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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

Registration date
31/01/2021

Overall study status
Completed

Last Edited
06/02/2023

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
n.hulbertwilliams@chester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nicholas Hulbert-Williams

ORCID ID
https://orcid.org/0000-0001-9041-5485

Contact details
School of Psychology
University of Chester
Parkgate Road
Chester
United Kingdom
CH1 4BJ
+44 (0)1244 511950
n.hulbertwilliams@chester.ac.uk

Type(s)
Public

Contact name
Prof Nicholas Hulbert-Williams

ORCID ID
https://orcid.org/0000-0001-9041-5485

Contact details
School of Psychology
University of Chester
Parkgate Road
Chester
United Kingdom
CH1 4BJ
+44 (0)1244 511950
n.hulbertwilliams@chester.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
239683

Protocol serial number
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

Study type(s)
Quality of life

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 developer all core-components of Acceptance and Commitment Therapy (ACT) as tailored to this population group.

Intervention Type
Behavioural

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

Key secondary outcome(s))
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

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

Healthy volunteers allowed

No

Age group
Adult

Sex
All

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
United Kingdom

England

Scotland

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

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

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?
Results article		25/06/2021	28/06/2021	Yes	No
Protocol article	protocol	20/08/2019	25/01/2021	Yes	No
HRA research summary			28/06/2023	No	No