BMJ Open  Supporting the provision of palliative care in the home environment: a proof-of-concept single-arm trial of a PalliativE Carers Education Package (PrECEPt)

Liz Forbat,1 Erna Haraldsdottir,2 Marsha Lewis,3 Ken Hepburn4

ABSTRACT

Introduction: Practical educational interventions for palliative carers are needed. Current supports frequently rely on carers travelling to a central venue to receive education. A substantial gap therefore exists around determining how high-quality relevant information can be delivered nationally, with limited cost implications, using educational methods that are acceptable to carers in palliative care. This study seeks to design and assess feasibility and acceptability of a distance-learning approach to educating carers.

Methods: This is an embedded mixed-method feasibility and acceptability study. It embeds an unblinded 1-arm pilot test, with subsequent qualitative interviews which will be used to inform the assessment of the intervention’s acceptability and feasibility. The theoretical framework is self-efficacy theory, whereby we seek to impact carers’ beliefs in their ability to carry out and succeed in caring tasks and situations. The educational materials focused on pain and nutrition/hydration will be developed in phase 1 with former carers (n=8) providing input into the content and style of materials. The educational package privileges adult-learning styles, recognising and responding to the learner’s context including their learning needs, prior knowledge and motivations for engaging in education. The materials will be tested with up to 24 current carers.

Analysis: Analysis will focus on determining recruitment processes for a full-scale study, data collection procedures/completion rates, queries directed to the hospice from carers involved in the feasibility work, mode of delivery and content of the materials. The primary outcome measure is self-efficacy, with other measures focused on caregiver preparedness and caregiving tasks, consequences and needs questionnaire. Adherence to educational components will also be collected and reported.

Ethics and dissemination: Ethical approval has been provided by the participating site, Calvary Healthcare, Canberra, reference 02–2016, and the Australian Catholic University. Results will be published in peer-reviewed journals, presented at conferences and a lay summary sent to participants.

Trial registration number: ACTRN12616000601437; Pre-results.

INTRODUCTION

Families are viewed as a unit of care in palliative services.1 Informal carers’ needs therefore should be identified and addressed as part of routine service provision. Carer resources and support, over and above patient diagnosis and symptom burden, predict carer burden and other carer outcomes.2 With policy and practice emphasis on home-based care and home as the preferred place of death, ensuring appropriate and adequate support for carers is critical. Such approaches need to be cognisant of carer need for knowledge, recognition of their emotional experience and the role they can play in supporting the patient.3 Further, interventions must recognise that carers may be reluctant to ask for...
help and not self-identify as a carer. Unmet needs have been documented in many studies and frequently include insufficient informational and emotional support across palliative care, as well as for specific patient/carer groups such as around cachexia. Practical educational interventions for carers are needed.

Educational interventions for carers are commonplace; education is proven to increase skills, improve caregiving competence and address information needs. Interventions are more likely to impact outcomes such as knowledge and self-efficacy, and preparedness for caregiving, rather than domains such as carer coping, or anxiety, depression or burden. Evidence from palliative care clearly demonstrates that one-to-one and group psychoeducation is effective in gaining support and knowledge, preparedness for caring, competence and having information needs met. However, these studies have typically been small scale and rolled out only in local areas.

A deficit of such models is that they frequently rely on carers travelling to a central venue to receive education. Studies have reported that carers decline involvement in supportive group interventions due to a desire not to leave the person they are caring for. As a response to these time and location concerns, a number of approaches have been tested, but not without their drawbacks. First, multimedia approaches have been adopted, for example, educational DVDs, and videos combined with internet-based programmes have reported positive feedback from carers and health professionals on being interesting and containing relevant content. The strength of such formats is that they can be used nationally, irrespective of the carers’ proximity to a specialist service, or their ability to attend an educational class at a prescribed time. However, in common with many approaches to caregiver education and information support, these interventions do not expressly articulate the learning and teaching styles adopted. Additionally, distance-learning methods are used widely in healthcare professional education, for example, nurses, surgical trainees and occupational therapy. Yet distance learning has not been widely explored for caregivers despite some early results in the dementia field offering promising feedback. While it is recognised that accessible, brief and easily delivered education needs to be available, a substantial gap remains around determining how high-quality relevant information can be delivered at a national level, with limited cost implications, using educational methods which are acceptable to carers in palliative care. This study seeks to design and assess feasibility and acceptability of a distance-learning approach to educating carers.

**Aim**

This study involves intervention development and an embedded proof-of-concept feasibility and acceptability study.

Specific aims are to:

1. Design an innovative distance-learning educational package (PrECEPt: PalliativE Carers Education Package). Two modules, identified as priorities in the literature will be developed.
2. Determine ideal content, learning-style preferences (eg, balance of videos/vignettes/quizzes), mode of delivery (online/printed), level of detail/complexity.
3. Determine the acceptability and feasibility of the educational package to carers and healthcare professionals.
4. To understand the processes involved in delivery of the key components of PrECEPt including recruitment processes for a full-scale study, data collection procedures/completion rates, queries directed to the hospice from carers involved in the feasibility work.
5. Determine sample size, recruitment and randomisation processes for a definitive trial.
6. Examine the impact of the intervention on carer self-efficacy.

**THEORETICAL FRAMEWORK**

We theorise that carer self-efficacy will increase through the provision of information, skills and confidence. The focus on self-efficacy is informed by the recognition that it is a key variable in the impact of caring, and consequently is a frequently measured variable in general caregiving and palliative care research. Education interventions have also determined that self-efficacy is a modifiable variable.

Self-efficacy theory refers to an individual’s confidence to carry out a specific task, and the belief in one’s own ability to succeed in a task or situation. Self-efficacy is linked with initiation and persistence of coping, and mediates the relationships between stressors and outcomes. Consequently, high self-efficacy is considered a predictor of continued caregiving, mediating the development of debilitating emotional responses such as depression, anxiety or pessimism. Anxiety and self-efficacy are linked, with carers reporting low self-efficacy having higher anxiety scores.

Bandura explains that expectations regarding self-efficacy are predicated on “four major sources of information: performance accomplishments, vicarious experience, verbal persuasion and physiological states” (p. 195). Consequently, this intervention will target those elements in the context of caregiving tasks and beliefs.

**METHODS AND ANALYSIS**

**Primary research question:** What is the ideal content and mode of delivery for a carer’s distance education resource?  
**Secondary research question:** Does the education package impact carer self-efficacy, or preparedness for caregiving?

**Design**

This is an embedded mixed-method feasibility and acceptability study. It embeds an unblinded one-arm study. This study involves intervention development and an embedded proof-of-concept feasibility and acceptability study.
pilot test, with subsequent qualitative interviews which will be used to inform the assessment of the intervention’s acceptability and feasibility.

Participants in the pilot trial will receive educational resource material focused on nutrition and hydration, and pain. Carers and patients will continue to receive usual care from the community palliative care team.

The design encompasses phases i/ii of the UK’s Medical Research Council (MRC) complex intervention framework. The study is underpinned by realistic evaluation methodology, which acknowledges the complexity of interventions and the contexts in which they are delivered and assessed. This methodology ensures that data are gathered from a range of relevant stakeholders to identify facilitators and barriers to delivery and uptake. The aim is also to produce findings that will inform the development of a fully powered multisite trial. The study has two phases:

Phase 1: intervention development (aim 1)
PrECEPt will be developed by (1) examining the extant literature with the aim of developing education material for carers and (2) holding focus groups with eight former carers of people in receipt of palliative care. The materials will be written by palliative care nurses, a psychosocial palliative care researcher and have input from a palliative care physician. The development of materials is outlined in figure 1.

PrECEPt will consist of two units which are identified as priorities in the palliative literature on caregiver needs: pain management and nutrition/hydration needs including dietary advice, feeding techniques, hydration. The topics covered in the units and information provided will be informed by pragmatic searches of nursing (CINAHL) and medical (PubMed) databases, focusing primarily on recent relevant systematic reviews. The materials will be framed as information for family members, recognising the conceptual difference for carers in drawing on this policy discourse.

The materials will be pitched at a reading level of grade 6–7, which is the equivalent of a reading age of 11–12 years, using Flesch-Kinnard scores generated by Microsoft Word. The grade level is calculated on the average number of syllables per word and the average number of words per sentence. The choice of literacy level reflects educational materials of patients with cancer, building on proposed best practice.

The educational package will privilege adult-learning styles, recognising and responding to the learner’s context including their learning needs, prior knowledge and experience, and motivations for engaging in education. A blended approach will be adopted, incorporating didactic elements, reflexive exercises and video vignettes illustrating caregiving scenarios and potential solutions.

Distance-learning approaches will be adopted to overcome the limitations and equality disparities in offering face-to-face support to carers. Distance education is underpinned by three core elements: dialogue, structure and learner autonomy. Dialogue refers to the interaction between the educator’s voice and the learner, which is built into the course package. In PrECEPt, dialogue is epitomised by an authorial voice which seeks to ‘walk alongside’ the learner and present information as if in one-to-one conversation with them. This approach intends to facilitate rapport between teacher and intended learner which is associated with better outcomes for learners. Structure refers to the variability in learners’ preferences in engaging with the objectives. Autonomy relates to the control that the learner has in creating a learning plan, and how much they wish to learn and implement.

Flexible learning also underpins the approach, with the educational package being offered to carers to use in a way that suits their circumstances, such as their preferences for amount of information, and their motivations and goals for engaging in the materials. To this end, the materials will be presented in a hierarchical fashion with core information about basic issues presented initially, progressing to increasingly complex scenarios with greater depth of explanation. Carers can then choose the level which best suits their practical situation, current knowledge base and readiness for information by moving through the materials at their own pace starting and stopping wherever fits their needs. The printed materials will be structured from basic information, through to more moderate levels of information to more sophisticated explanations of anatomy and physiology, with attendant suggestions for managing likely problems facing caregivers.

The education package will be framed around case studies of carer–patient dyads. These dyads will facilitate
problem-based learning, which is a learner-focused pedagogical technique that allows for contextualised and applied learning. Evidence from healthcare suggests that problem-based learning offers strength in engendering clinical knowledge and skills. For carers, problem-based learning will be addressing key problems which are documented in the literature, for example, carers’ own needs and identity.

Consequently, PrECEPt will outline a range of presenting problems alongside activity-focused elements to encourage the reader to engage in reflection, to promote ‘deep learning’, that is, learning which deeply engages the individual. This activity approach builds on reflexive practice which is an established component of healthcare education for staff. In addition to prompting carers to identify their own solutions, the educational package will integrate suggestions and responses to the identified problems, drawing from evidence in the clinical literature. The materials will cover basic physiology and anatomy to explain the aetiology of symptoms, and psychoeducational elements to address the anxiety and distress which these symptoms prompt in carers.

In addition to written materials, filmed vignettes will be developed which illustrate caregiving scenarios, offering practical illustrations of problems and potential solutions. For example, a video might show a caregiver preparing a small meal, while describing his decision-making in what is on the plate, size of meal and how he will offer it to the person he is looking after. Videos are frequently used in distance education, and increasingly a core mode of delivery of massive online open courses. Within PrECEPt, the films will complement the written materials, and will vary in length from 2 to 7 min. Storyboards will be developed to outline the narrative and key learning points to be illustrated by the actors, and prompt reflection from the carers.

The development of the materials will be informed by Bandura’s model, targeting performance accomplishments (by modelling, desensitisation, exposure and instruction), vicarious experience (through modelling in the videos and vignettes), verbal persuasion (through embedded suggestion of the ability to master tasks, and provision of instruction) and physiological states (through addressing triggers for emotional arousal, attribution errors and exposure). The materials prompt carers to discuss any queries they have with relevant healthcare professionals, but otherwise are conceptualised as stand-alone packages that do not require new or additional input from healthcare providers.

The draft educational materials will be presented to former caregivers for feedback, discussion and refinement. It is expected that several iterations of the learning resource will be required, including both written and video materials.

Phase 2: feasibility study (aims 2–5)
Up to 24 carers of people currently receiving palliative care will be invited to feasibility test PrECEPt. They will be interviewed to aid refinement of the materials and recruitment processes. To manage likely loss to follow-up, the sample size factors in over-recruitment, and seeks to achieve a final sample size of 16 carers who complete the educational materials.

Staff at the recruiting site will also be interviewed to gain feedback on recruitment processes, and the impact of the trial on interactions with the staff team (eg, capturing information on whether more/different informational queries were received). Carers will receive the educational materials by post, and be informed that the trial lasts for 6 weeks during which they can read and use the materials. At the end of 6 weeks, they will be asked to complete outcome measures, and choose if they wish to retain or return the materials.

Setting, sample and recruitment
Recruitment will proceed through a single site: the Australian Capital Territory’s specialist outpatient palliative care service at Clare Holland House, Canberra, Australia. This service provides both inpatient and outpatient services to residents across the Territory, and beyond. It is staffed by a multidisciplinary team including medical, nursing, allied health, social work and pastoral care practitioners. Recruitment will proceed through the community palliative care team, who provide specialist palliative care to patients and carers where their symptoms cannot be managed by primary palliative care.

Phase 1: Eight former carers will participate in focus groups. These carers will be purposively sampled to include individuals who will be articulate about their informational and support needs, and be able to contribute to the development of the materials. Former carers were sought in order to reduce burden to current carers, and ensure recruitment did not decrease the potential pool from which phase 2 participants were drawn. Recruitment will be supported by the community palliative care team, using the following criteria:

Inclusion criteria:
I. Former carer, residing in the Australian Capital Territory;
II. Supported someone with nutrition/hydration and or pain management needs;
III. Bereaved at least 3 months previously, following guidance from Bentley and O’Connor;
IV. Aged over 18 years and able to give informed consent;
V. No formal diagnosis of major psychiatric disorder.

Phase 2: Current informal carers, supporting someone with nutrition/hydration and or pain management issues will be invited to test PrECEPt, to determine proof-of-concept for this novel approach to carer education.

The community palliative care team will identify how many patients they have in their caseload (n=126 currently). All patients will be allocated a numeric code. A sample will be identified using a random number
Inclusion criteria:

I. Recognised as the main carer for a patient receiving specialist palliative care;
II. Supporting someone with nutrition/hydration and/or pain management needs;
III. Carer and patient are both aged over 18 years, and able to give informed consent;
IV. Proficient in English language;
V. Patient’s life expectancy >12 weeks;
VI. The patient resides at home (not in residential aged care or receiving end-of-life care as an inpatient), though patient and carer do not have to live together;
VII. No formal diagnosis of major psychiatric disorder.

For both phases, carers will be sent invitation letters, requesting opt-in to the study within 2 weeks. The invitation letter will be sent from the hospice manager, who has no clinical or research role. Interested carers will be prompted to email or phone the research team indicating accepting or declining involvement. Written consent of carers will be gained at the start of the focus groups in phase 1. Phase 2 participants will provide initial verbal consent by calling the lead researcher to opt-in to the study. Subsequently, they will be sent a consent sheet for signing when baseline measures are taken. Multiple cycles of recruitment will be undertaken until the sample size is achieved.

Postintervention individual face-to-face interviews will be conducted with participants in phase 2. If more than 16 carers remain involved in the study, then purposive sampling will be used, with interviewees stratified for degree of change. Participants who withdraw from the trial will not be approached to participate in interviews. Although their experience may shed useful light on the materials and trial processes, we anticipate that withdrawals will stem from increased complexity of the home-care situation and consequently that an interview would be unduly burdensome.

Participant timelines and flow through the study are illustrated in figure 2. Recruitment is pending (due to start in July 2016); enrolment will start in August 2016.

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intervention, and its success or otherwise. Participants will be asked about the most and least helpful elements of the educational materials, reasons for using the materials, how long they spent using them, whether parts were used multiple times, views on their willingness to participate if it were a randomised trial, the timing of the education, their use of the specialist palliative care service in answering any questions related to pain and nutrition/hydration, and whether anything could be changed or added to the educational materials.

Interviews with healthcare staff will elicit views on the acceptability and feasibility of the intervention; for example, eligibility criteria, method of recruitment, timing of offering the intervention in relation to the patient’s trajectory, duration of intervention.

Researchers will be available to participants throughout the study period. A follow-up reminder phone call will be placed if outcome measures are not received within 2 weeks of distribution. All data proffered by carers on withdrawal, adverse effects or unintended consequences will be logged and reported.

Carer demographics will be collected including age, gender, education level, occupation, relationship to patient and patient diagnosis. Further patient-level data will not be sought.

Outcome measures

The primary outcome measure assesses self-efficacy. The secondary measures reflect an interest in assessing changes to carer outcomes more generally including self-report preparedness and competency. The outcome measures follow, where relevant, recently published European Association of Palliative Care White Paper reporting outcome measure use in palliative care.62

Primary outcome measure:

Self-efficacy will be measured using the Ugalde tool.63 This is a 21-item, 4-factor, self-report questionnaire which has been validated in cancer carers. The four factors are: resilience, self-maintenance, emotional connectivity and instrumental caregiving. Test–retest reliability and internal consistency were excellent (0.73–0.85 and 0.81–0.94, respectively).

Secondary outcome measures:

▸ Cancer Caregiving Tasks, Consequences and Needs Questionnaire (CaTCoN). This is a 41-item scale to measure the extent of cancer caregiving tasks and consequences, and the caregivers’ needs (mainly concerning information and communication received during contact with healthcare professionals).64

▸ The Preparedness for Caregiving Scale.65 This is an eight-item questionnaire that assesses how ready caregivers perceive they are for their role. Reliability was acceptable with Cronbach’s α ranging from 0.86 to 0.92.66 Caregiver competence refers to the perceived adequacy of an individual’s performance as a caregiver.

▸ A further bespoke questionnaire will capture core data on use (adherence) and feedback on the educational materials.

Recruitment and retention rates will be reported, and seek to be comparable to or exceed published rates in carer education studies using face-to-face delivery methods (see table 1 below). Consequently, this study aims to determine whether eligibility of around 43% and recruitment which equals or improves on 23–30% is achievable. Retention will be monitored, and compared against the wide-ranging experience of comparable studies.

Analysis plan

Collectively, data will be used to guide the refinement of the educational materials, and inform methodological parameters for a later scaled-up fully powered trial and provide an assessment of the feasibility and acceptability of the approach. Analysis of eligibility, and recruitment rates, will allow for national estimates to be calculated on number of potentially eligible carers across the country.

<table>
<thead>
<tr>
<th>Study</th>
<th>Eligibility</th>
<th>Recruitment</th>
<th>Retention</th>
<th>Confounders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hudson et al70</td>
<td>43% eligibility</td>
<td>23% uptake (15 of 64</td>
<td>87% (retained 13 of</td>
<td>Involved carers of hospitalised patients which may therefore indicate a population with greater time to participate than those caring in their own homes</td>
</tr>
<tr>
<td></td>
<td>(64 carers from 149 admissions)</td>
<td>carers)</td>
<td>15 carers)</td>
<td></td>
</tr>
<tr>
<td>Hudson et al11</td>
<td>Eligibility data not stated</td>
<td>Not stated</td>
<td>59% (retained 44 of 74)</td>
<td>Required carers to attend a palliative care service 3 times</td>
</tr>
<tr>
<td>Hudson et al17</td>
<td>Eligibility data not stated</td>
<td>30% (106 of 358 eligible carers)</td>
<td>25% (27 of 106 retained)</td>
<td>3 time points assessed, with considerable loss to follow-up if all 3 data points are required (45/106 reduced to 27/106)</td>
</tr>
<tr>
<td>Harding et al16</td>
<td>Eligibility data not stated</td>
<td>25% (40/70 carers approached)</td>
<td>36/40 retained in the intervention group at T1 (90%), 24 at T2 (60%) and 15 at T3 (37.5%)</td>
<td>6 weekly sessions of 90 min</td>
</tr>
</tbody>
</table>
The focus group data (phase 1) will be used to generate and comment on the educational materials without being subjected to formal analysis.

As this is a feasibility and proof-of-concept study, formal power calculations and hypothesis testing are not appropriate, as the study is not designed to formally test for difference. Data from the primary and subsidiary outcome measures (phase 2) will be analysed using descriptive statistics, and if adequate data are generated, then basic inferential statistics (paired t-tests) will be used to identify statistically significant changes in outcomes. Multiple imputations will be used if required. These data will be used to inform power calculations for a later fully powered trial. Intention-to-treat analysis will be used. Since this study is a single-armed trial, recruitment estimates will be calculated cautiously, informed both by enrolment in phase 2 and qualitative interview data on recruitment processes in phase 2.

Baseline demographic characteristics will be reported as mean and SD for continuous data and number (percentage) for categorical data. Analysis of the adherence checklist data will proceed using frequency counts to identify elements of the educational materials which are most and least frequently used.

Qualitative interview data from phase 2 will be digitally recorded, transcribed and managed using NVivo (V.10) software. The data will be analysed thematically. Analysis will proceed through a five-stage process of familiarisation, identifying a thematic framework, indexing the data, synthesising across respondents and data interpretation to form key themes. Analysis will be conducted by the chief investigator (a psychooncology researcher), nurse researchers and a social science research assistant. Carer and health professional data will be analysed separately and then synthesised to identify overlapping, complementary and discordant themes, both of which will be reported. Data analysis will focus on identifying features of acceptability and feasibility of the intervention and provide in-depth understanding of the content of the educational material, and trial processes such as the timing of provision of the resources.

Members of the research team will have access to the cleaned data set.

ETHICS AND DISSEMINATION

Any required protocol amendments will be submitted to the Calvary Health Care Ethics Committee. The trial is registered with the Australian New Zealand Clinical Trials Group. All study participants will be asked to provide written consent. Data will be held in locked cabinets and password-protected electronic files. All identifying details will be removed, and replaced with alphanumeric identifiers. Data in paper form will be stored in a locked cabinet in a locked office and destroyed after 5 years. Computerised data will be stored in a password-protected file, destroyed after 5 years. No public access to the data is planned.

Criteria for discontinuing the trial for an individual relate to stated carer burden, or death of the person they are caring for. Carers will self-define burden and consequently decide themselves if they wish to continue. Death of the patient will trigger contact from the research team to offer condolences; the educational package may be retained by the carer or returned depending on their preference. Adverse events will be reported to the ethics committees.

The study was designed with input from former caregivers, who advised on the study design and initial topics to designed and delivered. Carers who are enrolled into the study are covered by indemnity for negligent harm through insurance provided by the study sponsor. Ancillary care will be provided by the hospital, including psychosocial support and pastoral care. Should the study indicate feasibility and acceptability, then a further fully powered trial will be planned to evidence efficacy and findings shared with clinicians, carers and patients through accessible summaries of the study results.

Results will be published in peer-reviewed journals, presented at conferences and a lay summary sent to participants. Authorship will be allocated using the guidelines for authorship defined by the International Committee of Medical Journal Editors.

Steering committee

The study has an international steering committee comprising experts in palliative care education, and distance learning for carers of people with dementia, and national lead bodies for carers (Carers Australia) and palliative care (Palliative Care Australia).

DISCUSSION

This study centralises the need to address the informational needs of informal carers in palliative care community settings. It tests whether a distance-learning approach can address the difficulties of supporting carers to feel supported in their role which have been highlighted in the literature. The longer term aims of this work are to inform a national efficacy trial, of distance-learning approaches to supporting carers to develop and apply caring knowledge and skills, for those unable to attend education sessions in person. If the findings indicate that the concept and approach is acceptable to carers, further modules could be developed, for example, preparing for death/dying, and additional modules for carers of patients with non-malignant conditions.

The proof-of-concept trial will not measure the distal impact of the education on patients through more competent and supported carers, evidenced by reduced patient symptomatology, nor on the patient/carer relationship, which is likely also to be impacted by greater self-efficacy of the carer.
REFERENCES


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