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Cognitive behavioural therapy (CBT) for adjustment to early stage multiple sclerosis: Manual development and a randomised controlled trial comparing CBT to supportive listening

Submission date 07/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/04/2008	**Overall study status** Completed	
Last Edited 22/10/2012	**Condition category** Nervous System Diseases	

Plain English summary of protocol
http://www.southampton.ac.uk/samstrial/trial/about_the_trial1.html

Study website
http://www.soton.ac.uk/samstrial

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RHM MED 0726

Study information

Scientific Title

Acronym
saMS (Supportive Adjustment for Multiple Sclerosis)

Study objectives
Multiple sclerosis (MS) is a chronic progressive degenerative neurological disease affecting around 1 in 1,000 people in the UK. Although rarely fatal, MS produces a range of unpleasant and disabling symptoms. The course of MS is idiosyncratic and unpredictable and although the majority of patients experience a relapsing-remitting form of the illness, ultimately most patients experience a transition towards persistent disability. The nature and presentation of MS poses multiple psychosocial challenges. Individuals are faced with uncertainty about the future, unpleasant and unpredictable symptoms, treatment regimes and drug side effects. Since MS can have profound consequences including disruptions to life goals, employment, income, relationships, social and leisure activities and daily activities, it is unsurprising that it poses challenges for psychological adjustment.

The purpose of this study is to develop and test an intervention based upon the principals of cognitive behavioural therapy (CBT) to assist people in the early stages of MS to adjust to living with the disease.

The study aims to:
1. Develop a CBT manualised programme for adjusting to MS that can be delivered by general nurses receiving basic training in CBT and regular supervision
2. Determine whether patients with early stage MS who undertake a CBT course for adjustment to MS will demonstrate significantly greater reductions in key adjustment outcomes (less distress, and improvements in work and social adjustment) than those assigned to a Supportive Listening comparison condition
3. Examine the changes in beliefs, cognitions and behaviours in the two treatment groups and determine whether changes in these variables mediate improvements in distress and work and social adjustment
4. Conduct a cost-effectiveness analysis of the interventions
5. Evaluate the interventions from a patient perspective using qualitative methods

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by the Thames Valley Research Ethics Committee in February 2007 (ref: 07/MRE12/6)

Study design

Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet
Patient information can be found at: http://www.soton.ac.uk/samstrial/links/index.html

Health condition(s) or problem(s) studied
Multiple sclerosis

Interventions
Participants will be randomly allocated to either the CBT or Supportive Listening arm.

CBT arm:
Participants in the CBT arm will look at the way that their thoughts, feelings, behaviours and physiology interact and influence how MS affects their lives. The treatment is structured and different topics will be covered in different sessions. The manual consists of 9 chapters which can be used as appropriate to the individual's needs:
1. Introduction to adjusting to MS
2. Adapting to living with MS
3. Setting goals and problem solving
4. Symptom management
5. How to tackle negative and unhelpful thoughts
6. Improving the quality of your sleep
7. Managing stress
8. Managing social relationships
9. Preparing for the future
Participants will work with their nurse-therapist in setting tasks or homework to do in between the sessions. Participants have 8 sessions of CBT over 10 weeks. This is delivered by general nurses specially trained as nurse-therapists. 2 sessions are face-to-face, 6 are by telephone.

Supportive Listening arm:
Participants in the Supportive Listening arm will have the opportunity to talk freely, extensively and confidentially about their experiences, thoughts and feeling about MS and its effect on their lives. The listening skills we will use in this trial are based on the theories and counselling techniques of Carl Rogers. These core skills include asking open questions, active listening skills such as minimal encouragers and paraphrasing, empathising, reflecting and summarising. The purpose is to provide the participant the opportunity to talk and express themselves in a non-judgmental, safe environment. The person should experience empathy from the therapist and

feel listened to. Participants have 8 sessions of Supportive Listening over 10 weeks. This is delivered by general nurses specially trained as nurse therapists. 2 sessions are face-to-face, 6 are by telephone.

Questionnaire assessments will be carried out at baseline, mid-therapy, post-therapy and at 6 and 12 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be assessed at baseline, mid-therapy, post-therapy and at 6 and 12 months:
1. Distress, assessed by the General Health Questionnaire (Goldberg, 1978)
2. Work and Social Adjustment, assessed by the Work and Social Adjustment Scale (Mundt et al., 2002)

Secondary outcome measures
The following will be assessed at baseline, post-therapy and at 6 and 12 months, unless specified otherwise:
1. Social support, assessed using the Significant Others Scale (SOS; Power et al., 1988) at baseline, post-therapy and at 6 and 12 months
2. Beliefs About Emotions (BAE-6; Rimes & Chalder, publication in preparation)
3. Illness perceptions, assessed using the Brief Illness Perception Questionnaire (B-IPQ; Broadbent et al., 2006)
4. Cognitive and Behavioural responses to symptoms (CBSRQ; Moss-Morris et al., publication in preperation)
5. Acceptance, assessed by the Acceptance of Chronic Health Conditions (ACHC) Scale (Stuifbergen et al., in press)
6. Dyadic adjustment, assessed by the Dyadic Adjustment Scale (DAS-4; Sabourin et al., 2005) at baseline and post-therapy
7. Dysfunctional beliefs, assessed by the Psychological Vulnerability Scale (PVS; Sinclair & Wallston, 1999)
8. Health status, assessed by Euroqol (Curtis & Netten, 2006) at baseline, 6 and 12 months
9. Health service usage/costs, assessed using the Client Service Receipt Inventory (CSRI, Beecham & Knapp, 2001) at baseline, 6 and 12 months

Overall study start date
31/01/2008

Completion date
31/01/2009

Eligibility

Key inclusion criteria
1. Definite diagnosis of MS
2. Diagnosed within the last 10 years
3. Some degree of ambulation (with aid if necessary). Equivalent to Extended Disability Status

Scale (EDSS) <6.5
4. Stabilised on medication (Disease modifying drugs: minimum of 3 months since started; Anti-depressants: stable dose for minimum of 2 months)

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Gross cognitive impairment that would make participation in therapy problematic or distressing (must score >20 on Telephone Interview for Cognitive Status-Modified to be eligible)
2. Serious psychological disorders for whom treatment would be inappropriate (including psychotic disorders of active substance abuse)
3. Other co-morbid serious chronic illness (e.g., a malignancy)
4. Currently participating in other psychological therapies

Date of first enrolment
31/01/2008

Date of final enrolment
31/01/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
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Sponsor type
University/education

Website
http://www.soton.ac.uk

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (refs: 839/06 and 072/07)

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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	23/08/2009		Yes	No
Results article	results	01/04/2013		Yes	No