Interventions to improve participation amongst underserved population groups in young person and adult national screening programmes in the UK: a systematic review

APPENDIX 2

Trial summary tables including risk of bias

Contents

Allgood (2016) BSP

Primary reference		Allgood et al (2016) 'A Randomised Trial of the Effect of Postal Reminders on Attendance for Breast Screening'						
Trial registration #		ISRCTN02240458						
Additional resources		Supplementary materials referenced but could not find online						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT (quasi-randomised by final digit of SX number)	No	22,828 women aged 50-70 scheduled for a routine screening appointment in the North West of England (Bolton, Bury, Rochdale, Wigan and Liverpool). November 2012 to December 2013.	Primary: Uptake (within 30 days of first offered appointment) Secondary: Uptake (within 90 days of first offered appointment) Uptake (within 180 days of first offered appointment) From trial registration: Subgroup analysis (details unspecified) Costs	No reminder [11,445]	Postal reminder sent a few days before scheduled appointment [11,383]	SES [2,521 in most deprived quintile; 4,745 in next most deprived] Previous non-responders [173] First-time invitees [3,586] Age <60 [12,298]	Uptake within 180 days will be used as the primary endpoint for this review to maximise the number of events (uptake) available and for broad consistency with other uptake endpoints.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Could not be blinded but did not know they were in a trial N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	N
RoB 1.3	N	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	Subgroup analyses planned but specific groups not pre-specified (in trial registration) PN
Quasi-randomised?	Yes	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	No	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Y						
	-	RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	SES	Previous non-attenders	First-time invitees	Age (<60)	Comments
Uptake (30 days)	NFA	pre.A-REM-PO	Pre-specified? in part No interaction by IMD (results not reported)	Pre-specified? in part 36/90 v 37/83 40.0% v 44.6% OR: 1.20 (0.65, 2.21)	(aged 50-52 prevalent screen) Pre-specified? in part 1050/1772 v 1157/1814 59.3% v 63.8% OR: 1.21 (1.05, 1.39)	Pre-specified? in part 3861/6179 v 4068/6119 62.5% v 66.5% OR: 1.19 (1.10, 1.29)	The trial registration pre-specifies "subgroups" but does not identify which subgroups. Overall: 64.2% v 68.2%, OR: 1.19 (1.13, 1.26), p<0.001
Uptake (90 days)	NFA	pre.A-REM-PO	No interaction by IMD (results not reported)	47/90 v 43/83 52.2% v 47.8% OR: 0.98 (0.54, 1.79)	1152/1772 v 1266/1814 65.0% v 69.8% OR: 1.24 (1.08, 1.43)	4298/6179 v 4442/6119 69.6% v 72.6% OR: 1.16 (1.07, 1.25)	Overall: 71.1% v 74.1%. OR: 1.16 (1.09, 1.23), p<0.001
Uptake (180 days)	NFA	pre.A-REM-PO	No interaction by IMD (results not reported)	48/90 v 44/83 53.2% v 47.8% OR: 0.98 (0.54, 1.80)	1164/1772 v 1280/1814 65.7% v 70.6% OR: 1.25 (1.08, 1.44)	4365/6179 v 4495/6119 70.6% v 73.5% OR: 1.15 (1.06, 1.25)	Overall: 72.1% v 74.8%, OR: 1.14 (1.08, 1.22), p<0.001
Comments	The authors did not respond to a request for more data on SES subgroup.						

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes. Letter available in supplementary materials
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	NW England in low uptake area
Is there anything else not covered in the tables above?	No

Allgood (2017) BSP

Primary reference		Allgood et al (2017) 'Effect of Second Timed Appointments for Non-Attenders of Breast Cancer Screening in England: A Randomised Controlled Trial'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT Odd/even SX numbers (unique identifiers with NHSBSP)	No	26,054 women aged 50-70 who had not attended an appointment in 6 English centres (Derby, Hull, Plymouth, Sheffield, southeast London, west London) from 02/06/14 to 30/09/2015	Uptake (within 90 days of original appointment) Secondary: Uptake (within 180 days of screening episode being opened)	Open invitation to call to book a second appointment [13,247]	Second timed appointment (fixed date and time) [12,807]	Recent non-attenders [all; 26,054] Persistent non-attenders (older prevalent screens) [8,728] First-time invitees [4,089] SES [7,018 in most deprived quintile; 7,348 in next most deprived] Note that first-time invitees and persistent non-attenders were identified by age	Both of these interventions are used with the BSP, with DH advising NHSE to used second timed appointments (although these are not universally used). Letters kept as similar as possible in the two arms. Note that the secondary endpoint here (uptake within 180 days) is more consistent with the aims of this review and the other trials included in it. There is a relatively large imbalance in sample size between the groups for such a large trial, around 3 standard errors from the expected 50/50 allocation. Baseline characteristics are, however, well-balanced.

							(50-52 or 53-70) combined with no record of previous screening.	

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[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)


RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Y	RoB 2.1	Could not be blinded but unaware they were in a trial N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Predictable due to quasi-randomisation with allocation by SX number. Unlikely to cause important bias, but note the large number of exclusions and imbalance in sample sizes for each arm. N	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	N
RoB 1.3	Baseline characteristics appear balanced but the difference in sample sizes between groups is large and there were post-randomisation exclusions	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	N

	PN								
Quasi-randomised?	Yes	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	**Y**						
	-	RoB 2.7	NI						
Risk-of-bias	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction	Unpredictable	Direction		Direction		Direction		Direction	
Comments	Large number of post-randomisation exclusions with a larger than expected imbalance in sample sizes between the arms. Unclear if this has introduced systematic bias.								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Test	Recent non-attenders (whole trial)	Persistent non-attenders	SES	First-time invitees	Comments
Uptake	R-OPEN-PO	R-FIXED-PO	Pre-specified? Yes Within 90 days: 1632/13247 v 2861/12807 12% v 22% RR: 1.81 (1.70, 1.93) p<0.0001 Within 180 days: 1784/13247 v 3054/12807 13% v 24% RR: 1.77 (1.67, 1.88) p<0.0001	Pre-specified? Yes Within 90 days: 82/4445 v 283/4283 2% v 7% RR: 3.58 (2.80, 4.58) p<0.0001 Within 180 days: 97/4445 v 307/4283 2% v 7% RR: 3.28 (2.61, 4.13) p<0.0001	Pre-specified? Yes Within 90 days: IMD5 353/3623 v 639/3395 10% v 19% RR: 1.93 (1.69, 2.20) p<0.0001 IMD4 398/3703 v 768/3645 11% v 21% RR: 1.96 (1.73, 2.22) p<0.0001 Within 180 days:	Pre-specified? Yes Within 90 days: 147/2072 v 347/2017 7% v 17% RR: 2.42 (1.99, 2.95) p<0.0001 Within 180 days: 163/2072 v 369/2017 8% v 18% RR:2.33 (1.93, 2.80) p<0.0001	

					IMD5 386/3623 v 682/3395 11% v 20% RR: 1.89 (1.66, 2.14) p<0.0001 IMD4 434/3703 v 825/3645 12% v 23% RR: 1.93 (1.71, 2.17) p<0.0001		
Comments							

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'adj' if adjusted for other factors

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (well described but not explicitly reproduced in supplementary materials)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (both arms are; intervention more in line with DH advice to NHSE)
Any other issues with generalisability or external validity?	No

Is there anything else not covered in the tables above?	No

Atri (1997) BSP

Primary reference		Atri et al (1997) 'Improving Uptake of Breast Screening in Multiethnic Populations: A Randomised Controlled Trial using Practice Reception Staff to Contact Non-attenders'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	cRCT Clusters are GP practices; minimisation based on number of full-time principals, previous uptake, percentage of minority ethnic women aged 50-64 in wards within 0.5km of practice and invitation batch	No	2,064 women aged 50-64 who had not attended for breast screening, from 26 GP practices in Newham (London), January-August 1995 26 of 37 eligible practices (with 57/75 eligible GPs) agreed to participate. Practices were grouped geographically into 9 batches for the screening round and called sequentially by the Central and East London Breast Screening Service	Uptake (within 6 months of the last batch of appointments; minimum follow-up four months, maximum of one year; data from screening centre)	No intervention [1,069 non-attenders in 14 practices of 2,822 eligible for screening] Control practices received the same lists of non-attenders as intervention practices but no training or advice on how to proceed	2 hour group training for GP reception staff [995 non-attenders in 12 practices of 2,672 eligible for screening] Receptionists were given training on the breast screening programme and barriers to participation, and asked to contact all non-attenders by telephone where possible, by letter if not	Recent non-attenders [all; 2,064] Minority ethnic [1,433] Indian [355] Pakistani [214] Black [287] Bangladeshi [132] Chinese [26] Other [86] Not reported [333]	GPs asked to routinely check and amend lists for the screening service, with appointments sent in batches using the amended lists. A second letter was sent to non-attenders 4 weeks after their initial appointment. All practices received a list of women who had not attended within 8 weeks of the last appointment in their batch. All practices were asked to note the ethnicity of the women on the list of those not attending within 8 weeks: White, Indian, Pakistani, Black (British, Caribbean or African), Bangladeshi, Chinese, Other, Unknown. One intervention practice failed to report ethnicity, overall 80% of ethnicities were recorded. Women who moved practices were reported in their original practice (ITT). 8% of the intervention group had moved (40), died (8), were abroad or away long-term (15), or had recently had a mammogram (15). These were retained in the analysis (ITT).

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[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)
[d] specify whether each USG is the whole trial population or a subgroup (W/S), and whether identified by individual or area demographics (I/A) to yield 2-letter codes: WI, WA, SI, SA

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Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Minimised on a large number of factors relative to clusters Y	RoB 2.1	Could not be blinded but did not know they were in a trial N	RoB 3.1	20% missing for ethnicity, uptake data likely good Y	RoB 4.1	Variable length of follow-up but not biased between arms N	RoB 5.1	PY
RoB 1.2	Cluster trial, GPs responsible for determining eligibility and delivering intervention (with NFA on control arm) N	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	GP practices fairly similar but some quite large imbalances in ethnicity recorded (with more, higher uptake, Indian women on intervention) PY	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Yes (minimised on several factors)	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Strong ITT approach, unclear if adjustment for clustering was adequate (multilevel logistic regression model) PY						
	-	RoB 2.7	NA						
Risk-of-bias	Some concerns	Risk-of-bias	Low	Risk-of-bias	Low	Risk-of-bias	Low	Risk-of-bias	Low

Direction	Favours experimental	Direction		Direction		Direction		Direction	
Comments	There are some fairly large imbalances within minority ethnic groups, with more Indian women on intervention and a very high uptake for Indian women compared to others (including White). This difference could easily have arisen by chance (especially given the small number of clusters) but may exaggerate the overall treatment effect. However, the direction of effect is broadly consistent within groups defined by ethnicity.								
Risk-of-bias	Some concerns		Direction	Favours experimental					

Results

Endpoint	Control	Test	Recent non-attenders (whole trial)	Indian	Non-Indian minority ethnicity	Comments
Uptake	post.R-NFA-	post.R-HCP-TEL/PO	Pre-specified? Yes 40/1069 v 90/995 4% v 9% *Raw* OR: 2.4 (1.1, 5.9) p=0.04 *Adj* OR: 2.3 (1.1, 5.3) p=0.04	Pre-specified? Yes 8/149 v 40/206 5% v 19% Note the fairly large imbalance in denominators. Indian women in this study had the highest uptake, OR compared to white women 2.2 (1.3, 3.8) and so this subgroup likely to have been cherry-picked because of result	Pre-specified? Yes Pakistani: 3/86 v 6/128 3% v 5% Black: 6/150 v 11/137 4% v 8% Bangladeshi: 2/112 v 2/20 2% v 10% Chinese: 1/12 v 1/14 8% v 7% Other: 3/55 v 2/31 5% v 6% Not reported: 3/133 v 6/200 2% v 3% [White: 14/372 v 22/259, 5% v 8%]	Ethnicity was reported for 80% of non-attenders (one intervention practice did not report ethnicity). 3/12 intervention practices did not contact non-attenders and one contacted fewer than 10 women. A letter or phone contact was attempted for 646 (65%) in the intervention arm (314 by letter, 219 by phone, 113 by both). No contact with 349 women. Of those phoned, 96 did not answer, 175 spoken to personally, 61 another family member took the call.
Comments	Adjusted ORs adjusted for practice size, previous uptake, batch number and ethnicity (plus some other unspecified individual characteristics). Note the fairly large imbalance in denominators by ethnicity. Indian women in this study had the highest uptake on the intervention arm, OR compared to White women 2.2 (1.3, 3.8), with other groups usually having slightly lower or similar uptake to White women.					

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Training described but limited detail available
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	High proportion of minority ethnic population, Newham (east London). Trial conducted in 1995.
Is there anything else not covered in the tables above?	No

Bankhead (2001) BSP

Primary reference		Bankhead et al (2001) 'Improving Attendance for Breast Screening among Recent Non-Attenders: A Randomised Controlled Trial of Two Interventions in Primary Care'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	fRCT Random permuted blocks, stratified by practice, using sealed envelopes and audited time sheets	No	1,158 recent non-attenders (>1 month after missed appointment) in 13 general practices (of 53 eligible) with low uptake (<60%) in London and West Midlands. Trial took place during the third round of NHS BSP October 1996 to June 1997. Practices excluded if fully or mostly computerised (not reliant on paper records) or small patient population or involvement in a parallel BSP trial.	Uptake (within 6 months of randomisation) Cost-effectiveness	No intervention [289]	GP letter with information leaflet and instruction in 14 languages for non-English speakers to get the letter translated [291] Opportunistic flag in notes (yellow card prompt in paper notes) with request to discuss and offer information leaflet, doubling as a record of GP interactions [290] GP letter + opportunistic flag in notes [288]	Recent non-attenders [all; 1,158]	Quite an old trial, selecting practices which were not yet computerised which may affect generalisability in the modern era. Individual rather than cluster randomised as it was considered contamination would be less given the selection of non-attenders (ie GPs would not necessarily know who the non-attenders were).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
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Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

	Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
	RoB 1.1	Y	RoB 2.1	Unaware of participation in trial N	RoB 3.1	10 missing Y	RoB 4.1	N	RoB 5.1	PY
	RoB 1.2	Sealed envelopes cannot be entirely secure PY	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
	RoB 1.3	N	RoB 2.3	Possible cross-contamination due to non-cluster design NI	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
	Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
	Stratified or minimisation ?	Yes (by practice)	RoB 2.5	Control group most prone to contamination NI			RoB 4.5	NA		
		-	RoB 2.6	Y						
		-	RoB 2.7	NA						
	Risk-of-bias	Low	**Risk-of-bias**	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
	Direction		Direction	Favours (non-flag) comparator	Direction		Direction		Direction	
	Comments	This question may be better addressed through a cluster design due to greater awareness amongst GPs possibly contaminating the (non-flag) control group. However, GPs would not necessarily be aware of who had not attended screening and any contamination would tend to reduce the apparent treatment effect.								
	Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Intervention	Recent non-attenders (whole trial)	First-time invitees	Comments
Uptake	R-NFA-	R-GPL-PO	Pre-specified? Yes 17/287 v 31/288 5.9% v 10.8%	Pre-specified? Yes /96 v /106 *"From logistic regression models adjusting for the other intervention and practice, there was no evidence of differential effects of the two interventions according to either consultation in the past 3 years or screening history. Respectively, the p values for the relevant interaction effects were 0.26 and 0.44 for the letter, and 0.85 and 0.58 for the flag (ignoring whether or not the flag had been activated)."*	
	R-NFA-	R-FLAG-GP	Pre-specified? Yes 17/287 v 29/289 5.9% v 10.0%	Pre-specified? Yes /96 v /92 *"From logistic regression models adjusting for the other intervention and practice, there was no evidence of differential effects of the two interventions according to either consultation in the past 3 years or screening history. Respectively, the p values for the relevant interaction effects were 0.26 and 0.44 for the letter, and 0.85 and 0.58 for the flag (ignoring whether or not the flag had been activated)."*	
	R-NFA-	R-GPL+FLAG-PO+GP	Pre-specified? Yes 17/287 v 35/284 5.9% v 12.3%	Pre-specified? Yes /96 v /100 *"From logistic regression models adjusting for the other intervention and practice, there was no evidence of differential effects of the two interventions according to either consultation in the past 3 years or screening history. Respectively, the p values for the relevant interaction effects were 0.26 and 0.44 for the letter, and 0.85 and 0.58 for the flag (ignoring whether or not the flag had been activated)."*	Flag is no more effective than a letter and the combination does not appear to improve uptake. Interaction letter + flag: OR: 0.65 (0.29, 1.47), p=0.30 RR: 0.68 (0.33, 1.40)
	R-NoGPL-	R-allGPL-PO	(regardless of flag allocation) 46/576 v 66/572 8.0% v 11.5%		

			OR: 1.51 (1.02, 2.26) p=0.04 RR: 1.44 (1.01, 2.07)		
	R-NoFLAG -	R-allFLAG-GP	(regardless of letter allocation) 48/575 v 64/573 8.3% v 11.2% OR: 1.39 (0.93, 2.07) p=0.10 RR: 1.34 (0.94, 1.91)		
Cost-effectiveness					Cost for an average practice (with 89 eligible patients): £113 for the letter with 51% of cost borne by practice; £160 for the flag with 78% borne by the practice; £274 for combined with 67% borne by the practice. The extra total health service cost per additional attendance at screening was £35 for the letter and £65 for the flag.
Comments	Flags remained in notes for 6.2 months on average (32/578 flags lost). 546 (94%) retrieved, with 34% of those activated (recording interactions), 95/274 in flag-only group and 90/272 in letter + flag. Only 47% of included women consulted the practice during the follow-up period; effectiveness of flags reduced by limited period of use.				

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Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (appendix)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Trial selected practices which were not yet computerised, which may limit generalisability today. Practices were selected for low uptake (based in London and Birmingham).
Is there anything else not covered in the tables above?	No

Bush (2014) DES

Primary reference		Bush et al (2014) 'Cluster Randomised Controlled Trial Evaluation of a Link Worker-Delivered Intervention to Improve Uptake of Diabetic Retinopathy Screening in a South Asian Population'						
Trial registration #		ISRCTN79653731						
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
DES	cRCT 10 GP practice clusters	No	851 recent non-attenders (of 2,680 total) from 10 GP practices with a high proportion of Asian patients in Coventry, UK. 1/01/2007 to 31/12/2007. Note intervention only delivered to 271 people who had not attended their first appointment; reported results based on whole practice regardless of eligibility for intervention.	Uptake (based on aggregate screening attendance data) No individual patient level data available; practices compared using aggregate practice data	NFA [580 non-attenders of 1,692 total]	Linkworker telephone call the day before 2nd appointment [271 non-attenders of 988] Three multilingual linkworkers allocated between practices	Recent non-attenders [all; 851] Note: practices chosen to have high proportion of South Asian patients registered but no detail on proportion of Asian patients are reported (ethnicity not routinely recorded)	160 of 271 people passed to linkworkers were contacted. No explanation for large difference in number of patients in control and intervention practices. Likely chance due to small number of clusters (no information on randomisation procedure reported). "Proof of concept" trial with small sample size. Unclear if adequate adjustment for clustering made. Adjusted analysis used previous year's uptake in multi-level model but whole-practice denominators probably not desirable given large imbalance in those who attended the first invite (66% v 73%).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	PY	RoB 2.1	(Probably) did not know they were in a trial PN	RoB 3.1	Aggregate practice data only (but 2nd appt numbers reported) Y	RoB 4.1	PN	RoB 5.1	PY
RoB 1.2	Cluster-randomised NI	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Large imbalance in average practice size, 66% v 73% attended first appt. No information on other baseline characteristics Y	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Odd approach to analysis; not adjusted for clustering PN						
	-	RoB 2.7	**NA**						
Risk-of-bias	**High**	**Risk-of-bias**	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction	Unpredictable	Direction	Unpredictable	Direction		Direction		Direction	
Comments	Large imbalance in attendance at first appointment and limited information on cluster characteristics. Especially problematic when aggregate data used for outcomes. The paper reports the numbers not attending first appointment, and the numbers attending second appointment, but uses the whole practice as a baseline. This is not a bad approach but there was a large imbalance in the numbers attending the first appointment (66% v 73%) and so whole practice baselines may not be appropriate. We will use the numbers eligible for intervention as the denominator but this is quite messy.								
Risk-of-bias	**High**		Direction	Unpredictable					

Results

Endpoint	Control	Test	Recent non-attenders (whole trial)	Comments
Uptake	NFA	Linkworker phone call	120/580 v 143/271 20.7% v 52.8% As reported (aggregate whole-practice data): 74% v 89% RD: 15% (4%, 27%) p=0.0162 Adjusted RD: 12% (7%, 17%) p=0.0007	Paper used whole practice as denominator but this seems more prone to bias than using the number eligible for intervention (ie did not attend first appointment) given the large imbalance in proportions attending first appointment (66% v 73%). Does not appear adequately adjusted for clustering (adjustment for clustering should increase the standard error whereas the adjusted results here shrink it). We used a conservative ICC of 0.03 to adjust results for this review.
Comments	Adjusted for previous year's uptake rates.			

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Described but limited detail on content of phone calls.
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	High Asian population, Coventry demographics. Limited information about GP practices reported.
Is there anything else not covered in the tables above?	No

Cadman (2015) CSP

Primary reference		Cadman et al (2015) 'A Randomized Controlled Trial in Non-Responders from Newcastle upon Tyne Invited to Return a Self-Sample for Human Papillomavirus Testing versus Repeat Invitation for Cervical Screening'						
Trial registration #		ISRCTN 39154605						
Additional resources		Protocol (very brief, web archive)						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
CSP	RCT Balanced blocks (size=4) with no stratification	Yes (post-randomisation consent requested for self-sampling group)	6,000 non-attenders after invite and a reminder in Newcastle, UK (including some due for early cytology repeat rather than the 3 or 5 year standard screening schedule). Identified from NHAIS records on 3rd September, 2012. All interventions delivered by post on 10th September, 2012.	Uptake (attendance at screening or return of self-sample kit within 3 months) Attendance at follow-up for cytology or colposcopy after an abnormal result	Second reminder [3,000]	Self-sample kit by post (Dacron) [3,000]	Recent non-attenders [all; 6,000] Age <35 [2,243] IMD (3,883; 2,747 in most deprived quintile, 1,136 in second most deprived) Note that for screening history the paper does not separate out first-time invitees from those with no previous cytology. We have therefore excluded the 25-29 age-group as a proxy for those who have previously missed screening vs those who have not been invited before. Long-term non-attenders (age >30 and last cytology >5 years ago or no previous cytology) [3,634]	Consent asked only from the intervention group after randomisation (single consent Zelen design). 3,789 women had a previous recorded cytology result (mean 92.9 months prior, se 57.77 months, range 0.10-416.48). 2,211 had no previous record of cytology. 438 (7%) letters/kits undelivered (226 v 212). Analysed on ITT basis.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)

[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Intervention group asked for consent (but ITT used) Y	RoB 3.1	7% undeliverable, analysed on ITT Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Paper states study team were blinded (independent mailing company used) Y	RoB 3.2	**NA**	RoB 4.2	Self-test v cytology Y	RoB 5.2	N
RoB 1.3	N	RoB 2.3	Informed consent may have influenced uptake in Intervention arm PY	RoB 3.3	**NA**	RoB 4.3	Can't not be aware of cytology vs HPV testing PY	RoB 5.3	Subgroups not reported as subgroups or pre-specified (but data available for this review) PN
Quasi-randomised?	No	RoB 2.4	PY	RoB 3.4	**NA**	RoB 4.4	N		
Stratified or minimisation ?	No	RoB 2.5	N			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction	Unpredictable	Direction		Direction		Direction	
Comments	Post-randomisation consent required from intervention arm, with some potential to influence uptake (in both direction). May not fully reflect real world.								
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	Previous non-attender (whole trial)	SES (IMD)	Age	Long-term non-attender	Comments
Uptake	2R-REM-PO	2R-HTK-PO	Pre-specified? Yes 183/3000 v 411/3000 6.1% v 13.7% *Raw* RR: 2.25 (1.90 to 2.65) *Adj* RR = 2.24 (1.90 to 2.64 SSK: 248 returned kits (1 not testable) and 164 attended for cytology	Pre-specified? No IMD4: 27/574 v 70/562 4.7% v 12.5% *Raw* RR: 2.65 (1.73, 4.07) IMD5: 73/1372 v 198/1375 5.3% v 14.4% *Raw* RR: 2.71 (2.09, 3.50)	Pre-specified? No **<35:** 63/1098 v 136/1145 *Raw* RR (25-29): 2.19 (1.41, 3.38) *Raw* RR (30-34): 2.00 (1.37, 2.92)	Not reported in detail	Subgroups were not prespecified (beyond covariate adjustment) but sufficient data reported to extract for this review.
Follow-up after positive result							188/205 v 167/183 (92% v 91%) negative cytology (in those attending for cytology in either group)
Comments	Adjusted for age, deprivation, time since last cytology						

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'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (note HPV triage is about to be introduced but not self-testing and limited effect on interpretation of this trial)
Any other issues with generalisability or external validity?	Newcastle, 2012 (18% non-white, area chosen to be less diverse, more stable than previous trial)
Is there anything else not covered in the tables above?	No

Chambers (2016) BSP

Primary reference		Chambers et al (2016) 'A Pilot Randomized Controlled Trial of Telephone Intervention to Increase Breast Cancer Screening Uptake in Socially Deprived Areas in Scotland (TELBRECS)'						
Trial registration #		ISRCTN06039270						
Additional resources		Protocol						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	RCT Using minimisation by age and SIMD quintiles (most deprived 3 quintiles)	Post-randomisation for those receiving phone calls (after identity established). All data were collected regardless of consent for ITT analysis.	856 women receiving a routine reminder letter for a missed screening appointment in a deprived area of Scotland (East of Scotland Breast Screening Centre, Dundee), Feb-June 2014. Targeted areas in the lowest 60% of socioeconomic areas in Scotland (based on SIMD). Availability of telephone numbers established before randomisation.	Taken from published protocol Primary: Uptake (within 3 months; based on routine data) Appointments made (within 3 months) Screening history (collected, no analysis specified) Secondary: Information collected from the two support arms on intention, anticipated regret, barriers Proportion with phone numbers available	Standard reminder letter with no further action [217]	1. Phone reminder [212] 2. Phone support [213] 3. Phone support plus two questions related to anticipated regret [214] All intervention groups also received the standard reminder letter Maximum of 5 attempts to call	Recent non-attenders [all; 856] Note: all included subjects were also from the 3 most deprived quintiles	Pilot study. Availability of telephone numbers established before randomisation, which increases the ability to deliver the interventions but will over-estimate the real world effect (70% of numbers were available from the larger pool of eligible women). All groups received the standard reminder letter. Those in the phone arms were asked for consent, with more intensive interventions offered to those in the support and support + anticipated regret arms (4 in the reminder arm, 40 and 45 in the phone support arms declined). *"The TEL group received a simple telephone call to remind them that they had not attended their scheduled appointment and to provide information on how they could rearrange this appointment. Participants allocated to the telephone support intervention (TEL-SUPP and TEL-SUPP-AR) were told that we were trying to understand why some women do not take up their invitation to attend for breast screening when invited, and asked whether they would be prepared to answer some questions. Consent was sought to audio-record the interviews to check for treatment fidelity, however, women who declined to be recorded could still participate."*

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	The support groups were asked for consent but don't seem to have been made aware that there were different study arms PN	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	N
RoB 1.3	N	RoB 2.3	Different rates of refusal dependent on arm (but ITT analysis) PY	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	N
Quasi-randomised?	No	RoB 2.4	Hard to establish how much refusals would reflect the real world PY	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Yes, minimised by age and SES (SIMD)	RoB 2.5	N			RoB 4.5	NA		
	-	RoB 2.6	Y						
	-	RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction	Favours comparator	Direction		Direction		Direction	
Comments	Informed consent obtained from phone groups, with more intensive phone interventions having higher rates of refusal (and no opportunity to refuse in control arm). These differences are likely to reflect the real world but inclusion in a trial may have increased rates of refusal (although very few refusals in the simplest phone intervention suggest that this may not be a large effect). This is an inherent problem for trials of uptake where informed consent is required due to the nature of an intervention; the trial was designed, conducted and reported to a high standard.								
Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Intervention	Recent non-attenders (whole trial)	Comments
Uptake	R-NFA-	R-REM-TEL	Pre-specified? Yes 15/217 v 35/212 6.9% v 16.5% *Raw* OR: 2.66 (1.4, 5.0) *Adj* OR: 3.28 (1.67, 6.44)	Note that all included subjects were from the 3 most deprived quintiles by postcode as well as recent non-attenders. Both are whole-group characteristics and so only reported here once.
	R-NFA-	R-HCP-TEL	Pre-specified? Yes 15/217 v 24/213 6.9% v 11.3% *Raw* OR: 1.71 (0.9, 3.4) *Adj* OR: 2.05 (1.01, 4.17)	
	R-NFA-	R-HCP+AR-TEL	Pre-specified? Yes 15/217 v 28/214 6.9% v 13.1% *Raw* OR: 2.03 (1.1, 3.9) *Adj* OR: 1.93 (0.97, 3.86)	
Made appointment	R-NFA-	R-REM-TEL	Pre-specified? Yes 19/217 v 43/212 8.8% v 20.3% *Raw* OR: 2.65 (1.5, 4.7) *Adj* OR: 3.20 (1.74, 5.89)	
	R-NFA-	R-HCP-TEL	Pre-specified? Yes 19/217 v 30/213 8.8% v 14.1% *Raw* OR: 1.71 (0.9, 3.1) *Adj* OR: 2.01 (1.06, 3.81)	
	R-NFA-	R-HCP+AR-TEL	Pre-specified? Yes 19/217 v 36/214 8.8% v 16.8% *Raw* OR: 2.11 (1.2, 3.8) *Adj* OR: 2.05 (1.10, 3.82)	
Telephone number available			Pre-specified? Yes	70% of 1,219 eligible women had a number available (13% later found to be invalid or wrong number).

Interviews (with support groups only)			Pre-specified? Yes	Mean interview length: Phone reminder: 2.2 minutes (range 0 to 6) Phone support +/- AR: 13.4 minutes (range 0 to 63) 97% in the two phone support groups did not mind being called and 65% said it was helpful. AR and intention were strongly related (n=57, r=0.69, p<0.001), and scores on AR and Intention were related to both making an appointment (AR: r=0.26, p=0.34; Intention: n=115 r=0.30, p=0.001) and attending (AR: r=0.28, p=0.24; Intention: r=0.25, p=0.006) but there was no overall impact of being in the AR group.
Comments	Adjusted ORs adjusted for age, SIMD vigintile [twentieths], screening history (attendance at previous screening round or first invitee)			

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes but might be difficult to precisely reproduce with the information given
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Targeted women from particularly deprived areas, Dundee
Is there anything else not covered in the tables above?	No

Hirst (2017) BCSP

Primary reference		Hirst et al (2017) 'Text-Message Reminders in Colorectal Cancer Screening (TRICCS): A Randomised Controlled Trial'						
Trial registration #		ISRCTN70904476						
Additional resources		Published protocol (Hirst, 2016) Supplementary tables						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	RCT "pseudo-randomised" with no explanation	No	8,269 adults aged 60-74 from 141 general practices in London, from 6 CCGs: Croydon, Greenwich, Hammersmith & Fulham, Hounslow, Lewisham, West London who had not returned a gFOBT by the end of week 7 (after a written reminder sent after week 5). January to March 2016. Eligible practices had to have existing messaging services to ensure consent for messaging. 144 of 295 practices consented to participate but 3 were excluded because they could not connect to the messaging provider (iPlato).	Uptake (adequate gFOBT kit returned with 18 weeks) Proportion of mobile numbers registered with GPs (inc per protocol analysis for this subgroup)	No text-message reminder [4,135] Note: standard practice includes a written reminder if kit not returned by 5th week. Both arms received this written reminder.	Additional text-message reminder if kit not returned after 7 weeks and mobile number available [4,134]	Recent non-responders [all; 8,269] Age [3,682 aged 60-64, 2,121 aged 70+] Male [3,973] IMD [1,727 most deprived quintile, 2,544 next most deprived] First-time invitees [1,542]	Each week, everyone who had been invited 7 weeks earlier and not returned a kit was randomised by a third party. Then if they had a mobile phone registered at the practice and were in the intervention group, a text reminder was sent. The paper comments on previous non-responders but offers analysis only by first or repeat invitee.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	"simple pseudo-random allocation" stratified by the 6 CCGs but no further details given PY	RoB 2.1	Not aware they were in a trial N	RoB 3.1	92 missing (46 on each arm), ~1% Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Text messages sent by automated system N	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	N
RoB 1.3	Baseline characteristics not reported by arm NI	RoB 2.3	**NA**	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	N
Quasi-randomised?	Not clear	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes (by CCG)	RoB 2.5	**NA**		Both ITT and per-protocol analyses reported (per protocol for availability of a mobile number)	RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction	Unpredictable	Direction		Direction		Direction		Direction	
Comments	Very little information given about 'pseudo' randomisation and baseline characteristics not reported by arm so impossible to check balance.								
Risk-of-bias	Some concerns		Direction	Unpredictable					

Results

Endpoint	Control	Test	SES	Age	Men	First-time invitees	Recent non-responders (whole trial)	Comments
Uptake	-NFA-	2R-REM-TXT	Pre-specified? Yes IMD4: 485/1285 v 482/1259 37.7% v 38.3% IMD5: 309/866 v 278/861 35.7% v 32.3% No evidence of interaction by SES (sub-sample sizes and two corrected numerators kindly supplied by the authors)	Pre-specified? Yes 60-64: 694/1861 v 713/1821 37.3% v 39.2% 70+: 444/1048 v 463/1073 42.4% v 43.2% No evidence of interaction by age (sub-sample sizes kindly supplied by the authors)	Pre-specified? Yes 732/1956 v 753 /2017 37.4 v 37.3% Test for interaction by gender: p=0.57 No evidence of interaction by sex (sub-sample sizes kindly supplied by the authors)	Pre-specified? Yes 282/809 v 297/733 34.9% v 40.5% *adj* OR: 1.29 (1.04, 1.58) p=0.02 Some evidence of a greater effect for first time invitees but in the context of a very large number of tests for interaction, p=0.02 is not strong. 34.9% v 40.5% with repeat invitees 41.1% v 40.5%.	Pre-specified? Yes 1648/4135 v 1674/4134 39.9% v 40.5% OR: 1.03 (0.94, 1.12) p=0.56 Per protocol (phone numbers available) OR: 1.05 (0.85, 1.28), p=0.67	Comparative results not reported by arm for USGs.
Registered mobile								49.4% had mobile numbers registered with their GP. 36.9% uptake for those with no registered mobile (reminder undeliverable) vs 43.6% for those with a mobile number available.
Comments	Very limited information on USGs. Tests for interaction reported in supplementary tables.							

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'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (described in supplementary materials)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	As reported in paper, only 93% of population have mobile phones (as of 2016, according to Ofcom) with only 39.8% of eligible population having a number registered with their GP (referenced to Kerrison, 2015). This trial was based in London which may differ from the rest of the population.
Is there anything else not covered in the tables above?	No

Hoare (1994) BSP

Primary reference		Hoare et al (1994) 'Can the Uptake of Breast Screening by Asian Women Be Increased? A Randomized Controlled Trial of a Linkworker Intervention'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	RCT Balanced blocks stratified by Pakistani/Bangladeshi heritage	No	527 women aged 50-64 with Asian names from 7 general practices in Oldham with a high proportion of Asian patients. Autumn 1991	Uptake (no time period defined; data from Greater Manchester screening office)	No intervention [263 randomised; 251 invited]	Linkworker visits a few weeks before screening invitations sent (language-appropriate interviews) [264 randomised; 247 invited]	Asian [all; 527 randomised; 498 invited] Pakistani [324 randomised; 308 invited] Bangladeshi [203 randomised; 190 invited]	59% of the intervention group were contactable, with 25% not resident at the address recorded for them. 29 (12 v 17) post-randomisation exclusions not included because subsequent information indicated they were ineligible. Length of residence in UK and age investigated as factors influencing uptake but not for subgroup interactions.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	May not have been aware they were in a trial but could not be blinded PN	RoB 3.1	No follow-up on post-randomisation exclusions but numbers fairly small PY	RoB 4.1	N	RoB 5.1	No protocol or trial registration referenced PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	N	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes (by ethnicity)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	29 post-randomisation exclusions (12 v 17), unclear potential for bias by allocation PY						
	-	RoB 2.7	PN						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments	Post-randomisation exclusions mean no follow-up available for some randomised subjects but ITT denominators are available and will be used for this review.								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Test	Asian (whole trial)	Pakistani	Bangladeshi	Comments
Uptake	-NFA-	pre.I-HCP-F2F	Pre-specified? Yes 117/251 v 122/247 47% v 49% p=0.53	Pre-specified? Unclear 79/155 v 83/153 51% v 54% p=0.56	Pre-specified? Unclear 38/96 v 39/94 40% v 42% p=0.79	
Comments	51% of subjects spoke Punjabi; 39% Bangla with only one English speaker. 17 women (12%) said they were literate in their own language, none could read English.					

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Fairly well described but difficult to reproduce precisely
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Asian women aged 50-64 (not 50-69 as for current screening programme); Oldham demographics (older women more likely to be first generation; Bangladeshis relatively new arrivals). Trial conducted in 1991, very early on in the history of the screening programme.
Is there anything else not covered in the tables above?	Method of identifying Asian women by name classifies most women by their husband or father's ethnicity and so will not be entirely accurate, missing some women and wrongly including others. The authors reference a paper which examines the reliability of this method. It is not perfect but there are few other options.

Judah (2018) DES

Primary reference		Judah et al (2018) 'Financial Disincentives? A Three-Armed Randomised Controlled Trial of the Effect of Financial Incentives in Diabetic Eye Assessment by Screening (IDEAS) Trial'						
Trial registration #		ISRCTN14896403 (retrospectively registered)						
Additional resources		Judah et al (2017) 'Incentives in Diabetic Eye Assessment by Screening (IDEAS) Trial: A Three-Armed Randomised Controlled Trial of Financial Incentives'						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
DES	RCT Simple randomisation with 1.4:1:1 ratio Anonymised IDs to maintain allocation concealment	No	1,274 (1,051 after post-randomisation exclusions) people aged >16 who had not attended eye screening for at least 2 years, and had not been invited within the previous 2 months. Identified from 1st Retinal Screening Database (contracted service) on 12 March 2015. London (Chelsea & Westminster and St Mary's hospitals), UK, 2015 May 2014 to August 2016	Uptake Additional management required following screening	Usual invitation with option to reschedule [524, 435 after exclusions]	1. Voucher for £10 cash on attendance [375, 312 after exclusions] 2. Voucher for 1 in 100 chance of winning £1000 lottery, entrance on attendance [375, 304 after exclusions] Incentive offers included with standard invitation, sent 4 weeks before appointment	Previous non-attenders [all;1,274, 1,051 after exclusions] SES [non-ITT numbers only; 304 in most deprived quintile, 468 in next most deprived] Age <36 [49; non-ITT numbers only]	Clinic dates alternated, with additional control dates, to remove seasonality. Incentive offers expired on the day of the appointment but could be extended to one rescheduled appointment. 223 post-randomisation exclusions (89, 63 & 71 respectively) a violation of ITT. Excluded because they attended in the interim (44.4%), or moved away (22.4%). No between group differences in reasons for exclusion (p=0.736).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Did not know they were in a trial N	RoB 3.1	N	RoB 4.1	N	RoB 5.1	Trial registered retrospectively PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	PY	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	N	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	Attendance occurred before voucher presented N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	No	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Large number of post-randomisation exclusions (unlikely to have been influenced by allocation and full ITT baselines available) N						
	-	RoB 2.7	N						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	Previous non-attenders (whole trial)	SES	Age (age group?)	Comments
Uptake	LT-INV-PO	LT-CASH-PO	Pre-specified? Yes 34/435 v 17/312 7.8% v 5.5% RR: 0.70 (0.35, 1.39) p=0.26 RD: -2% (-7%, 2%) p=0.19	Pre-specified? Unclear IMD4: /187 v /153 IMD5: 19/134 v 10/74	Pre-specified? Unclear <35?? /20 v /12	Note, all participants were selected from postcodes in the most deprived 60% by IMD (and thus the whole-trial results for previous non-attenders also apply for IMD60).
	LT-INV-PO	LT-LOT-PO	Pre-specified? Yes 34/435 v 10/304 7.8% v 3.3% RR:0.42 (0.18, 0.98) p=0.02 RD: -5% (-9%, 0.3%) p=0.01	Pre-specified? Unclear IMD4: /187 v /128 IMD5: 19/134 v 5/96	Pre-specified? Unclear <35?? /20 v /17	
	LT-INV-PO	LT-FIN-PO	Pre-specified? Yes 34/435 v 27/616 7.8% v 4.4% RR: 0.56 (0.34, 0.92) p=0.03 RD: -3% (-6%, 1%) p=0.02	Pre-specified? Unclear IMD4: /187 v /281 IMD5: 19/134 v 15/170	Pre-specified? Unclear /20 v /29	
Additional management required	LT-INV-PO	LT-CASH-PO	6/34 v 5/16 17.6% v 31.2% RR: 0.83 (0.53, 1.30) RD: -14% (-44%, 16%)			
	LT-INV-PO	LT-LOT-PO	6/34 v 2/10 17.6% v 20.0% RR: 0.97 (0.64, 1.48) RD: -2% (-36%, 31%)			
	LT-INV-PO	LT-FIN-PO	6/34 v 7/26 17.6% v 26.9% RR: 0.89 (0.67, 1.17) RD: -9% (-30%, 12%)			
Comments	Small number of people in IMD 60-70%					

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (vouchers reproduced in paper)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Participants selected from most deprived 60% of postcodes in Kensington, Chelsea and Westminster.
Is there anything else not covered in the tables above?	No

Kerrison (2015) BSP

Primary reference		Kerrison et al (2015) 'Text-Message Reminders Increase Uptake of Routine Breast Screening Appointments: A Randomised Controlled Trial in a Hard-to-Reach Population'						
Trial registration #		NCT01977599						
Additional resources		Supplementary information available with details of intervention						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT "pseudorandom" but no details given	No	2,240 first-time invitees to BSP in Hillingdon (an area with relatively low uptake of BSP), Nov 2012-Oct 2013 54/2294 (2.35%) returned an opt-out request and were removed from the trial	Primary: Attendance at original appointment Secondary: Uptake (attendance within 60 days) % cancelled appointments	No reminder [1,118]	Text message reminder 48 hours before original appointment [1,122]	First-time invitees [all; 2,240] IMD [132 in most deprived quintile; 645 in next most deprived]	No attempt to trace phone numbers for intervention arm where not already available to maintain ecological validity (ie reflect the real world). Consent forms sent with invite letters informing people that they were in a trial and offering the chance to opt out. 54 (2.35%) refused consent and were removed from the trial after randomisation. Unlikely to introduce bias as they did not know what arm they were on (assuming all opt outs were before reminders sent) but arguably should be included in denominators for ITT. Numbers opting out not reported by arm.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	"pseudo-random, no details given PY	RoB 2.1	Couldn't be blinded and were asked for consent after randomisation (but before they knew what treatment arm they were on) Y	RoB 3.1	54 (2.35%) opted out post-randomisation and were excluded Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	PY	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	NI	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	Yes	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Opt-outs (54, 2.35%) excluded after randomisation; unlikely to introduce bias but can't reconstruct ITT for this review PN						
	-	RoB 2.7	PN						
Risk-of-bias	**Low**	**Risk-of-bias**	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction	Unpredictable	Direction		Direction		Direction	
Comments	Post-randomisation informed consent and exclusions; the small number of opt-outs should have been included in ITT results								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Intervention	SES (IMD)	First-time invitees (whole trial)	Comments
Uptake within 60 days	NFA	Pre-appointment text message reminder	Pre-specified? Unclear (not in trial registration) No information reported	Pre-specified? Yes 703/1118 v 759/1122 62.88% v 67.65% OR: 1.23 (1.04, 1.47) p=0.02	
Attendance at first appointment			Pre-specified? Unclear (not in trial registration) IMD4: 157/317 v 189/328 49.5% v 57.6% OR: 1.39 (1.02, 1.89) p=0.04 IMD5: 32/66 v 41/66 48.5% v 62.1% OR: 1.75 (0.88, 3.51) p=0.11	Pre-specified? Yes 661/1118 v 722/1122 59.12% v 64.35% OR: 1.25 (1.05, 1.48) p=0.01	
% cancelled appointments			No information reported	Pre-specified? Yes 31/118 v 61/1122 2.77% v 5.44% OR: 2.02 (1.30, 3.13) p<0.01	
Comments	Of the 1122 women assigned to the text-message reminder only 456 (40.6%) had a mobile telephone number recorded on the GP clinical system, of which 380 (33/8%) were valid. reminder for their appointment. The authors were unable to provide additional data on uptake within 60 days by SES.				

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes, supplementary materials includes text message wording
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No
Is there anything else not covered in the tables above?	No

Kerrison (2018) BSS [combined with Kerrison (2017)]

Primary reference		Kerrison et al (2018) 'Use of Two Self-Referral Reminders and a Theory-Based Leaflet to Increase the Uptake of Flexible Sigmoidoscopy in the English Bowel Scope Screening Program: Results From a Randomized Controlled Trial in London'						
Trial registration #		ISRCTN44293755						
Additional resources		Kerrison et al (2017) 'Improving Uptake of Flexible Sigmoidoscopy Screening: A Randomized Trial of Nonparticipant Reminders in the English Screening Programme' McGregor et al (2016) 'Uptake of Bowel Scope (Flexible Sigmoidoscopy) Screening in the English National Programme' – pilot Supplementary materials (reminder letters, theory-based leaflet and development) Standard BSS leaflet (dead link)						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSS	qRCT "pseudo-randomised" from a pseudo randomly selected subset of eligible subjects. No explanation of pseudo-randomisation procedures.	No	1,383 people from GP practices in the London boroughs of Brent and Harrow "[pseudo] randomly selected" from those who had not responded to the original invitation or failed to attend an appointment within 12 months. Randomised Feb-August 2015, follow-up to October 2015 1,383 of 1503 non-participants pseudo-randomly selected for inclusion. Unclear why it was necessary to randomise only a subset when these numbers are so close, beyond some comments about controlling workload	Primary (from trial registration): Uptake (screened within 12 weeks of annual reminder) Uptake by gender Uptake after one round of annual reminders Uptake after two rounds of annual reminders Secondary: Patient preference for same sex practitioner Reasons for not responding to original invite	No reminder [461; 453 for second reminder] Note: abstract of Kerrison 2018 reports 460 instead of 453 remaining in control arm (inconsistent with reported total sample size)	1. Annual self-referral reminders with standard information booklet [461; 399 for second reminder] 2. Annual self-referral reminders with theory-based leaflet (based on Behaviour Change Wheel) [461; 366 for second reminder]	Previous non-attenders [all; 1,383]	The bowel scope screening programme uses pre-notification letters and an invitation with a timed appointment 2 weeks later, with reminders sent 2 weeks later and the appointment cancelled 2 weeks after that, with an invitation to self-refer up to the age of 60. This trial tests the use of (two) annual reminders for those who do not respond to the original invitation or standard reminder. Between 12 and 24 month reminder, 119 had attended screen, 38 moved out of area, 8 died.

				Reasons for participating after reminder Descriptive (not pre-specified): Adenoma detection rate Cost per additional attendance				

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Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	"pseudo-randomised" but no detail reported PY	RoB 2.1	Could not be blinded but were not aware they were in a trial PN	RoB 3.1	38 of 1,383 had moved out of area Y	RoB 4.1	N	RoB 5.1	Only gender prespecified as of interest (and not for treatment interaction) and limited detail in trial registration but approach to analysis is reasonable PY
RoB 1.2	NI	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Some differences in gender balance and previous non-attenders but not inconsistent with small sample size PN	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	Distinction between non-responders and non-attenders not pre-specified (and not reported in this review) PN
Quasi-randomised?	Possibly	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		

Stratified or minimisation ?	No information	RoB 2.5	**NA**			RoB 4.5	**NA**		
		RoB 2.6	**Y**						
		RoB 2.7	**NA**						
Risk-of-bias	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction	Unpredictable	Direction		Direction		Direction		Direction	
Comments	No information provided about pseudo-random procedures for selecting subjects and for randomisation but with no informed consent and reasonable approach is likely to have produced suitable groups. Distinction between non-attenders and non-responders appears to post-date the trial registration but is reported in addition to, rather than instead of, the whole group (all of whom had not been screened a year after their original invitation). This review is only concerned with the whole group results as interactions for treatment effect by other characteristics were not investigated.								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Test	Previous non-attenders (whole trial)	Comments
Uptake (attended appointment within 12 weeks of reminder)	LT-NFA-	LT-annREM-PO	Pre-specified? Yes 1st annual reminder: 1/461 v 48/461 OR: 53.46 (7.35, 389.05) *Adj* OR: 53.73 (7.38, 391.39) p≤0.001 At end of trial: 3/461 v 67/461 0.7% v 14.5% OR: 25.96 (8.10, 83.18) p≤0.001 *Adj* OR: 26.14 (8.14, 83.95)	
Uptake	LT-NFA-	LT-annERM-PO	Pre-specified? Yes 1st annual reminder: 1/461 v 70/461 OR: 82.35 (11.39, 595.58) *Adj* OR: 89.01 (12.28, 645.40) p≤0.001 At end of trial: 3/461 v 99/461 0.7% v 21.5% OR: 41.75 (13.13, 132.76) p≤0.001 *Adj* OR: 46.91 (14.68, 149.93) p≤0.001	There is a very large imbalance in the proportion of previous non-attenders (people who had initially made an appointment but not attended) in the theory-based leaflet arm (50 v 25). This could have arisen by chance but may introduce some bias as there was a much higher uptake amongst those who had previously made an appointment but did not attend vs those who did not respond at all (11% vs 17.3% after one annual reminder).
Uptake	LT-annREM-PO	LT-annERM-PO	Pre-specified? Yes 1st annual reminder: 48/461 v 70/461 OR: 1.54 (1.04, 2.28) p=0.03 *Adj* OR: 1.69 (1.13, 2.52) p≤0.01 At end of trial: 67/461 v 99/461 14.5% v 21.5% OR: 1.61 (1.14, 2.26) p=0.006	

			Adj OR: 1.80 (1.26, 2.55) p≤0.001	
Booked appt (booked appointment within 12 weeks of reminder)	LT-NFA-	LT-annREM-PO	Pre-specified? No 1st annual reminder: 1/461 v 64/461 OR: 74.16 (10.24, 536.97) *Adj* OR: 73.27 (10.11, 531.11) p≤0.001 At end of trial: 3/461 v 83/461 OR: 33.52 (10.51, 106.92) p≤0.001 *Adj* OR: 33.9 (10.6, 108.36) p≤0.001	
Booked appt	LT-NFA-	LT-annERM-PO	Pre-specified? No 1st annual reminder: 1/461 v 95/461 OR: 119.40 (16.57, 860.49) *Adj* OR: 130.36 (18.05, 941.54) p≤0.001 At end of trial: 3/461 v 126/461 OR: 57.42 (18.12, 182.00) p≤0.001 *Adj* OR: 65.25 (20.48, 207.90) p≤0.001	
Booked appt	LT-annREM-PO	LT-annERM-PO	Pre-specified? No 1st annual reminder: 64/461 v 95/461 OR: 1.61 (1.14, 2.28) p≤0.001 *Adj* OR: 1.78 (1.25, 2.54) p≤0.01 At end of trial: 83/461 v 126/461 OR: 1.71 (1.25, 2.34) p≤0.001 *Adj* OR: 1.93 (1.39, 2.66) p≤0.001	

Preference for same sex practitioner				Not reported
Reasons for previous non-participation				Not reported
Reasons for participating after reminder				Not reported
Adenoma detection rate				14/169screened (8.3%), 7 met the criteria for colonoscopy. One diagnosed with cancer. Number detected in each intervention arm: 3 v 11 (0 in control)
Costs				At 12 months: £8.37 (£6.38, £11.17) per additional attendance (standard booklet) and £8.75 (£7.05, £11.14) for theory-based leaflet. At 24 months: £18.31 (£12.00, £29.00) per additional attendance (standard booklet) and £16.93 (£11.97, £24.55) for theory-based leaflet.
Comments	Numerical results for subgroups by treatment arm sparsely reported (focus on USGs as a prognostic factor, not treatment effect): *"There was also strong evidence of a difference in uptake by initial episode status after adjusting for study group and other baseline characteristics, with former non-attenders being nearly twice as likely to book and attend an appointment than former non-responders (14.2 % and 8.0 %, respectively; OR 2.5, 95 %CI 1.4 – 4.4; P< 0.01). There was no evidence of an association between screening uptake and sex, regional IMD tertile, or area [borough] (all P values > 0.05)."* 43 people booked an appointment but did not attend (25) or cancelled (18). Limited reporting of secondary outcomes.			

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	London-based
Is there anything else not covered in the tables above?	No

Kitchener (2018a) CSP

Primary reference	Kitchener et al (2018a) 'A Cluster Randomized Trial of Strategies to Increase Uptake amongst Young Women Invited for Their First Cervical Screen: The Strategic Trial'
Trial registration #	ISRCTN52303479
Additional resources	Protocol (dead link) NIHR project page

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
CSP	cfRCT (276 general practice, 193 in Manchester and 83 in Grampian, cluster-randomised using Raab & Butcher minimisation algorithm for cRCTs, balancing for practice size and screening uptake.)	No	20,879 women due to receive their first invitation to cervical screening, from 276 GP practices in Trafford, Salford, Manchester and Grampian in April 2012 to December 2013 Eligible women in Manchester were aged 24.5 and aged 20 in Grampian. All were due to receive their first invitation to cervical screening within 3 months. Manchester subjects were contacted by LaSCA (the population-based register for the NHS CSP); in Grampian lists of eligible individuals were sent to the trialists for contact Only Manchester had access to online booking and so the second randomisation did not apply to Grampian practices	Uptake (at 3 and 6 months, from cytology records)	No pre-invitation PIL nor online booking [2,626 in factorial*; 8,303 total in no pre-leaflet & no online booking] *Grampian did not participate in the factorial randomisation to online booking	1. PIL posted before standard invitation to screening [2,352 in factorial*; 7,820 total in no pre-leaflet & no online booking] 2. Online booking information for sexual health clinics [2,115] 3. PIL posted before standard invitation to screening with online booking information for sexual health clinics [2,641] *Grampian did not participate in the factorial randomisation to online booking	First-time invitees [all; 20,879]	This is Phase I of a two trial project, with Phase II (Kitchener 2018b) randomising non-responders to a second intervention. Results are reported only in the factorial (ie pre-leaflet vs no pre-leaflet, and online booking vs no online booking).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Participants could not be blinded but not aware they were in a study Y	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Trialists sent Grampian interventions, Manchester automated N	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	N
RoB 1.3	N	RoB 2.3	**NA**	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	N
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes (minimisation)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Intervention	First-time invitees (whole trial)	Comments
Uptake	-NFA-	pre.I-WI-PO	Pre-specified? Yes At 3 months: 2002/10418 v 1970/10461 19.22% v 18.83% *strat* OR: 0.967 (0.879, 1.062) p=0.485 ICC=0.0099 At 6 months: 3191/10418 v 3256/10461 30.63% v 31.13% *strat* OR: 1.014 (0.928, 1.109) p=0.747 ICC=0.0157 (276 clusters)	OR adjusted for site and baseline uptake, similar to the factors used to stratify randomisation so these ORs can be regarded as adjusted for stratification factors and clustering only.
	-NFA-	pre.I-OPENonline-PO	Pre-specified? Yes (Manchester only) At 3 months: 770/4467 v 936/5267 17.24% v 17.77% *strat* OR: 1.021 (0.869, 1.200) p=0.802 ICC=0.0090 At 6 months: 1190/4467 v 1518/5267 26.64% v 28.82% *strat* OR: 1.097 (0.939, 1.282) p=0.242 ICC=0.0194 (193 clusters)	OR adjusted for baseline uptake (site not relevant as Grampian did not participate in this randomisation). This is partial accounting for the factors used to stratify randomisation and is adjusted for clustering, so these estimates likely to be better than those recalculated from the raw numbers.
Comments	Some additional analyses by vaccination status in Grampian are reported.			

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*
'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors
Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes. Leaflet referenced to: Sadler L, Albrow R, Shelton R et al. Development of a pre-notification leaflet to encourage uptake of cervical screening at first invitation: a qualitative study. Health Educ Res 2013; 28: 793–802.
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Manchester/Grampian, all first-time invitees in their early/mid 20s
Is there anything else not covered in the tables above?	No

Kitchener (2018b) CSP

Primary reference	Kitchener et al et al (2018b) 'A Cluster Randomized Trial of Strategies to Increase Uptake amongst Young Women Invited for Their First Cervical Screen: The Strategic Trial'
Trial registration #	ISRCTN52303479
Additional resources	Protocol (dead link) NIHR project page

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
CSP	cRCT (276 general practice clusters conducted in two phases, only phase 2 relevant for this review) Raab & Butcher minimisation algorithm for cRCTs, balancing for practice size and screening uptake. Sample size based on estimated ICC of 0.0265 based on the literature for a similar outcome.	No	10,126 non-attenders (within 6 months) previously included in a trial of first time-invitees from general practices in Greater Manchester, England and Grampian, Scotland (267 practices cluster-randomised for phase 2). April 2013 to November 2014. Practices re-randomised for Phase 2. Some women from phase 1 were excluded due to 3 month delay in starting phase 2 and changes of address which made them uncontactable. Nine practices lost for Phase 2, seven due to all eligible women having been screened and two where all eligible women had moved on. Phase 2 interventions took place 7.5 months after phase 1 intervention due to time needed to identify non-attenders at 6 months and prepare materials.	Uptake (within 12 months of intervention, based on cytology records; note that maximum follow-up for phase 2 was 10.5 months)	Standard reminder letter (open invite) [3,782; 101 practices]	1. Vaginal self-sample kit sent unrequested [32 clusters; 1,141] 2. Vaginal self-sample kit offered [33 clusters; 1,290] 3. Nurse navigator [34 clusters; 1007] 4. Timed second appointment [33 clusters; 1,629] 5. Choice of vaginal self-sample or nurse navigator [34 clusters; 1,277] 32-34 practices cluster-randomised to each intervention Note: arms 2 & 5 above not included in original trial registration	Recent non-attender [all; 10,126]	"[self-sample kit] sent or offered comprised either the Delphilavage or the RoversEvalyn Brush, which were used to obtain a vaginal sample, and packaging in which to return the sample compliant with transport regulation UN3373 for Category 3 Biological Substances." Kits mailed by the Screening Agency in Manchester and by the trialists in Grampian (using lists provided by ATOS).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Participants not aware they were in a study but could not be blinded Y	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Some deviations from original trial registration (two additional interventions) but not ad hoc in nature PY
RoB 1.2	Cluster trial Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	N
RoB 1.3	N	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	Different tests offered Y	RoB 5.3	N
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	N		
Stratified or minimisation ?	Yes (minimisation)	RoB 2.5	**NA**			RoB 4.5	**NA**		
		RoB 2.6	Y						
		RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	Recent non-attender (whole trial) cytology only	Recent non-attender (whole trial) (HPV or cytology or both)	Comments
Uptake	R-REM-PO	R-HTK-PO	1025/3782 v 248/1141 27.1% v 21.7%	1026/3782 v 342/1141 27.1% v 30.0% *strat* OR: 1.286 (1.056, 1.567) p=0.012 ICC: 0.0211	Due to multiple testing report uses Bonferroni correction, interpreting at 1% significance level in order to maintain overall 5% level
	R-REM-PO	R-HTK-OFFER	1025/3782 v 314/1290 27.1% v 24.3%	1026/3782 v 333/1290 27.1% v 25.8% *strat* OR: 1.056 (0.884, 1.262) p=0.548 ICC: 0.0211	Due to multiple testing report uses Bonferroni correction, interpreting at 1% significance level in order to maintain overall 5% level
	R-REM-PO	R-NN-TEL	1025/3782 v 229/1007 27.1% v 22.7%	1026/3782 v 230/1007 27.1% v 22.8% *strat* OR: 0.799 (0.642, 0.994) p=0.044 ICC: 0.0211	Due to multiple testing report uses Bonferroni correction, interpreting at 1% significance level in order to maintain overall 5% level
	R-REM-PO	R-FIXED-PO	1025/3782 v 471/1629 27.1% v 28.9%	1026/3782 v 472/1629 27.1% v 29.0% *strat* OR: 1.191 (0.975, 1.456) p=0.087 ICC: 0.0211	Due to multiple testing report uses Bonferroni correction, interpreting at 1% significance level in order to maintain overall 5% level
	R-HTK-PO	R-NN/HTK-TEL/PO	1025/3782 v 378/1277 27.1% v 29.6%	1026/3782 v 385/1277 27.1% v 30.2% *strat* OR: 1.058 (0.869, 1.289) p=0.573 ICC: 0.0211	Due to multiple testing report uses Bonferroni correction, interpreting at 1% significance level in order to maintain overall 5% level
Comments	ORs adjusted for practice attendance and PCT region, similar to stratification factors used for randomisation. Results reported at 12 and 18 months (4.5 and 10.5 months since Phase 2 intervention). ORs reported here for 18 month follow-up.				

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No (Manchester and Grampian)
Is there anything else not covered in the tables above?	No

Lancaster (1992) CSP

Primary reference		Lancaster et al (1992) 'Does the Offer of Cervical Screening with Breast Screening Encourage Older Women to Have a Cervical Smear Test?'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
CSP	RCT *"separated into nine batches ready for invitation, grouping together general practitioners or practices."* Unclear if this refers to stratified randomisation	No	2,131 (1,912 eligible for invitation, 1,794 of these also eligible for cervical screening) women aged 50-64 registered with 57 GPs, 10 "main" general practices and 28 GPs from "fringe" practices in or around North Manchester invited for breast screening when the mobile breast screening unit was based at Northern Hospital, 25/07/90 to 08/08/90. GPs were asked to check lists for eligibility before randomisation 219 (10%) reported to be ineligible (unclear if this was determined before or after randomisation, most likely before). 183 had moved away, 9 died, 5 screened recently, 22 "*varied reasons for not attending, the majority being ill*" A further 118 women were ineligible for cervical screening, primarily due to hysterectomy. Unclear why these were not excluded before randomisation Two practices had ~60% Asian women in their eligible group, the other 1-6%	Uptake of cervical screening (ascertained via outpatient and GP records, within ~8 weeks of invite for cervical screening done by GPs; note that this was therefore 11 weeks after BSP invite for the group invited to have a smear test on attendance at mammography) Effect on uptake of breast screening	Invited for CSP at same time as BSP invite [965] BSP/CSP invite sent approximately 3 weeks before timed appointment for mammography (cervical screening offered at walk-in clinic or GP)	Offered cervical screening when attending for mammography [947] BSP invite sent approximately 3 weeks before timed appointment for mammography (cervical screening offered at walk-in clinic or GP)	Asian women (identified by surname) [172]	This study aimed to increase uptake of cervical screening for older women who were eligible for breast screening. Note that cervical screening is offered every 5 years for ages 50-64 whereas breast screening is every 3 years. Thus this intervention implies a slightly more frequent invite for cervical screening. (This study took place very early in the timeline of population-based screening.) This trial is aimed at 50-64 year old women, who have a higher uptake for CSP than younger women in the current screening programme (the authors report that was not the case when this trial took place). Pap tests offered in a nearby outpatient clinic close to the mobile unit, with a female nurse and no appointment needed. Leaflets included with the invite and offered on attendance stated that they could ask their GP to do the pap test instead. Helpline number offered for enquiries. Translated versions of written materials were available and included in materials sent to those with Asian names. Cervical screening histories ascertained from FHSA computer system or, if no details found, traced via North Western Regional Cytology Laboratory computer records. Coverage not perfect but likely to be good for the preceding 4.5 years (due to FHSA records).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
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Quality assessment (RoB 2)

RoB 2 cribsheet

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Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

	Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
	RoB 1.1	No details reported PY	RoB 2.1	Women were not aware they were in a trial N	RoB 3.1	Regional records didn't provide 100% coverage and 118 post-randomisation exclusions due to unsuitability for cervical screening N	RoB 4.1	Different periods of follow-up for two groups to allow for 8 weeks since invite to CSP; reasonable given design PN	RoB 5.1	No protocol or trial registration mentioned PY
	RoB 1.2	NI	RoB 2.2	Y	RoB 3.2	PY	RoB 4.2	See comment above PN	RoB 5.2	PN
	RoB 1.3	Only age reported with limited detail (no table of baseline characteristics); some imbalance in those with no cervical smear within 5 years (146 v 121) NI	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	Walk-in clinic and GPs might be informed by individual women but no reason to think this affected record-keeping (they could only become aware once the outcome had occurred) PN	RoB 5.3	Analysis of Asian women not prespecified, motivated by very different BSP attendance rates between practices Y
	Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
	Stratified or minimisation ?	Unclear, probably by GP practice	RoB 2.5	**NA**			RoB 4.5	**NA**		
		-	RoB 2.6	Post-randomisation exclusions, mainly due to hysterectomy; unlikely to have introduced systematic bias PY						

		-	RoB 2.7	NA						
	Risk-of-bias	Some concerns	Risk-of-bias	Low	Risk-of-bias	Low	Risk-of-bias	Low	Risk-of-bias	Some concerns
	Direction	Favours intervention	Direction		Direction		Direction		Direction	Unpredictable
	Comments									
	Risk-of-bias	Some concerns		Direction	Favours intervention (probably, due to imbalance in previous non-attenders)					

Results

Endpoint	Control	Test	Asian	Previous non-attenders (cervical)	First-time invitees (cervical)	Comments
Uptake (CSP)	Combined invite	Invite to CSP on attendance for BSP	Pre-specified? No, exploratory based on viewing results No detailed information on uptake of cervical screening reported separately for Asian women Only 7 of the 195 women in either group (of 1,794 eligible) who attended for cervical screening were Asian. Not reported by intervention group and number of Asian women eligible not reported.	Pre-specified? Unclear Previous smear >5 years ago: 62/146 v 24/121 42% v 20%		Very small group of Asian women with limited ability to draw conclusions. Subgroup reported only to examine effect on breast screening uptake due to large variation in uptake between practices, with 2 of the 4 very low uptake practices having a high proportion of Asian women. Overall, 33% uptake of breast screening for Asian women compared to 56% for non-Asian. Overall uptake of cervical screening was much higher in the combined invitation group (28% v 13% for those attending breast screening; 17% v 10% of all randomised, p<0.001).
Uptake (BSP)	Combined invite	Invite to CSP on attendance for BSP	25/86 v 32/86 29% v 37% *"not statistically significant"*			8% lower attendance for breast screening when combined with cervical screening invite (compared to 2% lower for non-Asian and 3% overall) but numbers too small to determine whether this effect is likely to be real or due to chance. either overall or for an interaction with Asian ethnicity.
Cytology outcome						Borderline changes found in 1/195 (0.5%) with 174/195 (89%) normal. Inadequate 9/195, infection 3/195, slides broken or lost 8/195.
Opt outs						7 women rang the enquiry line to opt out of CSP
Comments						

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'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Limited detail of written materials but idea is simple to reproduce
Is the control arm used for this review comparable to current NHS-SP practice?	No (invitations are not routinely combined)
Any other issues with generalisability or external validity?	No (North Manchester demographics)
Is there anything else not covered in the tables above?	No

Libby (2011) BCSP

Primary reference	Libby et al (2011) 'Pre-Notification Increases Uptake of Colorectal Cancer Screening in All Demographic Groups: A Randomized Controlled Trial'							
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	RCT "simple random sampling was computer generated within the IT system"	No	59,953 people aged 50-74 included in the Scottish national colorectal cancer screening programme, 13/04/09 to 29/05/09 with follow-up to 27/11/09. 10/14 Scottish NHS boards were taking part in the colorectal screening programme at that time and one declined to participate.	Uptake (defined as return of kit, with 26-32 weeks depending on date of invite) Uptake data from screening lab with record linkage for demographics.	Posted FOBT kit with invitation letter and 'Know the facts' information booklet; no pre-notification letter sent [19,987] Note: this control arm is not relevant for this review as pre-notification letters are now standard practice	1. Pre-notification letter sent 2 weeks in advance of FOBT kit and 'Know the Facts' information booklet [19,975] 2. Pre-notification letter with 'Know the facts' information booklet sent 2 weeks in advance of FOBT kit [19,991] Planned screening dates for all groups were unaffected by the pre-notification letters (that is, the letters were sent 2 weeks in advance of the fixed schedule for sending kits)	SIMD [3,755 in most deprived quintile, 7,130 in next most deprived] Sex [19,631 men] Age [8,578 aged 50-54, 9,431 aged 55-59, 8,044 aged 60-64, 6,335 aged 70+] First-time invitees [22,477] Note: these numbers exclude the original control group	This trial considers both the use of a pre-notification letter and the timing of the information booklet. It took place early in the establishment of the Scottish national programme and 3 of the 9 NHS boards had participated in a pilot screening programme. Residence in one of these three areas was used to identify those who had previously been invited. The date the FOBT kits was sent was unaffected by inclusion in the trial, so all pre-notification letters sent 2 weeks ahead of original FOBT schedule. There were fewer people in the most deprived quintiles, and more in the least deprived quintiles, than expected, suggesting that the participating boards were less deprived on average than Scotland as a whole. Note that Scotland starts screening at age 50 rather than 60, as in England.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
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Quality assessment (RoB 2)

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Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Possible some households received different invites; not aware they were in a trial PN	RoB 3.1	Y	RoB 4.1	Follow-up defined to a calendar date (27/11/09) rather than a fixed period from randomisation but unlikely to introduce bias PN	RoB 5.1	NI
RoB 1.2	Y	RoB 2.2	Fully automated so researchers were blinded N	RoB 3.2	**NA**	RoB 4.2	PN	RoB 5.2	PN
RoB 1.3	N	RoB 2.3	**NA**	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments	No protocol or trial registration referenced so difficult to tell how many subgroups were pre-specified. Cross-tabulations by age/sex and sex/IMD may result from fishing trips but that is not a problem for this review.								
Risk-of-bias	Low			Direction					

Results

Endpoint	Control	Test	SES	Age	Men	First-time invitees	Comments
Uptake	I-PNL-PO	I-PNL+PIL-PO	Pre-specified? Unclear SIMD4: 1655/3603 v 1888/3626 45.9% v 52.1% p<0.0001 across all three treatment groups SIMD5: 730/1871 v 801/1848 39.0% v 43.3% p<0.0001 across all three treatment groups	Pre-specified? Unclear 50-54: 1947/4268 v 2129/4276 45.6% v 49.8% 55-59: 2485/4799 v 2727/4743 51.8% v 57.5% 60-64: 2264/3877 v 2545/4004 58.4% v 63.6% p<0.0001 across all three treatment groups 70+: 1820/3204 v 1902/3150 56.8% v 60.4% p<0.001 across all three treatment groups	Pre-specified? Unclear 4801/9704 v 5457/9833 49.5% v 55.5% p<0.0001 across all three treatment groups Test for interaction by sex: p=0.28	Pre-specified? Unclear 5795/11242 v 6461/11237 51.5% v 57.5% p<0.0001 across all three treatment groups	Substantially higher uptake overall for pre-notification. Unadjusted OR 1.23 (1.181, 1.279); adjusted for sex, age, SIMD and previous invite 1.24 (1.193, 1.294).
Uptake	I-PNL-PO	I-PNL+PIL-PO	Pre-specified? Unclear SIMD4: 1655/3603 v 1755/3504 45.9% v 50.1% SIMD5: 730/1871 v 858/1907 39.0% v 45.0%	Pre-specified? Unclear 50-54: 1947/4268 v 2177/4302 45.6% v 50.6% 55-59: 2485/4799 v 2687/4688 51.8% v 57.3% 60-64: 2264/3877 v 2494/4040 58.4% v 61.7% 70+: 1820/3204 v 1929/3185 56.8% v 60.6%	Pre-specified? Unclear 4801/9704 v 5347/9798 49.5% v 54.6%	Pre-specified? Unclear 5795/11242 v 6370/11240 51.5% v 56.7% p<0.0001 across all three treatment groups	Substantially higher uptake overall for pre-notification. Unadjusted OR 1.21 (1.159, 1.254); adjusted for sex, age, SIMD and previous invite 1.22 (1.168, 1.267).
Comments	Note that the comparisons above are reported against the original trial control arm. Only data for the two pre-notification arms are considered in this review. Uptake included all 34,249 kits returned, 88 of these could not be tested: 55 kits had expired, 23 were incomplete, 8 were spoiled, 2 were unused. Estimated that increase in uptake from 54% to 59% would translate into approximately 11 additional cancers diagnosed per 100,000 population.						

	Cross-tabulations also provided for age*sex and sex*IMD but no tests for interaction reported; effects within subgroups broadly consistent with each other and the overall result (in the context of a large number of hypothesis tests reported).

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (pre-notification letter reproduced in Appendix 1 of paper)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (control arm of this study was not used for this review because pre-notification already standard in England)
Any other issues with generalisability or external validity?	Scotland only, relatively less deprived group than Scotland overall
Is there anything else not covered in the tables above?	No

Lo (2014) BCSP

Primary reference		Lo et al (2014) 'Preformulated Implementation Intentions to Promote Colorectal Cancer Screening: A Cluster-Randomized Trial'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	cRCT Week of invite (8 weekly clusters)	No	23,182 adults (60-69 years old) invited for first round of screening by London screening hub over an 8 week period (August to November 2009)	Uptake (return of test kit; timeframes etc not defined in detail) and interaction with SES (IMD tertile) Routine hub data	Standard instruction leaflet with FOBT kit [10,768]	Standard leaflet + three preformulated intention plans ("top test tips") addressing common barriers (practicalities, forgetting, negative feelings about the test) [12,414]	SES (IMD tertiles) [8,123] <65 [16,610] Men [11,513]	The authors note that presenting the implementation intentions in a leaflet rather than a questionnaire might limit effectiveness. The problem encountered by the ASCEND trials may also affect this one; clustering by week over only 8 weeks may leave a disproportionate number of first-time invitees on one arm or the other. There is no breakdown by screening history. The authors were contacted but are unable to ascertain whether this issue may have affected the trial.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)

[b] inc details of measurement

[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)


RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Cluster-randomised by week of invite Y	RoB 2.1	Participants did not know they were in a trial; small possibility that would notice the difference if different leaflets delivered to the same household PN	RoB 3.1	PY	RoB 4.1	Uptake not fully defined PN	RoB 5.1	PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	Unclear definition of uptake PN
RoB 1.3	NI	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	Weeks randomised (treated as clusters)	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	N						
Risk-of-bias	Some	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments	Reporting is a little sparse in places with no reference to a protocol or trial registration and no table of baseline characteristics.								
Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Test	SES (IMD)	Age	Sex (male)	Comments
Uptake (return of FOB test kit)	K-PIL-PO	K-PIL+IMP-PO	Pre-specified? Yes Most deprived tertile: 1257/3804 v 1522/4319 33.0% v 35.2% OR: 1.10, 95% CI (1.01, 1.21) p=<0.05 [not clear if adjusted or corrected for ICC] (no sub-sample sizes reported) *Interaction (multivariate regression, controlling for age and sex: "significant"* *OR 1.11 (1.04, 1.18)* Results by IMD tertile are quoted in the comment column.	Pre-specified? Probably 60-64: 3108/7798 v 3460/8812 39.9% v 39.3% 65-69: 42.0% v 40.9% (not considered underserved, over 70s not included in screening programme at this time)	Pre-specified? Probably 2001/5336 v 2194/6177 37.5% v 35.5%	Overall uptake did not differ significantly between control and intervention (40.4% v 39.7%), OR: 0.97 (0.91, 1.04). Very small ICC of 0.0004 (p=0.09) indicating negligible effect of clustering by week of invite. Modest interaction by IMD with a small benefit in most deprived tertile compared to a small detriment in least deprived tertile. "As illustrated in Figure 2, the intervention had a small, positive effect for the most deprived tertile, OR = 1.10, 95% CI [1.01, 1.21], no significant effect in the middle tertile, OR = 0.92, 95% CI [0.81, 1.04], and a small, negative effect in the least deprived tertile, OR = 0.90, 95% CI [0.82, 0.99]."
Comments	Numerators and denominators kindly supplied by the authors.					

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes. Figure 1 reports the "top test tips" incorporated into the standard leaflet
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	London-only, may affect generalisability to other parts of the UK
Is there anything else not covered in the tables above?	No

McAvoy (1991) CSP

Primary reference	McAvoy et al (1991) 'Can Health Education Increase Uptake of Cervical Smear Testing among Asian Women?'							
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
CSP	RCT Described as "randomised" once in the abstract (and also as a "cohort study") with no reference to randomisation elsewhere. The authors have kindly confirmed that groups were selected using random number tables. Allocation method was stratified by age, religion, post code area and responder/non-responder in previous study Larger sample sizes for the visited groups due to anticipated higher refusal rate (the authors have kindly confirmed that the larger sample size for video group is due to this consideration)	Yes, for those visited, but randomised before consent Not informed of the nature of the materials until they had agreed to take part, implying that randomisation occurred before consent; control group not contacted and so did not give consent; postal group also not asked for consent 159 women declined to participate in the two visited groups	737 "randomly selected" Asian women aged 18-52 with no record of a previous cervical screen. Leicester, sample identified February 1987; visits took place from April to November 1987. The same group of women had previously been selected for a study on contraception by the same group, excluding those who had previously been screened for cervical cancer *"The term "Asian" in this study refers to those who are of New Commonwealth and Pakistani ethnic origin or descent, including those from Bangladesh and east Africa."*	Uptake (measured by checking local cytology records two and four months after the final home visit; study completed before a computerised system was introduced)	No contact [124] Note that this opportunistic control arm is out of scope for this review; the posted PIL and factsheet arm will be considered the control arm for this review	1. Posted leaflet and factsheet [131] 2. Visited (with pre-notification letter 7-10 days in advance) and shown a leaflet and factsheet [219] 3. Visited (with pre-notification letter 7-10 days in advance) and shown a 5 minute video [263] Up to two further visits/phone calls made to attempt to contact people who were not at home; written materials left on first visit *"As women in the two groups that were visited had the option of declining to participate in the study numbers recruited to these two groups were increased to allow for a 50% non-response rate."* Note that this does not fully explain the much larger	Asian women (all; 737)	Video and written materials produced in several different languages: English, Gujarati, Punjabi, Urdi, Hindi and Bengali. Written materials based on Women's National Cancer Control Campaign resources, *Calling All Women* strip cartoon (leaflet) and factsheet on information provided by WNCC and North Tees district health education service. The factsheet and video covered very similar information and where to go for cervical screening. 42 in the video group requested that the video be left behind to view in their own time; the research assistants returned the following day to administer the questionnaire and collect the video. Overall response rate was 73%: video/visit: 22 (8%) not contactable, 170 (71%) agreed to participate leaflet/visit: 18 (8%) not contactable, 153 (76%) agreed to participate 114 interviews in Gujarati 110 in English 59 in Punjabi 33 in Urdu 7 Hindi 1 Bengali 184 women indicated they had limited ability to read the written materials, with 165 having little or no English. Demographics similar to the local Asian population with a slight over-representation of Muslims, possibly due to higher rates of consent to an identifiably Muslim researcher. The

						number in the video group, although an additional adjustment may have been made to account for higher video refusal		researcher was familiar to many of the participants due to involvement in the previous study.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)

[b] inc details of measurement

[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Limited information, simple random numbers used to allocate to groups PY	RoB 2.1	Y	RoB 3.1	8% not contactable but included in analysis Y	RoB 4.1	Follow-up period 4 months after trial ended so some had much more follow-up; this primarily affects the control group excluded from this review (with thanks to the authors for clarification) PN	RoB 5.1	No protocol mentioned but analysis is not unreasonable PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	NI	RoB 2.3	Some in the video group requested to be allowed to view it in their own time but this likely mirrors the real world to at least some extent PN	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	N
Quasi-randomised?	Can't tell	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Appears to be ITT PY						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments	Only the two visited groups had the opportunity to decline but reported results appear to be ITT so no bias introduced. Follow-up period differed substantially for the control group, and to some extent the intervention groups, with the post sent in batches and visits occurring throughout the period of the trial. The entire sample was identified before the trial started and so the control group was followed up for the full 11 months whereas as the intervention groups' follow-up would vary between 4 and 11 months (kindly confirmed by the authors). The no contact control group is out of scope for this trial so this is not a large concern.								
Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Test	Asian (whole trial)	Comments
Uptake	-WI-PO	-HCP+WI-F2F	Pre-specified? Yes 14/131 v 57/219 11% v 26% RD: 15% (5.5%; 25.1%)	
Uptake	-WI-PO	-HCP+VID-F2F	Pre-specified? Yes 14/131 v 80/263 11% v 30% RD: 19% (10.8%; 28.7%)	
Uptake	-HCP+WI-F2F	-HCP+VID-F2F	Pre-specified? Yes 57/219 v 80/263 26% v 30%	
Cytology				No abnormal cytology reported for 157 attending for cervical screening
Comments	Analysis of difference for all 4 groups: p<0.0001. Time between visit and smear: <1 week to 42 weeks (mean 13 weeks), with no sig diff in time interval between the two visited groups. No correlation overall with age, education, uptake more likely for Hindus and those born in Africa (46%) or UK (46%), and less if born in Pakistani (34%) than born in Indian (43%).			

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	No (but some reference given to source materials)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (but very early in the lifetime of the CSP, materials and procedures likely to be somewhat different)
Any other issues with generalisability or external validity?	Asian women. Leicester demographics
Is there anything else not covered in the tables above?	No
Response?	Yes
Comment	Helpful clarification received (see above)

McGregor (2016) BCSP

Primary reference	McGregor et al (2016) 'Reducing the Social Gradient in Uptake of the NHS Colorectal Cancer Screening Programme Using a Narrative-Based Information Leaflet: A Cluster-Randomised Trial'
Trial registration #	ISRCTN: 74121020
Additional resources	Supplementary Appendix 1 in Supplementary Material available online at http://dx.doi.org/10.1155/2016/3670150 Raine et al (2017) 'Testing Innovative Strategies to Reduce the Social Gradient in the Uptake of Bowel Cancer Screening: A Programme of Four Qualitatively Enhanced Randomised Controlled Trials' Wardle et al (2016) 'Effects of Evidence-Based Strategies to Reduce the Socioeconomic Gradient of Uptake in the English NHS Bowel Cancer Screening Programme (ASCEND): Four Cluster-Randomised Controlled Trials'

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
BCSP	cRCT	No	150,417 people (age 59-74) due for routine screening in England (country-wide) over a 10 day period in March 2013	Uptake (returned "adequate" gFOBT within 18 weeks) Secondary: Time taken to return FOBt *Not reported but listed in trial registry:* Proportion of spoilt kits Proportion of non-delivered kits Incremental cost per screening invitation All of the above outcomes analysed by IMD quintile, and also using other socioeconomic variables	Standard invite and "The Facts" information booklet with gFOBT (PIL) [76,695]	Additional narrative information leaflet ("People's Stories") (EWI) [73,722]	Socioeconomic gradient (IMD) [23,849 IMD5, 26,282 IMD4] (note: the whole trial population was used to assess SEG, not selected for high deprivation) Age [sample size not reported] Sex [73,394] Previous non-responders [45,101] First-time invitees [27,791]	Randomisation was by day the invite was produced, stratified by hub. The Huber/White sandwich estimator was used to account for clustering. Substantially different numbers on each arm within two of the hubs. There is no explanation in the paper for why this happened. The authors note the need to integrate the narrative leaflet with the existing structure of the screening programme, with logistics dictating that it was sent with the initial invite and not the gFOBT kit, and in addition to the standard booklet, may have reduced potential to influence uptake. This is one of a series of concurrent trials (ASCEND) which tested 4 interventions, randomised independently of each other.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Randomised by day, stratified by hub (50 'clusters') Y	RoB 2.1	Small possibility that households received both types of invite and also noticed it; very minimal risk PN	RoB 3.1	Very little missing data. Y	RoB 4.1	PN	RoB 5.1	Y
RoB 1.2	Hubs could not be blinded and knew the daily allocation in advance; unlikely to cause problems but note that the imbalances in allocations for two hubs seem very large compared to the other ASCEND trials. PY	RoB 2.2	N	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	Trial registration doesn't prespecify details of analysis but the unadjusted result is reported. Some secondary outcomes specified in the trial registry are not reported but this review is focused on the primary outcome. PN
RoB 1.3	Relatively large differences in screening status. However, on review these imbalances were considered likely to fall within what would be expected by chance. PN	RoB 2.3	NA	RoB 3.3	NA	RoB 4.3	Letter might be included with returned kit but risk is minimal. PN	RoB 5.3	Influencing the SES gradient was the primary purpose of the trial. Other USGs were only pre-specified as "other socioeconomic variables" and may have been selected, or may have been the only other demographics available, but are obviously relevant demographics to consider amongst a limited set available with this trial design. PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		

Stratified or minimisation ?	Yes (stratified by hub)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	The analysis was adjusted for age, gender, hub and screening round to take account of imbalances between groups. PY						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments	An independent statistician was asked to review the imbalances observed between the arms with respect to screening history and considered that they were likely to fall within what would be expected by chance, although it was not possible to verify a lack of bias from the available data.								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Test	SES (IMD)	Age	Sex (male)	Previous non-responder	First-time invitees	Comments
Uptake	K-PIL-PO	K-PIL+EWI-PO	Pre-specified? Yes IMD4: 7083/13385 v 6535/12897 52.9% v 50.7% *Adj OR:* 1.00 (0.94, 1.06) p=0.95 IMD5: 5580/12127 v 4966/11722 46.0% v 42.4% *Adj OR*: 0.92 (0.86, 0.98) p=0.02 Overall: *Interaction*: p=0.44 (adjusted model p=0.11)	Pre-specified? Unclear <65: 19014 v 18264 55.2% v 53.3% *Adj OR:* 1.01 (0.97, 1.05) p=0.67 65+: 25890 v 23558 61.2% v 59.7% *Adj OR:* 0.98 (0.92, 1.04) p=0.45	Pre-specified? Unclear 21093/37609 v 19323/35785 56.1% v 54.0% *Adj OR*: 0.98 (0.94, 1.03) *p*=0.50	Pre-specified? Unclear 3284/22892 v 3113/22209 14.3% v 14.0% *Adj OR*: 0.97 (0.90, 1.04) *p*=0.35	Pre-specified? Unclear 6231/12510 v 7678/15281 49.8% v 50.2% *Adj OR*: 1.03 (0.99, 1.08) p=0.14	Overall result 58.5% v 56.7% returned Raw OR: 0.93 (0.81, 1.06), p=0.27 Adjusted OR: 1.00 (0.96, 1.03), p=0.80 No interactions with IMD within each of the other subgroups (by age, sex or screening status) were found.
Time to return	K-PIL-PO	K-PIL+EWI-PO	-	-	-	-		Median 26 days (10, 126) v 26 days (11, 126)
Spoilt kits	K-PIL-PO	K-PIL+EWI-PO	-	-	-	-		1,204 spoilt kits (595 v 609)

Comments	Only adjusted models are reported in detail. Results are reported cross-tabulated by IMD quintile and hub but not the precise denominators (reported as % of sample size).

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (narrative leaflet available at http://dx.doi.org/10.1155/2016/3670150)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No
Is there anything else not covered in the tables above?	There was disagreement regarding the importance of observed imbalances between groups in relation to screening history, which the available data and communication with the authors was not able to resolve. Further review by an independent statistician concluded that the imbalances are likely to fall within what would be expected by chance.

Meldrum (1994) BSP

Primary reference	Meldrum et al (1994) 'Tailored Written Invitations for Second Round Breast Cancer Screening: A Randomised Controlled Trial'							
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N]**	**Comment**
BSP	RCT Randomised using random number tables	No	3,083 women (aged 50-65) from 14 general practices being invited for screening by North West Glasgow Breast Screening Centre, July 1992 to February 1993 110 letters undeliverable (included in denominator for ITT)	Uptake (within 6 weeks of original appointment time; no explicit statement of where data obtained from but likely routine screening data) Acceptability (using semi-structured phone interviews with a random sub-sample of those receiving tailored letters, with prior consent to be surveyed)	Standard letter (inc GP endorsement) and information booklet [1,531]	Tailored letter making reference to screening history (inc GP endorsement) and information booklet [1,552]	Previous non-attenders [509] First-time invitees [756]	Those who did not attend screening were sent a second standard letter 4 weeks after the original screening appointment (same for both groups).

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Not aware they were in a trial N	RoB 3.1	All missing outcomes included in denominator Y	RoB 4.1	Very short follow-up PN	RoB 5.1	PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Limited information, screening status only PN	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	**Low**	Direction							

Results

Endpoint	Control	Intervention	Previous non-attender	First-time invitee	Comments
Uptake	I-INV-PO	I-INDIV-PO	60/256 v 38/253 23% v 15% RD: -8.4% (-15.2%, -1.6%) p=0.02 (Bonferroni 0.06)	201/372 v 230/384 54% v 60% RD: 5.9% (-1.2%, 12.9%) p=0.1	Overall there was no difference between the groups, 60% vs 62%, RD: 2% (-2%, 5%), p=0.4.
Acceptability					66/80 (83%) consented to be interviewed (48 attenders, 18 non-attenders). Acceptability of the tailored letter was high, no negative comments from attenders or non-attenders. Many had not paid much attention to the contents. 6/66 felt the screening history was inaccurate (2 had been screened before but their age allocated them to first-time invitee group).
Comments					

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Well-described but no example text
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No (took place in NW Glasgow)
Is there anything else not covered in the tables above?	No

O'Carroll (2015) BCSP

Primary reference	O'Carroll et al (2015) 'Anticipated regret to increase uptake of colorectal cancer screening (ARTICS): A randomised controlled trial'
Trial registration #	ISRCTN74986452
Additional resources	URLs for plain English summary (http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-attitudes-to-health-and-bowel-screening-in-scotland-artics) and trial website (http://www.psychology.stir.ac.uk/research/chbc/artics) no longer available Protocol Supplementary tables

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
BCSP	RCT	No People receiving questionnaires were informed that "we are studying the effects of attitudes towards screening, and how they influence FOBT returns."	60,000 adults (50-74) from the Scottish National Screening Programme, 01/10/2012 to 31/05/2014 59,366 analysed, exclusions: 13 addresses not in Scotland 115 died 104 transferred out of Scotland 391 undelivered 7 refusals 4 withdrew from screening	Primary: Return of gFOBT within 6 months (excluding uncompleted kits but including spoiled or invalid kits, using routine data) Secondary (from ISCTRN): 1. Health Locus of Control Scale 2. Perceived disgust (ick factor) 3. Perceived benefit of returning the FOBT kit 4. Intention to return the FOBT test	Standard pre-notification letter [19,797; 19,604 after exclusions]	Two intervention arms, both including the standard pre-notification letter, including questions about perceived disgust, perceived benefit and intention to return questions and additional questions as follows: **+ HLOC** [20,040; 19,828 after exclusions] + Health Locus of Control questionnaire [18 item scale] (HLOC) with SAE for return of questionnaire Two 'filler' questions added to make both questionnaires the same length and format **+ HLOC + AR** [20,163; 19,934 after exclusions] +HLOC	Scottish Index of Multiple Deprivation IMD5 [10,019] IMD4 [11,431] Age 60-64 [9,823] 70+ [9,386] (to check with PHE re 50-59) Sex male [29,104] Previous failure to return kit [26,832] * note different definitions of previous non-responders (ethnicity was not available due to study design)	This study was, in part, designed to examine reasons for non-participation as well as increase uptake. HLOC is a questionnaire designed to measure the extent to which people believe their health outcomes are under their own control, down to fate, or the actions of an external authority (eg doctors). Perceived disgust and perceived benefit measured using modified versions of the ICK factor (4 items) and perceived benefit scales (2 items) described fully in O'Carroll 2011. Design of the questionnaire based on recommendations of a Cochrane review (Edwards et al, 2009), eg coloured ink, stamped rather than franked SAEs, university sponsorship). Simple 1:1:1 randomisation conducted by the external IT company which runs the Scottish national FOBT screening programme, with unique identifiers on questionnaires to allow linking to demographic factors. The researchers were not involved in randomisation. Uptake defined as kit returned within 6 months but upper end of range reported as 276 days (>6 months).

						+ Anticipated Regret questions (AR) with SAE for return of questionnaire 'If I did not complete and return my test kit I would later feel regret' (first question of survey) and 'If I did not complete and return my test kit, I would later wish I had' (penultimate question with final question measuring intention to return)		

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Limited details PY	RoB 2.1	Intervention arms were told the questionnaires were part of a study but not that it was comparative or what the interventions were PN	RoB 3.1	Roughly 1% missing for reasons largely unrelated to the study (only 7 indicated refusal to participate) Y	RoB 4.1	Uptake within 6 months but upper end of range reported 276 days PN	RoB 5.1	Analysis was pre-specified in protocol, but not very specific PY
RoB 1.2	Y	RoB 2.2	N	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	Less emphasis on primary outcomes in published paper but raw data given in supplementary tables and used for this review N
RoB 1.3	N	RoB 2.3	**NA**	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	USGs pre-specified N
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments	Very small number of exclusions unlikely to affect ITT (primarily death and moving away, small number of refusals [7] and opt-outs [4]. Mediator analyses were based on bootstrapping and computation to fill in missing data and a 34.4% return rate of questionnaires so very high risk of bias for that analysis, but it is not relevant to this systematic review as not analysed by USG.								
Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Test	SES (SIMD)	Age	Sex (male)	Previous non-returns	Comments
Uptake	I-PNL-PO	I-PNL+HLOC-PO	Pre-specified? Yes SIMD4: 2024/3841 v 1993/3848 52.7% v 51.8% SIMD5: 1495/3296 v 1492/3368 45.4% v 44.3% NB: this study labels SIMD from most deprived (1) to least deprived (5). We have reversed these for consistent labelling with other studies	Pre-specified? Yes 50-54: not included in English screening programme 55-59: not included in English screening programme 60-64: 1986/3244 v 1935/3258 61.2% v 59.4% 70+: 1897/3068 v 1907/3147 61.8% v 60.6%	Pre-specified? Yes 5278/9603 v 5267/9723 55.0% v 54.2%	Pre-specified? Yes One previous failure: 1629/4261 v 1631/4410 38.2% v 37.0% 2+ previous failure: 604/4549 v 609/4584 13.3% v 13.3%	Overall result: Unadjusted OR: 0.98 (0.94, 1.02) Adjusted OR: 0.97 (0.91, 1.01) Protocol mentions taking account of reminders but doesn't appear in analysis.
Uptake	I-PNL-PO	I-PNL+HLOC+AR-PO	Pre-specified? Yes SIMD4: 2024/3841 v 1998/3742 52.7% v 53.4% SIMD5: 1495/3296 v 1510/3355 45.4% v 45.0% NB: this study labels SIMD from most deprived (1) to least deprived (5). We have reversed these for consistent labelling with other studies	Pre-specified? Yes 50-54: not included in English screening programme 55-59: not included in English screening programme 60-64: 1986/3244 v 2008/3321 61.2% v 60.5% 70+: 1897/3068 v 1936/3171 61.8% v 61.1%	Pre-specified? Yes 5278/9603 v 5329/9778 55.0% v 54.5%	Pre-specified? Yes One previous failure: 1629/4261 v 1680/4282 38.2% v 39.2% 2+ previous failure: 604/4549 v 636/4746 13.3% v 13.4%	Overall result: Unadjusted OR: 1.00 (0.97, 1.05) Adjusted OR: 1.00 (0.95, 1.06) Protocol mentions taking account of reminders but doesn't appear in analysis.
Comments	Overall response rate 34.4% for return of questionnaires (overall uptake 57.2%). HLOC-only arm had a slightly higher response rate: 35.1% v 33.7%; difference 1.4% (0.5%, 2.4%). Higher return rates for older, female, least deprived, previous kit returns and fewer previous failures to return.						

	Not reported by FTI, only number of previous returns (which will include FTI and previous non-responders). Results for moderation analysis using 34.4% questionnaire response rate as to whether effect on uptake of AR is moderated by intention to screen is not included here as not relevant to the questions of this systematic review (effect on intention to be screened was not analysed by USG).

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (details given in report, protocol and references)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Depends on any differences between programme in Scotland vs England and Wales. Starting age differs (50 in Scotland and 60 in England and Wales currently)
Is there anything else not covered in the tables above?	No

O'Connor (1998) BSP

Primary reference		O'Connor et al (1998) 'Can Postal Prompts from General Practitioners Improve the Uptake of Breast Screening? A Randomised Controlled Trial in One East London General Practice'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	RCT Minimisation (by previous non-attendance, CSP non-attendance and Turkish ethnicity)	No	473 women (with three post-randomisation exclusions) due for routine screening invite in a GP training practice in Hackney, England (7 principals), identified by GP practice using prior notification lists, March 1996 Exclusions: mammography within 3 years, under investigation for breast disease, terminal illness, living abroad, moved away, no consultations within 5 years, those for whom no cervical smear data was available	Uptake (within 3 months, based on routine screening programme data)	Standard invite [234]	GP letter sent 2 weeks before standard invite due [236]	Previous non-attenders [145] First-time invitees [109]	GP letters signed by GPs who knew the patient best. Turkish translation sent to Turkish patients. Unclear if subgroups by ethnicity and cervical non-attendance were planned but not reported; sample sizes too small to be useful so not followed up with the authors. Three post-randomisation exclusions, 2 recently screened and 1 moved away.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Unaware they were in a trial N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Limited information apart from by stratification factor PN	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Yes (by previous attendances for BSP and CSP and Turkish ethnicity)	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	3 exclusions after randomisation, no impact on results Y						
	-	RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments	Ethnicity and cervical screening non-attendance used to stratify minimisation; unclear if subgroup analyses were planned but not reported but given the sample sizes, one subgroup is a reasonable approach and the one reported is the most obviously relevant.								
Risk-of-bias	Low	Direction							

Results

Endpoint	Control	Intervention	Previous non-attender	First-time invitee	Comments
Uptake	NFA	GPL	Pre-specified? Probably 24/72 v 24/73 33% v 33% RD: 0% (-15.8%, 14.9%) Interaction: p=0.23 Apparently large benefit for first-time invitees (+15%) but trial too small to provide reliable evidence on this finding	Pre-specified? Probably 22/56 v 29/53 39% v 55% RD: 15.4% (-3.1%, 34.0%) Interaction: p=0.23 Apparently large benefit for first-time invitees (+15%) but trial too small to provide reliable evidence on this finding	Overall result 51% v 57%, RD: 5.5% (-3.5%, 14.5%)
Comments					

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'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Letter described, precise text not reproduced
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Deprived area of East London, large Turkish population
Is there anything else not covered in the tables above?	No

Offman (2013) BSP

Primary reference	Offman et al (2013) 'A Randomised Trial of Weekend and Evening Breast Screening Appointments'							
Trial registration #	ISRCTN70398358							
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	RCT (partial cluster randomisation by week for the two office hour arms) Randomisation ratio 3:1:1:1 Randomisation was done in two stages. Pseudo-random numbers within the computerised breast screening invitation system were used to allocate to office hours (both arms) or the two out-of-hours arms. The two office hours arms were then allocated by week of invitation, using pseudo-random numbers	No	19,409 (19,362 after post-randomisation exclusions) women aged 47-73 due to be invited for routine breast screening in Greater Manchester or Bristol. June 2010 to July 2011. Women were excluded from the study if they had opted out of the screening programme. Women who had been defined as requiring a special appointment because of disability or breast implants were excluded after randomisation.	(From trial registration) Primary: Uptake (within 120 days of original invitation; source of data not stated but likely to be routine screening centre records) Secondary: Attendance at first offered appointment offered Subgroups by screening history (prevalent/incident), age group, previous attenders/non-attenders No details given for measurement of attendance, but likely to be routinely collected attendance data from the screening centres	Standard office hour appointment [9,410] In all groups, including control, the invitation letter stated explicitly that the appointment could be changed if inconvenient	1. Office hour appointment with option to change to out-of-hours [3,519] 2. Weekday evening appointment [3,271] 3. Weekend appointment [3,162] Arms also combined in pairs to compare office hours vs out-of-hours	Previous non-attenders [3,710] (defined as last screen >1500 days prior [1586] or missing date of previous screen [230] or prevalent screens aged >52 [1,894]) Age [8,814 <60]	Study originally excluded women who needed special appointments due to disability or breast implants, but it was difficult to identify these women in advance and so they were excluded after randomisation (a violation of ITT). 47 people (0.24%) were excluded for these reasons. Evening appointments were scheduled between 5pm and 7pm in Bristol and 4.30pm and 7pm in Manchester, on at least two days a week excluding Fridays. The other arms were scheduled from 8.45am (Bristol) or 8.50am (Manchester) to 4.30pm, for both weekdays and weekends.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)

[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)


RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Not aware they were in a trial N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	Y
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	N
RoB 1.3	Not reported by group NI	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	No details on how measurement made but likely routine data PN	RoB 5.3	Odd selection of results reported/not reported with very limited detail in supplementary materials. PY
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	No	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	47 (0.24%) post-randomisation exclusions but unlikely to have been influenced by allocation PY						
	-	RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Some concerns
Direction		Direction		Direction		Direction		Direction	Unpredictable
Comments	Difficulty in assessing eligibility led to some post-randomisation exclusions, violating ITT. The numbers are small and knowledge of allocation unlikely to have introduced substantial bias. Incomplete reporting by arm and of subgroups (despite supplementary tables being provided) and lack of information about baseline characteristics by arm raise some concerns.								
Risk-of-bias	Some concerns		Direction	Unpredictable					

Results

Endpoint	Control	Test	Previous non-attenders	Age	Comments
Uptake	I-FixOH-PO	I-FlexOH-PO	Pre-specified? Yes 591/1933 v 225/650 30.6% v 34.6% Interaction by screening status: p=0.246	Pre-specified? Yes <60 3334/4523 v 1044/1408 73.7% v 74.1% Interaction by age: p=0.098	Overall results: Office hours: 6900/9410 (73.3%) Office hours with option to change to out of hours: 2678/3510 (76.1%) Evening: 2445/3271 (74.8%) Weekend: 2295/3162 (72.6%) *"In subgroup analyses, significant heterogeneity of the comparison of the two major arms was observed by prevalent/incident status (P=0.042) and season of appointment (P=0.001)(Supplementary Table 1). Attendance within 120 days (Supplementary Table 2) was particularly low for initial office hour appointments for prevalence episodes (53.6%) and particularly high for initial office hour appointments for incidence screens (82.1%). Attendance was significantly lower for out-of-hours appointments than for office hours appointments in summer (71.3% vs 76.1%, OR=0.779, p=0.001), but significantly higher in spring (79.9% vs 76.6%, OR=1.215, p=0.041) and autumn (71.0% vs 68.7%, OR=1.116, p=0.037). Attendance was 77% for both major arms in winter."*
	I-FixOH-PO	I-EVENING-PO	Pre-specified? Yes	Pre-specified? Yes <60	*"No significant heterogeneity [of effect] was observed for the difference between the initial weekday evening and initial weekend appointment arms."*
	I-FixOH-PO	I-WEEKEND-PO	Pre-specified? Yes	Pre-specified? Yes <60	
	I-OH-PO	I-OOH-PO	Pre-specified? Yes	Pre-specified? Yes <60	
Attendance at original appointment	I-FixOH-PO	I-FlexOH-PO	Pre-specified? Yes	Pre-specified? Yes <60	This outcome not reported for subgroups.
	I-FixOH-PO	I-EVENING-PO	Pre-specified? Yes	Pre-specified? Yes <60	
	I-FixOH-PO	I-WEEKEND-PO	Pre-specified? Yes	Pre-specified? Yes <60	
	I-OH-PO	I-OOH-PO	Pre-specified? Yes	Pre-specified? Yes <60	
Comments	*"...there was no significant difference in attendance between offering office hour and out-of-hours appointments (the two major arms) [74.1% v 73.7%, OR=0.980 (0.915, 1.048)]. The three out-of-hours study arms (office hour option to out-of-hours, evening, and weekend) were then compared with the standard invitation to an office hour appointment. Attendance was significantly higher for those whose invitation to an office hour appointment included the option to change to out-of-hours (76.1% vs 73.3%, odds ratio (OR)=1.158, P=0.001) ...there was no statistically significant increase in attendance for initial evening or weekend appointments. Comparing the two initial out-of-hours appointments, evening vs weekend, attendance was significantly lower in those offered a weekend appointment (72.6% vs 74.8%, OR=0.894, P=0.049)."* *"The majority of reasons for rescheduling of the first-allocated appointment fell into the catch-all category of 'inconvenient' ranging from 81.8% for the first-allocated evening to 86.9% for the first-allocated weekend appointments (Supplementary Table 3). The differences in reasons for rescheduling among the arms are significant (P=0.001), mainly due to fewer women allocated to weekend or evening appointments citing 'work' or 'other'."*				

	The authors did not respond to a request for further information.

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No
Is there anything else not covered in the tables above?	No

Raine (2016a) BCSP

Primary reference	Raine et al (2016a) 'Impact of General Practice Endorsement on the Social Gradient in Uptake in Bowel Cancer Screening'
Trial registration #	ISRCTN: 74121020
Additional resources	Appendix A Raine et al (2017) 'Testing Innovative Strategies to Reduce the Social Gradient in the Uptake of Bowel Cancer Screening: A Programme of Four Qualitatively Enhanced Randomised Controlled Trials' Wardle et al (2016) 'Effects of Evidence-Based Strategies to Reduce the Socioeconomic Gradient of Uptake in the English NHS Bowel Cancer Screening Programme (ASCEND): Four Cluster-Randomised Controlled Trials'

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
BCSP	qRCT Allocation by "day-within-hub" for the 5 screening hubs over 20 consecutive days in June 2013 (100 day/hub units randomised).	No	265,434 people due for routine screening invites from 6,480 GP practices in England (80% of all 8,142 practices agreed to participate)	Uptake (returned "adequate" gFOBT within 18 weeks) Secondary: Incremental cost per screening invitation (as reported, based on charge for modifying the IT system for the trial) *Not reported but listed in trial registry:* Time taken to return FOBt Proportion of spoilt kits Proportion of non-delivered kits All of the above outcomes analysed by IMD quintile, and also using other socioeconomic variables	Standard pre-notification letter [134,011]	GP-endorsed pre-notification letter (GPE) [131,423] (sent from screening hub with a single sentence 'banner' noting that their GP endorsed BCSP)	Socioeconomic gradient (IMD) [38,714 in most deprived quintile][SA] (note: the whole trial population was used to assess SEG, not selected for high deprivation) Age [no sample sizes reported] Men [129,857] Previous non-responders [80,736] First-time invitees [45,869]	Randomisation was by day the invite was produced, stratified by hub). The Huber/White sandwich estimator was used to account for clustering. 2/100 day/hub allocations were excluded because the wrong letter was sent in error. This appears to have occurred in two different screening hubs, one on each arm of the trial. . This is one of a series of concurrent trials (ASCEND) which tested 4 interventions, randomised independently of each other.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

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	RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Randomised by day, stratified by hub (100 hub-day clusters) **Y**	RoB 2.1	Small possibility that households received both types of invite and also noticed it; very minimal risk **PN**	RoB 3.1	2/100 day/hub allocations were excluded because the wrong letter was sent in error. This appears to have occurred in two different screening hubs, one on each arm of the trial. 562/134011 & 547/131423 missing (<0.5%) for IMD. **N**	RoB 4.1	**PN**	RoB 5.1	**Y**
RoB 1.2	Hubs unaware of daily allocation in advance, informed consent not required **Y**	RoB 2.2	**N**	RoB 3.2	**N**	RoB 4.2	**N**	RoB 5.2	Trial registration doesn't prespecify details of analysis but the unadjusted result is reported (although ideally it would have been stratified by hub to match the randomisation). Some secondary outcomes specified in the trial registry are not reported (time to return and proportion spoiled) but this review is focused on the primary outcome. **PN**
RoB 1.3	Imbalances in screening history were, on review, likely to fall within what is expected by chance. **PN**	RoB 2.3	**NA**	RoB 3.3	Missing outcome data occurred for documented reasons which were unrelated to the outcome (the wrong letter was sent in error to all the patients in the affected	RoB 4.3	**N**	RoB 5.3	Influencing the SES gradient was the primary purpose of the trial. Other USGs were only pre-specified as "other socioeconomic variables" and may have been selected, or

					clusters). The exclusions were not influenced by patient characteristics. **N**				may have been the only other demographics available, but are obviously relevant demographics to consider amongst a limited set available with this trial design. **PN**
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes (stratified by hub)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Results were adjusted for age, sex, hub and screening episode to account for imbalances between arms. **PY**						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments	An independent statistician was asked to review the imbalances observed between the arms with respect to screening history and considered that they were likely to fall within what would be expected by chance, although it was not possible to verify a lack of bias from the available data.								
Risk-of-bias	**Low**	Direction							

Results

Endpoint	Control	Test	SES (IMD)	Age	Sex (male)	Previous non-responder	First-time invitee	Comments
I-INV-PO	I-GPE-PO	GPE	Pre-specified? Yes IMD4: 11839/23007 v 11902/22450 51.5% v 53.0% *Raw OR*: 1.06 (0.98, 1.16) *p*=0.15 *Adj OR*: 1.09 (1.04, 1.15) p=0.001 IMD5: 8324/19540 v 8433/19174 42.6% v 44.0% *Raw OR*: 1.06 (0.97, 1.15) *p*: 0.19 *Adj OR*: 1.07 (1.01, 1.13) p=0.02 Overall: Interaction with IMD: p=0.27 Interaction with IMD in adjusted model: p=0.49 Interaction with IMD included as a continuous variable (no other variables included): p=0.11	Pre-specified? Unclear 60-64: 33480/ v 33331/ 54.8% v 55.9%***** *Adj (for IMD) OR*: 1.05 (0.98, 1.12) *p*=0.2 Interaction with IMD: p=0.06 70+: 16176 v 15807 58.8% v 58.7%***** *Adj (for IMD)*: OR: 0.99 (0.89, 1.10) p=0.9 Interaction with IMD: p=0.32 *****exact sample sizes within age groups not reported	Pre-specified? Unclear 35832/65420 v 35813/64437 54.8% v 55.5% *Adj (for IMD) OR*: 1.03 (0.96, 1.12) p=0.4 Interaction with IMD: p=0.13	Pre-specified? Unclear 5675/40295 v 5357/40441 13.3% v 14.0% *Adj (for IMD) OR*: 1.06 (1.00, 1.13) p=0.055 Interaction with IMD: p=0.22	Pre-specified? Unclear 11646/23582 v 11465/22287 49.4% v 51.4% *Adj (for IMD) OR*: 1.09 (1.01, 1.16) Interaction with IMD: p=0.44	Effect on the socioeconomic gradient of uptake was analysed using the whole trial population. The most deprived quintile (IMD5) is extracted here for analysis. The overall test for interaction suggests there was no important effect on the gradient (that is, the intervention appeared equally successful in all quintiles defined by IMD). For the whole trial population, unadjusted OR 1.03 (95% CI 0.95 to 1.11, p=0.49 Adjusted OR 1.07 (95% CI 1.04 to 1.10, p<0.0001)
Cost	-	-	-	-	-	-	-	One off cost of £78k to modify IT systems.
Comments	Age, sex, screening status (incident, prevalent, prevalent previous non-responders) and screening hub were used for model adjustment for the whole trial results and the results for each IMD quintile. However, the results for age, sex and previous non-responders included adjustment for IMD and an interaction term with IMD (as a continuous variable) but were not adjusted for the other demographic variables.							

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHSSP practice?	Yes
Any other issues with generalisability or external validity?	No

Is there anything else not covered in the tables above?	There was disagreement regarding the importance of observed imbalances between groups in relation to screening history, which the available data and communication with the authors was not able to resolve. Further review by an independent statistician concluded that the imbalances are likely to fall within what would be expected by chance.

Raine (2016b) BCSP

Primary reference		Raine et al (2016b) 'A National Cluster-Randomised Controlled Trial to Examine the Effect of Enhanced Reminders on the Socioeconomic Gradient in Uptake in Bowel Cancer Screening'						
Trial registration #		ISRCTN: 74121020						
Additional resources		Supplementary files 1 & 2 (copies of reminder letters) Raine et al (2017) 'Testing Innovative Strategies to Reduce the Social Gradient in the Uptake of Bowel Cancer Screening: A Programme of Four Qualitatively Enhanced Randomised Controlled Trials' Wardle et al (2016) 'Effects of Evidence-Based Strategies to Reduce the Socioeconomic Gradient of Uptake in the English NHS Bowel Cancer Screening Programme (ASCEND): Four Cluster-Randomised Controlled Trials'						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	cRCT	No	168,480 people due to receive a reminder (kit not returned within 4 weeks) in England from 8/7/2013 to 2/8/2013 (country-wide) Trial overlapped with GPE part of the ASCEND trial and some people were included in both	Uptake (returned "adequate" gFOBT within 18 weeks) by socioeconomic status (IMD) Secondary: Incremental cost per screening invitation (as reported, based on charge for modifying the IT system for the trial) *Not reported but listed in trial registry:* Time taken to return FOBt Proportion of spoilt kits Proportion of non-delivered kits All of the above outcomes analysed by IMD quintile, and also using other socioeconomic variables	Usual reminder (SRM) [90,413]	Enhanced reminder (ERM) [78,067] "[T]wo additions to the usual letter: a banner reading 'A reminder to you' at the start of the letter and a brief restatement of the screening offer at the end of the letter."	Socioeconomic gradient (IMD) [30,930 IMD5; 31,532 IMD4][SA] (note: the whole trial population was used to assess SEG, not selected for high deprivation) Age [85,161 <65 years; 30,668 70-74 years] Sex [87,159 male] Recent non-responders [all; 168,480] Previous non-responders [83,191] First-time invitees [35,754]	Randomisation was by day the invite was produced, stratified by hub. The Huber/White sandwich estimator was used to account for clustering. Data were excluded for one day for one hub due to a protocol violation (one hub day out of 100 hub days randomised). This is one of a series of concurrent trials (ASCEND) which tested 4 interventions, randomised independently of each other.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Randomised by day, stratified by hub (100 day/hub clusters) Y	RoB 2.1	Small possibility that households received both types of invite and also noticed it; very minimal risk PN	RoB 3.1	Data were excluded for one day for one hub due to a protocol deviation (one hub day out of 100 hub -days randomised). The exclusion of this data is a violation of intention-to-treat (ITT). 0.4% missing IMD status N	RoB 4.1	The authors note that some randomised individuals may have returned their original kit before the reminder arrived but don't seem to have cross-referenced to check. PN	RoB 5.1	Y
RoB 1.2	Hubs unaware of daily allocation in advance, informed consent not required Y	RoB 2.2	N	RoB 3.2	N	RoB 4.2	N	RoB 5.2	Trial registration doesn't prespecify details of analysis but the unadjusted result is reported. Some secondary outcomes specified in the trial registry are not reported (time to return and proportion spoiled) but this review is focused on the primary outcome. PN
RoB 1.3	Moderate imbalances between groups in age and previous screening history. It appears, on review, that the imbalances in screening history may be greater than what would be expected by chance. PY	RoB 2.3	NA	RoB 3.3	Missing outcome data for the excluded hub day were not influenced by patient characteristics. N	RoB 4.3	N	RoB 5.3	Influencing the SES gradient was the primary purpose of the trial. Other USGs were only pre-specified as "other socioeconomic variables" and may have been selected, or may have been the only other demographics available, but are obviously relevant demographics to

									consider amongst a limited set available with this trial design. PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	Yes (stratified by hub)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Results were adjusted for age, sex, hub and screening episode to account for imbalances between arms. PY						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction	Favours comparator	Direction		Direction		Direction		Direction	
Comments	Although there is an ITT violation, only 1% of clusters were excluded and there is an adjusted analysis to help deal with imbalances. An independent statistician was asked to review the imbalances observed between the arms with respect to screening history and considered that they may not fall within what would be expected by chance.								
Risk-of-bias	**Some concerns**		Direction	Favours comparator					

Results

Endpoint	Control	Test	SES (IMD)	Age	Sex (male)	Previous non-responder	First-time invitees	Comments
Uptake	R-REM-PO	R-ERM-PO	Pre-specified? Yes IMD4: 3436/16853 v 3104/14679 20.4% v 21.1% *Adj OR:* 1.09 (1.02, 1.17) p=0.009 IMD5: 2198/16489 v 2040/14441 13.3% v 14.1% *Adj OR:* 1.11 (1.04, 1,20) p=0.003 Interaction with IMD in adjusted model: p=0.005 (larger effects in 3 most deprived quintiles, little effect in least deprived)	Pre-specified? Unclear Age <65: 12229/46771 v 10251/38390 26.1% v 26.7% *Adj (for IMD) OR:* 1.03 (0.96, 1.11) p=0.44 Interaction with IMD as a continuous score: p=0.06 70-74: 3585/15861 v 3241/14807 22.6% v 21.9% *Adj (for IMD) OR:* 0.96 (0.83, 1.10) p=0.56 Interaction with IMD as a continuous score: p=0.79 Overall: No evidence of an interaction by age group.	Prespecified? Unclear 11201/46839 v 9899/40320 23.9% v 24.6% *Adjusted (for IMD) OR:* 1.04 (0.95, 1.14) p=0.41 Interaction with IMD as a continuous score: p=0.37 Overall: No evidence of an interaction by sex.	Pre-specified? Unclear 2329/43329 v 2394/39862 5.4% v 6.0% *Adjusted (for IMD) OR:* 1.12 (1.03, 1.23) p=0.008 Interaction with IMD as a continuous score: p=0.43 **Recent non-responders (whole trial)** 22712/90413 v 20166/78067 25.1% v 25.8% *Raw* OR: 1.04 (non significant, 95% CI not reported) *Adjusted* OR: 1.07 (1.03, 1.11) p<0.001	Pre-specified? Unclear 5398/21271 v 3739/14483 25.4% v 25.8% *Adjusted (for IMD) OR:* 1.02 (0.95, 1.10) p=0.51 Interaction with IMD as a continuous score: p=0.12	Effect on the socioeconomic gradient of uptake was analysed using the whole trial population. The most deprived quintiles (IMD 4 & 5) are extracted here for analysis. The overall test for interaction suggests a fairly strong effect on gradient (this is only reported for the adjusted model).
Costs								One-off cost of £78k to alter IT systems (note that this is identical to the cost reported in Raine 2016a but this may be due to the nature of contracts rather than the same figure reported twice).

Comments	Age, sex, screening status (incident, prevalent, prevalent previous non-responders) and screening hub were used for model adjustment.

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (letters provided in supplementary materials)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No
Is there anything else not covered in the tables above?	There was disagreement regarding the importance of observed imbalances between groups in relation to screening history, which the available data and communication with the authors was not able to resolve. Further review by an independent statistician concluded that the imbalances in screening history may not fall within what would be expected by chance.

Richards (2001) BSP

Primary reference		Richards et al (2001) 'Cluster Randomised Controlled Trial Comparing the Effectiveness and Cost-Effectiveness of Two Primary Care Interventions Aimed at Improving Attendance for Breast Screening'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	fcRCT Cluster-randomised (random number tables) within strata defined by area and practice size One randomised practice was later found to be ineligible and was replaced with a comparable practice from a list of reserves	No	6,133 women aged 50-64 invited for screening in the third round of the NHS BSP from 24 general practices with low uptake (<60% in second round) with at least 100 eligible patients in London and West Midlands, July 1997 to August 1998, not participating in the parallel trial and not computerised Excluded 229 women who had been screened within the previous year, had undergone bilateral mastectomy, inappropriate for screening (GP judgement) or had moved away	Uptake (within 6 months of practice being screened for trial, routine screening centre data) Cost-effectiveness	No intervention [1,721]	GP letter with information leaflet and instruction in 14 languages for non-English speakers to get the letter translated sent 1 month before screening invite [1,818] Opportunistic flag placed in notes 6 months before screening invite due (green card prompt in paper notes) with request to discuss and information leaflet, doubling as a record of GP interactions [1,232] GP letter + opportunistic flag in notes [1,362]	Previous non-attenders [901] First-time invitees [1,513]	Excluded computerised practices which may limit relevance. Run in parallel with Bankhead 2001 (for recent non-attenders) with different GP practices participating in each trial. Just under 10% are listed as "unable to assess attendance" (100, 115, 81 and 105 respectively) but reasons include "being screened" or "recently screened", "deceased". Most of these seem to have been retrospectively found ineligible after inclusion in the cluster, which is not ideal but unlikely to cause major problems and the numbers are consistent between groups.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Y	RoB 2.1	Not aware that they were in a trial N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	PY
RoB 1.2	One practice found to be ineligible after cluster randomisation; replaced with a comparable practice from reserve list which may not have been blinded to allocation. N	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	N
RoB 1.3	Some imbalance between practice characteristics on 2nd round uptake and slightly more previous non-attenders on control. May be due to small number of clusters rather than necessarily a problem with the randomisation. PN	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	N
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Yes (by area & practice size)	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	One practice found to be ineligible after randomisation, replaced by a comparable practice. Strictly a violation of ITT but not an easy problem to solve and						

			unlikely to have caused a large bias. PY						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Some concerns**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction	Letter + flag practices had a lower uptake in previous screening round	Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Intervention	Previous non-attenders	First-time invitees	Comments
Uptake	pre.I-NFA-	pre.I-GPL-PO	Pre-specified? Yes /318 v /235 No significant interaction for letter vs no letter by screening history (p=0.34)	Pre-specified? Yes /414 v /446 No significant interaction for letter vs no letter by screening history (p=0.34)	Overall results: 897/1621 v 1097/1703 For all receiving a letter: *Adj* OR: 1.31 (1.05, 1.64) p=0.015 ICC=0.023 estimated from the 6 control clusters
	pre.I-NFA-	pre.I-FLAG-GP	Pre-specified? Yes /318 v /155 Interaction found for flag vs no flag by screening history (p=0.0004 and p=0.002 when controlling for consultation history). *"However, interpretation is not straightforward as the effect of the flag seems to be enhanced among women previously invited, regardless of whether or not they have ever attended, and reduced among those with unknown screening history."*	Pre-specified? Yes /414 v /289 Interaction found for flag vs no flag by screening history (p=0.0004 and p=0.002 when controlling for consultation history). *"However, interpretation is not straightforward as the effect of the flag seems to be enhanced among women previously invited, regardless of whether or not they have ever attended, and reduced among those with unknown screening history."*	Overall results: 897/1621 v 752/1151 For all receiving a flag: *Adj* OR: 1.43 (1.14, 1.79) p=0.0019 ICC=0.023 estimated from the 6 control clusters
	pre.I-NFA-	pre.I-GPL+FLAG-PO+GP	Pre-specified? Yes /318 v /193 (Comments on interactions in the two cells above)	Pre-specified? Yes /414 v /364 (Comments on interactions in the two cells above)	Overall results: 897/1621 v 854/1257 Interaction letter + flag: *Adj* OR: 1.41 (0.88, 2.28) p=0.16 ICC=0.023 estimated from the 6 control clusters
Cost-effectiveness					Overall results: The extra total health services cost per additional attendance was £26 for the letter and £41 for the flag. NHS perspective using costs from published sources estimated at 1998–9 prices
Comments	Flags remained in notes for median of 5.8 months, 97% (2514) retrieved and of these 54% (1347) activated; 57% in flag-only and 51% in letter + flag. All models (adjusted ORs reported in the comments) were adjusted for the effects of clustering by general practice and the practice characteristics of second round uptake, number of partners in the practice (single or multi-handed) and area.				

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*
'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors
Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Paper-only practices, may be limited applicability for flags in the modern era (trial conducted 1997-8). City practices (London & Birmingham) selected for low uptake (<60%) in second screening round.
Is there anything else not covered in the tables above?	No

Rutter (2006) BSP

Primary reference	Rutter et al (2006) 'An Implementation Intentions Intervention to Increase Uptake of Mammography'							
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT 3 arms quasi-randomised roughly 5:3:2 using the list of eligible people from the screening centre; every 5th page (each with 5 names) assigned to non-assessment and every other page split 60:40 using blocks	No	2,082 (1,894 after post-randomisation exclusions) people due to be invited for screening from two screening cohorts in Kent, 2000-2001	Uptake (time period not defined; data from screening centre)	1. No assessment (untreated control) [425; 386 after exclusions] 2. Assessment-only, survey without implementation intention questions (placebo control) sent shortly before invite to screening due [633; 582 after exclusions]	Implementation intentions (planning to overcome barriers to screening) and survey questions sent shortly before invite to screening due [1,024; 926 after exclusions] Three barriers addressed: changing an inconvenient appointment, arranging travel, getting time off work.	First-time invitees [516] Previous non-attenders [109]	137 post-randomisation exclusions due to related medical investigations or self-referral for screening (a violation of ITT but unlikely to introduce substantial bias). Missing data on 51 ("screening centre had failed to record attendance details"). The latter statement seems to refer to missing screening history. Both assessment groups received questionnaires shortly before they were due to receive an invitation to screening. Survey questionnaire included questions about intention and beliefs based on the Theory of Planned Behaviour.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)


RoB 2 cribsheet

The RoB 2 cribsheet (updated version published 22/08/19) is embedded (left). The tool has been compressed into the table below (with some of the information required included in the summary table above). Hover over the links in the table to see the questions. Delete colour-coded answers as applicable and add any comment required.

RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Quasi-randomised, validity dependent on random ordering of lists used PY	RoB 2.1	Could not be blinded but probably not aware they were in a trial PN	RoB 3.1	2-3% missing data for screening history and some post-randomisation exclusions PY	RoB 4.1	Time period for uptake not defined; probably not inappropriate but no information provided NI	RoB 5.1	No protocol or trial registration referenced PY
RoB 1.2	PN	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	(Uninformative) statistical tests on baseline characteristics reported without any actual information provided. No baseline characteristics reported beyond screening history (obscured by table layout), slightly fewer FTI and more previous attenders on assessment-only arm. NI	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	Yes	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Some post-randomisation exclusions (probably not introducing bias) and weak analysis but data is available to provide reasonable estimates for this review PN						

	-	RoB 2.7	N						
Risk-of-bias	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction	Unpredictable	Direction		Direction		Direction		Direction	
Comments	Baseline characteristics not reported but screening history can be reconstructed from Table 1. The proportions in intervention and no treatment arm are very similar but the assessment-only control arm has slightly fewer first-time invitees (19% v 26% on both the other two arms) and more previous attenders (78% v 73% on both the other two arms) and 2.4% previous non-attenders compared to 0.8% and 1% on the other two arms. Reporting overall is weak.								
Risk-of-bias	Some concerns	Direction	Unpredictable						

Results

Report uptake first (or primary outcome if uptake not reported). Repeat rows in table for each endpoint and treatment comparison reported within underserved subgroups, with text comment for any endpoints not reported numerically or not within USGs. Use the 3-letter codes to identify control and intervention(s). Report USGs in the order suggested in the table but replace titles with more accurate descriptors as appropriate.

Endpoint	Control	Intervention	First-time invitees	Previous non-attenders	Comments
Uptake	NFA	Implementation intentions	Pre-specified? Unclear 80/107 v 188/270 74.8% v 69.6%	Pre-specified? Unclear 3/25 v 6/48 12.0% v 12.5%	Overall: 310/386 (80.3%) v 731/926 (78.9%)
	Assessment -only	Implementation intentions	Pre-specified? Unclear 91/139 v 188/270 65.5% v 69.6%	Pre-specified? Unclear 11/36 v 6/48 30.6% v 12.5%	Overall: 467/582 (80.2%) v 731/926 (78.9%)
Comments	72% response rate to questionnaire (73% v 70%). Both control groups had slightly higher uptake than the intervention group. The treatment effects are reported as "not significant" and much of the paper is spent on a post hoc analysis of those who completed the planning questions within the intervention group. This approach is based on a common fallacy. People who comply with treatment often have better outcomes than those who do not even if there is no benefit to treatment at all, because compliers are different from non-compliers. This is why we use randomised controls and intention-to-treat.				

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Fairly well-described (implementation questions included in report)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No (Kent demographics 2000-1, early in the history of the BSP)
Is there anything else not covered in the tables above?	No

Shankleman (2014) BCSP

Primary reference		Shankleman et al (2014) 'Evaluation of a Service Intervention to Improve Awareness and Uptake of Bowel Cancer Screening in Ethnically-Diverse Areas'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	cRCT (cluster randomised by GP practice; two randomised interventions with non-randomised control practices)	No	3,886 first-time invitees and previous non-responders from 18 GP practices in 3 deprived London boroughs: City & Hackney, Newham, and Tower Hamlets. April to December 2012 (9,113 total including the non-randomised control practices). Practices were invited to exclude people for whom the intervention was inappropriate (diagnosis of colorectal cancer, needed palliative care or had opted out). Practices were selected at random from lists of practices and invited to participate until 6 practices in each borough had consented. Practices not selected (or not consenting to be randomised to an intervention above the median practice size for the area (24 practices in total) were used as a non-randomised control.	Uptake (based on aggregate data for each practice over three quarters, April to December 2012; no data on individuals for uptake or receipt of intervention were available) Note that the reported recruitment and follow-up periods are the same, April to December 2012. Aggregate uptake data will include some people screened before the trial and exclude some returning kits after it had finished.	Usual care [5,227 in 24 practices] NB: non-randomised control group	1. Phone health-promotion [2034 in 9 practices] 2. Face-to-face health promotion group sessions [1852 in 9 practices] Both groups received GP endorsed letters and localised NHS BCSP leaflet sent 2 weeks after 'screening due date' with a phone call a week later, either to provide information (phone arm) or as a reminder of the invitation to attend a group session and answer any questions, with alternative sessions dates offered where appropriate. A second reminder call was made a day before the session date.	Previous non-responders [1,712 in randomised intervention groups] Men [1,916 in randomised intervention groups] First-time invitee [913]	This is a difficult trial design which encountered some problems in obtaining accurate 'ITT' lists for delivering the intervention, with aggregate data revealing 13.5% more eligible people invited to screening than were identified to the trialists. The uptake measure is a proxy, based on uptake in each practice for the duration of the trial regardless of an individual's inclusion in the trial and no follow-up beyond the end of the trial period. Less than half had telephone numbers available to deliver the intervention. Some practices had participated in a pilot study the previous year, some had not. *"Sensitivity analyses were performed where the same analyses were repeated after excluding the 12 GP practices involved in the pilot study run during 2011 which targeted the population aged 60 at the time (Massat et al, 2014). Three of the 12 GP practices which offered a similar HP intervention in the 2011 pilot study were included in the intervention set in the current project; four were included in the comparison set."*

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Non-randomised controls excluded from this review PY	RoB 2.1	Interventions could not be blinded; unclear if they were aware that they were participating in a trial Y	RoB 3.1	Outcome not directly measured on participants, face-to-face group likely to be more delayed than phone N	RoB 4.1	Outcome not directly measured on participants Y	RoB 5.1	PY
RoB 1.2	Cluster trial with each practice delivering a single intervention for the duration (with 'ITT' lists provided to identify eligible subjects and practices invited to exclude those considered unsuitable). N	RoB 2.2	Health promotion team aware, lab probably unaware Y	RoB 3.2	N	RoB 4.2	Monthly group sessions vs personal phone calls with no follow-up beyond the end of the trial. Face-to-face group inherently less likely to be included in aggregate follow-up period Y	RoB 5.2	PN
RoB 1.3	Only gender reported but substantial differences in proportions between groups Y	RoB 2.3	PN	RoB 3.3	PN	RoB 4.3	NA	RoB 5.3	N
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Yes (by borough)	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Incomplete 'ITT' lists and very indirect outcome measure; no account taken of clustering PN						
	-	RoB 2.7	Aggregate data used for outcome over same period as recruitment,						

			with face-to-face group likely to have more delayed intervention PY						
Risk-of-bias	**High**	**Risk-of-bias**	**High**	**Risk-of-bias**	**High**	**Risk-of-bias**	**High**	**Risk-of-bias**	**Low**
Direction	Unpredictable	Direction	Unpredictable	Direction	Comparator (phone)	Direction	Comparator (phone)	Direction	
Comments	This is a very messy trial design with a non-randomised control group (RoB assessments based on the two randomised intervention arms). Attempts to pre-select particular types of people from the practice clusters meant a complex procedure to identify them in advance ('ITT' lists) but these lists were difficult to produce and incomplete. The outcome measure is based on aggregate data for each practice and so will include some people sent a kit before the trial began and exclude others who returned it after follow-up ended, with allocation to a monthly group session likely to delay return of kit on the face-to-face arm. Two practices on the telephone arm included a substantially lower proportion of women than the other practices, with no explanation for this discrepancy.								
Risk-of-bias	**High**		Direction	Unpredictable, probably comparator					

Results

Report uptake first (or primary outcome if uptake not reported). Repeat rows in table for each endpoint and treatment comparison reported within underserved subgroups, with text comment for any endpoints not reported numerically or not within USGs. Use the 3-letter codes to identify control and intervention(s). Report USGs in the order suggested in the table but replace titles with more accurate descriptors as appropriate.

Endpoint	Control	Intervention	Men	Previous non-responders	First-time invitee	Comments
Uptake	K-HCP-TEL	K-HCP-F2F	??/1046 v ??/870 No significant interaction for effect size	People who had been invited for screening previously but not returned a kit. 165/826 v 203/886 20.0% v 22.9%	Prevalent screens age 59-60 (age-based proxy for FTI) 228/497 v 171/416 45.9% v 41.1%	Most results reported for interventions v the non-randomised control (which is excluded from this review). No uptake numbers for men reported. No adjustment for clustering. Both interventions were more effective than the non-randomised control, with phone being at least as effective as face-to-face. There was a weak suggestion that face-to-face was more effective for men. A potential interaction with sex and ethnicity was noted by the authors, with group sessions potentially being less effective for Pakistani and Bangladeshi women who may be more reluctant to attend. In the incident (new invitees) group, overall uptake increased from 34% to 44%, and in the previous non-responders from 13% to 21.5% (both compared to non-randomised controls) with little effect seen in the large group of previous responders included in error as their baseline uptake was already very high (78.3%).
Phone number available						48% and 45% of subjects could not be contacted due to no or the wrong number in GP records.
Comments	There were a number of problems caused by the complex design of the trial. The intention was to recruit only first-time invitees and those who had not returned a previous kit. This required the advance provision of 'ITT' lists which were not made available on time for the first few months of the trial and were not always accurate, with a large number (1,255 and 1,686 respectively) of previous responders included in error in the final 4 months of the trial when a change in IT systems meant that information about screening status was not available. The aggregate uptake data suggested that 13.5% more people had been invited for screening than appeared on the 'ITT' lists. The follow-up period is reported as the same dates as the recruitment period, meaning that the aggregate practice data will not perfectly coincide with the interventions delivered and the face-to-face group may have been more likely to return a kit late due to the need to attend a group session. The authors did not respond to requests for more information about the missing numerators.					

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	No. Very limited detail, approach and skills specific to the "community organisation with experience of telephone outreach to increase uptake of cancer screening in East London" which was commissioned to deliver the interventions. No supplementary materials referenced.
Is the control arm used for this review comparable to current NHS-SP practice?	No (the non-randomised control arm is not being considered for this review)
Any other issues with generalisability or external validity?	London-based
Is there anything else not covered in the tables above?	No

Sharp (1996) BSP

Primary reference		Sharp et al (1996) 'Breast Screening: A Randomised Controlled Trial in UK General Practice of Three Interventions Designed to Increase Uptake'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	RCT 1:2:2 ratio to increase power for the two nurse interventions; no details of how randomisation achieved	No Consent was required for home visit arms, but not consent to be in a trial	799 (782 after post-randomisation exclusions) women aged 50-64 registered with 27 GPs in Lambeth, Southwark and Lewisham who had not attended for first round screening after two appointments had been offered, excluding those who had declined screening, had been screened elsewhere, or had moved away	Uptake (within 12 weeks of intervention; from screening unit records) Subgroup analyses based on variables from the questionnaire previously completed by a subset of women included in the RCT which had been shown to be related to attendance in the first phase of this study (a survey)	GP letter encouraging attendance [162 randomised; 160 after exclusions]	1. GP letter offering nurse visit (to ascertain reasons for non-attendance) [313 randomised; 307 after exclusions] 2. GP letter offering nurse visit (to ascertain reasons for non-attendance and deliver health education) [324 randomised; 315 after exclusions]	Previous non-attenders [all; 799] Age [<60, no sample size reported]	Both home interview groups received a semi-structured interview focusing on reasons for non-attendance, knowledge of local screening unit and information about discussions with family members. Two short self-report scales on self esteem and locus of control. The health education component was 10 minutes providing informal health education message, tailored to the issues raised in the first part of the visit. 17 post-randomisation exclusions, based on checking date of screening against date of randomisation and continued local residence. Year of study not reported.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	No details of randomisation given PY	RoB 2.1	Consent asked for home visits Y	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	No protocol or trial registration referenced but study clearly well-planned PY
RoB 1.2	NI	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	NI	RoB 2.3	Consent for home visits could be withheld but unclear whether type of consent required differed from real world context PN	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	Can't tell (probably not)	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Small number of post-randomisation exclusions (in violation of ITT) with some possible bias in assessing change of address in the visited arms PY						
	-	RoB 2.7	N						
Risk-of-bias	Some concerns	**Risk-of-bias**	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction	Unpredictable	Direction	Favours experimental	Direction		Direction		Direction	
Comments	Limited detail on method of randomisation and limited baseline characteristics reported by group (only age was available; postcode not used to examine SES)								
Risk-of-bias	Some concerns		Direction	Unpredictable					

Results

Endpoint	Control	Test	Recent non-attenders (whole trial)	Age	Comments
Uptake	post.R-GPL-PO	post.R-HCP-F2F	Pre-specified? Yes 21/160 v 24/307 13.1% v 7.8% RD: -5.3% (-11.3%, 0.7%)	Pre-specified? Unclear 21 tests for interaction were performed with only age being "significant at the 5% level", with the greatest effect of the health education intervention in the middle age group (55-59). Limited information given but note that this is not strong evidence, as reported, in the context of a large number of tests for interaction.	
Uptake	post.R-GPL-PO	post.R-HCP+HEd-F2F	21/160 v 36/315 13.1% v 11.4% RD: -1.7% (-8.0%, 4.6%)	As above	
Comments	p=0.14 for ANOVA test of difference between the three groups Delivering nurse based interventions was difficult, with around 14% of subjects moving between randomisation and initial contact (ascertained for the home visit groups only) and a further 20% uncontactable despite a correct address. 30% declined visits. The authors were unable to provide additional information for the results by age.				

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Fairly well-described but difficult to precisely reproduce without more detail
Is the control arm used for this review comparable to current NHS-SP practice?	No (all three arms are interventions which are not currently part of routine practice)
Any other issues with generalisability or external validity?	SE London (non-attenders)
Is there anything else not covered in the tables above?	No

Smith (2015) BCSP

Primary reference		Smith et al (2015) 'The Effect of a Supplementary ('gist-Based') Information Leaflet on Colorectal Cancer Knowledge and Screening Intention: A Randomized Controlled Trial'						
Trial registration #		ISRCTN62215021						
Additional resources		Pilot for Smith 2017 (ASCEND 'gist' leaflet, ID225)						
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BCSP	RCT List of eligible patients prepared before randomisation; randomised blocks with households allocated to the same arm	No All groups were informed (post-randomisation) that they were participating in a study	4,452 adults aged 45-59 (3,706 households) who had not yet been offered gFOBT screening, from 4 UK GP practices, July 2012-March 2013 Exclusions included: severe cognitive impairment, recent diagnosis of serious illness, under surveillance for colorectal cancer, non-English speaking Practices selected using IMD, three serving deprived areas and one affluent - Liverpool A (IMD 77.3) - Liverpool B (IMD 37.6) - Manchester (IMD 43.6) - Stockport (IMD 10.8) 4,429 included; 22 incorrect addresses and one deceased 990 questionnaires returned, 26 excluded due to discrepancy (on age and sex) between practice and questionnaire data 964 (21.9%) returned questionnaires analysed	Knowledge (9 true/false items reflecting 'core' knowledge per GMC screening guidelines); threshold 55.5% (5/9) for "adequate" knowledge, scoring "don't know" as incorrect. Screening intention (4 point scale indicating strength and direction of intention to use gFOBT if offered) Acceptability of materials (not read, read part, read all, read more than once)	'The Facts' standard BCSP information leaflet (reading age 13-15 years) & materials resembling national screening programme as much as possible (participants knew it was not a real invite). [466 returned usable questionnaires] Reminders sent after 3 weeks	As for the control arm plus 'The Gist' simplified information leaflet (reading age 9-11 years) [498 returned usable questionnaires]	Numeracy (assessed by a single question asking which is the higher risk: '1 in 100', '1 in 1,000' or '1 in 10'.	Pilot study for Smith 2017. Pilot included in the review as it includes additional outcomes not included in the main trial. Main trial assesses uptake Leaflets were different colours (no explanation why). The 'gist' leaflet was included with the 'facts' leaflet. The authors note that this may have affected outcomes by increasing the amount of material to read.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
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Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Households allocated same intervention; no informed consent. N	RoB 3.1	21.9% returned, with some questions not answered by respondents N	RoB 4.1	Unclear how well validated some outcome measures (eg numeracy) were PN	RoB 5.1	Trial registration is not very detailed; some data-dependent decisions (eg combining intention answers) N
RoB 1.2	List randomised using blocks, not concealed but limited information available to researchers PY	RoB 2.2	Y	RoB 3.2	Much of the missing data probably not missing at random, as noted by the authors N	RoB 4.2	PN	RoB 5.2	PN
RoB 1.3	N	RoB 2.3	N	RoB 3.3	Y	RoB 4.3	Y	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	Y	RoB 4.4	PN		
Stratified or minimisation ?	No (but note that households were allocated to the same intervention)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	A large proportion of allocations were to multi-member households but no account taken of clustering N						
	-	RoB 2.7	Y						
Risk-of-bias	**Low**	**Risk-of-bias**	**High**	**Risk-of-bias**	**High**	**Risk-of-bias**	**Some concerns**	**Risk-of-bias**	**Some concerns**
Direction		Direction	Unpredictable	Direction	Unpredictable	Direction	Unpredictable	Direction	Unpredictable
Comments	This is a pilot study for a 'gist' leaflet, effects on knowledge and intention. Low response rates will inevitability affect generalisability and may cause some bias in results. No account taken of allocation by household.								
Risk-of-bias	**High**		Direction	Unpredictable					

Results

Endpoint	Control	Intervention	Numeracy (low)	Comments
Knowledge	PIL	SWI	Pre-specified: yes No significant interaction (p=0.625 for continuous score, p=0.130 for binary "adequate" score)	High knowledge overall (mean 7.7/9) and 93.1% scoring > 55.5% ("adequate"). Gist + Facts scores were a few % higher on most items (7 of 9) and overall 90.9% v 95.2% had "adequate" knowledge (p=0.009).
Intention			No significant interaction (p=0.936)	73.8% v 75.7% with strong intention to screen.
Acceptability			No significant interaction (p=0.367)	
Read leaflet			**Low numeracy group:** Controls: 79.1% read 'The Facts' booklet Intervention: 84.5% read the Gist leaflet; 72.2% read 'The Facts' booklet	83.9% v 79.7% reported reading all materials, with Gist + Facts group more likely to report reading Gist (88.6%) rather than Facts (80.5%).
Comments	Higher response rate from more affluent practices; 31.8% for Stockport v 13.0% Manchester, with 18.1% and 19.6% for the Liverpool practices.			

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'adj' if adjusted for other factors

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Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (leaflet included in Smith 2017)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	Low response rate already mentioned; population were selected to be unscreened (slightly younger than screening population) and with a focus on more deprived practices
Is there anything else not covered in the tables above?	No

Smith (2017) BCSP

Primary reference	Smith et al (2017) 'Reducing the Socioeconomic Gradient in Uptake of the NHS Bowel Cancer Screening Programme Using a Simplified Supplementary Information Leaflet: A Cluster-Randomised Trial'
Trial registration #	ISRCTN: 74121020
Additional resources	'Gist' leaflet reproduced at https://bmccancer.biomedcentral.com/articles/10.1186/s12885-017-3512-1#Sec13 Raine et al (2017) 'Testing Innovative Strategies to Reduce the Social Gradient in the Uptake of Bowel Cancer Screening: A Programme of Four Qualitatively Enhanced Randomised Controlled Trials' Wardle et al (2016) 'Effects of Evidence-Based Strategies to Reduce the Socioeconomic Gradient of Uptake in the English NHS Bowel Cancer Screening Programme (ASCEND): Four Cluster-Randomised Controlled Trials'

NHSSP	Design[a]	Consent?	Population & setting	Outcome(s)[b]	Control [N][c]	Intervention(s) [N][c]	USGs [N][d]	Comment
BCSP	cRCT Randomised by day within hubs	No	163,525 people (age 59-74) due for routine screening in England (country-wide) over a 10 day period in November 2012. Those not registered with a GP (~4%) could not be included and those who had opted out of screening were not included	Uptake (returned "adequate" gFOBT within 18 weeks) by socioeconomic gradient (IMD quintiles) Secondary: Overall uptake SES differences in uptake within age, sex, hub and screening status Time taken to return gFOBt Proportion of spoilt kits Screening result [not prespecified] Diagnostic outcome [not prespecified]	Standard invitation booklet [79,104]	Additional 'gist' leaflet [84,421]	Socioeconomic gradient (IMD) [25,034 IMD5; 28,216 IMD4] (note: the whole trial population was used to assess SEG, not selected for high deprivation) Age [no sample sizes reported] Male [79,659] Previous non-responders [50,919] First-time invitees [25,444]	Randomisation was by day the invite was produced, stratified by hub. The Huber/White sandwich estimator was used to account for clustering. The authors note that the need to deliver the 'gist' leaflet with the standard information booklet may have reduced potential impact by increasing the overall amount of information. 62 health promotion activities and 17 research projects were also being undertaken during the trial but they were not limited to occurring on the same days as the intervention. This is one of a series of concurrent trials (ASCEND) which tested 4 interventions, randomised independently of each other.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)

[b] inc details of measurement
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Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		Domain 2: adherence		Domain 3: missing data		Domain 4: measurement		Domain 5: pre-specification	
RoB 1.1	Randomised by day, stratified by hub (50 'clusters') Y	RoB 2.1	Small possibility that households received both types of invite and also noticed it; very minimal risk PN	RoB 3.1	Y	RoB 4.1	PN	RoB 5.1	Y
RoB 1.2	Hubs could not be blinded and knew the daily allocation in advance; unlikely to cause problems but note that the imbalances in allocations for two hubs seem quite large. PY	RoB 2.2	N	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	Trial registration doesn't prespecify details of analysis but the unadjusted result is reported. N
RoB 1.3	Small differences between the groups for IMD quintiles. However, on review these imbalances were considered likely to fall within what would be expected by chance. PN	RoB 2.3	NA	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	Influencing the SES gradient was the primary purpose of the trial. Other USGs were only pre-specified as "other socioeconomic variables" and may have been selected, or may have been the only other demographics available, but are obviously relevant demographics to consider amongst a limited set available with this trial design. PN
Quasi-randomised?	No	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		

Stratified or minimisation ?	Yes (stratified by hub)	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	The analysis was adjusted for age, gender, hub and screening round to take account of imbalances between groups. PY						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments	An independent statistician was asked to review the imbalances observed between the arms with respect to screening history and considered that they were likely to fall within what would be expected by chance, although it was not possible to verify a lack of bias from the available data.								
Risk-of-bias	**Low**		Direction						

Results

Endpoint	Control	Test	SES (IMD)	Age	Sex (male)	Previous non-responder	First-time invitee	Comments
Uptake	K-PIL-PO	K-PIL+SWI-PO	Pre-specified? Yes IMD4: 6987/13469 v 7663/14747 51.9% v 52% IMD5: 5316/12660 v 5322/12374 42.0% v 43.0% Overall: Interaction with IMD: p=0.48	Pre-specified? Unclear <65: 18200/33589 v 19727/35920 54.2% v 54.9% *Raw OR:* 1.03 (0.94, 1.13) p=0.52 *Adj OR:* 1.03 (0.99, 1.07) p=0.13 (adjusted for gender, hub and screening round) 70+: 9744/17136 v 10269/17794 56.9% v 57.7% *Raw OR:* 1.04 (0.90 to 1.19) p=0.64 *Adj OR:* 1.06 (0.99 to 1.13) p=0.08 (adjusted for gender, hub and screening round)	Pre-specified? Unclear 21273/38433 v 23068/41226 55.4% v 56.0% *Raw OR:* 1.02 (0.92, 1.14) p=0.65 Interaction: none found (no detail reported)	Pre-specified? Unclear 3479/24551 v 3836/26368 14.2% v 14.5% *Raw OR:* 1.03 (0.94, 1.13) p=0.50 *Adj OR:* 1.03 (0.96, 1.09) p=0.44 (adjusted for age, gender and hub) Interaction with prior screening status: none found (no detail reported)	Pre-specified? Unclear 5981/12410 v 6466/13034 48.2% v 49.6% *Raw OR:* 1.06 (0.96, 1.16) p=0.23 *Adj OR:* 1.04 (0.98, 1.10) p=0.17 (adjusted for age, gender and hub) Interaction with prior screening status: none found (no detail reported)	Overall increase of 0.38% Raw OR: 1.02 (0.92, 1.13), p=0.77 Adjusted OR: 1.03 (0.99, 1.06), p=0.15 Interactions by IMD also reported within subgroups; none found.
Time to return			-	-	-	-	-	22 days (11,142) v 23 days (12,142)
Proportion spoilt			-	-	-	-	-	1,256 (0.8%), "similar" by arm and IMD quintile
Undelivered kits			-	-	-	-	-	822 (0.5%), "similar" by arm and IMD quintile

Abnormal result			-	-	-	-	-	1703 (1.8%) abnormal results
Diagnostic outcome			-	-	-	-	-	Known for 1,377 (80.9% of the 1.8%) with detailed tabulation given in non-paywalled supplementary materials.
Comments								

* note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted

'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)

'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes, 'gist' leaflet reproduced at https://bmccancer.biomedcentral.com/articles/10.1186/s12885-017-3512-1#Sec13
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No
Is there anything else not covered in the tables above?	There was disagreement regarding the importance of observed imbalances between groups in relation to screening history, which the available data and communication with the authors was not able to resolve. Further review by an independent statistician concluded that the imbalances are likely to fall within what would be expected by chance.

Stead (1998) BSP

Primary reference		Stead et al (1998) 'Improving Uptake in Non-Attenders of Breast Screening: Selective Use of Second Appointment'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT Odd/even SX numbers	No	2,229 women from the Warwickshire, Solihull and Coventry breast screening programme who did not attend their initial invitation and had not opted out of screening. October 1996 to February 1997.	Uptake (definition and measurement not described in detail)	Open invitation to schedule an appointment [1,228]	Fixed second appointment [1,001]	Recent non-responders [all; 2,229] Previous non-responders [958 not attending previous round; 815 never-attenders] Socioeconomic status (Townsend scores) [no numbers reported] First-time invitees [701]	Surprisingly large imbalance in numbers on each arm.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Could not be blinded but were not aware they were in a trial N	RoB 3.1	Y	RoB 4.1	No detail on how uptake measured but likely routine PN	RoB 5.1	No protocol or trial registration referenced but overall approach reasonable PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Limited details reported (age only), note the large imbalance in numbers on each arm NI	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	PN	RoB 5.3	Subgroup analyses are not reported well and there is some flexibility in how to define groups by screening history PN
Quasi-randomised?	Yes	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Subgroup analysis was poorly reported but results are ITT Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**	**Risk-of-bias**	**Low**
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	**Low**		Direction						

Results

Report uptake first (or primary outcome if uptake not reported). Repeat rows in table for each endpoint and treatment comparison reported within underserved subgroups, with text comment for any endpoints not reported numerically or not within USGs. Use the 3-letter codes to identify control and intervention(s). Report USGs in the order suggested in the table but replace titles with more accurate descriptors as appropriate.

Endpoint	Control	Intervention	Recent non-attenders (whole group)	SES	Previous non-attender	First-time invitee	Comments
Uptake	R-OPEN-PO	R-FIXED-PO	Pre-specified? Yes 151/1228 v 228/1001 12.3% v 22.8% RD: 10.5% (7.3%, 13.7%) p<0.001	Pre-specified? Unclear Not reported in detail, no relationship between Townsend score and effect of invite type found	Pre-specified? Unclear Did not attend previous (2nd) round: 27/512 v 35/446 5.3% v 7.8% RD: 2.5% (-6.6%, 5.7%) p>0.1 Did not attend any previous round (extracted from table 1): 21/429 v 26/386 4.9% v 6.7% Reported a large effect in those who attended the previous round (20.9% difference, from 27.2% to 48.1%) but there is considerable scope for cherry-picking and no clear pre-specification of how this analysis would be performed	Pre-specified? Unclear 35/389 v 76/312 9% v 24%	This trial took place in round 3 of the breast screening programme and so no-one included had received more than 3 invitations to screening. There were 7 different classifications for screening history based on invited/attended in rounds 1-2 and some flexibility in how to define previous non-attenders (based on one round or two). Subgroups were analysed within groups with no test for interaction reported.
Comments							

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes (text not reproduced but interventions are straightforward)
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (both arms are used in the screening programme)
Any other issues with generalisability or external validity?	Warwickshire, Solihull and Coventry with a fairly high uptake (71.5% attendance, 76.5% after second appointments)
Is there anything else not covered in the tables above?	No

Stein (2005) CSP

Primary reference		Stein et al (2005) 'Improving Uptake of Cervical Cancer Screening in Women with Prolonged History of Non-Attendance for Screening: A Randomized Trial of Enhanced Invitation Methods'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
CSP	RCT	No	1,140 women aged 39-64 who had not attended for screening for at least 15 years (or never). Selected randomly from a list of 8,186 identified from records held by Devon Patient and Practitioners Services Agency (PPSA). Interventions delivered over 3 weeks in June 2001.	Uptake (within 90 days of intervention; based on PPSA register) Cost	No intervention [285]	1. Phone call from a nurse [285; 63 excluded by GP & 111 non contactable by phone] 2. Letter from a celebrity (Claire Rayner) [285; 66 excluded by GP] 3. Letter from a local NHS Screening commissioner (Public Health doctor) [285; 64 excluded by GP]	Persistent non-attenders [all; 1,140]	Control group selected at random from the sampling frame at the time of analysis. Not ideal but should not introduce bias if done carefully using the same methods (which are not described). Post-randomisation exclusion for deceased, moved away, hysterectomy, learning disability. But ITT analysis used, so these (correctly) included in baseline.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported. Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	Not aware they were in a trial but could not be blinded Y	RoB 3.1	Just over a fifth excluded from the three intervention arms after randomisation so no intervention delivered but ITT analysis used Y	RoB 4.1	N	RoB 5.1	Control arm may have been an afterthought PY
RoB 1.2	PY	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Slightly lower number of previous smears in celebrity letter group but consistent with play of chance N	RoB 2.3	N	RoB 3.3	**NA**	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	**NA**	RoB 3.4	**NA**	RoB 4.4	**NA**		
Stratified or minimisation ?	No	RoB 2.5	**NA**			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	Persistent non-attenders (whole trial)	Comments
Uptake	LT-NFA-	LT-HCP-TEL	Pre-specified? Yes 5/285 v 4/285 1.8% v 1.4%	111 were uncontactable by phone; 63 excluded by GP (ITT results reported). No exclusions from control group as GPs not contacted.
	LT-NFA-	LT-HCPcomm-PO	Pre-specified? Yes 5/285 v 13/285 1.8% v 4.6% p=0.09 vs both control and celebrity letter p=0.055 vs phone call	66 excluded by GP (ITT results reported). No exclusions from control group as GPs not contacted.
	LT-NFA-	LT-celeb-PO	Pre-specified? Yes 5/285 v 5/285 1.8% v 1.8%	64 excluded by GP (ITT results reported). No exclusions from control group as GPs not contacted.
Costs				Average cost per woman and per attender: Phone call: £2.04 and £145.12 Commissioner letter: £0.65 and £14.29 (and £23.21 per additional attender) Celebrity letter: £0.65 and £37.14
Comments	Very small trial with lower uptake than assumed for the design (10% uptake assumed for baseline). Table 3 reports 5 people attending screening on the control arm whereas the flowchart states 4. 5 is consistent with other reporting (which suggests identical results for control and celebrity letter).			

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'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Letters and phone script described but not reproduced
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No (Devon, 2001)
Is there anything else not covered in the tables above?	No

Szarewski (2011) CSP

Primary reference		Szarewski et al (2011) 'HPV Self-Sampling as an Alternative Strategy in Non-Attenders for Cervical Screening – A Randomised Controlled Trial'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
CSP	RCT	Yes (post-randomisation in intervention arm only)	3,000 non-attenders after invite and first reminder from Westminster PCT, June-December 2009. Identified through NHAIS, June 2009.	Uptake (attendance for cytology or return of SSK within 6 months) Follow-up for those testing positive for HPV	Standard second reminder [1,500]	Self-sample kit (Qiagen) [1,500] HPV positive subjects were invited for colposcopy at the same time as cytology	Recent non-attenders [all; 3,000] IMD [1,668 in two most deprived quintiles, 855 in most deprived quintile, 813 in second most deprived]	Post-randomisation consent (single consent Zelen design). Both groups were sent a survey questionnaire collecting demographic and psycho-social information and reasons for non-attendance. High minority ethnic population; materials provided in Cantonese, Arabic, Farsi, Bengali and Portuguese.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)


RoB 2 cribsheet

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RoB should be assessed with respect to ITT uptake for all trials. State where ITT results cannot be constructed from the published report, or uptake is not reported.
Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	PY	RoB 2.1	Intervention arm asked for informed consent Y	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	No protocol or trial registration mentioned PY
RoB 1.2	Y	RoB 2.2	Y	RoB 3.2	**NA**	RoB 4.2	Different tests and single-arm informed consent Y	RoB 5.2	Unclear if definition of uptake thought through (return of kit sometimes reported without attendance for cytology instead) PN
RoB 1.3	N	RoB 2.3	Post-randomisation consent may have influenced uptake in intervention arm PY	RoB 3.3	**NA**	RoB 4.3	Can't not be unaware of different tests PY	RoB 5.3	PN
Quasi-randomised?	No	RoB 2.4	PY	RoB 3.4	**NA**	RoB 4.4	N		
Stratified or minimisation ?	No	RoB 2.5	N			RoB 4.5	**NA**		
	-	RoB 2.6	Y						
	-	RoB 2.7	**NA**						
Risk-of-bias	Low	**Risk-of-bias**	Some concerns	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction	Unpredictable	Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	SES	Recent non-attender (whole trial)	Comments
Uptake	2R-REM-PO	2R-HTK-PO	Pre-specified? Unclear IMD4: 17/420 v 26/393 4.0% v 6.6% IMD5: 16/402 v 23/430 4.0% v 5.1% (NB: the numbers in the intervention group appear to be for return of SSK only; overall 37% of responders in this arm attended for cytology without returning a kit)	Pre-specified? Yes 68/1500 v 153/1500 4.5% v 10.2% (96 returned SSK, 57 attended cytology without returning kit)	
Follow-up after positive test					
Cytology outcome					Control arm only: 68 attended for cytology, 3 tests were inadequate, 3 showed dyskaryosis (2 borderline, 1 severe)
Comments	69 women (39 v 30) had attended for screening in the 3 months before the study but their results had not yet been entered on the computer. Were included in ITT analysis. The corresponding author has sadly passed away and the other authors were unable to provide additional information.				

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'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes
Is the control arm used for this review comparable to current NHS-SP practice?	Yes (note HPV triage is about to be introduced but not self-testing and limited effect on interpretation of this trial)
Any other issues with generalisability or external validity?	Westminster demographics, 2009; 27% minority ethnic, low CSP uptake
Is there anything else not covered in the tables above?	No

Turner (1994) BSP

Primary reference		Turner et al (1994) 'Improving Breast Screening Uptake: Persuading Initial Non-Attenders to Attend'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSP	qRCT Quasi-randomised using last digit of unique CHI number	No	465 people aged 50-64 who had not responded to invite within a month in four GP practices within a single health centre in Aberdeen	Uptake (within one month of second reminder; source of data not stated, likely to be routine screening centre data) Costs	Standard second (reminder) invitation [231]	Standard second (reminder) invitation with a GP-signed letter [234]	Recent non-attenders [all; 465] Previous non-attenders [205] First-time invitees [84]	Previous non-attenders are a subgroup of recent non-attenders who had also not attended previous rounds of screening. Year of trial not reported.

[a] RCT, cRCT (cluster-randomised), qRCT (quasi-randomised), fRCT (factorial design), xRCT (crossover design); combine pre-fixes where required (eg xcRCT)
[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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Answer section 5.2 with respect to outcomes (eg multiple definitions or measurements) and section 5.3 with respect to subgroups reported (note where answers are mixed).

Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Y	RoB 2.1	N	RoB 3.1	Y	RoB 4.1	N	RoB 5.1	PY
RoB 1.2	Quasi-randomised using CHI number but unlikely to influence inclusion Y	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	N	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	Yes	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	No	RoB 2.5	NA			RoB 4.5	NA		
	-	RoB 2.6	Y						
	-	RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Intervention	Recent non-attenders (whole trial)	Previous non-attenders	First-time invitees	Comments
Uptake	R-REM-PO	R-REM+GPL-PO	Pre-specified? Yes 22/231 v 49/234 10% v 21% Risk difference: 11.4% (5%, 20%) p<0.01	Pre-specified? Unclear 3/104 v 7/101 2.9% v 6.9%	Pre-specified? Unclear 4/42 v 7/42 9.5% v 16.7%	
Costs						1.1p per photocopied GP letter. Six seconds additional time for GP receptionist. No opportunity costs identified. Marginal cost of 9.6p per additional screening.
Comments						

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Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	Yes. Letter text reproduced in paper.
Is the control arm used for this review comparable to current NHS-SP practice?	Yes
Any other issues with generalisability or external validity?	No (conducted Aberdeen, early 1990s)
Is there anything else not covered in the tables above?	No

Wardle (2003) BSS

Primary reference		Wardle et al (2003) 'Increasing Attendance at Colorectal Cancer Screening: Testing the Efficacy of a Mailed, Psychoeducational Intervention in a Community Sample of Older Adults'						
Trial registration #								
Additional resources								
NHSSP	**Design[a]**	**Consent?**	**Population & setting**	**Outcome(s)[b]**	**Control [N][c]**	**Intervention(s) [N][c]**	**USGs [N][d]**	**Comment**
BSS	RCT No details of how randomisation was done; fairly large difference in sample size between the groups but not implausible with simple randomisation	No	2,966 people aged 55-64 allocated to the screening arm of a UK trial of effectiveness of flexible sigmoidoscopy for screening who had indicated that they would probably, but not definitely, attend for screening if invited (those who said they were unlikely to attend were excluded from the effectiveness trial). This trial took place in six (of 14) UK centres (hospitals offering FSS) during the second and third years of the effectiveness trial. That trial ran from November 1994 to March 1999 so this trial presumably recruited during 1996-7. It is not stated which six centres were included.	Uptake (attendance at FS screening at any time within 3 months of invitation) Attitudes and expectations (survey questions)	Usual screening invitation [1,513] Unclear when survey questionnaire sent to controls. Paper states *"demographic questions [were sent] at the same time as the booklet (or matched times for controls)"* implying that controls may have been sent the survey 2-3 weeks before they received the invitation to FSS.	Psychoeducational booklet mailed 2-3 weeks before the usual screening invite along with survey questionnaire for non-uptake endpoints [1,453]	Townsend deprivation score (similar "neighbourhood type" used for Scotland) [no subsample sizes reported]	Note that this trial took place before the BSS screening programme was established and so did not include reminders. Invitations included the questionnaire used to measure attitudes and expectations, which was sent to both arms of the trial. Randomising people who were part of the effectiveness trial meant that they could only include people with a relatively high propensity to attend (those who had said they would definitely or probably attend for FSS were included in the effectiveness trial, with this trial randomising a subset of those who answered probably but not definitely).

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[b] inc details of measurement
[c] total N for this arm of the trial (report total number analysed for USGs in the next column)

Quality assessment (RoB 2)

RoB 2 cribsheet

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Domain 1: randomisation		**Domain 2: adherence**		**Domain 3: missing data**		**Domain 4: measurement**		**Domain 5: pre-specification**	
RoB 1.1	Little information given; relatively large imbalance between numbers on each arm but not implausible with simple randomisation PY	RoB 2.1	Intervention could not be blinded but participants unaware of this element of the trial N	RoB 3.1	PY	RoB 4.1	N	RoB 5.1	No mention of a protocol PY
RoB 1.2	PY	RoB 2.2	Y	RoB 3.2	NA	RoB 4.2	N	RoB 5.2	PN
RoB 1.3	Limited detail but what is reported is balanced PN	RoB 2.3	N	RoB 3.3	NA	RoB 4.3	N	RoB 5.3	PN
Quasi-randomised?	No (probably)	RoB 2.4	NA	RoB 3.4	NA	RoB 4.4	NA		
Stratified or minimisation ?	No (probably)	RoB 2.5	NA			RoB 4.5	NA		
		RoB 2.6	No explicit statement of ITT and some sample size imbalance between arms PY						
		RoB 2.7	NA						
Risk-of-bias	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low	**Risk-of-bias**	Low
Direction		Direction		Direction		Direction		Direction	
Comments									
Risk-of-bias	Low		Direction						

Results

Endpoint	Control	Test	SES	Sex	Comments
Uptake	pre.I-svy-PO	pre.I-svy+PSY-PO	Most deprived tertile: 43% v 48% Moderate but not statistically significant interaction (p=0.11) with treatment	Higher attendance overall among men than women (55% v 49%) but no evidence of an interaction with treatment effect.	Overall attendance 49.9% v 53.5% (p<0.05) Middle tertile: 52% v 60% Least deprived tertile: 55% v 53%
Attitudes & expectations			No substantial interactions by SES (limited detail reported).	Some gender differences with women more likely to report negative attitudes but more likely to respond positively to a negative test, less likely to attend. No significant interactions with treatment other than fatalism with the booklet reducing fatalism amongst men but not women (p<0.001) but note that this result was obtained in the context of a few dozen hypothesis tests.	53.7% returned the survey (53.6% v 53.8%), with a lower response rate from the most deprived tertile (47% v 56%, 59%). 67.7% of respondents attended for FS compared to 33.1% of non-respondents but there was no significant interaction with the treatment effect (30.6% v 35.6% for non-responders, 66.6% v 68.9% for responders). Consistent positive (and statistically significant) effect found on all questionnaire items, consistent with the improvement in uptake. Detailed results of the survey are given in Table 1 of the published paper. Note that it is unclear when the control group were sent the questionnaire; it may have been 2-3 weeks before they received the invitation to sigmoidoscopy which may have influenced the comparison with those who received the booklet at this time.
Comments					

***** note whether cluster trials are adjusted for an ICC and, for all trials, whether the reported results were *adjusted and if so, how:*

'raw' if not adjusted
'strat' if adjusted only for factors used to stratify the randomisation (or for baseline measurement of the outcome)
'adj' if adjusted for other factors

Where more than one result is reported, the order of preference is strat > raw > adj

Additional considerations

Are the intervention(s) well-described **and** reproducible?	No. There is a lengthy description of the approach but no link to the booklet offered.
Is the control arm used for this review comparable to current NHS-SP practice?	Probably yes. Reminders/pre-notification?
Any other issues with generalisability or external validity?	Yes. Subjects were selected from those included in a trial of effectiveness of FS, which only included people who had said they would definitely or probably attend for screening. It therefore excludes those least likely to attend for FS.
Is there anything else not covered in the tables above?	