

Could a Person Centred Communication (PCComm) training intervention for recruitment nurses improve patient participation in RCTs in palliative care?

Karen Spencer, Anne Marie Sowerbutts, Jane Griffiths, Chris Todd
Division of Nursing, Midwifery & Social Work



Introduction

- Recruitment to RCTs problematic
- An example of a RCT which failed to recruit - PLACE (Prevention of Lymphoedema after Axillary node Clearance by External compression)
- Could PCComm training improve recruitment?

PLACE (Prevention of Lymphoedema after Axillary node Clearance by External compression)

Trial Aim

- The purpose of the PLACE trial was to test the efficacy of external compression garments in preventing the onset of lymphoedema, after axillary surgery (axillary node clearance)



RCT - Trial Design

Patients with an arm swelling increase
4-8.9% checked at 1,3, 6 &
9 months



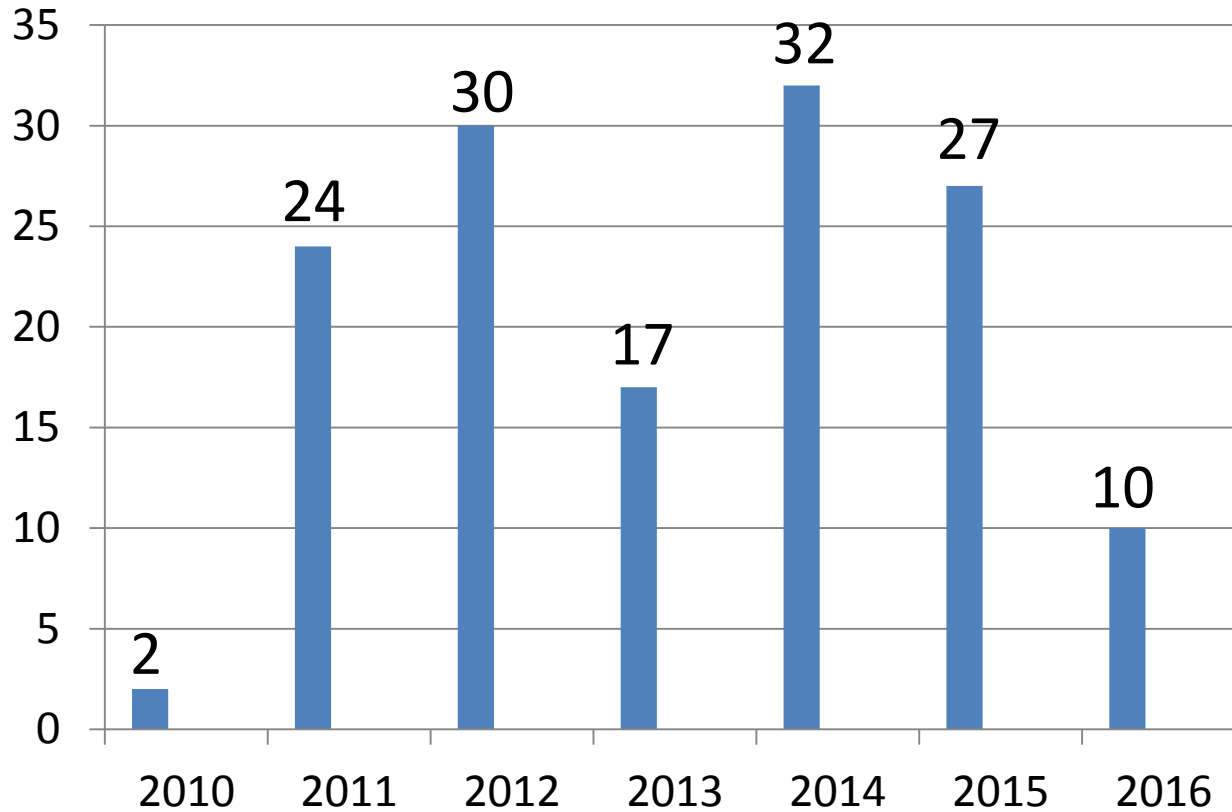
RANDOMISATION

Standard management
(written advice including
exercises)

Intervention, application of
compression garments to
affected arm, together
with standard
management for 1 year

Sample Size - Multi-site RCT (n=15 sites)

Target
270
Actual
143



Qualitative Study

NIHR commissioned qualitative research to explore recruitment problems

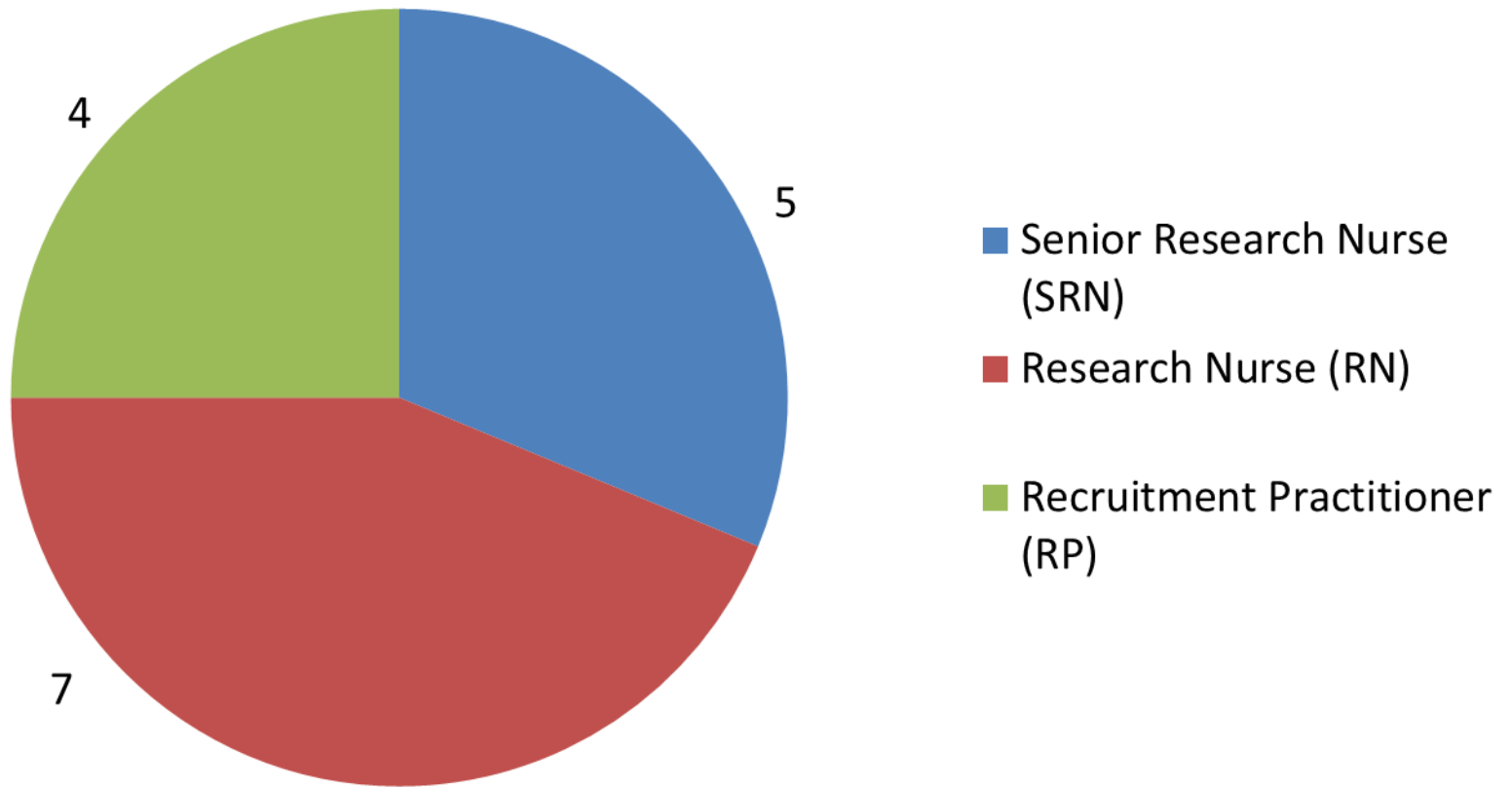


Aim of staff interviews;

- Explore staff recruitment practices and shared decision making during recruitment to a breast cancer multi-site randomised controlled trial (RCT)

PLACE recruitment

Staff Sample (n=16)



1. Wait and see culture

“If there has been quite a jump from their previous measurements and it is just simply to do with the fact that they have been over using their arm, patients are more than happy to watch and wait. I don’t know if that, kind of, stops them I suppose from getting on the trial.” (RP)

“If patients had a high measurement at three months, we’d say,...you’re due to see me again in three months. If it’s still up then I can recruit you then? There is enough going on when they’re at 3 months post-surgery.” (RN)

2. Conflicting roles – Nurse *versus* Recruiter

“At any stage if a patient seems tearful and a little anxious, that has to be brought into the mix as well. I’d kind of leave it, like everyone else, and wait.” (RN)

“I’ve noticed that some patients might start radiotherapy around the three month follow-up appointment and, they’ll have the radiotherapy on the same side as well. They are not in the right frame of mind to be recruited.” (RN)

3. Misunderstanding the trial arms and equipoise

“I think it is very evident, like, why numbers are low, it’s not baffling though to be honest. If the study was presented to me, and they give me the option of say fifty, fifty of getting the sleeve or not I personally would want something done about it. I would want the Lymphoedema referral.” (RP)

“So I usually explain that it’s a 50/50 chance of getting either the controller, where it’s just arm exercises we give you to do, or the computer randomises you to have the sleeve.” (RP)

4. Existing recruitment culture overruled Protocol

“I don't know about other sites but here it's not necessarily about recruiting.....but caring for the patient is more important than recruiting to PLACE.” (RP)

“Here if a patient is looking like they are eligible we tend to give them the information leaflets about standard care and say see you next time. So sometimes it feels a bit like we're making them ineligible for PLACE by making them better, I suppose most of the people I work with, they're nurses and that's what they do.” (RP)

Summary

- Recruitment staff employed their own interpretation of eligibility criteria
- Conflicting roles lead to paternalistic approach
- Clinician led recruitment encounters
- Poor communication about trials
- Lack of shared decision making

Above led to low recruitment rates

Communication training intervention for managing recruitment encounters

- Develop standards and training for staff
- Could encourage palliative care nurses involved in research to reflect on their dual roles
- As well as more generic training;
 - Explaining RCTs
 - Equipoise
 - Shared decision making
 - More person centred approach as opposed to current paternalistic encounter

