Measuring the impact of extended cancer survival on broader aspects of life and well being:
The PROACT study

Valerie Shilling, Rachel Starkings, Valerie Jenkins, Lesley Fallowfield
Sussex Health Outcomes Research and Education in Cancer (SHORE-C), Brighton and Sussex Medical School, UK

Abstract number:227

Background

As new treatments offer the genuine prospect of extended survival to patients with advanced cancer, 'Quality of Survival' is gaining traction as an important construct to assess.[1]
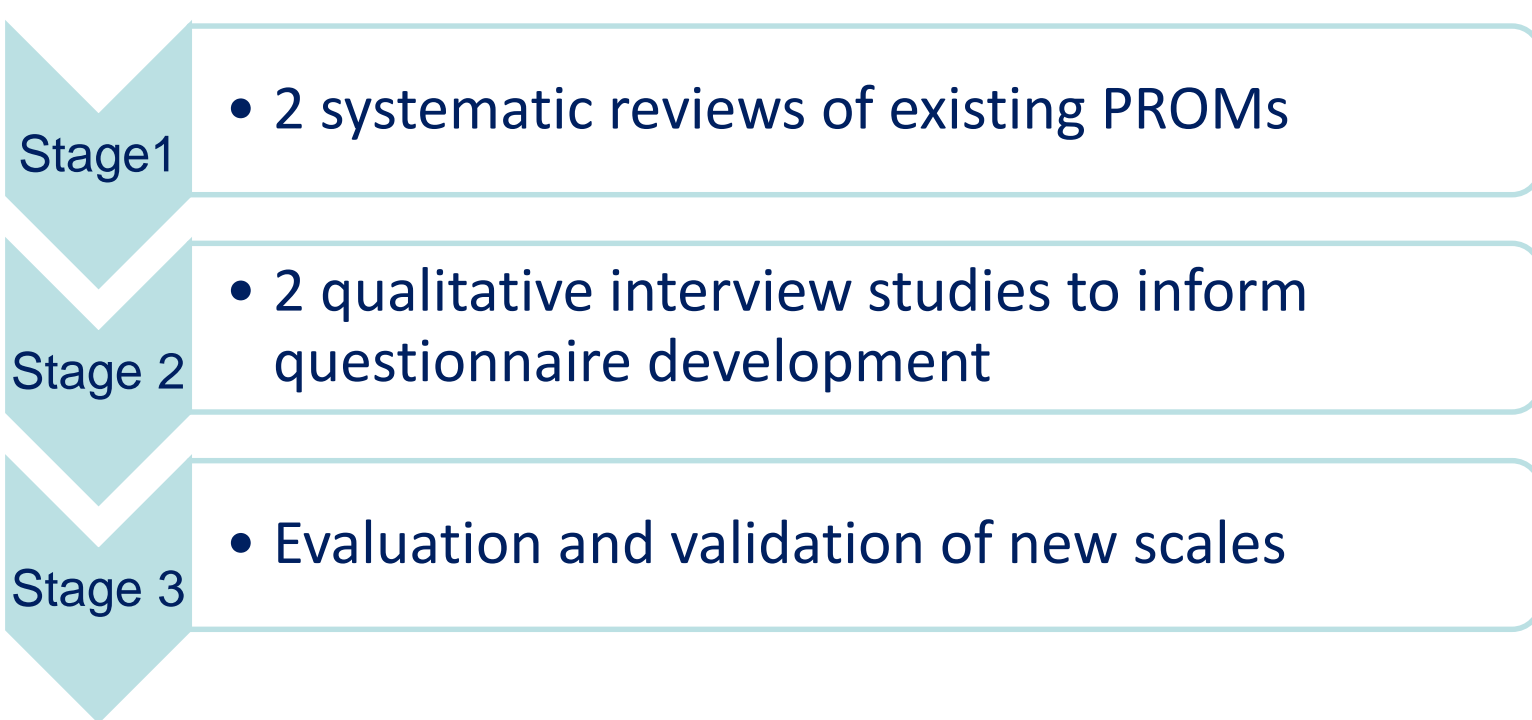
Living with cancer and its treatment affects many aspects of life impacting on roles and responsibilities yet formal assessment of these impacts is not normal practice and there is a need for rigorously developed, well-validated measures for both patients (Pt) and informal caregivers (Cg).

We present an overview of the Patient Reported Outcomes impact of Age and Carer role demands associated with Treatment (PROACT) study, detailing the development of such tools.

Overview

PROACT is a 3 stage project; the primary aim is to develop and evaluate two new scales measuring broad life impacts of cancer and cancer treatment for:

1) **Patients** – our measure is intended to be used alongside generic Health Related Quality of Life Measures such as the FACT-G or the EORTC QLQ-C30

2) **Informal caregivers** – intended to be a standalone measure

- Stage1
  - 2 systematic reviews of existing PROMs
- Stage 2
  - 2 qualitative interview studies to inform questionnaire development
- Stage 3
  - Evaluation and validation of new scales

Patient and Public Involvement

In Stage 2, we worked with 5 people with a lived experience of cancer or who were supporting someone with cancer. They offered advice about and reviewed:

- Topic guides for interview study 1
- Item long lists to test in interview study 2
- Final scales
- The dissemination of findings via a study newsletter

Methods

Stage 1: Systematic reviews

Searches were conducted in MEDLINE, EMBASE, CINAHL and PsycINFO and restricted to English for instrument used and article language.

Abstracts were independently screened by two reviewers against a predefined set of inclusion/exclusion criteria.

Information on studies was systematically extracted and synthesised by one reviewer and checked by another.

Patients
Searches run between Mar 2015 and Jan 2016
Full details: Catt et al doi:10.1007/s11764-016-0580-1

Caregivers
Searches run between Nov 2014 and Jan 2015
Full details: Shilling et al doi:10.1007/s11136-016-1239-0

Stage 2: Qualitative interview studies

Interview study 1

In depth interviews about impact on broader aspects of life and wellbeing.

Thematic analysis used to generate lists of potential scale items to test in study 2.

Interview study 2

Cognitive interviews using a mixture of:

- 'think aloud' technique
- specific probes around comprehension, retrieval, judgement and response

Scale items were revised, added and removed in an iterative fashion through the course of the study.
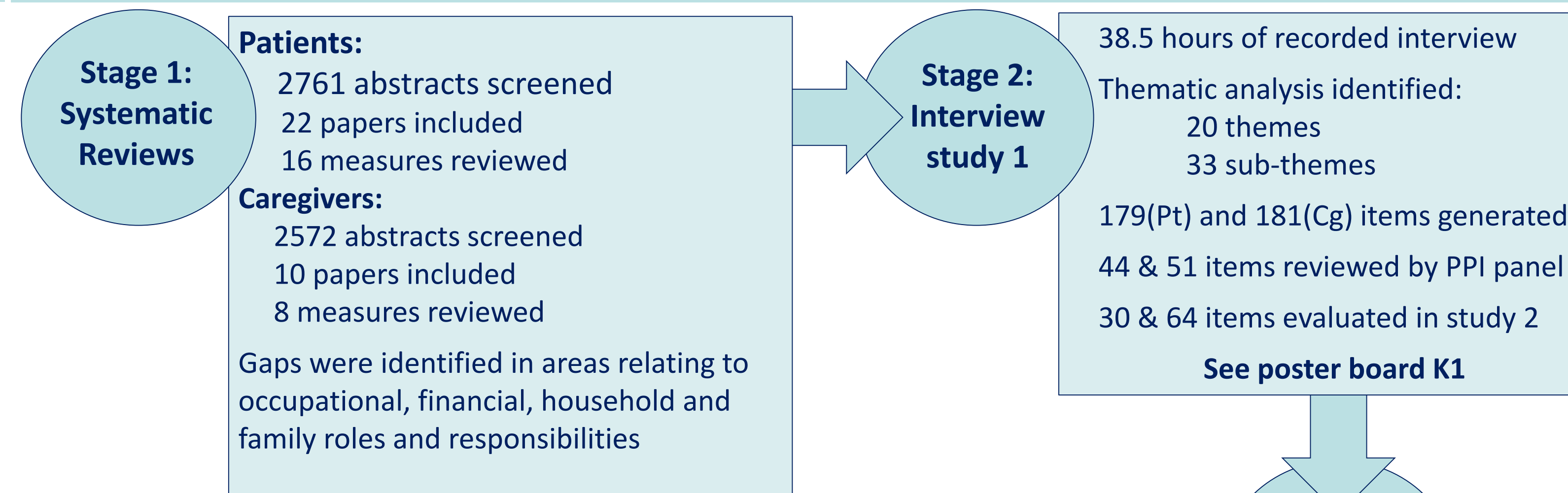
Participant Characteristics

Stage 2: Interview study 1
- 24 Pt-Cg dyads: 9 melanoma, 9 gynae, 6 lung
- Pt age 39-84 median 62yrs
- Cg age 19-85 median 54yrs
- Cgs were partner (N=15), child (N=5), sibling (N=2), friend (N=2)

Stage 2: Interview study 2
- 20 Pt-Cg dyads: 7 melanoma, 6 gynae, 4 lung, 3 breast
- Pt age 39-79 median 63.5yrs
- Cg age 18-76 median 54.5yrs
- Cgs were partner (N= 17), child/child's spouse (N=3)

Results

Stage 1: Systematic Reviews

Patients:
- 2761 abstracts screened
- 22 papers included
- 16 measures reviewed

Caregivers:
- 2572 abstracts screened
- 10 papers included
- 8 measures reviewed

Gaps were identified in areas relating to occupational, financial, household and family roles and responsibilities

Stage 2: Interview study 1

38.5 hours of recorded interview
Thematic analysis identified:
- 20 themes
- 33 sub-themes

179(Pt) and 181(Cg) items generated

44 & 51 items reviewed by PPI panel

30 & 64 items evaluated in study 2

See poster board K1

Stage 2: Interview study 2

51 changes were made to the Pt scale including:
- 4 items deleted
- 3 items added

94 changes were made to the Cg scale including:
- 9 items deleted
- 5 items added

Scales for evaluation in Stage 3

Patients (29 items)	Caregivers (60 items)
Family and home life (N=13)	Family and support (N=12)
Financial wellbeing (N=8)	Relationships and communication (N=7)
Jobs and careers (N=8)	Lifestyle and Outlook (N=12)
	Health and wellbeing (N=14)
	Financial wellbeing (N=6)
	Jobs and careers (N=9)

Example items

Patient Scale	Caregiver Scale	Item on both Scales
I feel responsible for the financial security of my family	*Friends and family have taken on some of my responsibilities at home to give me more time to support (name of patient)*	*I feel supported by my employer*

Summary and Conclusions

- We identified a need for robust measures of broad life impacts of cancer for patients and informal caregivers.
- We have developed 2 such scales which focus in particular on family roles and responsibilities, such as caring for children/grandchildren and financial and employment responsibilities.
- These are currently under evaluation in Stage 3 of PROACT with 120 patient-caregiver dyads across four tumour types.
- Once validated these scales should prove useful to clinicians and researchers, enabling wider ranging and longer term evaluation of new treatments in clinical trials, to aid decision-making about treatment options and supportive interventions.

Acknowledgement

References: [1]Fallowfield L, Nadler E, Abernethy AP, Gilloteau I, Greaney M, Gater A, Orsini L, Subar M, Dastani HB, Lyman GH. Quality of survival (QoS) concept framework to assess the quality of prolonged life in advanced melanoma (MEL): principles and application related to treatment with nivolumab (NIVO)[abstract]. In: Proceedings of the 18th ECCO-40th ESMO European Cancer Congress; 2015 Sept 25–29; Vienna, Austria. Abstract number 3331.