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An early tailored cognitive behavioural therapy intervention for depression in individuals newly diagnosed with multiple sclerosis

Submission date
05/09/2017

Recruitment status
No longer recruiting

Registration date
20/10/2017

Overall study status
Completed

Last Edited
08/08/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Multiple sclerosis (MS) is a condition that causes a wide range of different symptoms, from vision, arm and leg movements, balance or sensation. It can cause mild to serious disabilities. Compared to other chronic diseases and neurological (brain) disorders, rates of depression in individuals with MS is high, in particular around the time of diagnosis. To our knowledge there is no research, in Australia or internationally, specifically examining the psychological treatment of individuals presenting with psychological concerns in individuals within 5-years post Multiple Sclerosis diagnosis (considered newly diagnosed). The aim of this study is to examine the use of an early tailored Cognitive Behavioural Therapy (CBT) (a type of talking therapy that helps individuals learn skills targeting their thinking and behaviour) for depression in individuals newly diagnosed with Multiple Sclerosis.

Who can participate?
Adults aged 18 to 65 who are diagnosed with MS in the last five years.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive a specialised CBT therapy which helps them learn skills to target their thinking and behaviour. Those in the second group receive a supportive listening based treatment that helps participants express themselves in a non-judgmental and empathetic environment. Both groups attend the therapy for one an hour a week for eight weeks. Participants are followed up at three and six months to assess their depressive symptoms.

What are the possible benefits and risks of participating?
Participants may benefit from speaking a psychologist about their concerns and learning skills to effectively manage their depressive, anxiety, pain and fatigue symptoms. There are no anticipated risks with participating.

Where is the study run from?
1. The Royal Melbourne Hospital (Australia)
2. St Vincent's Hospital Melbourne (Australia)

When is the study starting and how long is it expected to run for?
May 2016 to January 2024

Who is funding the study?
MS Research Australia (Australia)

Who is the main contact?
Dr Litza Kiropoulos
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016.164

Study information

Scientific Title
A Phase II randomised controlled trial of an early tailored cognitive behavioural therapy based intervention for depression in those newly diagnosed with multiple sclerosis

Acronym
ACTION-MS

Study objectives
The aim of this study is to compare an 8-week tailored Cognitive Behavioural Therapy intervention with an 8-week Supportive Listening intervention to treat depression, anxiety and other MS-related concerns among individuals who are newly diagnosed with Multiple Sclerosis and who are mild to moderately depressed and living in Melbourne, Australia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Melbourne Health Human Research Ethics Committee, 19/08/2016, ref: HREC/16/MH/165

Study design
The study is a prospective, parallel group, assessor-blind randomized controlled multicentre (including sites in Victoria, Australia) trial among 60 adult participants who have been newly diagnosed with MS (within 5 years of having received a diagnosis) with mild to moderate depression (i.e., scored between 14-28 on the Beck Depression Inventory-II).

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Mild to moderate depression among individuals newly diagnosed with MS

Interventions
Participants are randomised to either receive a specialised eight-week Cognitive Behavioural Therapy (CBT) based psychological intervention (a type of talk therapy that helps individuals learn skills targeting their thinking and behaviour) or an 8-week Supportive Listening (SL) based psychological intervention (a type of therapy that helps individuals to talk and express themselves in a non-judgmental and empathetic environment).

SL intervention involves the participant talking through their problems with the support of a psychologist. The psychologist listens to the concerns and provides counselling. The CBT sessions involves learning skills to manage depression and anxiety, such as managing unhelpful

thinking styles and behaviours, in addition to learning helpful ways to manage associated pain and fatigue.

Both interventions include one-hour weekly face-to-face psychological therapy sessions for eight weeks with a psychologist working on this project in a consultation room at the Royal Melbourne Hospital in Melbourne, Australia.

Participants are followed up at three and six months to assess their depressive symptoms.

Intervention Type
Mixed

Primary outcome measure
Severity of depression is measured using the Beck Depression Inventory-II (BDI-II) at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months.

Secondary outcome measures
1. Level of anxiety is measured using State Trait Anxiety Inventory (STAI) at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
2. Fatigue is measured using the Fatigue Impact Scale at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
3. Pain impact measured using Pain Effects Scale at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
4. MS illness acceptance is measured using Acceptance of Chronic Health Conditions Scale (ACHC) at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
5. Sleep quality is measured using Pittsburgh Sleep Quality Index at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
6. Quality of life is measured using Multiple Sclerosis Quality of Life (MSQOL) at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
7. Social support is measured using Perceived Social Support Scale at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months
8. Resilience is measured using The Resilience Scale for Adults at baseline (pre-intervention), 8 weeks (post-intervention), 3 months and 6 months

Overall study start date
23/05/2016

Completion date
31/01/2024

Eligibility

Key inclusion criteria
1. Mild to moderately depressed patients with MS
2. Diagnosed with MS within the last 5 years and are considered newly diagnosed.
3. Adult (i.e., 18-65 years old)

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Gross cognitive impairment that would make participation in the 8 one hour sessions of Cognitive Behavioural Therapy distressing
2. Unable to speak or read English
3. Acute organic brain syndrome (e.g., delirium)
4. Serious psychological disorder (e.g., psychosis)
5. Assessed with the BDI-II and the SCID-5 as being severely depressed
6. Already undertaking psychological treatment for depression/anxiety
7. Taking antidepressants for less than two months

Date of first enrolment
14/06/2017

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Australia

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

Study participating centre

St Vincent's Hospital Melbourne
41 Victoria Parade
Fitzroy
Melbourne
Australia
3065

Sponsor information

Organisation
Multiple Sclerosis Research Australia

Sponsor details
PO Box 625
NSW
Sydney
Australia
2059

Sponsor type
Research organisation

Website
https://msra.org.au/

ROR
https://ror.org/02caat392

Funder(s)

Funder type
Research council

Funder Name
MS Research Australia

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 08/08/2024:
A manuscript related to this trial is currently in preparation and will be submitted by the end of the year.

Previous publication and dissemination plan:
The trialists intend to publish their results in a high-impact peer-reviewed journal in 2020.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from (Dr Litza Kiropoulos, email: litzak@unimelb.edu.au, consent from participants has been obtained for sharing de-identified data). Data will become available at the completion of the trial and publication of the trial results.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/01/2020	22/01/2020	Yes	No
Statistical Analysis Plan			08/08/2024	No	No