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Version: Accepted Version

Article:
Lamb, KA, Backhouse, MR and Adderley, UJ (2016) A qualitative study of factors impacting upon the recruitment of participants to research studies in wound care - The community nurses' perspective. Journal of Tissue Viability, 25 (3). pp. 185-188. ISSN: 0965-206X

https://doi.org/10.1016/j.jtv.2016.03.004

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A Qualitative Study of Factors Impacting Upon The Recruitment Of Participants To Research Studies In Wound Care – The Community Nurses' Perspective

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Abstract

Objective

The focus of this study was to identify the factors that impact upon the recruitment of participants to research studies in wound care from the community nurses' perspective.

Method

A qualitative approach utilising classic grounded theory methodology was used. Semi structured interviews were used to generate data and data analysis was facilitated by using QSR International's NVivo10 qualitative data analysis software (2012) [1].

Results

Eight participants consisting of community registered nursing staff of differing levels of seniority took part in the study. Four main themes emerged from the data:

- knowing about the impact of research studies,
- knowing about the patient,
- knowing about the research team and,
- knowing about the study.

Conclusions

There are a number of factors in addition to the eligibility criteria that influence community nurses when identifying potential participants for wound care trials. These factors limit the recruitment pool so may affect the transferability and generalisability of research findings to the intended population. The design of future recruitment strategies and the planning of study initiation training should take these factors into account.

Key words

Research, grounded theory, nursing staff, wounds and injuries, community health nursing, patient selection.

1. Introduction

It is estimated that 200,000 of the population has at least one wound [2] which impacts upon their quality of life. The financial burden of wound care on health resources is immense with the provision of wound care accounting to an

estimated £2.3 to £3.1 billion per year in 2005 and 2006 which equates to around 3% of the total NHS budget [3]. The majority of patients with chronic wounds are cared for within the community setting with wound care making up a large proportion of community nursing work in the United Kingdom [4]. There is a wide range of products available for nurses to choose from but a relatively limited evidence base to inform decision making in wound treatment choice [2]. Over recent years there has been an increasing amount of research undertaken to meet the need for a more robust evidence base in wound care [5,6]. Much of this takes place in the community setting.

Studies' recruitment targets need to be met in a timely, effective and efficient manner to prevent costly study extensions, delays to the implementation of findings and to ensure that the requirements for continued Comprehensive Research Network (CRN) financial support are met. Gul and Ali, (2010) [7] report on the financial and ethical implications of delayed or inefficient recruitment which they say can threaten the internal and external validity of a research study whilst Bowrey and Thompson (2014) [8] highlight how difficult it can be to recruit the most appropriate participants quickly to ensure the judicious conduct of the study. Another study of recruitment into randomised, controlled, multicentre trials [9] found that time and financial extensions are often requested due to difficulties achieving target sample size. More understanding of the issue to inform practical actions is needed if recruitment targets are to be met as planned.

The issue of patients' rights to be involved in research also deserves consideration. In the UK, the National Health Service (NHS) requires that research activity dovetails with care provision. The NHS Constitution (2015) [10] pledges that all eligible prospective study participants are offered the opportunity and choice to take part in relevant studies, which includes wound care studies. In the UK, as so much wound care occurs in the community, community nurses are essential for the identification of potential trial participants for wound care studies; these nurses are effectively the gatekeepers into trial participation. Therefore, the aim of this study was to explore recruitment to wound care studies from the community nurses' perspective and to gain greater understanding of the factors which facilitate and hinder recruitment.

2. Methods

A qualitative approach using classic ground theory [11] was used to inform the design of this study.

2.1 Sampling

A purposive theoretical sampling technique was used to generate the study sample [11]. Participant criteria were recorded to ensure that a range of factors were represented (Table 1) and explored to guide the theoretical sampling process in an attempt to ensure effective data saturation.

Participants were sought from a district nursing service in a community trust in the north of England. The inclusion criteria specified professionally registered community nurses working as staff nurses or senior nurses. Research is described as one of the key components of registered nurses working in a tissue viability specialist role [12] so tissue viability specialist nurses were, excluded because of their different role in terms of trial recruitment. Unregistered community staff (such as healthcare assistants) were also excluded because they did not have responsibility for identifying prospective research study participants.

2.2 Data Collection

Semi structured interviews were used to generate data and these interviews were audio-recorded and transcribed. Interview length ranged from 20 to 55 minutes and took place in a pre booked private room within one of the organisations buildings being mutually agreed between both parties. The interviewer held a research position within the organisation but did not have any managerial responsibility for any of the participants and was known to some of the participants due to the organisations wounds research activity.

2.3 Data Analysis

Data analysis was undertaken in line with classic grounded theory recommendations. Initial analysis was conducted after each interview, noting theoretical memos to inform the level of data saturation and to guide the pursuance of emergent themes. Data analysis involved the coding of the data, the emergence of themes from these data and subsequent theory development. Within each theme a number of sub themes emerged which further explained each theme's meanings and parameters. QSR Internationals NVivo10 qualitative data analysis software (NVivo) [1] was used to support this process.

3. Ethics and Approvals

Permissions were granted from the educational institution, the local research and development department and from the organisation's head of service for District Nursing.

4. Results

4.1. Demographic data

Eight community nurses who met the inclusion and exclusion criteria were recruited to the study over an 8 month period in 2014. The participants ranged in seniority from Community Staff Nurse to Senior Manager with varying research experience. There was a wide range in length of time since qualifying as a registered nurse and also in the time spent in community practice (see Table 1). Six of the participants were educated to degree level, two of whom had studied or were studying at Master's level. The remaining two participants were educated to diploma level.

Table 1 Study participant demographic data

Participant No.	Banding*	Locality	Post Registration Education and Level	Length of time qualified	Length of time working in community setting	Previous involvement in recruitment to wound care studies?
1	5	B	Degree	10-19 years	10-19 years	Yes
2	5	A	Degree	0-9 years	0-9 years	Yes
3	Band 6 (protected Band 7)	C	Degree	30-39 years	30-39 Years	Yes
4	Band 6 (protected Band 7)	A	Degree/ Some Masters level education	10-19 years	0-9 years	Yes
5	5	E	Diploma, Conversion Course	40-49 years	20-29 years	Yes
6	8a	A	Degree Studying for MSc	20-29 years	10-19 years	No
7	6	E	Degree	40-49 years	10-19 years	Yes
8	5	D	Diploma	0-9 years	0-9 years	Yes

(*Band 5- Registered Nurse practising in the community, Band 6- Registered Nurse with an additional community qualification practising as a District Nurse, Band 7- as band 6 with additional leadership and management responsibilities, Band 8a- Senior manager responsible for a number of community staff.)

4.2 Themes

Four key themes emerged from the data:

- knowing about the impact of research studies,
- knowing about the patient,

- knowing about the research team and,
- knowing about the study.

4.2.1. Knowing about the impact of research studies

The participants talked about how being actively involved in research impacted on different aspects of their clinical practice. There was recognition that research did '*have a place'* in their practice and recognition that most of the nurses research involvement was in wound care. It was noted that this may be due to the organisation's wound care service being more proactive in this field than other services that they were clinically involved with.

The participants also talked about the impact of research findings on patients. The application and implementation of new knowledge from research was recognised as being key to the provision and delivery of high quality care to patients.

> *'if you come back with some better way for us to work or a dressing or whatever might impact on time, cost and quality of care for the patient'*

There was some appetite to know more background information about research studies to understand the research process through to implementation of the findings.

However, participants were conscious of the time pressures associated with research activity especially as they were already under a lot of pressure, clinically. They reported that this meant that research activity was not always prioritised and stated that they would like to have dedicated time for research activity.

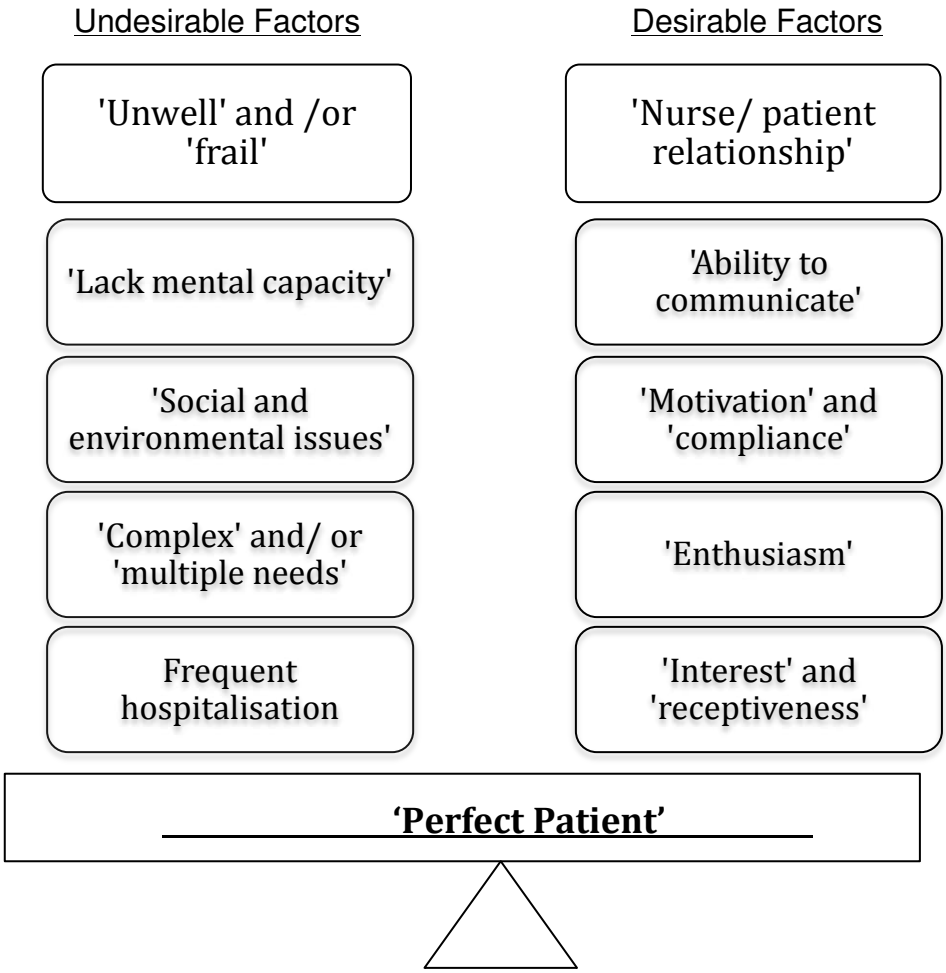
> *'not having the time, not having a protected time, so that it's not given relevance'*

4.2.2. Knowing about the patient

References were made to the thought processes and considerations that nurse participants made when deciding which of the patients on their caseloads to approach in relation to wound care study recruitment (or whether to approach them at all). When reviewing the patient's suitability for taking part a number of the nurse participants said that they looked at the person as a whole. One participant described this as trying to find the '*perfect patient*'. This not only involved assessing the patient in relation to the study's eligibility criteria but also involved an additional multi-factorial review of the patient and their circumstances. A range of factors were described which both increased

and decreased the likelihood of the nurses approaching a patient about a study (Figure 1).

Figure 1- Factors denoting a 'perfect patient'



Factors on the right are those which contribute to a patient being considered a 'perfect patient' and would encourage recruitment. The factors on the left are those that nurses also considered but which would detract from a patient's 'perfectness' for recruitment into a study. When considered together these describe the elements and concept of a 'perfect patient'.'

Participants said that their focus was to enable and build trust with the patient so that they would have the ability to say 'no' without worrying that the care that they receive would be compromised.

> *'it's hard for them to say 'no', when they know us and say 'I would rather not' well that's absolutely fine we don't want them thinking they're not going to get the best care because they've declined.'*

There was also a suggestion that having a good rapport and trust with their patients meant that the nurse participants could be more assured that the patient would agree to take part in the studies because they wanted to, rather than in an attempt to 'please' the nurse. There was a feeling, though, from one of the nurse participants, that if rapport did not exist with a patient that this would not help with the process.

> *'the likelihood is if you feel that there isn't a rapport that the client would probably say 'no''*

4.2.3 Knowing about the research team

The community nurses also identified that it was important to know about the research team. They stated how it was important to know who the research nurses were and for them to be considered as part of the wider team. This was important not only to enable easy contact but also to be able to assess the research nurses' acceptability to the potential patient recruit.
The nurses felt that it was important to both 'protect' the patient and to maintain their own nurse/ patient relationship.

> *'they don't want some research nurse that they don't know coming along and possibly not, you know, as they said don't know whether she's nice, don't know who she is'*

The importance of having regular contact with the clinical research nurses was stressed so that information could be given on a face to face basis about studies, how teams could get involved and to encourage engagement. The nurses recognised, though, that the research team also faced time pressures which made this difficult.

4.2.4 Knowing about the study

The nurse participants discussed the importance of knowing about different aspects of research studies, so that they felt that they were part of and involved in the process. However, it was often felt that information was not always available or was too complicated. Knowing about the methodological structure and conduct of the study was expressed as being important so that a judgement about the quality of the study could be made-

> '*that actually the actual work that's been undertaken is at the quality that you want it to be so that it's actually it's valid research'*

Knowledge of and understanding of study eligibility criteria was stated as being important so that there was clarity of the type of patients and wounds required. The nurse participant's understanding of their role in the use of eligibility criteria in recruitment to studies was *'to identify patients that we perceived to be eligible for the trial'* but if there was uncertainty about patients' eligibility the decision regarding potential inclusion was referred to the clinical research nurse.

The nurse participants felt it was particularly important to have study information before, during and after the study. However, in previous studies in which they had been involved, they reported that they were not always informed of the results. This may impact on future enthusiasm and engagement.

One of the participants talked about a specific study that she had been involved in with a specific specialist nurse-

> *'we met her a few times, she went to see some of the patients and we never heard anything about that after.'*

But there was a feeling that even if feedback was received there was not the time to read the research papers for the outcomes of the research completely.

5. Discussion

The findings from this study highlight some of the factors that influence community nurses within their role of identifying potential participants for wound care studies.

It was encouraging to find that in an organisation which has some previous experience of identifying patients for wound care trials, community nurses were very positive about being involved in research and the potential benefits for patients and the clinical team.

However, there was some evidence that research activity may be perceived as a 'fair weather' activity that is threatened by the clinical workload demands. As these demands increase this is likely to have an impact on clinical nurses' ability to commit to research activity. This may, in turn, impact upon the timeliness of study recruitment and lead to extra costs in terms of study extensions. It may also impact upon quality of care with evidence to suggest that there is a positive relationship between individuals and healthcare

organisations that actively take part in research and an increased 'likelihood of a positive impact on healthcare performance'.[13]

Importantly, the findings indicate that the nurse participants not only considered study eligibility criteria but also appear to introduce additional factors to both include and exclude patients. These additional factors may be in relation to the patient's health (e.g. multiple needs requiring complex care packages, frequent hospitalisation), social situation (e.g. isolation, bereavement), environmental issues relating to ensuring the nurses safety and their willingness to take part, even though some of these factors have been inclusion criteria for some trials. Although the nurse participants' intention may be to only involve the patients that they think would best suit each research study, in essence, they are introducing a pre-screening element to the recruitment process. The excluded patients will not even appear on a study screening log which means that valuable data relating to key characteristics of the population is being lost. This is particularly important as it disenables those that are aging or have co-morbidities, for example, from taking part in research studies. The result of this pre-screening is to create a hidden population for which the size and demographics are unknown as neither the patient nor the research nurse will be aware that the clinical nurse is making these judgements.

5.1 Limitations

This is a small-scale preliminary study so any conclusions must be tentative. It is also important to note that the organisation from which these nurse participants were recruited is very active in wound care research so this may not be considered a typical population of community nurses. The results of this study, therefore, cannot be assumed to be transferable to other populations. It would be useful to replicate this study in other community trusts.

6. Conclusion

This study raises some interesting issues about recruitment into wound care studies and how the reported additional screening may reduce the generalisability of study results.

The results of this study may be useful to inform education about identifying patients to recruit into studies. It is important that community nurses understand the importance of adhering to the eligibility criteria to maximise recruitment and to avoid contravening the NHS Constitution pledge. This will ensure that all patients are offered the opportunity to participate in research

studies optimising the transferability and generalizability of results to those in need of wound care.

Funding-

This report is independent research supported by the National Institute for Health Research / Chief Nursing Officer Clinical Academic Training Programme Masters in Clinical Research Scheme. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health.

Conflict of Interest: none

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