Nurses' experiences of participating in a randomised controlled trial (RCT) in the community

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Abstract

There is a dearth of experience and sharing of experiences by community nursing agencies in the conduct of clinical trials in the community. The objective of this research was to explore and identify the challenges and opportunities that arose when two community nursing services implemented a randomised controlled trial (RCT) in the community. An exploratory study was undertaken with the nurses responsible for implementing the trial at the operational level. Three focus group discussions were convened with the nurses. Key themes from the data were extracted and summarised. The eight key themes emerging from the analysis of the focus group data were – being part of a trial, expectations versus the real RCT experience, benefits associated with implementing the trial, responses to the trial of other nurses not directly involved in the RCT, clients' responses to the trial experience, challenges, strategies to refine research processes and further involvement in research.

This study offers insights into the experiences of clinicians and researchers involved in implementing a clinical trial in community settings. These include what worked well, what the pitfalls were and how they might have been avoided, and strategies for organisations wishing to undertake a clinical trial or to refine their existing research processes. Additionally, some lessons for everyday practice were identified as requiring follow-up as impacting not only on the conduct of a RCT but clinical care at all times.

This paper provides guidance as to how to actively involve nurses in research not just to gather data and find study recruits, but as significant contributors to decisions about research design and implementation so that they are better equipped to inform and lead future research endeavours.

Introduction

Despite the fact that the randomised controlled trial (RCT) is seen as the most powerful research method for minimising bias when evaluating health technologies [1], it is used infrequently as a methodology for nursing research and even less so by nurses in the community setting when undertaking wound-related research. A literature search found no papers specifically related to nurse-led community RCTs and, in a systematic review of papers reporting barriers to participation in RCTs, of the 78 papers reviewed only 12 were set in the community [1]. There is therefore a clear requirement for more nurse-designed and nurse-led RCTs to ensure that nurses can continue to claim and develop an evidence base as the foundation of their practice and healthcare delivery [2].

Added to this, the shift to community-based care as a sustainable healthcare solution continues to increase demand on community nursing services. Therefore, when a RCT involving two community nursing organisations was being conceptualised, the team decided that as well as collating and publishing the results of the RCT itself, it would also be valuable to share the experiences of the nurses involved in the trial and thus encourage more nurses to lead RCTs in the community setting.

The objectives of the study were therefore to:

- Explore and identify the challenges and opportunities that arose when two community nursing services implemented a RCT in the community.
- Use the nurses' experiences to identify strategies to refine the two services' existing research processes.
- Share these experiences to assist other nurses to design and lead RCTs in the community setting.

Method

Study design

This study used a descriptive approach to explore perceptions of what worked well and what could be improved when implementing a RCT. Key nurses involved in the RCT were invited to attend a number of focus groups and their feedback to a series of semi-structured questions was collated and analysed (Appendix 1).

Study setting

The RCT was conducted at two community nursing services in two Australian states, Victoria and Western Australia, and involved nine and five metropolitan service centres respectively. Although linked through an alliance to share ideas and work collaboratively, the two community organisations have their own policies, procedures and systems to suit their own health service environments and funding systems. The RCT they collaborated on was a study to compare the effectiveness of two antimicrobial dressings, cadexomer iodine and a nanocrystalline silver impregnated dressing, on colonised ulcers of the lower leg. After initial meetings between the research teams from each organisation to discuss high level design and funding applications, both organisations involved one clinical nurse from each of the service delivery centres that were participating in the trial to assist with the planning stages of the RCT.

The tools and process for data collection were slightly different at each organisation but data collected, protocols and eligibility criteria for client inclusion to the RCT were identical. These differences relate to who profiled the wound photos; the attending nurse at RDNS or the project coordinator at Silver Chain. In both instances, however, the same wound imaging software was used. How the data collection was attended was also a point of difference. Though hard copy forms were available to clinical staff at both sites, hard copy data collection was the principle method of data collection at Silver Chain, while data were collated using electronic assessment forms in Victoria. Both sites supplemented this information by extracting data from their respective electronic client record systems at the conclusion of data collection.

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Study population and sample

According to Patton's typology of sampling, a purposeful, criterion sampling approach was used to recruit participants to ensure the data were gathered from individuals who, following their involvement with the RCT, had considerable experience with implementing a trial in the community [3].

The study sample was recruited from a population of district nurses who met the eligibility criterion of being involved as team leaders and clinical specialists in the RCT with responsibility for coordinating the recruitment and data collection for the trial at their service centre. The sample was divided into two groups in Western Australia as it was thought this would allow for more open discussion given quite different recruitment success across the Western Australian service centres. Thus, one focus group was convened with nurses from one centre, while the second group discussion was convened with nurses from the remaining four RCT participating centres. Comparable recruitment success across the Victoria service centres occurred, therefore a single focus group discussion was convened in Victoria.

Focus groups

All those who led the RCT or were key team members (nurses specifically involved in the recruitment of clients to the trial as team leaders or clinical specialists) during the trial were sent an email invitation to attend a focus group discussion. Invitees were informed of the purpose of the focus group, that the discussion would be taped with the data stored securely, and that no data would be name-identified. A total of 24

nurses were invited to participate, of which 17 participated, providing a response rate of 71%.

The focus group discussions ranged from 1-2 hours in duration. They were facilitated by the project coordinators from each service using an agreed semi-structured moderator's guide. Three focus group discussions were convened in March/April 2007. One conducted in Victoria involved 10 clinicians and two conducted in Western Australia involved three and four clinicians respectively. It was determined that as teams at the Victorian site experienced a comparable level of success with respect to the recruitment of clients, they were a homogenous group suitable for a combined focus group discussion. As there was considerable variation in the number of recruits achieved across sites in Western Australia, it was felt there were important reasons, based upon the potential heterogenity of these individual's experiences, to convene two focus group discussions; one with the team of nurses from the site which recruited the majority of study participants in Western Australia, and the other with team representatives from the remaining sites that experienced more difficulties with respect to recruitment.

Data collection

One of the focus group discussions was taped and then transcribed verbatim by an experienced transcribing typist who had signed a confidentiality agreement prior to involvement. That transcript was subsequently used for analysis along with the output from the other two discussions where an independent note-taker summarised the discussions as they took place. These notes were supplemented by notes taken independently by the discussion facilitator. All three data sets were used for analysis.

Data analysis

Two researchers from the original RCT independently categorised and conceptualised the principle issues emerging from the data. Following this, the primary author proceeded independently to merge the results from her own and her colleague's analysis using a systematic approach. The categories and constructs were then reviewed and a consensus achieved between the analysis team. The analysis was then further considered by the broader research team.

Results

Eight themes were identified within the focus group data, with the following titles:

- Being part of a trial.
- Expectations versus the real RCT experience.
- Benefits associated with implementing the trial.
- Responses to the trial of other nurses not directly involved in the RCT.
- Clients' responses to the trial experience.
- Challenges.
- Strategies to refine research processes.
- Further involvement in research.

Any comments that researchers felt were related to more than one theme were put into the most applicable group.

The eight themes are described in some detail below.

Being part of a trial

In particular, clinical nurse specialists (CNS) and clinical nurse consultants (CNC) liked being involved in the preliminary discussions and preparation for the project. They also found the consultation process with the project officer to be useful and helped "iron things out before the trial started". Teamwork was also flagged as a good outcome of being part of the RCT.

Others indicated that the outcome of the RCT was exciting and stimulating because they were part of something progressive:

> *It was exciting because it was cutting edge, and we hadn't done anything like that within [organisation stated], no one worldwide had done anything like that.*

However, in a few cases, data collection was not seen as a positive of being involved in the trial, with some participants saying they got "fed up" with it.

Expectations versus the real RCT experience

A number of aspects of the trial were identified by nurses as different from what they had expected. Several nurses were surprised that more clients weren't recruited to the trial – "We expected more clients, expected a constant stream of clients".

Trial nurses reported that they were surprised that other nurses appeared to be "off-loading patients that they couldn't deal with – the difficult cases"; whilst others commented that even though the client was eligible, the nurses were saying they weren't, so as to not "lose hours"*. The impact of this was the delayed identification of recruits for the study. Once identified, these clients were randomly assigned. [*Note that when nurses state "lose hours" they mean their workload may be decreased because in some cases clients would be transferred to the care of another nurse once recruited to the trial].

Other comments indicated that the RCT was more work than expected:

I didn't think it would be as much work as it was, it was a huge workload and we didn't have extra hours or extra time.

Benefits associated with implementing the trial

Good client outcomes were identified as a major benefit of implementing the trial. "Long-term clients finally healed" and clients became "more positive "about their improvement and condition. One client was described as "skipping out of the clinic to open a bottle of champagne" after her wound healed.

At one service centre, weekly meetings were convened to discuss the RCT recruitment process and particular clients. This sharing of information and discussion led to problem solving from within the team and this process was seen as improving inter-team relationships as well as reiterating the advantage of collaboration. Being able to demonstrate the differential effectiveness of wound care treatments was also identified as a benefit of the trial – "It is good that the RCT will get data to help support the use of the appropriate antimicrobial".

A number of participants felt that the RCT would result in raising the profile of the organisation because we're doing "quality research" which gets us "more kudos". Another positive noted was that, as a result of the RCT, more nurses were confident about applying the compression bandaging system which was a standard requirement for all clients in the trial. For a range of reasons this was noted as a new learning experience or an infrequent practice by some nurses prior to the trial and therefore the discipline of the trial had reinforced its use by repetition and practice. Other comments related to nurses developing other new skills such as those around wound assessment and using hand-held Doppler ultrasound equipment.

It was also suggested that the RCT was a good way for nurses to reflect on their practice as it "made people stop and think about what they do". Nurses felt their credibility had also increased as a result of being involved:

It makes you feel you're achieving something more, bigger picture type stuff.

Responses to the trial of other nurses not directly involved in RCT

Nurses involved in the focus groups were asked to comment on any feedback about the trial that they had received from their colleagues who were not directly involved in the RCT. In some cases the participants reported other nurses were simply disinterested – "they weren't interested as it didn't involve them".

Others said they were seen by a few as nagging, "some nurses felt harassed – as RCT nurses were nagging them for recruits". A number of the nurses not involved felt bandages were being wasted as the study protocol required adherence to manufacturer's guidelines and to prescribed best practice. The comment that they (bandages) were "used only once then discarded, over a 12 week period this equals lots of bandages" was typical of this view. Interestingly, it was suggested by various participants that others took it personally that their clients were being "taken away" from them, as if it somehow reflected on their practice, whilst others with long-term clients wouldn't give them up as they said "the client wouldn't like it".

Active support for the trial was also demonstrated, with nurses describing some of their colleagues as "helpful in quiet periods" and almost "over keen to recruit". The trial also raised awareness of wound colonisation and new bandaging techniques and encouraged interest from other professionals "we had doctors wanting to get their client on the trial".

Clients' responses to the trial experience

The nurses reported overwhelmingly that their clients felt very positive about being able to take part in the trial – "our clients felt special for being allowed on it" – especially if they thought that participation could lead to faster wound healing:

Some were very keen; those with medium-long [term] wounds as they wanted to get them healed and be done with.

Surprise was expressed by several nurses that not all clients found compression bandaging to be uncomfortable. Clients were more accepting of compression than some nurses expected and it was thought in hindsight to be related to improved explanation of its efficacy. The bandaging was, however, found to be bulky by a number of clients and they complained of the restriction this placed on their choice of footwear.

An unexpected impact of the trial was that a few clients were a little frustrated with the hospitals as they perceived "the hospital was ignoring their care whilst they were on the trial", whereas others saw it as a "competition between the hospital and the (community) organisation". However, some clients had reservations about becoming involved on the trial on occasion because they felt the impact would be "too much trouble" i.e., it would "just hold the nurse up and interfere". Other clients believed being on the trial would incur longer visits and "they'd have to stay home".

Challenges

For a few nurse participants, data collection "got frustrating" and others felt the survey form was difficult to use as "the

categories were too narrow and limited". A small number of nurses believed they were involved too early in the documentation design process as it was time consuming and confusing, whereas others believed their involvement in the documentation set-up process was timely and beneficial as it increased their understanding of the data requirements during the trial. This difference in opinion was found to be related to study site.

The RCT eligibility criteria were seen as too narrow by a few nurses, in particular the omission of diabetic clients was highlighted as this greatly reduced the number of clients that could be recruited:

> *Diabetics were excluded from trial eligibility criteria – but are perceived to be the group that presents most commonly with leg ulcers.*

In many instances a high workload and competing priorities were identified as making it difficult to resource the study appropriately. The unpredictability of client recruitment was perceived as adding to this difficulty:

> *The hardest thing was hearing you had someone suitable and then having to drop everything and get out there.*

The ability to appropriately train new or casual nurses in the trial protocol and to keep the trial "top of list" for existing nurses were also seen as challenges. Some participants felt that because nurses in the community tend to work independently with fewer opportunities for face to face contact, it was difficult to constantly remind them of the RCT and of the tasks they were required to undertake. Disappointment that general practitioners (GPs) were not better informed was also expressed by a number of nurses – "We were getting referrals from GPs without them being aware of the trial".

Lack of experience with technology caused issues for a few too, in particular the difficulty associated with using a computerised digital wound imaging system and trying to take good quality photographs in clients' houses where lighting was poor.

Strategies to refine research processes

Nurses (involved in the focus groups) suggested a number of specific actions to form strategies to address key issues that they believed would refine the research process from their perspective; these have been summarised in Table 1.

Further involvement in research

When reflecting on the RCT and how it may affect future endeavours, many of the participants' comments were positive, saying "we could do it again". However, another view was that "if there was another trial everyone might groan and say no because you know what it involves".

There was also substantial feedback about how nurses balanced their direct and indirect time and the ambiguity around whether the time spent on the trial should be included as part of clients' care, which is considered direct time. One expressed view was "We shouldn't have to worry about whether we've done the indirect care time; we should just be worrying about getting it right because it is such an important trial". Another CNS suggested that "research is part of our role so if we're involved in a clinical trial then that should be factored into our time, instead of the direct care". [Note that 'direct care' is a classification of work time which is client-related and usually strongly encouraged by organisations, as compared to 'indirect' time which is seen as tasks not undertaken in the client's home or directly related to client care].

There were also responses from other nurses about potential implications they felt that the trial had for the acute care setting. Their responses suggested that through participation in the trial the profile of community nursing would be raised and seen as a valuable factor in hospital avoidance:

> *I think it's great, because I think it makes the acute sector suddenly look at the community and look at how much we do that keeps people out of hospital.*

Another nurse thought that if the trial produces strong evidence regarding the use of a preferential antimicrobial dressing, it could be used to support their choice of product to other healthcare providers with a spin off of "giving them kudos" – they could "fax it off to the vascular surgeon and say this is what the latest research shows".

Lastly, the participants felt that the lessons gained from conducting a RCT in the community setting had applicability to the community GP, inpatient and residential contexts.

Discussion

The findings suggest that while some aspects of the trial were seen positively and worked well for those involved, other aspects were received less favourably and were challenging for nurses. There were important lessons to be learned from both.

The strategy to specifically invite CNSs to participate in the planning and design stages of the RCT to increase their ownership of the trial was effective and early involvement in the planning part of the trial was acknowledged and appreciated. One needs to consider the potential that differing methods of data collection (paper versus electronic) and the responsibility for conducting the wound tracings at each site

Table 1. Strategies to refine the research process.

Issue	Strategy	Specific actions suggested
GPs unaware of RCT	Increase GP buy-in	Initiate earlier GP contact prior to trial commencement Increase direct contact with GPs to inform them of the study Present at GP division meetings Publish in GP division publications Inform practice nurses about research activities generally and trials specifically
Slow and low client recruitment rate	Identifying more suitable recruits earlier	Generate reports (as a prompt) throughout the trial for nurses of all new client referrals to organisation with appropriate diagnosis Introduce a competitive aspect with regard to recruited client numbers between service sites Plan more time before the RCT starts to accurately estimate numbers of potential recruits Assign one designated nurse member at each wound clinic to identify suitable recruits
Low nurse availability for RCT	Set up nurse team more efficiently and ensure only tasks requiring nurse input are allocated	Allocate two to three dedicated nurses at each service centre to allow for attrition/sickness Utilise a small dedicated group of nurses just to recruit Involve enrolled nurses – they review more wounds in some organisations Invite only nurses interested in particular research to participate (as will have the right focus and attention to detail) Ensure nurses are appropriately skilled with technology
Low nurse availability for RCT	Enlist organisational support	Obtain a guaranteed minimum hours for nurses seconded to work on trial Ensure research funding is sufficient for managers to back-fill positions and free up nurses for RCT
Keeping nurses/ stakeholders engaged	Constantly keeping the research front of mind and reminding nurses / stakeholders	Market RCT well: examples are nurses wearing RCT badges, using a RCT logo, posters and regular updates internal/external Visit hospitals/GPs/clinics before and during the trial to promote the RCT Regularly review all current clients, asking: "Why is the patient NOT suitable for RCT?" Provide incentives for nurses Feed preliminary RCT data back earlier to nurses and stakeholders
Lack of appropriately skilled nurses	Improve nurses' skills and ensure they feel supported	Visit (first time) in pairs with CNSs for support Set up regular meetings at service centres to discuss recruitment strategies / particular clients' cases
Missing data	Involve clients to assist	Ask clients (when appropriate) to remind nurses to complete data collection tools during visit
Missing data	Familiarise nurses with documentation early in trial	Give trial documentation to nurses earlier to practise completing before commencing trial Involve CNS in design of documentation early in planning stages of project to ensure it's user-friendly
Missing data	Employ a dedicated project officer	Recruit a project officer or employ methods to check data as the research proceeds and follow up or institute correctional action promptly if needed

It is acknowledged that to implement some of these strategies would incur additional costs and these need to be considered.

affected the data obtained from the focus group discussions. In particular, the added workload of attending to wound tracings and the challenges and gratification of applying the new wound measurement technology might have both burdened and enthused nurses at RDNS when compared to the experience of Silver Chain nurses.

A minority of nurses felt that being involved in the iterative process of document design and refinement complicated their understanding of the overall project. These nurses all worked in the participating organisation that designed the majority of the documentation from scratch. By contrast, the nurses in the organisation that were able to pick up final versions of the documentation and only make minor amendments to tailor it to suit their setting, all found that a very useful process. It was perhaps not surprising that some of the nurses involved in the original design work found the process difficult rather than beneficial. A more effective strategy therefore might be to invite just a small, appropriately selected group to participate in the early design work, with others being integrated into the team at later stages.

Improved client outcomes and contributing to the evidence-base concerning different treatment options were the most frequently identified benefits of involvement in the trial. This would suggest that future research studies need to be seen as both addressing relevant research questions and contributing to improved client outcomes for nurses to embrace them.

Strategies to help nurses feel part of something cutting edge which has the potential to raise the profile of the organisation and their own credibility can be expected to result in more nurse commitment to the project. The teamwork, support and sharing that some nurses emphasised as a benefit of this research involvement perhaps signals a need for community nurses to meet and discuss clinical care as routine practice. The regular meetings and communication among those involved in implementing the RCT were regarded as a bonus and efforts to engage staff in endeavours which contribute to improving client care should not therefore be undervalued.

The general detachment and negative perceptions of staff not directly involved in a RCT, particularly those around clients being "taken away" from them reflecting on their practice, could perhaps be minimised by ensuring that they are more informed and involved, if not in the specific data collection, then at least in the research process and outcomes.

The fact that participating clients felt 'special' when seeing the reported progress of their chronic wounds in serial photographs could be perceived to have been a motivator for their continuing participation in this study. It also reflects the need to provide clients with as much information as possible about their care and progress at all times. Details about a wound, such as a reduction in the amount of necrotic or sloughy tissue, may be a better indication of wound improvement than the overall wound size. In this situation a wound photograph may be more effective than demonstrating linear measurement or wound tracings.

Another way to encourage client participation would be to share good news stories (whilst maintaining client confidentiality) with nurses and clients in publications and on the organisation websites. This may also serve to diminish the misconceptions that a few clients expressed about being on the trial such as: that hospitals were "ignoring" their care (as, for the duration of the RCT, wound management was coordinated by the community nurses); that they (clients) had to stay at home; or that they were creating additional work for the nurse if they were part of the trial. A publicly accessed website could also provide a forum for discussion with a frequently asked questions section for both clients and nurses.

It is well known that clients do not always tolerate compression bandaging and there are many explanations for this, both in the literature and in the practice setting [4, 5] Therefore, the fact that some nurses were surprised when many trial clients didn't object to compression therapy needs to be acknowledged and explored. Notably, these comments were from the organisation where clients are normally expected to pay for their compression bandages and the bandages were provided free of charge to those clients recruited to the trial. This could suggest that the removal of cost as a barrier, as well as greater explanation of the efficacy of compression, are reasons for increased acceptability of compression bandaging and greater adherence by clients. The expectation of client resistance to compression therapy by nurses could indicate that, on some occasions, nurses put up the barrier rather than clients. Ensuring that clinicians understand, appreciate and can communicate the benefits of using single use bandaging as recommended is identified as an area requiring ongoing focus in the community.

Gate keeping may also partially account for the suggestion that "other" nurses wouldn't give up their long-term clients for the trial as the "client's wouldn't like it". Similarly, clients replicate this behaviour when they say their inclusion in the RCT would "just hold up the nurse and interfere". It is not unusual for trial nurses to put up barriers on behalf of their clients [1] or clients to want to please the nurse, so one needs to be clear about who is putting the barrier up and what it is in order to identify the most appropriate strategy to address it.

Nurses developing new skills as a consequence of their participation in a RCT is not only worth promoting

when trying to justify costs and rationale for conducting research projects within organisations, but also because it encourages best practice which can then be expected to lead to improved client outcomes. For many nurses it is an expectation that research is part of their overall professional development [6]. Participation in RCTs could be a motivator to attract and retain nurses as well as to promote the organisation and increase its credibility. However, some of the nurses' feedback regarding the impact of lack of technical skills also identified some potential areas for nurses' development if a specific technology is to be introduced on a permanent basis to that organisation. If not, then when selecting nurses to participate in a RCT, technology needs to be simple and user-friendly (and piloted before introduction) or only those nurses with the skill set appropriate for the technology should be invited to take part in a study.

Comments related to the restrictiveness of trial eligibility criteria are not uncommon and are often identified as the cause for not recruiting the pre-determined number of participants or premature abandonment of trials [1]. On the other hand, without a rigorous methodology to eliminate or control as many of the potentially confounding variables as possible, understanding the treatment effects and asserting the results of a RCT with confidence are not possible; and these facts alone justify both the effort and the sometimes restrictive criteria involved in the definition and observance of eligibility throughout a RCT. It follows that explaining the rationale for the methodology more comprehensively to nurses and participants is essential to achieving acceptance of the restrictions around who will be eligible for a trial and who is not. Conversely, ensuring the study does not exclude the most prevalent characteristics among the population of interest will ensure that findings are able to be broadly extrapolated. In the present context, research is needed on wound healing in clients with diabetes as diabetes is not only prevalent among older home care clients but is projected to affect 239 million people worldwide by 2010 [7].

It is essential when conducting research that all efforts are made to minimise burden to nurses in their own work context [8]. Assisting nurses to better understand and accept research and especially RCT methodology is also critical, as is the promotion of research as important and exciting.

The dialogue around whether nurses should consider and record time spent on trial-related tasks as direct or indirect time was a very important one particularly to the nurses, and discussion at the organisational level needs to settle this issue in a generic way and at the outset of each research trial, acknowledging that this will vary on a case by case (trial) basis. Like other community care staff, community nurses are required to collect data on how they spend their working time, for example travelling, making phone calls and providing client care. Care staff are encouraged to maximise the proportion of their time spent on direct care (that is time attributed to the client) because organisations are only funded for this. Thus minimising the time spent on activities not directly related to client care is of importance to clinicians and managers alike and researchers need to take the time to get this right for all concerned. Failure to do this can lead to tension amongst staff involved in data collection that is not directly related to client care; this is a problem that was identified by several focus group participants who felt they were not working as their organisation would wish.

If it were clearly identified by the organisation that any activity related to a particular research project was both legitimate and expected, this may alleviate this anxiety. One way to do this would be to capture all research activities as neither direct/indirect time but as separate 'research time'; this would have the added benefit of allowing an accurate calculation of costs to reimburse operational divisions. In some cases this could also provide a record for nurses to use as evidence of participation in research for their professional portfolio.

Finally, a significant benefit of involving nurses in the RCT as well as in the subsequent reflection process was that, despite the real challenges identified of implementing the trial, the majority of comments did indicate that these nurses would be able not only to repeat their research experience but also contribute to identifying and developing strategies that would work better next time. Also nurses felt this particular methodology and the lessons gained from their experiences implementing a RCT were transferrable to other health sectors such as GP surgeries and residential care where there is also a need for more nurse-led research.

Lessons for everyday practice

Although the aim of the focus group discussions was primarily to find out community nurses' experiences of participating in a RCT, issues related to usual practice also arose. Examples of these include some nurses lacking confidence with compression bandaging, not using bandages according to manufacturer specifications, and being surprised at clients' tolerance of compression bandaging. Therefore, training and monitoring of adherence to correct processes (that related to everyday practice) needs to be ongoing and for all staff, not just those involved in the RCT. One also needs to ensure there are no barriers to following process, for example, funding restrictions are not compromising the single use of bandages.

Limitations of this study

A limitation of this study is that the RCT commenced over a year before the focus groups were convened and, although some nurses were still actively involved, for others it had been quite some time since they had recruited clients to the trial. Second, these data were from one wound-focused RCT and as such these nurses and the focus groups may not have encountered, canvassed or addressed issues or more specific problems related to RCTs in other subject areas.

In addition, individuals self selected to be part of the focus groups and may therefore not be considered representative of all nurses involved in the trial. However, it should be noted that a large proportion (71%) took the opportunity to participate in a group and they provided both positive and negative feedback.

Lastly, different data recording methods were used at the two sites; one was tape recorded and another used a note taker. To reduce the likelihood of errors and omissions by the note taker, the facilitator also recorded notes immediately after the discussion and reviewed the note taker's records. With the data available from both sites largely complementary, it was felt both methods of data recording yielded data that was a true reflection of the discussion content.

Conclusions

This study offers insights into the experiences of clinicians and researchers involved in implementing a clinical trial in community settings. These have been used to identify what worked well, what the pitfalls were and how they might have been avoided, and in this process engaged and validated nurse input thereby actively involving them in the research. These nurses did more than gather data and find study recruits, they became actively involved in the research process. They have thus become significant contributors to decisions about future research studies and implementation, especially in a community care environment and, as a consequence, they are better equipped and more likely to inform and lead future research endeavours.

Additionally, some lessons for everyday practice were identified as requiring follow up as impacting not only on the conduct of a RCT but clinical care at all times.

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Appendix 1. Example focus group discussion questions.

1. How did you find the experience of being involved in a clinical trial?

2. How did your expectations going into the study matched up to the experience?

3. What were the benefits associated with implementing this trial?

4. What were the challenges associated with implementing this trial?

5. What are some strategies to address these challenges?

6. How did our own staff respond to the clinical trial experience?

7. How did our clients respond to the clinical trial experience?

8. What else should be done differently next time with respect to conducting a clinical trial in the community?

9. And what should be done the same next time with respect to conducting a clinical trial in the community?

10. What would you regard as future opportunities when implementing a wound-focused clinical trial in community nursing?

11. What do you think are the implications of this trial experience for community nursing?

12. What do you think are the implications of this trial experience for other health sectors?