

Development and evaluation of a psycho-educational intervention for patients with advanced cancer who have cachexia and their lay carers

Submission date 16/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/01/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 26/09/2014	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

<http://www.cancerresearchuk.org/about-cancer/trials/a-study-help-people-advanced-cancer-who-losing-weight>

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1

Study information

Scientific Title

Development and evaluation of a psycho-educational intervention for patients with advanced cancer who have cachexia and their lay carers: a randomised controlled trial

Study objectives

Patients and lay carers receiving a psycho-educational intervention in addition to standard care will have a clinically significant improvement in psychological well-being compared to those receiving standard care alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Cancer Palliative Care

Interventions

The intervention will comprise a DVD and a follow-up phone call. The content of the DVD has been informed by previous qualitative studies with this patient group which identified the problems and concerns experienced by patients and their lay carers.

The information contained within the DVD will specifically focus on:

1. Managing distress

2. Conflict and arguments over food
3. The psychological impact of appetite and weight loss, including body image
4. Diet and exercise
5. Fatigue management
6. Managing social situations
7. A mindfulness exercise

Scripts highlighting the content of the DVD.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. The effect of the psycho-educational intervention upon the patients psychological well being two weeks after gaining access to the intervention, as measured by the General Health Questionnaire-12 (GHQ)8.
2. The effect of the psycho-educational intervention upon the carers psychological well being two weeks after gaining access to the intervention, as measured the GHQ8.

Secondary outcome measures

1. The effect of the psycho-educational intervention upon the patients and carers level of distress from lack of appetite and weight loss two weeks after gaining access to the intervention, as measured by the Self-reported Eating Related Distress and Weight Related Distress Visual Analogue Scales (VASs) 9 and the patients Self-reported family and friends are pressuring me to eat VAS.
2. The effect of the psycho-educational intervention upon the patients and carers coping mechanism as measured by the COPE questionnaire 11
3. The effect of the psycho-educational intervention upon the carers perception of their readiness for their role two weeks following the intervention, as measured by the Preparedness for Care Giving Scale 12.
4. To explore the usefulness of the intervention for patients who have advanced cancer and cachexia and their lay carers, through conducting qualitative semi-structured interviews with carers three-month post-bereavement.

Overall study start date

01/01/2013

Completion date

31/08/2017

Eligibility

Key inclusion criteria

Participants will be patient carer dyads where the patient has a diagnosis of advanced cancer with cachexia.

1. Aged 18 and over
2. Can read and write English

3. Have a confirmed diagnosis of advanced and incurable cancer
4. Have weight loss which does not have the potential to be reversed
5. Have access to a DVD player

Patients will be asked to nominate a significant other who has observed the difficulties they are experiencing as a result of living with cancer cachexia. Inclusion criteria for the lay carers will include:

1. Aged 18 or over
2. Have regular face to face contact with the patient (at least five times per week)
3. Have access to a DVD player

All participants will be required to provide their written informed consent.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

200

Key exclusion criteria

1. They are not living in their own home
2. They are experiencing symptoms too severe to allow participation
3. They have not had an end of life conversation with a member of the palliative care/day services team
4. They do not have access to a DVD player

Date of first enrolment

01/01/2013

Date of final enrolment

31/08/2017

Locations**Countries of recruitment**

Northern Ireland

United Kingdom

Study participating centre

Queen's University Belfast
Belfast
United Kingdom
BT9 7BL

Sponsor information

Organisation

Queen's University Belfast (UK)

Sponsor details

University Road
Belfast
Northern Ireland
United Kingdom
BT7 1NN

Sponsor type

University/education

Website

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

ROR

<https://ror.org/00hswnk62>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The All Ireland Institute of Hospice and Palliative Care (Ireland)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration