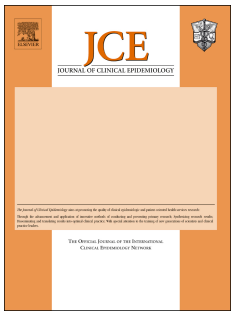

Three behaviour change theory informed randomised studies within a trial to improve response rates to trial postal questionnaires

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Abstract

Objective

Our aim was to design and evaluate a novel behaviour change approach to increase response rates to an annual postal questionnaire in three randomised Studies within a Trial (SWATs) and replicate the most promising SWAT.

Study Design and Setting

SWAT1 tested a trial logo sticker on questionnaire envelopes vs no sticker; SWAT2 tested a theoretically informed letter sent with the questionnaire versus a standard letter; SWAT3 tested a theoretically informed newsletter sent prior to the questionnaire versus no newsletter. The SWATs were conducted within a large dental trial (N=1,877 adults) and SWAT2 replicated in a different trial in a similar setting (N=2,372).

Results

SWAT1 improved response rates by 1.4%, 95% confidence interval (CI) (-7.2%, 10.0%). SWAT2 improved response rates by 7.0%, 95% CI (1.7%, 12.3%). SWAT3 improved response rates by 0.8%, 95% CI (-5.1%, 6.7%). Replication of SWAT2 as the most promising SWAT showed improvement in response rates of 1.0%, 95% CI (-3.2%, 5.3%). Pooled results from SWAT2 showed an overall improvement in response rates of 3.4%, 95% CI (0.1%, 6.7%).

Conclusion

A theory-based behavioural approach to design interventions to improve trial response rates showed small, but meaningful improvements. The approach presented here can be easily implemented and adapted to address other identified barriers to trial retention.

What is new?

Key findings

- We tested three theory-informed interventions, as studies within a trial (SWAT) with the aim of improving response rates to an annual postal questionnaire. All three interventions (SWAT 1, 2 and 3) improved questionnaire response rates compared with the control groups; only SWAT 2, comparing a theoretically informed cover letter with a standard cover letter, showed a statistically significant improvement.
- We replicated SWAT 2 in a different trial with a similar population. Meta-analysis, including both SWAT 2 studies, found evidence of a small but significant benefit of using the theoretically informed cover letter.

What this adds to what is known

- The evidence base on what works to improve retention in clinical trials is incoherent and lacks good evidence to demonstrate which strategies are likely to be more successful. We used a novel behaviour change approach to develop interventions based on theory. This approach identified potential barriers to return of a postal questionnaire which could be mapped onto a behavioural change techniques taxonomy
- A theoretically informed cover letter improved response rates significantly
- Replication of the cover letter intervention in a different trial increased strength of evidence

What is the implication, what should change now

- Using behaviour change techniques in the written communication between trial offices and trial participants to address potential barriers to return of a postal questionnaire is a robust and replicable method to improve trial retention that can be easily adapted to different settings, it is inexpensive and easy to implement.
- Trialists aiming to improve trial retention can use this theory informed, structured approach to design their interventions
- The cover letter intervention can be replicated in other trials.

1. Introduction

Randomised controlled trials (RCTs) are considered the gold-standard in the evaluation of clinical effectiveness, but poor retention rates can have an impact on the robustness of the evidence found. Missing data in RCTs is a common problem that leads to reduced statistical power and can introduce bias if the participants providing data differ from those that do not respond. Methods to minimise attrition in trials have been identified by Clinical Trial Units' directors as one of the top priorities in trial methodology (1), although research in this field has been scarce compared with other areas of trial methodology like recruitment (2).

Different strategies have been used to improve the return of a questionnaire (such as provide financial incentives, increase the number and nature of reminders, and/or revise the content covering letter), but the current evidence supporting each strategy is weak (2,3). There is no coherent evidence base to suggest how to implement specific strategies or to determine which of these strategies is more likely to be successful.

One way forward is to view the completion and return of a study questionnaire as a behaviour, the target behaviour being the patient returning the questionnaire. Developing behaviour change interventions based on theory is strongly recommended by the Medical Research Council guidelines for developing complex interventions (4), since without clear and explicit theory to describe and understand mechanisms related to behaviour, any interventions would not be generalisable. The theoretical domains framework (TDF) is a tool for identifying the theoretical factors that might help or hinder behaviours (5). The TDF collates similar constructs drawn from different psychological models into 14 theoretical domains (e.g. beliefs about consequences; knowledge). The approach has evolved to include systematic methodologies for identifying what specific behavior change techniques will overcome barriers (6).

Improving the Quality of Dentistry (IQuaD) is a trial based in the United Kingdom that used annual postal participant questionnaires to collect patient reported outcomes over 3 years. The first-year questionnaire had poor response rates. To address this, a novel behaviour change approach was designed and evaluated in three randomised studies within a trial (SWATs) (7) with the aim to increase response rates to the postal questionnaires issued in IQuaD. We also aimed to test the most promising intervention in a second trial, INTERVAL (8), and pool results from both studies.

2. Material and methods

2.1. Setting

The IQuaD trial used a split-plot design (9,10) and recruited 1,877 participants from 63 dental practices across Scotland and the North East of England from February 2012 until July 2013. IQuaD is described using the PICO framework below:

Population – Adults with good oral health that are regular attendees to the United Kingdom's National Health System primary care dental services

Interventions and Comparisons – Providing no scale & polish or 12-monthly was compared with the standard 6-monthly scale & polish. Personalised (intervention) vs standard oral hygiene advice (comparison) were also compared.

Outcome – IQuaD's primary clinical outcome was bleeding on probing (collected through clinical examination). Patient reported outcomes for the trial, including the primary patient reported outcome, a 7-point self-efficacy scale, were collected from participants via an annual postal questionnaire during a 3-year follow-up from randomisation.

The questionnaires were issued centrally by the trial office based in the Centre for Healthcare Randomised Trials (CHaRT), at the University of Aberdeen. Questionnaires were issued with a cover letter using a semi-automated process; if not returned within 3 weeks of issue of the first questionnaire, a reminder letter and second questionnaire was sent.

Replication was performed in the INTERVAL study (11), an individual randomised, parallel arm trial that randomised 2,372 participants from 50 dental practices in Scotland, England and Northern Ireland from July 2010 until July 2014. Following the PICO framework:

Population - Adults with good oral health that are regular attendees to the United Kingdom's National Health System primary care dental services

Interventions and comparison - 24-monthly or risk-based recalls (interventions) were compared with 6-monthly recall (comparison).

Outcome - The primary clinical outcome was bleeding on probing (collected through clinical examination). Patient reported outcomes for the trial, including the primary patient reported outcome, an oral health related quality of life scale (OHIP (12)), were collected from participants via an annual postal questionnaire during a 4-year follow-up from randomisation.

The questionnaires were issued central by the trial office at the University of Dundee. The same reminder system used in IQuaD was adopted in INTERVAL.

2.2. Participants

IQuaD participants were on average 48 (Standard Deviation (SD)=16) years old, 65% were female, they were regular attenders to the dentist and had overall a good oral health (9).

INTERVAL participants were also regular attenders to the dentists and with overall good oral health. They were on average 48 (SD=15) years old, 60% were female.

The three SWATs theory-informed development strategy is described below.

2.3. Intervention Development

- Stage 1: Interview of trial staff to assess their perceptions potential barriers for questionnaire response.
- Stage 2: Identification of potential modes of action using the TDF. Those were mapped onto behaviour change techniques (BCTs) that are known to (or likely to) change theoretical constructs within these domains (6). The BCTs also had to be feasible to operationalise in a letter or other printed format.
- Stage 3. Development of three interventions deliverable by mail to trial participants (by creating text or using prompts) that translate the domain targets and techniques.
- Stage 4. Validating the written content (backward translation exercise). **Supplemental tables 1-3** list the potential mode of action and behaviour change techniques used in each intervention and their operationalisation.

2.4. The studies within trials

SWAT 1: The sticker trial

Participants due to be issued the annual follow-up questionnaire at year 1 *(*March 2013 – August 2013) were randomised using simple randomisation via an automated, central randomisation service in a 1:1 participant randomised 2-arm parallel trial to receive the questionnaire either in a A4 brown opaque envelope with the IQuaD trial logo sticker added to the top left corner (intervention group) or envelope with no sticker (control group). To implement the randomisation, a random list was computer generated by an independent statistician. The sticker with the IQuaD logo, provided official credentials as well as a prompt to remind participants of the trial. SWAT 1 aimed to test if the addition of the sticker could prompt opening of the envelope and subsequently return the questionnaire. The intervention's image is presented in Appendix 1.

SWAT 2: The theory-informed letter trial

Participants receiving year 1 or year 2 follow-up questionnaires (December 2013-August 2014) were randomised via an automated, central randomisation service in a 1:1 participant randomised 2-arm parallel trial to receive either the standard cover letter (control group) or

theoretically informed letter incorporating BCTs in the text of the letter (intervention group). A centralised computerized system automatically randomised letters/newsletters using simple randomisation. By including selected BCTs in the theoretically informed cover letter, the aim was to encourage questionnaire return. SWAT 2 was replicated in the INTERVAL trial and it is freely available in the SWAT repository.

SWAT 3: The theory-informed newsletter trial

A newsletter was developed to incorporate some of the BCTs used in the theoretically informed letter in SWAT 2 (available in Appendix 2). Participants due to receive a newsletter informing them about the progress of the trial at year 2 follow-up (January 2015 – July 2015) were randomised via an automated, central randomisation service in a 1:1 participant randomised 2-arm parallel trial to receive the newsletter either 2 weeks prior to first issue of their postal questionnaire (Intervention group) or not receive a newsletter (control). Due to ethical constraints, all participants were required to receive a newsletter, so participants randomised to the control group received the newsletter after the SWAT intervention, either with a reminder (if they had not replied to the first questionnaire sent) or after return of their questionnaire to the trial office. Due to the enforced design of this SWAT, as well as testing whether the BCTs incorporated in a different format to the cover letter (ie a newsletter) encouraged return of questionnaires, we were able to test a second research question: does the timing of delivery of a newsletter affect response rates? The intervention group received the newsletter before the first questionnaires and the control group received it with the second (reminder) or after return of the first questionnaire.

2.5. Outcome

We measured response rate as returning a questionnaire within the reminder period, ie at least 6 weeks after the questionnaires were sent. For SWAT 3, response rate was measured at 3 weeks – after that, participants in the control group that had failed to reply to the first questionnaire received a newsletter.

2.6. Sample size

Samples sizes were calculated based on the number of available participants at the time of conducting each SWAT. For SWAT 1, a total of 500 participants (250 participants per arm) would allow us to detect an 11% difference in response rates between arms, assuming 65% response rate at baseline and an α of 0.05. For SWAT 2, 1100 participants would be sent annual questionnaires from 1st Jan 2014 to end July 2014. A sample of 550 per group would allow a difference of 8% (65% to 73%) to be detected with 80% statistical power at the 2-

sided 5% significance level. For SWAT 3, 1091 participants would have questionnaires sent from 1st Jan 2015 to end July 2015. A sample of 545 per group would allow a difference of 8.2% (60% to 68%) to be detected with 80% statistical power at the 2-sided 5% significance level. We assumed a lower baseline response rate of 60% for SWAT 3 because as of November 2014, 60% were returning their year 2 questionnaires.
The sample size calculation for the replication of SWAT 2 in INTERVAL was the same as the one used for the original SWAT 2 in IQuaD.

2.7. Statistical analysis

Results were analysed using an intention-to-treat framework and comparing the overall response rate in intervention and control arms for each SWAT separately. We used a two-sample test of proportions for large samples to calculate the difference of proportions confidence interval (13). We implemented this in Stata 15 using the command *prtest*.

To obtain pooled results of SWAT 2 interventions from IQuaD and INTERVAL, we have followed the Cochrane Collaboration guidance on meta-analysis which states that "Meta-analysis is the statistical combination of results from two or more separate studies." (14). Therefore, a fixed effect meta-analysis was calculated using the Mantel-Haenszel method. Analyses were done in Stata 15 (15).

2.8. Ethical approval

The East of Scotland Research Ethics Committee approved SWAT 2 on the 16th of December 2013 and its replication on the 21st of August 2015. SWAT 3 was approved by the same Committee on the 22nd of December 2014. SWAT 1 did not require any ethical approval.

3. Results

3.1. Studies within a trial results

SWAT 1: The sticker trial

Supplemental Figure 1 summarised the flow of participants in SWAT 1. In SWAT 1, 258 participants were randomised to the sticker arm and 259 to the no sticker. The addition of the IQuaD trial logo sticker did not significantly improve the response rate [51.9% vs 50.5%, difference +1.4%, 95% Confidence Interval (CI) (-7.2% to +10.0%)] (Table 1).

SWAT 2: The theory-informed letter trial

Supplemental Figure 2 summarised the flow of participants in SWAT 2. In SWAT 2, 596 participants were randomised to the intervention letter and 596 to the standard letter. The overall response rate in IQuaD for the intervention group was 72% and for the control group 65%. There was a +7.0% 95% CI (+1.7% to +12.3%) difference in the response rate between groups favouring the intervention (Table 1).

SWAT 3: The theory-informed newsletter trial

Supplemental Figure 3 summarises the flow of participants in SWAT 3. 558 participants were randomised to the intervention group and 532 to the control group. The response rate at 3 weeks was 49% vs 48% with no significant increase [difference +0.8%, 95% CI (-5.1% to +6.7%)].

The pre-notification newsletter did not significantly increase the overall response rate at 6 weeks [66.7% vs 69.4%, difference -2.7%, 95% CI (-8.2% to +2.8%), p-value=0.34], compared with sending the newsletter with reminder questionnaires.

Table 1 – Randomised studies within a trial results by randomised arm

	Response rate intervention group % (n/N)	Response rate control group % (n/N)	Proportion difference between response rates (95% Confidence interval) (%), p-value
SWAT 1 (Sticker vs no sticker)	51.9% (134/258)	50.5% (131/259)	1.4% (-7.2% to 10.0%), 0.75
SWAT 2 (Intervention letter vs usual letter)	71.8% (428/596)	64.8% (386/596)	7.0% (1.8% to 12.3%), 0.009
SWAT 3 (Newsletter vs no newsletter)	49.1% (274/558)	48.3% (257/532)	0.8% (-5.1% to 6.7%), 0.79

3.2. Replication of SWAT 2 and meta-analysis

For SWAT 2 replication, there were 957 INTERVAL participants randomised to the intervention letter and 910 to the standard letter. The response rate in INTERVAL was 67% for the intervention letter group and 66% in the standard letter group. There was a +1%

difference (95% CI -3.2% to +5.3%, p-value=0.65) between groups favouring the intervention.

Meta-analysis of the results of INTERVAL and IQuaD found a risk difference of +3.4% in favour of the intervention letter (95% CI (+0.1% to +6.7%), p-value=0.044) (Figure 1), showing a small but statistically significant benefit from the intervention letter when compared with the standard letter.

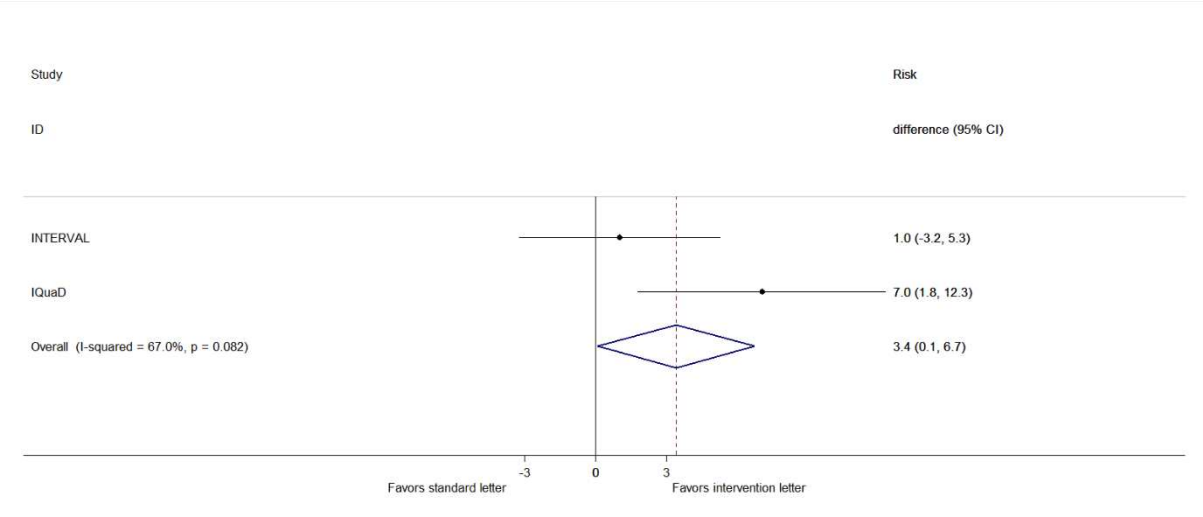

Figure 1: Meta-analysis results of standard letter versus intervention letter (SWAT 2) risk differences for patient questionnaires' response rate in IQuaD and INTERVAL represented in a forest plot

4. Discussion

We conducted three theory-informed randomised studies within a trial using a novel behaviour change approach to determine the effect on response rates to an annual postal questionnaire. All three interventions improved questionnaire response rates compared with the control groups. Only SWAT 2, comparing a theoretically informed cover letter with a standard cover letter issued with the questionnaire showed a statistically significant improvement. SWAT 2 was replicated in a different RCT recruiting participants in a similar setting. Our meta-analysis, including both studies, found evidence of a small but statistically significant benefit of using the theoretically informed cover letter.

To our knowledge, this is the first-time a theory-informed intervention using a validated behavioural framework to improve retention has been tested across multiple randomised controlled studies within a trial. This methodology provides trialists with a framework that is easily adaptable to address different barriers to trial retention. Our structured approach to intervention development aligns with the Medical Research Council guidelines (4) for developing complex interventions; we interviewed IQuaD trial team members to investigate

potential barriers and facilitators to retention and planned our interventions to address those, embedding behavioural change techniques in each intervention. Our results suggest the behaviour change techniques used addressed some of the barriers to return of questionnaires.

Barriers to return questionnaires may vary throughout a trial's lifetime. The newsletters (SWAT 3) were sent at a different follow-up time point (second year of follow-up) than the theoretically informed cover letter (SWAT 2) (mostly first year of follow-up, with a smaller number issued in year 2). We observed a difference in response to the intervention cover letter in SWAT 2 between year 1 and year 2 questionnaires (not published, information available upon request). Further research should investigate the best timing to optimise behaviour change interventions in improving trial retention.

Sample sizes in individual SWATs might not be large enough to detect small but meaningful improvements in response rates. Replication is a key element in conducting SWATs and we recommend that other researchers implement these interventions and report their results so these can be included in meta-analyses. To facilitate that process, SWAT 2 has been registered on the SWAT repository (SWAT 24; https://www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/). SWATs 1 and 3 are available as Appendices in the current paper. Researchers replicating these interventions are encouraged to use their data to start or update meta-analyses. Any improvement in response rate to follow-up postal questionnaires can be worthwhile, particularly if the changes leading to the improvement are inexpensive.

It is challenging to quantify costs and resources used in the context of running a SWAT. Even though the SWATs presented here were reasonably quick and inexpensive to implement, we have not presented costs of implementation (for example, cost opportunities of trial manager time preparing amendments for ethics approval, programmer time to set up randomisation of participants) and cost-effectiveness. We recognise that these are important factors when making decisions in a trial and this is a common limitation in SWATs across different areas (16).

Appropriate planning to prevent retention problems (instead of reacting to them) and stop/go criteria, like those considered in pilot studies, could help trialists conducting SWATs. Decisions about what interventions to select, how to take them forward, when to look at the data and whether to stop earlier in case of potential harm must happen quickly during a busy, real-life trial. Here, SWAT 3 presents an example of a challenge in which decisions had to be made within the constraints of ethical recommendations, all participants had to

receive a newsletter. As a result, we had to measure response rates in SWAT 3 earlier than expected and earlier than SWAT 1 or SWAT 2.

Trial retention is recognised as one of the most challenging and important problems in the conduct of randomised controlled trials and addressing it is a research priority for different stakeholders (2). However, research in this field is scarce with Brueton et al identifying the need to test different methods to improve retention (3). The most recent Cochrane review for strategies to improve retention found no evidence that the behavioural/motivational strategies used were either more or less effective than standard information for retaining trial participants (RR 1.08; 95% CI 0.93 to 1.24, P-value = 0.31) (273 participants; (17,18)). However, these strategies were implemented before the main trial started, as a prevention measure and without investigation of potential barriers and facilitators to retention in their contexts. We believe our behavioural approach represents a more robust strategy to improve trial retention.

Our SWAT 3 showed no evidence of a significant improvement in response rates for a pre-notification theory-informed newsletter compared with no newsletter. This contrasts with results from a previous study that reported a modest but significant improvement in response rates (1.6%) when comparing a pre-notification newsletter with no newsletter (19). However, the study targeted a different population (older women at risk of hip fracture), and the baseline response rate was already high (94.6%), making a comparison with our study challenging.

In conclusion, we have shown that using behavioural change techniques that address perceived barriers and facilitators to the return of a postal questionnaire can improve retention, but replication across similar and different settings is essential.

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Conflicts of interest / Funding Source declarations

Conflicts of interest: none.

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