

Developing a psychological support programme for people with cancer who are accessing hospice-based services

Submission date 16/01/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 31/01/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Finding out that cancer is not curable is difficult and upsetting, and better advice and support is needed to help patients to cope with their feelings and emotions. This study aims to better understand what sort of support is helpful at this time. The researchers will develop and test an intervention that we think can help people to better cope with their distress as they move into end of life care. They will then test how acceptable this intervention is for people with an incurable cancer diagnosis, and explore the effect of receiving this intervention on your quality of life and emotional distress.

Who can participate?

People with an incurable cancer diagnosis who have been referred to one of our two trial centres (Marie Curie Liverpool and Marie Curie Edinburgh) for specialist palliative care. Participants need to be over the age of 16 years, and have a life expectancy of four months or more to be involved with this study.

What does the study involve?

The first part of the study includes designing a new psychological intervention based on Acceptance and Commitment Therapy (ACT). In ACT, distress is understood to be a normal reaction to a difficult situation, and ACT supports people to become more resilient and understanding when in distress. The researchers will use existing ACT interventions for other patient groups (it hasn't yet been used in this setting as a brief intervention), adapting these for the palliative care setting. They will then deliver this intervention to 10 to 14 participants in a hospice day-care setting. They will ask participants to complete short questionnaires so that they can understand whether the intervention improves quality of life and reduces distress. Taking part will involve meeting with a psychologist every week for three weeks, and then once more as a follow-up appointment 4-6 weeks later. At the end of the trial, the researchers will ask participants whether they are willing to be interviewed to better understand their experience of taking part in this intervention.

What the possible benefits and risk of participating?

Whilst it is hoped that taking part in the research will be a positive experience for participants, the researchers also understand that talking about their illness and feelings with other people may be upsetting. Before agreeing to take part, participants are advised to consider whether they feel that discussing their illness and their hopes for this final phase of their life is something that they are able and willing to do. It is hoped that participants will benefit from talking about their experiences with the study psychologist who will work with them to provide support and new ways of thinking about their diagnosis.

Where is the study run from?

University of Chester (UK)

When is the study starting and how long is it expected to run for?

June 2016 to June 2019

Who is funding the study?

Macmillan Cancer Support (UK)

Who is the main contact?

Prof Nick Hulbert-Williams

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Contact information

Type(s)

Scientific

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

239683

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 239683; Open Science Framework (Ref: 46033; Date Registered 12/06/2018)

Study information**Scientific Title**

Brief Engagement and Acceptance Coaching in Community and Hospice Settings (The BEACHeS study): Development and pilot testing an evidence-based psychological intervention to enhance wellbeing and aid transition into palliative care

Acronym

BEACHeS

Study objectives

This work aims to develop, and pilot test, a brief, manualised psychological intervention to provide support to people with an incurable cancer diagnosis who are at the transition into specialist palliative care services. The aim is to further explore the feasibility of delivering this intervention within a hospice and community environment, and explore tentative mechanisms and processes of improvement in patient wellbeing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/04/2018, Wales Research Ethics Committee 4 Wrexham (Health and Care Research Wales Support Centre, Castlebridge 4, 15-19 Cowbridge Road, East Cardiff, CF11 9AB ; +44 (0) 2920 785736; tracy.biggs@wales.nhs.uk), ref: 18/WA/0087

Study design

Single-case experimental design employing mixed-methods data collection

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospice

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Quality of life and wellbeing in people with incurable cancer who have been referred to specialist palliative care settings

Interventions

SCED designs do not use a control group; instead each participant acts as their own control through a no-treatment baseline prior to commencement of the intervention.

The Brief Engagement and Acceptance Coaching for Hospice Settings (BEACHeS) Intervention contains five in-person, one-to-one sessions, each lasting 40-60 minutes. Following an initial assessment (session 1), active intervention content is delivered over three subsequent sessions, approximately one week apart. The fifth session, 1 month later, consolidated and maintained gains, and problem-solved difficulties. Active intervention sessions are designed to develop all core-components of Acceptance and Commitment Therapy (ACT) as tailored to this population group.

Intervention Type

Behavioural

Primary outcome measure

Quality of life measured using the FACIT-Pall scale at baseline, weekly through the intervention and at 1-month follow-up

Secondary outcome measures

1. Distress assessed using the single-item Distress Thermometer at baseline, weekly through the intervention and at 1-month follow-up
2. Quality of life assessed using a single-item quality of life question on a daily basis throughout the duration of the trial

Overall study start date

01/06/2016

Completion date

31/07/2019

Eligibility

Key inclusion criteria

1. Incurable cancer diagnosis
2. Received a referral to specialist hospice day or community care services
3. Life expectancy of 4 months or more
4. Over 16 years of age

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

10 to 14 participants

Total final enrolment

10

Key exclusion criteria

1. Under 16 years of age
2. Referred to palliative care for a diagnosis other than cancer
3. Receiving cancer treatment with curative intent
4. Life expectancy of less than 4 months

Date of first enrolment

01/05/2018

Date of final enrolment

30/06/2019

Locations

Countries of recruitment

England

Scotland

United Kingdom

Study participating centre

Marie Curie Edinburgh

Frogston Road West
Edinburgh
United Kingdom
EH10 7DR

Study participating centre**Marie Curie Liverpool**

Speke Road
Woolton
Liverpool
United Kingdom
L25 8QA

Sponsor information

Organisation

University of Chester

Sponsor details

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Sponsor type

University/education

Website

<http://www.chester.ac.uk/>

ROR

<https://ror.org/01drpwb22>

Funder(s)

Funder type

Charity

Funder Name

Macmillan Cancer Support

Alternative Name(s)

Macmillan, Society for the Prevention and Relief of Cancer, Cancer Relief Macmillan Fund, Macmillan Cancer Relief, MCS

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

A primary output from this study will be a published, open-access, delivery manual for the intervention. Although this will not have been robustly efficacy tested, we expect the data from this study may be sufficient to allow health care professionals to choose whether or not they wish to use this immediately.

Findings from this study will be published in peer-review journal articles and at a range of conferences, including palliative care, psychosocial oncology and psychological intervention audiences for maximised impact.

A lay summary will be available for participants and their families and to be circulated to key stakeholder organisations.

Intention to publish date

31/03/2021

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study are not publicly available in accordance with our informed consent agreement with participants. Participant-reported outcome measures are available from Prof Nick Hulbert-Williams (n.hulbertwilliams@chester.ac.uk) on reasonable request in a de-identified format. Individual demographic and clinical information will not be shared as these may identify individual participants. Data will be available immediately after publication of study outcome paper (expected mid 2021) for 3 years from date of release. Data will be available to other researchers or health professionals who may want access to the data for further research questions to be answered, or to inform service-delivery change. The exception will be early access to data for journal editors/reviewers if requested. All other requests will be considered on a case by case basis.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/08/2019	25/01/2021	Yes	No
Results article		25/06/2021	28/06/2021	Yes	No
HRA research summary			28/06/2023	No	No