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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	[_] Prospectively registered [_] Protocol
Registration date 08/01/2013	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 26/09/2014	**Condition category** Cancer	[_] Individual participant data [_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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(s)

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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

Northern Ireland

Study participating centre
Queen's University Belfast
Belfast
United Kingdom
BT9 7BL

Sponsor information

Organisation
Queen's University Belfast (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration