

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

<b>Submission date</b> 15/11/2012	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 07/12/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## 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

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**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