

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

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
07/01/2008	No longer recruiting	<input checked="" type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
11/04/2008	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
22/10/2012	Nervous System Diseases	

## Plain English summary of protocol

[http://www.southampton.ac.uk/samstrial/trial/about\\_the\\_trial1.html](http://www.southampton.ac.uk/samstrial/trial/about_the_trial1.html)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

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

### Study type(s)

Not Specified

### 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(s)

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)

### Key secondary outcome(s)

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 preparation)
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

#### **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

#### **Healthy volunteers allowed**

No

#### **Age group**

Not Specified

#### **Sex**

All

#### **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 or 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**

United Kingdom

England

**Study participating centre**

School of Psychology

Southampton

United Kingdom

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## Sponsor information

**Organisation**

University of Southampton and Southampton University Hospitals Trust (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)**

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 provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/04/2013		Yes	No
<a href="#">Protocol article</a>	protocol	23/08/2009		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes