

ORIGINAL ARTICLE

# Timing of electronic reminders did not improve trial participant questionnaire response: a randomized trial and meta-analyses

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## Abstract

**Objectives:** The objective of this study was to assess whether timing of short messaging service (SMS) reminders improved postal questionnaire return rates from participants in a randomized controlled trial (RCT).

**Study Design and Setting:** A Study Within A Trial (SWAT) embedded in a multicenter RCT evaluating three treatments for the frozen shoulder. Participants who provided a mobile telephone number were randomized to either prenotification SMS on the day of the questionnaire mail-out or postnotification SMS 4 days after questionnaire mail-out for the 3-month follow-up. The primary outcome was the proportion of participants who returned a valid questionnaire. A systematic review was undertaken to identify other embedded trials to perform a meta-analysis.

**Results:** Of the 269 participants, 122/135 (90.4%) returned a valid questionnaire in the prenotification arm and 119/134 (88.8%) in the postnotification arm (difference of  $-1.6\%$ ; 95% CI of difference:  $-8.9\%$ ,  $5.7\%$ ). There was no difference in time to response (HR = 1.04; 95% CI: 0.80 to 1.34) or need for additional reminders (OR = 0.71; 95% CI: 0.43 to 1.17). Meta-analysis of two RCTs showed no difference in response rates between prenotification and postnotification reminders (OR = 0.78 95% CI: 0.42 to 1.45).

**Conclusion:** Timing of SMS reminders did not improve response rates and time to response or affect the need for additional reminders. © 2020 Elsevier Inc. All rights reserved.

**Keywords:** Randomized controlled trial; SMS; Text message; Retention; Study Within A Trial; Meta-analyses

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**Availability of Data and Materials:** The anonymized data used and/or analyzed during the present study are available from the corresponding author on reasonable request.

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## 1. Introduction

Randomized controlled trials (RCTs) are the gold standard for investigating the efficacy, effectiveness, and safety of health care interventions [1]. Recently, the primary focus of RCTs has shifted from physician-reported clinimetric outcomes to patient-reported outcomes measures; these provide an invaluable insight into the impact of disease and treatment on patients' lives [2]. A convenient method to collect these data is through self-administered postal or electronic questionnaires. A major challenge with self-administered questionnaires is nonresponse. This can introduce bias and reduce the statistical power to detect differences between groups [3].

Short messaging service (SMS) reminders have been useful in retaining participants in a range of contexts, such as improving patient adherence to clinical follow-up and to medication [4,5]. They have also helped increase response rates to survey research [6,7]. SMS reminders are simple, are inexpensive, and can easily be implemented in a variety

**What is new?****Key findings**

- Timing of short messaging service (SMS) reminders did not affect response rates to postal questionnaires in the SWAT.
- Nor did a meta-analysis provide evidence overall that electronic reminders compared with no electronic reminders improved response rates

**What this adds to what was known?**

- Previous evidence suggested that postnotification SMS reminders were more effective than prenotification.
- This embedded trial and a meta-analysis of 2 trials did not support these findings.

**What is the implication and what should change now?**

- Further research should focus on different participant groups and both postal and electronic completion of questionnaires.

of settings. A large numbers of participants can be reached quickly and reliably in the United Kingdom where 96% of households use mobile phones [8].

RCTs often use SMS reminders to improve patient response to questionnaires; however, there is a paucity of evidence of their effectiveness and the results are equivocal [9–12]. The timing of the SMS reminders could have an important impact on response rate: SMS can be sent as a prenotification (before receipt of the postal questionnaire) or as a postnotification (after the receipt of the postal questionnaire). Only one trial has investigated the effect of the SMS timing on response rate [9]; this three two-arm RCT suggested that postnotification was more effective than prenotification.

Given the limited evidence available, we undertook a Study Within A Trial (SWAT) as a robust method to evaluate the effectiveness of timing of SMS messages embedded in a large multicenter orthopedic surgical trial [13]. This SWAT was registered with the Northern Ireland Hub for Trials Methodology Research Program (SWAT 44, ISRCTN1664238) with the protocol available online at their SWAT repository store. The SWAT is also registered with PROMETHEUS (PROMoting THE USE of SWATs; <https://bit.ly/2CP761A>), which is a national program of research funded by the Medical Research Council to facilitate the routine embedding of SWATs into RCTs. The objectives were to evaluate the effectiveness of the timing of SMS text messages as prenotification or postnotification reminders on questionnaire response rates, time to response,

and need for additional reminders. A systematic review and meta-analysis of other SWATs was undertaken to evaluate the effect of electronic reminders and their timing on improving participant questionnaire responses in RCTs.

**2. Methods***2.1. Host trial and participants*

This parallel two-arm RCT is embedded in the United Kingdom Frozen Shoulder Trial (UK FROST). In the host trial, 503 patients aged  $\geq 18$  years with the primary frozen shoulder were recruited in hospitals between the 1st of January 2015 and the 31st of December 2017. Participants were randomized to either early structured physiotherapy including a steroid injection, manipulation under anesthesia, or arthroscopic capsular release with manipulation under anesthesia. Participants were followed up at 3, 6, and 12 months with postal questionnaires. At recruitment into the host trial, participants with mobile phones who consented to be contacted by SMS were included in the SWAT. No additional inclusion criteria were used. The SWAT was initiated part-way through the host trial after the successful completion of the internal pilot which meant that 269 (53%) of the 503 participants in the host trial agreed to being texted to expect a study questionnaire and were included in the SWAT.

*2.2. Intervention*

At 3-month postrandomization into the host trial, participants in the SWAT were posted a self-administered follow-up questionnaire to be completed and returned using a prepaid envelope. The questionnaire was 12 pages in length and contained quality of life measures and questions about health care resource use.

Participants were randomized to either receive text messages as prenotification on the day of the questionnaire mail-out or postnotification 4 days after the questionnaire mail-out. The content for each reminder is shown in Table 1.

All participants were also sent a letter 2 weeks before the questionnaire was to be sent, 2- and 4-week letter reminders, and an option to complete an abridged telephone questionnaire after 6 weeks. At 12 months, the primary end point, all participants received an unconditional incentive of £5. During the trial, newsletters were also circulated to participants.

Questionnaires were sent from and returned to York Trials Unit (YTU). Mobile phone numbers were stored securely at YTU and the SMS was sent using a secure UK-based text message gateway service (IntelliSoftware).

*2.2. Randomization and blinding*

Participants were randomized to prenotification or postnotification after the 3-month follow-up questionnaires were sent. Randomization was achieved using computer-generated random permuted blocks with a 1:1 ratio,

**Table 1.** SMS reminders sent to participants

Study groups	SMS reminder content
Prenotification group	UK FROST Trial: You will receive a questionnaire in the post in a few days. Your answers are important; so please help by returning it as soon as you can. Thanks.
Postnotification group	UK FROST 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.

Abbreviation: SMS, short messaging service.

stratified by UK FROST treatment allocation. A statistician at YTU generated the allocation sequence and the assignment of participants to either SMS group. Participants did not know they were taking part in the SWAT and were therefore blinded.

### 2.3. Outcome measures

The primary outcome was the proportion of participants who returned a valid questionnaire at the 3-month follow-up. A valid questionnaire had to contain a completed response for the Oxford Shoulder Score (primary outcome of UK FROST).

Secondary outcomes were time to questionnaire return (number of days between the questionnaire being mailed out and it being recorded as returned) and the proportion of participants requiring at least one return reminder notice (in the form of a reminder at 2 and 4 weeks or a telephone call at 6 weeks).

### 2.4. Statistical analysis and sample size calculation

Statistical analyses were conducted with Stata 15 (Stata-Corp, College Station, TX) using two-sided statistical significance at the 5% level. The analysis was undertaken on an intention-to-treat basis by a statistician blind to group allocation.

Baseline characteristics of the participants of the SWAT and the host trial were compared descriptively.

For the primary outcome, the proportion of participants who returned a valid questionnaire in each group was calculated with a 95% confidence interval (CI) and the chi-squared test was used to assess statistical significance. A logistic regression adjusting for age, gender, and UK FROST treatment allocation was undertaken, and the odds ratio and associated 95% CI was reported. This included reporting the odds ratio and associated 95% CI for age and gender to assess whether these variables were predictors of questionnaire return.

The secondary outcome of time to questionnaire return was assessed using a Kaplan–Meier curve and the text message interventions were compared using the log-rank

test. We carried out Cox regression adjusting for age, gender, and UK FROST treatment allocation. Questionnaire return times were censored at 3 months (91 days) for the time to event analyses. The requirement for any additional reminders was analyzed for the primary outcome.

Return rates were compared descriptively between participants who were recruited in the SWAT and participants who were recruited into the host trial before the SWAT was initiated. We estimated that a sample size of approximately 300 participants for the SWAT (150 per group) would give us 80% power at the 5% significance level to detect differences in return rates of approximately 12% or more. However, as with all SWATs, we were limited by the sample size of the host trial [14].

### 2.5. Systematic review and meta-analysis

We undertook a systematic review and registered it with PROSPERO (available at [https://www.crd.york.ac.uk/prospero/display\\_record.php?RecordID=134318](https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=134318)). We performed an online search of nine databases from inception to the end of April 2019. The reference lists of included studies and relevant systematic reviews were hand-searched [15,16]. A list of databases searched and the search strategy for MEDLINE is included in Appendix A. When possible, RCTs were pooled with a random effects model (DerSimonian-Laird method) and statistical heterogeneity was examined using the  $I^2$  statistic. Subgroup analyses were also undertaken to test for an association between the use of an electronic reminder or not and questionnaire length (short, ie, <10 pages compared with long, ie, >10); the type of electronic reminder (combination of SMS and/or e-mail compared to SMS only); and timing of reminder (prenotification compared with postnotification). Risk of bias was assessed using the ROB2 tool and the quality of the evidence was assessed using the GRADE tool [17,18].

## 3. Results

In total, 269 participants were randomized to the SWAT, 135 (50.2%) to the prenotification and 134 (49.8%) to the postnotification group. The baseline characteristics for each group in the SWAT and the host trial are presented in Table 2.

A total of 241 (89.6%) participants in the SWAT returned a valid questionnaire at 3-month follow-up: 122 (90.4%) participants in the prenotification group and 119 (88.8%) in the postnotification group (difference of –1.6% with a 95% CI: –8.9% to 5.7%). The chi-squared test showed no evidence of a difference between groups in the proportion of participants returning a valid questionnaire ( $P = 0.67$ ). In the adjusted regression, the two groups did not differ in the likelihood of returning a valid questionnaire (OR = 0.93; 95% CI: 0.41 to 2.08;  $P = 0.85$ ).

**Table 2.** Baseline characteristics of participants in the SWAT and host trial

Characteristics	Prenotification (n = 135)	Postnotification (n = 134)	UK-FROST (n = 503)
Gender, n (%)			
Male	47 (34.8)	47 (35.1)	184 (36.6)
Female	88 (65.2)	87 (64.9)	319 (63.4)
Age in years, mean (SD)	54.0 (7.7)	53.1 (7.6)	54.3 (7.7)
Host trial allocation, n (%)			
ESP	28 (20.7)	27 (20.1)	99 (19.7)
ACR	55 (40.7)	55 (40.7)	203 (40.3)
MUA	52 (38.5)	52 (38.8)	201 (40.0)

Abbreviations: ACR, arthroscopic capsular release with manipulation under anesthesia; ESP, early structured physiotherapy including a steroid injection; MUA, manipulation under anesthesia; SWAT, Study Within A Trial.

Increasing age, however, was a statistically significant predictor of questionnaire return (OR = 1.09; 95% CI: 1.03 to 1.15;  $P < 0.01$ ), while being female was not (OR 1.71; 95% CI: 0.75 to 3.89;  $P = 0.20$ ).

The median time for questionnaire return was 14 days for prenotification (interquartile range [IQR]: 9 to 25) and 13 days for postnotification (IQR: 8 to 22 days). There was no statistically significant difference in the time to return the questionnaire between the two arms (HR = 1.04; 95% CI: 0.80 to 1.34). The results of the log-rank test showed no evidence of a difference in time to response between groups ( $P = 0.93$ ). Cox regression did not identify the timing of SMS reminder to be a significant predictor of time to return ( $P = 0.79$ ).

In total, 119 (44.2%) of the 269 participants required at least one return reminder: 64 (47.4%) in the prenotification group and 55 (41.0%) in the postnotification group (difference of  $-6.4%$ ; 95% CI:  $-18.2%$  to  $5.5%$ ). The chi-squared test showed no difference between groups in the proportion of participants requiring at least one reminder notice ( $P = 0.29$ ). In the adjusted regression, the two groups did not differ in the likelihood of requiring at least one reminder notice (OR = 0.71; 95% CI: 0.43 to 1.17;  $P = 0.18$ ).

When comparing participants who received no SMS reminders in the UK FROST trial to participants who were recruited to the SWAT, the return rates for the questionnaire were 87.2% (205/235) and 89.6% (241/269), respectively—a difference of 1.4%.

### 3.1. Systematic review and meta-analysis

Our search yielded 4,850 records; after deduplication, 3,728 abstracts were screened and 94 full texts were assessed for eligibility. Seven studies met the inclusion criteria including the study embedded in UK FROST; six were included in the meta-analysis including the present study [9–12,19,20]. One study could not be pooled in the meta-analysis as it used a different intervention and comparator [20]. Fig. 1 illustrates the study selection process.

The characteristics of the embedded studies and their host trials, the risk of bias assessment for the individual trials, and the GRADE assessment for the main meta-analyses are available as Appendices B and C [17,18].

Two RCTs (792 participants) were included in a meta-analysis of the effect on postal questionnaire response rates of prenotification compared with postnotification SMS reminders (Fig. 2) [9]. The results favor postnotification; however, this was not statistically significant (OR = 0.78 95% CI: 0.42 to 1.45;  $P = 0.44$ ). Statistical heterogeneity was high ( $I^2 = 52%$ ) owing to the limited number of RCTs and the wide variation of effects reported in our orthopedic and depressed patient populations [9]. Based on GRADE, the quality of evidence was very low.

We also included six RCTs to estimate the effect on postal questionnaire response rates of electronic reminders (SMS, e-mail, or both) irrespective of timing compared to no reminders (Fig. 3) [9–12,19]. Pooling these RCTs provides evidence in favor of electronic reminders for increasing response rates; however, the difference was not statistically significant (OR = 1.15 95% CI: 0.95 to 1.41;  $P = 0.16$ ). Statistical heterogeneity was low ( $I^2 = 0%$ ). Based on GRADE, the final quality of evidence was judged to be moderate.

The test for subgroup differences in these 6 RCTs indicates that when comparing electronic reminders with no reminders, there was no statistically significant subgroup effect for both questionnaire length (short compared to long) and electronic reminder modality (combination of SMS and/or e-mail compared with SMS only) with  $P = 0.09$  for both tests. There was no statistical heterogeneity in either subgroup analysis ( $I^2 = 0%$  for all subgroups). However, electronic reminders were more effective than no reminders in shorter questionnaires (OR of 1.51, 95% CI: 1.04 to 2.19,  $P = 0.03$ ). A combination of electronic reminders when available from trial participants (SMS and/or e-mail) was also more effective than no reminders (OR = 1.48, 95% CI: 1.04 to 2.09,  $P = 0.03$ ). The test for subgroup differences comparing the use of a prenotification or postnotification combination of electronic reminders compared with no reminders

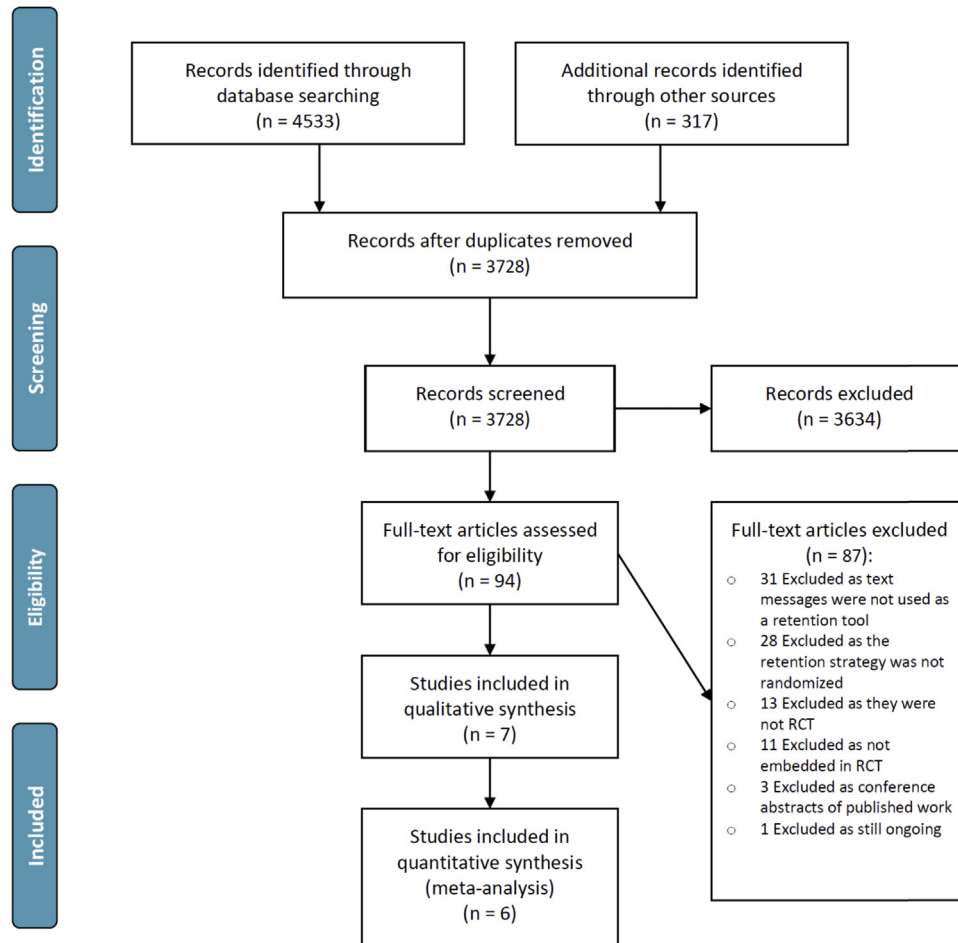


Fig. 1. PRISMA flowchart detailing the study selection process [21].

showed no statistically significant subgroup effect ( $P = 0.65$ ), and there was moderate heterogeneity in the postnotification subgroup ( $I^2 = 37\%$ ). The forest plots for the subgroup analyses are presented in Appendix D.

#### 4. Discussion

##### 4.1. Summary of main findings

This is one of the first SWATs undertaken as part of the PROMETHEUS initiative investigating the effect of SMS reminder timings on retention in RCTs [22]. We found no evidence to suggest that either prenotification or postnotification SMS reminders improved postal

questionnaire response rates and time to return of questionnaires or affected the need for additional reminders. When pooling our SWAT with another embedded trial, there was a suggestion that postnotification was more effective, but it was not statistically significant. Nor was there statistically significant evidence that overall electronic reminders compared with no reminder improved postal questionnaire return. However, there was evidence that electronic reminders could be more effective compared to no reminder for trials that included shorter questionnaires and those that used a combination of electronic reminders when available from trial participants, that is, SMS and/or e-mail.

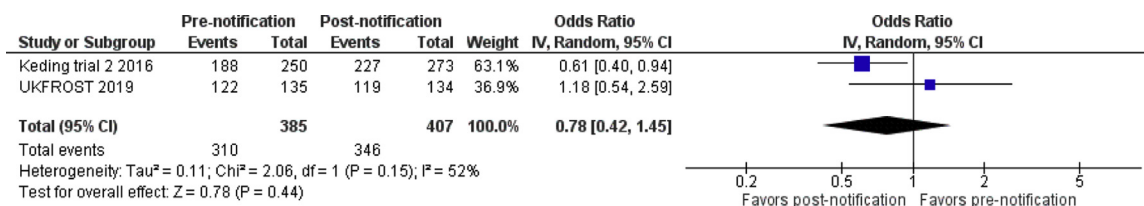


Fig. 2. Forest plot for prenotification compared with postnotification reminders.



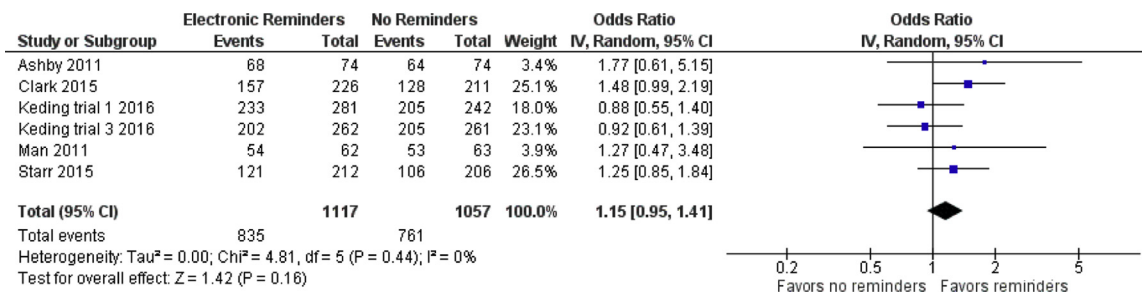


Fig. 3. Forest plot for the effect of electronic reminder compared with no reminder.

#### 4.2. Comparisons with existing literature

Only one other RCT has compared the effect on trial participant questionnaire return of prenotification with postnotification SMS reminders. In the study by Keding et al., postnotification significantly increased response rate and decreased time to response compared to prenotification at 6-month follow-up [9]. Our SWAT did not favor either prenotification or postnotification and tested the effect of timing of questionnaires at the 3-month follow-up. Our SWAT had higher return rates compared to the study by Keding et al., which could limit the potential effectiveness of the timing of the SMS message. Both RCTs evaluated treatments in different settings and patient populations. Keding's study is further complicated by the study design: a three two-arm RCT in the same population which meant participants were being re-randomized to different SMS reminder strategies every 3 month which raises the issue of carryover effect.

Only one previous systematic review has studied the role of additional reminders in improving retention; however, that review included RCTs evaluating SMS reminders, telephone reminders, and the provision of calendars with questionnaire due dates [23]. Only three RCTs were included which investigated the effect of SMS reminders, the largest of which compared SMS reminders with an emphasis on the social benefit of participation in RCTs to simple SMS reminders [20]. Brueton et al. found a small but nonsignificant increase in response rates when using additional reminders [23]. Little evidence exists assessing the effectiveness of SMS or electronic reminders over other forms of reminders.

#### 4.3. Strengths and weaknesses of the SWAT and meta-analyses

As with every SWAT, our findings are limited to the participants recruited in the host trial. In UK FROST, the participants were predominantly female and middle-aged. This study like many SWATs was underpowered, as the sample size was limited by the number of participants in the host trial and the intervention was not introduced from the outset. The host trial used multiple other retention strategies which may have contributed to the already high

questionnaire response rates (above 85%) as described in the methods and trial protocol [13]. The intervention was also at the 3-month follow-up when trial participants may still be highly motivated to complete questionnaires. We also intended the postnotification SMS and the postal questionnaire to be received synchronously to optimize its effect. However, it is possible that some participants quickly completed and returned the questionnaire without being exposed to the SMS reminder. Rather than this being a confounding factor, it was a pragmatic consequence of the specific intervention being tested.

We undertook a robust systematic review and meta-analyses assessing the effect of electronic reminders on the return of postal questionnaires. The meta-analysis comparing electronic reminders to no reminders included six high-quality studies embedded in host trials in a variety of specialties (medicine, surgery, and psychiatry) and settings (community, primary, and secondary care). All the RCTs were, however, based in the United Kingdom and investigated middle-aged participants. Only two RCTs included participants aged above 65 years and none included children or teenagers who have increasing access to mobile technology [8]. It also only applied to the return of postal questionnaires rather the electronic completion. There is, therefore, still limited generalizability. We omitted gray literature and unpublished trials which could introduce publication bias. Results from the subgroup analyses should be interpreted with caution because of the potential for confounding between studies in the comparisons made. The meta-analysis comparing prenotification against postnotification included only two studies, reporting different effects which resulted in a wide confidence interval. These factors lead to the very low GRADE certainty, which highlights the need for further research investigating the different timings of SMS reminders in improving retention in RCTs.

#### 4.4. Implications of findings for research and retention of trial participants

The role of SMS, or electronic reminders more generally, remains unclear in improving the return of postal questionnaires in RCTs; we are aware of only two other SWATs in progress investigating SMS as a retention tool in RCTs [24,25]. The findings of our meta-analyses have a very

low to moderate GRADE certainty and need to be interpreted with caution. Even a small increase in questionnaire response rate, however, could be useful given the ease of use of SMS reminders and their low cost.

Both the addition or not of SMS reminders and the timing of SMS reminders meet all the criteria of Trial Forge Guidance 2 for further investigation [26]. Future research should focus on the following:

- Generating further evidence to improve the GRADE certainty, especially investigating the timing of SMS reminders.
- Exploring the role of SMS reminders in other contexts. This includes further research to explore the effect of demographic factors on questionnaire return such as age, gender, and education. Targeting participant groups known to have poor engagement with trials, such as IV drug user, would be useful. Other areas worth exploring include the role of SMS reminders in long-term follow-up, their synergistic effect with other retention strategies, and their effectiveness with electronic questionnaires which can be completed immediately on mobile phones or other devices.
- SMS reminders have little direct benefit for participants. However, although some might appreciate a reminder, it is possible that participants find these irritating. An understanding of the acceptability of SMS reminders in improving retention would be beneficial.
- Although in principle an SMS reminder is inexpensive, its cost-effectiveness has not yet been explored.

## 5. Conclusions

SMS reminders are simple to implement, inexpensive, and increasingly being used in RCTs. Our SWAT in UK FROST, however, provided no evidence to suggest that pre-notification compared with postnotification SMS reminders improved postal questionnaire response rates and time to return of questionnaires or affected the need for reminders. The findings from the meta-analyses cautiously suggest that SMS reminders could be effective when combined with other retention strategies such as shorter questionnaires or other electronic reminders; however, further SWATs are required to provide robust evidence. Trialists should consider including embedded retention trials in their host RCTs to further evaluate the role of SMS and other electronic reminders, and their timing, in improving participant retention.

## CRedit authorship contribution statement

**Prasanna Partha Sarathy:** Conceptualization, Data curation, Formal analysis, Methodology, Writing - original draft, Writing - review & editing. **Lucksy Kottam:** Conceptualization, Data curation, Methodology, Writing - original draft. **Adwoa Parker:** Conceptualization,

Methodology, Supervision, Writing - original draft. **Stephen Brealey:** Conceptualization, Methodology, Writing - original draft, Writing - review & editing. **Elizabeth Coleman:** Conceptualization, Formal analysis, Methodology, Writing - original draft, Writing - review & editing. **Ada Keding:** Conceptualization, Formal analysis, Methodology, Supervision, Writing - original draft, Writing - review & editing. **Alex Mitchell:** Conceptualization, Formal analysis, Methodology, Writing - original draft, Writing - review & editing. **Matthew Northgraves:** Conceptualization, Methodology, Writing - original draft. **David Torgerson:** Conceptualization, Methodology, Writing - original draft. **Amar Rangan:** Conceptualization, Methodology, Writing - original draft.

## Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jclinepi.2020.03.001>.

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