

**Title:** Challenges and reflections from a multi-centre trial of a psycho-oncology intervention to support shared decision-making in breast reconstruction.

**Running title:** Reflections from a multi-centre psycho-oncology intervention trial

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The end of a research project is typically punctuated by reports, publications and presentations of the results. It is less common for papers to be published on the indispensable lessons learnt during the course of the project and shared with future researchers in the field. Sharing these learnings can be vital to the progression of a field and the best use of limited resources, and in recent years there has been increased discussion of such topics within the field of psycho-oncology. For example, with a focus on participant recruitment and retention challenges (Cooley et al., 2003; Goodwin et al., 2000; Sears et al., 2003; Stafford et al., 2019; van Lankveld et al., 2018). However, there has been limited discussion of the broader challenges of conducting psychosocial intervention research in clinical oncology settings, and how challenges with recruitment might interact with other elements of the research. In this paper we aim to begin to fill this gap in the published literature by sharing our experiences and reflections of conducting a multi-site National Health Service (NHS) trial exploring the effectiveness of a shared decision-making intervention (PEGASUS) with women considering breast reconstruction (Harcourt et al., 2017).

PEGASUS (Patient Expectations and Goals: Assisting Shared Understanding of Surgery) is a patient-centred intervention, aiming to support shared decision-making. It is designed to help healthcare professionals elicit patients' own goals and expectations for surgery, and facilitate discussion between patients and clinicians, with the aim of supporting shared decision-making and improving patient satisfaction with outcomes. It was first trialled in a single-site acceptability study within a large UK NHS hospital (Harcourt et al., 2016), prior to a multi-centre study across five sites to examine its effectiveness (Harcourt et al., 2017). The study was designed with input from staff at each site, patient representatives and a study steering group, and safeguards were built into the study design to oversee research governance, safety and the conduct of the study (for example, reporting structures between the sites, the research team and the study sponsor). These included:

- A management group, who met monthly to oversee day-to-day running of the study. This management group was comprised of the core research team, including: a professor of psychology, consultant clinical psychologist, research fellow, research associate, statistician, and health economist.

- A steering group who met every six months to oversee and advise running of the project and give expert advice. This steering group included expertise on breast reconstruction surgery, clinical psychology, statistics, lived experience, research governance, and intervention implementation; with staff from research sites, patient representatives, clinical psychologists working in psycho-oncology, and an independent chair.

Researchers were in frequent contact with each site throughout the study and offered planned site visits to support staff with any aspect of the study recruitment or intervention delivery at any time; however, despite these safeguards, challenges with participant recruitment, retention, intervention fidelity, varying staff buy-in and changes to surgical practice were encountered throughout the study. We hope that by sharing our reflections and learnings we can maintain a dialogue with other researchers and clinicians in this area, and help others to consider these challenges in their own research.

Recruitment is a recognised problem in single-site psycho-oncology intervention studies (van Lankveld et al., 2018) and our experience suggests this may be amplified further in multi-site studies, where it is not feasible for the researcher to be present to recruit or consent each participant. At large sites, multiple members of staff might be involved in recruitment, gaining consent and intervention delivery. Despite attempts to standardise these processes (with face-to-face training, information sheets, consent forms, detailed research protocol and intervention manuals), normal human bias will inevitably lead to differences in the framing of the information given and intervention delivery and we suspect that these differences in the recruitment process may have had a knock-on effect on retention of participants in our study. For example, if a participant has not gained a full appreciation of the importance of their role in the research and the demands of follow-up data collection during the recruitment process, then the value that participants place in their contribution may be diminished and this could reduce their likelihood of continued participation. However, moving beyond issues of participant recruitment and retention, we also believe broader systemic challenges impact on research in this context. Firstly, staff turnover in the UK's NHS has been described as reaching 'critical levels' (Brown, 2019; Buchan, J., Charlesworth, A., Gerschlick,

B., & Seccombe, 2019) and this presents a substantial challenge in maintaining good relationships with sites, keeping communication regular and consistent, and ensuring staff buy-in for the research. These are key elements for ensuring that all staff involved in the research process are clear on the necessary procedures, trained to deal with any problems they encounter, and motivated to do so.

Whilst all new staff were trained in the same manner as those involved in the research from the beginning, this was not in the same group setting as was provided in the first instance and this may have had an impact on their confidence or motivation to take part in the research. We appreciate that motivation to take part in this type of research can be particularly challenging when staff are working in a health service faced with increased targets, fewer resources and understaffing. We recommend that this is considered in remuneration for research sites and that this should translate into extra time not only for the research unit but specifically for those healthcare professionals involved in the study. In addition, our experiences highlight the importance of a 'study champion' at each site. This individual could play a vital role in communicating such challenges to the research team, with a focus on both initial integration of the research into the clinical setting and maintenance of the process, as well as promoting entire team commitment to research that depends on multiple team members being involved in recruitment and intervention fidelity. We see this as a vital position and recommend that the precise requirements of the role are set out clearly; for example, what is the champions' role when a new member of the team joins the study? What steps might the champion take to introduce, embed and maintain the fidelity of the intervention? In addition, when multiple sites are taking part in research, regular 'troubleshooting' meetings could be held (via phone or videocall) between these study champions and a member of the research team, in order to share challenges and successes, as well as building feelings of collaboration across sites and teams. Michie and colleagues (2014) have specifically addressed the design of interventions using the Behaviour Change Wheel, recognising that the implementation of an intervention is a complex piece of behaviour change involving many interacting components. Their approach includes the development of a clear flow chart setting out exactly Who is doing What to Whom, Where, When and How often. Not only is this a simple but invaluable device to promoting fidelity and highlighting any potential difficulties at the outset, but it can

help to identify the point in the intervention where any operational problems are arising.

These broader challenges highlight the difficult circumstances in which we are currently conducting research in the NHS, and the importance of considering the context in which research is taking place. In addition, multiple studies are often taking place at the same time within a single NHS service, potentially with similar eligibility criteria, and sites must carefully balance not overburdening patients who are already in a stressful situation, with the recognised motivation of many patients to contribute to research for the benefit of others. If a study is taking place over a longer period, as was the case with our PEGASUS trial, the number and nature of 'competing' studies taking place during that time becomes more complex still. It is suggested that consideration and thorough discussion of this wider research context (within the research team and with staff at participating research sites) during study set-up are important elements of research planning in order to mitigate these challenges where possible. For example, there may be discussion of other research studies currently taking place at a site and how multiple studies will be managed, or the specific challenges and stressors that an NHS site may anticipate when recruiting to a new study.

Multi-site intervention studies have the additional challenge of fitting into multiple systems and varying patient pathways across sites. This requires careful adaptation of the protocol at each site to enable the intervention to be delivered efficiently and effectively. Once a study is in place, there may be changes in hospital systems, clinical practice and patient pathways that can create further challenges. During the course of our study for example, one site changed its surgical protocols, which impacted significantly on the number of patients eligible to take part and how well the intervention fitted within the service. Furthermore, it could be argued that the results of a trial that was designed to fit a service at one point in time might not be relevant to newer systems. Research designs that are more flexible and suited to real-life clinical settings could address these challenges and would reflect more realistic use of an intervention outside of the confines of a carefully controlled trial set-up. We suggest new and evolving approaches such as realist evaluation offer a useful alternative that ensures research remains rigorous, but also ecologically valid. Importantly, such frameworks have built-in flexibility and acknowledge the

differences between contexts rather than taking a 'one size fits all' approach, and we recommend further exploration of these alternative approaches could be of great benefit to psycho-oncology research going forward. Importantly, however, we would also encourage close involvement of study sites during the design process in order to ensure that these decisions are made collaboratively and the challenges above are minimised wherever possible.

To conclude, large-scale multi-site studies are vital for exploring how an intervention can work in an ecologically valid context and allow us to deliver the large sample sizes that are increasingly demanded from policy makers, funders and publishers. However, the reality of working within multiple systems can add layers of complexity to an already demanding research process. Our own reflections on a recent project have highlighted the importance of study champions at each site, further consideration of the process by which participants were recruited, and the value of a realist evaluation approach to intervention research. We encourage researchers to reflect on the challenges outlined in this paper and explore potential facilitators and barriers during the design of their own research in order to mitigate for some of the challenges that appear common in this field.

Finally, we urge more transparency in reporting of psychosocial oncology intervention studies and support previously published pleas for "more extensive reporting about this issue" (van Lankveld et al., 2018; pg. 2296). Reflection on our own research has allowed us a valuable perspective on the reality of applied research and intervention implementation in a busy clinical setting, and we hope that this article has highlighted aspects of the research process that receive scant attention within published literature. Further opportunities to share and discuss experiences of the challenges of research in clinical settings could help ensure that such issues are considered in the design and planning of future studies and ultimately benefit psychosocial oncology intervention research.

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