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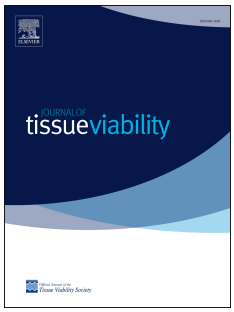

Exploring experiences of research nurse participation in conducting a randomised controlled trial of wound care treatments

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PII: S0965-206X(20)30108-X

DOI: https://doi.org/10.1016/j.jtv.2020.07.007

Reference: JTV 388

To appear in: *Journal of Tissue Viability*

Received Date: 28 October 2019

Revised Date: 4 June 2020

Accepted Date: 27 July 2020

Please cite this article as: Long J, Meethan K, Arundel C, Clarke E, Firth A, Sylvester M, Ian Chetter Exploring experiences of research nurse participation in conducting a randomised controlled trial of wound care treatments, *Journal of Tissue Viability*, https://doi.org/10.1016/j.jtv.2020.07.007.

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Exploring experiences of research nurse participation in conducting a randomised controlled trial of wound care treatments

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Funding

This project was funded by the NIHR Programme Grants for Applied Research (RP-PG-0609-10171). "The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care"

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Exploring feedback from research nurses in relation to the design and conduct of a randomised controlled trial of wound care treatments: a sequential, dependent, mixed-methods study

Abstract

Background

Research nurse involvement in trials is crucial to successful conduct, however their feedback on trial design and conduct is not necessarily always collected and shared.

This study was designed to explore research nurse feedback in relation to study and protocol design and implementation in the National Institute for Health Research Programme Grants for Applied Research funded Surgical Wounds Healing by Secondary Intention pilot and feasibility trial (SWHSI). The primary aim of this study was to inform the design and conduct of a proposed future, larger study in this area. Given the evidence gap, it was deemed prudent to share these findings for the benefit of others.

Methods

A sequential, dependent mixed methods study, comprising a Likert scale questionnaire and semi-structured interviews, explored the experiences, in relation to study design and conduct, of research nurses involved in the trial. Of the 10 research nurses involved in the trial, eight nurses completed a questionnaire and were interviewed. Questionnaire data was analysed using descriptive statistics and interview data using thematic analysis.

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Results

A range of questionnaire responses were provided, however at least 50% (n=4) of respondents indicated that they were happy with both the study design and conduct.

Interview data identified key themes to consider when involving research nurses in the design, delivery and conduct of RCTs; removing barriers to recruitment, time management, engagement strategies and resource provision.

Conclusion

Engagement of research nurses is important to enable effective trial conduct. Research teams should therefore consider how best to obtain and include input from all members of the research team from the outset. Furthermore, the sharing of feedback on research design and conduct, from the perspective of research nurses delivering trial recruitment and retention, remains crucial to effective and efficient trial conduct.

Trial Registration: Clinical Trial Registry: ISRCTN12761776. Date of registration: 10th December 2015.

Key Words: Randomised controlled trial, mixed methods, research conduct, nurses, experiences

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1. Introduction

Randomised controlled trials (RCTs) are the 'gold standard' research method for evaluation of the effectiveness of interventions [1]. The concerted involvement of both participants and healthcare professionals throughout the lifetime of a trial is therefore critical to their successful conduct and completion [3].

Systematic reviews regarding RCT design and conduct, from the perspective of healthcare professionals (e.g. consultants, nurses), has frequently focused specifically upon experiences in relation to barriers and facilitators for recruitment [6] [7] [8] [9]. This is not unsurprising, partly because recruitment is often difficult and secondly because barriers and strategies relating to recruitment often lend themselves well to publication [7]. Whilst this focus is important, knowledge and examples of best practice derived from experiences of trial conduct as a whole, may also offer useful information to contribute to the efficient design and conduct of trials [4] [5]. Sharing of comprehensive experiences of trial contact may therefore be beneficial.

Where systematic reviews of recruitment barriers and facilitators have been reported, the input of clinicians, nurses and other healthcare professionals, have often been combined into a single group ('clinicians') [6] [7]. This makes it difficult to identify the individual perspectives of these distinct groups. Given the substantial involvement of dedicated research nurses in the delivery and conduct of a trial, assessment of the feedback specifically from research nurses in relation to RCT conduct may be beneficial.

Some limited data is available from qualitative work conducted with nurses involved in research in secondary care settings [10] [11], however the majority of data available in relation to nurse experiences of participation in RCTs, has been derived from qualitative focus groups or interviews with nurses in community or primary care settings [12] [13] [14]. Newall et al (2009) identified, through semi-structured interview in focus groups, that inclusion of nurses in planning RCTs, including development of the data collection methods and study processes, is important to improve RCT conduct, as is fostering inclusiveness by the wider trial management

team [12]. Despite these translatable findings, feedback on study design, conduct and the experience of participation may not have been fully identified within these studies.

Given the limited reporting of healthcare professional experiences, and the limited focus on research nurses specifically, the objective of this study was to obtain and explore research nurse feedback in relation to study design and conduct.

Experiences of research nurses (both in community and secondary care settings), participating in the National Institute for Health Research Programme Grant funded pilot, feasibility trial; Surgical Wounds Healing by Secondary Intention (SWHSI) (ISRCTN12761776), were evaluated. The SWHSI study was a two-arm pilot, feasibility randomised controlled trial (RCT) which aimed to assess the methods for and feasibility of conducting a larger, definitive study of the clinical and cost effectiveness for negative pressure wound therapy (NPWT) for surgical wounds healing by secondary intention [15]. The findings were initially intended to inform the design, and conduct, of a proposed future, larger study of this nature however given the limited evidence base for effective involvement in research trials; it is prudent to share this accordingly.

2. Methods

A sequential, dependent, mixed-methods study, comprising a quantitative survey and qualitative interviews, was conducted. The findings of the quantitative study informed the qualitative interview topic guide, with integration of the findings occurring at the results point [16].

2.1 Setting and Sample

Study participants were drawn from three centres in the north of England, and included research nurses working in both acute and community care NHS Trust settings. Academic nurses, who formed part of the central trial management team, were not included in the sample.

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Convenience sampling was used, with all research nurses being approached to complete a questionnaire, and subsequently being invited to participate in an interview.

2.2 Data Collection

A Likert questionnaire (Appendix 1) was developed by the SWHSI programme team as a mechanism to identify any required changes to design methods or conduct for a larger, definitive study, in the same study population. Due to limited resources and time available, it was not possible to pilot test the questionnaire prior to use, however the programme team reviewed this comprehensively prior to implementation.

Research nurses were asked to complete the Likert scale questionnaire (Appendix 1) at the end of the SWHSI pilot, feasibility trial, to assess their perception of involvement in the study. This was returned directly to the Trial Manager for processing and evaluation. Wide variation in responses for each question, suggested a need for further exploration. To enhance the integrity of these findings, introduction of qualitative interview methodology was proposed, agreed and implemented by the Trial Management team.

Interviews were conducted using a semi-structured topic guide (Appendix 2), developed with comprehensive input and review from the SWHSI programme team. This was designed to ensure that any salient topics were covered and to provide an opportunity to discuss any other aspects of the study involvement, not previously considered. Due to limited resources and time available, it was not possible to pilot test the interview topic guide prior to use.

Interviews were completed face-to-face or by telephone, during working hours and at the NHS Trust site, by a female researcher, educated to MA level and with experience of qualitative interviewing. The interviewer was independent to the Trial Management team (but affiliated to the lead research site and the study Chief Investigator). Interviewees were aware of this affiliation prior to completing the interview. Interviews averaged one hour in duration and each was audiotaped. Where research nurses highlighted a particular issue, they were invited to make suggestions for improvement.

Given the limited number of participants in this study, this study was primarily exploratory and so data saturation was not a defined methodological aim.

2.3 Data Analysis

Questionnaire data was summarised using descriptive statistics to identify key areas to explore during the qualitative interviews.

Interviews were fully transcribed and analysed for thematic content [17], using Microsoft Excel. Due to resource limitations only one interviewer completed analysis and data was not subject to member checking. External review of the analysis processes and findings was however conducted through discussion and review by the wider study team.

Deductive thematic coding was conducted initially, using the five question topic areas (trial documentation and processes; screening and recruitment; visit management; communication; safety and training). Through this coding, four key themes were identified across each of the question topics: recruitment processes, visit management, engagement strategies and resource provision. To increase the credibility of study findings, thematic coding was triangulated with questionnaire data where possible.

Individual participants and their responses were pseudonymised to account for variation between the types of site (i.e. acute secondary NHS trust versus community NHS trust). Pseudonymisation was used to ensure that the type of study site (community or acute) was clear in the analysis given there was potential for sector specific nuances which would need to be considered when designing and conducting further research in the associated clinical field.

3. Results

A total of 10 research nurses actively worked on the SWHSI trial. Of these, eight nurses (80%) were invited to complete a Likert scale questionnaire, of which eight (100%) responded: six from acute and two from community NHS Trust settings. The nurses had, on average, 10 years of nursing experience, and three nurses were male (37.5%). Two nurses were not invited to complete a Likert scale questionnaire as they were away from work for a prolonged period.

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As shown in Appendix 1, overall, most of the research nurses found the eligibility criteria to be clear (Agree - 62.5%, n=5). The frequency, and completion of assessments and questionnaires was reported as manageable (agreement of 62.5% (n=5) and 75% (n=6) respectively), and assessments were reported by 50% (n=4) as being straightforward. Questionnaires and forms were reported to include relevant questions and answers (50% (n=4) agreement and 62.5% (n=5) agreement respectively). The processes implemented in the study were rated as clear by 50% (n=4) of respondents, with 62.5% (n=5) noting the support available from the management team as being sufficient.

All eight research nurses who provided a completed questionnaire were then interviewed to explore their responses, and comments provided as part of the questionnaire. All (n=8) completed an interview, either face to face (n=5) or by telephone (n=3). Across a range of question topic areas (trial documentation and processes; screening and recruitment; visit management; communication; safety and training), four key themes were identified: recruitment processes, visit management, engagement strategies and resource provision.

3.1 Recruitment processes

When completing the Likert questionnaire, trial documentation was well received and was generally found to be straightforward to complete (Strongly agree or agree, n=4, 50%). Building on this in interview it was noted that there were similarities to documents used in other previous studies. The documentation received conflicting opinions with regards length; some research nurses described the documentation as "too lengthy" whilst others considered it "about the right amount". Whilst quantitative data suggested that questionnaires largely asked all relevant questions (n=4, 50%) and included all relevant answers (n=5, 62.5%), when interviewed, nurses noted the time investment required to obtain all required information to be an issue, especially for those research nurses based in the community NHS Trust sites. This was because certain information was only available within the acute NHS Trust notes, which meant that a lot of time was spent chasing up this information.

"...the amount of information which is difficult to get hold of when you are in the community at a patient's bedside, rather than when you can read all the doctors notes and everything through (on) the ward" (RN03)

One of the biggest issues perceived by the nurses was the terminology used in study documentation. The research nurses queried whether the patient information leaflet was open to potential bias, perceiving the leaflet to have a clear intervention focus. This was despite prior review by the patient and public involvement group for the study.

"…*when I was reading that first time round I thought it was horrendously VAC (NPWT) centric and it made it sound like please don't be disappointed if you're not chosen to have VAC (NPWT)*". (RN04)

The screening process was noted as being "*a lot more intensive then I initially anticipated…I thought it would be quite easy to find some suitable and I really struggled to be honest" (RN03).*

Contrary to the Likert questionnaire responses, which identified 62.5% of respondents (n=5) found the eligibility criteria to be clear, through the interviews, it was identified that there had been some confusion over the inclusion/exclusion criteria, specifically in relation to the eligibility of patients with surgically debrided diabetic foot ulcers. This led to some nurses believing that the original protocol was altered and so resulted in them feeling undermined.

"…I saw and it was just a debridement, I said oh no sorry got to screen them out, then consultant decided to call up (CI) …it all came out it's like oh no hang on what sort of debridement was it? So that wasn't very nice because it then undermined me" (RN04)

When participants were potentially eligible for trial inclusion, the research nurses reported that they felt that some surgeons were reluctant to allow recruitment of their patients to the study, as there was a chance the patient would be randomised to receive the conventional dressing arm rather than topical negative pressure. They perceived this lack of equipoise to be because the consultant often had a preferred management plan for the wound and that if the patient was randomised for the trial then this may contradict the plan.

"….the surgeons like colorectal they were just not happy for the patients to go in, they would be like I'm not happy for you to randomise this patient and not get negative pressure". (RN05)

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Interview and Likert questionnaire responses in relation to randomisation process corresponded with the research nurses reporting in both that they had found the randomisation process to be straightforward but noted that for a larger trial, weekend availability would be beneficial.

3.2 Visit Management

The intensive screening process, as noted in relation to recruitment processes, was also reported to have affected the time it took to accommodate and carry out the follow up visits. This was especially pertinent as the trial progressed and more participants were recruited, resulting in there being less time available for screening.

Research nurses across both sites found that coordinating the follow up visits to coincide with the participant's regular clinic appointments was most efficient. This was due to the ease of having a set time and reassurance that the participants would be likely to attend.

"…it was easier for us to see them [patients] in the acute setting here when they came for the podiatry clinic or any other clinics here rather than going to visit them in their home". (RN06)

By carrying out the follow up visits in clinic, rather than at the participant's home, the research nurses were also able to make the most of their time. Due to the geographical area covered by the participating Trusts, the research nurses were often spending a considerable amount of time travelling to and from visits. One nurse noted that it *"… took me an hour and a half there and then an hour and a half back, so three hours just getting there and back" (RN05)* to complete one visit.

To try to minimise this, it was suggested that boundaries could be defined, by allocating postcode districts or by having separate teams dedicated to either recruitment or follow up visits. The research nurses also suggested that some follow up visits could be completed by telephone rather than face to face to minimise the travel burden for both nurses and participants.

Where it was not possible to facilitate visits in the acute setting, the research nurses had to arrange joint home visits, often trying to coincide their visits with those of the community nurses. The research nurses reported that while community nursing

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colleagues were willing to include them in their visits, coordinating these visits often proved difficult and time consuming.

"…Sometimes you'd be a week trying to arrange an appointment to go and see a patient in the community with the district nurse. You'd get there and they'd already been or they wouldn't turn up. You would leave messages and they'd never ring you back". (RN05)

To overcome this, the potential for the community nurses to measure and photograph the wound, on behalf of the study team, was suggested and was considered. Due to the inconsistency of the community or district nurses attending the visits and the subsequent training required, it was however deemed impractical to implement. The research nurses sometimes offered to undertake the routine clinical visit to prevent research nurse time being wasted waiting for the community nurse. Whilst this approach worked very well, it did mean that the research nurses were carrying out clinical tasks alongside research data collection, which would likely be unsustainable in a larger trial.

When completing the Likert questionnaire, the majority of the research nurses (n=6; 75%) indicated that the frequency of assessments was acceptable. When interviewed however, all of the research nurses reported follow up visits were too frequent and one research nurse suggested that reducing the frequency would have been useful, perhaps to "fortnightly visits or even once in every three to four weeks" (RN06).

The protocol required visits to be conducted for three weeks' post healing to complete wound photography. It was noted however that participants became less interested in attending the follow up visits especially once the wound was healed,

"One of my patients, someone that was working was like why do you still have to come?...It got a little bit trickier if they are going back to work and you're wanting to do post healing" (RN02)

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3.3 Engagement Strategies

Responses to the Likert questionnaire demonstrated a range of opinions with regards the ease of participant identification in the SWHSI study, with the same numbers of nurses (n=3, 37.5%) reporting it to be easy and not easy to identify participants for the study. This may be related to the confusion around inclusion and exclusion criteria as reported in relation to recruitment processes.

Interview data identified that the process of identifying potential participants varied across the sites. The most successful identification, screening and recruitment approach was surgeon led recommendations. Arrangements at one study site meant research nurses were able to screen potential participants pre-operatively and so were more successful in recruiting, possibly because of the direct involvement of the Principal Investigator (PI) and surgical colleagues introducing the study to patients.

During the trial, the research nurses reported spending a large proportion of their time trying to raise the profile of the trial by phoning and emailing Trust staff as well as visiting clinical areas. The research nurses thought that it was "…*good that we were going out and seeing patients to make the staff aware at the different bases throughout the city...keeping the research visible" (RN02)*

Despite the work to keep the study visible across the participating NHS Trusts, engagement from colleagues to support the study was inconsistent. The research nurses believed that ward and community nurses were happy for the research nurses to screen and join them on visits; however, there was also a perception that if NPWT was involved, then some nurses were reluctant to engage and would avoid the study. Reasons for this lack of engagement were thought to centre on treatment delivery. It was suggested that some ward and community nurses might have been lacking confidence in applying NPWT dressings, likely because in some areas this was devolved to tissue viability nurses, or because they thought a patient participating in the trial would increase the time required to complete a dressing change.

"….I do think the barriers there are the lack of expertise with the community nurses, they weren't be keen to identify patients for a more complicated treatment when they can do standard care" (RN02)

As noted in relation to barriers to recruitment, where NPWT was already widely used at site for the management of SWHSI, research nurses felt this could lead to a potential bias towards negative pressure dressings and so thus reducing equipoise during recruitment.

"…when I overheard the ward staff saying they are very pro VAC (NPWT) as well…it was difficult from the off when it's been sold at all angles and we're the only ones as the research nurses saying hang on a minute there is no evidence that's what we're trying to find out so we did feel we were the only ones saying this particular thing". (RN04)

Equipoise imbalance was thought to extend across the clinical team with a belief that this applied to both clinical nurses and surgeons. It was suggested that time spent during set up to facilitate and promote the trial at a peer-to-peer level *"…having a professor, maybe (the CI) coming along and having a natter round with the doctors" (RN04)* may have helped with this.

To increase study engagement, it was also suggested that delays between study training and recruitment commencing should be minimised to prevent any potential benefit and momentum from being lost by the time recruitment began.

3.4 Resource Provision

Difficulties in accessing equipment occurred in both acute and community NHS Trusts but this was more pronounced in the community settings. These difficulties were perceived to be attributable to funding constraints, with the increased cost associated with the NPWT dressings potentially preventing community or primary care providers from prescribing them, thus limiting availability.

"I remember trying to get this negative pressure piece of equipment from the community side and had to go through multiple people to try and get it, I think it was something to do with the funding…" (RN01)

"…the cost came into it in inner city practices some of the GPs weren't in my opinion… weren't willing to prescribe a more absorbent dressings that's because of the cost". (RN02)

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On one occasion, a participant was unable to receive their allocated treatment, as no NPWT devices were available in the NHS Trust. The research nurses often attempted to anticipate and to resolve access issues however; this did affect the time available to facilitate trial visits. When interviewed some research nurses suggested that it would have been useful for equipment packs including scissors or measurement probes to be provided by the trial to reduce the amount of time spent trying to gather equipment for visits.

Questionnaire data indicated that clinical assessments were straightforward (n=5, 62.5%), which may be due to components of data collection, such as measurement of wounds being routine clinical practice at sites. When interviewed however, the research nurses expressed uncertainty with regards recording of the deepest point of the wound, particularly if there was tunnelling in the wound. Accurate data collection of the deepest wound point was therefore reported to be open to interpretation, particularly given that *" ..wounds heal at different rates so what was once the deepest point a month later would be elsewhere…[there was] no accounting for this in the paperwork" (RN08)*

Concern was also expressed that some photographs taken did not accurately reflect the condition of the wound, and so did not "do it [the wound] justice" (RN05). It was therefore suggested that the protocol required additional clarification to reflect the required procedures for wound photography, for example specifying the distance of the camera from the wound, and clarifying if flash should or should not be used.

4 Discussion

As in previous research [6] [7] [8], removal of obstacles to recruitment was identified as a key issue in enabling study conduct and research nurse participation. Across a number of the qualitative themes, sufficient equipoise was deemed integral to the removal of recruitment barriers. Research nurses suggested that this could have been improved by liaising with individual sites in the early stages of set up to ensure the engagement of clinical or research staff who may have treatment preferences and so prevent any impact on recruitment activity being conducted [9].

Input at a peer-to-peer level may help to increase engagement. Research nurses suggested that input from the Chief Investigator, particularly with site doctors, may

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also assist with study promotion, increase equipoise and so enhance recruitment. The research nurses also noted they had been promoting the study locally themselves, which has potential to increase engagement within the nursing community. Research nurses did however report spending a significant proportion of time undertaking this engagement, and so it may be prudent for trial management teams to consider this activity within the study design to ensure that this does not overburden the local research nurses and impact on recruitment activity [18].

Equipoise imbalance was noted across two themes (Recruitment Processes, Engagement Strategies), and in accordance with research by Spilsbury et al [10], it was suggested that further investment could have been made to educate colleagues (across all relevant health professional disciplines) about the trial as a method of increasing wider engagement. The timing of this intervention was noted as critical; if conducted well in advance of recruitment, commencing colleagues may have forgotten about the study and so equipoise generated may be subsequently reduced. It is therefore suggested that promotional activity should be completed throughout set up and again immediately prior to recruitment commencing to give potential for best effect. As suggested by Newall et al [12], it may be useful to continue promotional activity throughout the duration of the study to maintain continued engagement and to reduce barriers to recruitment, which have previously been noted as deriving, in some instances, from lack of knowledge [12].

Whilst proposals for study processes made by a Chief Investigator, clinical co-applicants or a research institution are often well intentioned and empirically supported, they may not necessarily be the most practical, or efficient for research nurses to implement on ‘the ground’. Within this work, arranging study follow up visits was found to be a substantial challenge for research nurses, which corresponds to findings by Spilsbury et al [10]. Research nurses noted the benefits of linking research and clinical visits and utilising allied or affiliated services (for example community and district nurses) to help to arrange study follow up appointments. Significant planning may therefore be required, at the outset, to generate an effective network to support a study.

Follow up rate and methods should therefore be discussed to ensure that these are appropriate, and feasible, for research nurses to manage within the trial setting. This

corresponds to previous findings by Newall et al [12], who have suggested that nurses should be involved in the development of study processes. It may be most productive to start with a small group initially and to integrate other nurses as processes develop during study preparation. To facilitate this, it may therefore be relevant, and appropriate to include research nurse representation in the trial management team from the outset.

The findings of this research, performed across both acute and community settings, corroborate closely with previous research conducted in acute or community settings with regards healthcare professional involvement in research [6] [7] [8] [9] [10] [12]. Given this close corroboration, and as similar challenges in study conduct have been reported across a wide range of RCTs [18], these findings will apply to wound care trials as well as to trials beyond this clinical area.

4.1 Limitations

Likert questionnaire responses were provided directly to the Trial Manager and therefore data collection was not independent of the management team. This may have limited the honesty in the responses provided. This was likely mitigated to some degree by the use of qualitative interviews, which may have rendered more honest feedback.

The majority of research nurses who had been involved in study activity contributed questionnaire and interview responses however; two research nurses did not complete a questionnaire or an interview as both were away from work for a period of prolonged leave. It is therefore acknowledged that the views of the entire study team may not therefore be represented however this is likely to have had minimal impact on the findings.

Given the small number of sites, it was not possible to pilot test the questionnaire, which may have been beneficial to refine and focus the content of the interview topic guide prior to implementation. Given the limited number of research nurses involved it was also not possible to purposively sample for interview. While sampling bias may have affected the study findings the data provided does capture crucial information for future study design.

Due to limited available resources, a single researcher, independent to the Trial Management team, completed, analysed and coded the interviews. Member checking of findings was not completed due to resource implications. Failure to include these elements may have affected the credibility of the coding, and so the findings of this study. It is however worth noting that the analysis process and findings were discussed with and reviewed by the SWHSI Trial Management team, which should mitigate some of the impact here.

The researcher completing the interviews was affiliated to the lead research site and the study Chief Investigator, and was relatively inexperienced in the conduct of qualitative research. This may have influenced interview responses however, it is important to note that the initial purpose of this research was as a method to inform future research activity, and therefore it is not anticipated that this has had significant impact to this work.

4.2 Implications for Future Practice

Linking research activity to routine clinical visits may be beneficial to streamline study delivery and to reduce patient and clinician burden. It is therefore suggested that future trials consider whether research follow up can be conducted concurrently to clinical follow up. Linking research and clinical work as closely as possible has the added benefit of likely engaging additional members of the clinical team in research.

Input from both the local and central trial teams with individual research sites is crucial to facilitate publicity and education around clinical research (both generally and specifically in relation to the study). This input likely has the added benefit of improving engagement and so can further support recruitment activity. Future trials should therefore consider how best to publicise study activity to ensure clinical colleagues are sufficiently aware, and educated, about current or upcoming research trials in their locality. This may include, but certainly is not limited to, contact with sites by the chief investigator or facilitating discussions amongst local groups at a site. Consideration should be given to the timing of any such interventions to publicise the study and to promote equipoise, to ensure that efforts are not wasted because of any long delays to commencement of recruitment at sites.

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From the findings of this study, as reported above, research nurses should be included in discussions during the initial design and planning stages of a trial to benefit its design and conduct. In particular, involvement of research nurses in designing and developing processes for participant recruitment and retention, study conduct and intervention delivery is crucial to the successful conduct of a RCT.

5 Conclusions

This study makes a valuable contribution to the limited evidence base of experiences of research nurses involved in the conduct of randomised controlled trials, both in wound care and more generally. The qualitative methods used to elicit detailed experiences of research nurses, have provided a range of suggestions for improvement in both the design and conduct of randomised controlled trials.

From the findings derived in this study, engagement of all members of the research team during the early stages of study set up, and including contributions from research nurses when planning the logistics of study activity, are important in ensuring effective study conduct. Further work to explore the experiences of individuals involved in research studies, and the continued sharing of effective techniques, is crucial to evolving research design and conduct in the future.

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Abbreviations

GP – General Practitioner; NPWT – Negative Pressure Wound Therapy; RCT – Randomised Controlled Trial; REC – Research Ethics Committee; SWHSI – Surgical Wounds Healing by Secondary Intention; VAC – Vacuum Assisted Closure

DECLARATIONS

Ethics Approval and Consent to Participate

This work was conducted as part of the Surgical Wounds Healing by Secondary Intention Pilot Feasibility Trial, for which ethical approval was obtained: Yorkshire and Humber – Leeds East Research Ethics Committee (REC reference: 11/YH/0313). Verbal consent was provided for questionnaire and interview participation. Research nurses were given assurances that their responses would be anonymised.

Consent for Publication

Not applicable

Availability of Data and Materials

Not applicable

Competing Interests

The authors declare that they have no competing interests

Funding

This project was funded by the NIHR Programme Grants for Applied Research (RP-PG-0609-10171). "The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care”

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Acknowledgements

We would like to acknowledge the input from the SWHSI Trial team which contributed to this study, and to the nurses who provided their input for this work.

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Appendices

1) **Likert Scale**

2) **Copy of interview guide**

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Exploring experiences of research nurse participation in conducting a randomised controlled trial of wound care treatments - Highlights

- Removing barriers to recruitment remains crucial to successful trial conduct
- Engaging and involving sites in the design of the study and associated documentation and process is crucial
- Research nurse involvement in developing processes is key to ensuring successful operationalisation at site
- The timing of engagement should be considered to ensure greatest effect

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The authors of this paper declare there are no associated conflicts of interest.

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