ISRCTN13841211 https://doi.org/10.1186/ISRCTN13841211

The addition of ACT or a talking control to treatment as usual for the management of dysfunction in advanced cancer

Submission date 22/07/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2015	**Overall study status** Completed	
Last Edited 18/08/2023	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-2-talking-therapies-for-people-having-treatment-for-cancer-symptoms-canact

Contact information

Type(s)
Public

Contact name
Dr Marc Serfaty

Contact details
University College London
Department of Mental Health Sciences
Rowland Hill Street
London
United Kingdom
NW3 2PF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18493

Study information

Scientific Title
The addition of ACT or a Talking Control to treatment as usual for the management of dysfunction in advanced cancer: a feasibility randomised controlled trial

Acronym
CanACT

Study objectives
Aim:
To conduct a feasibility randomised controlled trial of the clinical and cost effectiveness of ACT compared to a talking control (TC) or treatment as usual (TAU) in the management of dysfunction in advanced cancer.

Objectives:
1. To test the feasibility of recruitment to/and attrition in people with advanced cancer into a randomised controlled trial of TAU plus ACT compared to TAU plus TC
2. To explore the feasibility of providing a therapist delivered intervention; individual ACT or TC
3. To assess the usefulness and acceptability of a number of clinical and economic outcomes
4. To determine whether data generated from outcomes in this trial support a larger RCT into the clinical effectiveness of ACT in advanced cancer patients
5. To obtain qualitative data about the experience of receiving ACT and TC

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES committee London – Riverside, 04/12/2014, ref: 14/LO/0813

Study design
Randomized; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Topic: Cancer; Subtopic: All Cancers/Misc Sites; Disease: All

Interventions
There are two intervention arms:
1. Treatment as usual (TAU) plus acceptance commitment therapy (ACT)
2. TAU plus talking control (TC)
Interventions will be described in detailed manuals to ensure core components are well defined and replicable. For ACT and TC, up to 8 sessions (each 1 hour) will be offered weekly and delivered within 3 months. Sessions will usually take place in a palliative care day therapy unit but the final 3 may occur at home if requested. Both ACT and TC will be delivered by the same therapist to reduce the effects of non-specific factors (e.g. warmth, professionalism).
1. ACT: a contextual behavioural approach which uses a collection of techniques aimed at increasing psychological flexibility to change outcomes. Psychological flexibility is the ability to persist in valued life activities alongside distressing or unwanted private events. There are two main processes
1.1. Mindfulness and acceptance (cognitive fusion and self as context)
1.2. Commitment and behaviour change (being present, defining valued directions and committed action)
We shall follow the work of Hayes et al (1999) and supplement the approach with the manual "Get out of your mind and into your life" (Hayes and Smith, 2005). Therapists will be familiar with the skills training manual "Learning ACT" by Luoma, Hyes and Walser (2005) and "ACT made simple" by Harris (2009). Psychological flexibility mediates outcomes in chronic pain (Wicksell et al, 2010); acceptance, mindfulness and values each mediate outcomes for generalised anxiety.
2. TC: this promotes use of common factors in therapy by encouraging the therapist to be warm and welcoming, allowing people to ventilate their feelings, feel heard and understood. It specifically discourages focusing on problem areas and stipulates that problem solving should not be attempted. The therapist is trained to adhere to guidelines and this approach has been used previously to control for common factors in therapy.

Intervention Type
Other

Primary outcome measure
FACT-G: A self-report 5 point Likert type scale, consisting of 27 questions taking 5 minutes to complete. It has four well-being domains (physical, social/family, emotional and activity) summed to a total score. With high internal consistency reliability and validity, it is recommended for assessing health-related quality of life in advanced cancer. A low score suggests poorer function. The mean score in a cancer population is 80.9 (SD 17.0). We shall select those with scores below the mean (pilot predicts 80% of population).

Secondary outcome measures
1. Psychological well-being: (5 minutes) Kessler-10 (K10, a 10-item self-report global measure of "psychological distress" in previous 4 weeks, taking 5 minutes to complete
2. Physical function: (5 minutes). Two minute walking test: the distance walked in 2 minutes (walking continuously, in a controlled space, at own speed, using an aid if necessary). One minute sit to stand test: number of times a person can stand up and sit down from a standardised chair over one minute.
3. Process of ACT: (10 minutes) Acceptance and Action Questionnaire II (AAQII): A 10 item scale measuring experiential avoidance that assesses willingness to accept undesirable thoughts and feelings, whilst acting in congruence with personal values and goals
4. Economic measures: (10 minutes)

4.1. EuroQol (EQ5D): A generic utility measure of quality of life consisting of 5-domains and a visual analogue scale, used in cost-effectiveness analysis
4.2. ICECAP-Supportive care measure: A seven item capability index for older people

Overall study start date
01/07/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. A clinical diagnosis of advanced cancer defined as disease not amenable to curative treatment, those with metastases at diagnosis, those at first or subsequent extensive recurrence and those receiving palliative treatments
2.Total FACTG score of < 81
3. Agreement to be randomised
4. Sufficient understanding of English to engage in ACT

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 54; UK Sample Size: 54; Description: 27 controls and 27 intervention.

Total final enrolment
42

Key exclusion criteria
1 Clinician estimated survival of less than 4 months
2. Age under 18 years

Date of first enrolment
01/09/2015

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Marie Curie Hampstead Hospice
Lyndhurst Gardens
London
United Kingdom
NW3 5NS

Study participating centre
St John's Hospice
60 Grove End Road
London
United Kingdom
NW8 9NH

Study participating centre
St. Joseph's Hospice
Mare St
London
United Kingdom
E8 4SA

Sponsor information

Organisation
Camden and Islington NHS Foundation Trust (UK)

Sponsor details
Early Intervention Services
125-133 Camden High Street
London
England
United Kingdom
NW1 7JR

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03ekq2173

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be submitted for publication in September 2015. The main analysis will be produced for publication before the end of the trial end date. Additionally, any qualitative data may also be submitted for publication if possible

Intention to publish date
01/09/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/02/2016		Yes	No
HRA research summary			28/06/2023	No	No

Other publications	Qualitative analysis of sessions	20/05/2022	18/08/2023	Yes	No
Results article		21/12/2018	18/08/2023	Yes	No