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Recruiting participants to a randomized controlled trial testing an intervention in palliative cancer care – The perspectives of health care professionals

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ABSTRACT

Purpose: The recruitment of participants to randomized controlled trials (RCTs) in palliative cancer care by health care professionals is often unsuccessful, which could result in failure to achieve study power. The purpose of this paper is to describe how health care professionals experienced recruiting patients and family caregivers to an RCT in palliative cancer care.

Methods: The study had a qualitative explorative design. Ten palliative home care settings were involved in the RCT and data were generated through focus group discussions and interviews with health care professionals who were responsible for the recruitment. The transcripts were analyzed with interpretive descriptive principles.

Results: The experiences of the health care professionals reveal that communicating the RCT-design to patients and family caregivers was a challenging part of the recruitment but was considered a process of learning over time. The delicate situation that participants were living under added to the challenge and health care professionals believed that the randomized design was contrary to their normal approach to always offer the best possible support.

Conclusions: The results contribute valuable knowledge for future trials in palliative cancer care. To promote successful recruitment, health care professionals may be in need of more training to improve their communication skills and it may be necessary to consider other research designs than the RCT.

1. Introduction

Randomized controlled trials (RCTs) are deemed the most reliable way to infer a causal relationship between an intervention and outcomes. The key feature of the RCT is prospective, random allocation of participants to an intervention and control arm (Polit and Beck, 2012). A challenging context for RCTs is the context of palliative cancer care, which uses an approach focused on promoting

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symptom relief and quality of life for patients with life-threatening illness and their families (WHO, 2017). It has been considered especially difficult in matters concerning identifying and recruiting participants which could impede the initiation and completion of trials (Grande and Todd, 2000). Sample sizes are often smaller than anticipated, even though significant time and resources are devoted to participant recruitment (Kutner et al., 2010). Health care professionals are usually the ones responsible for recruiting eligible participants to trials in palliative cancer care and may hence have a great influence on the success rate (Kars et al., 2016). RCTs could be regarded with skepticism by health care professionals as the potential benefits for participants could be questionable. Conducting trials in palliative care settings could also be questioned due to the vulnerability of patients and family caregivers (Holm et al., 2015; Kars et al., 2016), even though they often report positive attitudes to participate in research (Aoun et al., 2017).

An important area of palliative cancer care is supporting family caregivers (i.e. friends, relatives or partners) who often provide various forms of extensive care to the patient (Morris et al., 2015). This often constitutes a great burden which can lead to an increased risk of mental and physical ill-health (Williams and Mccorkle, 2011). Despite the obvious need for support, there are few interventions targeting family caregivers in palliative care and even fewer have been robustly tested (Kamal and Dionne-Odom, 2016). In general, interventions aiming to support family caregivers in palliative cancer care could be described as complex interventions which means that the intervention involves more than one component and unlike drug trials, the active ingredient could be hard to specify (Campbell et al., 2000). A recent review found 14 interventions directed at supporting family caregivers between 2004 and 2014, but, of these, only 7 were RCTs and recruitment problems were common, which led to insufficient study power (Chi et al., 2016).

It has been suggested that for complex interventions, quantitative outcome measures should be completed with qualitative evaluations of intervention processes (Campbell et al., 2000). To avoid recruitment problems and selection bias in future studies, it would be valuable to analyze the experiences of health care professionals when recruiting participants to an RCT in the context of palliative cancer care. Therefore, the aim of this study is to describe how health care professionals experienced recruiting participants to an RCT testing an intervention for family caregivers in specialized palliative cancer care.

2. Methods

This study has a qualitative approach with an explorative design. Ethics approval was obtained from a regional ethical review board (No. 2012/4:3, 2012/377-31/4).

2.1. Study context: a complex intervention

Data were collected from a psycho-educational group intervention trial for family caregivers at 10 palliative home-care settings in a metropolitan area in Sweden. The trial was orchestrated by the authors of this study, who were all part of the same research group. Health care professionals (nurses, physicians and social workers) at the palliative care settings were responsible both for recruiting participants to the trial and for delivering the intervention. One or two registered nurses at each setting had been selected by the head nurse to be mainly in charge of the recruitment process. The trial protocol was developed in accordance with the CONSORT-statement and has been registered at https://www.clinicaltrials.gov (ID: NCT02482415).

The trial was an RCT where family caregivers could be randomized to the intervention or to standard support. Before commencement of the trial, health care professionals from the 10 palliative home care settings were invited to a one-day workshop where the intervention content was covered and they were introduced to the recruitment process of an RCT. Health care professionals were instructed to recruit both patients and family caregivers to the trial. For convenient reasons, the recruitment would usually take place when the health care professionals made visits to provide care in the patients' homes. The inclusion criteria for patients were: being in receipt of palliative care, and having a limited life expectancy that was nevertheless longer than five weeks. Patients were not included in active data collection, but were asked to give their consent and nominate family caregivers to the trial. Thus, the recruitment process included two steps; recruiting patients, and then recruiting family caregivers. Family caregivers who were not living in the same home as the patient were contacted on telephone, or the patient was asked to pass on the invitation. If the patient accepted, the family caregiver(s), received written study information and were asked to complete a baseline questionnaire. This was sent to the authors, who randomized the family caregiver to either the intervention group or control group. The control group received standard support from the palliative care teams. The family caregivers received a letter informing them which group they had been allocated to and family caregivers who had been placed in the intervention group also received an invitation to the sessions.

The main purpose of the psycho-educational intervention was to increase family caregivers' feelings of preparedness for caregiving. The intervention was delivered in group format and included a structured program, focusing on the informational, practical and emotional needs of family caregivers. It has been thoroughly described in a previous article (removed for blinded review). During the intervention sessions, the health care professionals presented topics such as palliative care and symptom management, practical nursing care and emotional grief reactions. The intervention also included discussions and reflections between family caregivers.

In total, 270 family caregivers were recruited to the trial and 40 health care professionals were involved in the recruitment process. Every setting delivered the intervention 1–4 times.

2.2. Data collection

To evaluate the experiences of recruiting participants to a trial in palliative care, focus group discussions were held with health care professionals who had been involved in the recruitment process. To capture a deeper understanding of the experiences, interviews were also held with nurses who had been mainly responsible for the recruitment.

In total, 5 focus group discussions were carried out and 25 health care professionals (16 nurses, 4 physicians and 5 social workers) agreed to participate on two occasions within a period of 6 months, to capture experiences both from the early phase of recruitment and later. Two authors moderated each focus group with the use of an interview guide focusing on the experiences of recruiting participants. Examples of questions from the interview guide included “What strategies did you adapt when you recruited patients and family caregivers to the trial?” and “Which problems did you encounter in the process of recruitment?”

Within 5 months after trial completion, 9 interviews were performed by two authors of this study (Alvariza and Goliath) with 11 registered nurses, one man and 10 women, from 8 settings to further explore the aim of this study. For practical reasons, the interviews were carried out in different formats. One nurse was interviewed twice because there was not enough time to cover the