RESEARCH ARTICLE

Pre-notification and personalisation of text-messages to retain participants in a smoking cessation pregnancy RCT: an embedded randomised factorial trial [version 1; peer review: 1 approved, 1 approved with reservations]

Elizabeth Coleman[1], Rachel Whitemore[2], Laura Clark[1], Karen Daykin[2], Miranda Clark[2]

[1]York Trials Unit, Department of Health Sciences, University of York, UK, York, YO10 5DD, UK
[2]Division of Primary Care, Tower Building, University of Nottingham, Nottingham, NG7 2RD, UK

v1 **First published:** 22 Jul 2021, **10**:637
https://doi.org/10.12688/f1000research.51964.1
Latest published: 22 Jul 2021, **10**:637
https://doi.org/10.12688/f1000research.51964.1

Abstract

Background:
Low response rates in randomised controlled trials can compromise the reliability of the results, so ways to boost retention are often implemented. Although there is evidence to suggest that sending a text message to participants increases retention, there is little evidence around the timing or personalisation of these messages.

Methods:
A two-by-two factorial SWAT (study within a trial) was embedded within the MiQuit-3 trial, looking at smoking cessation within pregnant smokers. Participants who reached their 36-week gestational follow-up were randomised to receive a personalised or non-personalised text message, either one week or one day prior to the telephone follow-up. Primary outcomes were completion rate of questionnaire via telephone. Secondary outcomes included: completion rate via any method, time to completion, and number of reminders required.

Results
In total 194 participants were randomised into the SWAT; 50 to personalised early text, 47 to personalised late text, 50 to non-personalised early text, and 47 to non-personalised late text. There was no evidence that timing of the text message (early: one week before; or late: one day before) had an effect on any of the outcomes. There was evidence that a personalised text would result in fewer completions via telephone compared with a non-personalised text (adjusted OR 0.44, 95% CI 0.22–0.87, p=0.02). However, there was no

Open Peer Review

Reviewer Status ✔ ?

	Invited Reviewers	
	1	**2**
version 1 22 Jul 2021	✔ report	? report

1. **Phil J. Edwards**, London School of Hygiene and Tropical Medicine, London, UK

2. **Frances Shiely**, University College Cork, Cork, Ireland
University College cork, Cork, Ireland

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

evidence to show that personalisation or not was better for any of the secondary outcomes.

Conclusion
Timing of the text message does not appear to influence the retention of participants. Personalisation of a text message may be detrimental to retention; however, more SWATs should be undertaken in this field.

Keywords
Randomised Controlled Trial, Embedded Trial, SWAT, Retention, text, notification, personalisation, SMS

Corresponding author: Elizabeth Coleman (izzy.coleman@york.ac.uk)

Author roles: Coleman E: Data Curation, Formal Analysis, Software, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Whitemore R**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing; **Clark L**: Writing – Review & Editing; **Daykin K**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing; **Clark M**: Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: The MiQuit-3 project was co-funded by the National Institute for Health Research (NIHR) under the Programme Grants for Applied Research programme (RP-PG-0109-10020) and Cancer Research UK (CRUK) (C11232/A23434). The factorial SWAT was funded by the PROMETHEUS MRC programme grant.
The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

How to cite this article: Coleman E, Whitemore R, Clark L *et al.* **Pre-notification and personalisation of text-messages to retain participants in a smoking cessation pregnancy RCT: an embedded randomised factorial trial [version 1; peer review: 1 approved, 1 approved with reservations]** F1000Research 2021, **10**:637 https://doi.org/10.12688/f1000research.51964.1

First published: 22 Jul 2021, **10**:637 https://doi.org/10.12688/f1000research.51964.1

Introduction

Randomised controlled trials (RCTs) are the 'gold standard' for evaluating healthcare treatments. However, it is well documented that retaining participants can be difficult and low response rates to questionnaires can compromise the reliability and generalisability of the results[1,2]. A study within a trial (SWAT) can be used to test interventions to improve retention of participants[3].

There is research to support the concept that text messages are effective at improving response rates in trials[4–7]. There is insufficient evidence to determine if the timing of text messages improves questionnaire response rates, and limited papers exploring if personalisation (inclusion of the participants name) impacts response rate[8–11]. This SWAT aims to evaluate the effectiveness of the timing and personalisation of text messages within an RCT to add to the evidence base for both of these interventions.

Methods

Design

This two-by-two factorial study was embedded within the MiQuit-3 RCT. MiQuit-3 (ClinicalTrials.gov NCT03231553) is an RCT evaluating the effectiveness of a text-message, smoking cessation self-help support programme for pregnant smokers (MiQuit), and the protocol has been published previously[12]. This SWAT was embedded at the 36-week gestational time point. The approval for this SWAT and the MiQuit-3 trial was granted by East Midlands–Nottingham 1 Research Ethics Committee (NRES reference 13/EM/0427 and 17/EM/0327). As the SWAT was considered low risk, informed consent was not obtained from participants, and they were unaware of the SWAT. However, as part of the MiQuit-3 trial all participants consented to their anonymised data being used for further research, and being published. The SWATs are also registered with the Northern Ireland Hub for Trial Methodology Research SWAT Repository (SWATs 35 and 44; both registered December 2015).

Participants and randomisation

As with all SWATs, the sample size is limited by that of the host trial, and a formal power calculation has not been carried out. The SWAT was implemented mid-way through follow up for the host trial, and all participants that had not yet had their 36-week gestational follow-up were eligible to participate in the SWAT.

Participants in MiQuit-3 were blind to their participation in this SWAT; and were randomised 1:1:1:1 to each of the four groups (see Table 1). The randomisation was undertaken by a statistician independent of the host trial, and of the staff involved in sending the texts. Block randomisation, stratified by host trial allocation, and whether they had completed the previous follow-up; with varying block sizes of 4, 8, 12 and 16.

Interventions

This SWAT explored two different interventions; personalisation and timing of text messages (early; one week before follow-up, or late; one day before follow-up). Details of the text sent to participants can be found in Table one. A £5 voucher was given to all participants who completed a follow-up, additionally those who provided a saliva sample were given another £30 (£35 total).

Outcomes

The primary outcome was completion rate; defined as the proportion of the questionnaires completed over the telephone within the follow-up window (14 days).

Secondary outcome measures

The secondary outcome measures included:

- Completion rate where the questionnaire was completed by any method within the follow-up window (14 days)
- Time to response, defined as the number of days between the due date of the 36-week gestation

Table 1. Details of the SWAT interventions and combinations.

		SWAT 1 – Personalisation	
		Intervention 1: Personalised	**Control 1: Non-personalised**
SWAT 2 – Timing	**Intervention 2: Early notification**	MiQuit Trial: Hi [name], Thank you for taking part in the MiQuit3 trial. A member of the MiQuit3 team will call next week to complete the final questionnaire. Once completed we will send you a £ 5 or £35 voucher. Whether you have quit smoking or not we would love to speak to you. Thanks, [Researchers name].	MiQuit Trial: Thank you for taking part in the MiQuit3 trial. A member of the MiQuit3 team will call next week to complete the final questionnaire. Once completed we will send you a £ 5 or £35 voucher. Whether you have quit smoking or not we would love to speak to you. Thanks, [Researchers name].
	Control 2: Late notification	MiQuit Trial: Hi [name], Thank you for taking part in the MiQuit3 trial. A member of the MiQuit3 team will call tomorrow to complete the final questionnaire. Once completed we will send you a £ 5 or £35 voucher. Whether you have quit smoking or not we would love to speak to you. Thanks, [Researchers name].	MiQuit Trial: Thank you for taking part in the MiQuit3 trial. A member of the MiQuit3 team will call tomorrow to complete the final questionnaire. Once completed we will send you a £ 5 or £35 voucher. Whether you have quit smoking or not we would love to speak to you. Thanks, [Researchers name].

follow-up and the date the questionnaire was recorded as complete

- Number of attempts to contact required before the questionnaire was complete, or the maximum number of calls is reached.

Statistical analysis

The data were analysed in Stata v.15 (RRID:SCR_012763) on an intention-to-treat (ITT) basis, using two-sided tests at the 2.5% level, as this is a factorial design the Bonferroni correction was applied to allow for multiple testing[13,14]. Participants were excluded from the analysis if they had withdrawn prior to the time point.

The primary outcome and completion for all methods were compared using a logistic regression model. Time to response (days between questionnaire due and complete) was analysed using a Cox Proportional Hazards regression, those who compared the questionnaire early had their time set to 0.1, those did not complete were censored at either last contact date or 120 days if not contacted, and those who withdrew in the course of the SWAT were set to their withdrawal date. The assumptions for this model were assessed using Schoenfeld residuals[15]. The number of attempts to contact was analysed using a negative binomial regression model, due to evidence of overdispersion. All models were adjusted for host trial allocation, whether the participant had completed the previous follow-up, age, and both SWAT intervention allocations. All models were repeated with the inclusion of an interaction term to explore any possible interactions between the two SWAT interventions; with a significance level of 5%.

Stata is proprietary software: a freely available alternative software that could be used to undertake this analysis is RStudio (RRID:SCR_000432)[16].

Results

In total, 194 participants were randomised into the SWAT; 50 received the personalised text and early notification, 47 received the personalised text and late notification, 50 received the non-personalised text and early notification, and 47 received the non-personalised text and late notification[17]. Five participants withdrew prior to the implementation of the SWAT and are not included in the analysis. Additional participants were excluded from the analysis, where the covariates required for the model were not provided. Three participants were not contacted due to difficulties/adverse events associated with their pregnancy but are still included in the analysis under ITT principles. The flow of participants can be seen in Figure 1. Baseline characteristics by SWAT arm and overall, can be found in Table 2.

Primary outcome

The overall completion rate by telephone was 66.1% (125/189) within 14 days of the due date. There were similar completion rates of the questionnaire *via* telephone within three groups; 50.0% for personalised early (24/48), 52.3% (23/44) for personalised late, and 58.0% (29/50) of non-personalised

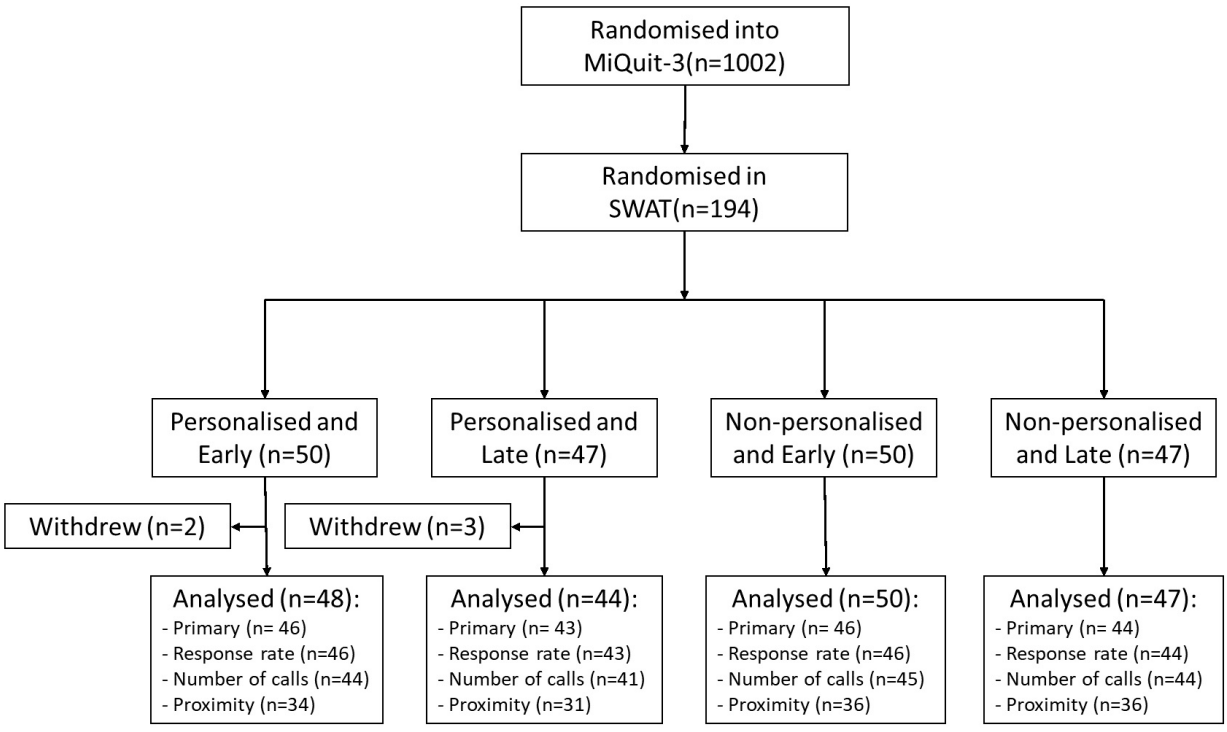

Figure 1. Flow of participants through the SWAT.

Table 2. Baseline characteristics for participants by SWAT allocation.

	Personalised & Early (n=48)	Personalised & Late (n=44)	Non-personalised & Early (n=50)	Non-personalised & Late (n=47)	Overall (n=189)
Age	N=48	N=44	N=46	N=44	N=182
Mean (SD)	25.4 (5.9)	27.9 (5.9)	27.1 (5.3)	27.2 (6.7)	26.9 (6.0)
Median (min., max.)	24 (17, 41)	27 (17, 41)	26 (16, 39)	28 (17, 41)	26 (16, 41)
Ethnicity: n(%)					
Caucasian	43 (89.6)	42 (95.5)	43 (86.0)	40 (85.1)	168 (88.9)
Non-Caucasian	3 (6.3)	1 (2.3)	2 (4.0)	4 (8.5)	10 (5.3)
Missing	2 (4.2)	1 (2.3)	5 (10.0)	3 (6.4)	11 (5.8)
Host trial allocation: n(%)					
Intervention	23 (47.9)	19 (43.2)	24 (48.0)	22 (46.8)	88 (46.6)
Usual Care	23 (47.9)	24 (54.6)	22 (44.0)	22 (46.8)	91 (48.2)
Missing	2 (4.2)	1 (2.3)	4 (8.0)	3 (6.4)	10 (5.3)
Completed Previous Follow-up: n(%)					
Yes	38 (79.2)	37 (84.1)	36 (72.0)	35 (74.5)	146 (77.3)
No	8 (16.7)	7 (15.9)	10 (20.0)	9 (19.2)	34 (18.0)
Missing	2 (4.2)	0 (0.0)	4 (8.0)	3 (6.4)	9 (4.8)

early and was slightly higher in the non-personalised late group, 66.0% (31/47).

There was no evidence for a difference in completion rate *via* telephone for the timing of the text message; adjusted odds ratio (OR) 0.86 (95% CI 0.44–1.67, p=0.65). There was evidence to suggest a difference in completion rate *via* telephone adjusted OR 0.44 (0.22–0.87, p=0.02) which implies those who received the non-personalised text were more likely to complete the questionnaire when completing *via* the telephone. Full details can be found in Table 3.

Secondary outcomes:
Full details for all secondary outcomes can be found in Table 4.

Response rates for all methods. There were similar completion rates of the questionnaire within each of the four groups; 64.6% for personalised early (31/48), 63.6% (28/44) for personalised late, 66.0% for early (33/50) and 70.2% (33/47) of non-personalised.

There is some, non statistically significant, evidence to suggest that there may be a difference in response rate for personalised *versus* non-personalised text reminders; adjusted OR 0.61 (95% CI 0.30–1.24, p=0.17), in favour of the non-personalised text messages. However, there was no evidence to suggest there was a difference in response rates in participants who received an early or late text message reminder; adjusted OR 1.06 (95% CI 0.52–2.15, p=0.87).

Number of attempts to contact required. The average number of calls required was 3.0 for all participants, with the average similar for each group (3.3 for both personalised early, 3.2 for personalised late, 3.1 for non-personalised early and 2.7 for non-personalised late). The maximum number of calls was reached for 55 of the 174 participants (31.3%) and was similar across three groups (38.6% for personalised and early, 31.7% for personalised and late, 31.1% for non-personalised early) and slightly lower in the non-personalised late group, 25%.

There was no evidence of a difference in number of contacts required between those who received an early text or a late text (p=0.45). There is also no evidence to suggest a difference between those who received a personalised or non-personalised text (p=0.23); adjusted incidence rate ratio (IRR)=1.14.

Time to respond. The average time to respond was 6.2 days (ranging from 5 days early to 103 days late). This was similar between those who received a personalised text (8.2 days for early *versus* 7.1 days for late) and those who received the non-personalised text (4.9 days for early *versus* 4.7 days for late), but there is a slight difference between those who received personalised or non-personalised texts.

Table 3. Primary analysis results.

Primary Outcome	Group	Statistic*	95% Confidence Interval	p-value
Response rate for all methods	Personalised vs. non-personalised	OR = 0.44	0.22 to 0.87	0.02
	Early *versus* Late	OR = 0.86	0.44 to 1.67	0.65
	Host trial allocation (Intervention *versus* Control)	OR = 0.63	0.32 to 1.22	0.17
	Completed previous follow-up (Yes *versus* No)	OR = 9.90	3.87 to 25.35	>0.001
	Age (years)	OR = 1.02	0.96 to 1.07	0.60

* OR = Odds Ratio

Table 4. Results for the secondary analyses.

Secondary Outcome	Group	Statistic*	95% Confidence Interval	p-value
Response rate for all methods	Personalised vs. non-personalised	OR = 0.61	0.30 to 1.24	0.17
	Early *versus* Late	OR = 1.06	0.52 to 2.15	0.87
	Host trial allocation (Intervention *versus* Control)	OR = 0.79	0.39 to 1.60	0.51
	Completed previous follow-up (Yes *versus* No)	OR = 8.45	3.60 to 19.86	>0.001
	Age (years)	OR = 1.05	0.99 to 1.11	0.12
Number of attempted to contact required	Personalised vs. non-personalised	IRR = 1.14	0.92 to 1.41	0.23
	Early *versus* Late	IRR = 1.08	0.88 to 1.33	0.45
	Host trial allocation (Intervention *versus* Control)	IRR = 1.11	0.90 to 1.37	0.33
	Completed previous follow-up (Yes *versus* No)	IRR = 0.64	0.50 to 0.82	>0.001
	Age (years)	IRR = 1.00	0.98 to 1.02	0.79
Time to response	Personalised vs. non-personalised	HR = 0.76	0.54 to 1.07	0.12
	Early *versus* Late	HR = 1.00	0.71 to 1.40	0.99
	Host trial allocation (Intervention *versus* Control)	HR = 0.87	0.62 to 1.21	0.40
	Completed previous follow-up (Yes *versus* No)	HR = 3.42	1.95 to 5.99	>0.001
	Age (years)	HR = 1.01	0.98 to 1.04	0.51

* OR = Odds Ratio, IRR = Incidence Rate Ratio, HR = Hazards Ratio

There was no evidence of a difference in time taken to respond between those who received the text early or late (p=0.99) or those who received a personalised or non-personalised text (p=0.12); suggesting that neither timing nor personalisation of the text message reminder affect the time taken to complete the questionnaire. The assumptions for the model held when examined using Schoenfeld residuals (p=0.66).

Interaction terms. All of the models were re-run with the inclusion of any interaction term between the two SWAT allocations. There was no evidence of an interaction for the completion rate, both by phone only (p=0.57) and all methods (p=0.54). There was also no evidence of an interaction for the number of contacts required (p=0.69), or the time to respond (p=0.88).

There were 1002 participants who were randomised into the MiQuit-3 trial. Of the 777 who were not included in the SWAT, and were due a 36-week follow-up, 499 completed the questionnaire (64.2%). This is similar to the completion rate for the participants in the SWAT (overall 66.1%).

Discussion

This factorial SWAT showed that the timing of the text message reminder had no effect on the response rate, the time to response, or the number of attempted to contact required; these results mirror what Partha *et al.* reported in their work[8]. It also showed that personalised texts have no effect

on response time, or number of attempts required. It did show that there was some evidence that sending a non-personalised text message reminder would have a larger increase in response than sending personalised text messages did. Cochrane *et al*. found no statistically significant difference in their study, but results favoured the non-personalised text[11]. As our work was conducted in a female-only population, who were between 17 and 41 years of age, the results here are only directly related to this population. Equally, as the SWAT was not powered to detect a difference, more SWATs should be undertaken in this area to allow the results to be combined in a pooled analysis to determine the true effect of the interventions, consider the effects on a wider population, and overall effectiveness.

Data availability

Underlying data

Figshare: Underlying data for 'Pre-notification and personalisation of text-messages to retain participants in a smoking cessation pregnancy RCT: an embedded randomised factorial trial'. https://doi.org/10.6084/m9.figshare.14224319.v1[17]

Reporting guidelines

Figshare: CONSORT checklist for 'Pre-notification and personalisation of text-messages to retain participants in a smoking cessation pregnancy RCT: an embedded randomised factorial trial'. https://doi.org/10.6084/m9.figshare.14229647.v1[18]

Acknowledgements

The authors would like to acknowledge Professor Tim Coleman, the Chief Investigator for the MiQuit-3 trial, and members of the MiQuit-3 trial involved in implementing the SWAT into the trial.

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**(1)1: 399.
PubMed Abstract | Publisher Full Text | Free Full Text

2. Adamson J, Hewitt CE, Torgerson DJ: **Producing better evidence on how to improve randomised controlled trials.** *BMJ.* 2015; **351**: h4923.
PubMed Abstract | Publisher Full Text

3. Treweek S, Bevan S, Bower P, *et al.*: **Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)?** *Trials.* 2018; **19**(1): 139.
PubMed Abstract | Publisher Full Text | Free Full Text

4. 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

5. 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

6. 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

7. Naughton F, Riaz M, Sutton S: **Response Parameters for SMS Text Message Assessments Among Pregnant and General Smokers Participating in SMS Cessation Trials.** *Nicotine Tob Res.* 2016; **18**(5): 1210–1214.
PubMed Abstract | Publisher Full Text | Free Full Text

8. Sarathy PP, Kottam L, Parker A, *et al.*: **Timing of electronic reminders did not improve trial participant questionnaire response: a randomized trial and meta-analyses.** *J Clin Epidemiol.* 2020; **122**: 70–77.
PubMed Abstract | Publisher Full Text

9. Keding A, Brabyn S, MacPherson H, *et al.*: **Text message reminders to improve questionnaire response rates in RCTs: findings from three randomised sub-studies.** *Trials.* 2015; **16**(Suppl. 2): 103.
PubMed Abstract | Publisher Full Text

10. Mitchell AS, Cook L, Dean A, *et al.*: **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].** *F1000Res.* 2020; **9**: 591.
Publisher Full Text

11. 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

12. Whitemore R, Leonardi-Bee J, Naughton F, *et al.*: **Effectiveness and cost-effectiveness of a tailored text-message programme (MiQuit) for smoking cessation in pregnancy: study protocol for a randomised controlled trial (RCT) and meta-analysis.** *Trials.* 2019; **20**(1): 280.
PubMed Abstract | Publisher Full Text | Free Full Text

13. StataCorp: **Stata Statistical Software: Release 15**. College Station, TX: StataCorp LLC, 2017.
Reference Source

14. Bland JM, Altman DG: **Multiple significance tests: the Bonferroni method.** *BMJ.* 1995; **310**(6973): 170.
PubMed Abstract | Publisher Full Text | Free Full Text

15. Schoenfeld D: **Partial residuals for the proportional hazards regression model.** *Biometrika.* 1982; **69**(1): 239–241.
Publisher Full Text

16. RStudio Team: **RStudio: Integrated Development for R.** RStudio, PBC, Boston, MA, 2020.
Reference Source

17. Coleman E: **MiQuit_SWAT_Data.csv.** *figshare.* Dataset. 2021.
http://www.doi.org/10.6084/m9.figshare.14224319.v1

18. Coleman E: **MiQuit SWAT CONSORT Checklist.** *figshare.* Journal contribution. 2021.
http://www.doi.org/10.6084/m9.figshare.14229647.v1

Open Peer Review

Current Peer Review Status: ✔ ?

Version 1

Reviewer Report 04 August 2021

https://doi.org/10.5256/f1000research.55180.r90184

?

Frances Shiely
[1] Trials Research and Methodologies Unit, HRB Clinical Research Facility, Mercy University Hospital, University College Cork, Cork, Ireland
[2] School of Public Health, University College cork, Cork, Ireland

Summary
This was a SWAT within the MiQuit-3 trial. The purpose of the SWAT was to establish if the timing or personalisation of text messages increases completion of a questionnaire. Study design was a 2 x 2 factorial SWAT. Participants who reached their 36-week gestational follow-up were randomised to receive a personalised or non-personalised text message, either one week or one day prior to the telephone follow-up. Primary outcome was completion rate of questionnaire via telephone. Secondary outcomes included: completion rate via any method, time to completion, and number of reminders required. The authors concluded that timing of the text message did not appear to influence the retention of participants. The authors concluded that personalisation of a text message may be detrimental to retention; however, more SWATs should be undertaken in this field.

Major Comments
My first comment is on the title, the purpose of the study and the conclusions drawn. The title, correctly refers to the retention of participants in the smoking cessation pregnancy RCT. The purpose of the SWAT though is to evaluate completion of a questionnaire, not retention in the host trial, as claimed in the conclusion in the abstract. I think this is conflated throughout and the authors need to consider this carefully and amend their paper. In fact, the registered SWATs in the NI SWAT repository give the outcomes in both as questionnaire completion. So therefore the conclusions drawn in the abstract and in the discussion are not supported by the data.

Abstract

- "There was evidence that a personalised text would result in fewer completions via telephone compared with a non-personalised text (adjusted OR 0.44, 95% CI 0.22–0.87, p=0.02)". This statement is confusing. The research question is personalised text message versus non-personalised text message. If using via telephone, then it should

be also say non-personalised text via telephone.

- Also, use text message, rather than text, throughout.

- "Personalisation of a text message may be detrimental to retention". I don't think your results support a statement this strong. Firstly, this is not a trial with an adequate sample size to make this claim. Secondly, when you included all methods of receiving the questionnaire (I think this is correct interpretation but it is challenging to establish in the current version of the paper as the detail on all methods is unclear) you did not find that personalised or non-personalised texts mattered. At best you can say, personalisation of a text message appears to affect questionnaire completion via telephone.

Introduction

- I like the succinct introduction.

Methods

- The methods says "The SWATs are also registered with the Northern Ireland Hub for Trial Methodology Research SWAT Repository (SWATs 35 and 44; both registered December 2015). It's a little confusing to the reader. It looks like you're conducting two SWATs. I understand what you have taken both of these SWATS and conducted the two in a 2 x 2 factorial design. However, make this clear to the reader.

- Replace the phrase "carried out" with conducted throughout. I know the phrase carried out is used all the time in literature but it is not correct unless you are describing physically carrying an object.

- I would use the word women rather than participants, given that it is a trial of pregnant women.

- The phrase "all participants that had not yet had their 36-week gestational follow-up were eligible to participate" suggests that some people were more than 36 weeks pregnant. Is this the case? Otherwise you could simplify it and say women who were 36 weeks pregnant. It's important to be clear on the timing of the intervention given that this is one of your outcomes.

- "Participants in MiQuit-3 were blind to their participation in this SWAT". Blinding is different to being unaware. Were they both blinded and unaware?

- "The randomisation was undertaken by a statistician independent of the host trial, and of the staff involved in sending the texts". Explain how the statistician did the randomisation, e.g. computer generated. Also, explain how he communicated that randomisation to the researcher assigning the women to each group.

- "Block randomisation, stratified by host trial allocation, and whether they had completed the previous follow-up; with varying block sizes of 4, 8, 12 and 16". This is not a sentence.

- "A £5 voucher was given to all participants who completed a follow-up...". Was this part of the host trial or the SWAT?

- "...additionally those who provided a saliva sample were given another £30 (£35 total)."

Where does the saliva sample come into it? Is this part of the host trial? Explain in the paper.

- How did you decide on how many to include for the SWAT. I accept that a sample size calculation is not required but a line in the paper on why you decided on (it appears to be 200) would be useful.

- In the secondary outcome, explain what you mean by completed by any method.

- "Time to response, defined as the number of days between the due date of the 36-week gestation follow-up and the date the questionnaire was recorded as complete". Are you certain all follow-up calls were made in 24 hours?

Statistical Analysis

- "The primary outcome was completion rate; defined as the proportion of the questionnaires completed over the telephone within the follow-up window (14 days)". However, you then go on to say that you used logistic regression to analyse this. Logistic regression is not suitable for four categories. I suspect what you mean is that you compared the completion rates across the two personalised/not personalised and again early/late. I can see you did this from the table. However, you need to articulate that in the text because it is currently confusing.

- In statistical analysis, a full stop after level and a new sentence for "As this is a factorial..."

- Full stop required in this sentence too. Also, I suspect the word "compared" in this sentence should read completed. - "Time to response (days between questionnaire due and complete) was analysed using a Cox Proportional Hazards regression, those who **compared** the questionnaire early had their time set to 0.1, those did not complete were censored at either last contact date or 120 days if not contacted, and those who withdrew in the course of the SWAT were set to their withdrawal date".

- Again the following is not a sentence, "All models were repeated with the inclusion of an interaction term to explore any possible interactions between the two SWAT interventions; with a significance level of 5%."

Results

- "Additional participants were excluded from the analysis, where the covariates required for the model were not provided". What additional participants? Quantify and explain please. Why were the covariates not 'provided'? Explain please.

- "Three participants were not contacted due to difficulties/adverse events associated with their pregnancy but are still included in the analysis under ITT principles". Commas are required to make sense of the sentence.

- In your flow chart, what does primary refer to, and proximity? Add an explanation or use a term that explains a little better. Also in the flow chart, you say response rate but provide the number of participants. This is not a rate.

- In the primary outcome, continue with your phraseology - the 14-day follow-up window rather than "within 14 days of the due date".

- I find the writing of the results very confusing. This sentence below suggests the outcome was completion rate via telephone versus completion rate via something else. "There was evidence to suggest a difference in completion rate via telephone adjusted OR 0.44 (0.22–0.87, p=0.02) which implies those who received the non-personalised text were more likely to complete the questionnaire when completing via the telephone". I'm wondering why you keep saying via telephone. It is particularly confusing when explaining the results. The last part above again says ... those who received the non-personalised text were more likely to complete the questionnaire when completing via the telephone". It looks like the method of completion is the purpose of the study.

- When you use the phrase "were more likely to", you must give the details of the comparison, i.e., more likely than who?

- It is implied, but not adequately explained, that some women completed the questionnaire by some other means. It is not clear how this was handled in terms of the numbers analysed throughout the study and this needs to be explained.

- For your tables 3 and 4, add the number of women. Why does the left column say "response rate for all methods" when the primary outcome is defined as the proportion of the questionnaires completed over the telephone..."

- The heading in the results section, "Response rates for all method", do you mean completion rates for all methods? A response rate is different.

- If you hang your hat on statistically significant evidence, by quoting CIs and p-values, to establish if your SWAT was effective, or not, then the following has no place in your paper. "There is some, non statistically significant, evidence to suggest that there may be a difference in response rate for personalised versus non-personalised text reminders; adjusted OR 0.61 (95% CI 0.30–1.24, p=0.17), in favour of the non-personalised text messages". You cannot say there is non-statistically significant evidence and then support that statement with statistics! Remove this please.

- The heading, "Number of attempts to contact required". Replace with, Number of attempts required to contact the women.

- What do you mean by the maximum number of calls, as stated here "The maximum number of calls was reached for 55 of the 174 participants..."?

- Contacts required is a new term introduced here " There was no evidence of a difference in number of contacts required". What do you mean by it?

- "The average time to respond was 6.2 days (ranging from 5 days early to 103 days late)". Respond to what, the phone call or the text, or the questionnaire?

- "This was similar between those who received a personalised text (8.2 days for early versus 7.1 days for late) and those who received the non-personalised text (4.9 days for early versus 4.7 days for late), but there is a slight difference between those who received personalised or non-personalised texts". If it is similar, how can there be a slight difference?

What point are you making here?

- Include the number of participants in the MiQuit Trial earlier in the paper when discussing the 200 randomised for the SWAT.

Discussion

- "It did show that there was some evidence that sending a non-personalised text message reminder would have a larger increase in response than sending personalised text messages did". This is misleading because it was not the case when all methods of questionnaire were included. Please amend the statement.

- The final sentence of the discussion needs to be reviewed. What do you mean by overall effectiveness?

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

Is the study design appropriate and is the work technically sound?
Yes

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

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

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

Are the conclusions drawn adequately supported by the results?
No

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Epidemiology; Trial Methodology; SWATs

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 29 July 2021

https://doi.org/10.5256/f1000research.55180.r90364

Phil J. Edwards
Department of Population Health, London School of Hygiene and Tropical Medicine, London, UK

This manuscript reports the results of a 2x2 factorial trial nested within an RCT of MiQuit, a text-message, smoking cessation self-help support programme for pregnant smokers. The nested factorial trial sought to evaluate the effect on response to a questionnaire administered over the telephone of two interventions applied to a pre-notification text message: (i) personalisation (text begins “Hi [name]”, or not), and (ii) timing of text messages (early: one week before follow-up, or late: one day before follow-up).

194 participants who had not yet had their 36-week gestational follow-up were randomised into this nested trial. Analysis of intervention effects was conducted using a logistic regression model.

The study found some evidence that personalised text messages reduced response (OR = 0.44; 95% CI 0.22 to 0.87; p=0.02); and no evidence that the earlier timing of text messages had an effect on response (OR = 0.86; 95% CI 0.44 to 1.67; p=0.65).

The manuscript is a clear and concise account of the study, citing the current literature. The study design is appropriate and the work appears to be technically sound. The authors appropriately recognise that their results are only generalisable to their study population (females aged 17 to 41 years).

The conclusions are adequately supported by the results, and the study makes a useful contribution to the data collection literature.

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: Evidence-based Data Collection

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.