BRIEF REPORT

SWAT 76 evaluation: randomised evaluation of sending pre-notification cards to trial participants before a face-to-face primary outcome measurement to increase attendance [version 1; peer review: 2 approved]

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Abstract

Background: Retention is considered the second highest trial methods priority in the UK after recruitment.

Methods: This Study Within A Trial (SWAT) evaluated whether sending a pre-notification card around one month before a face-to-face primary outcome measurement visit compared to not sending the card increased trial retention. The SWAT was a two-arm, parallel randomised (1:1 allocation ratio), stratified by centre, study. It was embedded within the ActWELL host trial, which evaluated whether women receiving lifestyle change counselling from volunteer coaches improved outcomes including weight and physical activity. The text on the card was not developed using formal behavioural change theory but did target factors thought to influence attendance.

The SWAT primary outcome was the difference in the proportion of participants attending the host trial primary outcome measurement visit. The secondary outcome was the direct cost of sending cards. Host trial participants and research staff at the primary outcome visit were blind to the SWAT. Analysis was intention-to-treat. GRADE was used the assess the certainty of evidence.

Results: 558 host trial participants took part in the SWAT and were included in the analysis. Sending a pre-notification card may result in a slight increase in attendance at a face-to-face primary outcome measurement visit: risk difference = 3.3% (95% confidence interval = -3.0% to 9.6%). This is GRADE low certainty evidence. A recording error meant it was unclear whether 17 participants allocated to the card were actually sent one but a sensitivity analysis did not change the overall result or conclusion. The direct cost of producing and sending the cards was £192 GBP (€213 EUR; $260 USD).

Discussion: Trialists could consider using pre-notification as they may

Open Peer Review

Reviewer Status ✓ ✓

	Invited Reviewers	
	1	**2**
version 1 08 Feb 2021	✓ report	✓ report

1. **Christopher Sutton**, University of Manchester, Manchester, UK
2. **Michelle E. Kho**, McMaster University, Hamilton, Canada

Any reports and responses or comments on the article can be found at the end of the article.

gain a slight increase in retention to face-to-face trial measurement visits but further evaluations are needed.

Keywords
SWAT, retention, pre-notification cards, randomised trial

This article is included in the Studies Within A Trial (SWAT) collection.

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Author roles: Treweek S: Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Gallant S**: Conceptualization, Investigation, Methodology, Project Administration, Resources, Visualization, Writing – Review & Editing; **Anderson AS**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Visualization, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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Introduction

Retention is considered the second highest trial methods priority in the UK after recruitment[1]. A recent UK study found that the median loss-to-follow-up in a sample of 151 trials was 11%[2]. Reminders are generally an effective way of increasing response rates to questionnaires and there is evidence that pre-notification (contacting participants to say that they will soon be sent a questionnaire) is beneficial, although it is not high certainty evidence[3].

There is no clear evidence from the Cochrane systematic review of trial retention interventions that pre-notification is effective for trial retention for face-to-face visits[4]. However, at the time the review was published, an ongoing Study Within A Trial (SWAT) in a trial involving women aged between 70 and 84 years at high risk of osteoporotic fractures did find that sending a newsletter to participants approximately six weeks before a trial questionnaire increased retention by around 1%[5].

SWAT question

Does sending a pre-notification card around one month before a face-to-face primary outcome measurement visit compared to not sending the card increase trial retention?

Methods

SWAT protocol

This SWAT is registered on the SWAT repository as SWAT 76. See: http://www.qub.ac.uk/sites/TheNorthernIreland-NetworkforTrialsMethodologyResearch/FileStore/Filetoupload,864300,en.pdf

Host trial

This SWAT evaluation was embedded in the ActWELL trial (ISRCTN11057518)[6]. ActWELL evaluates whether women who receive two, face-to-face lifestyle change sessions from volunteer coaches followed by up to nine telephone calls over a year, compared to no counselling, improves a range of lifestyle outcomes. The two primary outcomes were weight change and change in physical activity at 12-months. Women were invited to take part in ActWELL when they attended their routine mammography appointment (all women aged 50 - 70 in Scotland receive an offer of mammography every three years) at one of four Scottish National Health Service Breast Screening centres. A total of 560 women were randomised into the ActWELL trial.

Participants

All host trial participants were eligible.

Intervention

The intervention is a pre-notification card sent around one month before the face-to-face primary outcome measurement visit. The text on the card was not developed using formal behavioural change theory but did target factors thought to influence attendance. Women were thanked to make them feel valued, were told their data were valuable regardless of how things had gone in the trial and the number of other women in the trial was highlighted. The card was signed by the Chief Investigator of the host trial and the Chief Executive of Breast Cancer Now, the charity involved in delivering the host trial intervention. The card is shown in Figure 1.

Comparator

No pre-notification card.

Outcomes

Primary outcome: the difference in the proportion of participants attending the host trial primary outcome measurement visit (i.e., retention).

Secondary outcome: the direct cost of sending pre-notification cards.

Sample size

The sample size was determined by the host trial so no sample size calculation was done. See Trial Forge Guidance 1 for more information about SWAT sample size calculation[7].

Randomisation

Two-arm, parallel randomised with a 1:1 allocation ratio, stratified by centre. One of the authors (ST) prepared a central randomisation list for each centre for up to 150 participants using https://www.random.org/sequences/. This was then passed to the trial manager and trial administrator who sent out the pre-notification cards.

Figure 1. The ActWELL 12-month pre-notification card.

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We are really grateful to you for taking part in the study which is exploring lifestyle changes in women aged over 50. A year is a long time to commit to a study and we hope the visits, questionnaires and measurements are not too demanding. No matter what changes, if any, you may have made your contribution is valuable and we will learn a lot from your results.

The follow up call and final visit with the research nurse are every bit as important as your first visit.

ActWELL is recruiting well across our four Scottish sites and we should finish the study by the end of 2019. This will only be possible thanks to the continued co-operation and participation by yourself and other women taking part.

If you have any questions please do not hesitate to contact us.

Best wishes

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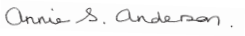

Baroness Delyth Morgan
Chief Executive
Breast Cancer Now

Figure 1. (continued)

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Blinding
Women in the host trial had no knowledge of the SWAT. Host trial primary outcome visits were organised and done by research nurses, who had no knowledge of the SWAT or host trial allocation. The SWAT primary outcome, retention, was objective.

Approvals
The study was approved by East of Scotland Research Ethics Service REC 1 as part of the host ActWELL trial (17/ES/0073). The low risk nature of the SWAT evaluation meant that individual informed consent from host trial participants to be involved was not required by the ethics committee, in line with most SWATs in the UK.

Statistical analysis
The difference in the proportion of attended visits between groups was calculated using Comprehensive Meta-Analysis Version 3 (https://www.meta-analysis.com/).

GRADE was used to assess the certainty of the evidence[8]. In addition to the numerical result, the result is summarised as an informative statement as per GRADE Guidelines 26[9].

Results
Two host trial participants withdrew before the 12-month host trial primary outcome measurement meaning 558 were included in the SWAT, which ran between March 2018 and July 2019 (Figure 2; Table 1). One host trial centre recruited 151 participants, which was beyond its recruitment target and one participant beyond the randomisation list for that centre. The extra participant was manually allocated to the comparator arm. A discrepancy between the randomisation log (which indicated who should get a card) and the host trial's tracker system (which confirmed that a card had been sent to a participant) meant that we could not confirm whether 17 participants who should have been sent the pre-notification card were actually sent one. Three further participants who should have received a card are known to have not been sent a card because the participant was called in for a host trial measurement visit before the card could be sent.

The summary statement below and the primary analysis in Table 1 are intention-to-treat as per the randomisation schedule. A sensitivity analysis done using the tracker data is also shown.

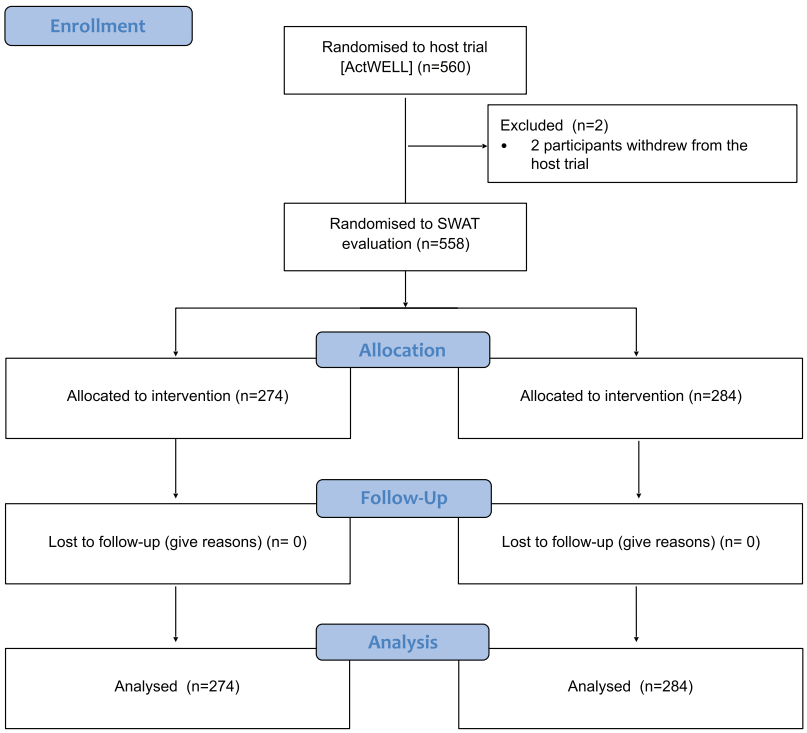

Figure 2. Flow diagram summarising the flow of participants through the SWAT evaluation.

Table 1. Attendance at the 12-month primary outcome measurement visit for those sent a pre-notification card and those not sent a card. A sensitivity analysis was done to explore the impact of a record-keeping error (see main text).

Attendance at 12-months- Intention-to-treat analysis (SWAT primary analysis)				
Allocated to be sent a pre-notification card (n=274)*		**Allocated to not be sent a notification card (n=284)**		
Attended visit	Did not attend visit	Attended visit	Did not attend visit	Risk difference (95% confidence interval)
231 (84%)	43 (16%)	230 (81%)	54 (19%)	3.3% (-3.0% to 9.6%)
*This includes three participants who were allocated to receive a card but who are known not to have been sent one.				
Attendance at 12-months- As per tracker system (sensitivity analysis)				
Tracker registers participant was sent a pre-notification card (n=254)		**Tracker registers participant was not sent a notification card (n=304)**		
Attended visit	Did not attend visit	Attended visit	Did not attend visit	Risk difference (95% confidence interval)
213 (84%)	41 (16%)	248 (82%)	56 (18%)	2.3% (-4.0% to 8.6%)
GRADE assessment				
Study limitations	No serious issues.			
Inconsistency of results	Downgrade 1 level because this is a single study (sparsity of data).			
Indirectness of evidence	No serious issues.			
Imprecision	Downgrade 1 level because confidence interval is wide and crosses risk difference of 0.			
Reporting bias	No serious issues.			

Summary statement of result: Sending a pre-notification card may result in a slight increase in attendance at a face-to-face primary outcome measurement visit. Risk difference = 3.3% (95% confidence interval = -3.0% to 9.6%). GRADE = low certainty evidence.

Direct costs

The direct costs of printing the cards was £72 GBP. Design work was extremely modest, bundled with other host trial design work and not charged separately. Second class (i.e., delivery within two days) postage costs were run through the University of Dundee mailroom at an estimated cost of £120 GBP. The total direct cost was therefore £192 GBP (€212 EUR; $259 USD).

Discussion

Sending a simple card about one month prior to a face-to-face primary outcome measurement visit may result in a slight improvement in attendance. This is GRADE low certainty evidence because there is just this single evaluation and it is imprecise.

We are not aware of other pre-notification interventions that target face-to-face trial visits. An upcoming 2021 update of the Cochrane retention review[4] found no additional pre-notification studies (ST is a co-author of this update). Mitchell and colleagues[5] added their evaluation to a meta-analysis of pre-notification evidence done outside trials and healthcare. As might be expected, there was substantial heterogeneity but the overall direction of effect was also in favour of pre-notification.

Strengths and limitations
We had a record-keeping error, which means we cannot say with confidence that all participants who should have been sent a pre-notification card were sent one. However, the number of participants affected was relatively small and our overall results and conclusion remain the same regardless of whether we analyse according to the randomisation schedule or the tracker system. There are currently only two evaluations of pre-notification in trials, our own of cards aimed at face-to-face visits and that of Mitchell and colleagues of a newsletter to increase questionnaire response[5]. This does not provide a broad range of contexts for this evidence base. Both evaluations were done in the UK and in women only.

Implications for trial practice
Trialists could consider using pre-notification as they may gain a slight increase in retention to face-to-face trial measurement visits.

Implications for SWAT research
Looking at the existing evidence and referring to Trial Forge Guidance 2 as to whether further SWATs evaluating this intervention are required[10], we conclude that more evaluations are needed because the GRADE certainty in the evidence is not high, there is only a single evaluation meaning cumulative meta-analysis cannot converge and few host trial contexts are included.

Further evaluations of pre-notification in trials could target either face-to-face or questionnaires but should aim to add new host trial contexts. Future host trials should involve men. Formal approaches to developing intervention content may increase effect sizes.

Data availability
Underlying data
Open Science Framework: SWAT 76 data for host trial ActWELL, https://doi.org/10.17605/OSF.IO/N64HU[11]

This project contains the following underlying data:

Primary analysis 8-1-2021 (public).csv

Sensitivity analysis 8-1-2021 (public).csv

Reporting guidelines
Open Science Framework: CONSORT checklist for 'SWAT 76 evaluation: randomised evaluation of sending pre-notification cards to trial participants before a face-to-face primary outcome measurement to increase attendance', https://doi.org/10.17605/OSF.IO/B78JT[12]

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Publisher Full Text

12. Treweek S: **SWAT 76 data for host trial ActWELL.** 2021, January 14.
Publisher Full Text

Open Peer Review

Current Peer Review Status: ✔ ✔

Version 1

Reviewer Report 27 April 2021

https://doi.org/10.5256/f1000research.53982.r79341

✔ **Michelle E. Kho**
School of Rehabilitation Science, McMaster University, Hamilton, ON, Canada

Treweek *et al.* conducted a study within a trial to evaluate whether a post card sent 1 month prior to an in-person primary outcome research visit improved retention within the multicentre ActWELL randomized trial of lifestyle coaching. 558 participants from the host trial were sent a pre-notification card. Of this cohort, 84% who were allocated a pre-notification card attended the primary outcome visit, compared to 81% who were not allocated a pre-notification card. This is a well-written, well-designed, and well-reported study. It will make important contributions to further understanding ways to improve retention to clinical trials. I have some considerations for the authors.

Moderate issues:

1. Results – To help the reader understand the impact on the trial, I recommend the authors first report the total number of women who attended their primary outcome follow-up visit, then report the proportion by group.

2. Results – I initially found Table 1 confusing. Since those who did not attend the visit is the complement of those who did attend a visit, I suggest reporting only those who attended the visit. The risk difference represents the difference between those who attended the visit. I also suggest adding the 95% CI around the estimates, and report 1 decimal point for consistency with the risk difference.

3. Can the authors report whether patients recalled receiving the pre-notification card before their outcomes visit?

4. Implications for trial practice – I suggest adding text to further contextualize the implications of the relative cost of this intervention, the overall investment costs in the enrolled patients to-date, and the importance of ascertaining the primary outcome. Even a 3% improvement in primary outcome ascertainment could affect trial results.

Minor issues:

1. Abstract – I suggest reporting absolute values in the intervention and control groups, then

the risk difference.

2. Introduction – I suggest adding a statement regarding the importance of the primary outcome in a trial and the need for interventions to optimize ascertainment.

3. Intervention – I suggest moving the text regarding behavioural change theory in the development of the pre-notification card from the methods to the limitations section of the manuscript.

4. Results – Data error for 17 participants (3%) – suggest also reporting % of total group to help the reader easily evaluate the small number. Interestingly, the risk difference was also 3%. The authors conducted a sensitivity analysis, and the results were similar. I suggest this is also a strength of the study.

5. Implications for trial practice. I suggest framing the study findings specific to 1-year follow-up measures.

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Critical care clinical trials; health research methodology; rehabilitation; physiotherapy

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 01 March 2021

https://doi.org/10.5256/f1000research.53982.r79342

Christopher Sutton
Centre for Biostatistics, University of Manchester, Manchester, UK

Overall, this is an excellent manuscript and an extremely welcome and useful addition to the literature on trial retention. The work provides a clear citation of the relevant literature.

The methodology is sound and the trial performed well; it has significant academic merit. There are, however, aspects of the methods and analysis which are a little under-specified and unclear, and suggestions for clarification are detailed below. Likewise, the statistical and economic analysis is appropriate, although I do suggest additional analyses and results be presented to enhance interpretation and generalisability.

The source data underlying the results are available. The conclusions are drawn adequately and supported by the results, with an appropriate sensitivity analysis performed to investigate the potential impact of some degree of failure to definitively send the pre-notification card to 20 participants allocated to receive the card.

Specific comments:

1. Introduction: clearly state that the previous SWAT of the impact of a newsletter on retention was statistically significant ($p<0.05$ … just!).

2. I would query the statement that “All trial participants were eligible.” From my perspective, the eligibility criteria were (a) Trial participant of the ActWELL trial (b) remaining in ActWELL at 1 month prior to the 12-month final follow-up.

3. The primary outcome would be better specified as a binary outcome measure (i.e. at the participant level e.g. “attendance at the host trial primary outcome measurement visit”).

4. Statistical analysis: the method of analysis should be stated, in addition to the software used.

5. In line with CONSORT 2010, for binary outcome measures both absolute and relative measures of effect are recommended. Across different trial populations, interventions, duration of follow-up etc., it is likely that there are different ‘control’ rates of retention and the impact of any intervention is probably more likely to be on a relative rather than an absolute scale. For example, the newsletter trial referenced in the Introduction (Mitchell *et al.*, (2012)) had a control group retention rate of 94.6% (and an absolute increase of 1.6% in the intervention group), compared with this trial which had a control group retention rate of 81.0% (and an absolute increase of 3.3%). It is therefore recommended that the results are also presented as a Risk Ratio (Relative Risk) or Odds Ratio.

6. I would like to see more information on the economic analysis. For example, how much did the intervention cost per participant retained?

7. In the Discussion and Strengths and Limitations, the authors state that there are no additional pre-notification studies; it would be better to stated that there are no additional *completed* pre-notification studies (there are at least two other pre-notification trials registered on the SWAT Repository Store (SWAT77 and SWAT86).

8. Reference list: references 11 and 12 re identical (Reference 12 should refer to the CONSORT checklist for this SWAT).

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Yes

Are sufficient details of methods and analysis provided to allow replication by others?
Yes

If applicable, is the statistical analysis and its interpretation appropriate?
Partly

Are all the source data underlying the results available to ensure full reproducibility?
Yes

Are the conclusions drawn adequately supported by the results?
Yes

Competing Interests: I am a Co-Investigator on the MRC-funded "Routinely embedding recruitment and retention interventions within randomised controlled trials" [PROMETHEUS] project with the lead author, Shaun Treweek.

Reviewer Expertise: Clinical trial methodology, particularly around trial conduct and retention methods.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.