

Protocol for a longitudinal qualitative interview study: maintaining psychological well-being in advanced cancer – what can we learn from patients' and carers' own coping strategies?

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ABSTRACT

Introduction: People with advanced cancer and their carers experience stress and uncertainty which affects the quality of life and physical and mental health. This study aims to understand how patients and carers recover or maintain psychological well-being by exploring the strategies employed to self-manage stress and uncertainty.

Methods and analysis: A longitudinal qualitative interview approach with 30 patients with advanced cancer and 30 associated family or informal carers allows the exploration of contexts, mechanisms and outcomes at an individual level. Two interviews, 4–12 weeks apart, will not only enable the exploration of individuals' evolving coping strategies in response to changing contexts but also how patients' and carers' strategies inter-relate. Patient and Carer focus groups will then consider how the findings may be used in developing an intervention. Recruiting through two major tertiary cancer centres in the North West and using deliberately broad and inclusive criteria will enable the sample to capture demographic and experiential breadth.

Ethics and dissemination: The research team will draw on their considerable experience to ensure that the study is sensitive to a patient and carer group, which may be considered vulnerable but still values being able to contribute its views. Public and patient involvement (PPI) is integral to the design and is evidenced by: a research advisory group incorporating patient and carers, pre-study consultations with the PPI group at one of the study sites and a user as the named applicant. The study team will use multiple methods to disseminate the findings to clinical, policy and academic audiences. A key element will be engaging health professionals in patient and carer ideas for promoting self-management of psychological well-being. The study has ethical approval from the North West Research Ethics Committee and the appropriate NHS governance clearance.

Registration: National Institute for Health Research (NIHR) Clinical Studies Portfolio, UK Clinical Research Network (UKCRN) Study number 11725.

ARTICLE SUMMARY

Article focus

- A qualitative, longitudinal study.
- Explores evolving experience.
- Seeks a patient-centred understanding of lived experience.

Key messages

- Potential development of a self-management intervention.
- Better understanding of patient and carer experiences and needs.
- New application of existing knowledge.

Strengths and limitations of this study

- Creative methodology provides new perspectives and a greater breadth of understanding.
- High potential attrition in a hard-to-reach research population could limit the sample.

INTRODUCTION

People with advanced cancer and their carers experience stress and uncertainty during their illness journey, which affects the quality of life and physical and mental health. These health issues are a burden to patients and carers, and can lead to increased National Health Service (NHS) costs if professional interventions are required. Acceptable, patient-centred and carer-centred, cost-effective interventions to promote the maintenance of well-being are needed.

We know from previous research that coping strategies influence stress, uncertainty and well-being.^{1–6} A pathological model of care predominates, focusing on anxiety and distress, with responses drawn from professionally mediated and led interventions.⁷ However, we also know that individuals can still experience well-being under difficult circumstances⁸ by

self-managing stress and uncertainty using a range of coping strategies.^{9 10}

Nevertheless, this knowledge has not been translated to those with advanced disease, who may use different coping styles compared with those in the earlier stages of illness.^{9 11–13} Perspectives over time are also rare,¹⁴ affecting the understanding of evolving processes and how early coping strategies affect later well-being. Qualitative research is required to gain the patients' and carers' own accounts of enacting successful coping strategies, the interaction between patient and carer strategies, and how individuals and families can be enabled to use effective strategies.

Our aim is to understand how people with advanced cancer and their carers learn about and develop positive coping strategies to self-manage stress and uncertainty in their lives and thus recover or maintain psychological well-being. We will use this information to work with patients and carers to develop and test a patient-centred and carer-centred intervention to enable the shared use of effective coping strategies. Our approach is novel, pragmatic and patient-centred and carer-centred in its focus on self-management of 'well-being' rather than 'ill health'.

Policy background

Research into how to live with cancer is a priority area,¹⁵ with psychological support for patients and carers identified as an unmet need.¹⁶ Guidance focuses on psychological care to deal with problems such as distress and anxiety,^{17–19} with an assumption that professional intervention is required.^{17–19} This pathologises the experience of anxiety, distress and uncertainty in advanced cancer and largely ignores patients' and carers' own coping strategies.²⁰ However, the National Cancer Survivorship Initiative identifies that a shift is needed towards support for self-management, based on individual needs and their assessment,²¹ and informed by research.

Theoretical approaches

Public health interventions are more effective if based on social and behavioural theories.^{22 23} The theory predicts that stress and uncertainty exist in illness situations that are ambiguous, complex, unpredictable and when information is unavailable or inconsistent.²⁴ Theories of uncertainty, stress and coping^{25 26} highlight that although such stressors can adversely affect quality of life,²⁴ they may also be spurs to positive coping. A focus on positive coping strategies to support and maintain well-being in response to stress and uncertainty therefore has theoretical merit.

Research required

A study is thus required which follows patients and carers with advanced disease over time, focuses on successful coping and explores the reality of coping strategies in the context of everyday lives.

METHODS AND ANALYSIS

The study will inform an intervention, following the steps of the Medical Research Council guidance on developing complex interventions.²³ The first stage is to develop the intervention; this is the focus of this protocol. Ultimately, we hope to design a patient-led and carer-led intervention which facilitates the self-management of stressors, promotes well-being and thereby reduces NHS demand.

Aims

Our focus is on understanding from the perspective of patients and carers

- A. What do people do to cope well living with advanced cancer? Why and when do they perceive these coping strategies as effective?
- B. How can healthcare professionals support effective coping strategies?
- C. What would be useful to support self-management and effective coping strategies as the first step in developing a patient-led and carer-led intervention?

Study design

We will use a longitudinal qualitative approach to allow a detailed, rich picture of contexts, mechanisms and outcomes to be explored at an individual level in order to examine why a particular coping strategy worked (or not) for whom and under what circumstances.^{27 28} A longitudinal approach also enables the study of evolving coping strategies in response to changing contexts such as crisis points, and a consideration of how patient and carer strategies inter-relate.

Participants' selection

This study will recruit people (and their informal carers) who are in the advanced stages of their cancer. We will purposively sample participants, using deliberately broad and inclusive criteria.

Patients' inclusion criteria

1. Adults >18 years. No upper age limit.
2. With advanced cancer, defined as those with metastatic disease at diagnosis, and/or where disease is progressing following treatment (local or metastatic spread) and/or where the prognosis is estimated to be less than a year.²⁹
3. Those whom their healthcare professionals judge have the capacity to give informed consent to participate in the research.

Carers' inclusion criteria

1. Adults >18 years. No upper age limit.
2. An informal carer for a patient recruited to the study. This person will be identified by the patient as the person they get most support from, not necessarily a family member.

Recruitment

We will recruit participants through two tertiary cancer centres. The study has been adopted to the UK Clinical Research Network (UKCRN) portfolio, allowing the use

of local National Institute for Health Research (NIHR) research team resources (a research nurse and a data manager) to recruit patients and carers, with the support of the research team. Potential patient participants will be approached face-to-face by the research nurse in the hospital outpatient clinic setting, and if they express an interest in the study, they will be given an information pack about the study (participant's information sheet, reply slip, prepaid reply envelope and information to hand to their nominated informal carer). They will be asked to return the reply slip to the research team, indicating their willingness or otherwise to participate in the study.

To maximise recruitment efficiency, we will identify a key contact at each site. The key contact will liaise with clinical staff to identify potential participants and ensure that recruitment material is available when needed. To optimise the heterogeneity of the sample, we will purposively recruit from clinics in palliative care (to recruit those in the palliative phase with any cancer diagnosis), breast and prostate (to recruit those who have entered an advanced disease phase after initial diagnosis), colorectal (to recruit those diagnosed with advanced disease) and lung (to recruit those with a truncated life expectancy).

We will purposively sample with reference to gender, cancer diagnosis, stage of disease and anticipated prognosis. This will facilitate the exploration of whether stress and uncertainty are experienced or managed differently through the illness trajectory. Recruited patients will be asked to nominate the 'person they get most support from', and provided with an information pack for their identified informal carer. The content of this is, with the exception of the response form, identical to that of the patient pack. To ensure that the researcher is aware of the respondents' status in the study when arranging interview appointments by telephone, carer response forms will be printed on coloured paper. Separate packs will be provided to support individuals' independent decision making on whether to participate.

We plan to recruit approximately 30 patients and their carers over a 12-month period. We wish to maximise our ability to collect longitudinal data at two time points, hence the large initial sample size, as we know that attrition is an issue with this patient population.^{28 30} We will liaise regularly with the research nurses and clinical staff, identifying and approaching potential patient participants to collate outline information about those who were approached but who chose not to participate in the study. This will be limited to gender, age, tumour group (as defined within the study) and clinicians' comments on individuals' immediate response to suggested participation.

Data collection

We will conduct interviews 4–12 weeks apart. Separate interviews with patients and carers will be conducted, although interviews can be jointly held if preferred.

Separate interviews will allow exploration of individual coping styles and how these are constructed and maintained. Joint interviews have the potential to explore how a shared coping style is constructed. We anticipate that most interviews will be conducted in the home setting, but alternatives will be offered if preferred. Written informed consent will be obtained by the interviewer prior to the start of each of the interviews with each of the participants.

The timing between interviews will be determined by participant preference, knowledge of potential future stressors or care transitions (eg, timing of clinic visits), and illness trajectories. There will be a minimum of 4 weeks between interviews and a maximum of 12 weeks. Our current longitudinal research projects demonstrate that a flexible approach to the timing of data collection is preferred by patients and maximises data collection opportunities at a time when participants can be vulnerable. Therefore, to increase retention, a provisional date for the second interview will be agreed at the close of the first visit. This ensures clarity for participants and will be confirmed by telephone 24 h prior to the appointment to ensure that it is still appropriate and convenient.

A topic guide rather than a fixed schedule will guide but not constrain the interviews, ensuring that interviews are driven by participant issues. Interviews will be conversational to aid in developing rapport to explore complex and potentially emotional issues. Interviews will acknowledge that there will be times when people will feel they are coping well, and times when coping is more challenging. Interviews will explore the nature of coping styles used by participants, with the topic guide evolving as categories are discovered through the data collection and analysis. Interviews are likely to last for about an hour, but this may vary depending on the participants.

Topic guide

- A. Summarising experiences as the patient/carer to set agenda, level of disclosure and terminology.
- B. Probing events, that is, Could you tell me a bit more about what happened then? How do you cope with that? Did you get support from anyone at this time? What do you think you learnt from this experience? Have you applied this to any other situation?
- C. As the rapport builds, ask for examples of 'crisis points' or when the participants felt they coped well or not so well and what made these situations different.
- D. Exploring what helps participants to manage/who has been helpful. How participants manage thoughts and feelings. How they develop coping skills.
- E. Expectations of future events and planned coping strategies.
- F. Situations that have happened since the first interview and reflections on coping. Whether they have developed new strategies or adapted previous strategies.
- G. What skills or knowledge would have been helpful to develop coping skills?

Data analysis

Data analysis will be iterative, with initial analytical insights informing further data collection and choice of participants. Interviews will be audio recorded and transcribed, with NVivo used to organise data. Two members of the research team will be involved in in-depth coding of data, with regular discussion of data and its analysis with the study research advisory group. This group includes patient and carer representatives alongside clinical and academic members. As analysis proceeds, the group will use selected, anonymised extracts of both raw data (eg, interview transcripts) and manipulated data (eg, framework matrices produced from coded transcripts) to discuss various aspects to ensure that multiple perspectives are addressed in their interpretation. The Research Advisory Group will also be involved in writing up the study findings for the final dissemination.

Data collection will continue until saturation of data is reached. Transcripts will be analysed line by line to identify themes using the constant comparative method, with two foci for initial analysis. First, individual accounts will be analysed longitudinally,³¹ examining the data for factors which facilitated or hindered coping. Second, accounts will be compared and contrasted between participants. The analysis will focus on effective coping styles and self-management of stressors.

Timescale

The study timescale is shown in [table 1](#).

ETHICS AND DISSEMINATION

Public and patient involvement

Public and patient involvement (PPI) is integral to the conduct of this study, and we have not only incorporated the input of a user as named applicant and the PPI group at one of the recruitment sites, but also set up a research advisory group including patient and carers. This provides a source of valuable experience including recognition that the life-limiting nature of the illness we

are studying means that recruiting patients and carers in advance of study initiation is challenging. Members of the research team will also work alongside patient and carer partners to identify and address specific support or training needs to enable their effective participation.

Ethical issues

Patients with advanced cancer may be vulnerable, with a high symptom burden and poor prognosis, but still value being able to contribute their views,³² and feel that exclusion from research removes autonomous decision-making and choice.³³ The research team will draw on their considerable experience in conducting research in this area to ensure a design sensitive to this patient and carer group. We have worked with patients, carers and clinical teams to discuss the acceptability of the research aims, design and local implementation.

Interviews will be organised at a time and place to suit the participants, and conducted by researchers with experience of discussing sensitive topics. Written consent will be obtained from all participants, and regular checks made that participants are happy to continue. Arrangements will be made to inform participants of support agencies if required.

Research data and patient-related information will be managed in accordance with relevant regulatory approvals. The study has been adopted onto the NIHR Clinical Studies Portfolio under the UKCRN study ID 11725 (2011), ethics approval granted on 12 December 2011 by the North West Regional Ethics Committee under application number 11/NW/0739 and the NHS Research and Development (NHS R&D) approval dated 8 February 2012.

Methods of dissemination of findings

Multiple methods of disseminating the findings to clinical, policy and academic audiences will include a written report of the study for the study funders, Dimpleby Cancer Care, including an executive summary with

Table 1 The planned timescale

	Months	Research activity
Phase 1	1–6	<ul style="list-style-type: none"> ▶ Establish a research advisory group ▶ Plan allocation of resources for staff and equipments ▶ Submit protocol to the North West Research Ethics Committee ▶ Submit protocol for NHS R&D approvals
Phase 2	4–18	<ul style="list-style-type: none"> ▶ Start recruitment at both sites (staggered start dates) ▶ Data collection ▶ Initial interview data analysis
Phase 3	17–30	<ul style="list-style-type: none"> ▶ Complete interview data analysis ▶ Hold focus groups with patients and carers to consider findings in order to identify the basis for potential interventions ▶ Finalise data analysis following focus groups ▶ Write final report for the funder ▶ Develop publications and presentations for dissemination of findings

NHS R&D, National Health Service Research and Development.

clearly identified practice and policy implications to benefit patients, carers and healthcare professionals. We will use open access publishing in high-quality, peer-reviewed journals whose audiences encompass practitioners, managers and policy makers to facilitate dissemination. We will also make conference presentations to maximise our ability to reach and impact appropriate audiences, including practitioner, educational and research partner audiences.

We will work with our local cancer networks to develop dissemination activities such as workshops and training sessions/study days/training events. A key element will be to engage health professionals in the findings from the study. We will work with our patient and carer representatives to begin developing an appropriate intervention, determined by the findings, but which might incorporate elements, such as patient-written/carer-written materials, structured support sessions or integration with a four-tier model of psychological support for level 1–3 practitioners.

Contributors DR is the lead author of this paper with input from CW, principal investigator on the study. CW wrote the original protocol in collaboration with academic and lay colleagues GG, LC, LA, PL and MLW. All authors have read and approved the final version of the manuscript.

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Competing interests None.

Ethics approval North West Research Ethics Committee.

Provenance and peer review Not commissioned; internally peer reviewed.

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