



RESEARCH ARTICLE

REVISED Optimising retention success: a research team’s experience of following-up participants recruited to a pilot trial through community pharmacies in England [version 2; peer review: 2 approved]

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V2 First published: 25 Aug 2020, 9:1042
<https://doi.org/10.12688/f1000research.25372.1>
 Latest published: 15 Feb 2021, 9:1042
<https://doi.org/10.12688/f1000research.25372.2>

Abstract

Background: The CHAMP-1 (Community pharmacy: Highlighting Alcohol use in Medication appointments) pilot trial aimed to explore an intervention discussing alcohol during medication consultations with community pharmacists. It presented various challenges regarding patient retention, as participants were recruited by their pharmacist and followed-up remotely by a trained researcher, who they had not met, two months later. We discuss our actions and experiences of completing follow-up activities.

Methods: Community pharmacists recruited patients aged 18 and over, attending a Medicine Use Review (MUR) or New Medicine Service (NMS) consultation, and drinking alcohol at least twice per week. Pharmacies were randomised to conduct their consultations as usual (control), or to incorporate the Medicines and Alcohol Consultation (MAC) intervention. All participants were followed-up by a researcher after two months to complete data collection via telephone or post. We employed standard follow-up strategies, including a plan to text participants with a reminder in advance of their follow-up.

Results: Forty-seven of 51 participants (92%) completed the two month follow-up. Thirty-eight (81%) responses were provided by telephone and nine (19%) by post. Of the 38 follow-up calls completed by telephone, 17 (45%) participants were reached at first attempt; 16 (42%) at second attempt; and five (13%) at the third attempt. We observed a high percentage of data completion across telephone and postal collection methods. Participants were willing to discuss potentially sensitive issues, such as alcohol consumption, anxiety, and depression, with a researcher who was external to the pharmacy team.

Conclusions: The results suggest that patients recruited to a trial by

Open Peer Review

Reviewer Status

	Invited Reviewers	
	1	2
version 2 (revision) 15 Feb 2021	 report	 report
version 1 25 Aug 2020	 report	 report

1. **Christopher Partlett**, University of Nottingham, Nottingham, UK
2. **Roberta Littleford** , The University of Queensland, Brisbane, Australia

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

community pharmacists are willing to take part in data collection activities, and remote follow-up can be successfully conducted by researchers. The techniques employed to encourage high levels of retention should be investigated further in a larger study, alongside consideration of optimal strategies to collect data within community pharmacies.

Keywords

Pharmacy services and practice, Trials/Randomised controlled trials, Health services research

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Author roles: **Watson M:** Conceptualization, Formal Analysis, Funding Acquisition, Investigation, Project Administration, Visualization, Writing – Original Draft Preparation; **van Dongen A:** Investigation, Project Administration, Writing – Review & Editing; **Hewitt C:** Conceptualization, Data Curation, Formal Analysis, Methodology, Validation, Writing – Review & Editing; **Mandfield L:** Data Curation, Formal Analysis, Validation, Writing – Review & Editing; **Stewart D:** Conceptualization, Investigation, Methodology, Project Administration, Writing – Review & Editing; **Watson J:** Conceptualization, Methodology, Writing – Review & Editing; **McCambridge J:** Conceptualization, Funding Acquisition, Methodology, Supervision, Writing – Review & Editing

Competing interests: No competing interests were disclosed.

Grant information: The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: The CHAMP-1 research programme is funded by the NIHR Programme Grants for Applied Research programme [grant number RP-PG-0216-20002]. The MRC funded PROMETHEUS programme provided financial support to investigate the methodological feasibility of sending text messages to participants, and their effect on retention. Unfortunately there were unexpected, isolated technical difficulties that affected the implementation of this work.

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

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How to cite this article: Watson M, van Dongen A, Hewitt C *et al.* **Optimising retention success: a research team's experience of following-up participants recruited to a pilot trial through community pharmacies in England [version 2; peer review: 2 approved]** F1000Research 2021, 9:1042 <https://doi.org/10.12688/f1000research.25372.2>

First published: 25 Aug 2020, 9:1042 <https://doi.org/10.12688/f1000research.25372.1>

REVISED Amendments from Version 1

We have updated our manuscript following peer review to ensure it focuses less on the main study, and more on our experiences of participant retention; including our actions, factors that may have affected retention, and potential strategies to consider in the future.

Any further responses from the reviewers can be found at the end of the article

Introduction

Community pharmacies are a dynamic environment with professionals who are keen to provide care and support for a wide range of healthcare service users. There are around 11,600 community pharmacies in England, and 89% of the population are able to reach such facilities within a 20-minute walk¹, allowing pharmacies to be at the core of communities and patient care. Over time, the role of a community pharmacist has expanded beyond the traditional dispensing duties², including taking on wider public health roles and research activities. Research in this setting is, however, not without its challenges, with time constraints and remuneration³ having been reported as difficulties previously. More widely, difficulties in retaining research participants recruited to trials is a common issue and represents a significant risk to the statistical power and analysis of trial results⁴, while also potentially introducing bias and reducing generalisability⁵.

The CHAMP-1 (Community pharmacy: Highlighting Alcohol use in Medication appointments) pilot cluster trial is part of a programme of work which aims to collaborate with the pharmacy profession and patients, to produce an intervention discussing alcohol within routine medication consultations. The design of the trial was informed by pre-trial studies conducted by the CHAMP-1 research team, including observational and interview work with patients and pharmacists^{6,7}. The pre-trial work guided development and implementation of the intervention, rather than follow-up procedures. Outcome data collection in the trial provided a challenge as participants were recruited by their community pharmacist but followed-up by a trained researcher who the participant had no prior contact with. We used the standard follow-up procedures of York Trials Unit, though were uncertain how successful they would be in these circumstances.

Full results of the pilot trial and the experiences of the community pharmacists involved are reported elsewhere^{8,9}. This paper focuses specifically on our experiences of contacting participants and the techniques used in an attempt to maximise our follow-up rate.

Methods

The pilot trial's primary clinical outcomes were the total weekly UK units (8g of ethanol per unit) of alcohol consumption in the week prior to follow-up, and confidence in medications management. Details of the trial's methodology are reported elsewhere⁸.

Twenty-seven community pharmacies in Yorkshire, England expressed an interest to be involved in the pilot trial, of which four were excluded (two had previous CHAMP-1 involvement and two did not respond) and 23 were assessed for eligibility. Of these, two were found to be ineligible (one postponed a telephone call three times, the other was not enthusiastic about the focus of the intervention) and 11 were excluded for varying reasons (three were unable to commit to the training days, three were unable to commit time to the study overall, two did not have approval from their manager or organisation, two did not respond, and one was not accredited to complete Medicine Use Reviews (MURs)). Ten pharmacies were deemed to be eligible and were randomised to conduct their Medicine Use Review (MUR) or New Medicine Service (NMS) consultations as usual (control), or to incorporate the Medicines and Alcohol Consultation (MAC) intervention. Five pharmacies were randomised to the control group, and five were randomised to provide the intervention. Randomisation for the trial was at the level of the community pharmacy (with one practitioner per pharmacy). A separate randomisation sequence investigating the methodological feasibility of sending text messages to participants and their effect on retention was generated using block randomisation stratified by pharmacy.

Participant recruitment was conducted by community pharmacists, and all participants were followed-up with a telephone call from a trained researcher two months after entering the trial and having their consultation with the pharmacist. During the telephone call, the trained researcher collected outcome data using a Case Report Form (follow-up questionnaire). The follow-up questionnaire asked participants details about their health and wellbeing. This included a question about alcohol consumption; a potentially sensitive issue. We compared a short alcohol measure consisting of two questions based on alcohol consumption in the last seven days ("On how many days did you have a drink containing alcohol?" and "How many units of alcohol did you drink on a typical day when you were drinking?"), against a long alcohol measure (seven day recall diary). We also collected data regarding the participant's confidence in medication management (PROMIS)¹⁰, medication adherence (ProMAS)¹¹, health related quality of life (EQ5D-5L)¹², anxiety (GAD-7)¹³, and depression (PHQ-8)¹⁴.

The research team considered the potential challenges to successful follow-up, such as the two month time lapse between the consultation and follow-up call, and the willingness of participants to speak about their health and wellbeing to someone they did not know. To facilitate trial follow-up, the study team established various procedures to address these such as: asking participants for more than one telephone number if available (e.g. a landline and mobile telephone number); asking for the participant's preferred days and times for contact; sending a text message to remind them that a researcher would be contacting them in the near future to conduct their follow-up telephone call; attempting to contact participants three times before sending the follow-up questionnaire¹⁵ (the same form as that completed by telephone) by post; calling from one single telephone

number to enable participants to recognise the number if they were unable to be contacted at the first attempt; and leaving voicemail messages where possible requesting that participants return the call. Participants who completed follow-up were given a £10 ‘thank you’ gift card. This was explained in the patient information sheet¹⁵ provided during recruitment and mentioned early in the conversation during the follow-up telephone call.

Results

The CHAMP-1 pilot trial recruited 51 participants from 10 pharmacies. Of these, 55% were men and 45% were women¹⁵. The mean age of those involved was 66.5 years. Forty-seven (92%) participants were successfully followed up at two months. Thirty-eight (81%) of the 47 responses were provided by telephone and nine (19%) participants completed the follow-up questionnaire after being sent it by post, having not responded to the telephone calls. Four participants did not respond to the telephone calls or return the follow-up questionnaire by post and therefore their outcome data was not collected.

All participants provided at least one telephone number and 34 (67%) participants provided a mobile telephone number, and therefore were possibly more likely to be contactable if they were not at the location of their landline telephone. Forty-eight participants (94%) also consented to receiving a text message that would remind them about the follow-up telephone call; however, of these, 15 (31%) did not provide a mobile number to enable this to occur. Due to technical difficulties, only seven of the text messages were sent as planned.

Of the 38 follow-up calls completed by telephone, 17 (45%) participants were successfully reached at the first attempt of contact by the trained researcher; 16 (42%) at the second attempt; and five (13%) at the third attempt. Having made contact, nine of the participants requested that the follow-up call be arranged for a more convenient time and this was scheduled accordingly. Eight of these calls were completed successfully as arranged, with five participants requesting this at the first attempt at contact, and three asking during the second. The ninth participant arranged their follow-up call after one attempt at contact; however, they did not engage with the re-arranged or subsequent telephone calls. If no contact had been made after three call attempts, the follow-up questionnaire, which was the same as that completed by telephone, was posted to the participant.

We observed a high percentage of data completion using both telephone and postal methods, as shown in Appendix 1. The long alcohol measure was completed best by telephone (89% fully completed by telephone, 33% fully completed by post (95% CI: 13.7% to 80.8%; $P=0.0064$)); however the PROMIS measure¹⁰ had fewer items missing when completed by post (100% fully completed by post, 79% fully completed by telephone (95% CI: -10.5% to 36.3%; $P=0.1355$)). Comparison data regarding the short and long alcohol recall measures are presented in the pilot trial paper⁸.

Discussion/conclusions

The trial involved participants with a range of ages and therefore is broadly representative of the type of patients that use community pharmacies. We were unable to meet our recruitment target due to various factors, some of which were beyond our control, and these have been described previously⁸. As the study was conducted in only one geographical location, this presents a limitation that may hinder generalisability. Whilst this was a small pilot cluster trial, it describes the initiatives used to encourage a successful follow-up rate in potentially challenging circumstances. The results suggest that patients recruited within community pharmacies are willing to complete further data collection activities which do not involve their pharmacy or pharmacist, and are willing to discuss potentially sensitive issues such as alcohol consumption and mental health. Repeated efforts to make contact were required for over half of participants.

Study retention may have been affected by factors largely or entirely outside of our capacity to influence; such as the participant’s view on pharmacists providing advanced services, their relationship with the pharmacist, the number of medicines being taken, co-morbidities, and whether the participant was visiting their regular pharmacy or not. Several of the pharmacists worked in pharmacies that were next to a doctor’s surgery, and participants may expect to have such discussions with a doctor or practice pharmacist, rather than a community pharmacist. A participant’s experience of their MUR or NMS consultation (with or without the MAC intervention) may also have affected our retention rate, as a higher retention rate may be anticipated with a more positive experience.

Follow-up questionnaire completion rates were good, irrespective of whether data was collected over the telephone or by post. Participants had completed the EQ5D-5L and PROMIS measures as part of the recruitment process, and therefore may have felt more comfortable with such questions during follow-up, having seen them previously. Some of the measures used were completed better by telephone, others by post; and such considerations will be important when planning future research, to encourage thorough data completion.

It is important to ensure that all necessary information is collected whilst completing recruitment procedures, as approximately a third of participants consented to receive a text message reminder about their follow-up telephone call, however did not provide a mobile number for this to be sent to. Study documentation was reviewed by the research team during pharmacy visits, however it was not considered appropriate to retrospectively contact participants for their mobile number if they had provided an alternative telephone number.

Future research is needed with larger samples and longer follow-up periods to examine other potential mechanisms that contribute to successful follow-up of trial participants recruited in this clinical setting. Due to the technical difficulties encountered when investigating the methodological feasibility of sending text messages to participants, and their effect on retention; it would be beneficial for this element of work to be

repeated. Future strategies to improve retention may involve considering if and how pharmacists and/or pharmacy staff can be involved in follow-up and retention activities; whether data collection completed in pharmacies can be improved by using electronic resources; and whether questionnaire completion rates can be improved by offering web or app based access to them.

Data availability

Underlying data

Open Science Framework: CHAMP-1 Pilot Retention Data. <https://doi.org/10.17605/OSF.IO/9DQ4W15>.

This project contains the following underlying data:

- CHAMP-1 Pilot Retention Data.csv
- Participant demographic data.csv
- Appendix 1 - Data completion for follow up questionnaires by method of completion

Extended data

Open Science Framework: CHAMP-1 Pilot Retention Data. <https://doi.org/10.17605/OSF.IO/9DQ4W15>.

This project contains the following extended data:

- CHAMP1_FUpLong_v2 (49582 – Activated, VersiForm)_Reference.pdf (follow-up questionnaire)
- CHAMP1_FUpShort_v2 (13283 – Activated, VersiForm)_Reference.pdf (follow-up questionnaire)
- REFERENCE 2A CHAMP-1 Pilot Patient Consent Form Version 2.0 07.05.2019.pdf
- REFERENCE 2A CHAMP-1 Pilot Patient Information Sheet Version 2.0 07.05.2019.pdf

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

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Open Peer Review

Current Peer Review Status:  

Version 2

Reviewer Report 08 March 2021

<https://doi.org/10.5256/f1000research.54527.r79563>

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Roberta Littleford 

The University of Queensland, Brisbane, Australia

I would like to thank the authors for considering the reviewer's comments to produce a clear report of their embedded sub-study while directing the reader to supplementary information covering the pilot and main studies.

I support the revised version and have no further comments.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Clinical Trial Specialist.

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 03 March 2021

<https://doi.org/10.5256/f1000research.54527.r79562>

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Christopher Partlett

Nottingham Clinical Trials Unit, Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK

I would like to thank the authors for carefully considering my initial comments and giving such a clear and detailed response.

I am happy that the revised version addresses my initial comments and I have no further comments to make.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Medical Statistics & Trial Methodology.

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.

Version 1

Reviewer Report 18 December 2020

<https://doi.org/10.5256/f1000research.27996.r74512>

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Roberta Littleford 

The University of Queensland, Brisbane, Australia

The article's aim is to present the research team's experience of following-up participants recruited into a pilot trial assessing an intervention discussing alcohol consumption habits during routine medication consultations within a community pharmacy environment. There are several issues the authors should consider addressing.

The manuscript's narrative focuses on the overarching main study, thereby omitting details required to describe the presented articles aims.

The premise of optimising retention strategies and therefore retention success are not systematically studied or quantified.

The authors present the important role that community pharmacists had in the main study's intervention, but pharmacists are out with the retention and follow-up scope and the authors do not postulate if intervention delivery had an impact on retention.

Standard follow-up strategies were employed.

The abstract will require to be amended if the recommendations provided below are addressed.

Introduction: The introduction mainly addresses the challenges related to pharmacists being researchers, but their role is limited within the scope of the retention and follow-up strategies employed, which were conducted by University researchers.

This section would benefit from a description of the literature that was considered when designing the follow-up strategies, and report upon the outcomes from the pre-trial work that were implemented into the design.

Methods: This section concentrates on the overarching main study, providing significant detail related to sample size, randomisation, and analysis (which can be addressed separately in the main study manuscript), thereby limiting information required to address the retention and follow-up methodology.

The primary outcome of the main study could be presented to provide some context.

This section requires to be rewritten to incorporate a robust methods section of the retention and follow-up strategies employed.

Including a clarification of the randomisation methods employed for SMS, consent and an outline of the actual method(s) used - automated manual by pharmacists or researcher. Further details here would assist in describing the limitations in the discussion.

The methods section does not currently describe the validation status of the questionnaires used, including self/researcher completion and how the visualisation of the units of alcohol and VAS were addressed during telephone follow-up calls versus in-person completion (the results/discussion section should address any noted differences).

The tense within the section varies throughout; this section should use past tense.

Discussion

The optimisation and limitations of the project should be addressed in more detail.

It may be prudent for the authors (with access to the main study results) to consider and discuss elements that may have impacted retention and follow-up; intervention delivery, impact of tokens, number of medicines, co-morbidities, usual pharmacy/new pharmacy, location within-GP practice or independent.

The authors should consider expanding on possible future strategies for trials, for example including pharmacists as part of the follow-up and retention success strategies, self-completion contact details, web/app questionnaire completion.

The rationale of failing to recruit the required sample size (63%) for the main study should be addressed, and also providing the reasons for pharmacy ineligibility and criteria for exclusion, leading to 13/23 (56%) of pharmacies being excluded. These factors may impact future success strategies.

There appears to have been significant training employed with weekly follow-up at pharmacies by the research team. However, the manuscript does not report if data monitoring was conducted, which may have identified the 33.3% missing mobile numbers.

The authors should consider adding the project timelines to give context to trial efficiency.

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

No

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

Partly

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

No

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

Not applicable

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: Clinical Trial Specialist.

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.

Author Response 05 Feb 2021

Michelle Watson, University of York, UK, York, UK

The authors of the manuscript thank the peer reviewers for their comments and have made the following changes based on their suggestions:

Abstract

- We have updated the abstract to reflect the changes made to the manuscript based on peer review comments.

Introduction

- We have added that loss to follow-up presents a risk to generalisability and may introduce bias.
- We have added a statement advising that the pre-trial work guided development and implementation of the intervention, and did not investigate follow-up procedures; therefore standard procedures were followed. The paper references the pre-trial work publications should readers wish to look into this further.

Methods

- We have removed the methodology for the pilot trial and included a reference to the publication describing this instead.
- We have added the reasons for excluding pharmacies.
- We have added further information about the randomisation methods.
- We have stated the measures which were included in the follow-up questionnaire.
- We added details about the follow-up questionnaire and measures used.

Results

- We have presented data regarding telephone or postal completion of the follow-up questionnaire.

Discussion

- We have again provided a reference to the pilot trial publication as this covers many of the points raised during review.
- We have reflected further on the factors that may have affected retention and the limitations of our work, including geographical spread, amongst others.
- We have discussed the data regarding telephone or postal completion of the follow-up questionnaire.

- We have discussed potential follow-up and retention strategies that future research could focus on.

Competing Interests: No known competing interests.

Reviewer Report 22 October 2020

<https://doi.org/10.5256/f1000research.27996.r72701>

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Christopher Partlett

Nottingham Clinical Trials Unit, Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK

The authors present an interesting case study exploring the feasibility of conducting follow-up for a pilot randomised trial within the community pharmacy setting. While I think this article is certainly worthy of indexing, I have some recommendations to improve the article.

Firstly, and most importantly, I found that the methods section (of both the abstract and the main article) read similarly to the methods section of a main trial publication. Since the article is focussing on the experience of following-up participants, the methods section should focus on this aspect of the trial. For instance, the final paragraph of the methods section is most pertinent to this article. Other important aspects of trial design would be better placed in the background, while less relevant aspects of the trial design could be omitted completely (and perhaps replaced with a reference to the trial protocol). This change would significantly improve the overall readability of the article.

I have listed some other minor comments below:

- The authors state in the final paragraph of the introduction that loss to follow-up represents a significant risk to statistical power and analysis. I would add that it also presents a potential risk to the generalisability of the trial findings.
- A limitation of the study is a lack of geographical spread, which may hinder generalisability of the findings within this article. This should be noted in the discussion.
- Ideally, the reasons for exclusion and ineligibility of pharmacies should be listed.

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?

Yes

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

Not applicable

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: Medical Statistics & Trial Methodology.

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.

Author Response 05 Feb 2021

Michelle Watson, University of York, UK, York, UK

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Methods

- We have removed the methodology for the pilot trial and included a reference to the publication describing this instead.
- We have added the reasons for excluding pharmacies.
- We have added further information about the randomisation methods.
- We have stated the measures which were included in the follow-up questionnaire.
- We added details about the follow-up questionnaire and measures used.

Results

- We have presented data regarding telephone or postal completion of the follow-up questionnaire.

Discussion

- We have again provided a reference to the pilot trial publication as this covers many of the points raised during review.
- We have reflected further on the factors that may have affected retention and the limitations of our work, including geographical spread, amongst others.
- We have discussed the data regarding telephone or postal completion of the follow-up questionnaire.
- We have discussed potential follow-up and retention strategies that future research could focus on.

Competing Interests: No known competing interests.

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