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MIA-MS: The effectiveness of an online mindfulness based cognitive therapy intervention programme in improving well-being in people with multiple sclerosis

Submission date
28/01/2013

Recruitment status
No longer recruiting

Registration date
24/04/2013

Overall study status
Completed

Last Edited
20/01/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Due the nature of the illness, people with Multiple Sclerosis (MS) can be prone to psychological problems such as stress, anxiety and depression. This can also result in exacerbation of physical symptoms. It is therefore important for people with MS to take care of their psychological health as well as their physical symptoms. Cognitive Behavioural Therapy (CBT) has been proven to improve well-being in people with MS. Recent research has taken a slightly different approach to traditional face-to-face CBT by delivering such interventions to people with MS over the telephone and have obtained promising results. It is suggested in the literature that mindfulness based interventions that incorporate elements of CBT may also be a way to positively influence health outcomes in people with MS through awareness and acceptance of their illness. Mindfulness based interventions such as the one in this study have been found to be effective in people with other health problems. This study aims to see if it can also work well for people with MS. This study aims to deliver a 4 week online Mindfulness Based Cognitive Therapy (MBCT) programme to people with MS with aim of improving well-being.

Who can participate?
This study aims to recruit between 50 and 100 people with a self reported probable or definite diagnosis of MS based on medical opinion. Participants will be over 18. Participants will be recruited on online MS support forums.

What does the study involve?
Adverts will be placed on online MS forums inviting people to take part. People who wish to find out more will be directed to an information sheet. People who are interested in taking part will then consent to taking part and answer a questionnaire including questions about their MS status, views about their illness, mindfulness, and well-being. Half of the eligible participants will be randomly allocated to take part in the programme straight away and the other half will be placed on an 4 month waiting list before taking part in the programme. The programme will be delivered online and consists of 12 sessions accessed 3 times a week over a 4 week period. Each

session consists of a video presentation of a given topic. At the end of the presentation participants will take part in a meditation session alongside an audio presentation. Participants are encouraged to continue to use the exercises outside of the sessions. Once the programme is completed, participants will complete the same questionnaire again to see if improvements in well-being have occurred since beginning the programme. Those in the waiting list will also complete the same questionnaire and these results will be compared to those who took part in the programme. There will then be a 4 week follow-up period before completing the questionnaire again. This is to see if the effects of the programme are lasting. After the follow-up, those in the waiting list group will be invited to take part in the programme. A year after completing the programme participants will be invited back once more to complete the questionnaire to see if the participants are still using the exercises and if they have been helpful long term.

What are the possible benefits and risks of participating?
The aim of the study is to improve well being in people with MS. It is hoped that this programme will do so. Participants will learn skills that they can continue using in their daily life even after taking part in the study.
Questions are asked about participants well being which may cause some distress. If participants feel uncomfortable answering such questions they may withdraw from the study and seek further help. Advice is given of where to seek such help. The meditation exercises are fairly passive relaxation exercises that do not require much movement and so are suitable for people who may have physical disabilities. Participants are made aware that if they do feel discomfort beyond what is normally acceptable as a result of doing such exercises then they should stop. Participants are able to withdraw at any time and are made fully aware of this.

Where is the study run from?
National University of Ireland, Galway, Republic of Ireland.

When is the study starting and how long is it expected to run for?
It is anticipated that the advert will go out on the online forums beginning of February 2013. The advert will be available for approximately 8 weeks. The initial study will take approximately 16 weeks, followed by a 1 year follow up.

Who is funding the study?
National University of Ireland, Galway, Republic of Ireland.

Who is the main contact?
Dr Brian McGuire
brian.mcguire@nuigalway.ie

Study website
http://mia-ms.cloudaccess.net/

Contact information

Type(s)
Scientific

Contact name
Dr Brian McGuire

Contact details
Clinical Psychology Programme
NUI Galway
2nd Floor, Woodquay Court
Galway
Ireland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effectiveness of an online mindfulness based cognitive therapy intervention programme in improving well-being in people with multiple sclerosis: a randomised controlled trial

Acronym
MIA-MS

Study objectives
People who take part in the online intervention will experience significant improvements in stress, anxiety and depression and coping compared to people in a wait list control group.

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)
Other

Study type(s)
Treatment

Participant information sheet
http://mia-ms.cloudaccess.net/information.html

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
After completing the baseline/screening questionnaire participants will be randomly allocated to the intervention or a 4 month waitlist control group.

Intervention group: 12 sessions; 3 a week over a course of 4 weeks. The intervention will be delivered online and will have links to the 12 sessions as well as details to contact us, outside support they can seek, the original participant information sheet as well as a diary to download and complete as they progress through the sessions. Participants will be e-mailed 3 times a week with a link to the session that they are to complete next. Each session consists of a PowerPoint presentation with audio voiceover elaborating on the PowerPoints. Sessions also include activities that participants are encouraged to take part in, in their own time. Following the PowerPoint presentation there is an audio meditation exercise. Participants are encouraged to continue to practise these exercises in their own time also. Each session takes about 30-40 minutes to complete.

Waitlist control group: This group will not actively be doing anything in relation to this study during this time.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Depression, Anxiety and Stress and coping measured on self report questionnaires, Depression, Anxiety and Stress Scales (DASS), Coping with Multiple Sclerosis Scales (CMSS)

Both primary and secondary outcomes will be measured at baseline, before commencing the intervention programme or wait list wait. The same measurements will be obtained at 4 weeks (after completing the intervention programme/wait list) and again at a 4 week follow-up for both groups. Participants will be invited to answer a questionnaire at longer follow at 3 months. Participants in the waitlist control group will be invited to take part in the intervention at this point. In addition to the above listed assessment time point, those who complete the intervention and follow-up will be followed up at 1 year.

Secondary outcome measures
Mindfulness, illness perceptions measured on self report questionnaires (Cognitive and Affective Mindfulness Scale Revised (CAMS-R); Illness Perceptions Questionnaire - Revised (IPQ-R)

Overall study start date

10/02/2013

Completion date
10/08/2014

Eligibility

Key inclusion criteria
1. People self reported probable or definite diagnosis of multiple sclerosis based on medical opinion.
2. Participants will be over 18 and not currently experiencing symptoms of psychosis.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
At least 64 (32 in each group)

Key exclusion criteria
1. People without a probable or definite diagnosis of multiple sclerosis
2. People under 18

Date of first enrolment
10/02/2013

Date of final enrolment
10/08/2014

Locations

Countries of recruitment
Australia

Canada

Ireland

United Kingdom

United States of America

Study participating centre
Clinical Psychology Programme
NUI Galway
2nd Floor, Woodquay Court
Galway
Ireland
-

Sponsor information

Organisation
National University of Ireland, Galway (NUIG) (Ireland)

Sponsor details
Psychology Department
University Road
R. O. I
Galway
Ireland
-

Sponsor type
University/education

Website
http://www.nuigalway.ie/

ROR
https://ror.org/03bea9k73

Funder(s)

Funder type
University/education

Funder Name
National University of Ireland Galway, R. O. I (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