

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

<b>Submission date</b> 05/09/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 20/10/2017	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/08/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
litzak@unimelb.edu.au

## Contact information

**Type(s)**

Public

**Contact name**

Dr Litza Kiropoulos

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## Additional identifiers

**Protocol serial number**

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

### **Study type(s)**

Treatment

### **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(s)**

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.

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

65 years

### **Sex**

All

## **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

ROR

<https://ror.org/02caat392>

## Funder(s)

**Funder type**

Research council

**Funder Name**

MS Research Australia

## 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 (Dr Litza Kiropoulos, email: [litzak@unimelb.edu.au](mailto: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?
<a href="#">Protocol article</a>	protocol	20/01/2020	22/01/2020	Yes	No
<a href="#">Statistical Analysis Plan</a>			08/08/2024	No	No