

ORIGINAL ARTICLE

Telephone call reminders did not increase screening uptake more than SMS reminders: a recruitment study within a trial

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Abstract

Objectives: The aim of the study was to compare the response rates and costs of phone call vs. short message service (SMS) screening reminders to prospective randomized controlled trial (RCT) participants.

Study Design and Setting: This study was a randomized evaluation within a large Australian diabetes prevention RCT. Participants were men aged 50–74 years, overweight or obese, without a previous type 2 diabetes diagnosis. Those eligible on a prescreening questionnaire who did not attend a further screening assessment within 4 weeks were randomized to receive an SMS or phone call reminder ($N = 709$). The primary outcome was attendance for further screening assessment within 8 weeks of prescreening.

Results: Attendance was 18% (62/354) in the SMS reminder group, and 23% (80/355) in the phone reminder group, with no statistically significant difference in response according to reminder type (relative risk = 1.29, 95% confidence interval [CI]: 0.96–1.73, $P = 0.09$). The lower confidence limits for response to SMS (95% CI: 14–22%) and phone reminders (95% CI: 18–27%) did not include the 8-week attendance rate before this evaluation, 12%. Phone reminders cost substantially more than SMS reminders (AU\$6.21 vs. AU\$0.53 per reminder).

Conclusion: SMS reminders were as adequate a method as phone reminders to boost RCT screening uptake and were considerably more affordable. © 2019 Elsevier Inc. All rights reserved.

Keywords: Participant recruitment; Recruitment strategies; Randomized controlled trials; Telephone reminders; Text message reminders; Study within a trial

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What is new?**Key findings**

- There was no statistically significant difference in screening uptake based on whether a short message service (SMS) or phone call reminder was performed; however, either reminder was more effective than no reminder.
- SMS reminders were substantially cheaper to perform than phone call reminders.
- Phone call reminders may be more effective than SMS reminders in men aged ≥ 65 years.

What this adds to what was known?

- Compared with phone call reminders, SMS reminders are an adequate and affordable method of boosting randomized controlled trial (RCT) screening uptake.

What is the implication, and what should change now?

- RCTs with high participant attrition during the screening process may benefit from implementing SMS screening reminders to improve recruitment, particularly if phone call reminders are not feasible due to the large numbers of reminders to be made or the limited trial budget available for reminder activities.

1. Introduction

Recruitment of participants to randomized controlled trials (RCTs) is challenging, and an estimated 50% of trials fail to reach their recruitment targets [1,2]. Disease prevention RCTs face additional recruitment challenges compared with those for disease treatment, reporting higher attrition of volunteers at each stage of recruitment [3]. Several explanations for this observation have been proposed. First, disease prevention RCTs commonly seek to enroll healthy individuals who may perceive their risk of disease to be low, reducing their motivation to participate in clinical research [4,5]. Second, participants in disease prevention RCTs must usually be identified directly from the general public rather than through clinician referral [6,7]. Lack of involvement in recruitment by a potential volunteer's personal clinician may leave an individual unsure about the suitability of the trial for them [8] or misunderstanding the trial processes [4], reducing interest in participation.

In RCTs where attrition during early recruitment and initial screening phases is important, interventions to address participant uncertainty and low motivation may boost recruitment, saving time and money. In studies

evaluating the use of participant reminders [9–11], phone calls increased RCT enrollment among individuals who failed to respond to an initial mailed invitation compared with no reminder [10] and to a mailed reminder [11]. Also, a series of four short message service (SMS) reminders increased enrollment (compared with no reminder) among participants who did not respond after initial screening [12]. Elsewhere, health services research shows strong evidence that SMS reminders are as effective as phone call reminders for improving attendance at clinic appointments [13–15]. However, to our knowledge, no randomized evaluation has been published comparing SMS and phone reminders to improve recruitment to RCTs [16]. Unlike an SMS, a phone call reminder provides the opportunity to build rapport and to clarify specific uncertainties, arguably more important for participants interested in joining a disease prevention RCT than for patients due to attend a pre-booked clinic appointment for disease management. By contrast, SMS reminders have the advantage of being cheaper [13], less intrusive, and providing written information that participants can refer to later.

Men are underrepresented in disease prevention and health promotion RCTs [7,17] despite experiencing higher rates of avoidable mortality than women [18]. In the past, men have been mischaracterized as disinterested in health promotion and disease prevention, but there is growing recognition that men care about their health and engage with health services if they are tailored to their needs [19,20]. Men may prefer to monitor their own health needs and gather information independently before making the decision to engage with professional health services [21]. We hypothesized that SMS reminders may address this preference for independent decision-making in our male participants.

This study within a trial (SWAT) aimed to compare, in randomized fashion, the efficacy and cost-effectiveness of phone call and SMS reminders in improving attendance for screening assessments for a large multicenter diabetes prevention RCT (registered as SWAT 88 on the SWAT repository).

2. Methods**2.1. Setting**

This reminder study was conducted in the context of the Testosterone for Diabetes Mellitus (T4DM) trial. The design of the T4DM study is published elsewhere [22], but briefly, T4DM is a Phase III, multicenter, double-blind, placebo-controlled trial of testosterone for the prevention of diabetes or reversal of newly diagnosed diabetes (trial registration ACTRN12612000287831). The trial is run through six Australian hospital-based centers and is coordinated by a central university-based coordinating center. Eligible T4DM participants were men aged 50–74 years, obese or

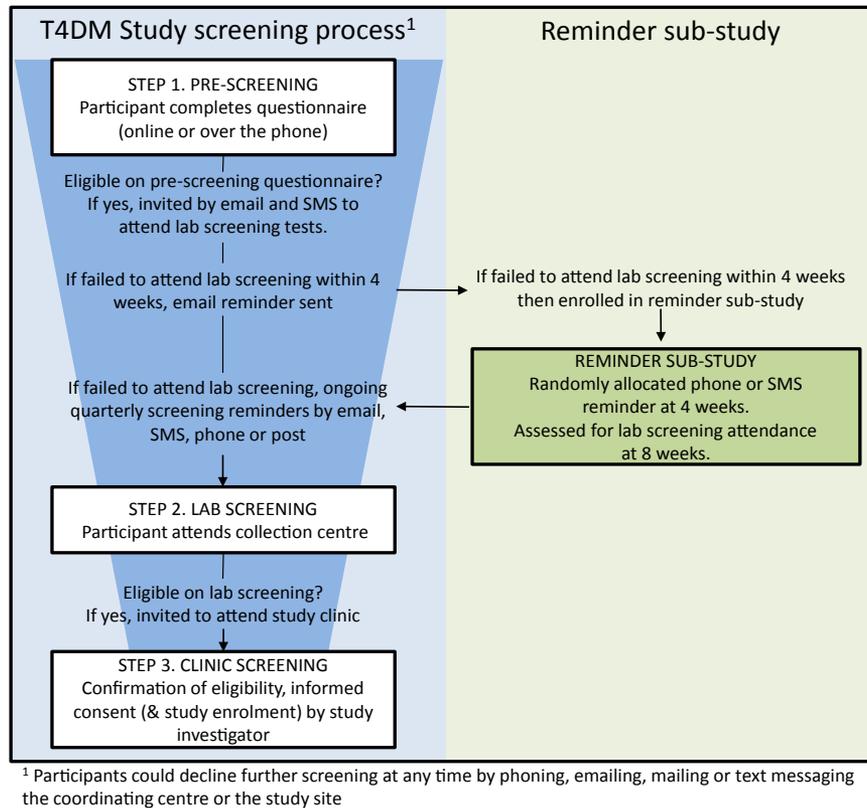


Fig. 1. Testosterone for Diabetes Mellitus study screening process and reminder study design.

overweight, with prediabetes or newly diagnosed type 2 diabetes, and a serum testosterone ≤ 14 nmol/L. The trial used a three-step semiautomated approach to participant screening (Fig. 1). Men from the general population were invited to complete a prescreening questionnaire (Step 1), either online or over the phone. Those who were eligible were then invited by e-mail or mail to attend one of 1,300 contracted pathology collection centers for laboratory screening tests (Step 2), and if eligible, for final screening and study enrollment at the nearest study center (Step 3).

2.2. Rationale for the reminder study

Of participants who were eligible on the prescreening questionnaire before the commencement of this reminder study, approximately 50% attended laboratory screening within 4 weeks of prescreening. Nonattenders received up to 10 screening reminders per year, including an automated e-mail reminder at 4 weeks after prescreening, quarterly e-mail and SMS reminders, and approximately annual phone call and postal reminders. Despite these reminders, only 12% of nonresponders at 4 weeks proceeded to attend by 8 weeks, and a further 8% proceeded to attend after 8 weeks. In total, 40% of all potentially eligible participants did not proceed past prescreening, representing a substantial missed recruitment opportunity. This reminder study was conceived to evaluate the impact on laboratory

screening rates of phone call or SMS reminders at 4 weeks after prescreening.

2.3. Design of the reminder study

The reminder study was a parallel-group RCT. Individual participants were randomized in a 1:1 ratio to receive either an SMS or phone call reminder 4 weeks after completing the T4DM prescreening questionnaire if they had not attended laboratory screening within 4 weeks of prescreening. Participants were excluded if they had declined laboratory screening. All participants had previously consented to receive reminders as part of the standard prescreening consent process; therefore, further consent to randomization was deemed unnecessary.

2.4. Interventions

2.4.1. SMS screening reminder

SMS reminders were sent by the central coordinating center within 1 to 2 days of randomization using an online bulk SMS service. The SMS reminder message (see text below) was designed to provide key enrollment information as well as including a peripheral cue based on the concept of social proof [23] (looking to the actions of others for reassurance in situations of uncertainty) to encourage action by the study participants.

SMS reminder text

It's not too late to join the T4DM study. [Number] men around Australia are already taking part. Why not book your blood tests today?

Text *FORMS* if you need another copy of your blood test forms. Text *DECLINE* to opt out.

More info: askt4dm@ctc.usyd.edu.au or 1300865436.

2.4.2. Phone screening reminder

Phone reminders were conducted by two staff at the central coordinating center. Calls were made within 4 days of randomization with one further attempt made if the first call was not answered. If the participant could not be reached on the second attempt, a voicemail message was left, if possible. Staff members were provided with a reminder call script, which included the following discussion points:

- Reminding the participant that they had registered for the T4DM study
- Asking if they were still interested in joining the study
- Explaining that the next step was to attend for their laboratory screening tests and explaining what this involved
- Asking if they needed to have another copy of their laboratory screening forms sent to them
- Asking if they had any other questions about laboratory screening or joining the T4DM study in general
- Giving the participant the opportunity to decline further study screening and enrollment

2.5. Ethics

The use of phone and SMS screening reminders was approved by each ethics committee overseeing the main T4DM study: Sydney Local Health District HREC—CRGH, the Human Research Ethics Committee (TQEH/LMH/MH), the South Metropolitan Health Service Human Research Ethics Committee, and Bellberry Human Research Ethics Committee.

2.6. Outcomes

The primary study endpoint was attendance for laboratory screening within 8 weeks of prescreening completion (i.e., within 4 weeks of receiving the phone or SMS reminder). Attendance at the collection center was determined using assay results uploaded electronically, in real time, by the contracted pathology company and imported into the main study's clinical data management database using a validated process.

The secondary endpoint was the cost of performing the reminders. Total cost was made up of direct and indirect (staffing) costs. The direct cost of SMS reminders was measured by referring to invoices and billing information from the bulk SMS service. The direct cost of phone

reminders was estimated based on the flag fall and per minute costs of calling a mobile number from the coordinating center. This information was combined with the average call duration to calculate an average phone call cost. The time taken to conduct SMS and phone reminder calls was estimated by maintaining a log of the time spent on reminders over two 1-week periods, one at the beginning of the reminder study, and one at the end. Time tracking included not only the time to make or send the reminder but also the time to reply to participant questions either by phone or SMS. This information was combined with the hourly staffing cost to calculate the indirect (staffing) cost. All costs are quoted in Australian dollars.

2.7. Sample size

Based on prior experience, a response rate of 17% in the SMS reminder arm was assumed. To achieve 80% power, with a two-sided significance level of 5%, 540 participants would be required to detect a 10% higher response rate in the phone reminder compared with the SMS arm (27%). If the response rate in the SMS arm were only 14%, 540 patients would have more than 95% power to detect an increase in response to 27% in the phone arm. Ten percent was chosen as the likely minimum effect that would be considered operationally meaningful.

2.8. Randomization

Confirmation of eligibility and randomization was performed weekly by a central, automated computer system. After confirmation of eligibility, men were randomized by minimization and stratified by center, age group (50–59, 60–64, 65–69, 70–74 years), and participant's screening questionnaire completion method (online or phone).

2.9. Statistical methods

All analyses were performed according to the intention to treat principle. Baseline characteristics were summarized using counts and percentages for categorical variables, and mean and standard deviation for continuous variables. Intervention groups were compared using a chi-square test. Relative risks (RRs) and 95% confidence interval (CI) were used to summarize this effect. *P* values for interaction terms were obtained from logistic regression. Subgroup analyses for age (50–64 and 65–74 years), how men heard about the study (mail, radio, other), and prescreening questionnaire completion mode (online vs. phone) were prespecified in the protocol. However, as 98% of men completed their screening questionnaire online and only 2% by phone, this subgroup analysis was not undertaken. Cost-effectiveness was estimated by calculating incremental cost-effectiveness ratios (ICERs). No adjustments were made for multiple comparisons. Analyses were performed using SAS v 9.4 (Cary, NC).

3. Results

The T4DM study was open to recruitment from January 2013 to February 2017. In that time, 19,022 participants were screened, and 1,007 were randomized. The reminder study opened to recruitment in June 2016 and closed in October 2016, the week that the calculated sample size was attained. During that period, 2,315 participants were screened to the main study, and 709 of them were eligible for the reminder study (having neither attended nor declined laboratory screening within 4 weeks of completing the screening questionnaire). All 709 eligible participants were randomized, with 354 men allocated to SMS reminders, and 355 men to phone call reminders (Fig. 2). Of the 709 men who participated in the reminder study, 142 (20%) attended for laboratory screening within 8 weeks, and 28 (4%) went on to be enrolled in the main T4DM study. Enrollment was ceased the week that the calculated sample size was reached. Characteristics of the men participating in the screening reminder study are shown in Table 1, with the two intervention arms well-balanced.

3.1. Reminder delivery

Of participants randomized to receive an SMS reminder, 312 of 354 (88%) were sent the reminder, with the remaining 25 participants not sent a reminder due to having attended laboratory screening before the reminder could be sent, having provided an invalid mobile phone number or

having only provided a landline number (Fig. 2). By comparison, of the participants randomized to receive a phone reminder, staff spoke to 237 of 355 (67%) and left a voicemail for an additional 38 (11%). The remaining 99 participants did not receive a phone reminder due to having attended laboratory screening before the reminder phone call could be made, having provided an invalid phone number, or having not picked up the phone reminder calls and having no facility to leave a voicemail message. All participants were followed for response and included in the analysis, regardless of whether the allocated intervention was delivered or not.

3.2. Response to the reminder

There was no statistically significant difference in response to phone vs. SMS reminders (23% vs. 18%, respectively, RR = 1.29, 95% CI: 0.96–1.73, $P = 0.09$; Table 2). The difference in response was not affected by how men heard about the study ($P = 0.13$; data not shown). However, in older men (aged 65–74 years), compared with younger men (aged 50–64 years), there was a trend for greater uptake in the phone compared with the SMS arm (39% vs. 15%, RR = 2.26, 95% CI: 1.12–4.56; P for age interaction = 0.07). This difference could not be explained by higher success rates in reaching men by phone in the older group. In fact, a higher proportion of younger men were contactable by phone, with staff successfully speaking to 68% of men aged 50–64 years and 59% of men aged 65–74 years.

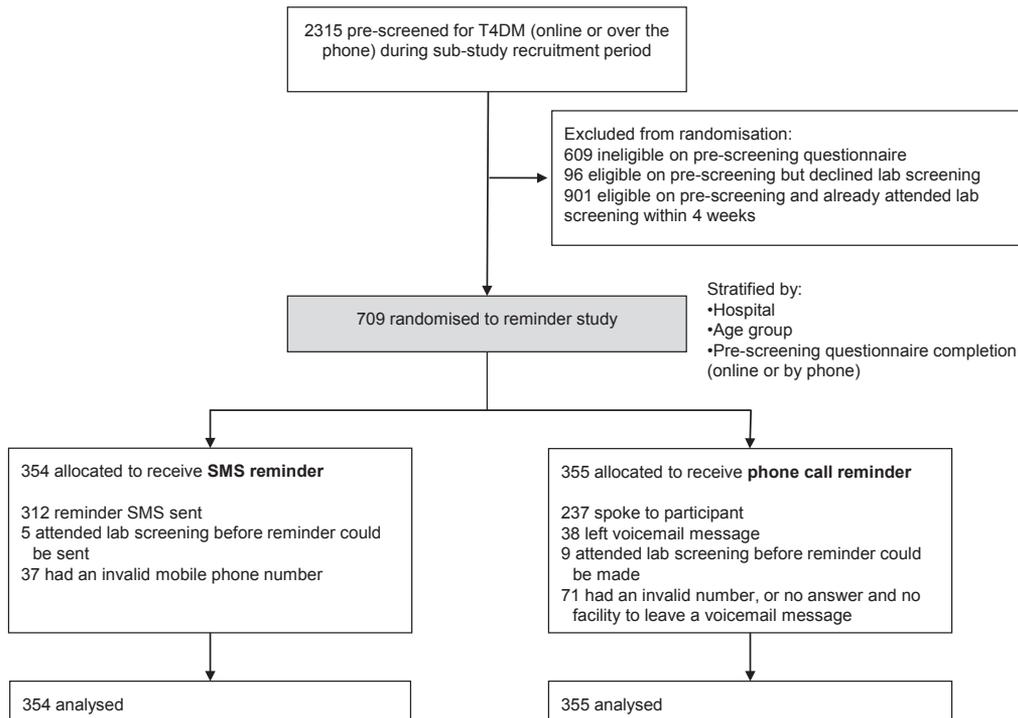


Fig. 2. Reminder study CONSORT diagram.

Table 1. Characteristics of all reminder study participants ($N = 709$)

Characteristic	SMS reminder at 4 wk, ($n = 354$)	Phone reminder at 4 wk, ($n = 355$)
Age, mean \pm SD, y	58.5 \pm 6.0 y	58.1 \pm 6.0 y
Center		
Center 1	89 (25%)	90 (25%)
Center 2	74 (21%)	76 (21%)
Center 3	69 (19%)	66 (19%)
Center 4	57 (16%)	54 (15%)
Center 5	38 (11%)	42 (12%)
Center 6	27 (8%)	27 (8%)
Prescreening completion method		
Online	350 (99%)	348 (98%)
Information line (phone)	4 (1%)	7 (2%)
How they heard about the study		
Mail-out	197 (56%)	195 (55%)
Radio	123 (35%)	121 (34%)
Other/not specified	34 (10%)	39 (11%)

Abbreviations: SD, standard deviation; SMS, short message service.

3.3. Cost of reminders

The cost of phone call reminders (\$6.21 per reminder) was more than 10 times that of SMS reminders (\$0.53 per reminder), with most of the additional cost due to the additional staff time required to make the phone calls (Table 3). Staff spent approximately 4 minutes on each phone call reminder made. By comparison, the staff time per SMS reminder was negligible. It took a total of 3 minutes to send an entire batch of SMS reminders, irrespective of the number of reminders included.

The ICER of phone call reminders compared with SMS was AU\$112.05, meaning that if reminders were made by phone, an additional AU\$112.05 would be spent for each additional participant who attended laboratory screening. However, in men aged 65–74 years, the ICER of phone calls compared with SMS was AU\$31.45.

4. Discussion

4.1. Summary of findings

In this randomized evaluation of screening reminders, there was no statistically significant difference in response to phone call and SMS reminders (RR = 1.29, 95% CI: 0.96–1.73, $P = 0.09$). However, the overall attendance rate in those who received a phone or SMS reminder was 20% at 8 weeks, compared with the previously observed attendance rate of 12% in the main study. As in similar studies [13,14], we found that phone reminders were substantially more expensive to perform than SMS reminders (AU\$6.21 vs. AU\$0.53 per reminder). We hypothesize that the personal nature of phone reminders may have been more important to participants \geq aged 65 years, as in that subgroup, we observed a higher response rate to phone reminders (33% compared with 15% to SMS reminders), and the ICER for phone calls compared with SMS reminders was consequently lower (AU\$31.45 compared with the overall ICER of AU\$112.05).

4.2. Implications for future practice

SMS messages are an effective communication tool in various healthcare settings including reminders for clinic appointments [13,24], repeat testing after mass screening [25,26], and adherence to treatment regimens [27,28]. Still, published accounts of using SMS reminders to boost recruitment to RCTs remain scarce. Our results provide evidence that SMS reminders may be an appropriate lower cost, but similarly effective, alternative to phone reminders in the RCT recruitment setting. SMS reminders may be particularly worthwhile when phone reminders are not feasible due to the large numbers of reminders to be made or the limited trial budget available for reminder activities.

4.3. Limitations and areas for future research

The overall response rate to reminders in our study (20% by 8 weeks) was higher than that has been reported in previous reminder studies (13% [11], 12% [10], 8% [9], and 3.5% [12]). A possible explanation for the higher rate may be that the recipients of reminders in our study had

Table 2. Response to reminder delivered 4 weeks after completing prescreening^a

Recruitment outcome	SMS reminder ($n = 354$)	Phone reminder ($n = 355$)	RR (95% CI)	P value	Interaction P value
Attended laboratory	62 (18%)	80 (23%)	1.29 (0.96–1.73)	0.09	
Attended laboratory by age					0.07
50–64 y	53/292 (18%)	60/294 (20%)	1.12 (0.81–1.57)		
65–74 y	9/62 (15%)	20/61 (33%)	2.26 (1.12–4.56)		
Randomized to T4DM trial ^b	6 (2%)	9 (3%)			

Abbreviations: CI, confidence interval; RR, relative risk; T4DM, Testosterone for Diabetes Mellitus.

^a Response defined as attendance for laboratory screening tests by 8 wk after completing prescreening.

^b Participants who attended laboratory screening within 8 wk after completing prescreening and went on to be randomized to the main T4DM trial at any time following laboratory screening. The study was not powered for this outcome; therefore, statistical testing is not presented.

Table 3. Cost of performing SMS and phone reminders^a

Cost component	SMS	Phone
Direct cost per reminder	\$0.18	\$0.54
Cost of staff time per reminder	\$0.35	\$5.67
Total cost per reminder	\$0.53	\$6.21

^a All costs are quoted in Australian dollars.

already completed a prescreening questionnaire, selecting for willingness to participate in the trial. In addition, the responses to phone and SMS reminders were evaluated in the context of our existing screening processes, including e-mail and SMS communications with participants after prescreening (Fig. 1), and these communications may have increased the observed response rate. These factors may impact the generalizability of our results. For example, it remains possible that phone reminders remain superior to SMS reminders in situations where participants are yet to respond to the initial invitation to participate in the trial and where no prior communications have been sent to participants. Furthermore, the T4DM study recruited only men aged 50–74 years. Our findings suggest that older participants may prefer phone reminders, and this has implications for RCTs recruiting participants who are older or younger than those included in our study. We hypothesize that SMS reminders may have been particularly appealing to our all-male participant cohort because they supported men to make an independent decision about trial participation. Reminder preferences in women may therefore differ and would merit investigation.

In a nonrandomized comparison, we found that attendance following either SMS reminder (18%, 95% CI: 14–22%) or phone reminder (23%, 95% CI: 18–27%) was higher than the previously observed attendance rate at 8 weeks of 12%. We elected not to include a “standard care” arm (neither phone call nor SMS reminder) in this randomized evaluation due to concerns that it might hamper the main study, particularly given the existing evidence on the effectiveness of screening reminders [9–11]. Future studies, if conducted earlier in their host trial’s recruitment phase, could include a “standard care” or no reminder arm. This would allow calculation of a reminder cost per randomized participant to guide decisions about whether reminders (either phone or SMS) are more or less cost-effective than other strategies designed to boost recruitment, for example, mass mail outs or advertising to invite more people to participate in the study.

In addition to the analyses reported here, we conducted an exploratory evaluation of subsequent reminders conducted more than 8 weeks after prescreening. These data are not shown here but suggested that a subsequent phone reminder to men who did not respond to an initial SMS reminder was almost three times more effective than a further SMS reminder (13% and 5%, respectively). Thus, further investigation of the impact of subsequent reminders may be of merit.

We reported higher reminder delivery in the SMS group (88% delivered) compared with the phone group (67% delivered, 78% if voicemail messages are also included). However, this apparent difference in intervention delivery fidelity is likely to be an artifact of how delivery was measured in each group. For phone reminders, we recorded whether the participant was spoken to on the phone or if a voicemail message was left. For SMS reminders, we could record only whether the SMS message was sent without bouncing back. We could not determine whether the participant received and read the SMS reminder. Thus, the actual delivery rates in each arm may be more similar than our estimates suggest. Furthermore, any difference in reminder delivery fidelity between the arms would likely also occur if these reminders were incorporated into practice.

The SMS reminder message in this evaluation included key information about trial participation and informed the participant that large numbers of men had already joined the trial, a peripheral cue to action based on the concept of social proof. This approach is underpinned by the Elaboration Likelihood Model of persuasion [23], which states that persuasion to action can occur through either a central (cognition-based) or peripheral (cue-based) route, with the peripheral route requiring less motivation and effort to process. Elsewhere, messages of scarcity (communicating that limited number of places are available) [9] and quotes from participants [12] were effective in boosting RCT recruitment using SMS reminders. Future research could extend these findings by evaluating manipulations in the content of SMS reminders using a theory-based approach [29,30]. It is possible that by optimizing the content of SMS reminder messages, response rates can be further improved.

5. Conclusion

Compared with SMS reminders, phone call reminders were more costly and did not significantly increase the screening uptake rate of nonresponders in this large multicenter RCT. There was some suggestion that phone call reminders were more effective than SMS reminders in men \geq aged 65 years. SMS reminders were substantially cheaper and quicker to perform than phone call reminders, making them a promising approach for boosting recruitment in RCTs with limited budgets.

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