ISRCTN23380065 https://doi.org/10.1186/ISRCTN23380065

Exploring the cost effectiveness of Mindfulness Based Cognitive Therapy for Cancer (MBCT-Ca)

Submission date
15/11/2012

Recruitment status
No longer recruiting

Registration date
28/11/2012

Overall study status
Completed

Last Edited
07/12/2017

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Mindfulness Based Cognitive Therapy for Cancer (MBCT-Ca) is a group-based treatment that has been developed for people with cancer. It involves attending one class a week for eight weeks. Each class is led by a trained teacher, includes between 7 and 12 people, and lasts about two and a half hours. During the classes participants learn how to do mindfulness meditation. This would include learning how to pay attention to breath and body, and exercises to help participants become more aware of the moment-to-moment changes in mind and body. The aim of this study is to determine the cost and benefits of delivering MBCT-Ca as compared with patients receiving treatment as usual (TAU) in participants who have received active cancer treatment within the last 12 months.

Who can participate?
Patients aged over 18 from across North Wales who have received active cancer treatment within the last 12 months

What does the study involve?
Participants are randomly allocated to receive an 8-week MBCT-Ca intervention straight away (intervention group) or after a waiting period of about 6-8 months (control group). Participants complete questionnaires on joining the study, after the intervention period and again after a 3-month follow-up. At the end of the study, measures of well being are compared between the two groups to see if there are any differences.

What are the possible benefits and risks of participating?
Participants have the opportunity to participate in a study which can be interesting and which may enable them to feel that they are helping others and that some benefit may come from their difficult experiences. Participants have the opportunity to experience a new treatment /training. This treatment/training is additional to usual treatment. There are no known risks associated with taking part in this study.

Where is the study run from?
Bangor University in collaboration with Betsi Cadwaladr University Health Board (BCUHB) (UK)

When is the study starting and how long is it expected to run for?
Recruitment will start at the end of 2012. Participants will be enrolled on the study for 6-8 months, and recruitment will continue until June 2013 or until 120 participants have completed the study

Who is funding the study?
Tenovus (UK)

Who is the main contact?
Lucy Bryning
l.bryning@bangor.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Lucy Bryning

Contact details
CHEME, IMSCaR
Bangor University
Dean Street
Bangor
United Kingdom
LL57 1UT
+44 (0)1248 388550
l.bryning@bangor.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cost effectiveness of MBCT-Ca delivered in addition to treatment as usual (TAU) as compared with TAU alone: a pilot pragmatic randomised controlled trial

Study objectives

It is hypothesised that MBCT--Ca may be of benefit to cancer patients as a routine intervention with the potential to reduce depression and anxiety and to enhance quality of life (QoL). The null hypothesis is that there will be no difference between groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Wales Research Ethics Committee - West, 20/08/2012, ref: 12/WA/0095

Study design
Pilot prospective randomised single-blinded pragmatic trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Mental health of post-treatment cancer patients

Interventions
The intervention group will receive an 8 week Mindfulness Based Cognitive Therapy for Cancer (MBCT-Ca) course delivered in addition to usual treatment, whereas the control group will continue with their treatment as usual before receiving MBCT-Ca after a wait period of approximately six months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The EQ-5D (EuroQol, 1990) will provide the primary outcome measure of effect required to generate Quality Adjusted Life Years (QALYs) and the CSRI will provide the primary outcome measure of cost. These measures will be used to calculate the cost per QALY to determine the probability that MBCT-Ca is cost-effective.

Secondary outcome measures
1. Number of eligible patients identified by the oncology teams
2. Proportion of patients prepared to accept entry to the randomised pilot study
3. Proportion considered appropriate for MBCT-Ca after orientation by the course teacher
4. Proportion of patients that complete the 8-week course of MBCT-Ca
5. Proportion of patients returning completed forms at each time point up to 4 months after intervention
6. Quantitative measure of quality of life and capabilities to include health related quality of life (HRQoL) assessed by EORTC-QLQ-QC30 and ICECAP-A.
7. Measure of anxiety and depression HADS
8. Measure of participant wellbeing - WHO-5
9. Self compassion short form (SCS-SF)
10. Five Facet Mindfulness Scale short form (FFMS-SF)
11. Teacher Competence Measure (MBI-TAC)

Overall study start date
30/11/2012

Completion date
01/06/2014

Eligibility

Key inclusion criteria
1. Adult patients (aged 18 years and over) who have received (or who are currently receiving) active cancer treatment including surgery, chemotherapy, radiotherapy, hormone therapy or a combination of these within the last 12 months
2. Patients able to attend the course venue weekly to undertake MBCT-Ca

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120. The research aims to inform a sample size for a prospective RCT. The sample size is derived pragmatically.

Key exclusion criteria
1. Patients who have not been offered active treatment for their cancer i.e. those receiving only symptomatic care

2. Patients who are unable or unwilling to complete English language group sessions and questionnaires for reasons of literacy, language or cognitive impairment
3. Patients lacking capacity to give informed consent

Date of first enrolment
30/11/2012

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
CHEME, IMSCaR
Bangor
United Kingdom
LL57 1UT

Sponsor information

Organisation
Bangor University (UK)

Sponsor details
c/o Professor Robert T. Woods
IMSCaR
45 College Road
Bangor
Wales
United Kingdom
LL57 2DG

Sponsor type
University/education

Website
http://www.bangor.ac.uk/

ROR
https://ror.org/006jb1a24

Funder(s)

Funder type
Industry

Funder Name
Tenovus (UK)

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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