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

Submission date
09/05/2008

Recruitment status
No longer recruiting

Registration date
06/10/2008

Overall study status
Completed

Last Edited
16/03/2020

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 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
c.l.cooper@sheffield.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Cindy Cooper

Contact details
Clinical Trials Research Unit
University of Sheffield
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA
+44 (0)114 222 5454
c.l.cooper@sheffield.ac.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00678496

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
University of Sheffield
Clinical Trials Research Unit
Regent Court
30 Regent Street
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
University of Sheffield (UK)

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Charity

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

Alternative Name(s)
mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes