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RESEARCH ARTICLE

Optimising retention success: a research team's experience of following-up participants recruited to a pilot trial through community pharmacies in England [version 1; peer review: awaiting peer review]

Michelle Watson, Anne van Dongen, Catherine Hewitt, Laura Mandefield, Duncan Stewart, Judith Watson, Jim McCambridge

Department of Health Sciences, University of York, York, YO10 5DD, UK

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Abstract

Background: Community pharmacies support a range of patients and medical conditions, and form an important part of comprehensive, holistic healthcare services. The role of a community pharmacist has changed significantly over recent years, developing to include research activities. The CHAMP-1 (Community pharmacy: Highlighting Alcohol use in Medication aPpointments) pilot trial aimed to explore an intervention discussing alcohol during medication consultations. It presented various challenges regarding patient retention, and various actions were taken to address these, which are discussed in this manuscript.

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.

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.

Conclusions: The results suggest that patients recruited to a trial by community pharmacists are willing to take part in data collection activities, and 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.

Open Peer Review

Reviewer Status *AWAITING PEER REVIEW*

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

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

Corresponding author: Michelle Watson (michelle.watson@york.ac.uk)

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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 walk[1], 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 duties[2], including taking on wider public health roles and research activities. Research in this setting is, however, not without its challenges, with time constraints and remuneration[3] 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 results[4].

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[5,6]. 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. Full results of the pilot trial will be reported elsewhere. This paper focuses specifically on our experiences of contacting participants and the techniques used in an attempt to maximise our follow-up rate.

Methods

Ethical approval for the CHAMP-1 pilot trial was provided by South West - Frenchay Research Ethics Committee (19/SW/0082). The trial was registered with the ISRCTN registry (ISRCTN57447996) on 17th June 2019. All participants provided written informed consent to participate in the trial as described in the Participant Information Sheet[7].

At least four clusters per arm are recommended for cluster pilot randomised, controlled trials[8]. Assuming an average of eight participants per pharmacy are recruited, we planned to recruit 80 participants from 10 successfully recruiting pharmacies (equivalent to 70 participants in an individually randomised trial, assuming an intracluster correlation coefficient (ICC) 0.02). A trial of this size will allow a completion rate of 80% to be estimated within a 95% confidence interval of ±9%[9]. If we identify 160 eligible subjects, then we will be able to estimate a participation rate of 50% to within a 95% confidence interval of ±8%.

Randomisation for the pilot trial was undertaken by an independent York Trials Unit statistician using minimisation. Minimisation was undertaken in minimPy using naïve minimisation with base probability 1.0 (i.e. deterministic minimisation) using marginal balance as the distance measure and with minimisation factors having a weighting of 1. Randomisation 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.

Analyses for the pilot trial were conducted in R (R Development Core Team and R Core Team, 2011) following the principles of intention-to-treat with participant outcomes analysed according to their original, randomised group, where data are available, irrespective of deviations based on non-compliance. Analyses regarding the text message aspect of the trial were conducted in Microsoft Excel (2016).

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 and 11 were excluded for varying reasons. 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. The median cluster size was five in the control arm, and four in the intervention arm. One pharmacist from each of the pharmacies received training in the recruitment and study procedures for the trial; with those randomised to the intervention arm receiving additional training on the MAC. The MAC intervention is intended to help patients to think through whether drinking alcohol affects their medication use, the conditions for which they are prescribed, and their health more broadly; and to enable pharmacists to skilfully engage with these issues in a person-centred manner. The intervention involved pharmacists attending two practice development training days; using a MAC guide which summarised the structure of the intervention and core content within medication consultations; engaging with a range of learning support resources; receiving individually tailored weekly practice development support site visits or telephone calls by the MAC support team; and an invitation to engage in peer support.

Participant recruitment was conducted by community pharmacists, and patients were eligible for the trial if they were aged 18 and over, attending for a MUR or NMS consultation with their pharmacist, and drinking alcohol at least twice per week. Patients were excluded from the trial if they had received alcohol treatment in the past 12 months.

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. The research team considered the potential challenges to successful follow-up based on pre-trial feasibility work, 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 questionnaire[7] (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 sheet[7] 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 women[7]. 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. If no contact had been made after the third attempt, the follow-up questionnaire, which was the same as that completed by telephone, was posted to the participant. 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, and their data collection was completed by post.

Discussion/conclusions

The trial involved participants with a range of ages and medical conditions and therefore is broadly representative of the type of patients that use community pharmacies. 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. Repeated efforts to make contact were required for over half of participants.

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.

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.

Data availability

Underlying data

Open Science Framework: CHAMP-1 Pilot Retention Data. https://doi.org/10.17605/OSF.IO/KCPHQ[7].

This project contains the following underlying data:

- CHAMP-1 Pilot Retention Data.csv
- Participant demographic data.csv

Extended data

Open Science Framework: CHAMP-1 Pilot Retention Data. https://doi.org/10.17605/OSF.IO/KCPHQ[7].

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
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