The effectiveness of a nurse-led intervention to support family caregivers in end-of-life care: Study protocol for a cluster randomized controlled trial

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Abstract

Aim: To evaluate the feasibility of a structured nurse-led supportive intervention and its effects on family caregivers in end-of-life care at home.

Background: Family caregivers are crucial in end-of-life care. They may experience burden due to the responsibilities associated with caregiving. Some family caregivers feel insufficiently prepared for their caregiver role. Nurses have a unique position to provide supportive interventions at home to reduce caregivers' burden and improve preparedness. However, few nurse-led interventions are available to support family caregivers in end-of-life care at home.

Design: We will perform a cluster randomized controlled trial. The clusters consist of twelve home care services, randomly assigned to the intervention group or the control group.

Methods: The study population consists of family caregivers of patients in the last phase of life. In the intervention group, nurses will systematically assess the supportive needs of family caregivers, using an assessment tool and the method of clinical reasoning. Family members of the control group receive care as usual. Primary outcome is burden measured by the Self-Rated Burden Scale. Secondary outcomes are preparedness for caregiving, caregiving reactions and acute (hospital) admissions of the patient. In addition, the feasibility of the intervention will be evaluated. The study was funded in October 2016 and was ethically approved in April 2019.

Impact: Findings from this study will contribute to the scientific and practical knowledge of nursing interventions to support family caregivers in end-of-life care.

Trial registration: The Netherlands Trial Register (NL7702).

KEYWORDS

burden, end-of-life care, family caregivers, needs-assessment, nursing, nursing intervention, preparedness caregiving, support, trial
INTRODUCTION

Patients in the last phase of life mostly want to be cared for and die at home (Higginson et al., 2014). Without the help of family caregivers that would be impossible for many patients (Visser et al., 2004). In the broad definition of Stajduhar et al. (2010), family caregivers are defined as: ‘individuals who provide any physical, emotional and instrumental support or assistance to individuals with a life-limiting illness that they view as family members’. Family caregivers are often intensively involved with personal and emotional care, and with household tasks and the coordination of care (Stajduhar et al., 2010). For instance, in the United Kingdom, family caregivers provide care a median of 69 hr each week in the final three months of life (Rowland, Hanratty, Pilling, van den Berg, & Grande, 2017). The important work that family caregivers provide may result in both positive and negative experiences. Nurses are in a unique position in primary health care to support family caregivers. However, little is known about which nursing interventions are effective on family caregivers’ well-being (Becqué, Rietjens, van Driel, van der Heide, & Witkamp, 2019; Hudson, Remedios, & Thomas, 2010).

BACKGROUND

Caring can be rewarding and meaningful (De Korte-Verhoef et al., 2014; Payne, 2010). An Italian study (Morasso et al., 2008) reported that family caregivers felt personal growth, sense of self-efficacy and improved family relationships as positive aspects of caring. However, many family caregivers who provide end-of-life care also experience a heavy to severe burden due to the physical, emotional and financial responsibilities associated with caregiving (De Korte-Verhoef et al., 2014). They have to cope with the impending loss of a family member and providing care in itself can be a source of stress. Approximately 25% of family caregivers experience emotional suffering related to the patient’s death or their caregiving experience (Morasso et al., 2008). Burden of family caregivers may be a key cause for (acute) hospital admissions of the patient (Jack & O’Brien, 2010). Family caregivers who feel less burdened have been shown to be more able to provide end-of-life care at home until the time of death (Jack & O’Brien, 2010; Visser et al., 2004).

Some family caregivers feel insufficiently prepared for the many demands they might face and experience (Aoun, Kristjanson, Hudson, Currow, & Rosenberg, 2005) and feel inadequately supported by the healthcare staff (Morasso et al., 2008). Healthcare professionals such as nurses usually focus on the patients and their needs for care and treatment and involve family caregivers only when needed in patient care (Witkamp, Droger, Janssens, van Zuylen, & van der Heide, 2016). Ideally however, the position of the caregiver should not only been seen as ‘co-caregiver’ but also as ‘co-client’ (Harding & Higginson, 2003).

Nurses have a unique position to assess the needs of family caregivers and to provide supportive interventions aimed at reducing caregivers’ burden and improving preparedness (Kennedy, 2005). In the Netherlands, since 2015, nurses in the primary healthcare setting are responsible for the decision which and how much home care is needed and the allocation of nursing home care. This responsibility is laid down in the Healthcare Insurance Act (Harder, Zilverentant, & Oonk, 2019). Together with the patient and their family, the nurse defines goals and plans for care, organizes care and evaluates processes and outcomes of care. Family caregiver needs may be included in this process (Payne, 2010), but it is unknown how and to what extent nurses allocate supportive care for caregivers. Additionally, few nursing interventions are available to support family caregivers in end-of-life care at home (Becqué et al., 2019; Hudson et al., 2010).

THE STUDY

Aim

This study aims to evaluate the effects of a structured nurse-led supportive intervention on family caregivers in end-of-life care at home and to evaluate the feasibility of this intervention.

Design

We will conduct a cluster randomized controlled trial. In this trial, we will evaluate the effects of a new nurse-led supportive intervention on the well-being of family caregivers at home and the feasibility of this intervention. This trial was registered at the Netherlands Trial Register (NL7702). The full form can be accessed online at https://www.trialregister.nl/trial/7702.

Setting

Twelve home care services in the southwest region of the Netherlands were invited to participate as research clusters. They will be randomly assigned to the intervention group or the control group by using a random number generator on the computer.

Study population

The study population consists of family caregivers of terminally ill patients (e.g. people with advanced cancer or advanced organ failure) receiving home care. We define the family caregiver as ‘family member or friend who is mostly involved with the care, or the person who is the first contact person of the patient’. Participating patients can have one or more family caregivers.

Inclusion and exclusion criteria

Family caregivers caring for patients with a life expectancy up to six months will be included. Nurses will identify these patients by
answering ‘no’ to the adapted surprise question: ‘Would you be surprised if this patient would die within six months?’ (Gane, Braun, Stott, Wellsted, & Farrington, 2013; Straw et al., 2019). Family caregivers of patients who are estimated (by the nurse or general practitioner) to have a life expectancy of at most 2 weeks will be excluded. Other inclusion criteria are that the family caregiver must be 18 years or older, able to provide written informed consent and able to complete a Dutch questionnaire.

3.6 | Intervention

To identify effective nursing interventions on family caregiver support and prevention of burden, we conducted a systematic narrative review (Becqué et al., 2019). We identified four intervention components: psychoeducation, needs-assessment, practical support with caregiving and peer support. This review showed that multicomponent nursing interventions were the most successful, whereas needs-assessment seems to be one of the most effective single components (Becqué et al., 2019).

One of the studies included in the review found effects of an intervention with a needs-assessment (Aoun et al., 2015), the Carer Support Needs Assessment Tool (CSNAT) which is a valid tool to measure the support needs of family caregivers in palliative home care. (Aoun et al., 2015; Ewing, Austin, Diffin, & Grande, 2015). Our intervention is based on this CSNAT. The CSNAT comprises 14 domains where family caregivers commonly say they require support to: (a) enable them to care for the patient at home; or (b) increase their own health and well-being. Completion of the CSNAT is the start of a process, consisting of five steps. First, the CSNAT tool is introduced to the family caregiver (step 1). Then the family caregiver uses the tool to identify domains where they need more support (step 2). A conversation between the family caregiver and the nurse determines needs and priorities (step 3) and this will lead to a shared action plan (step 4). Finally, family caregivers’ needs will be regularly reviewed (step 5) (Ewing et al., 2015; Ewing & Grande, 2013). The CSNAT is thus integrated in a person-centred process, led by the family caregiver, the so-called ‘CSNAT-Approach’.

The CSNAT tool was translated into the Dutch language following scientific translation standards and subsequently validated for palliative care practice in the Netherlands (van Vlierden, 2016).

3.7 | Training

Nurses in the intervention group will be trained to use the CSNAT approach. The training is built on the CSNAT training programme developed in Cambridge, with two added themes: (a) how to address varying support needs of family caregivers and (b) clinical reasoning skills. Nurses will learn how they can justify the indicated end-of-life care and support using nursing diagnoses.

The training programme consists of an e-learning, two plenary group sessions and two intervision sessions (totally 23 hr). The e-learning focuses on raising awareness of different types of family caregivers with their specific needs. Information, reflective questions and films are used in this e-learning. In the group sessions the nurses are trained to use the CSNAT approach including clinical reasoning, mainly by role plays. In the intervision sessions nurses reflect on how they apply their new skills in clinical practice. The nurses working at home care organizations in the control group will not receive the training; they will provide care as usual.

3.8 | Primary outcomes

3.8.1 | Burden

The primary outcome in this study is burden measured by the Self-Rated Burden Scale (SRB), published in Dutch (van Exel et al., 2004) (Table 1). The SRB is a feasible and valid instrument for assessing the burden of informal caregiving. It was developed and evaluated among informal caregivers of stroke patients and consists of a single question: ‘how burdensome do you feel caring for or accompanying your partner/family member is at the moment?’.

| Outcomes | Measurement instruments                                      | Timepoints                        |
|----------|-------------------------------------------------------------|-----------------------------------|
| Primary outcome | Caregivers’ burden | Self-Rated Burden Scale (SRB), 1 item, visual analogue scale 0–100 (Van Exel et al., 2004) | T0 (at baseline) and T1 (one month after T0, postintervention) |
| Secondary outcomes | Caregivers’ burden | Self-Rated Burden Scale (SRB), 1 item, visual analogue scale 0–100 (Van Exel et al., 2004) | T0–T3 |
|             | Caregivers’ preparedness for caregiving | Preparedness for Caregiving Scale (PCS), 8 items, 5-point Likert scale (0–4) (Archbold et al., 1990, Hudson and Hayman-White 2006) | T0–T3 |
| The incidence of acute admissions of the patient | Nursing files | 4–6 weeks following patients’ death or hospital/hospice admission |
3.9 | Secondary outcomes

3.9.1 | Caregiver reaction

The caregiver reaction assessment (CRA) will be used to further specify the nature of burden. With the CRA the negative and positive response of family caregivers caring for a person in the final phase of life will be assessed. The CRA is a self-report questionnaire, consisting of 24 items and comprising four negative subscales (disrupted schedule, financial problems, lack of family support, health problems) and one positive subscale (self-esteem) (Given et al., 1992). Answers will be scored on a 5-point Likert scale ranging from 1 to 5. For each subscale, a total mean score will be calculated with a range between 1 and 5. The higher the score how stronger the impact of the attribute (either negative or positive).

The CRA was developed and tested in the study conducted by Given et al. (1992) among caregivers of patients with chronic physical and mental impairments. This study revealed good psychometric properties. The CRA was translated into Dutch and then evaluated among caregivers of people with cancer in the Netherlands by Nijboer, Triemstra, Tempelaar, Sanderman, and van den Bos (1999). This study showed that the CRA is a feasible, reliable and valid instrument to assess the reactions of giving care.

3.9.2 | Preparedness for caregiving

Preparedness for caregiving is defined as perceived readiness for multiple domains of caregiving role, such as providing physical care, providing emotional care, dealing with stress of caregiving and responding to handling emergency situations (Archbold, Stewart, Greenlick, & Harvath, 1990). Preparedness in these domains will be measured by the Preparedness for Caregiving Scale (PCS) (Archbold et al., 1990). The PCS is a self-rated questionnaire consisting of eight items, investigating how well-prepared family caregivers believe they are for multiple domains of caregiving. Answers are rated on a 5-point scale ranging from 0 (‘not at all prepared’) to 4 (‘very well prepared’). The scale is scored by calculating the mean of all items answered with a score range of 0–4. A higher score represents better preparedness. The psychometric properties of the PCS have been tested in caregivers of patients in palliative care and demonstrated it is a valid and reliable instrument (Pucciarelli et al., 2014). We (two researchers) translated the original English version of the PCS into Dutch independently and it was translated backward by two native English speakers. Differences in the forward and the backward translation were discussed until consensus was reached. The pre-final version was submitted to an advisory panel of family caregivers for feedback; they provided minor comments which were addressed in the final version.

3.9.3 | Acute admissions

Acute admissions and place of death will be retrieved from patients’ healthcare records. We define acute admission as an unplanned admission (known less than 36 hr in advance). Halfway and at the end of our study, the researcher will check patient records and check the occurrence of acute admissions and, if applicable, place of death.

3.9.4 | Feasibility

To investigate the feasibility of the intervention and its adaptation to home care practice, seven nurses of the intervention group will be interviewed. The researcher will check in patient records (in the intervention group) what is documented by the nurse about the nursing process: family caregivers’ supportive needs, nursing diagnoses and supportive interventions. Data will be collected by using a data extraction form. Furthermore, family caregiver participants will be asked to send the CSNAT forms to the researcher to investigate how the CSNAT is used and which items are completed.

3.10 | Recruitment, consent and data collection

Family caregivers will be approached by the nurses for participation in the study. If they are interested, the nurse will inform the researcher and pass on their contact details with permission of the family caregivers. The researcher will contact the family caregiver and provide oral information on the study purpose, the intervention. Family caregivers who agree to participate are asked to provide written consent. We also ask patients to provide written consent to check their records. Participants may withdraw from the study at any time without effect to their care. They will not receive any incentive for participation.

After informed consent, family caregivers in both the intervention and control group will be invited to complete the questionnaires (SRB, CRA, PCS) at 2–4 timepoints, depending of the illness trajectory of the patient:

- at baseline (T0),
- one month after baseline (T1),
- one month after T1 (T2),
- 4–6 weeks following the patient’s death (T3).

The questionnaires will take around 15–20 min to complete.
3.11 | Statistical analyses

Analyses will be performed following the intention-to-treat principle. Descriptive statistics will be used to compare characteristics of family caregivers (gender, age [in years], relation to patient, living with patient, diagnose patient and the intensity of informal care [hours per week]) at baseline (T0) between the intervention and control group, using independent sample t tests and chi-square tests. Multilevel/multivariate analyses will be used to examine outcomes in the intervention and control group on T1, taking into account potential variation in age of the family caregivers and intensity of the informal care provided. Repeated measures analysis of variance will be conducted to assess the development of outcomes over time. All statistics will be two-sided and considered significant if \( p < .05 \). If necessary, imputation will be used to handle missing data (max. 20%).

3.11.1 | Other outcomes

The incidence of acute admissions of patients in the intervention and control group will be calculated. Experiences of nurses using the CSNAT approach will be qualitatively analysed.

3.12 | Sample size calculation

This study will consist of a sample size of 92 family caregivers in each group (184 in total). Assuming that we will evaluate 184 family caregivers, using a significant level of 5% and an intra-cluster correlation coefficient of 5%, we will have a power of 75% to demonstrate a difference of 15 points on the SRB.

3.13 | Validity and reliability

The included questionnaires (SRB, CRA, PCS) have been tested for validity and reliability for various settings and countries (Archbold et al., 1990; Given et al., 1992; Nijboer et al., 1999; Pucciarelli et al., 2014; van Exel et al., 2004). Furthermore, we will reduce the biases in estimating the effects of the intervention. In this nursing trial, it is impossible to blind the participants and nurses for the intervention. But blinding of the analysis will be achieved by withholding information from the analytic researcher about how the intervention and control groups are coded.

4 | ETHICAL CONSIDERATIONS

The research protocol was reviewed and approved by the Medical Ethics Review Committee in April 2019 (NL68453.078.18). All participants will receive oral and written information on the study and sign an informed consent before entering the study. Family caregivers of patients who are cared for by a home care organization in the intervention group may receive the CSNAT intervention, even if they decline to participate in the study.

5 | DISCUSSION

Few studies on nursing supportive interventions to support family caregivers in end-of-life care with a robust design are available (Becqué et al., 2019). Findings of this cluster randomized controlled trial will contribute to the scientific and practical knowledge of nursing interventions to support family caregivers caring for patients in the last phase of life. Additionally, this study will yield a training programme and implementation manual to implement this new intervention in nursing practice.

5.1 | Limitations

A potential limitation of our study is that inviting and informing home care organizations and nurses about the study, may have influenced the awareness of nurses in the control group. In addition, only home care organizations who were positive about our research responded to our invitation to participate. It is possible that these organizations already had a high priority for palliative care.

We believe that the CSNAT approach will not be a burden for family caregivers but completing 2-4 questionnaires may be a barrier for participation. We therefore developed a questionnaire that is as short as possible. However, attritions are a common problem in trials in end-of-life care because of the vulnerability of family caregivers and the unpredictable illness trajectory of the patient (Hui, Glitza, Chisholm, Yennu, & Bruera, 2013).

Finally, we realize that the intervention implementation process (training of the nurses, time, resources and adaptation) is crucial for the impact of the intervention (Moore et al., 2015). In our study we will evaluate the implementation process by interviewing nurses and screening patient records. This will offer us the opportunity to interpret our findings in the light of the implementation process.

6 | CONCLUSION

This study will evaluate the effects of a structured nurse-led supportive intervention on family caregivers in end-of-life care. The evidence gained from this study will provide nurses insight into how to support family caregivers and to address their needs. This may improve the well-being of family caregivers.

ACKNOWLEDGEMENTS

The authors thank Roeline Pasman and Wilco Kruiswijk for their contribution to the training. This study is funded by the Netherlands Organisation for Health Research and Development (ZonMw) (Grant number 844001313).
CONFLICT OF INTEREST
The authors declare that they have no conflict of interest.

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**How to cite this article:** Becqué YN, Rietjens JAC, van der Heide A, Witkamp E. The effectiveness of a nurse-led intervention to support family caregivers in end-of-life care: Study protocol for a cluster randomized controlled trial. *J Adv Nurs*. 2020;76:1266–1272. https://doi.org/10.1111/jan.14326

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