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An evaluation of an online mindfulness programme for people with multiple sclerosis

Submission date
30/01/2018

Recruitment status
No longer recruiting

Registration date
07/03/2018

Overall study status
Completed

Last Edited
16/11/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

IBackground and study aims
Multiple Sclerosis (MS) is a lifelong disease of the nervous system (i.e. the brain, spinal cord and optic nerves). Symptoms can vary from mild sensational problems such as tingling to severe disability. The cause is currently unknown and there is no cure. MS typically develops between the ages of 20 and 40 and is twice as common in women as men. Approximately 2.3 million people worldwide have a diagnosis of MS. MS is typically diagnosed in young to mid-adulthood, at which age, family and career are very important. Potential disruptions to social relationships due to mobility issues, sexual dysfunction and financial problems following employment issues can further impact on emotional wellbeing in people with MS. It is therefore not surprising that people with MS report feeling depressed, anxious, distressed, tired and in pain. Thus, the psychological well-being of people living with MS is also of great importance. Research indicates that mindfulness interventions have been found to alleviate MS-related symptoms. Mindfulness has been defined as 'paying attention, in a particular way; on purpose, in the present moment and non-judgmentally' and thus, can encourage more positive coping responses. The aim of this research is to develop an online mindfulness programme for people living with MS.

Who can participate?
Adults aged 18 and older who are diagnosed with MS.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the MindfulnessforMS programme which consists of eight weekly sessions. Participants are contacted in order to be motivated to continue with the programme. Those in the second group are on a waiting list until after those in the first group are finished the progeamme. Participants are followed up at a three month follow up to assess their distress levels, severity of their symptoms, pain, anxiety symptoms, health-related quality of life and other aspects.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in the quality of life, well-being and other MS-related symptoms. There are no direct risks associated with participating.

Where is the study run from?
Centre for Pain Research (Ireland)

When is the study starting and how long is it expected to run for?
March 2016 to February 2019

Who is funding the study?
Irish Health Research Board and the Medical Research Charities Group Joint Funding Scheme (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
MRCG-MSIRELAND/HRB-14-07-2016

Study information

Scientific Title
Comparing the clinical- and cost-effectiveness of an internet-delivered mindfulness-based program with waitlist controls among adults with progressive MS

Study objectives
1. The online mindfulness based intervention will reduce distress for people living with either primary or secondary progressive MS
2. The online mindfulness based intervention is a clinically- effective and cost effective programme for people living with primary or secondary progressive MS

Ethics approval required

Old ethics approval format

Ethics approval(s)
National University of Ireland Galway Research Ethics Committee, 11/05/2017

Primary study design
Interventional

Study design
The design is a single-blind randomised controlled trial comparing the effects of an internet-delivered mindfulness training intervention with a waitlist control condition for people living with MS. Participants will be assessed at three time points: baseline, post-intervention and 3-month follow up. Any modifications to the protocol which may impact on the conduct of the study will require a formal amendment to the protocol. Such amendment will be agreed on by the Irish Health Research Board and the Medical Research Charities Group Joint Funding Scheme (MRCG-MSIreland/HRB-14-07-16) research group and approved by the relevant ethics committee prior to the implementation of the modifications. Minor administrative changes to the protocol will be agreed on by the Irish Health Research Board and the Medical Research Charities Group Joint Funding Scheme (MRCG-MSIreland/HRB-14-07-16) research group and will be documented in a memorandum

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple Sclerosis (MS) is a chronic, lifelong disease of the nervous system characterised by demyelination of the nerve cells in the central nervous system. Demyelination is irreparable and can occur anywhere in the nervous system; thus, it is associated with any number of symptoms, depending on where the damage is located (Mohr & Cox, 2001). The cause of MS is currently unknown and there is no cure.

Approximately 2.3 million people are diagnosed with MS worldwide (National Multiple Sclerosis Society, 2012), with diagnosis twice as common in women as men. MS typically manifests between the ages of 20 and 40, with a sudden onset of symptoms - sometimes with large gaps of remission, while other cases are characterised by continuous deterioration. Symptoms can vary from mild sensational problems (e.g. tingling) to severe disability. However, due to the often physiologically disabling nature of the illness, MS has long been associated with poorer wellbeing and characterised by a number of psychological impacts. For example, the stressful nature of MS symptoms has been linked with depression (Matson & Brooks, 1977), affecting up to 50% of people living with MS in their lifetime (Feinstein, 2011). Furthermore, psychological issues could be responsible for further relapses and exacerbations of symptoms (Ackerman et al., 2002).

Interventions
The intervention consists of eight online, mindfulness-based sessions over an 8-week period. The content of the mindfulness sessions have been developed specifically for people living with MS and qualitative data obtained from participative health research workshops with MS patients and MS-specialist nurses (conducted by our Centre for Pain Research) for online delivery.

The focus of the therapy is mindfulness-based distress reduction with the addition of cognitive therapy exercises (e.g. exploring individual thoughts regarding MS and how these thoughts

relate to anxiety and low mood); and the programme consists of information, in-session activities, relevant mindfulness metaphors and mindfulness exercises. The MindfulnessforMS intervention has been developed into an online format by a postdoctoral psychologist who has expertise in both the mindfulness approach and developing online psychological treatment interventions (CPD), under the supervision of a licensed clinical psychologist (BEM). The experimental treatment will be hosted on a Centre for Pain Research managed website, and the programme will be delivered via an interactive online platform.

Over the course of the trial, those participants in the experimental group will be prompted to complete each weekly session by a reminder sent to their email via the online platform. Participants receive an email after each completed session, thanking them for completing each session, notifying them of the availability of the next session, to motivate participants to continue with the programme and to provide them with some contact time with the researchers should they have any questions. The emails are structured to maintain the participant sample, avoid participant attrition and facilitate the programme's utility; the emails are not part of the treatment regimen. Adherence to the trial intervention will be monitored automatically via the online delivery platform and adherence to the trial assessments will be monitored via the online survey provider. If a participant wishes to discontinue their assigned intervention, access to the intervention will be withdrawn from the participant and this will be reported as attrition. However, in an attempt to enable follow-up data collection and prevent missing data, the study participant are retained in the trial whenever possible.

Overview of the online MindfulnessforMS intervention programme
1. Introduction to Mindfulness: This includes an introduction to the online programme and concept of mindfulness, initial expectations for programme recorded, mindfulness of Body and Breath guided exercise and the practice record sheet is provided.
2. Auto Pilot: This session discusses awareness as alternative to being "on autopilot". It also goes through body scan guided meditation and the practice record sheet is provided.
3. Pleasant Events: This session discusses regaining freedom by removing judgment and blame, goes through mindful Movement guided meditation and the practice record sheet and the pleasant events diaries are provided.
4. Dealing with Barriers: This includes recognising the difference between reality and the ideal world, breathing and body guided mediation, and the practice record sheet and unpleasant events diaries are provided.
Halfway Recap: This is a session available immediately after Session 4, that reviews sessions so far. It asks for reflection on what is being learnt and what participants can do to get the most out of the remaining sessions.
5. Staying Present: This session discusses staying present in light of negative emotions, goes through sounds and thoughts guided meditation and the practice record sheet is provided.
6. Acceptance: This session discusses the practice of noticing and observing the present state instead of trying to change it. It explores difficulty guided meditation, and the practice record sheet and difficulty engagement diaries are provided.
7. Thoughts are not Facts: This introduces Warning Signs and Plans of Action as dictators of responses, befriending guided meditation, and the practice record sheet and black box worksheets are provided.
8. How Best to Take Care of Myself: This session recaps programme, encourages making time to focus on oneself, being aware accepting rather than controlling. It also returns to initial expectations and reflection on lessons learnt. It goes through three Minute Breathing Space guided meditation and the practice record sheet is provided.

Participants allocated to the waitlist control condition do not receive the internet-delivered MindfulnessforMS intervention at that time. They are contacted and advised that they have

been allocated to the waitlist control group, at which time they are given an opportunity to ask questions regarding the trial. The start dates of controls are recorded and they are contacted by email with links to the further online assessments. All participants, including the waitlist control group, are offered the opportunity to utilise the online MindfulnessforMS intervention after the 3-month follow-up assessment.

Intervention Type
Behavioural

Primary outcome(s)
General levels of distress are measured using the 12-item General Health Questionnaire (GHQ-12) at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up

Key secondary outcome(s)
1. Severity of current symptoms of depressive disorders are measured using the Beck Depression Inventory (BDI) 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
2. Pain severity and the degree of interference with function is measured using the Beck Pain Inventory short form (BPI-SF) at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
3. Health-related quality of life measured using the EQ-5D at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
4. Impact of fatigue in the day-to-day functioning of patients is measured using the fatigue severity scale (FSS) at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
5. Anxiety is measured using the Generalised anxiety disorder 7-item scale (GAD-7) at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
6. Health related quality of life is measured using the medical outcomes short form-12 at 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
7. Physical and psychological impact of MS is measured using the Multiple Sclerosis Impact Scale (MSIS-29) 3 time points such as week immediately pre intervention, during the week post intervention and at 3 month follow up
8. Medication and health service use is measured using the client service receipt inventory (CSRI) at baseline, post-treatment and follow up

Completion date
01/05/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or more
2. Diagnosis of primary or secondary progressive MS
3. Internet access
4. Not currently undergoing any form of psychological treatment
5. First language English
6. Resident in Ireland, not currently experiencing a psychotic illness and/or cognitive impairment.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Participants undergoing any form of psychological treatment
2. Participants experiencing a psychotic illness and/or cognitive impairment
3. Participation in any other form of psychological intervention in addition to the study intervention is prohibited during the trial

Date of first enrolment
01/06/2018

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Ireland

Study participating centre
Centre for Pain Research
National University of Ireland
Galway
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Sponsor information

Organisation
Irish Health Research Board and the Medical Research Charities Group Joint Funding Scheme

ROR
https://ror.org/003hb2249

Funder(s)

Funder type
Charity

Funder Name
Irish Health Research Board and the Medical Research Charities Group Joint Funding Scheme

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from the study contact.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes