ISRCTN93263909 https://doi.org/10.1186/ISRCTN93263909

Mindfulness Intervention for Multiple Sclerosis (MIMS)

Submission date
21/11/2012

Recruitment status
No longer recruiting

Registration date
28/11/2012

Overall study status
Completed

Last Edited
14/12/2017

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Multiple sclerosis (MS) is an incurable, chronic disease of the central nervous system. There is a substantial literature on the challenges of adjusting to MS but few have taken into account the differential challenges for people with relapsing remitting MS and those with a progressive form of the illness. This study focuses on people with progressive type of MS. Mindfulness based courses have been shown to effectively reduce anxiety, depression and pain in patients with chronic physical illnesses. The aim of this study is to assess the effectiveness of an easy to access mindfulness based cognitive therapy (MBCT) course, which aims to reduce distress for people affected by primary or secondary progressive MS.

Who can participate?
You can take part in this study if you have primary or secondary progressive MS, and if you have Internet access. Also, you can take part if you haven't received any formal training in mindfulness methods and if you are not currently receiving any other psychological treatment. This is because we would like to see whether our course is helpful and we won't be able to do so if you have completed similar courses before or if you are receiving additional psychological help. Unfortunately, you won't be able to take part in this study if you have severe problems with concentration because some elements of the course require good attention. Also, in case you are highly distressed, this type of treatment might not be the most appropriate for you. We will discuss these issues with you over the phone before the start of the course and we may suggest an alternative approach for you.

What does the study involve?
The research project will involve a comparison between an 8-week mindfulness course group and a waiting-list (control) group. You will be randomised into one of the two groups and depending on the group you are assigned to you will either join the mindfulness course straight away or in case you are assigned to waiting list group, you will have the chance to join a mindfulness course in 5 months time. The sessions of the mindfulness course will take place once a week for about an hour. Angeliki will facilitate the sessions and 4 more people with progressive MS will take part in the course with you. You will not have to travel for these sessions. The course will be delivered through videoconferences. As part of the programme we will ask you to practice mindfulness meditation regularly using the CDs we will provide you. We

will record the sessions so that we can check that Angeliki is conducting the sessions in exactly the way that was planned. Further, we will ask participants of both groups to fill in questionnaires at three times; a month before the programme starts for the mindfulness course group, when the course finishes and 20 weeks after the course has finished. Participants of the waiting list group will be asked to refrain from taking part in any other mindfulness course during this period. These questionnaires will take about an hour to fill in. You can complete these questionnaires through a website. If you have been assigned to the waiting group, you will not require filling in any extra questionnaires when you start your mindfulness course. At the end of the course, you will be invited to meet with an independent researcher who will ask you about your experiences and your views about the programme. He will arrange a convenient time with you to conduct an informal interview on the telephone for about one hour. The interviewer will not be a member of the team involved in this project. The independent researcher will tape-record your interview and transcribe it omitting your name or any other identifiable information before giving the transcripts to the research team to study it at a later date. Then we will delete the recordings of the interviews. If you want to take part in the mindfulness programme but do not want to do this interview you do not have to. You can also change your mind if you agree to do the interview but decide you no longer want to at a later date.

What are the possible benefits and risks of participating?
We cannot promise the study will help you but the evidence so far show that mindfulness courses are helpful for people with chronic conditions. Further the information we get will help us make the course more relevant to the needs of people with progressive MS. The main disadvantage of taking part is simply the time and effort it will take. It is also possible that exploring issues to do with your illness may be difficult for you. However, mindfulness approaches are designed to help people to feel better and we don't expect that people will feel any worse as a result of taking part. If, through taking part in the research, it becomes clear that you are having any major difficulties (e.g. with depression) we will refer you to further sources of support.

Where is the study run from?
King's College London (UK)

When is the study starting and how long is it expected to run for?
November 2012 to November 2013

Who is funding the study?
MS Society (UK)

Who is the main contact?
Angeliki Bogosian
angeliki.bogosian@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Angeliki Bogosian

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
MIMS trial, v1

Study information

Scientific Title
Pilot evaluation of distance delivered mindfulness based cognitive therapy for people affected by primary and secondary progressive multiple sclerosis

Acronym
MIMS

Study objectives
The aims of the project are:
1. To evaluate the potential efficacy of an 8-week Mindfulness-Based Cognitive Therapy (MBCT) programme for people with progressive MS in terms of improvements in anxiety, depression and quality of life in a pilot randomised controlled trial of people affected by primary and secondary progressive MS.
2. To identify potential process mechanisms of MBCT in progressive MS (i.e. increases in use of mindfulness skills, acceptance, and self-compassion).
3. To assess the potential cost effectiveness of MBCT.
4. To assess people's experiences of the MBCT so that further modifications can be made to the protocol if suggested.
5. To test the methods and trial processes (i.e. retention rates, refusal rates, failure/success rates, drop out, (non) adherence to practice, suitability of eligibility criteria, time and resource problems) to inform a larger scale phase III trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London City Road and Hampstead Research Ethics Committee, 09/10/2012, ref: 12/LO/1394

Study design
Pilot randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Primary and secondary progressive multiple sclerosis

Interventions
Mindfulness based cognitive therapy

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The General Health Questionnaire (Goldberg & Williams, 1988) is designed to measure general levels of distress in people in the community and medical settings. The measure is uncontaminated by the experience of MS related somatic symptoms and a recent study showed the GHQ was the most treatment responsive measure of psychological distress in three discrete MS samples (Hobart, Riazi, Lamping, Fitzpatrick, & Thompson, 2005).

Secondary outcome measures
1. Self-efficacy for managing chronic disease (Lorig et al., 1996). This is a brief 6-item scale. We chose this scale, as it is much less burdensome for participants and it covers several domains relevant to many chronic illnesses, including MS, symptom control, role function, emotional functioning and communicating with health professionals. This scale has been used to previous psychological clinical trials (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001).
2. Pain intensity will be assessed with a numerical rating scale (Price, Bush, Long, & Harkins, 1994) (scaled from 0 to 10) addressing the average pain, which is associated with MS according to the patient's point of view. Thereby, 0 represents no pain and 10 the most painful sensation

imaginable.
3. Fatigue Severity Scale (FSS; (Krupp, LaRocca, Muir-Nash, & Steinberg, 1989) is a 9-item widely used scale. It assess the impact of fatigue in the daily living of patients with three items related to physical impact, three items to the psychological environment and the remainder three are more generic (Bergamaschi, Romani, Versino, Poli, & Cosi, 1997). The FSS has been chosen to measure fatigue in many MS studies (Bergamaschi et al., 1997; Flachenecker)
et al., 2002; Leocani et al., 2001) and clinical trials (Krupp et al., 1995; Montalban et al., 2002)
4. Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983). This scale has been found to be effective in assessing the symptoms of severity of anxiety and depression in both secondary and primary care patients (Herrmann, 1997).
5. Multiple Sclerosis Impact Scale (MSIS-29; Hobart et al., 2001). This scale measures the physical (20 items) and the psychological (9 items) impact of multiple sclerosis. MSIS-29 scales have shown good variability, small floor and ceiling effects, high internal consistency and high test-retest reliability (Hobart et al., 2001; Hobart et al., 2005).

Overall study start date
26/11/2012

Completion date
30/11/2013

Eligibility

Key inclusion criteria
1. Participants must be diagnosed with primary progressive or secondary progressive MS by a neurologist and defined as people with MS with documented decline in neurological function for a period of a year or more without relapses
2. Participants must have internet access at home
3. Participants must have significant level of distress determined by a score of greater than 3 on the General Health Questionnaire (GHQ-12); (Goldberg & Williams, 1988). This cut-off score was determined following recommendations for MS (Lincoln et al., 2011; Nicholl, Lincoln, Francis, & Stephan, 2001) that participants scoring 3 or above in total were classified as having clinically significant distress.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Participants who have severe cognitive impairment that would make participation in the MBCT and home practice of mindful meditation problematic or distressing. This will be assessed using the Telephone Interview for Cognitive Status-Modified (TICS-M, (Brandt et al., 1993).

People with a score of less than 20 will be excluded.
2. Participants who have high suicide risk, in which case their needs are more appropriately addressed by a referral to another psychological service (e.g. psychiatrist, clinical psychologist, MS special mental health nurse). This will be assessed using the Clinical Outcome of Routine Evaluation (CORE-10; (Evans et al., 2002). People with a score above 20 will be excluded and referred to further support.
3. Participants who have serious psychological disorders for which MBCT would be inappropriate (including psychotic disorders or active substance abuse problems)
4. Participants who have severe hearing impairment
5. Participants who are currently participating in other psychological therapies
6. Participants who have prior formal training in mindfulness methods

Date of first enrolment
26/11/2012

Date of final enrolment
01/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Hodgkin Building
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Sponsor type
University/education

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ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Charity

Funder Name
MS Society (UK) ref: 961/11

Alternative Name(s)
Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2015		Yes	No