ISRCTN10423371 https://doi.org/10.1186/ISRCTN10423371

Effectiveness of a Multiple Sclerosis (MS) specific psychological intervention for depression and anxiety in those newly diagnosed with MS

Submission date
07/04/2016

Recruitment status
No longer recruiting

Registration date
28/04/2016

Overall study status
Completed

Last Edited
20/12/2016

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is one of the most common diseases of the central nervous system (brain and spinal cord). Healthy nerves are coated in a fatty casing (myelin sheath) which helps messages to travel quickly and smoothly along nerves. When a person is suffering from MS, the immune system, which normally helps to protect against infection, attacks the myelin sheath, stripping it from the nerves (demyelination). This demyelination means that messages cannot travel along the nerves effectively, causing a range of disturbances including loss of vision, problems with balance and coordination and weakness in the arms or legs. Depression is very common in people with MS and has been reported to be particularly bad at the time of diagnosis or the early stages of the disease. Cognitive behavioural therapy (BCT) is a type of taking therapy which works by changing the way a person thinks and behaves. There is currently little to no research looking at the effectiveness of CBT in the treatment of depression in the first two years following diagnosis. The aim of this study is to evaluate the effectiveness of an eight week course of tailored CBT for people with MS suffering from depression.

Who can participate?
Adults with MS who are suffering from depression.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in an eight week face to face course of CBT based therapy. His involves weekly sessions lasting for two hours (1.5 hours for the first session), and help to improve quality of life, sleep difficulties, MS illness acceptance, active coping skills, social support and resilience. Those in the second group receive treatment as usual for the duration of the study. At the start of the study and then again after 8 ad 20 weeks, participants in both groups complete a range of questionnaires in order to assess their depressive symptoms and quality of life.

What are the possible benefits and risks of participating?
Participants may benefit from improvement in their depressive symptoms. There are no notable risks involved with taking part in the study.

Where is the study run from?
Royal Melbourne Hospital (Australia)

When is the study starting and how long is it expected to run for?
October 2011 to December 2016

Who is funding the study?
University of Melbourne (Australia)

Who is the main contact?
Dr Litza Kiropoulos

Contact information

Type(s)
Public

Contact name
Dr Litza Kiropoulos

Contact details
Melbourne School of Psychological Sciences
University of Melbourne
Victoria
Melbourne
Australia
3010

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A pilot randomised controlled trial of a tailored cognitive behavioural therapy based intervention for depression in those newly diagnosed with multiple sclerosis

Study objectives
Primary aim:
To assess the efficacy of a tailored 8-week individualised CBT intervention in the treatment of depressive symptoms in individuals who are within 2 years of a multiple sclerosis diagnosis.

Secondary aim:
To examine improvements in levels of anxiety, fatigue, pain, sleep quality, quality of life, coping,

MS illness acceptance and resilience at post and 20 week follow up time points and to evaluate satisfaction and adherence to the tailored intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Melbourne Health Human Research Ethics Committee 11/10/2011, ref: 2011.112

Study design
Single-centre pilot parallel group randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Depression in multiple sclerosis

Interventions
Participants are randomly assigned using a computer generated random numbers table using an allocation ratio of 1: 1 to 1 of the 2 treatment groups.

Intervention group: The tailored intervention is an 8-week face to face cognitive behavioural based intervention aimed at decreasing the level of depression (primary outcome), anxiety, fatigue and pain impact and to contribute to improvements in levels of quality of life, sleep difficulties, MS illness acceptance, active coping skills, social support and resilience (secondary outcomes) in those newly diagnosed with MS. All sessions (apart from the first session which is 1.5 hours) are 1 hour in duration.

Control group: Those allocated to the treatment as usual (TAU) do not obtain any psychological treatment for depression or anxiety for the duration of their involvement in the trial (20 weeks). Individuals receive usual medical care from their neurologist which may include up to 3 visits for medication review during the course of involvement in the current trial.

Participants in both groups are followed up at 8 and 20 weeks.

Intervention Type
Behavioural

Primary outcome(s)
Level of depression measured with the Beck Depression Inventory-2 at baseline, 8 and 20 weeks.

Key secondary outcome(s))
1. Level of anxiety measured with the State Trait Anxiety Inventory at baseline, 8 and 20 weeks
2. Level of fatigue impact with the 5-item Modified Fatigue Impact Scale at baseline, 8 and 20 weeks
3. Level of pain impact on mood and behaviour measured with the Pain Effects Scale (PES) at baseline, 8 and 20 weeks

4. Multiple Sclerosis related quality of life measured with the Multiple Sclerosis Quality of Life at baseline, 8 and 20 weeks
5. Sleep quality was measured with the Pittsburgh Sleep Quality Index at baseline, 8 and 20 weeks
6. Coping was measured with the Ways of Coping questionnaire at baseline, 8 and 20 weeks
7. Acceptance of MS illness was measured with the Acceptance of Chronic Health Conditions Scale at baseline, 8 and 20 weeks
8. Level of social support was measured with the Perceived Social Support Scale at baseline, 8 and 20 weeks
9. Level of resilience was measured with the Resilience Scale for Adults at baseline, 8 and 20 weeks
20. Level of therapeutic alliance was measured with the Helping Alliance Questionnaire-Version 2 at 8 weeks
11. Acceptance of the CBT based intervention was measured with a 5-item measure developed by the first author at 8 weeks
12. Patient satisfaction with the CBT intervention was measured with an 18-item Patient Satisfaction Questionnaire designed by the first author at 8 weeks

Completion date
01/12/2015

Eligibility

Key inclusion criteria
1. Having a definite diagnosis of MS from a neurologist
2. Scoring at least 10 on the Beck Depression Inventory-2 (BDI-2)
3. Not currently undertaking other psychological treatment for depressive and anxiety symptoms for the length of participation in the current trial
4. Speak English fluently
5. No current or lifetime diagnosis of psychosis
6. No current substance dependency
7. No gross cognitive impairment
8. No changes to medications prior and during involvement in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. No definite diagnosis of MS by a neurologist
2. Currently undertaking other psychological treatment for depressive and anxiety symptoms
3. Not able to speak English fluently
4. Current or lifetime diagnosis of psychosis

5. Current substance dependency
6. Gross cognitive impairment
7. Changes to medications prior or during involvement in the trial

Date of first enrolment
01/10/2013

Date of final enrolment
01/10/2014

Locations

Countries of recruitment
Australia

Study participating centre
Royal Melbourne Hospital
300 Grattan Street
Melbourne
Australia
3050

Sponsor information

Organisation
University of Melbourne

ROR
https://ror.org/01ej9dk98

Funder(s)

Funder type
University/education

Funder Name
University of Melbourne

Alternative Name(s)
University of Melbourne in Australia, The University of Melbourne, Melbourne University, UNIMELB

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/12/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes