





RESEARCH ARTICLE

A randomised trial of the effects on recruitment and retention of including a wet-ink signature and photograph in the patient invitation letter for a clinical trial: results from a Study Within a Trial (SWAT 3 and SWAT 53)[version 1; peer review: 1 approved, 1 approved with reservations]

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Abstract



Background: There is uncertainty about the effects of modifications to trial patient invitation letters on recruitment and retention. However, such documents are important.


Methods: A 2x2 factorial design embedded a pair of randomised Studies Within a Trial (SWAT) within a large host trial (CLEAR), to evaluate the effects of including wet-ink signatures and photographs in the patient invitation letter. Patients were randomised to receive one of four invitation letters: with a wet-ink or generic signature, and with or without a photograph. The primary outcome was the proportion of invited patients who joined the CLEAR trial. The secondary outcome was the proportion of patients retained in the trial.


Results: 368 letters were given to potential participants in the CLEAR trial and 121 (33%) joined. Proportions for each randomised group were generic signature and no photograph: 38% (33/88); generic signature and photograph: 32% (28/88); wet-ink personal signature and no photograph: 29% (26/91); wet-ink personal signature and photograph: 34% (34/101). There was no evidence of a significant difference in recruitment between those receiving the patient invitation letter containing a wet-ink versus generic signature (odds ratio (OR): 0.86, 95% confidence intervals (CI): 0.55 to 1.32, p=0.49) or photograph versus no photograph (OR: 0.99, 95% CI: 0.64 to 1.53,

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$p=0.97$). Retention was similar for the wet-ink and generic signature groups (OR: 1.20, 95% CI: 0.35 to 4.16, $p=0.77$) but significantly better when a photograph was used (OR: 5.40, 95% CI: 1.12 to 26.15, $p=0.04$, based on 2 withdrawals in the photograph group versus 9 in the no photograph group).

Conclusions: These SWAT add to the evidence base for the effects of modifications to clinical trial documentation on recruitment and retention. We found including a photograph may improve retention. Although these analyses are underpowered, they will contribute to meta-analysis of similar comparisons.

ISRCTN registration: 89040295 (06/07/2018)

Keywords

SWAT, Study Within a Trial, Methodology, Recruitment, Retention, Randomised trial, Patient invitation letter



This article is included in the **Studies Within A Trial (SWAT)** collection.

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Author roles: **Anand R:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Project Administration, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Bradley J:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Supervision, Writing – Review & Editing; **O'Neill B:** Conceptualization, Methodology, Supervision, Writing – Review & Editing; **McAuley DF:** Conceptualization, Methodology, Supervision, Writing – Review & Editing; **Clarke M:** Conceptualization, Methodology, Supervision, Writing – Original Draft Preparation, Writing – Review & Editing

Competing interests: MC is one of the founders of the SWAT repository and has written and spoken widely about SWAT. The other authors declare no competing interests.

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Introduction

Clinical trials depend on the willingness of a sufficient number of healthcare professionals and patients to dedicate their time and commitment to participate. Good recruitment is essential to the adequate conduct of a trial (Fisher *et al.*, 2012) but is often difficult to achieve. For example, data from a review of large phase 3 randomised trials in the United Kingdom (UK) found that the recruitment target was met in only 56% of the trials (Walters *et al.*, 2017). If the required levels of patient recruitment are not met, this has implications for the trial's statistical power, likelihood of publication, validity, cost and duration, and leaves important questions about patient care unanswered (Glasgow *et al.*, 1996; Bower *et al.*, 2014). Currently, there are few evidence-based solutions to improve recruitment to trials and uncertainty about the effects of modifications to trial documentation (Treweek *et al.*, 2018a), even though documents such as patient invitation letters feature in almost all trials. The Study Within a Trial (SWAT) approach for testing the effects of interventions that might improve recruitment or retention in clinical trials seeks to fill this gap by embedding a methodology study in an ongoing host clinical trial (Treweek *et al.*, 2018b). Some SWAT use an observational design (Elfghi *et al.*, 2020) while others, such as this, use a randomised design to allocate participants to different interventions (Bensaoud *et al.*, 2020).

Rationale for this SWAT

The invitation letter could influence whether a patient joins a trial. Different methods of personalisation, such as hand-written signatures by a member of the clinical research team or the inclusion of a friendly doctor photograph might affect patient recruitment, based on the mere-exposure effect or familiarity principle (Zajonc, 2001).

Aim and objectives

Our aim was to explore if the type of signature or inclusion of a photograph in the patient invitation letter would impact on recruitment and retention in a clinical trial of treatment for bronchiectasis (CLEAR; ISRCTN 89040295, registered 6th July 2018; Bradley *et al.*, 2019).

Methods

Ethical considerations

In accordance with the ethical approval for these SWAT (North East - Tyne & Wear South Research Ethics Committee, reference number 17/NE/0339), informed consent was not obtained from the participants but written informed consent to join the CLEAR trial was obtained from the patients or their legal representative before they were randomised into the CLEAR host trial. The CLEAR trial was registered on ISRCTN (89040295) on 6th July 2018. This paper is reported in line with the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Anand, 2021c).

Study design

We used a 2×2 factorial design to embed a pair of randomised SWAT in a large trial of treatment for bronchiectasis to evaluate the effects of including wet-ink signatures and photographs in the patient invitation letter. The host trial (CLEAR) was designed with Patient and Public Involvement (Bradley *et al.*, 2019). In short, CLEAR is a yearlong trial where patients could be randomised to take a twice daily nebulised intervention along with daily tablets, weekly home spirometry and to attend five trial related visits. All patients who were potentially eligible for the CLEAR trial were eligible for the SWAT. The SWAT were registered in the SWAT Repository (Queen's University Belfast, 2020). The first is a variation of SWAT 3 (Maguire & Clarke, 2014) and the second is SWAT 53 (Anand & Green, 2017). They were tested together in a 2×2 factorial randomised design.

SWAT 3 relates to the nature of the signature on the invitation letter, with interventions being

1. Invitation letter personally signed using wet ink by the local principal investigator.
2. Invitation letter generically signed and printed electronically as "The CLEAR Trial Team".

SWAT 53 relates to the inclusion of a generic doctor-patient photograph in the invitation letter with interventions being

1. Invitation letter includes a generic doctor-patient photograph.
2. Invitation letter does not include a doctor-patient photograph.

The 2×2 design generated four different invitation letters (Table 1), which are available in the *Extended data* (Anand, 2021b).

Table 1. Factorial design to combine two Studies Within a Trial (SWAT) in the CLEAR trial.

2×2 factorial design		Photograph	
		Photograph	No photograph
Signature	Personal	Personal wet-ink signature + photograph	Personal wet-ink signature + no photograph
	Generic	Generic signature + photograph	Generic signature + no photograph

Outcomes

The primary outcome of the SWAT is proportion of recipients who joined the CLEAR trial. The secondary outcome is the proportion of recruited participants who were retained in the CLEAR trial. These outcomes are taken from the routine data collected for the CLEAR trial.

Sample size

The sample size for the SWAT is based on the sample size for the CLEAR trial.

Implementation of the SWAT

Recruitment packs were prepared centrally based on recruitment estimates for each site, with each pack having a unique Pack Identifying Number on the envelope containing the patient invitation letter. These Pack Identifying Numbers were randomly generated for each site using mixed block sizes and one of the four invitation letters was placed in each pack in accordance with this randomisation. Packs were prepared into bundles so that each bundle contained a random sequence of patient invitation letters and the bundles were sent to the sites with instructions on how to distribute them, along with other site initiation materials. Each pack contained an invitation letter, patient information sheet and informed consent form. The recruitment strategy for the CLEAR trial involved directly approaching potential participants who were regularly attending their respiratory clinic and giving them a recruitment pack. Potential participants were also identified within relevant databases and the recruitment pack was sent to them by post to their home address. Before the recruitment pack was given or posted to a patient, the Pack Identifying Number was recorded against the relevant Patient Identification Number on the screening log for the CLEAR trial. In this way, the randomised intervention was concealed from the patient and others involved in their recruitment until they had entered the SWAT. Participants could not be blinded to the SWAT intervention they received, but they were not aware of the SWAT or the hypothesis being tested.

Statistical methods

The primary analysis compares the proportion of potential participants who joined the CLEAR trial in the randomised groups for wet-ink versus generic signature and for photograph versus no photograph. The secondary analysis compares retention in the CLEAR trial for these two comparisons. Analyses were done using the statistical software R (R Project for Statistical Computing RRID:SCR_001905; Version 1.2) and the statistical calculator on MedCalc (MedCalc Software Ltd. Odds ratio calculator. Version 20.023) was used to calculate the odds ratio (OR), associated 95% confidence interval (CI) and p-value for each comparison. The threshold for statistical significance was set to $p=0.05$.

Results

All 14 sites in the CLEAR trial implemented the SWAT. The results presented here are final, as recruitment to the CLEAR trial was paused in March 2020 because of the coronavirus disease 2019 (COVID-19) pandemic and upon reopening in 2021 did not continue this SWAT substudy, but follow-up continued.

Period for data collection

All analyses are based on data obtained between the opening of the CLEAR trial in June 2018 through to May 2020.

Primary outcome (recruitment)

In total, 368 packs were given to patients across all sites (Anand, 2021a). The breakdown by type of invitation letter is shown in Table 2. A total of 121 (33%) of the invited patients joined the CLEAR trial.

Recruitment comparative analysis

The separate pairings were compared using odds ratios. Overall, no significant differences were found across the comparisons as shown in Table 3.

Secondary outcome (retention)

16 patients who joined the CLEAR trial and whose invitation letter had been randomised for these SWAT subsequently withdrew from the trial. Of these, 11 patients withdrew their consent under their own decision, while 5 were withdrawn

Table 2. Types of invitation letter with number and proportion of recipients who joined the CLEAR trial.

Randomised intervention (Type of invitation letter)	Distributed (n=368)	Declined (n=247)	Enrolled (n=121)	Proportion enrolled (33%)
Wet-ink signature and photo	101	67	34	34%
Wet-ink signature and no photo	91	65	26	29%
Generic signature and photo	88	60	28	32%
Generic signature and no photo	88	55	33	38%

Table 3. Comparative analysis between Photo vs No photo and Wet signature vs Generic signature and different types of letter, and the overall effect on recruitment. An odds ratio greater than 1 indicates that recruitment is more likely to occur in the first group listed in the comparison. CI=confidence interval.

Comparison	Odds ratio	95% CI interval	Z statistic	P value
1. Photo <i>versus</i> No Photo	0.99	0.64 to 1.53	0.032	0.9745
2. Wet Signature <i>versus</i> Generic Signature	0.86	0.55 to 1.32	0.695	0.4870
Comparison	Odds ratio	95% CI interval	Z statistic	P value
3. Generic Signature and No Photo <i>versus</i> Generic Signature and Photo	1.29	0.69 to 2.49	0.791	0.4288
4. Generic Signature and No Photo <i>versus</i> Wet-ink Signature and No Photo	1.50	0.80 to 2.81	1.268	0.2050
5. Generic Signature and No Photo <i>versus</i> Wet-ink Signature and Photo	1.18	0.65 to 2.15	0.550	0.5825
6. Generic Signature and Photo <i>versus</i> Wet-ink Signature and No Photo	1.17	0.62 to 2.21	0.473	0.6362
7. Generic Signature and Photo <i>versus</i> Wet-ink Signature and Photo	0.92	0.50 to 1.69	0.269	0.7876
8. Wet-ink Signature and No Photo <i>versus</i> Wet-ink Signature and Photo	0.79	0.43 to 1.46	0.759	0.4476

Table 4. Types of invitation letter with number and proportion of CLEAR participants who were retained in the CLEAR trial.

Randomised intervention (Type of invitation letter)	Recruited (n=121)	Withdrew (n=11)	Retained (n=110)	Proportion retained (91%)
Wet-ink signature and photo	34	1	33	97%
Wet-ink signature and no photo	26	4	22	85%
Generic signature and photo	28	1	27	96%
Generic signature and no photo	33	5	28	85%

for reasons outside the patient's control such as adverse events or decisions by their responsible clinician. Therefore, the analysis of retention uses data for a total of 110 (91%) patients: the 105 patients who remained in the CLEAR trial and the 5 who were withdrawn for reasons beyond their control (Table 4).

Retention comparative analysis

Retention was similar for the wet-ink and generic signature groups (OR: 1.20, 95% CI: 0.35 to 4.16, $p=0.77$) but significantly better when a photograph was used (OR: 5.40, 95% CI: 1.12 to 26.15, $p=0.04$) a 12% difference in retention based on 2 withdrawals in the photograph group versus 9 in the no photograph group (Table 5).

Table 5. Comparative analysis between Photo vs No photo and Wet signature vs Generic signature and different types of letter and the overall effect on retention. An odds ratio greater than 1 indicates that withdrawal is more likely to occur in the first group listed in the comparison. CI=confidence interval.

Comparison	Odds ratio	95% CI interval	Z statistic	P value
1. Photo <i>versus</i> No Photo	0.19	0.04 to 0.90	2.095	0.036
2. Wet Signature <i>versus</i> Generic Signature	0.83	0.24 to 2.89	0.287	0.774
Comparison	Odds ratio	95% CI interval	Z statistic	P value
3. Generic Signature and No Photo <i>versus</i> Generic Signature and Photo	4.82	0.53 to 44.00	1.394	0.163
4. Generic Signature and No Photo <i>versus</i> Wet-ink Signature and No Photo	0.98	0.24 to 4.10	0.025	0.980
5. Generic Signature and No Photo <i>versus</i> Wet-ink Signature and Photo	5.89	0.65 to 53.47	1.576	0.115
6. Generic Signature and Photo <i>versus</i> Wet-ink Signature and No Photo	0.20	0.02 to 1.96	1.378	0.168
7. Generic Signature and Photo <i>versus</i> Wet-ink Signature and Photo	1.22	0.07 to 20.47	0.140	0.889
8. Wet-ink Signature and No Photo <i>versus</i> Wet-ink Signature and Photo	6.00	0.63 to 57.31	1.556	0.120

Discussion

The analyses reported here did not reveal a significant difference in recruitment between the various types of invitation letter. However, this is not surprising given the relatively small sample size available for this analysis. For example, if 33% of the invited patients in a control group agree to join the trial, a sample size of approximately 3800 invitees would be needed to detect an improvement of 5% (to 38%), with 90% power at the 5% significance level. For the secondary outcome, one significant association was found, with patients who had received a letter that contained a photograph being more likely to remain in the CLEAR trial, however, this finding is based on small numbers and does not take account of the possibility of multiplicity affecting the likelihood of statistically significant results. If a trial retained approximately 90% of enrolled patients, a sample size of approximately 1200 recruited participants (3600 invitees) would be needed to detect an improvement of 5% (to 95%), with 90% power at the 5% significance level.

There are several factors to consider in these findings. Firstly, each SWAT tested minor changes to a small part of the overall recruitment pack that were in total 14 pages. Other information, such as the actual trial medication interventions, may have had greater influence on the decision made. Secondly, the intervention is non-verbal, while a large part of recruitment to trials involves verbal communication between trial staff and potential participants, so it is possible verbal discussions carry more influence especially in patients with chronic disease. Thirdly, the social psychological aspects of the mere-exposure effect can also work in reverse. For instance, rather than a patient having a positive preference for the familiarity of the wet signature and doctor photograph, they may not be happy with past experience of their clinical environment or care.

The analysis is consistent with the limited previous research into invitation material design. For instance, SWAT 3, 4 and 5 (Maguire *et al.*, 2015) and SWAT 23 (Parker *et al.*, 2018). Other studies also found limited differences in recruitment (Cockayne *et al.*, 2017; Knapp *et al.*, 2020; Man *et al.*, 2015; Sheridan *et al.*, 2020). However, one study (Gilbert *et al.*, 2017) which aimed to enrol patients to a stop smoking programme, found that letters personalised to include an individual's risk factors significantly increased participation, suggesting evaluating a more personalised approach for recruiting patients may have more impact than generic changes. Another study found handwriting the patient's name on the invitation letter, rather than printing it, decreased recruitment possibly due to handwriting being perceived as less professional (McCaffery *et al.*, 2019). We note an ongoing study exploring invitation letter design on recruitment (Grønbech, 2018).

Strengths of this analysis are that it is the first to simultaneously implement these two interventions in a 2×2 factorial design, with the use of allocation concealment and randomisation of the invitation letters. Overall, there were no major issues in implementation and the SWAT was administered with minimal cost. However, there were some imbalances in

the types of invitation letters distribution (Table 2), likely due to mixed block sizes and the fact that sites were not recruiting patients at the same rate. Additionally, this SWAT did not encounter any of the issues regarding approvals, costs and site uptake encountered in some other SWAT (Martin-Kerry *et al.*, 2019). The key limitation for this study is that it is an analysis based on convenience sampling. The CLEAR trial was paused in March 2020 due to the COVID-19 pandemic including all recruitment with a reopening planned for late 2021. It was anticipated that the revised recruitment strategy, that was primarily over the telephone, would alter the effect of the letters. Additionally, given the general challenges of re-opening recruitment and the revised time frame for trial completion, the management group agreed it would be beneficial for sites to focus their resources towards recruitment and answering the clinical questions of CLEAR. Based on the results of this analysis, continuing the SWAT in CLEAR would not alone detect an effect, therefore we hope this SWAT gives confidence to other trialists to replicate it in other studies.

Conclusions

These SWAT add to the evidence base for the effects of modifications to clinical trial documentation on recruitment and retention. Although these analyses are underpowered, they will contribute to meta-analyses of similar comparisons for this important question for clinical trials, as identified in the Prioritising Recruitment in Randomised Trials study (PRioRiT y) (Healy *et al.*, 2018).

Data availability

Underlying data

Zenodo: underlying data. <https://doi.org/10.5281/zenodo.5792978> (Anand, 2021a).

Extended data

Zenodo: Invitation letters design. <https://doi.org/10.5281/zenodo.5654301> (Anand, 2021b).

Reporting guidelines

Zenodo: CONSORT checklist for 'A randomised trial of the effects on recruitment and retention of including a wet-ink signature and photograph in the patient invitation letter for a clinical trial: results from a Study Within a Trial (SWAT 3 and SWAT 53)'. <https://doi.org/10.5281/zenodo.5824882> (Anand, 2021c).

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

Acknowledgements

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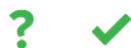
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Lydia O'Sullivan 

Health Research Board - Trials Methodology Research Network, University of Galway, Galway, Ireland

Thank you for the opportunity to review this interesting paper which describes a pair of SWATs evaluating the effect of using a wet-ink signature and a photograph included on invitation letters, on the recruitment and retention of participants to a respiratory trial. It's great to see that 14 different trial sites carried out this SWAT and that both recruitment and retention were considered.

This is a concise and clearly written paper and the rationale for the SWAT is well described. I have made a few minor suggestions below:

- The authors could consider clarifying in the Introduction, for those not familiar with the SWAT methodology, that SWATs are designed so as to not interfere with the outcome of the host trial.
- The authors state in the Introduction that invitation letters feature in almost all trials. I worked for a number of years recruiting to and monitoring oncology clinical trials in an outpatient setting and invitation letters were rarely used – patients were approached with an information leaflet only. I'm not suggesting that invitation letters are not useful and clearly practices vary depending on the type of the trial, the requirements of the ethics committee, local operating procedures etc. But you might consider slightly re-wording this sentence.
- Who prepared the recruitment packs? Someone not involved in approaching potential participants?

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: Clinical trial conduct; clinical trial methodology; evidence synthesis.

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.

Reviewer Report 01 August 2022

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Rustam Al Shahi Salman 

Centre for Clinical Brain Sciences, University of Edinburgh, Edinburgh, UK

Anand *et al.* provide a very clear report of a well-designed (but imprecise) study within a trial (SWAT) of the effects on recruitment and retention of including a wet-ink signature and photograph in the patient invitation letter for a clinical trial. With a study sample size of 368, the SWAT did not find a significant difference in recruitment between those receiving the patient invitation letter containing a wet-ink versus generic signature, but they found that including a photograph in the invitation letter may improve retention.

I have only a few suggestions:

1. Could you put the article in the context of the PRioRiTy I and PRioRiTy II James Lind Alliance PSPs in the introduction?
2. Could you provide 95%CI for the proportions described in the abstract to indicate the precision of the study?
3. Could you provide the natural frequencies of the numerators and denominators and

proportions in each group for the wet-ink versus generic signature and photograph versus no photograph comparisons in the abstract and Tables 3 and 5, for ease (to save the reader needing to calculate them themselves)?

4. Elfgi *et al.*, 2020, Bensaaud *et al.*, 2020, Gilbert *et al.*, 2017, McCaffery *et al.*, 2019, and Grønbech, 2018 are not referenced.

5. Could you give an indication of which ongoing RCTs are addressing SWAT 3 and SWAT 53, so that the reader understands to what extent and when these questions may be answered?

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: Stroke and clinical trial design/methods.

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.

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