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Promoting preparedness for family caregiving – a randomised controlled intervention in palliative care

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**PROMOTING PREPAREDNESS FOR
FAMILY CAREGIVING - A RANDOMISED
CONTROLLED INTERVENTION IN
PALLIATIVE CARE**

Maja Holm



**Karolinska
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ABSTRACT

Background: Patients with incurable illness are increasingly being cared for in their homes with the help of palliative home care. However, in this system family caregivers also play an important role and often take a great responsibility for the patient's care. Family caregivers often lack preparedness for the situation, which could have negative consequences on their health and wellbeing.

Methods: The overall aim of this thesis was to develop and test a psycho-educational intervention for family caregivers in specialised palliative home care and to study processes and effects of the intervention. The psycho-educational intervention was developed based on the theoretical framework of Andershed and Ternstedt with focus on family caregivers' need for education and practical and emotional support. The intervention was delivered by health professionals and tested as a randomised controlled trial (RCT) at 10 specialised palliative home care settings, including an intervention arm and a control arm with standard support. The thesis includes four studies of which two (I, II) had a qualitative design and focused on processes involved in or considered relevant for the intervention. Two studies (III, IV) had a quantitative approach and focused on the effects of the intervention. The overall aim of the intervention was to improve family caregivers' feelings of preparedness for caregiving. In total, 194 family caregivers participated in the RCT with 96 family caregivers in the control arm and 98 in the intervention arm

Aim and results of studies: The aim of Study I was to study how family caregivers' experienced their preparedness for caregiving in palliative care. The results showed that preparing for caregiving was viewed as an ongoing process by family caregivers and that it was related to the process of preparing for the patient's death.

The aim of Study II was to explore the experiences of delivering and participating in the intervention from the perspectives of health professionals and family caregivers. The intervention was generally perceived as a positive experience and both groups highlighted that it could be used a tool to support family caregivers to become better prepared.

The aim of Study III was to investigate the effects of the intervention compared to standard support in short- term and long-term. The results showed that the intervention had significantly improved family caregivers' feelings of preparedness for caregiving both in short-term and long-term.

The aim of Study IV was to investigate the characteristics of family caregivers who did not benefit from the intervention. The results indicated that family caregivers who did not benefit were significantly less vulnerable at baseline than those who did. Hence, they might not have had the same need for the intervention to become better prepared.

Conclusion: In conclusion of the four studies, the psycho-educational intervention could be valuable as a part of the health professional work to support family caregivers and increase their chances to become better prepared for caregiving. For the development of future

interventions, it is important that family caregivers who are perceived as vulnerable are not excluded from participating, because they could be in most need of them.

Keywords: Palliative care, family caregivers, preparedness, intervention studies

LIST OF SCIENTIFIC PAPERS

- I. Holm, M, Henriksson, A, Carlander, I, Wengström, Y & Öhlen, J. (2015). Preparing for family caregiving in specialized palliative home care: an ongoing process. *Palliative and Supportive Care*. Vol:13 (3) 767-775
- II. Holm, M, Carlander, I, Fürst, C-J, Wengström, Y, Årestedt, K, Öhlen, J & Henriksson, A. (2015). Delivering and participating in a psycho-educational intervention in palliative home care – a qualitative study from the perspectives of health professionals and family caregivers. *BMC Palliative care*. Vol:14
- III. Holm, M, Årestedt, K, Carlander I, Fürst, C-J, Wengström, Y, Öhlen, J & Alvariza, A. Short-term and long-term effects of a psycho-educational intervention in specialised palliative home care – results from a randomised controlled trial. *Psycho Oncology* (E-pub Oct 2015)
- IV. Holm, M, Årestedt, K, Carlander I, Wengström, Y, Öhlen, J & Alvariza, A. Characteristics of family caregivers who did not benefit from a successful psycho-educational intervention in palliative cancer care: a prospective correlational study. *Cancer Nursing* (E-pub Feb 2016)

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1 INTRODUCTION

During my last semester as a nursing student, a few classmates and I were invited to an information meeting with first-line nurses from various clinics in the local hospital. One of them came from a specialised palliative care setting and even though I had no previous experience and very limited knowledge of the concept of palliative care, I was immediately drawn by the way she described the approach at her unit. The holistic approach to care from the perspective of the patient with a great focus on quality of life was something I had found lacking during my training as a nurse and my work as a nurse assistant and this led me to start working there when I had graduated. Working in the palliative care setting included not only caring for the patients on the hospital ward, but also working in the specialised palliative home care team, which served patients in their own homes across the region. Working in this kind of home care included a high degree of independence and the administering of advanced medical treatment and symptom relief. For a newly registered nurse, this task was complex and challenging as it encompassed a great focus on advanced medical caregiving. However, during my visits to the patients' homes, I was also hit by the difficult situation that many family caregivers were living under. While I just dropped in for a short while to start an infusion or give an injection, they often spent 24 hours a day as caregivers and faced a very heavy responsibility for the patient's care. While I had regulated working hours, including lunch breaks and free days, they had no such privileges. Family caregivers could be of different ages, genders and backgrounds, and sometimes they were more than one. However, they all had one thing in common; they were close to the patient and were affected by the patient's incurable illness. As a PhD candidate I have been given the opportunity to study the complex situation of family caregivers and concentrate my research on how they can be supported during ongoing palliative care. The thesis you are holding in your hands presents a group intervention delivered in three sessions for family caregivers during palliative home care. The aim of the intervention is to make family caregivers better prepared for their situation. My experience as a nurse has shown me that family caregivers often lack information and knowledge of how to provide care as well as emotional and practical support. While I hardly think this intervention can provide all the answers, it can certainly provide some important pieces of the jigsaw!

2 ABBREVIATIONS

WHO = World Health Organisation

EAPC = European Association for Palliative Care

RCT = Randomised Controlled Trial

ICC = Intraclass correlations

PCS = Preparedness for Caregiving Scale

CCS = Competence for Caregiving Scale

RCS = Rewards for Caregiving Scale

CBS = Caregiver Burden Scale

HI = Health Index

HADS = Hospital Anxiety and Depression Scale

MSPSS = Multidimensional Scale of Perceived Social Support

3 BACKGROUND

3.1 PALLIATIVE CARE

The modern definition of palliative care stems from the hospice movement, pioneered by Cecily Saunders. The movement was a protest against a perceived medicalization of the dying process. Saunders established that death was a natural part of life and that dying should be viewed from a holistic perspective with focus on the patient's physical, mental, social and existential needs. Both the patient and the family members should be supported to live in the most optimal way as possible in the situation.¹ The World Health Organisation (WHO) has built its definition of palliative care from the hospice philosophy. According to the WHO, death is to be regarded a normal process of life and the primary aim is to improve quality of life and reduce pain and other difficult symptoms associated with life-threatening illness. It has been stated that a palliative care approach could be applied in earlier stages of the illness, combined with medical treatments, not just at the end of life.²

The European Association for Palliative Care (EAPC) distinguishes between general and specialist palliative care. General palliative care is provided in settings that have good basic competence in palliative care, such as geriatric or oncology clinics; however, palliative care is not the main focus of their organisation. Specialist palliative care is provided by health professionals who have extensive knowledge about palliative care of patients affected by life-threatening illness, who have complex needs. They usually adopt a multidisciplinary approach with health professionals working in teams to provide care in the patient's home.³

It has been argued that palliative care should be regarded as a basic human right and should be approached as a public health issue. Changes to the health care systems in the modern western world has brought new challenges to palliative care on a population level.⁴ Most western countries have ageing populations^{5,6} and the development of modern medicine can allow for individuals to live longer with complex conditions and impaired capacities.⁷ Another trend seen in the public health systems in the western world, is that the number of hospital beds has been reduced,⁸ with an increased occurrence of outpatient care.^{9,10} The efforts of family caregivers have become increasingly important to this system. Communication between health care professionals and families has been highlighted as a core aspect.¹¹

Sweden is a country where these two trends have been very evident. The average life expectancy has increased and is now over 80 years for both men and women.⁵ Further, there has been a particularly drastic decrease in the number of hospital beds over the last decades. Even in comparison to other western countries, Sweden has a small number of available hospital beds per citizen.¹² Patients with advanced needs are increasingly receiving care through their municipalities or primary care.¹³ There has also been a development of specialised palliative home care settings with health professionals working in teams to provide care.¹⁴ This system relies heavily on family caregivers and from a public health perspective; it has been stressed that this group must not be overlooked in the delivery of palliative care. When someone is in need of palliative care, this impacts the entire family and the circumstances and characteristics of dying and death will also affect their quality of life.⁴

3.2 PALLIATIVE FAMILY CAREGIVING

Family caregivers in palliative care are defined in this thesis as any friend, relative or partner who is involved in the care of a patient with severe, life-threatening illness.¹⁵ Eighteen percent of the adult population in Sweden describe themselves as family caregivers to a patient cared for at home. It is most common to care for a parent, a spouse or a child.¹⁶ International studies have shown that a majority of patients in palliative care want to be cared for at home during their illness trajectory and that four out of five do not change their preferences as their illness progresses.^{17,18} Although there are great variations,¹⁹ family caregivers in palliative home care often face numerous tasks involving the practical and medical caregiving for the patient while also providing emotional and social support and maintaining household chores. They often need to act as spokespersons for the patient and coordinators of the patient's care.²⁰ The economic impact of their contribution to the health care system is often substantial,²¹ and without the presence of a family caregiver, the patient's odds of dying at home decreases.²²

A generally dark picture has been painted of the involvement of family caregivers in palliative home care, but positive aspects of the situation have also been reported.²³ Family caregivers may experience a deeper bond with the patient²⁴ as well as feelings of reward and meaningfulness in the situation.²⁵ The home environment also makes it easier to uphold a sense of normality in the situation.²⁶ However, it has been demonstrated that family caregivers in palliative home care have an increased risk of physical and mental ill-health²⁷ and may experience a great burden, symptoms of anxiety and depression, and lack of communication with health care services.²⁵ Being a family caregiver to a patient in palliative care is a complex situation. Although most caregivers take on the situation willingly, they may experience many conflicting emotions and a range of unmet needs of their own.^{26,28} While caring for a patient in palliative care, family caregivers are often involved in a process of grief and may be at risk of developing complicated grief reactions.^{29,30} They may not necessarily find support within the family and could thus be more vulnerable.³¹ Hence, there are many reasons for health professionals to focus on supporting family caregivers to become better prepared.

3.3 PREPAREDNESS FOR PALLIATIVE FAMILY CAREGIVING

Preparedness for caregiving is defined in this thesis as the perceived readiness for various domains of the caregiver role, such as providing practical care and emotional support, but also to manage the stressors related to caregiving.^{32,33} It could be described as a resource that could help family caregivers in palliative care adapt to their situation.³⁴ Preparedness refers to readiness for caregiving which differs from skill or competence to provide care.³³

Preparedness for caregiving has both a practical and an emotional aspect; knowing what to do, but also coping with emotions and stress.³⁵ In family caregiving, feelings of being prepared have been associated with several positive aspects and could be regarded as a protective factor against negative consequences; less burden and anxiety and stronger feelings of rewards and hope in the situation.^{33,36} It has also been found that increased feelings of preparedness in family caregivers could affect the patient in a favourable way.³⁷ Preparing for caregiving has been described as a transition where family members willingly or unwillingly prepare for the role as caregivers.³⁸

In palliative home care, family caregivers may experience a great lack of preparedness for the situation as they often have little experience in caring for a dying patient.³⁹ Receiving support from health professionals could increase the chances of the patient receiving successful care and remaining in the home,²² and could improve the wellbeing of family caregivers.²³ Family caregivers have various and extensive needs for support, from the time of the patient's diagnosis, throughout the illness trajectory.²⁸ In order to become better prepared, family caregivers need support in practical, emotional and existential dimensions.³² It has been highlighted that family caregivers in particular need information to acquire practical nursing skills, which is often found lacking,⁴⁰ as well as open communication with health professionals about the patient's condition.⁴¹ To family caregivers in the home, it could also be important to acquire skills in how to provide symptom relief and administer medications and gain access to physical resources to assist in daily living. They may also be in need of information in order to navigate through the health care system.²⁶ Apart from practical and informational support needs, family caregivers need psychosocial support to uphold a sense of normality.²⁸

Family caregivers in palliative care not only need to prepare for caregiving, but also for the patient's future death,³⁸ and might react with feelings such as shock, anger and grief.⁴² Feelings of being unprepared have been associated with additional problems in bereavement,^{43,44} while it has been suggested that family caregivers who feel well-informed and prepared during the illness trajectory would experience fewer problems in bereavement.^{45,46} Because preparedness has an important role to play in caregiver wellbeing, it has been highlighted that it should be an important component in the design of supportive interventions for family caregivers in palliative care.⁴⁷

3.4 INTERVENTIONS IN PALLIATIVE FAMILY CAREGIVING

Supportive interventions aimed at family caregivers in palliative care have generally been few, although there have been a slight increase over the years and more studies with rigorous intervention designs have been reported.⁴⁸ A Cochrane review from 2011 found 11 trials directed at family caregivers delivered with randomised controlled design (RCT),⁴⁹ which is considered to be the most reliable way to test interventions. A recent review from 2015 found 14 behavioural or educational interventions directed at family caregivers between the years 2004 and 2014. Seven of these were RCT trials, three were comparative, and four were quasi-experimental. The authors concluded that although there has been an increase in the development of interventions and that they generally have reached positive outcomes, there is a need for more RCTs tested in larger samples with effect size calculations to assess the impact of the intervention.⁵⁰ Because effects tend to be small, there is also a need to investigate potential barriers to intervention effectiveness.²¹

Trials in palliative care have been associated with difficulties when it comes to recruiting and retaining participants.⁵¹ There has been a general uncertainty in choosing appropriate outcome measures for interventions in palliative care.⁵² A conceptual oversight has pointed out variables that should be considered important when measuring family caregivers' experiences and in the development of interventions. These key variables included family caregivers' preparedness, competence and rewards for caregiving as well as their experiences of burden, health anxiety and depression.³⁴ Trials aimed towards supporting family caregivers

in palliative care could be characterised as complex trials, as they include more than one component or variable rather than a single casual factor.⁵³ The holistic nature of palliative care which aims towards promoting individual family caregivers' needs could make it difficult to define interventions precisely and uniformly, unlike more standardised interventions. It has been suggested that trials in palliative care need to include a blend of qualitative and quantitative methods, measuring both the processes and effects of the intervention, which could allow both for sensitivity to the complexities of palliative care and the testing of an intervention's effectiveness.⁵⁴

A common intervention design is psycho-educational, which includes both supportive and educative components and can be delivered both individually and in group-format.⁵² The design involves a structured program geared towards providing information about things such as the patient's disease process and practical issues related to caregiving.⁵⁵ It also includes supportive activities between family caregivers.⁵⁶ Psycho-educational interventions have been effective, especially in promoting family caregivers' feelings of preparedness for caregiving, but also in promoting their competence and providing rewards for caregiving in palliative care.⁵⁷⁻⁶⁰ In Sweden, two supportive group interventions directed at family caregivers in palliative care have been qualitatively studied. The groups were experienced as valuable as they presented an opportunity to meet others in the same situation, and to share experiences and knowledge. This promoted social support and a sense of cohesion.^{61,62} A group intervention program with a psycho-educational design delivered by health professionals in specialised palliative home care was found to be effective in promoting family caregivers' feelings of preparedness, competence and rewards for caregiving.⁶³ Qualitative results also gave a positive image of the psycho-educational intervention, as family caregivers experienced the program as interesting and confirming and gave the participants a sense of safety, belonging and warmth.⁶⁴ Otherwise, few intervention trials directed at family caregivers have been reported in the Swedish context.⁶⁵

It could be assumed that the difficulties in including participants and in choosing intervention designs and appropriate outcome measurements for evaluation, which are described above, could be an explanation of why there are few interventions directed at family caregivers and a lack of studies delivered with an RCT design.

4 RATIONALE

There is a general trend and policy that patients in palliative care should be cared for at home which is often in accordance with their own wishes. Family caregivers play a key role and often face a great deal of responsibility for which they are insufficiently prepared. Family caregivers are involved in a complex situation and may experience difficulties, both when it comes to practical caregiving and with emotional distress. This lack of preparedness could lead to a negative impact on many family caregivers' health and wellbeing, because research has found that preparedness for caregiving could be a protective factor against negative consequences such as burden and anxiety and could promote stronger feelings of rewards and hope in the situation. Due to the importance of preparedness for caregiver wellbeing, there is a need to develop more knowledge about this phenomenon and how it could be promoted. There are many good reasons for health professionals to focus on supporting family caregivers during ongoing palliative care, as it could improve their feelings of preparedness and influence their wellbeing in a positive way. It is noteworthy that although the number of interventions directed at family caregivers has increased, there are still very few interventions, especially those with rigorous designs to evaluate effectiveness. Therefore, there is an urgent need to develop and evaluate both processes and outcomes of supportive interventions directed at family caregivers in palliative care to make them better prepared for the situation.

5 THEORETICAL FRAMEWORK

5.1 THE INVOLVEMENT OF FAMILY CAREGIVERS IN PALLIATIVE CARE

Andershed and Ternstedt^{66,67} have developed a theoretical framework focusing on the involvement and principal needs of family caregivers in palliative care. The framework should not be considered an explanation, but rather, as a framework for increased understanding of the family caregiver situation. The authors conclude that the involvement of family caregivers in palliative care could be experienced either as “involvement in the dark”, where the family caregiver feels isolated and unseen and experience a lack of communication with health professionals, or as “involvement in the light”, where the family caregiver experience meaning and coherence in the situation and feel informed and acknowledged by health professionals.

Andershed and Ternstedt have theorised that the involvement of family caregivers in palliative care could be illustrated as three components or principal needs; these are: knowing, being and doing.

Knowing

Knowing represents family caregivers’ need for, and active seeking of, knowledge. Family caregivers need to obtain continuous information about the patient’s diagnosis, symptoms and prognosis. They also need to know things about the patient; how he or she feels, and how they experience the situation. In addition, they need to obtain knowledge from health professionals about the planning of the patient’s care and possible alternatives. They may also need to seek information on their own. In conclusion, they need to gain a full overview of the situation. Knowing is a crucial concept in the framework because it could be described both as being a part of family caregivers’ involvement, but also as a prerequisite for involvement in the form of being and doing. Through knowing, family caregivers can easier be able to choose how to be involved in the patient’s care, which also promotes the being and doing of family caregivers. Having trust in their own resources is important to family caregivers, and hence, health professionals should focus on supporting their potential for increased knowing.

Being

Being represents the existential and emotional component of involvement in palliative care. The family caregiver has a need to be present and spend time with the patient in different ways, such as by taking time away from his or her own work. Being also involves a deeper form of involvement, described as sharing the patient’s world through communication and the exchanging of feelings of love and affection.

Doing

Doing is a more task-oriented component than the other two, and includes doing things for the patient that he or she is incapable of because of the illness. This involves practical nursing care such as helping with medicines, food, personal hygiene and mobilisation, as well as taking over household duties that the patient would normally do, such as cooking, cleaning or washing. Another task is related to making contact with health care providers and speaking

on behalf of the patient in the involvement of their care, not only with health professionals, but also with family and friends.

To promote meaningful involvement, gaining respect from health professionals through openness, sincerity, confirmation and connection is highlighted as an important aspect. Conversely, involvement with health professionals that lacks respect, good communication and honesty promotes negative involvement. The authors also theorise that a “sufficiently long” illness trajectory promotes a meaningful involvement, while a rapid trajectory has a negative influence. Other things could also influence the involvement of family caregivers, such as their own health, social support or religious beliefs.

The framework by Andershed and Ternstedt was chosen as the basis for the intervention studied in this thesis. The intervention was constructed based on family caregivers’ principal needs of knowing, being and doing. As was demonstrated in the background section of this thesis, the involvement of family caregivers’ in palliative home care is often demanding and they may feel unprepared for the situation. Therefore, it could be assumed that they are in need of information and emotional and practical support, which could promote meaningful involvement.

6 AIMS

The overall aim of this thesis is to develop a psycho-educational intervention aiming to promote preparedness for caregiving in family caregivers in palliative home care and to study the processes and effects of the intervention.

The overall hypothesis is that a psycho-educational intervention in palliative care will increase family caregivers' feelings of preparedness for caregiving, their competence and rewards for caregiving, sustain their wellbeing and decrease negative consequences related to caregiving such as burden, anxiety and depression.

Study I

To explore the experience of preparing for caregiving among family caregivers during specialised palliative home care.

Study II

To explore the experiences of delivering and participating in a psycho-educational intervention in specialised palliative home care from the perspectives of health professionals and family caregivers in specialised palliative home care.

Study III

To investigate the short-term and long-term effects of a psycho-educational group intervention for family caregivers in specialised palliative home care.

Study IV

To investigate the characteristics of the family caregivers who did not benefit from a successful psycho-educational group intervention in palliative care compared with the characteristics of those who did.

7 METHODS

7.1 DESIGN

The thesis has a multi-methodological approach encompassing both qualitative and quantitative studies. The framework of the thesis concerns a psycho-educational group intervention aiming to improve preparedness for caregiving in family caregivers in palliative care. The intervention is delivered as an RCT including an intervention arm and a control arm and has been modified based on the results from a previous exploratory trial by Henriksson and colleagues^{63,64} (referred to in text as the original trial). The psycho-educational approach means that the intervention involves a program to provide both education and support to family caregivers.⁵⁰ The modified intervention was developed based on Campbell's model for phased intervention development⁵³. The four studies in the thesis are all based on the sample of family caregivers who choose to participate in the RCT. In addition, Study II also includes a sample of health professionals. The trial protocol was developed in accordance with the CONSORT statement⁶⁸ and has been registered at <https://www.clinicaltrials.gov/> ID: NCT02482415.

Table 1. Overview of studies in the thesis

Study	I	II	III	IV
Design	Interpretive descriptive	Interpretive descriptive	Randomised controlled trial	Prospective-correlational
Participants	12 family caregivers	13 family caregivers and 25 health professionals	194 family caregivers	82 family caregivers
Data collection	Individual interviews	Individual interviews and focus group discussions	Validated questionnaires	Validated questionnaires and socio-demographic questions
Data analysis	Constant comparative analysis	Framework analysis	Descriptive and inferential statistics	Descriptive statistics
Phases in intervention development (Campbell's model)	Modeling	Modeling and exploratory	Definitive randomised controlled trial	Definitive randomised controlled trial

7.2 METHODOLOGICAL FRAMEWORK

The development and delivery of the modified intervention (described in 7.3) was based on Campbell's⁵³ framework for the design of complex interventions to improve health. A complex intervention is defined as involving more than one component and the active ingredient could be hard to specify. The authors suggest a phased approach to develop and evaluate the intervention to enable evidence for later clinical implementation. An integration of qualitative and quantitative research is advocated in order to study both processes and effects of the intervention

and ideally the intervention should be delivered as an RCT. The phases are most often integrated and, thus, do not have to be delivered in chronological order.

1. Theory: This was a preclinical phase where evidence that the intervention would have effect was studied. Based on the results from the original trial, relevant theories were explored and hypotheses for a modified intervention were stated.
2. Modelling: This phase took place both in Study I and Study II. The processes of the intervention and their interrelation and potential barriers to change were explored through qualitative research. Previous studies were also taken into account.
3. Exploratory trial: The original trial was considered an exploratory phase where the feasibility, acceptability and outcome measures were tested. This was used as a basis for the modified intervention. Study II in this thesis was used to define the modified intervention and its components.
4. Definitive randomised controlled trial: The modified intervention was tested in an RCT against standard support in Studies III and IV. Issues such as sample and effects size, inclusion and exclusion criteria, randomisation and dropouts were addressed.
5. Long term implementation: Not done in this project.

7.3 DEVELOPMENT AND DELIVERY OF A PSYCHO-EDUCATIONAL INTERVENTION

7.3.1 Intervention development

As was described above, the intervention described in this thesis was built and modified based on the results from an original quasi-experimental intervention trial directed at family caregivers. The trial included a psycho-educational intervention that was delivered at three specialised palliative care settings in a metropolitan area in Sweden. The original intervention was delivered in group-format by health professionals in six sessions. The intervention program included topics that were considered relevant to family caregivers in palliative care based on existing research and knowledge. The intervention program was also found to be well-received and effective in promoting the perceived preparedness for caregiving of the participants as well as their feelings of competence and rewards for caregiving.^{63,64} The modified intervention in this thesis was built from these results.

The original intervention included a comparison group, but was not randomised controlled, which is considered the safest way to test the effects of an intervention. Hence the modified intervention was delivered as an RCT with an intervention and control arm. The original intervention was not based in any theoretical framework and the intervention program was not standardised, which made it difficult to decide whether intervention delivery had been consistent. Therefore, relevant theory was explored to find a suitable foundation on which to build the modified intervention, and it was decided that the framework of Andershed and Ternstedt would be used as the theoretical basis for an intervention manual. The manual consisted of a compendium with different topics presented by health professionals. It encompasses the three concepts of knowing, being and doing, which are described as the primary needs of family caregivers involved in the care of a patient in palliative care. The primary aim of the modified intervention was to promote preparedness for caregiving in family caregivers, including practical, emotional and existential aspects of caregiving. The main

approach of the intervention manual is based on knowing, which means promoting family caregivers' knowledge about things such as the patient's illness and symptoms (physician session), hygiene and nutritional problems (nurse session), and grief reactions and supportive needs (social worker/priest session). Through increased knowing, family caregivers are also given the opportunity to become better prepared in practical caregiving (doing) and managing their own and the patient's emotions (being).

The development of the intervention manual took place in close cooperation between researchers and a reference group of health professionals from clinical palliative care. The health professionals were invited to a one-day workshop where the manual was developed and the theoretical and organisational components of the intervention were covered. They were also given a chance to meet health professionals from other settings and discuss their strategies for the intervention and exchange experiences. Researchers and health professionals kept close contact through several meetings and telephone calls before and after the intervention started, allowing health professionals to ask questions about the intervention and the research process. Results from the original intervention trial showed that many patients had died during the intervention and that family caregivers had dropped out of the research project as a result of this. This led to the conclusion that six sessions were too many. The duration of time patients spend in palliative care is generally short and the settings have limited resources. Thus it was decided that the modified intervention should be shortened to three sessions. However, it was also decided that the sessions should be longer, meaning that the intervention would still encompass the same time frame.

Table 2. The intervention structure and content

Session	Session 1. Group leader (registered nurse) + physician	Session 2. Group leader (registered nurse)	Session 3. Group leader (registered nurse) + social worker, or priest
Main topic	Palliative care and symptom management	Daily life and practical nursing care	Emotional reactions and grief
Examples of content	<ul style="list-style-type: none"> • The concept of palliative care • Symptom management • End-of-life care 	<ul style="list-style-type: none"> • The new role as a family caregiver • Eating difficulties • Providing personal and intimate care 	<ul style="list-style-type: none"> • Emotional reactions • Coping, hope and resilience • Resources in society
The participants arrive	The group leader receives the participants. Coffee/tea and snacks are served.		
Topic for the day (60-90 min)	A health professional presents the topic of the day. Participants are invited to ask questions and engage in discussions.		
Reflection (20-30 min)	Participants are invited to reflect upon the topic of the day.		
Conclusion (10 min)	The session is concluded with a short relaxing exercise.		

7.3.2 Settings and power

Letters with study information and a request to participate were sent to 10 specialised palliative home care settings in a metropolitan area in Sweden covering about 2.2 million people. All 10 settings agreed to participate. The settings included both public, private profit and private non-profit agencies and the regional public health care organisation allowed the patient to choose which setting to enlist in. The settings offered multi-professional advanced palliative care to patients in their own home and were staffed by physicians and registered nurses 24 hours a day. Other health professionals involved in the care included social workers, priests, nutritionists and occupational and physical therapists. Every setting enrolled between 70 and 200 patients. The professionals made more or less regular visits to the patients and their families depending on the patient's condition and needs. They provided help with things such as medications, advanced symptom relief, palliative treatments and existential support. If the patient was in need of basic personal care, this could be granted by home care teams of the municipality, but was not provided by the specialised palliative home care. Patients affected by various palliative conditions were represented at the settings, such as cancer, coronary, pulmonary and neurological diseases.

Inclusion criteria for family caregivers were; being a family caregiver to a patient in specialised palliative home care over the age of 18 with knowledge of the Swedish language. The inclusion criteria also stipulated that the patient should have a limited expected survival, but that it should be at least 5 weeks, to increase the chances of family caregivers completing the intervention.

Power calculations for the intervention project were conducted based on the primary outcome of the intervention, the preparedness for caregiving scale. Due to effect sizes from the original intervention trial,⁶³ power size was calculated for a medium effect. For the use of a regression model, the required sample was determined to be 55 ($f^2 = 0.15$, $\alpha = 0.05$, $1-\beta = 0.80$). As it was expected that each patient should be represented by 2 family caregivers on average, the required sample size was doubled to 110; 55 in each arm (control and intervention).

7.3.3 Research procedure and randomisation

The intervention was delivered as an RCT at each of the 10 settings. One or two registered nurse(s) acted as group leaders and were mainly responsible for inviting and including family caregivers to the trial. The patient was first asked to give his or her consent and to nominate one or several family caregivers to be invited. The patient was not included in active data collection, but was asked to give permission for some information being collected from the patient journal (diagnosis, place of care, time of care). If the patient accepted, the family caregiver(s) was approached with study information and a request to participate. Family caregivers who accepted were given a baseline questionnaire, which had a coded number, unique for the patient. When the family caregiver had completed the questionnaire, it was sent by mail to the responsible researchers. The coded number was used to randomly allocate the family caregiver to one of two arms; the psycho-educational intervention or to a control arm with standard support from the setting. (Figure 1). Standard support was provided by health professionals as part of their visits to the patient and included opportunities for individual support. Allocation took place with the help of a list based on block randomisation, stratified for the 10 specialised palliative settings. Because the code number followed the patient, this guaranteed that family caregivers of the

same patient were randomised to the same arm. A letter was sent to the family caregivers to inform them which arm they had been allocated to.

A total of 270 family caregivers were included in the study at baseline; 122 were allocated to the control group, and 148 to the intervention. Due to attritions before the trial had commenced, the final baseline sample was 194 family caregivers; 96 in the control arm, and 98 in the intervention arm. Reasons for attritions were mainly the deterioration and death of the patient. In the final baseline sample, 175 patients were represented and their mean age was 72 years. 90% of the patients had a cancer diagnosis of some sort.

Table 3. Characteristics of family caregivers in control arm and intervention arm

Baseline characteristics	Control arm (n=96)	Intervention arm (n=98)	P-value
Age. mean (SD)	60 (14.3)	63 (13.4)	0.225 ^a
Gender. n (%)			0.388 ^b
Women	61 (63.5)	68 (69.4)	
Men	35 (36.5)	30 (30.6)	
Cohabit with patient. n (%)			0.254 ^b
Yes	49 (51.0)	58 (59.2)	
No	47 (49.0)	40 (40.8)	
Relation to patient. n (%)			0.129 ^b
Spouse	40 (41.7)	54 (55.1)	
Parent	35 (36.5)	32 (32.7)	
Other	21 (21.8)	12 (12.2)	
Education level. n (%)			0.829 ^b
University degree	46 (47.9)	41 (41.8)	
Other	50 (52.1)	57 (58.2)	
Outcome measurements at baseline. mean (SD)			
PCS – preparedness	17.4 (6.9)	16.8 (6.4)	0.548 ^a
CCS – competence	6.5 (3.1)	6.4 (2.7)	0.842 ^a
RCS – rewards	28.6 (7.8)	28.0 (7.8)	0.605 ^a
CBS – general strain	2.4 (0.7)	2.3 (0.7)	0.637 ^a
CBS – isolation	2.4 (0.8)	2.4 (0.9)	0.846 ^a
CBS – disappointment	2.1 (0.7)	2.1 (0.7)	0.703 ^a
CBS – emotional involvement	1.8 (0.7)	1.9 (0.7)	0.547 ^a
CBS – environment	2.1 (0.7)	2.0 (0.7)	0.486 ^a
HI – health	3.3 (0.6)	3.2 (0.7)	0.472 ^a
HADS – anxiety	7.6 (4.4)	8.0 (4.3)	0.578 ^a
HADS – depression	5.3 (3.6)	5.2 (3.5)	0.852 ^a

SD: Standard deviation

^a: *t*-tests

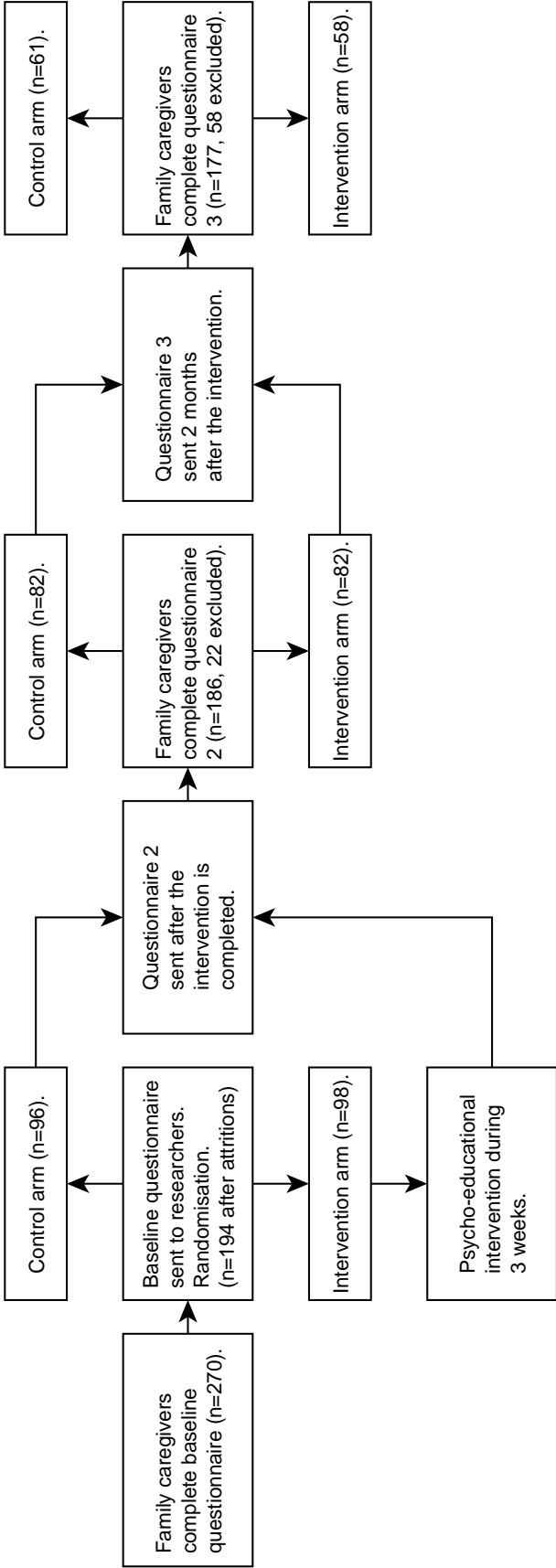
^b: χ^2 -tests

7.3.4 Intervention delivery

The psycho-educational intervention was delivered in three group sessions at each of the 10 palliative care settings. (Table 2). In total, the intervention program was delivered 21 times. On average, four family caregivers participated in the group intervention. Seventy percent attended all three sessions, 20% attended two, and 10% attended all three sessions. The topics of the

intervention manual were presented by a member of the professional team (physician, nurse, and social worker/priest). Each session took place at the palliative care setting that the family caregiver belonged to and was planned to last two hours. Usually, the intervention session was held once a week after ordinary working hours to make sure as many family caregivers as possible could attend. Throughout the intervention delivery, a nurse acted as group leader and took part in every group session. The intervention manual was used as a framework for the sessions; however, there was room for flexibility in the delivery. For example, if family caregivers had an interest in a specific topic, such as symptom management, this could be deeper developed and discussed in the group. Because the intervention included both supportive and educative components, the program also consisted of reflections and thoughts regarding the topics of the manual.

Figure 1. The research process



7.4 STUDIES I AND II – PROCESSES OF THE INTERVENTION

Studies I and II had a qualitative approach and focused on processes involved in or considered to be important to the psycho-educational intervention. The two studies partly consisted of data from the same data collection. Family caregivers were invited to individual interviews and health professionals were invited to focus group discussions.

7.4.1 Design

As a design for the qualitative studies, interpretive description was chosen. This design has been developed by Sally Thorne⁶⁹ and has been described as a methodology that is more specific than general qualitative research. Interpretive description is inspired by grounded theory, phenomenology and ethnography and, in the interpretive descriptive approach, reality is described as subjective and the researcher and the object interact to influence each other. The approach places a great weight on theoretical fore-structure. Unlike other qualitative designs, the researcher should not bracket his or her existing knowledge, but rather, use it as a tool. It is important to study existing literature and theoretical concepts in order to demonstrate that there is a research gap that needs to be filled. Interpretive description influences both data collection and data analysis, which are simultaneous processes. The data collection should be focused on achieving variation and a multitude of experiences. In the inductive analysis, the researcher should use his or her fore-structure as a lens through which to view the data material. The data analysis aims for a conceptual description of the patterns of a specific phenomenon. It is possible to draw inspiration from many other methods in the analysis, including coding or writing memos, as long as the interpretive descriptive perspective is kept. The results will reflect a number of different patterns of experiences, but can never show all variations. Interpretive description does not generate facts but rather a “constructed truth”.

7.4.2 Participants

In Study I, 14 family caregivers from both the control and the intervention arms were strategically invited for interviews. Because the study focused on their experience of preparedness for caregiving, the sampling was made based on their scores of a statistical instrument measuring preparedness in the baseline questionnaire, the preparedness for caregiving scale (PCS). The sampling focused on men and women of different ages who had scored high or low on the PCS. Twelve family caregivers agreed to participate; 6 from the intervention arm, and 6 from the control arm.

Study II included family caregivers who had participated in the intervention and focused on their experiences. Because 6 participants in Study I were from the intervention arm, they were also included in Study II. However, because the material was considered too small to perform a meaningful analysis, another 7 family caregivers who had participated in the intervention were invited, with a focus on reaching maximum variation in things such as care setting, age, gender and relation to the patient. They were interviewed by telephone. The final sample was 13 family caregivers.

In Study II, health care professionals were also invited to take part in focus group discussions about their experiences of delivering the intervention. In total, 40 professionals were involved in delivering the intervention and, of these, 25 agreed to participate. All 10 palliative care settings

were represented among the professionals, who had between 3 and 20 years of experience of working in palliative care. The largest group of participants consisted of nurses who had acted as group leaders, but physicians, social workers and priests were also represented.

7.4.3 Interviews with family caregivers

The individual face-to-face interviews took place at the family caregiver's preferred setting. It could be the research centre, their own home or at a public place. An interview guide was used with open-ended questions focusing the family caregiver's experience of preparedness and, for those who belonged to the intervention arm, their experience of participating in the psycho-educational intervention program. The interviews lasted between 40 and 120 minutes and were all audiotaped.

The family caregivers who were invited for telephone interviews were given the opportunity to choose an appropriate time when they wanted to be contacted for the interview. An interview guide was used for the telephone interviews, focusing the family caregivers' experience of participating in the intervention. The telephone interviews were audiotaped.

7.4.4 Focus group discussions with health professionals

The focus group discussions were carried out at two time points at the research centre; with three groups and two groups respectively, within a time period of six months. This was done to increase variation; to gather experiences from the early phase of delivering the intervention as well as those from after having delivered the intervention one or several times. Two researchers from the research group took part in every focus group; one who acted as a facilitator who guided the group with focus on their experiences of inviting family caregivers and preparing for the sessions as well as delivering the practical intervention. The other researcher took notes and asked probing questions for clarification. The focus group discussions were audiotaped.

7.4.5 Data analysis

The analysis of Study I was inspired by a constant comparative technique, which was considered to be in accordance with the approach of interpretive description where data collection and analysis should be two concurrent processes. The interviews were transcribed verbatim and read several times to establish familiarity with the material. Coding was carried out with the help of the NVivo qualitative data management software. The research question of exploring family caregivers' experience of preparedness for caregiving in palliative care guided the analysis. In line with the interpretive descriptive approach, initial coding was inductive and broad-based, searching for patterns within the material. Memos were written and continuously discussed in the research group to establish a dialogue with the material. The patterns found in the material led to the interpretation that preparedness for caregiving could be experienced as an ongoing process by the family caregivers – preparing for caregiving. This made the data analysis more focused, with two questions guiding the continued work: “How do family caregivers describe their process of preparing for caregiving?” and “What influenced their process of preparing?” With these questions as a base, the analysis led to the identification of three sub-processes in the overall process of preparing for caregiving.

In Study II, a framework analytic approach (FA) was used. The two datasets of interviews with family caregivers and focus group discussions with health professionals were transcribed

verbatim and analysed separately. The FA approach allows for a structured, but still flexible, process of analysis in 5 steps, which is in line with the principles of interpretive description. The transcripts were first read several times by the members of the research group in order to become familiar with them. The research question of exploring the experiences of delivering and participating in the psycho-educational intervention was in focus. In the second step, themes and subthemes were derived from the data material through the intense reading. Step three included going back to the transcripts to decide which theme was reflected in each section and how themes and subthemes were related. This allowed for further immersion into the data and themes and subthemes were refined to reflect data more accurately. This ensured that the data fit only one theme and were not repeated. In the fourth step, the material was reduced to brief sentences to make it more easily managed. The fifth step included going back to transcripts and audio records to check the summaries against the original data. The results from the two datasets were merged, focusing common and different experiences both within and between the two groups.

7.5 STUDIES III AND IV – EFFECTS OF THE INTERVENTION

Studies III and IV had a quantitative approach, focusing on the effects of a psycho-educational intervention on family caregivers, which was designed to promote preparedness for caregiving (primary outcome). Study III compared the effects of the intervention to standard support (control arm), while Study IV sought to investigate the characteristics of family caregivers in the intervention arm who did not benefit from the intervention compared to family caregivers who did.

7.5.1 Design

Study III focused on the effects of the psycho-educational intervention upon which the project rests and was delivered as an RCT with two arms. The participants were either randomised to a psycho-educational intervention in group-format with three sessions or to a control arm with standard support offered by the palliative care setting. Randomisation was based on a random number sequence, using a computer randomised number generator, and stratified for the 10 home care settings. Randomised permuted blocks of four were used. A coded number, which was unique to the patient, was used for the randomisation of the family caregiver(s).

Study IV had a prospective-correlational design and focused on finding differences between family caregivers who did not benefit from the intervention and those who did. The rating of the primary outcome, the preparedness for caregiving scale (PCS), between baseline and the first follow-up was used to decide whether the family caregivers had benefited. If the family caregiver had $PCS \leq 0$ they were considered not to have benefited. If they had $PCS \leq 1$, they were considered to have benefited.

7.5.2 Participants

Participants in Study III consisted of family caregivers who agreed to participate in the intervention study and were randomised to either of the two arms. Because the analysis was based on per-protocol principles, only family caregivers who completed the intervention or who received standard support were included in analysis ($n=194$), hence the sample consisted of 98 family caregivers from the intervention arm and 96 from the control arm. (Table 3).

In Study IV, the focus was on family caregivers who had participated in the intervention and the first follow-up ($n=89$), which meant that the control arm was excluded. In addition, 7 family caregivers were excluded due to the death of the patient, leaving 82 family caregivers as the final sample.

7.5.3 Data collection

Studies III and IV are based on the same data collection, which consisted of questionnaires at baseline and upon completion of the intervention (Figure 1). Study III also included a follow-up two months after the intervention. Considering the often-short duration of care in palliative care, this was considered a long-term follow-up. The questionnaires consisted of socio-demographic questions and validated statistical instruments. The instruments were all designed to measure outcomes that have been identified as important to family caregivers,³⁴ and with consideration given to the research results covered in the background section of this thesis. These were: preparedness, competence and rewards for caregiving, caregiver burden, health, and anxiety and depression. Socio-demographic questions included questions about the family caregivers' age, gender, socio-economic and marital status, relation to the patient, education level, any physical or mental illness and use of medication. Data were also collected from the patient's journal regarding diagnosis, time of care and place of care.

The statistical instruments included:

7.5.3.1 Primary outcome

The Preparedness for Caregiving scale (PCS) is designed to measure caregivers' perceived readiness to provide care in real time.^{32,70} It was originally developed for family caregivers of elderly people living in their own homes, but has also demonstrated good reliability for caregivers in palliative care.⁷⁰⁻⁷² The scale consists of eight items answered on a five-point Likert-type response scale ranging from 'not at all prepared' (0) to 'very well prepared' (4) with a total score ranging from 0–32. It demonstrated good internal consistency with a Cronbach's alpha of 0.94 for the intervention trial.

7.5.3.2 Secondary outcomes

The Caregiver Competence Scale (CCS) measures the self-perceived adequacy of caregivers in real time and was originally developed for family caregivers of dementia patients. It has also been found to be valid and reliable to use in palliative care.^{63,70,71,73} The scale consists of four items on a four-point Likert-type scale ranging from 'not at all competent' (0) to 'very competent' (3) with a total score ranging from 0–12. Cronbach's alpha was 0.90 for the trial.

The Rewards of Caregiving Scale (RCS) was developed to measure personal, self-rated rewards in caregivers of dementia patients⁷⁴ and has been found to be reliable to use in palliative care.^{70,71} It originally consisted of three subscales (rewards of caregiver learning, rewards of being there, rewards of meaning for oneself). For the quantitative studies in this project, a modified version of the scale was used, excluding the learning scale as it was developed specifically for dementia caregivers. The abbreviated scale consists of 10 items on a five-point Likert-type scale. The score ranges from 'not rewarding at all' (0) to 'very rewarding' (4) with a total score ranging from 0–40.⁷⁴ Cronbach's alpha was 0.94 for the trial.

The Caregiver Burden Scale (CBS) was originally developed to measure self-perceived burden in caregivers of stroke patients. It is a 22-item scale divided into five dimensions; general strain, isolation, disappointment, emotional involvement and environment. The items are answered on a four-point Likert-type scale, ranging from 'not at all' (1) to 'often' (4), where higher scores indicate greater caregiver burden. The item scores of each dimension are summed and a mean value for each dimension is calculated with scores ranging from 1–4.⁷⁵ Cronbach's alpha results were 0.87, 0.72, 0.72, 0.74, and 0.70 for the five dimensions, respectively, in the trial.

The Health Index (HI) has been designed to measure self-perceived health. It consists of 11 items answered on a four-point Likert-type scale ranging from 1–4 with a higher value indicating better health. The total score ranges from 11–44.⁷⁶ For Study IV, both the total score and two single items were used. The single items focused on the family caregivers' perceived health in the last week and their overall rating of their health. Cronbach's alpha was 0.85 for the trial.

The Hospital Anxiety and Depression Scale (HADS) was developed to identify anxiety and depression.^{77,78} It has previously been used among family caregivers in palliative care.⁶³ It includes two subscales with seven items for each scale: anxiety and depression. The items are answered on a four-point Likert-type scale ranging from 0–3 with a higher value indicating higher levels of anxiety/depression.⁷⁸ For each subscale, the total score ranges from 0–21. Cronbach's alpha was 0.87 and 0.82 for the two subscales in the trial.

Study IV also included another instrument; the Multidimensional Scale of Perceived Social Support (MSPSS) which was used to measure family caregivers' experiences of social support. The scale includes 12 items, which are answered on a 1–7 Likert-type scale where higher values indicate higher perceived social support. The MSPSS includes three subscales; family, friends and significant others. The subscales have a total score of between 4 and 28 each. Cronbach's alpha was 0.95, 0.94 and 0.95 for the three subscales respectively.

7.5.4 Data analysis

Both Studies III and IV were analysed using statistical analysis with the help of the STATA program, version 13:1. Data validation was conducted before analysis and one independent person manually controlled the data file against all questionnaires. Missing items were replaced if they did not exceed 20% for each scale. Person mean imputation⁷⁹ was used to replace missing items and, in total, 52 missing items were replaced.

For Study III, comparisons between baseline characteristics of the intervention and control arm were conducted using χ^2 -tests for categorical socio-demographic variables and *t*-tests for continuous variables. Because the study design allowed for more than one family caregiver of the same patient, the principle of non-dependence could be questioned in this study. Intraclass correlations (ICC) with multilevel modelling were used to evaluate whether the principle was violated. Results showed that the ICC deviated from zero for CBS-general strain (ICC = 0.16), CBS-isolation (ICC = 0.29), and HI (ICC = 0.42) for the short-term follow-up, and the PCS (ICC = 0.10), CB-general strain (ICC = 0.42), CBS-emotional involvement (ICC = 0.82), HI (ICC = 0.76), and HADS-anxiety (ICC = 0.73) for the long-term follow-up. This led to the use of linear regression analyses based on robust variance estimates for clustered data, i.e. family caregivers of the same patient, to test the effects of the intervention between baseline and the

two follow-ups. This technique relaxes the assumption of independence and only standard errors are affected, not the estimated coefficients.⁸⁰ The difference between the baseline and follow-up scores was included as an outcome variable while the scores of the arms (control arm as reference category) were included as predictor variables. Analyses were undertaken based on a per-protocol approach with $p < 0.05$ taken to be statistically significant. Cohen's f^2 was calculated to assess the effect size, with 0.02 considered a small effect size, 0.15 a medium effect, and 0.35 a large effect.⁸¹ Because the primary outcome was preparedness for caregiving in real time, it was decided that, in the cases where the patient had died, the family caregiver(s) should be excluded from analysis.

The analysis of Study IV was based on data from the intervention arm. Family caregivers who failed to complete the PCS were also excluded because the PCS was used to determine whether the family caregiver had benefited from the intervention. Various statistical methods were used to make comparisons between the two groups, depending on the level and distribution of data. χ^2 -tests were used for categorical socio-demographic variables (gender, marital status, education, occupation, and illness) and unpaired t -tests for continuous variables (age, years since patient diagnosis). If the expected values of contingency cells were below 5, the Fisher's exact test was applied for categorical variables (relation to patient, financial status, patient diagnosis and time in palliative care). For continuous self-reported outcomes, the non-parametric Mann-Whitney U-test was used (PCS, CCS, RCS, CBS, HI, HADS, MSPSS) as most of them were skewed and they could be considered either numerical or ordinal data. The statistical significance level was set at $p < 0.05$, while $p < 0.1$ was set as a considerable trend towards significance.

7.6 ETHICAL CONSIDERATIONS

A great emphasis was placed on ethical principles in this intervention project. Family caregivers in palliative care could be viewed as a vulnerable study population, making the four basic ethical research principles of autonomy, beneficence, non-maleficence and justice⁸² of special importance. According to the Helsinki Declaration for ethics, research on vulnerable groups should only be carried out if it promotes the group's interests and could not be done on any equivalent non-vulnerable group.⁸³ In this case it would have been very difficult to carry out research on another group, because the situation of family caregivers in palliative home care could be considered very unique and complex. The research in this thesis aims to promote the preparedness of family caregivers through an intervention and there is a lack of previous such interventions, hence the research should benefit this group. According to the principle of justice, it could be argued that it would be discriminatory to exclude vulnerable groups from participating in research. Ethical approval was granted from a regional ethical review board (2012/377-31, 2012/2191-32, 2013/934-32).

To honour the principles of autonomy and non-maleficence, special consideration was given to asking for informed consent from the participants. Written and verbal information was given to both patients and family caregivers before inclusion in the study and, in some cases, the information was updated. In order to protect the patients, they were asked to give their consent before the family caregiver was approached to participate in the trial as it was considered unethical not to let the patient have a say in the matter. Written informed consent was also obtained from family caregivers before their enrolment. The information provided to them underlined that their participation was voluntary and that their consent could be withdrawn at

any time without any consequences for themselves or the patient's care. It was also underlined that personal information would be protected. Family caregivers were also given a phone number to the research group to contact if they had any questions. When family caregivers were included, their names were replaced with a code number, which was used to randomly allocate the family caregiver to either the intervention or control arm. To protect the family caregivers, the list of code numbers along with audio files and transcripts from interviews were kept in locked storage with only the researchers having access.

Apart from family caregivers, the studies also included a sample of health professionals. The 10 palliative care settings received written information about the trial and its purpose before agreeing to participate. Meetings were also arranged to give health professionals at each of the settings the opportunity to ask questions and receive more information about the trial. Informed consent was also granted by the health professionals to take part in the focus group discussions. The personal information of the health professionals who participated in the focus groups was also protected.

Questions could be raised about whether the study design of RCT compromises the ethical principle of justice as it excludes half of the family caregivers from taking part in the intervention program. However, it was very clearly stated in the written information that the chance of being randomised to the intervention arm was 50%. It was also stressed that even if family caregivers would not be allocated to the intervention arm, they would still be offered standard support from their palliative care setting. An RCT has the highest rate of evidence and there is a great need to develop and test interventions aiming to support family caregivers in palliative care, which motivates the use of this trial design. Because the psycho-educational intervention had not yet been tested, it could not be determined beforehand that it would be more effective than the standard support provided to family caregivers.

8 RESULTS

The overall results of the four studies in this thesis indicate that a psycho-educational group intervention for family caregivers delivered during ongoing palliative care could be an important instrument to make family caregivers better prepared for caregiving. The results show that preparing for caregiving could be described as an ongoing process through the illness trajectory (Study I). The potential of the intervention for making family caregivers better prepared was highlighted both by health professionals and family caregivers in focus group discussions and interviews (Study II) and statistical results also confirm that the intervention program was effective in improving family caregivers' feelings of preparedness, both in the short and long term (Study III). The results also indicated that family caregivers who did not improve their preparedness for caregiving by the intervention were less vulnerable at baseline than those who did (Study IV).

8.1 STUDY I: PREPARING FOR CAREGIVING AS AN ONGOING PROCESS

The results from Study I suggested that the experience of preparing for caregiving in family caregivers of a patient in palliative home care could be described as an ongoing process through the entire illness trajectory and the palliative and end-of-life stages. This process was described as unpredictable by the family caregivers and influenced by many factors, such as changes in the patient's condition and prognosis. The process of preparing for caregiving was much related to and sometimes interchangeable to the process of preparing for the patient's death and the family caregiver's experience of grief.

The process of preparing for caregiving was illustrated through three different sub-processes; which were named "awaring", "adjusting" and "anticipating". These sub-processes could take place both independently and dependently of each other and did not necessary take place in a linear order.

8.1.1 Awaring, Adjusting, Anticipating

"Awaring" could be described as a growing realisation of a life situation that had in many ways changed for the family caregiver. Receiving the news of the patient's serious condition was usually the first step into the "awaring" process, but family caregivers were also gradually faced with expectations to care for the patient in different ways. To some, the caregiving role was something they willingly prepared for; described as something done out of love and duty towards the patient. Others had more ambiguous feelings and stated that they wanted to be regarded as family members rather than family caregivers. The "awaring" process was continuously influenced by things such as changes in the patient's symptoms and needs, which forced family caregivers to prepare for additional aspects of caregiving. A need for privacy and grief in this process was expressed by family caregivers as well as support from health care professionals.

The "adjusting" sub-process included the need to prepare for previously unknown challenges. Even if the family caregivers were involved in the patient's care in different ways, the palliative condition and the relationship with the patient had irrevocably changed. The process included preparing for practical aspects of caregiving, which was described as something very challenging, as family caregivers often had to find new strategies and solutions to problems.

They also expressed a wish to find a balance in the situation and take time to prioritise their own needs and wishes. “The adjusting” process was very much influenced by the family caregivers’ personal qualities and attitude towards caregiving. Viewing caregiving as something natural and rewarding seemed to facilitate the process.

“Anticipating” was described as a mental process where family caregivers willingly or unwillingly started preparing for the death and dying of the patient. Family caregivers had ambiguous feelings towards this process as many wanted to live for the day with the patient, but they had still started thinking towards the dying process and what life without the patient would be like. Because the prognosis was usually uncertain, the situation could be described as frustrating as family caregivers did not know how much time they would need to prepare for or how far away the end would be. The family caregivers all described a limit to what they were prepared to cope with in the caregiving role in the home and reflected about whether they would manage to keep the patient in the home until the end. The health professionals were described as having a key role in providing information and support regarding the prognosis of the patient.

8.2 STUDY II: EXPERIENCES OF DELIVERING AND PARTICIPATING IN THE PSYCHO-EDUCATIONAL INTERVENTION

The results from Study II explored the experiences of taking part in the intervention from the family caregiver point of view but also from the perspective of the health professional. The participants shared their thoughts about the pre-intervention process, the intervention manual and their experiences of the strengths and weaknesses of the intervention.

8.2.1 The pre-intervention process

Health professionals described the process of preparing for and inviting family caregivers to take part in the intervention as the most demanding part of delivering the intervention. The inclusion criterion that the patient should have a survival time of at least 5 weeks was considered difficult to follow as the prognosis was often uncertain and health professionals had to spend a lot of time going through patient journals to identify patients who were in the appropriate palliative phase. Inviting and informing patients and family caregivers about the study also demanded time and energy from the professionals, which their employers did not always credit them for. A sense of fear was expressed in inviting family caregivers who could be hurt by sensitive intervention topics such as dying and death. Family caregivers of patients who suffered from malign diseases were easier to target because their trajectory was considered to be more predictable than for patients with pulmonary or coronary diseases. The family caregivers also stated that in many cases, they did not have the active caregiver role that the intervention program was adapted to. However, they believed that the intervention program could prepare them for a future and more active role. Generally, they appreciated that everyone was not in the same stage of the palliative trajectory, which allowed them to exchange their different experiences.

8.2.2 The intervention manual

Another major part of the time health professionals spent on working with the intervention was going through the intervention manual and learning how to use it, which some considered time-consuming. The professionals regarded the manual as a supportive instrument for the intervention sessions and considered it important to be flexible and to deliver the topics in their

own words from their experience in palliative care. The topics included in the manual were regarded in a positive light by family caregivers, who believed that they were a framework that offered a spring-board for further discussions and interactions within the group, even when it came to difficult subjects such as dying and death. Although the topics and their content was not always something that family caregivers felt that they could relate to, they viewed it as interesting and important and something that could make them better prepared for the role as caregivers.

8.2.3 Positive and negative aspects of delivering and participating in the intervention

The experience of delivering the intervention was described as something that was very satisfying by health professionals. They felt that they received positive feedback by the participants and felt rewarded both personally and professionally for their work. Despite many years of experience in palliative care, they found that they had learned new things from being in the intervention groups, which made them more aware of the needs of family caregivers in their daily work. They also found that the intervention program had made family caregivers better prepared. Both health professionals and family caregivers believed that the intervention had led to closer relations between the palliative care setting and the families they visited. Family caregivers also emphasised that taking part in the intervention made them feel acknowledged by health professionals, but also that interacting with other family caregivers was rewarding to them. However, health professionals and family caregivers both stated that more than three sessions would have been favourable as three meetings was considered too short a time to develop relationships.

8.3 STUDY III: EFFECTS OF PARTICIPATING IN THE PSYCHO-EDUCATIONAL INTERVENTION

The effects of the intervention in Study III were calculated based on the questionnaires that family caregivers from the intervention and control arms completed at baseline and follow-up. No significant differences were found between family caregivers in the two arms at baseline.

8.3.1 Short-term and long-term effects

In total, 186 family caregivers completed questionnaires at the first follow-up (return rate 95.9%) and, of these, 22 were caregivers to a patient who had died, resulting in their exclusion from data analysis. After accounting for these, 164 family caregivers remained for analysis; 82 from the control arm, and 82 from intervention arm. Statistical analyses showed that family caregivers from the intervention arm had significantly increased their preparedness for caregiving compared to family caregivers from the control arm who had received standard support. ($\beta=1.51$, $t(1)=2.06$, $p=0.041$, $f^2=0.02$). They had also significantly increased their competence for caregiving ($\beta= 1.04$, $t(1) =3.24$, $p =0.001$, $f^2 = 0.06$). No significant effects were found on rewards for caregiving, caregiver burden, health, anxiety or depression.

For the long-term follow-up, two months after the intervention had been delivered, 177 family caregivers responded to the questionnaires (return rate 91.2%). Of these, 58 family caregivers had experienced the death of their patient, which meant that they were excluded from analysis. In total, 119 family caregivers remained for analysis, 61 from the control arm and 58 from the

intervention arm. The statistical analyses showed that family caregivers in the intervention arm had significantly higher preparedness for caregiving compared to the control arm ($\beta = 2.25$, $t(1) = 2.57$, $p = 0.012$, $f^2 = 0.05$). No significant effects were found on competence or rewards for caregiving, caregiver burden, health, anxiety or depression.

Table 4. Mean ratings at baseline, follow up1 and follow up 2

Family caregiver Outcomes	Control arm			Intervention arm		
	Baseline. mean (SD)	Follow up 1. mean (SD)	Follow up 2. mean (SD)	Baseline. mean (SD)	Follow up 1. mean (SD)	Follow up 2. mean (SD)
PCS – preparedness	17.4 (6.9)	16.9 (6.5)	16.9 (5.4)	16.8 (6.4)	18.4 (5.2)	17.9 (5.6)
CCS – competence	6.5 (3.1)	5.8 (2.9)	6.2 (2.9)	6.4 (2.7)	6.8 (2.7)	6.5 (2.8)
RCS – rewards	28.6 (7.8)	27.5 (7.7)	26.3 (8.5)	28.0 (7.8)	26.2 (8.0)	24.6 (9.1)
CBS – general strain	2.4 (0.7)	2.5 (0.6)	2.5 (0.7)	2.3 (0.7)	2.5 (0.7)	2.6 (0.7)
CBS – isolation	2.4 (0.8)	2.5 (0.8)	2.5 (0.9)	2.4 (0.9)	2.5 (0.9)	2.6 (0.9)
CBS – disappointment	2.1 (0.7)	2.2 (0.6)	2.3 (0.7)	2.1 (0.7)	2.2 (0.7)	2.3 (0.7)
CBS – emo involvement	1.8 (0.7)	1.9 (0.7)	1.9 (0.7)	1.9 (0.7)	1.9 (0.7)	1.9 (0.8)
CBS – environment	2.1 (0.7)	2.2 (0.6)	2.2 (0.7)	2.0 (0.7)	2.0 (0.7)	2.1 (0.8)
HI – health	33.6 (4.7)	32.9 (4.8)	32.6 (4.6)	34.1 (5.0)	33.6 (5.1)	32.6 (5.7)
HADS – anxiety	7.6 (4.4)	7.9(4.0)	7.6 (4.1)	8.0 (4.3)	8.1 (4.4)	7.7 (5.0)
HADS – depression	5.3 (3.6)	5.6 (3.7)	5.6 (3.9)	5.2 (3.5)	5.9 (4.2)	6.1 (4.5)

Table 5. Evaluation of intervention effects based on linear regression analysis

Family caregiver outcomes	Follow up 1.			Follow up 2.		
	Independent variable	Beta (SE)	P-value	Independent variable	Beta (SE)	P-value
PCS - preparedness	Intervention	1.51 (0.7)	0.041	Intervention	2.25 (0.9)	0.012
CCS – competence	Intervention	1.04 (0.3)	0.001	Intervention	0.51 (0.4)	0.194
RCS – rewards	Intervention	-0.03 (0.8)	0.968	Intervention	0.30 (1.2)	0.805
CBS – general strain	Intervention	0.03 (0.1)	0.605	Intervention	0.06 (0.1)	0.506
CBS – isolation	Intervention	0.04 (0.1)	0.605	Intervention	-0.03 (0.1)	0.811
CBS – disappointment	Intervention	0.03 (0.1)	0.642	Intervention	0.07 (0.1)	0.376
CBS – emo involvement	Intervention	-0.01 (0.1)	0.843	Intervention	-0.05 (0.10)	0.621
CBS – environment	Intervention	-0.04 (0.1)	0.597	Intervention	-0.01 (0.1)	0.819
HI - health	Intervention	-0.04 (0.5)	0.933	Intervention	-1.03 (0.7)	0.140
HADS – anxiety	Intervention	0.08 (0.4)	0.856	Intervention	0.14 (0.6)	0.829
HADS – depression	Intervention	0.45 (0.44)	0.316	Intervention	0.61 (0.6)	0.290

8.4 STUDY IV: CHARACTERISTICS OF FAMILY CAREGIVERS WHO DID NOT BENEFIT FROM THE INTERVENTION

The results from Study IV, investigating the characteristics of family caregivers who did not benefit from the intervention, were based on data from family caregivers who participated in the psycho-educational intervention and completed the PCS-scale at baseline and in the first follow leaving 82 family caregivers for analysis. Their rating of the PCS-scale between baseline and follow-up showed that 37 (45%) had not increased their preparedness for caregiving ($PCS \leq 0$)

while 45 (55%) had increased it ($PCS \geq 1$). These two groups were referred to as the non-benefit and the benefit group respectively.

There were few differences between family caregivers in the non-benefit group compared to the benefit group when it came to socio-demographic data. A tendency was found that the non-benefit group were more often not in active work (retired, on sick leave or unemployed) compared to the benefit group ($p=0.058$). No differences were found between the groups when it came to sex, age, marital status, morbidity, socio-economic background, relation to the patient or patient diagnosis or time of care. Looking at the baseline ratings of the outcomes, family caregivers in the non-benefit group generally seemed to be less vulnerable. They had scored significantly higher in their ratings of their preparedness ($p<.001$) and competence for caregiving ($p=0.003$). They also experienced a significantly lower caregiver burden in their environment ($p=0.048$) and better health, both in the total score ($p=0.045$) and in a single item asking about their overall health ($p=0.026$). They also had a tendency towards less feelings of depression ($p=0.098$).

Table 6. Differences in self-reported outcomes at baseline between non benefit/ benefit group

Variable	Non benefit Md q1-q3	Benefit Md q1-q3	Z-value	P-value
PCS – preparedness	22 (16-24)	14 (10–18)	4.856	<0.001
CCS – competence	8 (6-9)	6 (4-8)	2.950	0.003
RCS – rewards	28 (21-33)	28.5 (22-35.5)	-1.000	0.281
CBS – general strain	2.5 (1.6-3.1)	2.38 (2-2.8)	0.779	0.391
CBS – disappointment	2 (1.4–2.6)	2.2 (1.8–2.6)	-0.362	0.758
CBS – isolation	2.33 (1.7-3)	2.67 (1.7-3)	-0.243	0.903
CBS – emo. involvement	1.67 (1-2.7)	1.67 (1.3-2.3)	-0.034	0.959
CBS – environment	1.67 (1.3-2.3)	2 (1.7-2.7)	-1.930	0.048
HI– total score	36 (34-39)	34 (31-37)	2.063	0.045
HI – general health	4 (3-4)	3 (3-3)	2.177	0.026
HI– last week	3 (3-4)	3 (3-4)	1.062	0.349
HADS – anxiety	6 (5-8.5)	9 (5-10)	-1.651	0.146
HADS – depression	4 (2-6.5)	6 (3-7)	-1.714	0.098
MSPSS – family	25 (20-28)	23.5 (19-26)	1.175	0.190
MSPSS – friends	23 (18-26)	21 (16-25)	0.643	0.432
MSPSS – significant others	25 (22-28)	24 (18-28)	0.240	0.704

9 DISCUSSION OF FINDINGS

9.1 PREPAREDNESS FOR CAREGIVING

Taken together, the qualitative and quantitative findings presented in this thesis show that the psycho-educational group intervention could successfully help family caregivers become better prepared for caregiving. The statistical evidence showed a small but significant increase in preparedness for caregiving, both at completion of the intervention and at the long-term follow-up two months later (Study III). Interviews with family caregivers and focus group discussions with health professionals also indicated that the intervention was experienced as a valuable tool that could improve the possibilities for family caregivers to become better prepared (Study II). This is an important result, given that preparedness could be regarded as a protective factor against negative consequences in palliative care.^{33,36}

Previous research has shown that in order to increase preparedness for caregiving, family caregivers need information and practical and emotional support.^{35,84} From the findings, it could be argued that the theoretical framework by Andershed and Ternstedt,^{66,67} which this psycho-educational intervention was built on, is a suitable framework with which to design interventions aiming at making family caregivers better prepared. The intervention manual is built on the knowing, being and doing, which could be described as the educational, practical and emotional components that family caregivers need in order to become better prepared for caregiving. The main focus of the intervention is to promote knowledge and information (knowing) and thereby also support family caregivers in their being and doing. Preparedness for caregiving has been described as feeling ready, both when it comes to practical caregiving, but also for the emotions and stress related to caregiving.⁷⁴ It could be assumed that if the intervention makes family caregivers more knowledgeable and informed, it could also make them feel better prepared for the emotional and practical challenges of their involvement in caregiving.

Study I in this thesis also adds knowledge to the concept of preparedness for caregiving. The findings show that family caregivers experience their preparedness as an ongoing process with three sub-processes that were named “awaring”, “adjusting” and “anticipating”. An earlier study has described preparedness in a similar way, as a transition through the illness trajectory.³⁸ The fact that the intervention demonstrated effects on preparedness for caregiving indicates that the process could be influenced in a positive direction and that it is not merely affected by the patient’s condition and needs. Findings also indicate that family caregivers who felt less prepared for caregiving at baseline benefited more from the intervention (Study IV). Unlike competence for caregiving, the effect on preparedness was also maintained at the long-term follow-up, which shows that it could be important to focus on preparedness in order to influence caregiver wellbeing over time. If family caregivers feel prepared, it could possibly facilitate the sub-process of “awaring” over time (Study I), as it was very much influenced by changes in the patient’s condition. This could also make it easier for family caregivers to concentrate on “adjusting” to the changes and feeling less frustrated in the “anticipating” process.

Findings from Study I also indicate that the process of preparing for caregiving was intimately related to the process of preparing for the patient’s death as the family caregivers were in constant awareness that the patient’s time was limited. It has been stated that grief experienced by family caregivers before and after the patient’s death should be viewed as a continuum and

that family caregivers could be in need of support through the entire palliative trajectory, not just after the patient has died.⁸⁵ An interesting question would therefore be whether the psycho-educational intervention could promote not only preparedness for caregiving, but also preparedness for death, something that was not studied in this thesis. Earlier research has stated that information and support from health professionals about medical, practical and spiritual aspects could make family caregivers less anxious and better prepared for death.^{86 87} It seems plausible to assume that the intervention could promote this.

9.2 THE INTERVENTION

The intervention significantly improved its primary outcome: family caregivers' feelings of preparedness for caregiving, both in the short term and in the long term, compared to the control arm (Study III). It also significantly improved their competence for caregiving in the short term. No negative effects of the intervention were found, however, the intervention did not show any effects on family caregivers' rewards for caregiving, caregiver burden, health, anxiety and depression. Earlier research has concluded that it is important to have realistic aims of what interventions can influence and it is possible that this brief intervention did not have the potential to influence more global outcomes such as health or depression.⁴⁸

The intervention was delivered as an RCT, which means that the findings have a high standard of evidence. There has been a shortage of interventions in palliative care delivered with an RCT-design and policymakers and health professionals are in need of guidance of which support to offer, hence this intervention fills an important gap. Further, it has been highlighted that few previous interventions in palliative care have been developed that have been based within any theoretical or conceptual framework,²⁵ while this intervention was based on the theories of Andershed and Ternstedt, which was considered relevant as it concerned the involvement of family caregivers in palliative care. However, conducting RCTs in palliative care has been associated with specific challenges. Recruiting and retaining participants is often difficult, due to the vulnerability of the situation.⁵¹ Attritions are often high, resulting in insufficient sample power and modest effect sizes.⁵² This intervention demonstrated sufficient power, although attritions were also high, depending mainly on the vulnerability of the situation with patients getting worse and dying. The effect sizes of the trial were quite small according to Cohen's definition,⁸¹ although no stated clinically meaningful differences have been found for the preparedness for caregiving scale, which was the main outcome. The intervention was compared to the standard support provided in the palliative care setting and although the significant effects of the intervention were small, they still show that the intervention made a difference to family caregivers.

It is difficult to pinpoint exactly where the effectiveness of this intervention lay as it could be considered a complex intervention involving several components apart from the intervention program.⁵³ According to the framework of Campbell and colleagues,⁵³ it is important to integrate quantitative and qualitative findings in order to evaluate a complex intervention. In interviews, family caregivers mentioned the importance of meeting other family caregivers in the same situation and sharing experiences, which has also been found to be an important aspect of previous intervention studies in palliative care.⁶⁴ Another important aspect of interventions directed at family caregivers could be the opportunity to meet and communicate with health professionals.⁸⁸ In interviews, family caregivers stated that they felt seen and acknowledged by

being invited to the intervention and felt closer to the palliative care setting by being in the groups and meeting the health professionals. Andershed and Ternstedt^{66,67} have highlighted that respect from health professionals through openness, sincerity, confirmation and connection is an important aspect in the involvement of family caregivers in palliative care, something that health professionals in the intervention seem to have promoted. It is also reasonable to assume that the personal qualities and personalities of the health professionals would have affected the way they delivered the program and how family caregivers experienced and responded to the intervention. Although the intervention was delivered with the help of a standardised manual, health professionals were given the opportunity to be flexible in their delivery as long as all the topics in the manual were covered.

Another thing that might have influenced the findings could be where the family caregivers were situated in their process of preparedness (Study I). The process was described as ongoing through the patient's illness trajectory and hence family caregivers could be in very different phases of the process, which could also influence how they experienced the content of the intervention. In Study II, family caregivers described that the content of the intervention was not always applicable to their individual situation, which could be explained by where they were currently situated in the process of preparedness. The caregiving situation has also been described as a process with different phases where the family caregiver gradually grows into a more active role.⁸⁹ If family caregivers had not yet reached this active role it is possible that they experienced the intervention as unsuited for their situation. However, family caregivers also highlighted that the intervention program could help them prepare for future challenges. This indicates that it could be appropriate to use instruments like the PCS continuously to determine family caregivers' need of support in their process of preparedness.

The modest effect size of this RCT could be compared to that of the original intervention which this modified intervention was built from.⁶³ The findings from the original trial showed medium effect sizes on preparedness, competence and rewards for caregiving, although it was not delivered as an RCT. The greater effect size and effect on rewards for caregiving could possibly be explained by the fact that the original intervention was delivered in six sessions, while this intervention program had reduced the number of sessions to three. Both professionals and family caregivers expressed a desire to have more sessions. However, it has previously been found that interventions in palliative care need to be brief, considering the often short and unpredictable illness trajectories.⁸⁸ Study IV's exploration of family caregivers who did not benefit from the intervention could also provide some explanations of why the effect size was small. The findings showed that family caregivers who did not benefit were less vulnerable at baseline than those who did, according to their ratings of several caregiver outcomes. Hence, they might not have had the same need for the psycho-educational intervention that family caregivers in the benefit-group did and could have been difficult to influence. This opens up a discussion about which groups of family caregivers might benefit from an intervention and which groups should be included. Health professionals also reported a fear of including family caregivers who were considered to be vulnerable in the intervention (Study II), which could account for the characteristics of family caregivers in the project and why the effects size was small. The overall baseline rating showed that the sample in both the control and intervention arms generally reported moderate levels of preparedness competence and rewards for caregiving, as well as strong feelings of health and low levels of burden, anxiety and depression. This could indicate

that the room for improvements was small,⁹⁰ as the findings in Study IV indicate that family caregivers who were more vulnerable benefited more from the intervention.

9.3 THE ROLE OF HEALTH PROFESSIONALS

The findings demonstrate the important role of health professionals both in inviting and preparing for the intervention as well as in the actual delivery of the psycho-educational intervention directed at family caregivers in palliative care. From the findings it seems that the intervention brought health professionals and family caregivers closer together (Study II). Family caregivers stated that health professionals made them feel seen and acknowledged through the intervention and that they experienced the topics as interesting and important. Their positive experiences could be explained by the fact that the health professionals who were involved in delivering the intervention were experienced in palliative care and familiar with the topics that they presented from the intervention manual. Previous research has indicated that experienced health professionals feel more comfortable communicating with family caregivers about sensitive topics such as dying and death compared to professionals with less experience.⁹¹ However, health professionals expressed that they had developed a new sensitivity to the situation of family caregivers by delivering the intervention. Andershed and Ternstedt have concluded that understanding the situation that the family caregivers are in could make it easier for health professionals to provide them with support. From the qualitative findings in this thesis (Study II), it seems as though the intervention could contribute to this.

Inviting family caregivers to the intervention and preparing for the sessions by going through the manual demanded much time from the health professionals who were involved and they expressed a sense of pressure about the situation. This could be described as a vital part of successful intervention delivery and therefore needs to be addressed in the development of future interventions. It has been stated that in order to support family caregivers optimally, health professionals need to find time to focus on their needs and concerns.⁸⁸ However, the health care systems could make this difficult as the resources are often stretched only long enough to last for the patient. Hence, additional resources are needed for health professionals to focus on family caregivers.⁹² It is also possible that health professionals would have benefited from more comprehensive introduction and training in using the inclusion criteria and in inviting family caregivers. Recruiting participants to trials in palliative care has been described as a common problem due to the patient's vulnerability.⁵¹ From the findings it could be interpreted that health professionals acted as a form of gatekeeper, in wanting to protect those family caregivers who they perceived as vulnerable. In this trial, consent from the patient was also demanded which could have made recruiting participants increasingly difficult. To avoid problems with gatekeeping in future interventions, greater importance should be placed on focusing on the autonomy of family caregivers and patients to allow them to make their own choices about participating in research.⁹³

Previous research has shown that family caregivers find participating in group interventions valuable as it gives them a chance to find support and exchange experiences.^{62,64} This intervention generated similar findings. However, another positive result of this intervention was that it seems to have also been beneficial to the health professionals who delivered it. Health professionals reported that they felt rewarded and lifted by delivering the intervention and that they received positive feedback from family caregivers. Research has concluded that

communication between health professionals and family caregivers is a key aspect in successful family caregiving.⁴⁷

9.4 METHODOLOGICAL CONSIDERATIONS

This research project has been carried out with a multi-methodological approach including both quantitative studies to calculate the effects of the intervention and qualitative studies focusing the intervention processes. The intervention was developed based on the model developed by Campbell and colleagues and could be regarded as a complex intervention. Including qualitative studies could make the complex intervention easier to define by providing sensitivity to the complexities of the palliative care settings. The inclusion of qualitative studies also increases the validity of the trial. The intervention was delivered in clinic, by health professionals in specialised palliative care, which should make the process of implementation easier, as the findings are likely to be implemented in similar settings.

9.4.1 Sample reflections

As has already been stated, the sample included in the intervention was generally quite well-adjusted, which could have influenced the effect size of the intervention. As was found in Study IV, family caregivers who were more vulnerable were more likely to benefit from the intervention. A limitation of this intervention trial is that there were no recordings made of the family caregivers who declined when they were asked to participate in the research project. It would have been valuable to know the numbers and characteristics of family caregivers who refused and possibly also their reasons for not wanting to participate. Judging from the fact that the overall sample was well-adjusted, it is possible that family caregivers who did not participate might have been more vulnerable.

Although the intervention was not developed to be adapted to any particular diagnosis, 90% of the participants in the trial were family caregivers to a patient with a cancer diagnosis. From the focus groups with health professionals it seems as though they found it easier to adapt the inclusion criteria to family caregivers of patients with cancer, because their illness trajectory was considered to be more predictable. An inclusion criterion for this trial was that family caregivers should be able to understand the Swedish language. This could be described as a limitation of the sample, because Sweden has experienced high levels of immigration over the last years and there could be many family caregivers who were not yet able to communicate in Swedish in the palliative care settings who might have benefited from taking part.

9.4.2 Trustworthiness

In the qualitative studies, I and II, an interpretive descriptive⁶⁹ design was used. The concept of representative credibility has been highlighted as an important aspect to increase the trustworthiness of the findings. The sample and data quality needs variation and breadth in order to illustrate the phenomenon that is studied as thoroughly as possible. In the qualitative studies in this thesis, family caregivers of different backgrounds, ages and genders were included in interviews. The participants in Study I were included on the basis of their scoring of the PCS, focusing on high and low scorers and thereby granting variety in the sample. Health professionals (Study II) were included on the basis of being involved in delivering the intervention, but it was also considered important to include all professional categories involved

in the intervention (physicians, nurses and social workers/priests). In the qualitative analyses, the researchers worked in close collaboration. Patterns and themes were continuously discussed and compared between the researchers.

Data for Study II were collected through more than one method (interviews and focus groups), which is considered to be a strategy that could strengthen the dependability of the findings. Dependability is considered to be something that can vary depending on the researcher's skills and abilities.⁹⁴ The telephone interviews, which were included in Study II, demanded sensitivity from the researcher because the face and body language of the interviewed person could not be observed and responded to. It is possible that these difficulties influenced the quality of the data. The transferability of the qualitative findings refers to the extent to which the findings can be transferred to other settings and groups.⁹⁴ To strengthen the transferability, detailed descriptions were made of the settings, the intervention design, the number and characteristics of participants in the studies, data collection methods and analytic processes.

In the interpretive descriptive approach,⁹⁵ the researcher's pre-understanding is not something that should be bracketed, but rather, considered as a tool that should be used in the research process. In this case, the researchers all had experience of working with patients in palliative care and of providing support to family caregivers. This could have been a helpful part of the problem-formulation and the analysis of data in the studies. However, according to interpretive description, it is important to be aware of and be reflexive about your pre-understanding as a researcher. The research process also included continuous discussions and reflections between the researchers, which challenged pre-understandings and led thoughts in new directions. In the analysis, there was a continuous strive not to make conclusions too quickly from the material, a strategy which is in accordance with the interpretive descriptive perspective.

9.4.3 Validity and reliability

The intervention trial presented in the quantitative studies has several strengths. The intervention was delivered as an RCT which is considered the safest way to test interventions.⁵² Because no differences were found between the intervention and control arms at baseline, it could safely be assumed that the effects on preparedness and competence for caregiving could be attributed to the intervention. The trial took place at 10 different palliative care settings and included a sufficient sample power based on power calculations, which also adds to its strength. The intervention was delivered with the help of an intervention based in theory and professional experiences. The manual ensures consistency in the delivery of the intervention and makes it easier to replicate and implement. The trial protocol has been registered, which makes the intervention process more transparent. The effects of the intervention were measured using validated outcome measurements that demonstrated sufficient internal consistency. The reliability of the findings was also strengthened by the fact that an independent person manually checked the data file against the questionnaires and that any data entry errors were corrected.

A limitation of the RCT was that it was not blinded, which creates a risk of selection bias.⁵² There were a large number of attritions from the study, particularly from the intervention arm, mainly because of the death of the patient. This led to a substantially smaller sample in the follow-ups compared to baseline. The palliative care contributes a difficult setting for the delivery of interventions, because the prognoses of patients are often uncertain. The intervention

was compared to standard support from the palliative care setting. Because there were 10 different settings involved in the RCT, the standard support could vary slightly between the different settings, which could influence the findings.

A potential risk of bias in the analysis of the intervention effects was the fact that more than one family caregiver could represent the patients. This could be considered a violation of the assumption of non-dependence and, therefore, regression models with clustered data were used to calculate the effects. The analysis was based on a per-protocol approach rather than intention-to-treat, which is the standard way to evaluate the effects of an intervention. Family caregivers of patients who had died were excluded from analysis. Using intention-to-treat principles could have created a risk of underestimating the effects of the intervention, which could be described as unethical,⁹⁶ hence the per-protocol approach was chosen.

No power analysis was calculated for Study IV because the sample was limited only to family caregivers who completed the intervention. This could have increased the risk of committing Type II errors and hence it was decided to include tendencies for significance in the result ($p < 0.1$). However, these findings should be interpreted cautiously.

10 CONCLUSIONS

Participating in a theoretically-based psycho-educational intervention delivered by health professionals during specialised palliative home care increased family caregivers' feelings of preparedness for caregiving both in the short term and long term compared to family caregivers who received standard support. The interventions' potential of improving preparedness for caregivers was also highlighted in the interviews with health professionals and family caregivers.

Preparedness for caregiving, the main outcome of the intervention, was experienced by family caregivers as an ongoing process throughout the patient's illness trajectory and was intimately tied to their preparedness for the patient's death. From the findings it seems as though the intervention could influence the process of preparedness in a positive way, but it is also possible that family caregivers responded differently to the intervention depending on where they were situated in their process of preparedness.

Family caregivers who did not benefit from the intervention perceived themselves as less vulnerable at baseline than those who did. It is possible that because they already felt sufficiently prepared for caregiving, they were not in need of an intervention to improve their preparedness for caregiving.

Health professionals have an important part to play in the recruiting to and delivery of interventions in palliative care. The findings indicate that the intervention brought family caregivers and health professionals closer together and led to improved communication. Delivering the intervention was also a positive and rewarding experience for health professionals.

11 IMPLICATIONS

Trends at population level in Sweden and other countries point towards ageing populations and increased levels of outpatient care where family caregivers play a key role. Supporting family caregivers in palliative care has therefore been highlighted as an important public health issue and policymakers should make it a priority to form guidelines for providing support to family caregivers based on empirical research. From the findings in this thesis, a psycho-educational intervention based in theory could be used by health professionals at specialised palliative care settings as an instrument improve the chances of family caregivers to improve their preparedness for caregiving. An intervention manual has been adapted to be used as a support in delivering the intervention and makes it easier to replicate. The manual is developed for a Swedish context, but with some societal adaptations, it could also be used in other countries. It could also be possible to adjust the manual to other settings than palliative care, such as cancer care or elderly care. The intervention is brief and the group design makes it possible to support several family caregivers at the same time.

An aspect that appears to be very important to successful intervention delivery is that health professionals are given appropriate time and resources to work with the intervention, especially when it comes to organising the intervention sessions and inviting family caregivers to attend. It is also important that family caregivers who appear to be vulnerable are not excluded from participating in interventions as they could be in special need of support in order to become better prepared. Because resources are often limited, it could be necessary to direct support towards family caregivers who could be expected to benefit most from it.

12 FUTURE RESEARCH

In order to acquire a more complete overview of the effects of the psycho-educational intervention, it would be prudent to continue following the family caregivers over time and measure their outcomes after the patient's death. Because previous research has indicated that preparedness for caregiving and preparedness for death would be interrelated, it would be valuable to find out whether the intervention had any effects on family caregivers' preparedness for the patient's death and their experience of grief compared to the control arm.

The findings in Study IV of this thesis indicated that there could be a possible need to use screening instruments in order to target family caregivers who might benefit from an intervention, rather than offering it to everyone. However, this needs to be explored further with qualitative measurements.

Health economic benefits of the intervention have not been investigated in this thesis. Because of limited resources in the health care systems, this is an important issue that should be explored further. A possible way of measuring could be to investigate whether the intervention has made it possible for patients to remain in their homes rather than being hospitalised.

According to the methodological framework of Campbell and colleagues, the final phase in the delivery of complex interventions is to examine the implementation into practice with particular regard to the rate of uptake, intervention stability and possible adverse effects. Because this was not studied in this thesis, there is an urgent need to continue studying the intervention with regards to the processes of implementation.

There is a need to continue the development of supportive interventions for family caregivers in palliative care and also investigate their possible effect on the patient receiving care. It must be established whether family caregivers need interventions, both in group-format and individually, and whether the interventions should include entire families or merely the primary caregiver.

13 SWEDISH SUMMARY/SVENSK SAMMANFATTNING

Bakgrund

Förändringar inom sjukvårdssystemen i dagens moderna samhälle har inneburit att alltfler patienter med svår sjukdom numera vårdas i hemmet där närstående ofta får ta ett stort ansvar. De får ofta bidra med olika former av vård och stöd till den sjuke samtidigt som de också måste hantera sin egen sorg över den sjukes tillstånd. Situationen har beskrivits som komplex; även om närstående tar sig an rollen som vårdare frivilligt upplever många motsägelsefulla känslor i situationen. Studier visar att närståendes hälsa och välmående ofta påverkas.

Det har visat sig att närstående som känner sig mer förberedda på att vårda ofta kan hantera situationen bättre och att denna förberedelse även kan kopplas till närståendes förberedelse för det förestående dödsfallet. Att främja känslan av att vara förberedd kan därför vara en viktig komponent i stödet till närstående.

Det saknas forskning kring interventioner riktade mot närstående som genomförts med randomiserad kontrollerad design, vilket är ansett som det säkraste sättet att testa interventioner på. Det är därför angeläget att fortsätta utveckla och testa interventioner för att göra närstående inom palliativ vård mer förberedda för situationen.

Syfte

Syftet med denna avhandling är att utveckla en intervention i syfte att förbättra närståendes känsla av förberedelse inom palliativ vård och att studera effekter av och processer inom denna intervention genom fyra delstudier.

Studie I: Att utforska närståendes upplevelse av förberedelse för att vårda inom palliativ hemsjukvård

Studie II: Att utforska vårdpersonals och närståendes upplevelser av att genomföra respektive delta i en intervention i form av ett stödprogram i gruppformat.

Studie III: Att undersöka effekter av en intervention i form av ett stödprogram i gruppformat för närstående vilken genomförts med randomiserad kontrollerad design

Studie IV: Att undersöka vad som utmärker de närstående som inte haft effekt av en intervention i form av ett stödprogram i gruppformat.

Metod

En intervention i gruppformat med stödjande och utbildande syfte (psycho-educational) utvecklades, med en teoretisk grund som bygger på Andershed och Ternestedts modell för närståendes villkor inom palliativ vård. Fokus ligger främst på närståendes behov av att veta, att vara och att göra, vilket kan beskrivas som kunskapsmässiga, emotionella och praktiska behov. Interventionen fokuserar på att ge kunskap (att veta) vilket också kan bidra till att närstående blir mer förberedda inom de praktiska (att göra) aspekterna av att ge vård till en svårt sjuk person och även ges verktyg att hantera sina känslor (att vara).

Interventionen genomfördes som en randomiserad kontrollerad studie av vårdpersonal vid 10 specialiserade palliativa hemsjukvårdsenheter. Närstående som tackade ja till att vara med blev antingen randomiserade till att delta i stödprogrammet (interventionsgrupp) eller till att få stöd på sedvanligt vis (kontrollgrupp). Totalt tackade 270 närstående ja till att delta och samtliga delstudier bygger på detta urval. Interventionsgruppen fick delta i stödprogrammet som genomfördes i tre träffar vid var och en av enheterna och varje gång var en medlem av vårdpersonalen närvarande (läkare/sjuksköterska och kurator/präst). Till hjälp och stöd hade vårdpersonalen en interventionsmanual med olika teman som framarbetats av vårdpersonal och forskare i samarbete.

Studie I och II är kvalitativa studier och bygger delvis på samma urval av intervjuer med närstående. Studie I innehåller både närstående från kontroll och interventionsgruppen medan Studie II endast innehåller närstående från interventionsgruppen. Studie II bygger även på fokusgrupper med vårdpersonal.

Studie III och IV är kvantitativa studier som bygger på statistiska mätningar. I Studie III fick närstående från interventions- och kontrollgrupp fylla i enkäter före och efter samt två månader efter stödprogrammet. Enkäterna handlade om närståendes känsla av förberedelse för att vårda (primärt utfallsmått) samt deras känsla av kompetens och egen behållning för att vårda, deras känsla av börda, hälsa, ångest och depression. Studie IV bestod enbart av de närstående som deltagit i interventionen och deras mätningar före och efter stödprogrammet.

Resultat

Både kvalitativa och kvantitativa resultat visar att en intervention i form av ett stödprogram kan ge närstående förutsättningar att öka sin känsla av förberedelse för att vårda. I intervjuer beskrev närstående förberedelse som en pågående process genom hela patientens sjukdomsförlopp med tre olika subprocesser: att bli medveten, att anpassa sig och att se framåt. Förberedelse för rollen som närstående till en svårt sjuk person var även nära förbunden med att förbereda sig för det väntade dödsfallet och det var på så vis en gemensam process (Studie I). Vid intervjuer med närstående som deltagit i interventionen och fokusgrupper med vårdpersonal som genomfört den framhölls att stödprogrammet upplevdes som ett sätt att främja närståendes förberedelse. (Studie II). Programmet upplevdes som positivt och lärorikt och ansågs ha lett till att närstående och vårdpersonal fick bättre kontakt och att närstående kände sig sedda av vårdpersonalen. Närstående som deltagit i interventionen fick även en statistiskt signifikant ökad känsla av förberedelse både på kort och lång sikt jämfört med kontrollgruppen. De fick även på kort sikt en ökad känsla av kompetens för att vårda (Studie III).

Interventionen ledde inte till någon statistisk förbättring i närståendes självskattade behållning av att vårda, deras upplevelse av börda, hälsa, ångest eller depression. De effekter som uppmättes var generellt små. De närstående som inte hade effekt av interventionen skattade vid baslinjen sin känsla av förberedelse, kompetens och hälsa högre samt sin känsla av ångest och börda i sin miljö lägre än de som hade effekt (Studie IV). Vårdpersonal framhöll att de haft svårigheter vid inbjudningarna av närstående och att de känt en osäkerhet inför att tillfråga vissa närstående som upplevdes sårbara (Studie II). De närstående som deltog i projektet kan beskrivas som välanpassade baserat på sina skattningar vid baslinjen.

Slutsatser

Ett stödprogram i gruppformat kan vara ett effektivt sätt för vårdpersonal att stödja närstående att öka sin känsla av förberedelse för att vårda över tid. Förberedelse för att vårda har av närstående beskrivits som en pågående process och resultaten antyder att stödprogrammet kunde påverka denna process på ett positivt sätt för närstående. Det är också möjligt att närstående reagerade olika på stödprogrammet beroende på var de befann sig i sin pågående förberedelseprocess.

Resultaten visar på vårdpersonalens stora betydelse för att framgångsrikt kunna genomföra stödjande interventioner i palliativ vård. Det krävs dock att vårdpersonal ges tid och resurser för att kunna stödja närstående på bästa sätt. Av resultaten kan det ses som viktigt att vårdpersonal inte undviker att bjuda in närstående som upplevs som ”sårbara” om liknande stödprogram ska genomföras då resultaten från denna avhandling tyder på att de kan vara i störst behov av interventionen.

Då interventionen genomförts med hjälp av en manual underlättas möjligheterna att kunna använda den vid andra palliativa enheter. Resultaten antyder att vårdpersonalens resurser i högre grad skulle kunna inriktas mot de närstående som upplevs mest sårbara och i behov av stöd. Detta skulle kunna ske med hjälp av screening med statistiska instrument. Det krävs dock mer forskning för att kunna rekommendera sådana åtgärder.

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