yes	Identification as a randomised trial in the title
	1b	Yes	Structured summary of trial design, methods, results and conclusions (for specific guidance see CONSORT for abstracts)
Introduction			
Background and objectives	2a	Yes	Scientific background and explanation of rationale
	2b	Yes	Specific objectives or hypotheses
Methods			
Trial design	3a	Not reported	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	NA	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Yes	Eligibility criteria for participants
	4b	Yes	Settings and locations where the data were collected
Interventions	5	No	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
Outcomes	6a	Yes	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	NA	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	Yes	How sample size was determined
	7b	NA	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:			
Sequence generation	8a	Yes	Method used to generate the random allocation sequence
	8b	Not reported	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Not reported	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
Implementation	10	Not reported	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	Not reported	If done, who was blinded after assignment to interventions (e.g. participants, care providers, those assessing outcomes) and how
	11b	Yes	If relevant, description of the similarity of interventions

Section/topic	Item No.	Compliant	Checklist item
Statistical methods	12a	Yes	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Yes	Methods for additional analyses, such as subgroup analyses and adjusted analyses
Results			
Participant flow (a diagram is strongly recommended)	13a	Yes	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	No	For each group, losses and exclusions after randomisation, together with reasons
Recruitment	14a	Yes	Dates defining the periods of recruitment and follow-up
	14b	NA	Why the trial ended or was stopped
Baseline data	15	No	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	Yes	For each group, number of participants (denominator) included in each analysis and whether or not the analysis was by original assigned groups
Outcomes and estimation	17a	Yes	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)
	17b	NA	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	NA	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	Not reported	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
Discussion			
Limitations	20	Not reported	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Not reported	Generalisability (external validity, applicability) of the trial findings
Interpretation	22	No	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
Other information			
Registration	23	Pre-registry	Registration number and name of trial registry
Protocol	24	No	Where the full trial protocol can be accessed, if available
Funding	25	Yes	Sources of funding and other support (such as supply of drugs), role of funders

NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Orton *et al*. 1991[109]	**Inclusion criteria**	Women aged 45–64 invited to attend for second-round screening by mammography	**Intervention**	Routine screening by mammography with a false-positive result	**Psychological**	Acceptability of screening
Study design	Cross section	**Exclusion criteria**	Not reported	***N***	$n = 50$	**Screening attendance**	Reattendance
Study centre	Aylesbury, Oxfordshire	***N***	$n = 1582$	**Control**	Routine screening by mammography with a normal result	**Quality of life**	_
No. of centres	1			***N***	$n = 1532$		
Length of follow-up	NA						
Setting	Breast screening in Aylesbury Vale						
Funding	Not reported						
Conflicts of interest	Not reported						

Notes			
Definition of false-positive	If after screening a woman is asked to reattend for further assessment but no malignancy is found		
Aim	To find out whether the acceptability of screening or having a false-positive mammogram affected attendance at subsequent breast screening Only the measure of reattendance was disaggregated and is reported		
Methodological Issues			
Allocation to groups	NA		
Data analysis	Data were analysed with a chi-squared test		
Handling missing data	Not reported	**Ethics approval**	Not reported
Power calculation	Not reported		
Subgroup analysis	No		
Demographics			
Not reported			
Results			
Attendance at second-round screening			
	False-positive, *N* (%)	**Normal result, *N* (%)**	
Invited	50 (100)	1532 (100)	
Attended	46 (92)	1362 (89)	

NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Ong and Austoker 1997[110]	**Inclusion criteria**	Women invited for routine screening by mammography who were recalled for assessment	**Intervention**	Women invited for routine screening by mammography who were recalled for assessment	**Psychological**	Ad hoc questionnaire about the acceptability of information given in assessment invitations
Study design	Cross section	**Exclusion criteria**	Women recalled due to poor quality X-rays	***N***	$n = 1493$	**Screening attendance**	_
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	$n = 1493$	**Control**	NA	**Quality of life**	_
No. of centres	8			***N***	NA		
Length of follow-up	NA						
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign and the NHSBSP						
Conflicts of interest	Not reported						
Notes							
Definition of false-positive	Not reported						
Aim	Evaluation of women's experiences at the assessment clinic and their information needs there and afterwards, including a discourse analysis of open questions						

Methodological issues			
Allocation to groups	NA		
Data analysis	Contingency tables were used for comparison		
Handling missing data	Not reported	**Ethics approval**	Yes
Power calculation	Not reported		
Subgroup analysis	Yes/no		
Demographics			
Not reported			
Results			
Communication at the assessment centre and level of distress			

Communication	**Distressed/very distressed, % (*n*/*N*)**	**Somewhat/not distressed, % (*n*/*N*)**	***p*-value**
Women who had not talked with somebody at the centre about the reason for recall	33 (275/835)	32 (191/597)	NS
Women who would have liked to talk about the reason for recall	26 (214/835)	18 (108/597)	<0.0001
Women who thought they were not given enough information about the physical examination they had	6 (46/757)	4 (20/563)	<0.05
Women who thought they were not given enough information about the X-rays they had	9 (72/773)	4 (22/553)	<0.0005

Communication at the assessment centre and the role of breast care nurses

Communication	**Centres where women were not systematically provided with the opportunity to talk immediately before tests, % (*n*/*N*)**	**Centres where the breast care nurse provided women with the opportunity to talk in private immediately before tests, % (*n*/*N*)**	***p*-value**
Women who had talked at the centre about reason for recall:			
With 'somebody at the centre'	58 (611/1055)	93 (374/401)	<0.001
With a doctor or radiologist	31 (323/1035)	7 (26/391)	<0.001
With a nurse	9 (97/1035)	60 (234/391)	<0.001
Women who would have liked to talk about reason for recall	30 (310/1039)	4 (16/400)	<0.001
Women who stated that the test they had were not explained to them:			
Physical examination by a doctor	8 (82/981)	2 (7/381)	<0.001
X-rays	9 (88/996)	1 (5/379)	<0.001
Ultrasound	9 (39/413)	2 (5/212)	<0.005
Women who wanted more information about the tests they had:			
Physical examination by a doctor	6 (59/964)	2 (7/378)	<0.005
X-rays	9 (68/971)	2 (8/376)	<0.001
Ultrasound	10 (39/401)	3 (6/209)	<0.005

CRC, Cancer Research Campaign; NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Ong *et al*. 1996[111]	**Inclusion criteria**	Literature for women being recalled by UK breast screening assessment centres	**Intervention**	Evaluation of information given in the initial letter/ leaflet and prior to recall for further assessment	**Psychological**	Criteria for evaluating breast screening information material developed by Austoker and Ong 1994[112]
Study design	Cross section	**Exclusion criteria**	NA	***N***	*n* = 84	**Screening attendance**	_
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	*n* = 84	**Control**	NA	**Quality of life**	_
No. of centres	84			***N***	NA		
Length of follow-up	NA						
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign and the NHSBSP						
Conflicts of interest	Not reported						
Notes							
Definition of false-positive	Not reported						
Aim	To evaluate the health education literature for recalled women using criteria developed by Austoker and Ong 1994[112]						
Methodological issues							
Allocation to groups	NA						
Data analysis	Not reported						
Handling missing data	Not reported	**Ethics approval**	NA				
Power calculation	NA						
Subgroup analysis	No						

Demographics					
NA					
Results					
Topics relating to further investigation in the initial written materials inviting women for mammography					
Topic	**Mentioned in any of the written information**				**Mentioned in neither leaflet nor letter nor GP letter**
	In the letter % (*n*) of centres	**In GP letter % (*n*) of centres**	**In the leaflet % (*n*) of centres**	**In both letter and leaflet % (*n*) of centres**	**% (*n*) of centres**
Possibility of recall	46 (39/84)	5 (4/84)	99 (83/84)	45 (38/84)	1 (1/84)
The word 'cancer'[a]	1 (1/84)	4 (3/84)	52 (44/84)	1 (1/84)	49 (41/84)
Particularly worrying information in the recall letter or leaflet					
Topics mentioned	**Mentioned in any of the written information**			**Mentioned in neither recall leaflet nor recall letter**	
	In recall letter % (*n*) of centres	**In recall leaflet % (*n*) of centres**	**In both recall leaflet and letter % (*n*) of centres**	**% (*n*) of centres**	
One or more worrying items:	43 (35/82)	18 (15/82)	7 (6/82)	46 (38/82)	
Word 'cancer'	9 (7/82)	10 (8/82)	1 (1/82)	83 (68/82)	
Words 'treatment', 'something wrong', 'abnormality', or 'abnormal area of the breast'	20 (16/82)	4 (3/82)	1 (1/82)	78 (64/82)	
Word 'hospital'[b]	10 (8/82)	1 (1/82)	0	89 (73/82)	
Words 'not to worry'[c]	22 (18/82)	1 (1/82)	0	77 (63/82)	
Phrase 'nurse counsellor'	5 (4/82)	9 (7/82)	0	87 (71/82)	

Particularly stress-relieving information in the recall letter or leaflet

Topics mentioned	Mentioned in any of the written information			Mentioned in neither recall leaflet nor recall letter
	In recall letter % (*n*) of centres	In recall leaflet % (*n*) of centres	In both recall leaflet and letter % (*n*) of centres	% (*n*) of centres
One or more stress-relieving messages:	68 (56/82)	33 (27/82)	20 (16/82)	17 (14/82)
Most recalled women are found to have normal breasts	28 (23/82)	6 (5/82)	4 (3/82)	30 (25/82)
Recall is part of second stage/routine screening	46 (77/82)	26 (3/82)	11 (9/82)	38 (31/82)
A substantial number of women are recalled	32 (26/82)	11 (9/82)	1 (1/82)	60 (49/82)

CRC, Cancer Research Campaign; NA, not applicable.

a Only when the word 'cancer' was mentioned when referring to further investigation (recall).

b 'Hospital' was only counted when it was mentioned other than in the context of address or directions.

c Similar phrases counted were 'not to be alarmed', 'not to be concerned', 'not to feel anxious', 'no cause for concern'.

Design		Participants		Arms		Outcomes	
Author and year	Austoker and Ong 1994[112]	**Inclusion criteria**	Women invited for routine screening by mammography who were recalled for assessment	**Intervention**	Women invited for routine screening by mammography who were recalled for assessment	**Psychological**	Ad hoc questionnaire including open questions to assess the reassuring or worrying nature of the content of recall letters and leaflets. They were also assessed for coverage of, reason for recall, way to the centre, who could come with them, how to change the appointment, how long it would be, who they would see, what tests would be carried out, when the results would be available and how to get more information
Study design	Cross section	**Exclusion criteria**	Not reported	***N***	*n* = 1493	**Screening attendance**	_
Study centre	CRC Primary Care Education Research Group, University of Oxford	***N***	*n* = 1493	**Control**	NA	**Quality of life**	_
No. of centres	8			***N***	NA		
Length of follow-up	NA						
Setting	NHSBSP clinics						
Funding	Cancer Research Campaign and the NHSBSP						
Conflicts of interest	Not reported						
Notes							
Definition of false-positive	Screened women who underwent further assessment and were found to have nothing wrong						
Aim	To assess the written information needs of women recalled for further assessment						

Methodological issues			
Allocation to groups	NA		
Data analysis	Contingency tables were used for comparison, with a two-sided, $p<0.05$ significance level		
Handling missing data	Not reported	**Ethics approval**	Yes
Power calculation	Not reported		
Subgroup analysis	No		
Demographics			
Not reported			
Results			
How women felt when they received the recall letter			
Reaction	***N* (%) women**	**Sample comments**	
Pleased	30 (2.0)	Very pleased to think I was having a proper check	
Neutral/not distressed	87 (5.9)	I just felt normal	
Somewhat distressed	497 (33.9)	Concerned though not unduly	
		I felt rather apprehensive	
		Nervous, but I think it is a good thing	
		Unpleasantly apprehensive	
Distressed	415 (28.3)	Nervous and very apprehensive	
		Anxious and worried	
		Frightened and worried	
		Worried, afraid	
Very distressed	439 (29.9)	I felt the whole bottom had fallen out of my world	
		I felt sick then faint, then I cried then I kept thinking what I have to do if I have cancer	
		Worried to death	
		Panic stricken, depressed. Convinced I was going to die	
		Completely devastated. Reason abandoned me	
All women	1468 (100)		

Reported need for more information: whether the topic was mentioned or not

Topic	Topic mentioned in letter/leaflet		Topic not mentioned in letter/leaflet		*p*-value
	% (*N*) women wanting more information		% (*N*) women wanting more information		
Why they were recalled	36	(383/1070)	46	(179/388)	<0.005
How to get to the centre	8	(71/854)	26	(75/290)	<0.0001
Who could come with them	5	(44/888)	35	(148/419)	<0.0001
How to change the appointment	2	(33/1436)	–		
How long the appointment would take	8	(17/222)	28	(248/900)	<0.0001
Who they would see	13	(168/1266)	33	(62/186)	<0.0001
What tests would be done	11	(65/606)	35	(298/847)	<0.0001
How to get more information	18	(143/783)	33	(212/633)	<0.0001

Reported need for more information and level of distress

Topic	Distressed/very distressed women		Somewhat/not distressed women		*p*-value
	% (*N*) women wanting more information		% (*N*) women wanting more information		
Why they were recalled	48	(403/834)	26	(157/598)	<0.0001
How to get to the centre	13	(83/659)	13	(64/497)	NS
Who could come with them	13	(102/762)	17	(94/557)	NS
How to change the appointment	2	(18/824)	3	(15/523)	NS
How long the appointment would take	27	(173/640)	20	(93/466)	0.007
Who they would see	18	(146/828)	13	(80/598)	0.030
What tests would be done	27	(224/828)	22	(130/599)	0.022
How to get more information	29	(237/811)	19	(116/616)	<0.0001

Preparing women in advance for possible recall

	Possibility of recall mentioned in the initial screening invitation, % (*N*)	Possibility of recall not mentioned in the initial screening invitation, % (*N*)	*p*-value
Distressed/very distressed women	23 (110/485)	30 (59/197)	<0.05

CRC, Cancer Research Campaign; NA, not applicable.

Design		Participants		Arms		Outcomes	
Author and year	Smith *et al*. 1991[113]	**Inclusion criteria**	Women attending assessment clinic following recall from routine mammography screening	**Intervention**	Three different versions of a recall letter giving increasing amounts of information. Letter two also gave contact details of a BCN	**Psychological**	Ad hoc questionnaire
Study design	Cross section	**Exclusion criteria**	Not reported	***N***	$n = 103$	**Screening attendance**	_
Study centre	Department of Community Health, University of Leicester	***N***	$n = 103$	**Control**	NA	**Quality of life**	_
No. of centres	1			***N***	NA		
Length of follow-up	NA						
Setting	Leicestershire Breast Screening Service						
Funding	Not reported						
Conflicts of interest	Not reported						
Notes							
Definition of false-positive	Not reported						
Aim	To test three different forms of recall letter and to develop and test an audit questionnaire						
Methodological issues							
Allocation to groups	NA						
Data analysis	Fisher's exact test or chi-squared tests were used						
Handling missing data	Not reported	**Ethics approval**	Not reported				
Power calculation	Not reported						
Subgroup analysis	No						

Demographics

Participants were from a predominantly white working class and middle class area

Results

How women felt when they received their invitation letter to return for further tests

Reaction	***N***	**%**
Positive (e.g. 'glad to be in such capable hands')	4	4
Neutral (e.g. 'I wasn't bothered')	10	10
Surprised	11	11
Upset (e.g. 'anxious', 'worried', 'upset')	44	44
Very upset (e.g. 'terrified', extremely anxious')	31	31
Total	100	100

Satisfaction of women with information about why they had to return to clinic and what would happen there

Letter version	**Satisfaction with information on:**	
	Reasons for recall, *N* (%)	**Events at the clinic, *N* (%)**
1	15 (50)	17 (63)
2	25 (71)	24 (74)
3	26 (81)	27 (90)
All versions	66 (68)	68 (76)
Chi-squared	7.243	5.817
p-value	0.027	0.055

Whether recalled women wanted to talk to the BCN

Letter version	**Answer**	***N***
1. Would telephone the BCN	Yes	25
	No	0
2. Did telephone the BCN	Yes	13
	No	0
3. Would telephone the BCN	Yes	17
	No	1

BCN, breast care nurse; NA, not applicable.