RESEARCH ARTICLE

An embedded randomised controlled retention trial of personalised text messages compared to non-personalised text messages in an orthopaedic setting [version 1; peer review: 1 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)

Keywords

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

Open Peer Review

Reviewer Status ✓

	Invited Reviewers
	1
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Any reports and responses or comments on the article can be found at the end of the article.

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Introduction

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

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

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[13].

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.

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[14].

Sample size

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

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[15]. 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

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

Text message type	Text message content
Personalised	"KReBS Trial: [*Title*] [*Surname*] 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

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[16]. 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, 2335 participants were recruited into the KReBS trial and 1470 were randomised to the SWAT (Figure 1). The average age was 66.8 years and 54.0% were female (Table 2[17]). 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[17]). 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

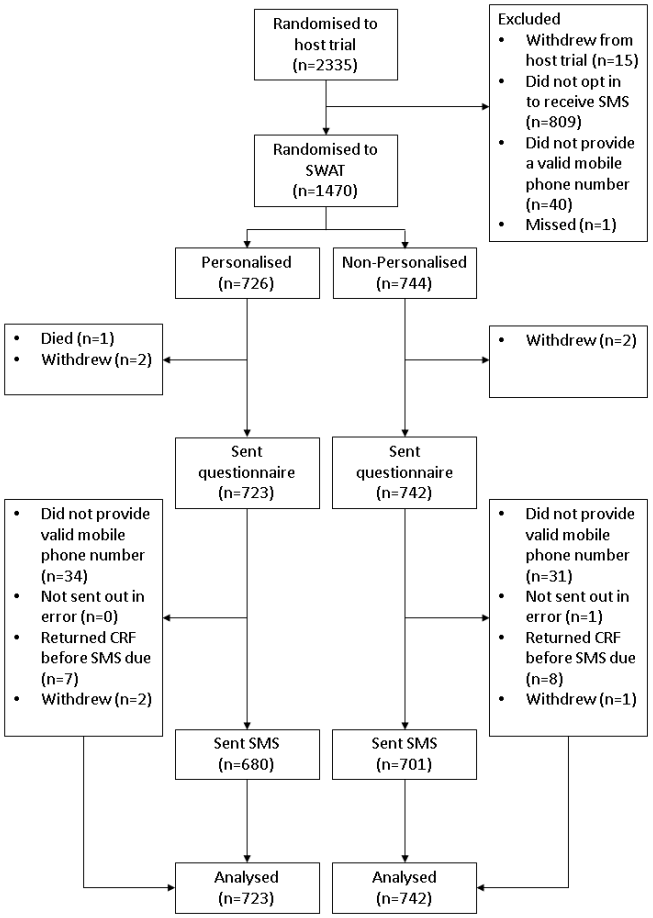

Figure 1. Study flow diagram.

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)

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[5].

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 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[17]

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[17]

References

1. Bower P, Brueton V, Gamble C, *et al.*: **Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities.** *Trials.* 2014; **15**: 399.
PubMed Abstract | Publisher Full Text | Free Full Text
2. Hewitt CE, Kumaravel B, Dumville JC, *et al.*: **Assessing the impact of attrition in randomized controlled trials.** *J Clin Epidemiol.* 2010; **63**(11): 1264–1270.
PubMed Abstract | Publisher Full Text
3. Edwards PJ, Roberts I, Clarke MJ, *et al.*: **Methods to increase response to postal and electronic questionnaires.** *Cochrane Database Syst Rev.* 2009; (3): MR000008.
PubMed Abstract | Publisher Full Text
4. McCaffery J, Mitchell A, Fairhurst C, *et al.*: **Does handwriting the name of a potential trial participant on an invitation letter improve recruitment rates? A randomised controlled study within a trial [version 1; peer review: 2 approved].** *F1000Res.* 2019; **8**: 659.
PubMed Abstract | Publisher Full Text | Free Full Text
5. Cochrane A, Welch C, Fairhurst C, *et al.*: **An evaluation of a personalised text message reminder compared to a standard text message on postal questionnaire response rates: an embedded randomised controlled trial [version 1; peer review: 2 approved].** *F1000Res.* 2020; **9**: 154.
PubMed Abstract | Publisher Full Text | Free Full Text
6. Ashby R, Turner G, Cross B, *et al.*: **A randomized trial of electronic reminders showed a reduction in the time to respond to postal questionnaires.** *J Clin Epidemiol.* 2011; **64**(2): 208–212.
PubMed Abstract | Publisher Full Text
7. Brabyn S, Adamson J, MacPherson H, *et al.*: **Short message service text messaging was feasible as a tool for data collection in a trial of treatment for irritable bowel syndrome.** *J Clin Epidemiol.* 2014; **67**(9): 993–1000.
PubMed Abstract | Publisher Full Text
8. Clark L, Ronaldson S, Dyson L, *et al.*: **Electronic prompts significantly increase response rates to postal questionnaires: a randomized trial within a randomized trial and meta-analysis.** *J Clin Epidemiol.* 2015; **68**(12): 1446–1450.
PubMed Abstract | Publisher Full Text
9. Keding A, Brabyn S, MacPherson H, *et al.*: **Text message reminders to improve questionnaire response rates.** *J Clin Epidemiol.* 2016; **79**: 90–95.
PubMed Abstract | Publisher Full Text
10. Man MS, Tilbrook HE, Jayakody S, *et al.*: **Electronic reminders did not improve postal questionnaire response rates or response times: a randomized controlled trial.** *J Clin Epidemiol.* 2011; **64**(9): 1001–1004.
PubMed Abstract | Publisher Full Text
11. Richmond SJ, Keding A, Hover M, *et al.*: **Feasibility, acceptability and validity of SMS text messaging for measuring change in depression during a randomised controlled trial.** *BMC Psychiatry.* 2015; **15**: 68.
PubMed Abstract | Publisher Full Text | Free Full Text
12. Haynes LC, Green DP, Gallagher R, *et al.*: **Collection of delinquent fines: An adaptive randomized trial to assess the effectiveness of alternative text messages.** *J Policy Anal Manag.* 2013; **32**(4): 718–730.
Publisher Full Text
13. Cook L, Northgraves MJ, Fairhurst C, *et al.*: **Knee Replacement Bandaging Study (KReBS) evaluating the effect of a two-layer compression bandage system on knee function following total knee arthroplasty: study protocol for a randomised controlled trial.** *Trials.* 2019; **20**(1): 261.
PubMed Abstract | Publisher Full Text | Free Full Text
14. Dawson J, Fitzpatrick R, Carr A, *et al.*: **Questionnaire on the perceptions of patients about total hip replacement.** *J Bone Joint Surg Br.* 1996; **78**(2): 185–190.
PubMed Abstract | Publisher Full Text
15. StataCorp: **Stata Statistical Software: Release 16.** College Station, TX: StataCorp LLC, 2019.
16. Mitchell A, Cook L, Dean A, *et al.*: **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].** *F1000Res.* 2020; **9**: 321.
Publisher Full Text
17. Mitchell A, Cook L, Dean A, *et al.*: **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.** 2020.
http://www.doi.org/10.17605/OSF.IO/KHJ8E

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Version 1

Reviewer Report 03 July 2020

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✔ **Michelle E. Kho**
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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[1]. 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?
Yes

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

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: 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.