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Title:
Why did we fail? Challenges recruiting parents with cancer into a psycho-educational support program

Date:
2019-12-01

Citation:
Stafford, L., Sinclair, M., Newman, L., Rauch, P., Barton, M., Gilham, L., Cannell, J., Mason, K., Joubert, L., Hocking, A. & Little, R. (2019). Why did we fail? Challenges recruiting parents with cancer into a psycho-educational support program. Psycho Oncology, 28 (12), pp.2425-2428. https://doi.org/10.1002/pon.5226.

Persistent Link:
https://hdl.handle.net/11343/286559

Clinical correspondence (brief research report), 2001 words.

Title: Why did we fail? Challenges recruiting parents with cancer into a psycho-educational support program.

Short running title: Failure to recruit to a parenting with cancer intervention.

Key words: Cancer, oncology, psycho-oncology, parenting, patient recruitment, pilot study, parent-child relationship.

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Ethics approval: Granted by The Royal Melbourne Hospital Multisite HREC (HREC/16/MH/182).

Key points

1. A psycho-educational group program was developed to support parents with cancer who are parenting children; however, pilot testing failed due to poor recruitment.
2. Semi-structured interviews were undertaken to understand factors contributing to the project's failure.
3. Physical relocation of the main recruitment site to form a comprehensive cancer precinct in the months preceding recruitment impacted upon staff capacity to prioritise research.
4. Unwieldy governance requirements adversely impacted upon research which had time-limited funding.
5. The provision of timely parenting support during early diagnosis may be most accessible if incorporated into standard care.

Background

Healthcare research has many functions, including determining whether interventions are feasible and effective in real world settings. However, conducting such research is fraught with difficulties, including recruiting participants. Less than 1/3 of randomised controlled trials meet their original recruitment goal(1), and the most common reason for terminating clinical trials is insufficient accrual rate(2). This study examined why recruitment for an intervention supporting parents with cancer was unsuccessful, despite the project garnering enthusiasm from health care professionals (HCPs) at participating study sites.

In 2019, an estimated 144,713 new cancer diagnoses will be made in Australia(3). Approximately 10% will be in people under 50(3), many of whom will have children and face the additional challenge of parenting with cancer. Children are significantly affected by parental cancer, and experience more psychosocial and internalizing problems(4). An important strategy to support both children and parents is parent-child communication(4). However, parents report insufficient guidance from HCPs in this area(4), especially concerning sharing their cancer diagnosis with their children(5). The need for programs for parents with cancer has been documented(4, 5), yet few psychosocial interventions target this population(6).

In 2016, we received competitive funding to develop an intervention to support individuals parenting pre-adolescent children (aged 3-12), who were receiving cancer treatment with curative intent or with a view to longer term survival (Supplementary Methodological Details). This 3-hour, psycho-educational group program entitled *SUpporting Parenthood in cancER* (SUPER) aimed to decrease parental stress and enhance children's psychosocial adjustment, by improving parenting efficacy and promoting family communication. The intervention was developed by an iterative process (Supplementary Figure 1) and informed by clinical experience, attachment theory and social-cognitive theory(7, 8). The content development and intervention design was driven by an expert, who was supported by an international multidisciplinary team including psychologists, psychiatrists, social workers, oncologists, experts in communication and parenting, and consumers with experience parenting young children during cancer treatment. The intervention was designed to be sustainable (i.e. limited participant burden, group-based) and cover key topics (Supplementary Table 1).

To determine feasibility and effectiveness, the intervention was to be piloted among 20-30 parents with cancer and co-parents at four tertiary hospitals. Multisite ethics and governance approval for the pilot was a protracted process, delaying recruitment. During this hiatus, planning for recruitment occurred, including 35 presentations made to HCPs. These presentations described the study and eligibility criteria, and resulted in identification of 56 clinic coordinators and oncology clinicians to serve as 'referrers' (Supplementary Methodological Details). Regular contact with these referrers was maintained and flyers were placed in staff areas.

Three months into recruitment, the project was discontinued because despite the referral of 21 individuals, only 16 consented to be contacted by researchers of whom 4 were recruited (Supplementary Figure 2). A great deal of time, effort and funding had been invested to develop this intervention, which now could not be tested. Understanding the barriers that impeded recruitment was essential, so they could be mitigated in future research. To investigate this, the study team conducted formal interviews with referrers a month after recruitment closed, following amendment of the original study protocol (HREC/16/MH/182).

Methods

The 56 HCPs identified as *referrers* were sent an email about cessation of the study and invited to be interviewed. Consenting HCPs underwent semi-structured, audio-recorded telephone interviews which were transcribed. Information collected included type of HCP, gender, years worked in oncology, cancer sub-speciality, employment site, and whether they had actually referred patients to SUPER. Open-ended questions were asked about referral barriers, recruitment strategies and perceptions of the intervention. Information from the interviews was synthesized and evaluated, using Thematic Analysis(9). Informal feedback was collated from field notes the researchers had made during the study (email exchanges, telephone conversations), including asking HCPs how recruitment could be improved. Informal feedback guided preliminary coding.

Results

Of the 56 eligible participants, four provided informal feedback, ten provided formal feedback, and six provided both (n=20) (Supplementary Table 2). Seven participants referred patients to SUPER. All participants (except two males who gave informal feedback) identified as female. Mean number of years worked in oncology was 16 (*SD= 9*), and 85% of participants were nurses. Interviews lasted for a mean 12 minutes (*SD=4*, range =9-19).

Three themes emerged from the feedback: external barriers, internal considerations, and HCP perceptions.

External barriers were factors unrelated to the study that influenced recruitment. Recruitment began ~6 months after physical relocation of the main recruitment site to form a comprehensive cancer precinct with two of the other recruitment sites. Whilst the precinct was fully operational when recruitment commenced, the adjustment period saw substantial changes in personnel and clinical processes, as well as workload increases. These factors impacted staff capacity to prioritise research.

> *"it came at a time when the hospital had moved location. There'd been a merger with other services and…there were changes in process...increases in patient numbers … everyone was finding their feet…learning new information, even the layout of the hospital."HCP11.*

HCPs emphasized that time constraints and workload increases meant medically-based discussions (diagnosis, treatment) were prioritized over research or psychosocial issues.

> *"I have to squeeze an hour consultation into 20 minutes. … I will definitely automatically pick the most important…treatment trajectory for this patient rather than anything else"HCP01*

Internal considerations were study-specific factors influencing recruitment. HCPs reported that most patients did not meet the eligibility criteria of 'receiving treatment with curative intent or with a view to longer term survival'. Where this was unclear or staging was incomplete, staff were reluctant to refer.

HCPs acknowledged that whilst the intervention was required as close to diagnosis as possible, it was not necessarily a high priority for patients who were already processing a lot of new information. Some HCPs considered a 3-hour intervention unrealistic for parents of young children.

> *"Certainly the timing of being relatively close to diagnosis, a lot of patients certainly do feel, and I think we as clinicians identify, that they've got a lot of competing priorities … when we approached patients to talk to them about it, we realised that this was actually quite a big additional request that they may not have identified with."HCP03*

HCPs perceptions included feedback from HCPs about the recruitment process. HCPs supported the intervention concept and thought it was of value to patients. HCPs stated that identification of eligible patients (i.e. asking if they had children) was a simple process. They could not suggest easier ways for researchers to identify eligible patients, as data on parental status and age of any children was not systematically recorded. Most identified that recruitment problems were due to external barriers (described above), rather than the efforts of the researchers.

Discussion

Celebrating success in clinical research is essential. However, recognising and evaluating failure is equally important. This study examined the factors leading to the failure to recruit to a pilot intervention for parents with cancer.

Superficially, SUPER was terminated due to low accrual rates. Indeed, recruitment difficulties have been documented in other psycho-oncology studies(6, 10, 11). A deeper examination of the circumstances surrounding this study revealed the key role of inopportune timing. Recruitment coincided with physical relocation of the main recruitment site, the associated period of adjustment directly affecting staff capacity. A systematic review of interventions for families with parental cancer reported that successful interventions require

careful planning and anticipating barriers(6). Whilst upheaval during the relocation and merger was anticipated, the impact 6 months later when recruitment commenced was unexpected. Sustaining institutional support for research during major systemic change is a challenge researchers must learn to meet.

Another unexpected issue was delays receiving multisite ethics and governance approval. Despite SUPER being a low risk psycho-educational intervention this process took 4 months because (a)the study was not assessed as low risk; (b)governance approval was required from four hospitals, each with different processes; and (c)inter-site collaboration agreements required input from institutional legal counsel. Governance approval was obtained so late in the year that it was not feasible to commence recruitment. This was to avoid recruitment coinciding with Christmas/New Year holidays and the extended school summer break (affecting staff availability, clinic closures and participant enthusiasm/holiday plans). Whilst project planning had allowed for some time contingencies, the extent of these delays were unforeseen. Our experience draws attention to the impact of unwieldy governance requirements on research, particularly longitudinal studies with time-limited funding(12).

Timing of the intervention in the cancer journey was problematic for recruiting staff. A significant issue for parents is 'telling the children' about their cancer (5, 13), thus for SUPER to be of value, it was required soon after diagnosis. A study on recruiting African American families into a parental cancer intervention, recommended targeting parents within the first months of diagnosis(14). Our research indicates that patients are at their least approachable at the time the intervention is of greatest value, thus an alternative to group support may be required. This may include treating HCP(s) discussing the impact of cancer on the family unit with patients soon after diagnosis and providing accessible resources (e.g. online, pamphlets, books); as part of standard care. However, this approach impacts clinical workload and may not apply to all patients. In SUPER, 4/21 patients approached by referrers declined contact from researchers because their support and information needs were being met. When providing psycho-social support, it is important to recognise that times of foreseeable distress may not always equate to a wish for help or treatment(11).

The *perceived* burden of participation in research can also impact recruitment(11). Whilst three hours was the minimum time needed to convey the key psychoeducational material, it may have been perceived as being too long (although this was not reported in feedback or given as a reason for declining participation). Another possibility is that recruitment difficulties reflected the practical restrictions facing people with cancer or the intervention being perceived as unnecessary, which has been reported elsewhere(15). In SUPER, 5/21 patients declined participation due to treatment, childcare or work commitments. We may have underestimated patient factors that could impact recruitment and the feasibility of the intervention, particularly the potential burden of the 3-hour intervention on top of existing medical, parenting and work commitments.

Options to counter these barriers include changes to standard care (discussed above) or altering the group program (offering after hours/more often, shorter program, providing childcare, a more accessible format (e.g., online)). In the wake of the SUPER pilot failure, the study team adapted the SUPER intervention into an audio-visual resource that is primarily delivered electronically.

The eligibility criteria may have restricted identification of patients (Supplementary Methodological Details), and the non-binary notion of prognosis proved a complexity for

some staff. Some staff struggled with the notion of living with disease or well-managed symptoms as distinct from being palliated/unwell; a distinction complicated when new treatments may change prognoses. For SUPER, this distinction was important as parents who anticipate living for some time have very different needs to those who are preparing for their death. One intervention could not address both scenarios, and exposing parents with a good prognosis to issues pertinent to parents with end-stage disease (or vice versa) was considered unwise. The identification of potentially eligible patients remains dependent on clinical recruiters. In order to provide timely, family-focused cancer care, systematic collection of relevant data (i.e., parental status, age of children) may be required.

Understanding the barriers to successful recruitment is essential, to avoid an intervention being developed for a vulnerable group of patients that cannot be tested. This paper adds to our collective experience and knowledge by offering an honest, systematic examination of reasons for failure.

Acknowledgements

Funding for this project was received from the Western and Central Melbourne Integrated Cancer Service. The authors wish to thank Professor Meinir Krishnasamy, Dr Ben Tran, Ms Monique Baldacchino, Associate Professor Philip Campbell and Dr Jayesh Desai, for their support and assistance with the development of this project. We also thank the Breast Cancer Network of Australia for providing access to the consumer researcher, Ms Leslie Gilham.

Conflict of interest statement

This manuscript has not been published and is not under consideration for publication elsewhere. The authors have full control of the primary data and agree to allow the journal to review the data upon request. We have no conflicts of interest to disclose.

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