

Process study within a pilot cluster randomised trial in community pharmacy: An exploration of pharmacist readiness for research

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INTRODUCTION

The potential for community pharmacies to deliver public health interventions is well recognised.^{1,2} In addition to dispensing and medication review services, policies in England have encouraged community pharmacies to provide public health services including sexual health screening, smoking cessation, cardiovascular risk screening, and alcohol interventions.^{3,4} The Healthy Living Pharmacy (HLP) framework in England requires all NHS community pharmacy contractors to be first level HLPs, promoting health, wellbeing and self-care; further levels are for commissioned prevention and treatment services.⁵

Alcohol is an important public health problem which is acknowledged as a causal factor in over 200 diseases.^{6,7} Existing guidance advises health and social care staff generally to opportunistically carry out screening and brief interventions for hazardous and harmful drinking as an integral part of practice during the course of routine NHS contacts.²

Community pharmacies have been promoted to undertake this role.^{8,9} This sits well with wider policy and clinical imperatives to better manage long term conditions and multimorbidities,^{4,10,11} alongside a need to develop interventions for older adults (the majority of whom will have long term conditions) who are hazardous or harmful drinkers.¹² However, there is currently no pharmacy specific guidance on delivery of alcohol interventions. A previous randomised controlled trial (RCT) of a community pharmacy-delivered brief intervention for alcohol found no differences in drinking outcomes amongst those who received the intervention and those who did not.¹³ Importantly, a nested qualitative process study from this trial,¹⁴ and subsequent observational studies of pharmacy practice,^{15,16} report ambivalence about the need for alcohol interventions among patients, low levels of alcohol-specific knowledge among pharmacists, and large variability in pharmacists' consultation and communication skills.

Informed also by examinations of the limitations of the wider evidence-base on brief interventions¹⁷⁻²¹ we have therefore developed a new approach that integrates attention to alcohol within existing pharmacist-led medicine review services. These services provide an opportunity to discuss the possible consequences of alcohol for the safety and effectiveness of medications, including adherence-related issues, the conditions for which these medicines are prescribed, and on health more generally. The Medicines Use Review (MUR) and the New Medicine Service (NMS) are services contracted to community pharmacies in England by the NHS to support people with long term conditions to improve adherence and management of their medicines. Pharmacies are remunerated for providing these services: £28 per MUR, up to a maximum of 400 per year, and up to £28 per NMS depending on numbers completed.²³ Our intervention, the Medicines and Alcohol Consultation (MAC), integrates a person-centred discussion of alcohol into routine delivery of these services. At the time of conducting this pilot trial both medicine review services (MUR and NMS) were provided in England by community pharmacy, but subsequent changes in the NHS have included decommissioning of the MUR.²⁴

Few trials of generic, pharmacist-led medicine reviews of the kind delivered in UK community pharmacy have been conducted; most previous trials are of medication reviews for specific health conditions.^{25,26} Evidence of effectiveness from the UK is limited to one RCT of the NMS.²⁷ In this trial, which allocated patients either to the NMS or to usual care, there was no recruitment in approximately one quarter of participating community pharmacies and there were various data collection limitations, for example it was not possible to record or estimate the number of patients approached. The trial reported a 10% difference in self-reported medication adherence at 10 weeks follow-up in favour of the NMS arm,²⁷ and

a non-significant difference of 9% at 26 weeks.²⁸ In the absence of a body of relevant trials-based evidence, the extent to which UK community pharmacists (CPs) would be able to conduct a trial investigating medicine review consultations was uncertain.

We conducted an external pilot trial in preparation for a definitive trial of the intervention. The aim of the pilot was to assess the acceptability and feasibility of conducting a cluster randomised trial of the MAC in community pharmacies, and included an embedded qualitative process study of pharmacists' practice development and experiences of the trial. Trial outcomes, including patient recruitment, are reported elsewhere.²⁹ Specific objectives addressed in this paper were to examine the process of recruiting CPs to the trial and CPs' experiences of trial participation, including patient recruitment, acceptability, research readiness, and training and support issues.

METHODS

Community pharmacist recruitment

The pilot trial was conducted in 10 community pharmacies within one defined geographic area (within 1.5 hours of travel time from York, UK). The trial received NHS research ethics approval (REC reference 19/SW/0082) and registered with the ISRCTN registry (ISRCTN57447996). We over-recruited from a planned sample size of 8 pharmacies in anticipation of pharmacy-level attrition. One CP from each pharmacy was eligible to participate in the trial, excluding locums, trainees, and other temporary practitioners; UK CPs require a General Pharmaceutical Council (GPhC) accredited degree (e.g MPharm or a BPharm/BSc prior to 2000) and a period of 12 months pre-registration which includes evidence of meeting the GPhC learning outcomes and registration examination. A multi-

stage CP recruitment process was implemented to assess motivation, commitment and capacity to participate. First, expressions of interest were sought from CPs in North Yorkshire by using Local Pharmaceutical Committee networks to advertise the trial. CPs who responded were then contacted by telephone to confirm eligibility according to the following criteria: likely to conduct sufficient numbers of NMS and MUR consultations in the study period; interested in the opportunity for practice development; able to participate in mandatory intervention and research training; expecting full availability without planned disruption in the pharmacy during the study period. Royal Pharmaceutical Society (RPS) Research Ready scheme registration,³⁰ which prepares pharmacists for engagement with researchers and hosting research, was not an inclusion criteria. This was because we could not be certain that enough accredited pharmacies would express an interest in the trial and we also provided extensive training for the trial (see below). We also confirmed that a payment would be made to each participating site to enable locum cover for training attendance and for other aspects of trial participation that might take extra CP time and thus place a burden on the pharmacy. After this 'in principle' eligibility stage, more detailed information about the trial was forwarded and followed-up with a further telephone discussion. Here, CPs were asked to confirm that they: understood the commitments required, including an expectation that at least 30 patients would need to be approached to recruit a target of 10; had obtained managerial approval to participate; would be available for attendance at intervention and trial training days on specified dates; were willing to be randomised and therefore may not receive the intervention training; and were willing to audio record consultations (with patient consent) for practice development and research purposes. Final selection decisions were based upon these responses and our assessment of the level of interest and commitment demonstrated in these discussions. All 10 eligible CPs provided written consent to participate and were subsequently randomized: five to the intervention arm and five to the control arm.

Randomisation took account of urban vs rural setting, independents vs multiples, and above and below median Index of Multiple Deprivation score for the pharmacy postcode.³¹

Trial research training

All trial CPs (both intervention and control) attended a research training day. This included an introduction to the study (background, rationale and design), the required Good Clinical Practice (GCP) training (delivered by the NIHR Clinical Research Network) and study specific training on patient recruitment. The latter involved familiarisation with the eligibility and recruitment process and forms, and several exercises (in pairs) to practice using these. Particular attention was paid to how to introduce the study in the context of recruiting patients to a MUR or NMS consultation (see below), and in obtaining informed consent from patients to take part in the trial appropriately. Suggestions on how to make the initial approach to patients had been discussed with the programme public and patient involvement group,³³ and these were discussed along with possible refinements for individual pharmacist style and circumstances.

Patient recruitment

MUR/NMS consultations are mostly opportunistic: patients are often flagged in a computer system as eligible for a consultation, and are usually approached by pharmacy staff (not the pharmacist) when in the pharmacy to pick up their medications if the pharmacist has time available. If the person approached agrees, the consultation then takes place with the pharmacist in a private consultation room in the pharmacy. The trial recruitment process was designed to fit into this routine practice, ensuring that the patient could participate in the medicines review if they did not want to take part in the trial.

After discussion of proposed research procedures at the research training day, it was agreed that the CPs would ask consecutive patients who responded positively to the initial approach for a MUR or NMS if they would also be interested in taking part in a study about improving medicines reviews. If the initial invitation to participate in the trial was accepted, the CP asked if the patient would be willing to complete a brief screening form. If eligible to participate the CP would provide the patient with a written information sheet about the study and the opportunity to ask questions, before asking the patient to complete and sign a consent form. Consent for consultations to be recorded was to be separately requested from patients in the intervention arm only, to assess the feasibility of using such data for a definitive trial process evaluation. Based on earlier (unpublished) feasibility work, we estimated that a third of MUR patients would be eligible for the trial, so we set a target for each CP to approach 30 patients. All patients were given a £10 high street shopping voucher on completion of a follow-up interview.

Trial support

All trial CPs received one-to-one support from the research team to support study participation and ensure adherence to recruitment protocols. A research team member visited each pharmacy in the first two weeks of patient recruitment to check initial trial eligibility form completion. Any errors or incomplete data fields were discussed with the CP. Direct observation and feedback on recruitment technique was also conducted where the opportunity arose during this visit. Researchers used a field guide checklist, including the flow of patients in the pharmacy and how they were approached for the trial. If recruitment could not be observed during a site visit, CPs were asked to describe their recruitment approach from start to finish. In both cases, any issues that emerged were discussed with the CP. Every week the support team discussed recruitment progress and any emerging difficulties for

individual CPs, with feedback from previous visits/calls and planning for subsequent ones. Support strategies for CPs included: emphasising targets and goal setting; identifying barriers and problem solving; emphasising learning from early recruitment; framing and practicing the recruitment pitch; emphasising successes; building commitment and consistency; and feedback from other CPs for comparison. Intervention CPs received additional support for practice development and intervention delivery purposes.

Trial acceptability

Semi-structured audio-recorded face-to-face interviews (lasting 40-105 minutes) were conducted with all 10 participating CPs at the end of the study period (end of September 2019) as part of a pilot trial process evaluation. Each CP was asked a set of questions using a topic guide to elicit their experiences of taking part in the trial. Interviews for intervention study participants were longer, covering their specific experience of intervention training and implementation. Both intervention and control groups were asked the same questions on how they became involved, experience of study recruitment, their thoughts on instruments used, reaction to the research process from patients, impacts on their usual practice and whether the research training equipped them appropriately for the study. This paper reports the key findings on their experiences of patient recruitment, and the research training and trial support. We contrast these with themes from three direct observations conducted during trial support visits. Data from observations (OBS) and interviews (INV) shown include a participant code: intervention group (INT- number) or control group (CON-number). Intervention and control CPs are identified as such in the findings since it is possible that their experiences of the trial were different.

Analyses

Interview transcripts and observation field notes were organised using a modified framework method³³ and analysed using thematic analysis.³⁴ The analysis here is focused predominantly on the CPs' reflections on the experience of being involved in trial research including research training and patient recruitment.

RESULTS

Community pharmacist recruitment

A total of 27 CPs responded to the call for expressions of interest in the trial. Four were excluded: two had previous involvement with the research programme and two did not respond to the follow-up email/call. Of the 23 assessed for eligibility, two were deemed ineligible; one because they postponed the call three times, the other because they were not enthusiastic about the practice development focus of the intervention. The remaining 21 CPs were emailed with further study information and received a second eligibility call. At this stage, 11 were excluded: three were unable to commit to attending three days training (one for research, two intervention); three said the time commitment overall was too great; one was not accredited to do MURs; two could not secure manager/organisational approval; and two did not respond. None of the selected 10 CPs were from RPS Research Ready pharmacies; their background and professional circumstances are summarized in Table 1. Two CPs worked at large national multiples, six worked at regional multiples, and two were independent pharmacists. One CP was a company managing director, three were superintendent CPs and three were pharmacy managers (all whilst also practicing). Years of post-qualifying pharmacy practice ranged from 1 to 40 years. Four were from pharmacies in a rural area, and six from an urban area. Deprivation deciles of the pharmacy locations ranged

from 1-10, however, eight pharmacies were in areas scoring seven or higher, and the median decile was nine, indicating that most were in areas of low deprivation.

Table 1: Pilot trial CP characteristics

CP	Arm	Role	Gender	Years of practice	IMD decile	Rural/Urban
1	Intervention	Managing Director	M	25	5	Urban
2	Intervention	Superintendent Pharmacist	M	40	9	Rural
3	Intervention	Pharmacy manager	F	2	9	Rural
4	Intervention	Pharmacist	F	13	7	Urban
5	Intervention	Superintendent Pharmacist	F	4	10	Urban
6	Control	Pharmacist	F	1	9	Urban
7	Control	Pharmacy Manager	M	16	1	Urban
8	Control	Pharmacist	F	3	8	Urban
9	Control	Pharmacy Manager	F	7	9	Rural
10	Control	Superintendent Pharmacist	F	21	8	Rural

Note: IMD= Index of Multiple Deprivation.

Interviews and observations

Four key themes emerged from analysis of the CP interviews: support for the idea of research in community pharmacy; acceptability of trial recruitment procedures, qualified by concerns about time; valuing practical aspects of trial training and support; and blurring of boundaries between research and practice. Overall, the CPs approached and recruited most patients through the MUR as envisaged, rather than NMS.

Support for the idea of research in community pharmacy

This group of CPs said they were supportive of research being conducted in community pharmacy and would recommend involvement to other CPs, although some observed that a culture of research was not strongly embedded in the profession:

...it's not something I've come across before, or not really heard much; but you do see trials for new services, I read about those; but other than that, I don't really come across much about research in pharmacy (INV-CON-8)

Consequently, prior research experience was limited. Few knew others who had taken part in research and none had taken part in a trial as a CP before. Research was considered useful if it could provide an evidence-base for practice, inform the design of services, improve patient outcomes, provide CPs with new skills or help to improve their professional status. For example, one CP said:

I think it's got a place. I won't say it's an essential role, but I think it's definitely got a place... They can't just come up with the ideas without any research or without any backup. So, that should be done first before there are any changes.... So, yes, it's [research] definitely got a place in pharmacy.... (INV-INT-2)

Despite viewing research as potentially providing an evidence-base for the profession, some expressed concern, and indeed ambivalence, about the burden of actually doing research alongside providing core services, as expressed by these two CPs:

I think we should be doing more [research]. At the same time we're having to do so much at the moment it's becoming a little bit difficult to take on any more. But I do think it's really important, because I do feel the need to prove ourselves, to prove I have spent all this time training, and if I'm saying to you it's really frustrating me stood at a checking bench checking prescriptions. I need to prove that my time is used better elsewhere. So these studies are actually really important even if I don't have time for them. I need to make time. (INV-CON-9)

Dare I say, there's enough to do at the moment in the day job, that adding in extra complexities...unless we can find time to decommission something else? (INV-INT-1).

The latter CP was a business owner who said that he had decided to join the trial himself rather than add to the existing pressure on the teams in his pharmacies:

Otherwise, what I felt would have happened is I'd have signed up to this, I'd have pushed the pressure onto one of my managers to do and they would have struggled to do it. Because not only am I asking them to do this, that and the other, I've now enrolled them on a trial and I've not given them any other time to do that (INV-INT-1).

One CP explicitly mentioned financial support as an incentive to take part in research:

...to be completely honest ... when you see something like a facilitation fee involved as well, this is a really difficult time for community pharmacy in terms of the finances. So especially for an independent group like ourselves we really need to be kind of taking opportunities to get any ... little sort of helps in terms of the finances as possible. (INV-INT-5)

Acceptability of trial recruitment procedures qualified by concerns about time

Evidence from research support contacts and the interviews suggested that the pressures on CPs' time were continuous and wide ranging, including in response to unanticipated difficulties such as consultation room availability, other services taking priority over medicine reviews (e.g. in response to staffing issues), or pharmacy targets for MURs being

reached. Within this context, the time taken to recruit patients was commonly raised as a challenge by both intervention and control CPs; they typically reported that the eligibility screening and informed consent process took approximately 10 minutes which seemed disproportionate to the similar amount of time usually available for conducting MURs. This felt uncomfortably long for 5 of the CPs, while some were also concerned about the impact on patients or the prospect of irritating them. Examples include:

...because most of the people that come obviously don't really want to wait in here, you know, 20–25 minutes... don't keep this guy in here for longer than he needs to be ... a fast, fast service is sort of expected in a pharmacy. So that's probably why – I've come from that culture of trying to get it, you know, in and out with the customers ... And you know, sometimes speed is linked to effectiveness so the faster you are serving somebody, then the better you are... I'm pretty sure that it was part of how I got trained. (INV-CON-7)

They [patients] were annoyed about it maybe a little bit, or I don't know, maybe not annoyed, a little bit irritated, that, you know, there's like loads of paperwork, they have to read that, they have to sign that, but nobody refused because of that. (INV-INT-4)

For three CPs, the commitment to involvement in research was contingent on routinely having a second pharmacist in branch. One had “double cover” in branch three days per week, and having this additional resource allowed more time to conduct the trial:

Okay, so, I mean, the most difficult thing was finding the time, okay? So right from the start, I decided that I would only do it when there are two pharmacists in the pharmacy, simply because we are a very busy pharmacy and it would be absolutely no

way I could have spent with a patient half an hour or twenty minutes. It would definitely be interrupted. So that wasn't ideal for the study...I'm not a pharmacist manager...for me, it's all about being with the patient (INV-INT-4)

Another who was a manager, found her managerial responsibilities took additional time that may have reduced recruitment:

I thought this is the perfect pharmacy for this study ... because we've got two pharmacists ... but practically I didn't account for the fact that it would only be myself doing all of that work. And I'm not just the pharmacist here, I'm the manager. I think actually in hindsight had I have turned it over to my co-pharmacist, who's downstairs perhaps she might actually have got you a few more (INV-CON-9).

Another CP, who owned the business, used the research participation fee to cover his time:

...the money that I was going to get for participating in the trial, I was going to make sure that I had double cover for a pharmacist so that I can give time... I wasn't interested in doing this as a way of trying to juggle two or three things. I felt if I was going to do it, I needed to do it properly (INV-INT-1).

This CP decided to schedule appointments with patients because he did not think he could fit the process into the usual ad hoc MUR recruitment practice. He organised double cover and used an intern CP trainee to call people to recruit, book and subsequently remind them of their appointments. He explained:

If you're doing a traditional MUR, people will sometimes say, yeah can you be quick, I've got the wife outside, or I need to catch a bus. So I wanted to not be constrained by the times that I had normally in clinical practice. So I felt that I gave everybody 45

minutes, of which half an hour was for the MUR and 15 minutes was the paperwork, turnaround and whatever... I think opportunistically, if I said to a patient, can I grab you up to half an hour, the recruitment would have been a lot poorer. I also think I would have been more worried about, I'm in here for half an hour, what's going to be outside when I come out there. (INV-INT-1).

The CP said this worked well for him, most people turned up, he enjoyed it and he thought it made people feel engaged: "You're building up a bit of a rapport with your own customers" (INV-INT-1). This was unusual practice and reflected the fact that CPs in the trial had different roles and levels of organisational responsibility, which influenced their abilities to engage with and conduct the work of the trial.

A control group CP found it difficult because as part of the usual MUR ad hoc recruitment practice customers were promised that MURs would take very little of their time:

I don't want to say it's five minutes and then the patient be sat there for ages, because then I think they're less likely to come in for an MUR in the future (INV-CON-8).

This CP's recruitment pitch for the trial emphasised the extra time burden for patients. She said she gauged the time MURs would take by the number of items prescribed and explained that MURs were not offered if there were other priorities in the pharmacy:

It depends on the items, but I usually think about five or ten minutes, sometimes if they're only on two items and they're really happy then they don't even take that long. If you get someone that's on ten or 15, like a big bag full, then obviously that's going to take about 20 minutes...on average I'd say about five to ten minutes... It's just a bit of a balancing act really; we've got to do MURs...so you've just got to try to

fit them in when you can...if we have a week where we're checking all the blister packs and the prescriptions, then we don't really have time for MUR (INV-CON-8).

Some CPs in each trial arm were concerned that finding people not eligible would disappoint those patients who had agreed to take part. Some in the control arm were not confident about their understanding of the study in order to explain it clearly. A combination of these factors led to some instances where CPs left patients with the impression that completing the eligibility section alone was participation in the study.

Valuing practical aspects of trial training and support

The CPs said that what they wanted from the research training day was to feel confident about what they had to do and able to manage the paperwork. All of the CPs were positive about the practical elements of the research training, with half identifying practicing the recruitment process with each other as the most useful aspect of the day (3 intervention and 2 control CPs). They valued the GCP training less and suggested that it could be shorter and more tailored to the community pharmacy setting; most had poor recall of the content covered and some considered it to have little direct relevance:

I get why we did the morning, like, the presentation, just to give you an insight on all the research methods and things... I think it went into a lot of detail that wasn't relevant, but it was interesting. But [what was useful was] ... the afternoon, just seeing all the paperwork and getting to try it with another person; and then seeing other people's feedback on it as well, was all quite useful, because sometimes people thought of things you hadn't thought of yourself (INV-CON-8)

...half of the day ... wasn't really applicable to me... the first half I'm sure it was compulsory to provide but it did seem a bit, you know, out of context, a bit too much for what I was supposed to be doing. But I mean I'm sure that there is a reason... I didn't get anything out of that half that I could use later on in this trial (INV-CON-7).

The trial support visits by the research team were successful in identifying initial problems with introducing the study to patients (4 CPs), incomplete recruitment forms (5 CPs), unexpected pressures on the private consultation room (1 CP), and difficulty approaching patients in every MUR/NMS consultation for participation in the study (5 CPs). The research team discussed these difficulties during the visits and in subsequent telephone support calls. The CPs appreciated this one-to-one research support. When asked how it was useful, several suggested the visits and calls were important in terms of how to talk to patients about the research and implementing the recruitment procedures, for example:

The support visit helped ensure that the recruitment forms were filled in correctly. I thought I'd filled them out perfectly, but there was a couple of things that we hadn't ticked or dated. So it was really great to just have someone re-clarify that. (INV-CON-9)

One CP who we were able to observe recruiting patients explained:

So it's only when you come back into practice and you've dummy-runned them, as I did, or you ran through it, it made a lot more sense. I actually found it really refreshing and I'm actually really pleased that you witnessed my first couple...because it provided that reassurance. If I hadn't done it right originally... I felt you helped me ...that support visit was very beneficial in that sense (INV-INT-1)

This CP appreciated the feedback on his observed practice. Such observation was easy to conduct in this instance because appointments were booked. In other pharmacies the possibility of practice observation depended on whether ad hoc recruitment took place at the site visit time.

Blurring of boundaries between research and practice

Most CPs reported that the recruitment process influenced their conduct of medicine review consultations in some way, with patients opening up conversation in response to specific screening questions (e.g. health behaviours and quality of life measures). The screening questions, especially if read aloud by the CP rather than given to the person to read (see below) meant that CPs knew more than usual about their patients before starting the MUR:

So by going through that five or ten-minute questionnaire with them, understanding their health needs, whether they'd smoked before, their exercise and how they feel today, it provoked discussion. As in people started to talk while you were in there.

So before you started the consultation properly, you felt that you'd got a bit more of a rounded individual (INV-INT-1).

This CP said he used this initial discussion to inform the remainder of his MUR. Another said that if the patient had ticked something relevant to the MUR such as forgetting to take their medication then she would bring it up in the consultation (INV-CON-8). Two reported that they pretended not to know this information in the actual consultation, which could be "awkward" (INV-INT-4). Conduct of the research thus altered actual practice in ways that were not intended.

Some CPs reported completing the screening form themselves by asking the patients the questions (INV 1,3,6,7,10) or letting the patients fill it out but guided them through it (INV 9), whereas others said they handed the form to the patients for them to complete (INV 2,4,5,8). Pharmacists who read the form to the patients said they did so when or because: patients could not read or did not have their reading glasses with them or were elderly or seemed daunted by reading through it (INV 1,3,6,9,10); they perceived it to be quicker (INV 1,7,9); and because it “felt more natural” completing the form themselves (INV 7).

Two CPs reported rushing the MURs because of the length of time they had already spent in the consultation room going through the trial recruitment process. As a result, one CP moved the recruitment process to the end of the consultation, which raises ethical issues. MUR consent practice, as opposed to informed consent for research, observed in this trial and in earlier studies was for verbal consent to be received at the beginning of the consultation and written consent sought at the end:

So all I need from you is a squiggle here. It's to say we won't trouble you for another review for a year and to say we can share any details with your GP (OBS-INT-1).

Patient recruitment in context

Recruitment of MUR patients to the trial was slower than expected; only one CP achieved the target of 10 patients. Changes to the NHS community pharmacy contractual framework coincided with the start of the trial and placed a ceiling of 200 MURs per pharmacy for the months April-September.²⁴ The impact on pharmacies and their capacity to recruit to the trial varied, with three reaching the MUR limit during the recruitment period. We extended the planned recruitment period from 8 to 12 weeks and encouraged the CPs to recruit NMS

patients. This meant that recruitment ran into the summer holidays (in August) which presented additional challenges. We found that some CPs took annual leave during this extended recruitment period, having helpfully delayed planned absence until after the original recruitment deadline, or colleagues' leave created unanticipated increases in workloads and no time to do medicine reviews. In these circumstances we worked with CPs to identify periods when they would be able to plan and undertake (mainly NMS) recruitment.

DISCUSSION

These CPs expressed a high level of commitment to participation in the trial, following a selection process. Nonetheless, we found that the time pressured, business orientated environment of community pharmacies makes undertaking a trial within NHS services in this setting challenging. This was evident at every stage of the research, from identifying CPs willing and able to participate in the trial, training and supporting CPs to recruit patients, to arranging interviews with the CPs at the end of the study. Interviews with CPs revealed a range of difficulties encountered in participating in the research. Participation in a research training day alone was insufficient to prepare CPs to undertake the trial recruitment; one-to-one support was required not just at the start, as we had expected, but throughout the recruitment period, and this was valued by the CPs.

The procedures for recruiting CPs to the pilot trial were implemented as planned. As deployed in previous studies,^{13,35} we used a staged approach to identifying and engaging with pharmacies and CPs to take part in the research. This aimed to ensure that the process of CP recruitment was rigorous and that only those who were able to commit to delivering all aspects of the research participated. The involvement of Local Pharmaceutical Committees

was particularly useful as a means of accessing all community pharmacies in a geographical region efficiently. We had much less success in identifying potential CPs via the nationally funded Clinical Research Network for supporting research in the NHS, suggesting a weakness in the pharmacy/primary care research support infrastructure in this particular region of England.³⁶ By design, the CPs who took part in this study were not representative of all CPs in Yorkshire: they volunteered an interest in the pilot trial and were selected on the basis of their willingness and ability (time-wise) to fulfill a tightly specified research role. However, the results demonstrate that the approach to CP recruitment to a trial is feasible. Time was an ever-present concern for the CPs. We were acutely aware of the competing demands on them from the outset of the study, having co-produced the intervention and consulted widely with practitioners and patients during the first phase of the programme.³² The fieldwork was planned to avoid the Easter public holidays, which we had been consistently advised by pharmacies as a particularly busy dispensing period. Our concerns were confirmed by trial support discussions and the interviews with CPs at the end of the study. CPs typically reported that the recruitment process took approximately 10 minutes; about the average time of an MUR^{15,22} and longer than observed NMS consultations.^{15,22} In this context, eligibility screening and informed consent were sometimes viewed by CPs as getting in the way of the usual opportunistic brief medicine review consultations, rather than an ethical and important component of the research, with research conveyed as a burdensome process for both CP and patient. Consistent with previous qualitative studies of trial recruitment,³⁷ pressures of time and meeting MUR targets could mean that clinical tasks in the pharmacy took precedence over trial recruitment and fidelity to the research protocol.

The CPs expressed concerns in the interviews that many patients did not want to spend long in the pharmacy when the purpose of their visit is to have their prescription filled: they were

not expecting a medicine review, let alone to be asked to consent to take part in a trial. This is consistent with patient recruitment data, where the most frequent reason recorded by CPs for patient non-participation in the trial was being ‘too busy’.²⁹ We worked with our patient advisory group to suggest a ‘pitch’ for the study that emphasised the potential to improve the service to patients. However, the difficulties some CPs had in adapting their usual approach to introducing medicine reviews to patients (and the management of these services in the pharmacy), to incorporate trial recruitment became apparent during observations and discussions with CPs. It was clear that the initial interaction between CP and patient was typically intended to gain a quick verbal agreement to do an MUR/NMS and to minimise scope for discussion. This reflects the opportunistic nature of these services, but also a change from usual practice where these services are first introduced to patients by other pharmacy staff as a “quick chat” with the CP.¹⁶ The decision to visit and observe CPs’ recruitment practice as early as possible as part of the research support input was thus fully justified. The findings also show that this was appreciated by the CPs.

The blurring of boundaries between the recruitment process and the content of the consultation was an unanticipated consequence in the trial, inadvertently altering it away from the usual check of a list of medicines into more of a discussion. This was found for CPs in both arms, and whilst the intervention aims to do just that, this is problematic for the control arm as it entails undermining the experimental contrast with usual practice.³⁸ The recruitment process is thus inadvertently impeding the study that we are seeking to do.³⁹ This can be addressed, at least to some extent, in training by spending more time working through recruitment scenarios to build familiarity and confidence with the process and materials, and reducing the content and time involved as much as possible. It may be unlikely, however, that

the problem can be eliminated altogether. Placing greater emphasis on building research time into medicine review routines at the CP recruitment stage may also help prepare CPs and their pharmacies for what is to come.

The broader implication of these findings is that it is intrinsically challenging to do research in a busy clinical setting such as community pharmacies and that much more could be done at a national strategic level to prepare CPs for the conduct of trials. The international literature points to lack of research knowledge, training and support as the most significant factors contributing to a lack of research competence and participation among the pharmacist profession.⁴⁰ The Royal Pharmaceutical Society (RPS) Research Ready scheme is implemented unevenly across England³⁰ and our CPs were not accredited with it, had no previous trials experience and had very limited experience of research in general. Most UK CP research experience has been reported to be audit based or service evaluations.⁴¹ The inputs required to support the CPs to conduct the pilot trial suggests the likely limitations of the RPS on-line self-accreditation Research Ready tool, which will not include the challenges of fitting research into unpredictable routine service delivery or hands-on practice of providing informed consent and eligibility screening procedures. Disruption to usual practitioner-patient relationships and discomfort from managing perceived conflicts in clinical and research roles can influence trial recruitment and informed consent processes.³⁷

⁴² More research is needed to investigate these issues in pharmacy settings in order to strengthen approaches to trial recruitment training and broader research support for the profession.

CONCLUSIONS

We worked productively with the participating CPs to identify and address issues raised in implementing the trial recruitment process which overall was acceptable to them. The conduct of trials in this setting is challenging. This study builds understanding of CP perceptions of the issues and adds to the literature on CP readiness for research. The study also suggests that research readiness may be enhanced with national level workforce development initiatives to better prepare pharmacists for participating in trials, and intensive individual support during their conduct.

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