# Behavioural interventions to increase uptake of FIT colorectal screening in Scotland (TEMPO): a nationwide, eight-arm, factorial, randomised controlled trial

*Kathryn A Robb, Ben Young, Marie K Murphy, Patrycja Duklas, Alex McConnachie, Gareth J Hollands, Colin McCowan, Sara Macdonald, Ronan E O'Carroll, Rory C O'Connor, Robert J C Steele*

## Summary

**Background** Uptake of colorectal cancer screening is suboptimal. The TEMPO trial evaluated the impact of two evidence-based, theory-informed, and co-designed behavioural interventions on uptake of faecal immunochemical test (FIT) colorectal screening.

**Methods** TEMPO was a 2×4 factorial, eight-arm, randomised controlled trial embedded in the nationwide Scottish Bowel Screening Programme. All 40 000 consecutive adults (aged 50–74 years) eligible for colorectal screening were allocated to one of eight groups using block randomisation: (1) standard invitation; (2) 1-week suggested FIT return deadline; (3) 2-week deadline; (4) 4-week deadline; (5) problem-solving planning tool (no deadline); (6) planning tool plus 1-week deadline; (7) planning tool plus 2-week deadline; (8) planning tool plus 4-week deadline. The primary outcome was the proportion of FITs returned correctly completed to be tested by the colorectal screening laboratory providing a positive or negative result, within 3 months of the FIT being mailed to a person. The trial is registered with clinicaltrials.gov, NCT05408169.

**Findings** From June 19 to July 3, 2022, 5000 participants were randomly assigned per group, with no loss to follow-up. 266 participants met the exclusion criteria; 39 734 (19 909 [50·1%] female and 19 825 [49·9%] male; mean age 61·2 [SD 7·3] years) were included in the analysis. The control group (no deadline, and no planning tool) had a 3-month FIT return rate of 66·0% (3275 of 4965). The highest return rate was seen with a 2-week deadline without the planning tool (3376 [68·0%] of 4964; difference *vs* control of 2·0% [95% CI 0·2 to 3·9]). The lowest return rate was seen when the planning tool was given without a deadline (3134 [63·2%] of 4958; difference *vs* control of –2·8% [–4·7 to –0·8]). The primary analysis, assuming independent effects of the two interventions, suggested a clear positive effect of giving a deadline (adjusted odds ratio [aOR] 1·13 [1·08 to 1·19]; p<0·0001), and no effect for use of a planning tool (aOR 0·98 [0·94 to 1·02]; p=0·34), though this was complicated by an interaction between the two interventions ($p_{interaction}$=0·0041); among those who were given a deadline, there was no evidence that receiving a planning tool had any effect (aOR 1·02 [0·97 to 1·07]; p=0·53), but in the absence of a deadline, giving the planning tool appeared detrimental (aOR 0·88 [0·81 to 0·96]; p=0·0030). In the absence of the planning tool, there was little evidence that the use of a deadline had any effect on return rates at 3 months. However, secondary analyses indicated that the use of deadlines boosted earlier return rates (within 1, 2, and 4 weeks, particularly around the time of the deadline), and reduced the need to issue a reminder letter after 6 weeks, with no evidence that the planning tool had any positive impact, and without evidence of interactions between interventions.

**Interpretation** Adding a single sentence suggesting a deadline for FIT return in the invitation letter to FIT colorectal screening resulted in more timely FIT return and reduced the need to issue reminder letters. This is a highly cost-effective intervention that could be easily implemented in routine practice. A planning tool had no positive effect on FIT return.

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See Comment page 1031

**School of Health and Wellbeing** (Prof K A Robb PhD, B Young PhD, Prof S Macdonald PhD, Prof R C O'Connor PhD), **School of Medicine, Dentistry, and Nursing** (M K Murphy PhD), **and Robertson Centre for Biostatistics, School of Health and Wellbeing** (Prof A McConnachie PhD, P Duklas MSc), **University of Glasgow, Glasgow, UK; EPPI Centre, UCL Social Research Institute, University College London, London, UK** (G J Hollands PhD); **School of Medicine, University of St Andrews, St Andrews, UK** (Prof C McCowan PhD); **Division of Psychology, University of Stirling, Stirling, UK** (Prof R E O'Carroll PhD); **School of Medicine, University of Dundee, Dundee, UK** (Prof R J C Steele FRCS)

Correspondence to: Prof Kathryn A Robb, School of Health and Wellbeing, University of Glasgow, Glasgow G12 8TB **katie.robb@glasgow.ac.uk**

## Introduction

Screening by self-sampled faecal immunochemical testing (FIT) reduces colorectal cancer mortality.[1,2] A major challenge for colorectal screening worldwide is achieving high uptake. Across European countries using FIT screening, uptake is around 50%.[3] In Scotland, colorectal screening is offered to people aged 50–74 years, every 2 years, with participants mailed a single-sample FIT. Current uptake is 66%, therefore a third of the eligible population are not participating and considerable inequalities in uptake by socioeconomic characteristics exist.[4]

Understanding screening behaviour and identifying precise targets for interventions are key to increasing

## Research in context

### Evidence before this study

Globally, uptake in population colorectal screening programmes is low. Deadlines for FIT return and problem-solving planning tools can be effective at supporting people who have adopted behavioural goals to realise their intentions. It is unclear whether they are effective at promoting participation in population colorectal screening programmes, where procrastination is a known barrier to completing mailed stool tests. We searched PubMed on Apr 12, 2024, with no date or language restrictions, using the search terms ("deadline" OR "timescale" OR "planning" OR "implementation intentions" OR "volitional help sheet") AND ("bowel" OR "colorectal") AND ("screening" OR "early detection") AND ("trial" OR "random*"). We found no randomised controlled trials evaluating deadlines or planning tools integrated into nationwide colorectal screening programmes.

### Added value of this study

To our knowledge, this is the first nationwide randomised controlled trial within a routine FIT colorectal screening programme to evaluate the impact of a suggested deadline for FIT return and a problem-solving planning tool intervention. Interventions were evaluated both singly and combined on the proportion of participants with a FIT returned within 3 months of the FIT invitation being mailed.

The TEMPO trial interventions were embedded into the mailed invitation to FIT colorectal screening within the Scottish Bowel Screening Programme which invites all adults aged 50–74 years every two years in Scotland. This approach minimised the risk of selection bias and meant that, if effective, the interventions could be easily implemented within the Programme. The interventions were theoretically and empirically informed and rigorously developed through a process of co-design. Service user acceptability of the interventions was also assessed in a subsample of participants. FIT return within 3 months of the FIT invitation being mailed provided objective data on screening uptake.

Compared to the standard invitation letter with no deadline for returning the FIT, the use of a deadline increased FIT returns at around the time of the deadline given and reduced the numbers of reminder letters that needed to be sent. There was no evidence that the planning tool improved FIT return rates. Acceptability of both interventions was high (>80%) among service users.

### Implications of all the available evidence

A suggested deadline for FIT return incorporated into the mailed invitation letter within a national colorectal screening programme achieving relatively high levels of uptake resulted in more timely FIT return and reduced the need to issue reminder letters. A problem-solving planning tool was not effective at increasing FIT return. The absolute increase in uptake with the deadline was modest (1·8–2·0%) but at a population level we estimate this could represent 39 000 additional participants and 23 colorectal cancer deaths avoided within a 2-year screening round in the Scottish Bowel Screening Programme. The deadline intervention is cost saving (no cost to add the sentence and would save money in reducing need for reminders) before any of the financial benefit of cancers identified early and colorectal deaths prevented. This offers a highly cost-effective intervention that could be easily implemented in routine practice, through adding a single sentence to the invitation letter.

uptake as described in the integrated screening action model and behaviour change technique taxonomy.[5,6] The intention–behaviour gap is well recognised within behavioural science.[7,8] Much of our behaviour is determined by factors other than conscious, deliberative control.[9] Indeed, forgetting and procrastination are acknowledged as key barriers to self-completed colorectal screening.[10,11] Brief behaviour change technique interventions, including goal setting, action planning, and problem solving, might support colorectal screening in those inclined to do the FIT but who fail to act. Goal setting and action planning initiate behaviour by prompting a person to plan when, where, and how to act, lessening the decision-making burden when that situation is encountered.[8] Currently, colorectal screening invitations in Scotland provide detailed information about where and how to act but exactly when to act is left open. There is some evidence that giving a specific time to act can increase screening uptake—eg, providing a fixed appointment time for breast and cervical screening increased uptake;[12] and a field experiment in the USA found both 1-week and 3-week deadlines led to small increases in FIT return.[13] However, the field experiment study[13] was limited in ecological validity, with FIT return of only 4·7% in the control group. It is yet to be established if a suggested deadline for FIT return is effective within a nationwide, population-based screening programme.

Planning tools, including if–then plans, support behaviour by encouraging people to link a crucial situation (if) with a solution (then),[8] facilitating automatic activation of the solution when the situation is encountered. If–then plans operationalised by volitional helpsheets[14] require users to physically draw a line to link a critical situation, for example, "If I keep putting off using the FIT…" with a solution, for example, "…then I'll put the FIT by the toilet to remind me." Such problem-solving planning tools have successfully reduced alcohol consumption and smoking and increased physical activity and uptake of cancer screening.[8,15–17]

The timeframe and planning tool (TEMPO) trial is the first in the world to evaluate the effect in a nationwide, population-based screening programme of: (1) a suggested FIT return deadline; (2) a problem-solving

planning tool; (3) the combination of a deadline and planning tool; and (4) the length of the deadline (1, 2, or 4 weeks) on FIT return. Service users' acceptability of both interventions was also assessed to inform implementation if the interventions were effective.

## Methods

### Study design

This was a 2×4 factorial, eight-arm, randomised controlled trial embedded within the Scottish Bowel Screening Programme's mailed invitation materials that are sent with the FIT to all eligible people. A subsample of trial participants took part in acceptability evaluation research via a cross-sectional survey and interviews. There was one study centre, the Scottish Bowel Screening Centre, Dundee, UK, which provides colorectal screening nationally in Scotland, sending FITs to approximately 1·95 million individuals every 2 years. The study design and methods are published in the protocol paper.[18] Ethical approval was granted from the National Health Service South Central—Hampshire B Research Ethics Committee (19/SC/0369). To maintain ecological validity and avoid selection bias, participants were not informed of the trial and thus were not asked to provide informed consent, an approach used in similar trials.[19,20] All participants were due to receive an invitation to colorectal screening and the standard information leaflet to support informed choice on colorectal screening was included. Although different invitation materials were tested, this did not limit the autonomy of participants to make an informed choice. The interventions were deemed to be of minimal risk, having been reviewed and approved by Patient and Public Involvement representatives and the Scottish Bowel Screening Programme. The potential benefit to the National Health Service (ie, determining effective methods of increasing colorectal screening) was viewed as outweighing any harm of testing different invitation materials. The trial is registered with ClinicalTrials.gov, NCT05408169.

### Participants

All people eligible for colorectal screening in Scotland (aged 50–74 years and who have not opted out of the programme, or aged 75 years and older who have opted into the programme; have a Community Health Index Number and were due to be sent a FIT; ie, more than 2 years since last FIT) were included in this study. There were no exclusions; all consecutive invitations were included. Participants' characteristics including age, sex assigned at birth, Scottish Index of Multiple Deprivation (SIMD), urban–rural classification, and FIT return information were obtained from the Scottish Bowel Screening Programme database; ethnicity data were unavailable. A subsample of trial participants was identified to be mailed an acceptability survey. Interview participants were sampled from survey respondents who indicated willingness to participate in further research. Consent for the survey was implied through its completion and return. Written informed consent for the interviews was obtained (appendix p 3).

See Online for appendix

### Randomisation and masking

Participants were randomly assigned using block randomisation to one of eight groups (figure 1) in a 2×4 factorial design: (1) no intervention (control; standard invitation); (2) 1-week suggested FIT return deadline; (3) 2-week deadline; (4) 4-week deadline; (5) problem-solving planning tool (no deadline); (6) planning tool plus 1-week deadline; (7) planning tool plus 2-week deadline; (8) planning tool plus 4-week deadline. Randomisation was performed by the method of randomised permuted blocks of length eight, so that in every eight screening invitation packages sent, exactly one of each type was included. The randomisation

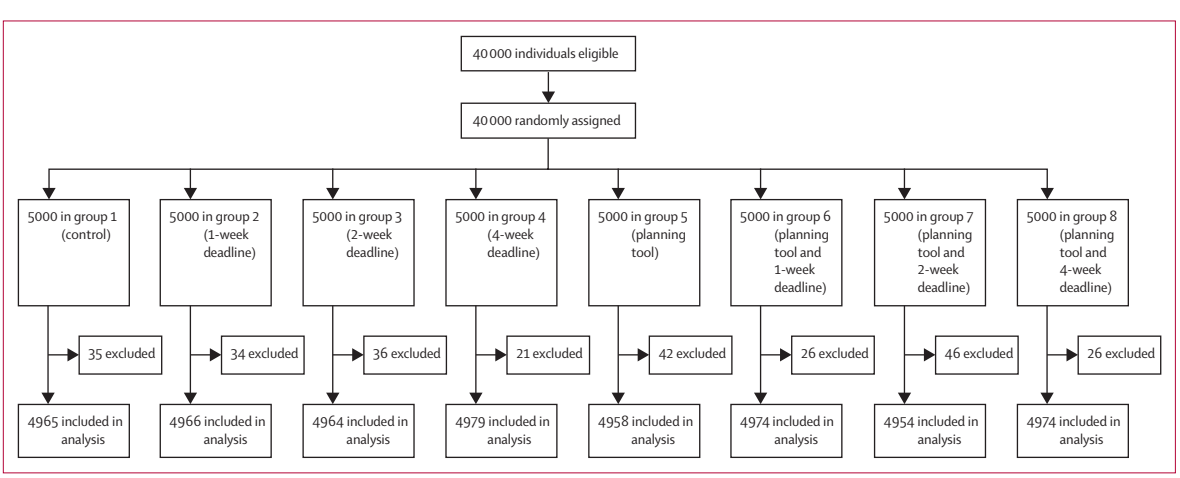


***Figure 1:*** **Trial profile**
For 266 participants it was not possible to link their postcode to a data zone to derive their Scottish Index of Multiple Deprivation quintile and their urban–rural classification and so they were excluded from analysis.

schedule was computer-generated at the Robertson Centre for Biostatistics, University of Glasgow, UK, and transferred via a secure web portal to the Scottish Bowel Screening Programme. The printing of the invitation letters with the deadlines and the adding of the planning tool was an automated process in accordance with the participants' allocation within this trial conducted by a mail handling company who's employees were therefore unblinded. The researchers, including those performing the analysis, were blind to the allocation. Individual participants were also blind to the existence of different allocations.

### Procedures

Both interventions were rigorously developed through a process of co-design with patient participant involvement.

Those allocated to a deadline intervention (groups 2–4 and 6–8) received a screening invitation letter (appendix pp 4–5) with one of three suggested deadlines added: 1 week, 2 weeks, and 4 weeks. The deadline was displayed centrally on the standard colorectal screening invitation letter as a bold, highlighted sentence (table 1). The suggested deadline used behaviour change techniques from the Behaviour Change Technique Taxonomy (version 1): (1.1) goal setting (behaviour), (1.4) action planning, and (7.1) prompts or cues.[6]

Those allocated to the planning tool intervention (groups 5–8) received a planning tool with their screening invitation (appendix p 6). The planning tool was a separate single sheet of A4 paper inserted into the colorectal screening invitation envelope. It asked participants to identify concerns they have with completing the FIT from a list and to link them to a tip from an adjacent list to help them overcome this concern. Details of the development[21] and content of the planning tool are reported in the protocol paper.[18] The planning tool contained behaviour change techniques from the Behaviour Change Technique Taxonomy (version 1): (1.2) problem solving and (1.4) action planning.[6] Usual reminder letters were sent in all groups approximately 6 weeks after the initial invitation if the FIT had not been returned. Participants could request a replacement FIT from the programme helpline and were automatically sent a replacement FIT in the event of an untestable or undated FIT return.

| | Suggested FIT return deadline | Deadline sentence |
|---|---|---|
| Groups 2 and 6 | 1-week deadline | "Please return your kit within 1 week (by [insert date 10 days from posting date]) or as soon as possible." |
| Groups 3 and 7 | 2-week deadline | "Please return your kit within 2 weeks (by [insert date 17 days from posting date]) or as soon as possible." |
| Groups 4 and 8 | 4-week deadline | "Please return your kit within 4 weeks (by [insert date 31 days from posting date]) or as soon as possible." |

FIT=faecal immunochemical test.

*Table 1:* **Suggested FIT return deadline intervention arms**

Approximately 5 months after the screening invitation, participants in the subsample were mailed a brief patient participant involvement informed acceptability survey (appendix pp 7–10).[22] We used random sampling from all eight groups, within a sampling frame based on anticipated survey response rates by FIT return (heavily weighted to non-FIT return) and SIMD (weighted to greater area deprivation). A reminder survey was sent to those who had not responded after 11 weeks. For the one-to-one telephone or video-call interviews, we used a quota sampling approach to achieve balance on: FIT return, sex, age, deprivation (SIMD) and intervention allocation (excluding group 1, control). A patient participant involvement informed semi-structured topic guide was used (appendix pp 11–13). Participants were offered a £30 gift voucher. Calls to the Scottish Bowel Screening Programme helpline relating to the interventions were also monitored.

### Outcomes

The primary outcome was the proportion of FITs returned correctly completed to be tested by the CRC screening laboratory providing a positive or negative result (usable), within 3 months of the FIT being sent to a person. The return and successful testing of any replacement FIT that was sent to a participant after the first FIT at study baseline was treated as a usable FIT return. FIT return was recorded by scanning personalised digital labels on the tests and the usable and interpretable test being recorded by the laboratory technician. This is the same method used within the Scottish Bowel Screening Programme to record FIT return, ensuring no loss to follow-up in the trial.

Secondary outcomes included whether a usable FIT return was obtained within 1, 2, or 4 weeks, or whether a reminder letter had to be sent.

Service users' acceptability of the two interventions was assessed as a secondary outcome using a self-reported survey based on theoretical framework of acceptability constructs (general acceptability, affective attitude, ethicality, and perceived effectiveness).[22] Participants were also asked which deadline would be most helpful (1 week, 2 weeks, 4 weeks, other, or none). Qualitative interviews aligned with the constructs assessed in the survey plus intervention coherence.[22] Cognitive and behavioural mechanisms were assessed in the survey and interviews but will be reported in a separate paper.

### Statistical analysis

The target sample size was decided using an a priori power calculation (nQuery version 9). The planning tool evaluation involved two groups of 20 000 participants. At a significance level of 2·5%, this gave 90% power to

detect an increase in uptake rates from 65·0% to 66·7%. Alternatively, if the intervention increased uptake rates from 65·0% to 68·0%, the 97·5% CI for the difference in uptake rates would have a width of ±1·1%. The deadline evaluation involved four groups of 10 000 participants. Comparing each intervention with the control group at a significance level of 0·8% (one third of 2·5%), there would be 90% power to detect increases in uptake rates from 65·0% to 67·6%. If an intervention increased uptake from 65% to 68%, the 99·2% CI for the difference in uptake rates would have a width of ±1·8%.

Analyses were first conducted with the deadline intervention as a binary variable (no deadline *vs* any deadline). Analyses were repeated with the deadline intervention as a four-level categorical variable. For each analysis, a series of regression models was fitted. Model 1 included terms for each randomisation, as independent effects, adjusted for age, sex, SIMD quintile, and urban–rural classification. The overall significance of each intervention was assessed using likelihood ratio tests, comparing model 1 to a model without the specific intervention. Intervention effect estimates from model 1 were reported as adjusted odds ratios, with 95% CIs and p values. Model 2 was the same as model 1 with the addition of terms to model an interaction between the two randomisations. The significance of the interaction was derived from a likelihood ratio test comparing model 2 with model 1. Intervention effect estimates for each randomisation were reported within strata defined by the other randomisation.

The same methods were applied to binary secondary outcomes (usable FIT return within 1, 2, and 4 weeks, and sending of reminder). For the primary outcome only, model 1 was also extended to include interactions between each randomisation and subgrouping factors of age (50–54, 55–59, 60–64, 65–69, ≥70 years), sex, SIMD, and urban–rural classification. Likelihood ratio tests were used to assess the statistical significance of each interaction. Intervention effect estimates were reported within each subgroup. A similar approach was used to analyse the time to usable FIT return, using a Cox proportional hazards regression model. The proportional hazards assumption was assessed using a test based on Schoenfeld residuals. Results were broadly similar to the main analyses, but there was considerable evidence of non-proportional hazards with respect to several factors in the models. As a post-hoc analysis, we fitted separate logistic regression models for usable FIT returns within each of the first 5 weeks after invitation, or at any point thereafter (up to 3 months after the invitation). Each model was fitted to the subset of the population who had not returned the FIT before that point. In this way, the effects of the interventions and adjustment covariates were allowed to vary over time, reflecting the non-proportional hazards observed in the Cox models. These models were then used to generate the predicted probability of FIT returns during each week after invitation, for the whole population, under alternative scenarios of receiving each possible combination of interventions. Differences over time in the predicted probability of FIT return, with 95% CIs and p values, were generated using bootstrapping with 1000 replicated datasets. The statistical analysis plan is provided in the appendix (pp 14–39).

| | All (N=39 734) | Randomised group | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Group 1 (n=4965) | Group 2 (n=4966) | Group 3 (n=4964) | Group 4 (n=4979) | Group 5 (n=4958) | Group 6 (n=4974) | Group 7 (n=4954) | Group 8 (n=4974) |
| Deadline | .. | None | 1-week | 2-week | 4-week | None | 1-week | 2-week | 4-week |
| Planning tool | .. | No | No | No | No | Yes | Yes | Yes | Yes |
| Age, years | 61·2 (7·3) | 61·2 (7·2) | 61·2 (7·3) | 61·2 (7·2) | 61·2 (7·3) | 61·1 (7·2) | 61·2 (7·2) | 61·2 (7·3) | 61·2 (7·3) |
| Sex | | | | | | | | | |
| Female | 19 909 (50·1%) | 2461 (49·6%) | 2503 (50·4%) | 2426 (48·9%) | 2538 (51·0%) | 2445 (49·3%) | 2526 (50·8%) | 2524 (50·9%) | 2486 (50·0%) |
| Male | 19 825 (49·9%) | 2504 (50·4%) | 2463 (49·6%) | 2538 (51·1%) | 2441 (49·0%) | 2513 (50·7%) | 2448 (49·2%) | 2430 (49·1%) | 2488 (50·0%) |
| SIMD, quintile | | | | | | | | | |
| 1 (most deprived) | 7248 (18·2%) | 893 (18·0%) | 888 (17·9%) | 871 (17·5%) | 945 (19·0%) | 903 (18·2%) | 919 (18·5%) | 909 (18·3%) | 920 (18·5%) |
| 2 | 7465 (18·8%) | 931 (18·8%) | 972 (19·6%) | 969 (19·5%) | 915 (18·4%) | 883 (17·8%) | 947 (19·0%) | 908 (18·3%) | 940 (18·9%) |
| 3 | 7993 (20·1%) | 996 (20·1%) | 1066 (21·5%) | 1033 (20·8%) | 974 (19·6%) | 985 (19·9%) | 965 (19·4%) | 975 (19·7%) | 999 (20·1%) |
| 4 | 8696 (21·9%) | 1087 (21·9%) | 1037 (20·9%) | 1053 (21·2%) | 1137 (22·8%) | 1119 (22·6%) | 1067 (21·5%) | 1096 (22·1%) | 1100 (22·1%) |
| 5 (least deprived) | 8332 (21·0%) | 1058 (21·3%) | 1003 (20·2%) | 1038 (20·9%) | 1008 (20·2%) | 1068 (21·5%) | 1076 (21·6%) | 1066 (21·5%) | 1015 (20·4%) |
| Urban–rural classification* | | | | | | | | | |
| Large urban | 11 981 (30·2%) | 1515 (30·5%) | 1504 (30·3%) | 1524 (30·7%) | 1481 (29·7%) | 1469 (29·6%) | 1492 (30·0%) | 1497 (30·2%) | 1499 (30·1%) |
| Other urban | 14 800 (37·2%) | 1827 (36·8%) | 1810 (36·4%) | 1832 (36·9%) | 1847 (37·1%) | 1909 (38·5%) | 1896 (38·1%) | 1836 (37·1%) | 1843 (37·1%) |
| Other | 12 953 (32·6%) | 1623 (32·7%) | 1652 (33·3%) | 1608 (32·4%) | 1651 (33·2%) | 1580 (31·9%) | 1586 (31·9%) | 1621 (32·7%) | 1632 (32·8%) |

Data are mean (SD) or n (%). FIT=faecal immunochemical test. SIMD=Scottish Index of Multiple Deprivation.*Large urban: settlements of 125 000 inhabitants or more; other urban: settlements of 10 000 to 124 999 inhabitants; other: small towns (settlements of 3000 to 9999 inhabitants) and rural areas (settlements of less than 3000 inhabitants).

***Table 2:*** **Baseline characteristics by randomised group**

| | Group 1 (n=4965) | Group 2 (n=4966) | Group 3 (n=4964) | Group 4 (n=4979) | Group 5 (n=4958) | Group 6 (n=4974) | Group 7 (n=4954) | Group 8 (n=4974) |
|---|---|---|---|---|---|---|---|---|
| Deadline | None | 1-week | 2-week | 4-week | None | 1-week | 2-week | 4-week |
| Planning tool | No | No | No | No | Yes | Yes | Yes | Yes |
| Usable FIT kit returned | 3275 (66·0%) | 3280 (66·0%) | 3376 (68·0%) | 3325 (66·8%) | 3134 (63·2%) | 3375 (67·9%) | 3323 (67·1%) | 3341 (67·2%) |
| Age, years | | | | | | | | |
| 50–54 | 676/1200 (56·3%) | 688/1218 (56·5%) | 725/1195 (60·7%) | 683/1212 (56·4%) | 639/1213 (52·7%) | 710/1207 (58·8%) | 711/1206 (59·0%) | 727/1211 (60·0%) |
| 55–59 | 588/930 (63·2%) | 569/915 (62·2%) | 618/929 (66·5%) | 603/929 (64·9%) | 534/905 (59·0%) | 605/921 (65·7%) | 585/927 (63·1%) | 586/919 (63·8%) |
| 60–64 | 730/1080 (67·6%) | 724/1106 (65·5%) | 739/1090 (67·8%) | 739/1096 (67·4%) | 711/1109 (64·1%) | 727/1088 (66·8%) | 727/1067 (68·1%) | 729/1096 (66·5%) |
| 65–69 | 708/977 (72·5%) | 676/922 (73·3%) | 714/987 (72·3%) | 689/938 (73·5%) | 681/970 (70·2%) | 717/977 (73·4%) | 719/976 (73·7%) | 711/968 (73·5%) |
| ≥70 | 573/778 (73·7%) | 623/805 (77·4%) | 580/763 (76·0%) | 611/804 (76·0%) | 569/761 (74·8%) | 616/781 (78·9%) | 581/778 (74·7%) | 588/780 (75·4%) |
| Sex | | | | | | | | |
| Female | 1675/2461 (68·1%) | 1720/2503 (68·7%) | 1691/2426 (69·7%) | 1811/2538 (71·4%) | 1607/2445 (65·7%) | 1766/2526 (69·9%) | 1739/2524 (68·9%) | 1726/2486 (69·4%) |
| Male | 1600/2504 (63·9%) | 1560/2463 (63·3%) | 1685/2538 (66·4%) | 1514/2441 (62·0%) | 1527/2513 (60·8%) | 1609/2448 (65·7%) | 1584/2430 (65·2%) | 1615/2488 (64·9%) |
| SIMD, quintile* | | | | | | | | |
| Q1 (most deprived) | 476/893 (53·3%) | 483/888 (54·4%) | 473/871 (54·3%) | 524/945 (55·4%) | 463/903 (51·3%) | 526/919 (57·2%) | 497/909 (54·7%) | 542/920 (58·9%) |
| Q2 | 576/931 (61·9%) | 579/972 (59·6%) | 612/969 (63·2%) | 564/915 (61·6%) | 526/883 (59·6%) | 593/947 (62·6%) | 550/908 (60·6%) | 597/940 (63·5%) |
| Q3 | 660/996 (66·3%) | 719/1066 (67·4%) | 712/1033 (68·9%) | 674/974 (69·2%) | 625/985 (63·5%) | 678/965 (70·3%) | 683/975 (70·1%) | 688/999 (68·9%) |
| Q4 | 775/1087 (71·3%) | 745/1037 (71·8%) | 760/1053 (72·2%) | 818/1137 (71·9%) | 768/1119 (68·6%) | 758/1067 (71·0%) | 796/1096 (72·6%) | 768/1100 (69·8%) |
| Q5 (least deprived) | 788/1058 (74·5%) | 754/1003 (75·2%) | 819/1038 (78·9%) | 745/1008 (73·9%) | 752/1068 (70·4%) | 820/1076 (76·2%) | 797/1066 (74·8%) | 746/1015 (73·5%) |
| Urban or rural classification* | | | | | | | | |
| Large urban | 931/1515 (61·5%) | 939/1504 (62·4%) | 975/1524 (64·0%) | 918/1481 (62·0%) | 876/1469 (59·6%) | 963/1492 (64·5%) | 945/1497 (63·1%) | 955/1499 (63·7%) |
| Other urban | 1203/1827 (65·8%) | 1203/1810 (66·5%) | 1249/1832 (68·2%) | 1248/1847 (67·6%) | 1185/1909 (62·1%) | 1279/1896 (67·5%) | 1221/1836 (66·5%) | 1262/1843 (68·5%) |
| Other | 1141/1623 (70·3%) | 1138/1652 (68·9%) | 1152/1608 (71·6%) | 1159/1651 (70·2%) | 1073/1580 (67·9%) | 1133/1586 (71·4%) | 1157/1621 (71·4%) | 1124/1632 (68·9%) |

Data are n (%). FIT=faecal immunochemical test. SIMD=Scottish Index of Multiple Deprivation. *Large urban: settlements of 125 000 inhabitants or more; other urban: settlements of 10 000 to 124 999 inhabitants; other: small towns (settlements of 3000 to 9999 inhabitants) and rural areas (settlements of less than 3000 inhabitants).

***Table 3:*** **Proportions of people who returned a usable FIT kit at 3 months**

Service users' acceptability was analysed using descriptive statistics for survey data and the framework method for interview data;[23] further details are described in the protocol.[18]

During the trial, on day 10 of 15 of invitations being sent, the death at age 40 years of Dame Deborah James from colorectal cancer was announced, a high-profile activist for colorectal cancer research in the UK. This gained considerable press coverage and might have affected FIT return as has been observed previously when cancer screening uptake increased following a celebrity death from cancer (eg, the Jade Goody Effect).[24] We therefore carried out sensitivity analyses to assess whether there was any evidence of return rates varying according to the day that the invitation was sent (ie, before *vs* after each specific date during the study), and whether the intervention effect varied according to date of invitation.

The data were analysed using R (version 4.0.4).

### Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

## Results

Between June 19 and July 3, 2022, 40 000 consecutive eligible individuals were randomly assigned (figure 1), and outcome data were extracted on Oct 5, 2022, with no loss to follow-up. For 266 participants (0·7%), it was not possible to link their postcode to a data zone to derive their SIMD quintile and their urban–rural classification, so these participants were excluded from subsequent analyses. The FIT return rate of these people was markedly lower than other participants' (163 [61·3%] of 266 *vs* 26 429 [66·5%] of 39 734). Unexpectedly, there was a statistically significant association (p=0·0085) between which deadline people were randomly assigned, and being excluded (appendix p 40), though in absolute terms, the differences were small (0·3%). The demographic characteristics of the remaining 39 734 participants were well balanced across groups. Overall, the mean age was 61·2 (SD 7·3) years, 19 909 (50·1%) were female and 19 825 (49·9%) were male, 7248 (18·2%) lived in the most deprived quintile whereas 8332 (21·0%) lived in the least deprived quintile, and most participants 26 781 (67·4%) lived in an urban area (table 2).

In total, seven labelled FITs were returned to the laboratory that were not usable and excluded, which did not have a considerable effect on the pattern of results. Therefore, only usable FIT return data are presented. In the control group (no planning tool, standard invitation letter), FIT return at 3 months was 66·0% (3275 of 4965). For those receiving a return deadline without the planning tool, FIT return at 3 months was 66·0% (3280 of 4966) with a 1-week deadline, 68·0% (3376 of 4964) with a 2-week deadline, and 66·8% (3325 of 4979) with a 4-week deadline. With the planning tool, FIT return at 3 months was 63·2% (3134 of 4958) with no deadline, 67·9% (3375 of 4974) with a 1-week deadline, 67·1% (3323 of 4954) with a 2-week deadline, and 67·2% (3341 of 4974) with a 4-week deadline (table 3, figure 2).

In the analysis that assumed the two interventions to have independent effects (model 1), provision of any deadline was associated with increased FIT return compared to no deadline (adjusted odds ratio [aOR] 1·13 [95% CI 1·08–1·19]; p<0·0001). Provision of a planning tool was not significantly associated with FIT return compared with no planning tool (0·98 [0·94–1·02]; p=0·34; table 4).

There were no observed interactions between either a deadline or a planning tool, and any of the demographic characteristics (table 4). Results were similar when allowing for differences between the three possible deadlines (appendix pp 41–42) with evidence of increased return rates with all deadlines, but not the planning tool, and no interactions with demographic characteristics.

Treating the deadline intervention as binary (no deadline *vs* any deadline), model 2 showed a significant interaction between the interventions (p=0·0041, table 4). In the absence of the planning tool, there was no evidence of an effect of receiving a deadline (aOR: 1·05 [0·98–1·13];

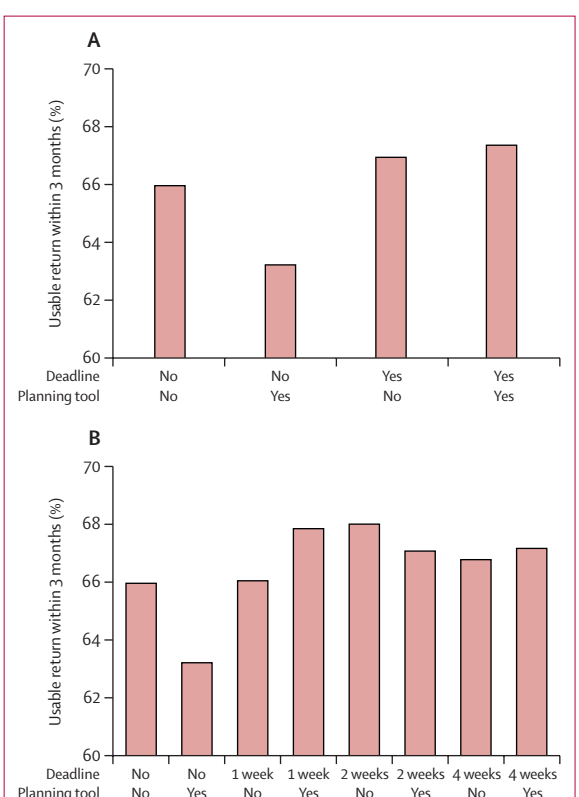


***Figure 2:*** **Usable FIT return within 3 months, by planning tool and deadline status**

(A) Treating deadline status as binary. (B) Considering each deadline separately.

| | Any deadline *vs* no deadline (adjusted odds ratios [95% CI]) | Planning tool *vs* no planning tool (adjusted odds ratios [95% CI]) |
|---|---|---|
| Overall (model 1) | 1·13 (1·08–1·19); p<0·0001 | 0·98 (0·94–1·02); p=0·34 |
| Interaction by age group, years (model 1a) | | |
| 50–54 | 1·19 (1·08–1·30); p=0·0004 | 1·01 (0·93–1·10); p=0·80 |
| 55–59 | 1·15 (1·03–1·29); p=0·010 | 0·94 (0·85–1·03); p=0·17 |
| 60–64 | 1·06 (0·95–1·17); p=0·29 | 0·96 (0·88–1·05); p=0·39 |
| 65–69 | 1·11 (0·99–1·25); p=0·066 | 0·98 (0·89–1·09); p=0·73 |
| ≥70 | 1·13 (0·99–1·30); p=0·067 | 1·01 (0·90–1·14); p=0·87 |
| $p_{interaction}$ | p=0·59 | p=0·76 |
| Interaction by sex (model 1b) | | |
| Female | 1·15 (1·07–1·23); p=0·0001 | 0·96 (0·90–1·02); p=0·14 |
| Male | 1·11 (1·04–1·19); p=0·0020 | 1·00 (0·94–1·06); p=0·94 |
| $p_{interaction}$ | p=0·51 | p=0·27 |
| Interaction by SIMD quintile (model 1c) | | |
| Q1 (most deprived) | 1·15 (1·03–1·28); p=0·010 | 1·04 (0·95–1·14); p=0·43 |
| Q2 | 1·04 (0·93–1·16); p=0·45 | 1·01 (0·92–1·11); p=0·89 |
| Q3 | 1·20 (1·08–1·34); p<0·0008 | 1·01 (0·92–1·11); p=0·78 |
| Q4 | 1·08 (0·97–1·20); p=0·15 | 0·93 (0·85–1·03); p=0·15 |
| Q5 (least deprived) | 1·18 (1·06–1·32); p=0·0034 | 0·90 (0·82–1·00); p=0·044 |
| $p_{interaction}$ | p=0·31 | p=0·21 |
| Interaction by urban–rural classification (model 1d) | | |
| Large urban | 1·12 (1·03–1·23); p=0·0081 | 1·00 (0·93–1·08); p=0·91 |
| Other urban | 1·19 (1·10–1·29); p<0·0001 | 0·96 (0·89–1·02); p=0·20 |
| Other | 1·07 (0·98–1·17); p=0·15 | 0·98 (0·91–1·06); p=0·66 |
| $p_{interaction}$ | p=0·20 | p=0·63 |
| Interaction between interventions (model 2) | | |
| Effect of a deadline without the planning tool | 1·05 (0·98–1·13); p=0·15 | .. |
| Effect of a deadline with the planning tool | 1·21 (1·13–1·30); p<0·0001 | .. |
| Effect of the planning tool without a deadline | .. | 0·88 (0·81–0·96); p=0·0030 |
| Effect of the planning tool with a deadline | .. | 1·02 (0·97–1·07); p=0·53 |
| $p_{interaction}$ | p=0·0041 | .. |

Deadline intervention treated as binary (no deadline *vs* any deadline). Model 1: each intervention as an independent effect. Model 1a–d: model 1 plus interactions by age, sex, SIMD, and urban–rural classification. Model 2: model 1 plus interaction between interventions. SIMD=Scottish Index of Multiple Deprivation. All models adjusted for age group, sex, SIMD, and urban–rural classification.

***Table 4:*** **Primary outcome—logistic regression analysis of usable FIT return within 3 months**

p=0·15, table 4). With the planning tool, the effect of being given a deadline appeared enhanced (aOR 1·21 [1·13, 1·30]; p<0·0001, table 4). However, this apparently stronger effect of the deadline in the presence of the planning tool was due to the particularly low return rate in the group who received the planning tool without a deadline (figure 2). This was evident in the effect estimate for receiving the planning tool within the subset who did not have a deadline (aOR 0·88 [0·81–0·96]; p=0·0030, table 4). Among those who received a deadline, there was no evidence that getting a planning tool had any effect (aOR 1·02 [0·97–1·07]; p=0·53, table 4). Considering the three different deadlines as having different effects, the patterns were similar, with a significant interaction between interventions (p=0·0054, appendix pp 41–42).

Secondary outcome frequencies and percentages are summarised in the appendix (p 43) and further analysis results presented (pp 44–48). As with the primary outcome, when considering the interventions to have independent effects, there was evidence that giving a deadline was associated with greater return rates, and fewer reminders sent, with the largest effect seen with a 2-week deadline (4·6% absolute reduction in reminders sent: 4422 [44·6%] of 9923 with no deadline *vs* 3966 (40·0%) of 9918 with a 2-week deadline; appendix p 43). For most outcomes, the numerically largest effect was seen with a 2-week deadline, except for usable returns within 1 week, for which a 1-week deadline was most effective (aOR 1·32 [1·24–1·40]; p<0·0001; appendix p 45). Considering the interventions to have independent effects, there was no evidence that the planning tool had any effect on any secondary outcomes.

Contrary to the primary analysis, there was little evidence of interactions between the two interventions in their effects on the secondary outcomes. Considering the deadline intervention as a binary variable, the interaction p value with respect to usable FIT returns within 4 weeks was 0·058, with a suggestion of reduced return rates when the planning tool was given without a deadline (aOR 0·93 [0·86–1·01]; p=0·066; appendix p 44). Otherwise, all interactions had p values greater than 0·10. Notably, a deadline reduced the odds that a reminder letter needed to be sent (aOR 0·83 [0·80–0·87]; p<0·0001), whereas the planning tool had no impact (1·00 [0·96–1·05]; p=0·85), with no evidence of an interaction between interventions (p=0·15; appendix p 44).

In summary, over a 3-month period, although there appeared to be a beneficial effect of receiving a deadline, there was an interaction between the two interventions, and this positive effect could largely be explained by an apparently detrimental effect of receiving the planning tool without a deadline. However, over shortened timescales, this interaction was not evident, and the use of a deadline was seen to increase return rates (whether the planning tool was given or not), whereas the planning tool had no discernible effect. This resulted in fewer reminder letters being sent in those who were given a deadline.

When analysing the time to usable FIT return using Cox regression, the results obtained were similar to those of the primary analysis. There was evidence of an interaction between the two interventions, due to a reduced return rate associated with the planning tool in those without a deadline (adjusted hazard ratio [aHR] 0·94 [0·89–0·98]; p=0·010), resulting in apparently greater effects of having a deadline in those with a planning tool (appendix p 47). However, in the absence of the planning tool, evidence of an increased return rate with any deadline was still seen (aHR 1·06 [1·02–1·10]; p=0·0028; appendix p 47), particularly with a 1-week

deadline (1·07 [1·02–1·12]; p=0·0075) or a 2-week deadline (1·09 [1·04–1·14]; p=0·0007; appendix p 48).

There was evidence of non-proportional hazards in the Cox models with respect to age, SIMD, and urban–rural classification, but also in respect to the deadline intervention (p=0·0034 for any deadline; p<0·0001 for separate deadlines), though not the planning tool intervention (p=0·20). Post-hoc analyses were carried out to investigate this, which modelled the probability of FIT return during each of the first 5 weeks after invitation, or at any point thereafter up to 3 months (appendix p 49). These results support the notion that getting a deadline increased return rates around the time of the deadline. In the presence of the planning tool, predicted final return rates were similar regardless of the length of the deadline, and clearly better than those without a deadline. Without the planning tool, those with a 2-week deadline had marginally higher predicted return rates than other deadline groups, or those with no deadline.

Response to the acceptability survey was 15·8% (1855 of 11719) with survey respondents being older and from less socioeconomically deprived areas (appendix p 55). Overall, both interventions were rated as acceptable or completely acceptable by more than 80% of participants in the exposed groups, with the deadline rated higher in acceptability than the planning tool. Those exposed to the interventions reported them as more acceptable than those who had not been exposed (appendix pp 56–57). A 2-week deadline was perceived as the most helpful deadline among those exposed (591 [43·9%] of 1395) and those not exposed (167 [37·5%] of 460) to any deadline (appendix p 56). Among those not exposed, a 4-week deadline was also perceived as helpful (161 [36·2%] of 460). The interview data broadly supported the survey data with both interventions viewed as acceptable to service users. Qualitative findings explaining intervention acceptability according to constructs of the theoretical framework of acceptability supported the quantitative findings and are summarised in the appendix (pp 58–60).

The Bowel Screening Centre Helpline receives around 350 calls per day and during the trial logged 21 calls regarding the deadline and 16 calls regarding the planning tool, suggesting the interventions were broadly acceptable to service users (appendix p 61).

The sensitivity analysis on Dame Deborah James' death suggested minimal impact on FIT return (appendix p 61).

## Discussion

The primary analysis of this nationwide, 2×4 factorial, randomised controlled trial was complicated by an interaction between the two interventions ($p_{interaction}$=0·0041). In the absence of a deadline, giving the planning tool appeared detrimental, and in the absence of the planning tool, there was little evidence that the use of a deadline had any effect on the primary outcome (usable FIT return rates at 3 months). However, secondary analyses indicated that the use of a deadline boosted earlier return rates and reduced the need to issue reminder letters. The control group (no deadline and no planning tool) had a 3-month FIT return rate of 66·0%. The highest return rate was seen with a 2-week deadline without the planning tool (68·0%; difference *vs* control 2·0%). The lowest return rate was seen when the planning tool was given without a deadline (63·2%; difference *vs* control –2·8%).

The results are complicated by interactions between the effects of the two interventions. Overall, the effects of the different deadlines could be attributed to a particularly low return rate in the group who received the planning tool without a deadline. However, analyses of secondary outcomes (return rates at 1, 2, and 4 weeks) as well as post-hoc analyses of weekly return rates, suggested that the deadlines do promote earlier FIT returns, particularly around the time of the deadline.

Any deadline reduced the number of reminder letters sent with the largest effect seen with a 2-week deadline (4·1% absolute reduction in reminders sent). Service users perceived both interventions as acceptable with higher acceptability of the deadline than the planning tool, and the 2-week deadline rated as most helpful.

The intervention effects might be considered small, although adding a deadline to the invitation letter is a near zero-cost intervention delivered at national scale. We estimate that a 2% increase in FIT returns would mean an additional 39 000 people participating in a 2-year Scottish Bowel Screening round, with approximately 23 colorectal cancer deaths being avoided as a result.[25] Similarly, a 4% reduction in the need for reminder letters would mean 78 000 fewer letters sent, a considerable saving of costs.

Although introduction of deadlines promotes earlier returns, the differences in return rates at 3 months are less clear. It could be that having missed a deadline, people are less likely to make a return. This is most evident in those given a 1-week deadline, who had the highest return rate within the first week, but given the short timeline, a large number of people will have missed the deadline. If these people were then less likely to make a return, it might explain why the return rates in this group were overtaken by other groups by 3 months. A 2-week deadline might strike a good balance between urgency (promoting rapid returns) and leniency (reducing the number who miss the deadline).

Another factor to consider is that everyone who had not made a return was sent a reminder after 6 weeks. This action might have served to reduce the differences between groups at 3 months. However, the finding that deadlines reduced the number of reminders that were sent offers a direct cost saving to the screening service through the use of a deadline.

This is the first study to assess the effectiveness of providing a deadline for FIT return to increase uptake

relative to a standard open invitation in a population-based national screening programme. In breast and cervical screening, providing a fixed appointment time increased uptake compared with an open invitation,[12] although attending a screening appointment is a different behaviour to completing and returning a test.[11] The deadline did not exacerbate inequalities, which interventions can;[26] however, it did not reduce inequalities, which remain a persistent challenge to screening programmes.

Provision of a problem-solving planning tool within the screening context has had mixed results. A trial of a planning tool in guaiac faecal occult blood test (gFOBT) colorectal screening participants in the North East of England found it to be ineffective relative to a standard invitation.[20] Our findings suggest that the planning tool developed for this study, with content and format based on qualitative and quantitative intervention development research and subsequent co-design, achieved service user acceptability but was not effective at increasing FIT return. However the literature is clear that planning tools are effective at changing behaviour in other contexts[8,15] including cancer screening.[16,17] Indeed, there is some evidence that there can be more utility with established behaviours where the cognitive link between a critical situation (if) and a solution (then) have previously been experienced[27] or in combining a planning tool with a motivational rather than a volitional intervention.[20] It is unclear whether a different planning tool or combination with another behaviour change technique could be effective within the Scottish Bowel Screening programme, and further research considering the possible mechanisms contributing to the failure of the planning tool to increase uptake, possibly via small-scale piloting, will be important.

The implications of the findings for practice are that mailed invitations to FIT screening should consider including a deadline for FIT return—a 2-week deadline might offer the best option in terms of impact and acceptability of the deadlines we tested. Inclusion of a deadline could increase the number of more timely FIT returns, as well as reduce the need to issue reminder letters. Our findings suggest the planning tool evaluated in this trial should not be used in practice. It will be important to establish if the impact of a deadline is effective in other settings; for example, self-sampling for cervical screening.[28]

Our findings show the potential for low-cost or no-cost behavioural interventions to increase participation in screening and reduce deaths from colorectal cancer. This is a considerable effect for an intervention which involves only adding one sentence to the invitation letter, which can be easily implemented into routine practice. In addition, by increasing uptake in response to the initial invitation letter, fewer reminder letters will need to be sent to non-responders at 6 weeks, and the burden on primary care and public health efforts outside the screening programme to increase uptake will also be reduced, further reducing costs. More broadly, the findings show the feasibility and value of implementing randomised trials at scale within a national screening programme, which could be used as a platform for an ongoing series of trials to maximise participation. Screening policy documents should recommend an openness to research and innovation within screening programmes to ensure continued, evidence-based improvement to existing and future screening programmes.

The TEMPO Trial had some limitations. We had to exclude 266 participants because their postcode did not link to SIMD. Although only seven unusable FITs were returned with a user-attached identification label, typically 4·5% of FITs are returned unlabelled and we were unable to assess differences between groups in those returned unlabelled. The interventions were delivered as written materials mailed with the FIT and might have been of limited benefit to those with low levels of literacy or unable to read English, although they were co-designed to include clear language and illustrations.[18] We were unable to determine any interactions with ethnic background or evaluate any effect on future screening rounds. It could be anticipated that the increase in FIT return would carry forward to the next screening round as past screening behaviour is a strong predictor of future participation.[29] Although the interventions are theorised to target the intention–behaviour gap in people who have already decided to screen, rather than influence that decision, their effect on engagement with the enclosed screening information is unknown and should be assessed in future research. We reduced our follow-up period to assess the primary outcome of FIT return from 6 months to 3 months from FIT invitation. This was a pragmatic decision due to constraints on resources because of the COVID-19 pandemic, and because data from the Scottish Bowel Screening Programme show minimal returns after 3 months. The survey assessing service user acceptability had a modest response rate (15·8%); however, this is probably due to oversampling people who did not return a FIT and people from more socioeconomically deprived areas in order to maximise insight from these groups.[11] The trial was also limited to the materials included with the initial invitation letter. It is currently unknown if a deadline or planning tool might be effective if included with a reminder letter and thus more targeted at procrastinators, or with a text message, or within a different screening programme. Finally, there is the possibility that if someone misses the deadline, they might be less likely to return the FIT; however, our message was designed to minimise this situation and a routine reminder with no deadline was sent after 6 weeks.

In conclusion, including a deadline of 2 weeks for FIT return in the invitation letter resulted in more rapid FIT returns, fewer reminder letters sent, and marginally higher return rates at 3 months, compared with the standard invitation in a nationwide trial embedded in the

Scottish Bowel Screening Programme. A 2-week deadline might be the most effective, and acceptable, compared with a 1-week or 4-week deadline. The planning tool had no positive effect on FIT return. A deadline for FIT return is a highly cost-effective intervention that could be easily implemented in routine practice through adding a single sentence to the invitation letter, increasing screening uptake and preventing colorectal cancer deaths.

#### Contributors

KAR conceived both the planning tool and deadline interventions and was a principal investigator on both grants. KAR and MM designed the intervention procedures, study materials, and evaluation with input from BY, SM, REO'C, RCO'C, CM, AM, PD, GJH, and RJCS. AM conducted the sample size calculations and designed and conducted the statistical analyses with PD. KAR submitted the original application for ethical approval and MM and BY drafted and managed approval amendments. KAR drafted the manuscript incorporating revisions from all authors. AM and PD accessed and verified the data. All authors had full access to all the data in the study and had final responsibility for the decision to submit for publication. All coauthors read, revised, and approved the final manuscript.

#### Declaration of interests

We declare no competing interests.

#### Data sharing

Details of the dataset used within the study and work arising from it will be available from the Robertson Centre for Biostatistics, University of Glasgow, Glasgow, UK. Use of anonymised data within research is given for the specified project purpose, future use is permitted but would require approval from LPAC and the Caldicott Guardian. There is no requirement for a data sharing agreement with the research team and no restrictions on data sharing. Any research group can approach and request permission to use datasets from the study team. The dataset will be archived on live servers within the Robertson Centre for Biostatistics. It will be archived for 5 years after completion and then moved to offline storage.

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