

#### **RESEARCH ARTICLE**

# An embedded randomised controlled retention trial of personalised text messages compared to non-personalised text messages in an orthopaedic setting [version 2; peer review: 2 approved]

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#### **Abstract**

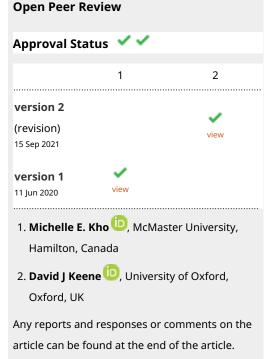
**Background:** Several studies have investigated whether personalising trial documentation can aid recruitment and retention. We did a 'study within a trial' (SWAT) evaluating the effectiveness of a personalised text message compared to a non-personalised text message, on the retention rate in a large orthopaedic trial.

**Methods:** The SWAT was embedded in the Knee Replacement Bandaging Study (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 (CI) and p-values.

**Results:** In total, 1465 participants were included in the SWAT. In the personalised group, 644/723 (89.1%) of participants returned a questionnaire, compared to 654/742 (88.1%) in the non-personalised group. The absolute difference in return rate was 0.9% (95% CI: -2.3% to 4.2%; p=0.57). There was no evidence of a difference between the groups in the likelihood of returning a questionnaire (OR 1.09; 95% CI: 0.79 to 1.51; p=0.61), the likelihood of returning a complete questionnaire (OR 1.11; 95% CI: 0.82 to 1.51; p=0.50) nor in time to return (HR 1.05; 95% CI: 0.94 to 1.17; p=0.40).

**Conclusion:** This SWAT adds to the growing evidence base for whether personalised text messages are effective.

**Registration:** ISRCTN87127065 (20/02/2017); SWAT 35 (01/12/2015)



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#### **Keywords**

SWAT, Study Within A Trial, attrition, SMS, text messages



This article is included in the Studies Within A

Trial (SWAT) collection.

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Author roles: Mitchell AS: 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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## **REVISED** Amendments from Version 1

We have added additional detail to the article in response to the issues raised by the reviewer. We have outlined how the validity of the phone numbers was checked at two different stages, and also provided detail on the pre-planned retention strategies.

We have also made a minor amendment to the results in light of a duplicate randomisation that was found in the host trial, which means that 2334 rather than 2335 participants were randomised to the host trial. This duplicate randomisation was not randomised to the SWAT and therefore has no other impact on the results. We have updated the figure to take this change into account

Any further responses from the reviewers can be found at the end of the article

#### Introduction

Clinical trialists have identified the recruitment and retention of participants as key issues for randomised controlled trials (RCT)<sup>1,2</sup>.

Several studies have investigated whether personalising trial documentation can aid recruitment and retention<sup>3,4</sup>. Recently, Cochrane *et al.* looked at the effect of personalised text messages compared to standard text messages in improving retention rates<sup>5</sup>. This study was carried out in response to a number of embedded trials evaluating the effectiveness of SMS messages in improving retention rates<sup>6–11</sup>, alongside a study suggesting personalised messages increased the payment of delinquent fines<sup>12</sup>.

To further add to the evidence on the effectiveness of personalised text messages, we did a 'study within a trial' (SWAT) evaluating the effectiveness of a personalised text message compared to a non-personalised text message on postal questionnaire response rates in a large orthopaedic trial.

#### Methods

#### Design

This paper details the methods and results of a SWAT embedded within the prospectively registered Knee Replacement Bandaging Study (KReBS) RCT (ISRCTN87127065, registered on 20 February 2017). 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 patients<sup>13</sup>.

#### **Participants**

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

#### Intervention

Participants in the SWAT were sent either a personalised or non-personalised text message (Table 1) four days after their 12-month questionnaire was sent.

The validity of the phone number given by participants was checked at two different stages. At the first stage, after randomisation, invalid numbers not beginning with "07", which are the first two digits of all UK mobile phone numbers were removed from the database, participants providing numbers such as these were not sent a text message. The second stage occurred at the point of the text messages being sent out. Some participants provided phone numbers that began with "07", but were actually invalid and therefore not picked up at the first stage. An attempt to send a text message to the phone number would have resulted in a failure in the message being delivered.

All SWAT participants received pre-planned retention strategies within KReBS. This consisted of a reminder letter and additional copy of the questionnaire if the participant had not returned a completed copy 4 weeks after sending out the original copy. If there was still no response following the postal reminder, participants were contacted by telephone to obtain the patient-reported outcomes.

#### Outcomes

The primary outcome was the proportion of participants who returned a 12-month questionnaire. Secondary outcomes were the 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 Score<sup>14</sup>.

#### Sample size

Since this was an embedded trial, the sample size was determined by the number of participants in the main KReBS trial<sup>13</sup>, which aimed to recruit 2600 participants.

Table 1. Description of the contents of the personalised and non-personalised text messages.

Text message type	Text message content
Personalised	"KReBS Trial: [ <i>Title</i> ] [ <i>Surname</i> ] you should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks"
Non-personalised	"KReBS Trial: You should have received a questionnaire in the post by now. Your answers are important; so please help by returning it as soon as you can. Thanks"

KReBS - Knee Replacement Bandaging Study

#### Randomisation

Participants were randomised into the SWAT using simple randomisation in a 1:1 allocation ratio. The allocation schedule was generated by a researcher at the York Trials Unit not involved in the recruitment or follow-up of participants.

#### 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 whether the text was personalised or non-personalised. Similarly, it was not possible to blind research staff to SWAT allocation.

#### **Approvals**

The SWAT was approved by the Research Ethics Committee North East – Newcastle and North Tyneside on 13/04/2018 (REC Number 16/NE/0400; Amendment Number 16/NE/0400/AM14). As the SWAT was deemed to be low risk, explicit informed consent was not obtained for participation.

#### Statistical analysis

Analyses were carried out using Stata v16.0<sup>15</sup>. 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 using 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 which was estimated using the two-sample test of proportions) used mixed effects regression, adjusting for SWAT allocation and host trial allocation as fixed effects and trial site as a random effect. Relevant parameter estimates are presented with associated 95% confidence intervals and p-values.

The proportion of participants who returned a 12-month questionnaire, and proportion complete, was analysed using logistic regression. A second SWAT evaluating receipt of a pen on response rates was also embedded in KReBS at 12 months<sup>16</sup>. In a sensitivity analysis, we additionally adjusted the primary model for pen SWAT allocation.

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, 2334 participants were recruited into the KReBS trial and 1470 were randomised to the SWAT (Figure 1). The average

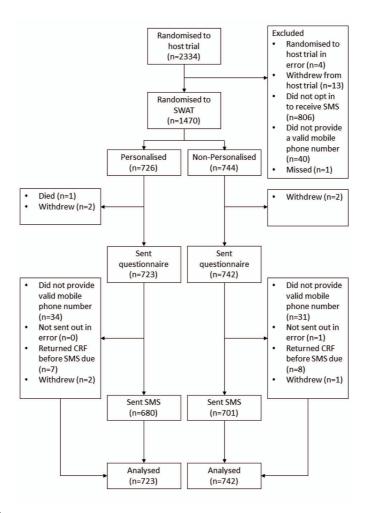


Figure 1. Study flow diagram.

age was 66.8 years and 54.0% were female (Table 2<sup>17</sup>). Five participants died or withdrew following randomisation and as a result 723 participants in the personalised group, and 742 in the non-personalised group, were sent a 12-month questionnaire and were included in the analysis. Of these, 680 (94.1%) of the 723 participants in the personalised group, and 701 (94.5%) of the 742 in the non-personalised group, were sent a text.

In the personalised group, 644/723 (89.1%) participants returned a questionnaire, compared to 654/742 (88.1%) in the non-personalised group (Table 3<sup>17</sup>). The absolute difference in return rate was 0.9% (95% CI: -2.3% to 4.2%; p=0.57). There was no evidence of a difference between the groups in the likelihood of returning a questionnaire (OR 1.09; 95% CI: 0.79 to 1.51; p=0.61), the likelihood of returning a complete questionnaire (OR 1.11; 95% CI: 0.82 to 1.51; p=0.50) nor in time to return (HR 1.05; 95% CI: 0.94 to 1.17; p=0.40). In total, 1465 participants were also randomised to the pen SWAT.

When the primary model was repeated with the addition of pen SWAT allocation, the results remained the same.

#### Discussion

This embedded trial found little evidence to suggest personalised text messages are more effective than non-personalised text messages in encouraging return and completion of questionnaires. The trial did not find evidence of a statistically significant difference between groups in any of the outcomes, although effect size estimates favoured the personalised group. On the other hand, while Cochrane and colleagues also did not find evidence of a statistically significant difference between groups, estimates of effect mostly favoured the non-personalised group.

The SWAT had a large sample size, which means the results can be generalised to other orthopaedic studies. However, completion rate was calculated as a proportion of all SWAT participants rather than all SWAT participants who returned

Table 2. Baseline characteristics of the study within a trial (SWAT) participants.

	Personalised (n=726)	Non-personalised (n=744)	Total (n=1470)
Gender, n (%)			
Male	335 (46.1)	340 (45.7)	675 (45.9)
Female	391 (53.9)	403 (54.2)	794 (54.0)
Missing	0 (0)	1 (0.1)	1 (0.1)
Age			
n (%)	726 (100)	743 (99.9)	1469 (99.9)
Mean (SD)	66.9 (8.5)	66.8 (8.5)	66.8 (8.5)
Median (IQR)	67.2 (60.7, 72.9)	67.0 (60.8, 72.4)	67.1 (60.8, 72.7)
Oxford Knee Score			
n (%)	576 (79.3)	582 (78.2)	1158 (78.8)
Mean (SD)	20.4 (8.0)	20.5 (8.0)	20.4 (8.0)
Median (IQR)	20 (14, 26)	20 (15, 26)	20 (15, 26)

Table 3. Descriptive summaries of primary and secondary outcomes.

	Personalised (n=723)	Non-personalised (n=742)	Total (n=1465)
Returned questionnaire, n (%)			
Yes	644 (89.1)	654 (88.1)	1298 (88.6)
No	79 (10.9)	88 (11.9)	167 (11.4)
Completed questionnaire, n (%)			
Yes	634 (87.7)	641 (86.4)	1275 (87.0)
No	89 (12.3)	101 (13.6)	190 (13.0)
Time to return, days			
n (%)	644 (100)	654 (100)	1298 (100)
Mean (SD)	15.9 (15.0)	17.0 (20.4)	16.5 (17.9)
Median (IQR)	10 (8, 16)	10 (8, 16)	10 (8, 16)

a questionnaire, and as a result questionnaire completion was highly correlated with questionnaire return. In addition, some participants included in the analysis did not receive a text message.

#### Conclusion

This SWAT adds to the growing evidence base for whether personalised trial documentation, in particular text messages, are effective.

#### **Data availability**

#### Underlying data

Open Science Framework: Underlying data and CONSORT diagram for an embedded randomised controlled retention trial of personalised text messages compared to non-personalised text messages in an orthopaedic setting. https://doi.org/10.17605/OSF.IO/KHJ8E<sup>17</sup>

This project contains the following underlying data:

- KReBS\_Text\_SWAT\_Clean.sas (Study data in SAS compatible format)
- KReBS\_Text\_SWAT\_Clean.csv (Study data in .csv format)
- KReBS\_Text\_SWAT\_Clean\_Key.xlsx (Key for datasets)

#### Reporting guidelines

Open Science Framework: CONSORT checklist for 'An embedded randomised controlled retention trial of personalised text messages compared to non-personalised text messages in an orthopaedic setting' https://doi.org/10.17605/OSF.IO/KHJ8E<sup>17</sup>

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**

# **Current Peer Review Status:**







Reviewer Report 10 May 2022

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# David J Keene 🗓

University of Oxford, Oxford, UK

Thank you for the invitation to review this interesting SWAT report. I note the other peer reviewers comments and responses. Overall this concise summary documents a well-designed and conducted SWAT. The authors are to be commended given the delivery was within a large and complex clinical trial.

My recommendations to improve the manuscript are as follows:

Abstract – the context of the intervention, a 'personalised text message', was not clear in isolation in the abstract, i.e. it was sent 4 day after sending a 12-month postal questionnaire to prompt completion.

#### Methods

The details of the KReBS trial are signposted but it would be helpful to have more background for the reader e.g. country, dates of conduct, main eligibility criteria for the main trial.

For the intervention, stating the aim of the personalised message would aid clarity, it appears to be a prompt rather than a reminder but would be good to be explicit about this.

Randomisation – how was the allocation schedule generated, computer programme?

The statistical approaches seem reasonable but this is not my area of expertise.

#### Discussion

Some interpretation of the results in the context of other trials that have used personalised vs non-personalised text messages for first time postal questionnaire completion would be informative. Other SWATs have looked at personalisation as a reminder SMS after no postal return rather than a proactive prompt. Differences in host trials may also be important, there were good

response levels in this host trial overall.

The 95% CI includes a small negative to positive effect on response rate (-2.3% to 4.2%). Would the authors see value of further SWATs to enable meta-analysis and improve precision in the estimates? With a low cost and simple intervention such as this, a marginal difference could be considered valuable.

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?

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

If applicable, is the statistical analysis and its interpretation appropriate? I cannot comment. A qualified statistician is required.

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:** Trauma, Orthopaedic and Rehabilitation Clinical Trials

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.

## **Version 1**

Reviewer Report 03 July 2020

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Michelle E. Kho 🗓

School of Rehabilitation Science, McMaster University, Hamilton, ON, Canada

Mitchell et al. elegantly describe a SWAT of personalized vs. non-personalized reminder text messages embedded in a randomized orthopaedic trial. The primary outcome was questionnaire return at 12 months, and the secondary outcomes were proportion of completed questionnaires, and time to questionnaire return. There was no difference in any outcome between groups.

#### Minor issues:

- 1. There is a large body of evidence outlining strategies to improve return rates of postal questionnaires<sup>1</sup>. The primary outcome in this study, questionnaire return at 12 months, could be confounded by the host trial efforts to improve postal questionnaire return. Can the authors report more information on the host trial efforts to optimize postal questionnaire return?
- 2. The questionnaire return rates for this subgroup of host trial participants was very high (~89%). Can the authors report the questionnaire return rates for the 809 people in the host trial who were not included in the SWAT, or if this is not available, the overall questionnaire return rate for the host trial?
- 3. In Figure 1, can you please clarify the difference between those excluded in the first box for "did not provide a valid mobile phone number" and those who were sent a questionnaire and "did not provide a valid phone number"?

#### References

1. Edwards PJ, Roberts I, Clarke MJ, Diguiseppi C, et al.: Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev.* 2009. MR000008 PubMed Abstract | Publisher Full Text

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?

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

Are all the source data underlying the results available to ensure full reproducibility?  $\mbox{\em Yes}$ 

Are the conclusions drawn adequately supported by the results?  $\ensuremath{\mathsf{Yes}}$ 

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Research methodology, trial design and reporting

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.

Author Response 31 Aug 2021

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

We thank the reviewer for her positive feedback and constructive comments, to which we have responded below. In addition to responding to the comments, we have made a minor amendment to the results of the paper, as since publication a duplicate randomisation was found, and therefore 2334 participants were randomised to the host trial, not 2335. This does not impact the results of the SWAT, as the duplicate randomisation was not given an allocation in the SWAT.

There is a large body of evidence outlining strategies to improve return rates of postal questionnaires1. The primary outcome in this study, questionnaire return at 12 months, could be confounded by the host trial efforts to improve postal questionnaire return. Can the authors report more information on the host trial efforts to optimize postal questionnaire return?

Thank you, we have added text under the Intervention section of the paper, describing the strategies used in the host trial to optimise questionnaire return.

The questionnaire return rates for this subgroup of host trial participants was very high (~89%). Can the authors report the questionnaire return rates for the 809 people in the host trial who were not included in the SWAT, or if this is not available, the overall questionnaire return rate for the host trial?

In total, 864 participants were not randomised to the SWAT. This number consists of the 806 who did not opt-in to receive SMS, and the 58 who had either withdrawn, did not provide a valid mobile phone number or were missed. Of these 864, 827 had not withdrawn by the 12-month time point and were sent a questionnaire. 704 returned the questionnaire, which corresponds to a response rate of 85.1%. This is slightly lower than the response rate observed in the SWAT, which may be due to participants who didn't opt-in to receive SMS or didn't provide a valid mobile phone number being less engaged with the study. Due to this being a post-hoc analysis, we have decided not to include this result in the publication.

In Figure 1, can you please clarify the difference between those excluded in the first box for "did not provide a valid mobile phone number" and those who were sent a questionnaire and "did not provide a valid phone number"?

We have added text describing the two stages of mobile phone number verification in the Intervention section of the paper.

**Competing Interests:** No competing interests were disclosed.

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