

Cognitive behavioural therapy software for the treatment of depression in people with multiple sclerosis

Submission date 09/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/10/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/03/2020	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 problems with movement, attention, concentration and memory. It has been found that depression (extreme low mood) is very common amongst MS sufferers, and can greatly reduce quality of life. Cognitive behavioural therapy (CBT) is a type of talking therapy which helps people to change the way they think and behave. In recent years, an online version of CBT has been developed (computerized cognitive behavioural therapy, cCBT) which allows more people to get access to the treatment that they could not have received otherwise. It is not known whether cCBT would be an effective treatment for depressed MS patients as it is not specifically designed for these patients. The aim of this study is to test the effectiveness of cCBT in treating depression in patients with MS.

Who can participate?

Adults with MS who are showing signs of depression.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group continue to receive their usual treatment, with no access to the cCBT programme. Those in the second group are given access to the cCBT programme "Beating the Blues", a computer-interactive programme for the treatment of anxiety and depression. The programme uses a series of eight interactive sessions which help patients to understand the causes and symptoms of anxiety and depression and to work on their specific problems ("thinking" and "doing" strategies). The eight sessions are designed to be taken weekly, and each session builds on the previous one. At the start of the study and then again after 8 weeks and 3 months, participants in both groups complete a number of questionnaires in order to find out if there have been any changes to their mood and quality of life.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Clinical Trials Research Unit, University of Sheffield (UK)

When is the study starting and how long is it expected to run for?
September 2009 to January 2010

Who is funding the study?
Multiple Sclerosis Society (UK)

Who is the main contact?
Dr Cindy Cooper
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Study website
<http://www.shef.ac.uk/ctru/cosmos/index.html>

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00678496

Secondary identifying numbers
112276

Study information

Scientific Title

Computerised cognitive behavioural therapy for treatment of depression in multiple sclerosis (MS) (CoSMoS): Clinical trial pilot study

Acronym

CoSMoS

Study objectives

The aim of this pilot study is to test the feasibility of a randomised control trial (RCT) of CCBT for depression in people with MS.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Northern and Yorkshire NHS Research Ethics Committee, 05/09/2008, ref: 08/H0903/41

Study design

Parallel group randomised pilot trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Patient information sheet can be found at: <http://www.shef.ac.uk/content/1/c6/07/73/06/Participant%20Information%20Sheet%20v1.pdf>

Health condition(s) or problem(s) studied

Depression in people with multiple sclerosis (MS)

Interventions

Participants are randomly allocated to one of two groups.

Intervention group: CBT software (Ultrasis - Beating the Blues®)

Control group: Treatment as usual

Ultrasis - Beating the Blues® is a computer-interactive programme for the treatment of anxiety and depression. It is based on cognitive behavioural therapy (CBT), which helps patients to identify and change unhelpful ways of thinking and to learn more effective ways of solving

problems. The programme consists of two interwoven strands: the cognitive (or "thinking") strategies and the behavioural (or "doing") strategies. Patients are helped to understand the causes and symptoms of anxiety and depression and to work on their specific problems. The programme consists of a 15 minute "Introduction to Therapy" video plus eight computer-interactive sessions of approximately 50 minutes each in duration. Each session consists of a mix of cognitive and behavioural strategies, which are customised to the patient's individual problems. The eight computer sessions are designed to be taken weekly, or thereabouts, and each session builds on the previous one. Patients can repeat sessions if they wish. The computer keeps track of which session they have reached.

Total duration of interventions: 8 weeks

Total duration of follow-up: 3 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Change in self-reported symptoms of depression: the difference between mean change scores of CCBT and standard care, as measured on the Beck Depression Inventory - Second Edition (BDI-II) 21-item self report instrument. Recorded at baseline, eight weeks or on completion of CCBT (whichever is later) and three months thereafter.

Secondary outcome measures

The following will be recorded at baseline, eight weeks or on completion of CCBT (whichever is later) and three months thereafter:

1. Depression as measured on the Patient Health Questionnaire-9 item (PHQ-9)
2. Anxiety measured on the Generalised Anxiety Disorder-7 item (GAD-7)
3. Disease-specific quality of life, measured on the Multiple Sclerosis Impact Scale-29 item (MSIS-29)
4. Generic health-related quality of life, measured on the 36-item Short Form health survey (SF-36)

Overall study start date

01/09/2008

Completion date

31/01/2010

Eligibility

Key inclusion criteria

1. Aged 18+, both males and females
2. Diagnosis of MS confirmed by neurologist
3. Beck Depression Inventory-II score of at least 14 on two consecutive occasions
4. Not currently or within past three months receiving any treatment from a psychologist, psychotherapist or psychiatrist
5. Willingness to be randomised to CCBT, at home or primary care facility or treatment as usual

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

Key exclusion criteria

1. Unable to read or write English
2. Beck Depression Inventory score of at least 29 on two consecutive occasions
3. Active suicidal ideas
4. Current or life-time diagnosis of any of the following:
 - 4.1. Psychosis
 - 4.2. Organic mental disorder
 - 4.3. Alcohol or drug dependency
5. Kurtzke Expanded Disability Status Scale (EDSS) score of 8.5 or above
6. Unable to use the CCBT package due to physical disability
7. Unable to use the CCBT package due to cognitive symptoms (mini-mental state of 20 below or if, in the opinion of the study psychologist, the individual would be unlikely to benefit from CCBT)

Date of first enrolment

01/09/2008

Date of final enrolment

31/01/2010

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

University of Sheffield

Clinical Trials Research Unit

Regent Court

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Sponsor information

Organisation

University of Sheffield (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.shef.ac.uk/researchservices/ro.html>

ROR

<https://ror.org/05krs5044>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (UK) (ref: 845/06)

Alternative Name(s)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, MS Society

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

31/12/2010

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/12/2011		Yes	No