






RESEARCH ARTICLE

Enclosing a pen to improve response rate to postal questionnaire: an embedded randomised controlled trial

[version 1; peer review: 2 approved]

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Abstract

Background: Poor response to questionnaires collecting outcome data in randomised controlled trials (RCTs) can affect the validity of trial results. The aim of this study within a trial (SWAT) was to evaluate the effectiveness of including a pen with a follow-up postal questionnaire on response rate.




Methods: A two-armed RCT was embedded within SSheW (Stopping Slips among Healthcare Workers), a trial of slip-resistant footwear to reduce slips in NHS staff. Participants were randomised 1:1 to receive a pen or no pen with their follow-up questionnaire. The primary outcome was the proportion of participants who returned the questionnaire. Secondary outcomes were: time to response, completeness of response, and whether a postal reminder notice was required. Data were analysed using logistic regression, linear regression and Cox proportional hazards regression.

Results: Overall, 1466 SSheW trial participants were randomised into the SWAT. In total, 13 withdrew from the host trial before they were due to be sent their follow-up questionnaire, 728 participants received a pen with their questionnaire, and 725 did not receive a pen. A questionnaire was returned from 67.7% of the pen group and 64.7% of the group who did not receive a pen. There was no significant difference in return rates between the two groups (OR 1.15, 95% CI 0.92 to 1.43, $p=0.22$), nor level of completeness of the questionnaires (AMD -0.01, 95% CI 0.06 to 0.05, $p=0.77$). There was weak evidence of a reduction in the proportion of participants requiring a reminder and in time to response in the pen group.

Conclusion: Inclusion of a pen with the follow-up postal questionnaire sent to participants in the SSheW trial did not statistically significantly increase the response rate. These results add to the body of evidence

Open Peer Review

Reviewer Status  

	Invited Reviewers	
	1	2
version 1		
09 Jun 2020	report	report
1. Anna Duncan , University of Aberdeen, Aberdeen, UK		
Magaly Aceves Martins , University of Aberdeen, Aberdeen, UK		
Hanne Bruhn  , University of Aberdeen, Aberdeen, UK		
2. Karen Bracken , The University of Sydney, Sydney, Australia		
Any reports and responses or comments on the article can be found at the end of the article.		

around improving response rates in trials.

Trial registration: ISRCTN [33051393](#) (for SSHEW). Registered on 14/03/2017.

Keywords

randomised controlled trial, embedded trial, postal questionnaire, response rate, pen



This article is included in the [Studies Within A Trial \(SWAT\)](#) collection.

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Author roles: **Cunningham-Burley R:** Investigation, Methodology, Project Administration, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Roche J:** Data Curation, Formal Analysis, Methodology, Software, Validation, Visualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Fairhurst C:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Investigation, Methodology, Software, Validation, Visualization, Writing – Review & Editing; **Cockayne S:** Conceptualization, Funding Acquisition, Investigation, Methodology, Project Administration, Resources, Visualization, Writing – Review & Editing; **Hewitt C:** Conceptualization, Data Curation, Formal Analysis, Funding Acquisition, Methodology, Resources, Software, Validation, Visualization, Writing – Review & Editing; **Iles-Smith H:** Funding Acquisition, Methodology, Project Administration, Writing – Review & Editing; **Torgerson DJ:** Conceptualization, Funding Acquisition, Methodology, Resources, Supervision, Validation, Writing – Review & Editing;

Competing interests: David Torgerson declares previous membership of NIHR HTA Commissioning Board and is Director of York Trials Unit which receives CTU funding from NIHR. Catherine Hewitt declares membership of NIHR HTA Commissioning Committee 2015-2020 David Torgerson is Chief Investigator of the Prometheus project. Catherine Hewitt is co-applicant on the Prometheus grant.

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Introduction

Randomised controlled trials (RCTs) are key to evaluating the effectiveness of interventions and often use postal questionnaires to collect outcome data. However, low response rates can limit the validity of the trial findings by reducing the power of the study and introducing bias¹.

Numerous strategies to increase response rates have been studied^{2,3} including sending a pen with the questionnaire. The pen acts both as a facilitator to aid completion of the questionnaire, and an incentive to return it^{4,5}. The effectiveness of this intervention is equivocal with some studies reporting an increase in response rate⁵⁻⁷ whilst others failed to show a positive impact^{4,8}. These studies displayed considerable heterogeneity and only two were embedded in RCTs^{6,7}. A Study within a Trial (SWAT) is a self-contained study embedded within a host trial that can be used to evaluate strategies designed to improve trial efficiency⁹. This SWAT evaluated the effectiveness of enclosing a pen with a follow-up postal questionnaire on response rates in the SSHeW trial¹⁰.

Methods

Design

This two-armed RCT was embedded in the SSHeW trial, a trial evaluating the effectiveness of slip-resistant footwear to reduce slips in NHS staff¹⁰. The SSHeW trial was registered (ISRCTN 33051393) and the trial protocol has been published¹⁰.

Participants

The SWAT was conducted in seven NHS Trusts in England and included all eligible participants in the SSHeW trial who were due to be sent their 14-week postal questionnaire between 04.07.2018 and 12.02.2019.

Intervention

The intervention group were sent a York Trials Unit, University of York branded pen with their questionnaire. The control group did not receive a pen.

Outcomes

The SWAT outcomes are outlined in [Table 1](#).

Sample size

As is usual with an embedded trial, a formal sample size calculation was not undertaken as the sample size was determined by the number of participants due to receive their 14-week questionnaire.

We anticipated that randomising 2,000 participants into the SWAT would provide 80% power to detect an absolute difference of 6% (two-sided $\alpha=0.05$) in response rates between the two groups, assuming a control rate of 60%.

Randomisation

Participants were allocated to either the intervention (pen) or control (no pen) group using simple randomisation in a 1:1 ratio. The allocation sequence was generated by the SSHeW trial statistician, who was not involved in sending out the questionnaires.

Blinding

Participants were not aware of their involvement in this SWAT but due to the nature of the intervention participants and study team members could not be blinded to group allocation.

Approvals

This SWAT was approved by the Department of Health Sciences Research Ethics Committee at the University of York and the Health Research Authority (HSRGC/2016/187/A).

Statistical analysis

Data were analysed using Stata version 15¹¹ on an intention-to-treat basis, using two-sided tests at the 5% significance level. The models used for each outcome are given in [Table 2](#), the values associated with the pen allocation from each model is presented with its 95% confidence interval and p-value. All models were adjusted for main trial group allocation (slip-resistant footwear or wait-list control) and pen sub-study allocation (pen or no pen).

Costing

The total cost of a standard SSHeW questionnaire pack was £2.42 (envelope and postage: £0.86; questionnaire and cover

Table 1. SWAT outcomes.

Outcome	Type	Definition
Proportion of participants who return questionnaire (Primary Outcome)	Binary (returned/not returned)	Proportion of 14-week questionnaires returned to York Trials Unit. (Returns were censored at 11.06.2019)
Time to response	Time to event (days)	Number of days between the date the 14-week questionnaire was sent and the date the returned questionnaire was received by York Trials Unit.
Completeness of response	Continuous (0–5)	Number of completed responses to 5 key questions on the 14-week questionnaire.
Reminder notice sent	Binary (sent/not sent)	Proportion of participants sent a reminder questionnaire (sent three weeks after the initial questionnaire if no response had been received, no additional pens were sent with reminders).
Cost	Continuous	Consideration of cost effectiveness of pen inclusion

letter: £0.65; pre-paid envelope and postage: £0.91). The additional cost of including a pen was £0.32. The cost analysis incorporates the changes in number of questionnaires returned and reminders required.

Results

A total of 1466 participants were included in the SWAT (pen, n=733; no pen, n=733). In total, 13 participants withdrew from the main SSHeW trial after they had been randomised into the SWAT but before being sent their follow-up questionnaire, leaving 1453 participants (Figure 1). Baseline characteristics are summarised descriptively in Table 3.

Results are presented in Table 4. Overall, 962 (66.2%) questionnaires were returned (pen, 67.7%; no pen, 64.7%) and an average of 4.9/5 items were completed. There was no evidence of a difference in return rate between the groups (OR 1.15, 95% CI 0.92 to 1.43, p=0.22), nor number of items completed (AMD -0.01, 95% CI 0.06 to 0.05, p=0.77).

There was weak evidence of a difference, in favour of the pen group, in both time to return (median time to return 15 vs

18 days; HR 1.12, 95% CI 0.98 to 1.27, p=0.09) (Figure 2), and in the proportion of participants requiring a reminder (OR 0.83, 95% CI 0.68 to 1.02, p=0.08).

Costing

A 3% difference in questionnaire response rate and an absolute difference in the percentage of participants who required a reminder of 1.1% were found. Considering these to be true effects, in order to receive one additional questionnaire, 33 participants would have to be sent a pen, at a cost of approximately 33x32p=£10.56. Approximately 91 participants would need to be sent a pen to prevent one reminder mailing and therefore to save £2.42. Hence, roughly one reminder is required per three retained participants, and the cost per retained participant is approximately £10.

Discussion

Whilst the results of all outcomes in this SWAT favoured the pen group, we found that the addition of a pen did not statistically significantly increase the response rate to, or completeness of, a follow-up questionnaire sent at 14 weeks post-randomisation among participants of the SSHeW trial. There was some evidence

Table 2. Analysis models.

Outcome	Analysis model	Value presented
Proportion of participants who return questionnaire	Logistic regression	Odds ratio (OR)
Time to response	Cox proportional hazards regression	Hazard ratio
Completeness of response	Linear regression	Adjusted mean difference
Reminder notice sent	Logistic regression	OR

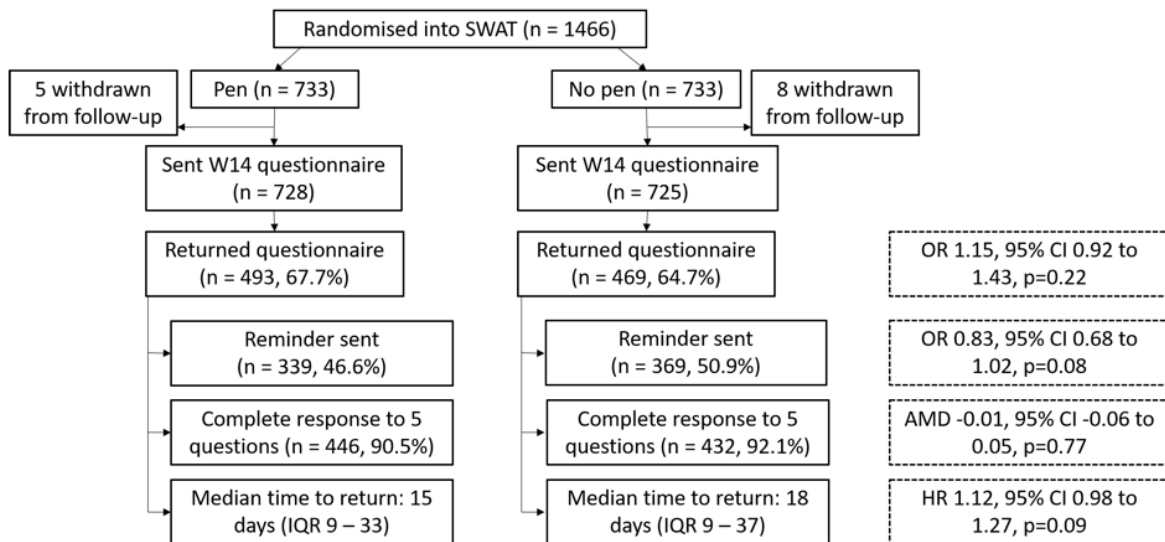


Figure 1. CONSORT flow diagram of participants in the embedded trial.

Table 3. Baseline characteristics of participants included in the analysis.

	Pen (n = 728)	No pen (n = 725)	Overall (n = 1453)
Main trial allocation, n (%)			
Usual Care	355 (48.8)	376 (51.9)	731 (50.3)
Intervention	373 (51.2)	349 (48.1)	722 (49.7)
Age (years), mean (SD)	43.0 (11.1)	42.9 (11.5)	43.0 (11.3)
Gender, n (%)			
Male	111 (15.3)	90 (12.4)	201 (13.8)
Female	616 (84.6)	635 (87.6)	1251 (86.1)
Prefer not to say	1 (0.1)	0 (0.0)	1 (0.1)
Job role, n (%)			
Admin and IT	44 (6.0)	51 (7.0)	95 (6.5)
Facilities	50 (6.9)	38 (5.2)	88 (6.1)
Direct patient care	610 (83.8)	614 (84.7)	1224 (84.2)
Other	24 (3.3)	22 (3.0)	46 (3.2)
Average working hours, mean (SD)	35.0 (5.2)	35.1 (4.9)	35.0 (5.0)
Injury resulting from a slip or fall (in previous 12 months), n (%)	43 (5.9)	30 (4.1)	73 (5.0)

Table 4. Summary of results. OD, odds ratio; HR, hazards ratio; AMD, adjusted mean difference

Results					
Returns, n/total (%)			OR	95% CI	p-value
Pen	No pen	Overall			
493/728 (67.7)	469/725 (64.7)	962/1453 (66.2)	1.15	0.92, 1.43	0.22
Time to response (days), median (IQR)			HR	95% CI	p-value
Pen	No pen	Overall			
15 (9-33)	18 (9-37)	16 (9-35)	1.12	0.98, 1.27	0.09
Completeness of response, mean (SD)			AMD	95% CI	p-value
Pen	No pen	Overall			
4.9 (0.4)	4.9 (0.4)	4.9 (0.4)	-0.01	-0.06, 0.05	0.77
Reminder sent, n/total (%)			OR	95% CI	p-value
Pen	No pen	Overall			
339/728 (46.6)	369/725 (50.9)	708/1453 (48.7)	0.83	0.68, 1.02	0.08

of a reduction in time to response and the number of reminders required.

It may be that, in this group of participants, the pen failed to act as a facilitator or was not a sufficient incentive to return the questionnaire, given the fact that participants in the trial already received a free pair of shoes (although offer of shoes was not conditional on returning the questionnaire).

However, the trial ultimately only had about 40% power to detect a difference of 3% in response rates (from 64.7 to 67.7%) and is therefore at risk of a type II error. Another potential weakness is that, due to the select population of healthcare workers, the results may not be generalisable to other populations or contexts.

The strength of this study is that it was a randomised trial.

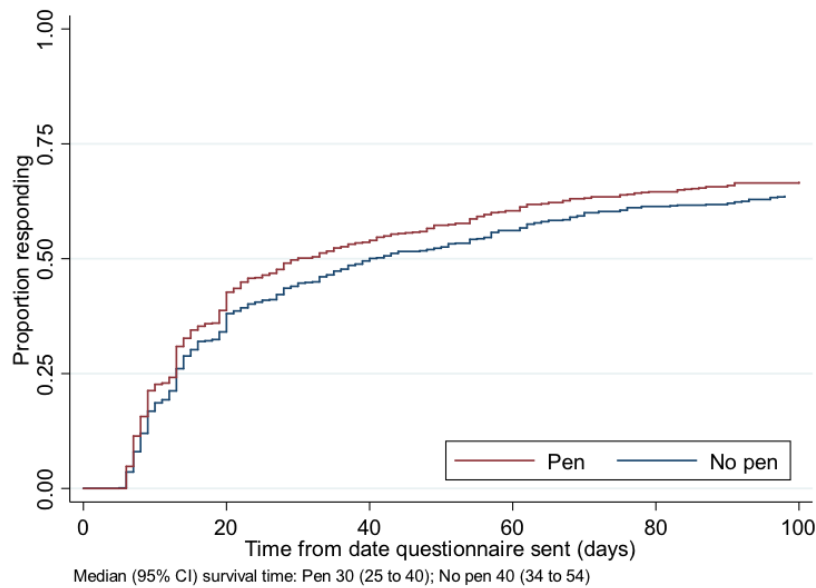


Figure 2. Kaplan-Meier curve for time to questionnaire return.

Conclusion

This SWAT suggests that enclosing a pen in a questionnaire mail out may be an effective method to increase response rates but was likely underpowered to detect a statistically significant difference of the 3% observed. Since pens are inexpensive, even a small difference is likely to be cost-effective. The results contribute to the body of evidence regarding this intervention and may be included in future meta-analyses to improve power.

Data availability

Underlying data

Open Science Framework: SSHeW Trial Pen SWAT, <https://doi.org/10.17605/OSF.IO/YQ76U>¹².

Reporting guidelines

Open Science Framework: CONSORT checklist for 'Enclosing a pen to improve response rate to postal questionnaire: an embedded randomised controlled trial', <https://doi.org/10.17605/OSF.IO/YQ76U>¹².

Data are available under the terms of the [Creative Commons Zero "No rights reserved" data waiver](#) (CC0 1.0 Public domain dedication).

Acknowledgements

The authors would like to thank the embedded trial participants who returned their trial documentation and the data administration staff at the YTU who worked to support the study.

The paper was written by the authors on behalf of the SSHeW Trial team, which is made up of the following individuals: Emily Bain (Health and Safety Executive); Sarah Cockayne (University of York); Rachel Cunningham-Burley (University of York); Caroline Fairhurst (University of York); Gillian Frost (Health and Safety Executive); Catherine Hewitt (University of York); Heather Iles-Smith (Leeds Teaching Hospital NHS Trust); Mark Liddle (Health and Safety Executive), Misbah Mogradia (Health and Safety Executive); David Torgerson (University of York), Michael Zand (Health and Safety Executive) and others. With the exception of Emily Bain and Misbah Mogradia, who supported Health Economic Evaluation for the host SSHeW Trial, all members of the SSHeW study team were involved in the designing this SWAT.

We would also like to acknowledge the support of individuals from the PROMETHEUS programme.

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Version 1

Reviewer Report 08 March 2021

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Karen Bracken

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This paper describes the result of a SWAT embedded within the SSHeW trial. The SWAT aimed to evaluate whether including a pen with a follow-up postal questionnaire would impact questionnaire response rate. The authors indicate that previous studies have yielded mixed results. The results of this SWAT add to the body of existing evidence.

The paper is clear and concise and addresses a common problem faced by trials; low response rates to questionnaires. The paper provides adequate detail for other trialists to replicate the intervention within their own trial. The inclusion of cost analyses is particularly useful.

I was interested to see that the cost of including the pen was very low and would have liked an explanation of the components of the cost (cost of pen, additional cost of postage and posting materials).

Like many SWATs, this SWAT was unavoidably constrained in sample size by the host trial, making conclusions difficult due to lack of power. It is unclear from the paper whether the authors expected that the sample size of 1466 was sufficient to detect an operationally important difference between groups. If not, then I suggest the conclusion be updated to make this clear, rather than stating that a statistically significant increase was not found. Would the authors suggest that further SWATs are needed in this area based on the Trial Forge guidance?

(<https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3980-5>¹)

Also, I suggest removing the observed power calculation from the discussion (<https://lesslikely.com/statistics/observed-power-magic/> provides an explanation as to why observed power calculations should be avoided).

References

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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?

Partly

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

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Trial operations and recruitment

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 02 September 2020

<https://doi.org/10.5256/f1000research.26098.r68921>

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Anna Duncan

CHaRT, University of Aberdeen, Aberdeen, UK

Magaly Aceves Martins

HSRU, University of Aberdeen, Aberdeen, UK

Hanne Bruhn 

Health Services Research Unit, University of Aberdeen, Aberdeen, UK

The current study is a SWAT – a Study Within A Trial. A SWAT is a methodological study aiming to add to the evidence base for randomised controlled trial design and conduct. In a SWAT an intervention to improve the conduct of trials is tested in an ongoing ‘host’ trial.

The current host trial was Stopping Slips among Healthcare Workers (SSHeW), a trial testing slip-resistant footwear with NHS Staff to reduce slips at work. The SWAT intervention was to include a pen with the follow-up questionnaire to test whether participants who received a pen were more likely to return their questionnaire than those participants who did not receive a pen. The authors also looked at whether inclusion of a pen with the questionnaire affected the time taken to send back the questionnaire; how complete the questionnaire was answered and; whether a reminder

had to be sent for return of the questionnaire. The SWAT was run on the 14 week post randomisation follow-up questionnaire. All SSHEW participants were randomised into the SWAT (n=1466). There were no significant difference in return rates between the two groups but weak evidence that including a pen might make participants return the questionnaire sooner and less will need a reminder.

This study reports findings contributing to the evidence base for how trial teams can increase questionnaire response rates in their trials, using the gold standard randomised comparison. This is a hugely important area as low response rates affect the conclusions that can be drawn from trial findings. Unfortunately, low questionnaire response rates are something which continues to affect a lot of trials.

We have a few comments which should be addressed:

ABSTRACT

No comments.

INTRODUCTION

It would be interesting to know if the authors expected there to be an issue with the questionnaire return rate in the host trial and what was the basis of this expectation (e.g. low response rate to previous questionnaires)? Please consider adding what the expected response rate for the host trial was. This could be added in the introduction or methods according to the authors preference. Commonly, SWATs are reactive so some background information to the approach in this SWAT would provide a helpful context.

The authors mention that the pen would act as facilitator and incentive, it would be helpful to have any reference to this use as a behavioural motivator or barrier.

METHODS

It would be interesting to know if the investigators found any issues with posting a pack including a pen, eg additional bulk causing any issues with standard franking machines. Did any changes have to be made to the process of posting out to include the pen?

RESULTS

No comments.

DISCUSSION

Please include some consideration as to whether the timing of the incentive to return questionnaires might have affected the findings. In many trials participants are followed-up for two years or longer and that is the point when it gets really tough to keep the response rate high (reviewers' personal experiences). It would be really valuable to have the authors thoughts on this for trial teams looking for help.

Paragraph 3 -The authors list a lack of power as a limitation. We'd suggest highlighting that many SWATs will be underpowered because they are generally unable to change the size of the host trial; they are made for meta-analysis really.

CONCLUSION

This is a very well conducted and clearly written article on a SWAT that investigated including a pen to improve response rates to a questionnaire, and importantly addressed the cost effectiveness of the intervention as one of the outcomes.

The results of the SWAT did not provide strong evidence in itself of the effectiveness of including a pen to improve response rates but the results add to the body of evidence and will be important to include in meta-analysis to examine the effectiveness of a pen as an incentive/facilitator in retention rates.

While the pen itself is inexpensive, when it is multiplied up over the issue of thousands of questionnaires is an additional cost any trials unit would have to justify to funder. The cost for a 3% gain is £10 per retained participant according to statement in Results (Costings) so not an insubstantial amount for weak evidence of an effect. Replication of this SWAT is needed to include other settings, different timepoints etc before concluding that including a pen may be effective and cost-effective way of improving response rates. The authors should expand on this in the concluding paragraph and consider revising sentence 2 of the concluding paragraph.

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?

I cannot comment. A qualified statistician is required.

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

Yes

Are the conclusions drawn adequately supported by the results?

Partly

Competing Interests: Hanne Bruhn: None. Anne Duncan: None. Magaly Aceves Martins: I am participating in the Cochrane Review Update on Strategies to improve retention in randomised trials.

Reviewer Expertise: Hanne Bruhn: Health Services Research and Trial Methodology. Anne Duncan: Trial Management and conduct and Trial Methodology. Magaly Aceves Martins: Nutrition and systematic reviewing.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

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