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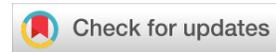
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RESEARCH ARTICLE

Using pens as an incentive for questionnaire return in an orthopaedic trial: an embedded randomised controlled retention trial [version 1; peer review: 1 approved with reservations]

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Abstract

Background: We did a ‘study within a trial’ (SWAT), evaluating the effectiveness of the inclusion of a pen with a postal questionnaire, compared to no pen being included, on the retention rate in a large orthopaedic trial.

Methods: The SWAT was embedded in the KReBS trial. The primary outcome was the proportion of 12-month questionnaires returned. Secondary outcomes were the proportion of questionnaires completed and time to questionnaire return. Binary data were analysed using logistic regression and time to return using Cox proportional hazards regression. Odds ratios (OR) and hazard ratios (HR) are presented, with associated 95% confidence intervals and p-values.

Results: In total, 2306 participants were randomised into the SWAT. In the pen group, 1020/1146 (89.0%) of participants returned a questionnaire, compared to 982/1147 (85.6%) in the no pen group. The absolute difference in questionnaire return rate was 3.4% (95% CI: 0.7% to 6.1%; p=0.01). There were statistically significant differences in questionnaire return rate (OR 1.34; 95% CI: 1.04 to 1.72; p=0.02), questionnaire completion rate (OR 1.39; 95% CI: 1.10 to 1.76; p<0.01) and time to questionnaire return (HR 1.16; 95% CI: 1.06 to 1.27; p<0.01) favouring the pen group.

Conclusion: This SWAT adds to the growing evidence base for whether pens are effective as an incentive for retention, and indicates their potential effectiveness.

Registration: KReBS trial registered on 20 February 2019, ID [ISRCTN87127065](https://doi.org/10.1186/1745-6216-10-10); SWAT registered on 1 April 2019, ID [SWAT92](https://doi.org/10.1186/1745-6216-10-10).

Keywords

SWAT, Study Within A Trial, attrition, follow-up

Open Peer Review

Reviewer Status ?

	Invited Reviewers
	1
version 1 04 May 2020	? report

1 **Frances Shiely** , University College Cork, Cork, Ireland

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

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Author roles: **Mitchell A:** Data Curation, Formal Analysis, Software, Writing – Original Draft Preparation, Writing – Review & Editing; **Cook L:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing; **Dean A:** Investigation, Project Administration, Resources, Writing – Review & Editing; **Fairhurst C:** Conceptualization, Data Curation, Formal Analysis, Investigation, Methodology, Software, Validation, Visualization, Writing – Review & Editing; **Northgraves M:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing; **Torgerson DJ:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Supervision, Writing – Review & Editing; **Reed M:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Introduction

Recruitment and retention of participants have been identified as serious issues for randomised controlled trials (RCTs)^{1,2}.

Incentives, both monetary and non-monetary, are used by UK clinical trials units as part of recruitment and retention strategies³. In particular, the use of pens has recently been evaluated as a non-monetary incentive for recruitment⁴, while in 2016, Bell *et al.* assessed whether pens were effective in improving retention⁵. The study by Bell and colleagues indicated that the inclusion of a pen with postal follow-up questionnaires may increase return rates; however, the authors stated that the results are uncertain and that further research is needed.

In response to this uncertainty, we did a 'study within a trial' (SWAT) evaluating the effectiveness of the inclusion of a pen with a postal questionnaire, compared to no pen being included, on the retention rate in a large orthopaedic trial.

Methods

Design

This paper details the methods and results of a SWAT embedded within the prospectively registered KReBS RCT (ISRCTN87127065). KReBS evaluated the effectiveness of a two-layer compression bandage compared with a standard wool and crepe bandage applied post-operatively on patient-reported outcomes in total knee replacement patients⁶.

Participants

The SWAT was conducted in 26 NHS hospital trust sites and was implemented after the start of KReBS follow-up. All KReBS participants were eligible for this SWAT provided they were not deceased or withdrawn from follow-up before being due to be sent their 12-month follow-up postal questionnaire.

Intervention

Participants in the SWAT intervention group received a pen (branded with the York Trials Unit and University of York logos) with their 12-month questionnaire. All SWAT participants received pre-planned retention strategies within KReBS.

Outcomes

The primary outcome was the proportion of participants who returned a 12-month questionnaire. Secondary outcomes were proportion of participants who completed the questionnaire and time to questionnaire return. A questionnaire was considered complete if the participant had answered 11 or more questions of the 12-item host trial primary outcome, the Oxford Knee Score⁷.

Sample size

Since this was an embedded trial, the sample size was determined by the number of participants in the main KReBS trial⁶, which aimed to recruit 2600 participants.

Randomisation

Participants were randomised into the SWAT in two batches, using a 1:1 allocation ratio, in a single large block the size of the

batch. The allocation schedule for each batch was generated by a statistician at York Trials Unit using Stata v15⁸.

Blinding

Participants were not informed of their explicit participation in the SWAT, but due to the nature of the intervention could not be blinded to receipt (or not) of a pen with their questionnaire. Similarly, it was not possible to blind research staff to SWAT allocation.

Approvals

The SWAT was incorporated into the host trial protocol and approved as part of Substantial Amendment 2 by the Research Ethics Committee North East – Newcastle and North Tyneside on 13/04/2018. As the SWAT was deemed to be low risk, and to avoid disappointment for participants who did not receive the additional incentive, informed consent was not obtained for participation in this SWAT.

Statistical analysis

Analyses were carried out using Stata v16.0⁹. A diagram detailing the flow of participants through the SWAT is provided, and baseline characteristics are presented by SWAT allocation. Outcomes are summarised descriptively. Statistical tests were two-sided, used a 5% significance level, and were done on an intention to treat basis. All analyses (except the calculation of the absolute difference in return rate) used mixed effects, adjusting for SWAT allocation and host trial allocation as fixed effects and trial site as a random effect. The absolute difference in return rates was estimated using the two-sample test of proportions. Relevant parameter estimates are presented with associated 95% confidence intervals (CI) and p-values.

The proportion of participants who returned a 12-month questionnaire was analysed using logistic regression. Questionnaire completion was analysed in the same manner.

Time to questionnaire return was analysed using a Cox proportional hazards shared frailty model. Participants who did not return a questionnaire were censored at 90 days.

Results

In total, 2335 participants were recruited into the KReBS trial and 2306 were randomised into the SWAT (Figure 1). The average age was 69.0 years and 55.2% were female (Table 1). A further 15 participants died or withdrew following randomisation and as a result, 1146 participants in the pen group, and 1147 in the no pen group, were sent a 12-month questionnaire and were included in the analysis.

In the pen group, 1020 (89.0%) of participants returned a questionnaire, compared to 982 (85.6%) in the no pen group (Table 2). The absolute difference in return rate was 3.4% (95% CI: 0.7% to 6.1%; p=0.01). There was a statistically significant difference between the groups in the likelihood of returning a questionnaire (OR 1.35; 95% CI: 1.05 to 1.73; p=0.02), and also in the likelihood of returning a complete questionnaire (OR 1.39; 95% CI: 1.10 to 1.76; p<0.01). In addition, there was evidence of a reduction

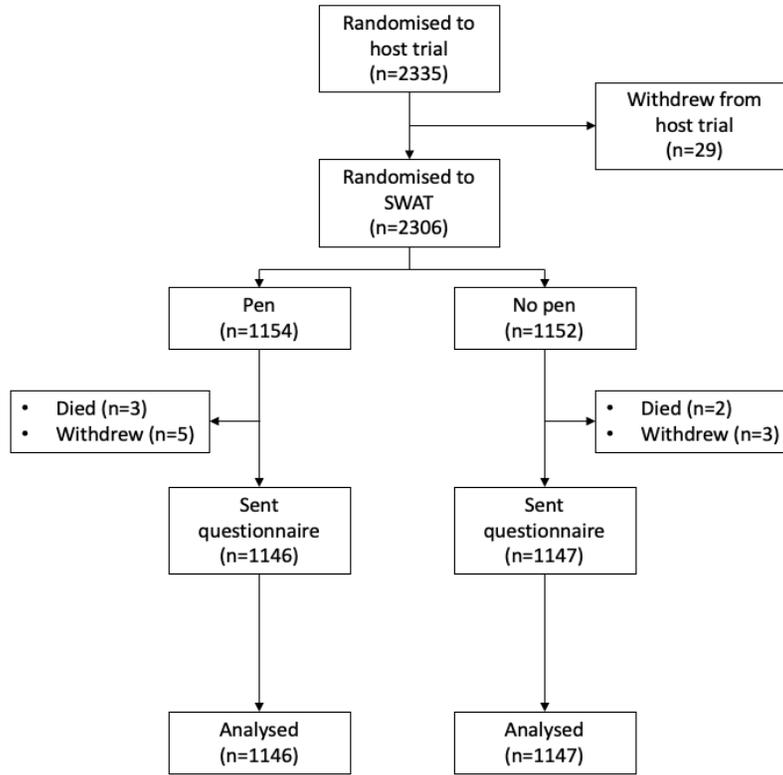


Figure 1. Study flow diagram.

Table 1. Baseline characteristics of the SWAT participants.

Variable	Pen (n=1154)	No pen (n=1152)	Total (n=2306)
Gender, n (%)			
Male	510 (44.2)	519 (45.1)	1029 (44.6)
Female	642 (55.6)	630 (54.6)	1272 (55.2)
Missing	2 (0.2)	3 (0.3)	5 (0.2)
Age			
n (%)	1152 (99.8)	1149 (99.7)	2301 (99.8)
Mean (SD)	68.8 (8.8)	69.2 (9.0)	69.0 (8.9)
Median (IQR)	69.1 (62.8, 74.9)	69.6 (62.7, 75.5)	69.3 (62.7, 75.3)
Oxford Knee Score			
n (%)	917 (79.5)	953 (82.7)	1870 (81.1)
Mean (SD)	20.2 (7.8)	20.2 (7.9)	20.2 (7.8)
Median (IQR)	20 (15, 25)	20 (14, 26)	20 (14, 25)

Table 2. Descriptive summaries of primary and secondary outcomes.

Variable	Pen (n=1146)	No pen (n=1147)	Total (n=2293)
Returned questionnaire, n (%)			
Yes	1020 (89.0)	982 (85.6)	2002 (87.3)
No	126 (11.0)	165 (14.4)	291 (12.7)
Completed questionnaire, n (%)			
Yes	1005 (87.7)	958 (83.5)	1963 (85.6)
No	141 (12.3)	189 (16.5)	330 (14.4)
Time to return, days			
n (%)	1020 (100)	982 (100)	2002 (100)
Mean (SD)	16.0 (18.0)	17.6 (19.7)	16.8 (18.8)
Median (IQR)	10 (7, 15)	11 (8, 19)	10 (8, 17)

in time to return in favour of the pen group (HR 1.16; 95% CI: 1.06 to 1.27; $p < 0.01$). See *Underlying data* for full, individual-level data¹⁰.

Discussion

There is strong evidence that the use of a pen as a non-monetary incentive in the KReBS trial increased the proportion of questionnaires returned and completed, and also decreased

the time to return. The decrease in time to return provides support to the findings of Bell *et al.*⁵. However, completion rate was calculated as a proportion of all SWAT participants rather than all SWAT participants who returned a questionnaire, and as a result questionnaire completion was highly correlated with questionnaire return. On the other hand, the large sample size of this SWAT means the results can be generalised to other orthopaedic trials.

Conclusion

This SWAT adds to the growing evidence base for whether pens are effective as an incentive for retention and indicates their potential effectiveness.

Data availability

Underlying data

Open Science Framework: Underlying data and CONSORT checklist for Using pens as an incentive for questionnaire return in an orthopaedic trial: an embedded randomised controlled retention trial. <https://doi.org/10.17605/OSF.IO/BEPN3>¹⁰.

This project contains the underlying data in CSV, SAS and V8XPT formats, alongside a data key.

Reporting guidelines

Open Science Framework: CONSORT checklist for ‘Using pens as an incentive for questionnaire return in an orthopaedic trial: an embedded randomised controlled retention trial’. <https://doi.org/10.17605/OSF.IO/BEPN3>¹⁰.

Data are available under the terms of the [Creative Commons Zero “No rights reserved” data waiver](#) (CC0 1.0 Public domain dedication).

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Open Peer Review

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Version 1

Reviewer Report 07 May 2020

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Frances Shiely

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Article Summary

This was a SWAT within the KReBS trial. The purpose of the SWAT was to evaluate the effectiveness of the inclusion of a pen with a postal questionnaire, compared to no pen being included, on the retention rate in a large orthopaedic trial. The authors conclude that pens are potentially effective as an incentive for retention.

Abstract

The background section needs to be amended as your SWAT did not evaluate retention in clinical trials. Likewise, the conclusion is not supported. Please see the comments on the conclusion section below.

Introduction Section

In the introduction section, you mention the Bell *et al.* study and state that the authors say the results are uncertain, and in response to this you conducted your study. However, say what the reason for the uncertainty is. It would be helpful to give support to the necessity for your research study to include the shortcomings of Bell *et al.* Please amend.

Methods Section

Intervention

All SWAT participants received pre-planned retention strategies within KReBS. This sentence is left hanging there with no further explanation. What were these retention strategies? When you say all SWAT participants received these retention strategies, do you mean the SWAT comparator group also? IF so, why is this sentence under the "intervention" heading? It implies that you are speaking about the intervention group only. Perhaps you'd be better saying both SWAT intervention and SWAT comparator groups received pre-planned retention strategies if that is what you meant. Please qualify.

Outcomes

I question the selection of the secondary outcome, the proportion of participants who completed the questionnaire. In reality, if someone begins, whether it's the York CTU pen or their own, what does the supply of the York pen have to do with the completion of the questionnaire?

You then go on in your results to state that questionnaire completion was highly correlated with

questionnaire return. How useful is this measure then? I would like to see the questionnaire completion rate removed as a focus of this SWAT. It additionally detracts from your main findings.

Randomisation

What do you mean by two batches, and why were there two batches?

Conclusion

Your conclusion is not supported by your results. Your conclusion should be that pens are effective as an incentive for returning questionnaires in postal studies, and also effective at increasing the time to return. You did not measure retention, as this was a postal questionnaire and not a follow-up of the patients at the centre. It's a stretch to extrapolate that filling out a questionnaire and returning it is a measure of retention in a clinical trial. I would be interested to know how many of those that received the pen return to the CTU for the main trial for their next appointment. Please modify your conclusions.

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

Partly

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?

Partly

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

Partly

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

No source data required

Are the conclusions drawn adequately supported by the results?

No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: clinical trial methodology

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, however I have significant reservations, as outlined above.

Author Response 26 May 2020

Alex Mitchell, University of York, UK, York, UK

We would like to thank the reviewer for the helpful comments and the interest shown in our paper. We hope that our responses are satisfactory. Please note that we will update the article in response to the points raised after we have received comments from additional reviewers.

The background section needs to be amended as your SWAT did not evaluate retention in

clinical trials. Likewise, the conclusion is not supported. Please see the comments on the conclusion section below.

Please see the response to your final point.

In the introduction section, you mention the Bell et al. study and state that the authors say the results are uncertain, and in response to this you conducted your study. However, say what the reason for the uncertainty is. It would be helpful to give support to the necessity for your research study to include the shortcomings of Bell et al. Please amend.

The results from Bell et al. were uncertain in that the primary outcome of questionnaire return was of borderline statistical significance, and the authors indicated that research across a range of participant groups was required.

All SWAT participants received pre-planned retention strategies within KReBS. This sentence is left hanging there with no further explanation. What were these retention strategies? When you say all SWAT participants received these retention strategies, do you mean the SWAT comparator group also? IF so, why is this sentence under the “intervention” heading? It implies that you are speaking about the intervention group only. Perhaps you’d be better saying both SWAT intervention and SWAT comparator groups received pre-planned retention strategies if that is what you meant. Please qualify.

Thank you for making this point. We can confirm that SWAT participants in both the intervention and comparator groups received pre-planned retention strategies. Participants were sent a reminder letter and a further copy of the questionnaire if they had not returned a completed copy 4 weeks after sending. If there was still no response following the postal reminder, participants were contacted by telephone to obtain the patient reported outcomes.

I question the selection of the secondary outcome, the proportion of participants who completed the questionnaire. In reality, if someone begins, whether it’s the York CTU pen or their own, what does the supply of the York pen have to do with the completion of the questionnaire?

You then go on in your results to state that questionnaire completion was highly correlated with questionnaire return. How useful is this measure then? I would like to see the questionnaire completion rate removed as a focus of this SWAT. It additionally detracts from your main findings.

We accept your point that the theory of how the inclusion of a pen influences completion rates is not immediately obvious. If a participant were to use their own pen, they may have had to spend some time trying to find one. This may lead to the participant becoming frustrated with the questionnaire, and thus decrease the probability of them completing it correctly. We hoped that by including a pen with the questionnaire, we would make the process easier for the participant.

We disagree that the completion rate should be removed as an outcome as this was pre-specified in the published KReBS protocol. While we agree with your point on its limitations, we have already outlined these in the discussion section, and believe this is a more scientifically sound approach than removing it from the paper.

What do you mean by two batches, and why were there two batches?

This SWAT was embedded at the 12 month time point and was only intended to include participants who had not died or expressly withdrawn from data collection up to this point. It was not logistically feasible to randomise participants in real time just before they were sent the questionnaire, and yet by randomising participants into the SWAT too early we risked participants withdrawing from the trial before they were sent the 12 month questionnaire. We balanced minimising the time between randomisation into the SWAT and being sent the questionnaire, and the resources required to randomise participants, by choosing to randomise two large sets ('batches') of participants. Shortly before the first participant was due to be sent their 12 month questionnaire we randomised participants into the SWAT (i.e. the study statistician was sent a list of participant ids to allocate to receive a pen or not), then any remaining participants were included in the second batch later on.

Your conclusion is not supported by your results. Your conclusion should be that pens are effective as an incentive for returning questionnaires in postal studies, and also effective at increasing the time to return. You did not measure retention, as this was a postal questionnaire and not a follow-up of the patients at the centre. It's a stretch to extrapolate that filling out a questionnaire and returning it is a measure of retention in a clinical trial. I would be interested to know how many of those that received the pen return to the CTU for the main trial for their next appointment. Please modify your conclusions.

Thank you for this comment, however we think we are justified in retaining use of the term 'retention' in the context of this trial. There were no clinic or YFU follow up appointments in the KReBS trial; it exclusively used postal follow up questionnaire to obtain outcome data. The primary outcome in KReBS was the participant reported Oxford Knee Score collected at 12 months.

Therefore, we used a broader definition of retention i.e. the return of outcome data via any means.

We believe this blog post by Shaun Treweek and Katie Gillies shows that this is in line with the definition of retention used in the SWAT community (

<https://blogs.biomedcentral.com/on-medicine/2017/09/01/trial-retention-its-time-for-cinderella-to-go-to->).

Competing Interests: No competing interests were disclosed.

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