

Evaluation of adjustment groups for people with Multiple Sclerosis

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/12/2012	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims?

Psychological problems affect the way people cope with their disability. Depression and anxiety are common in people with multiple sclerosis (MS). Improving psychological outcomes may improve quality of life. In addition it could reduce demands on other NHS services. Although drug treatments are available, these are not appropriate for everyone. Psychological treatments may provide an alternative, but there are few high quality randomised controlled trials investigating these for people with MS. Such trials are needed in order to determine whether psychological services should be developed further. The purpose of this study was to find out whether attending group treatment sessions, which offer ways to cope with anxiety and depression, was helpful. We developed a group programme and the feedback from people who attended the groups in our pilot study was very positive. We then wished to conduct a larger study to find out whether these groups should be provided as part of routine clinical practice. The plan was to find out whether the mood of people who were offered a group treatment was better than those who were not offered the treatment and to assess the costs to the NHS of providing the service.

Who can participate?

People with MS who were known to the MS service in Nottingham

What does the study involve?

We invited people with MS to complete questionnaires about their mood. Those who had low mood, according to their questionnaire scores, were invited to take part in the study. People were allocated on the basis of chance to attend group treatment sessions or to go on a waiting list.

Group A: Everyone was offered 6 fortnightly, group treatment sessions. The sessions lasted about 2 hours, with breaks, and each session had a topic of the day, such as: worry, gloom, relationships, problem solving, and the future.

Group B. These people were not offered the group treatment until after the study was completed. They received all other clinical services as usual.

At the end of the programme, everyone, both those who attended the group and those who did not, was asked to complete questionnaires. These included measures of mood, quality of life and the impact of MS on their lives to determine the effects of the treatment. These questionnaires

were repeated 3 months later to determine whether any benefits were maintained.
We also collected information on the costs of providing the service.

What are the possible benefits and risks of participating?
Participants may have had psychological treatment which would not otherwise have been available. There were no known risks associated with participating in this study.

Where is the study run from?
The MS service in Nottingham.

When is the study starting and how long is it expected to run for?
The study started in June 2008 and finished in September 2009

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

Who is the main contact?
Professor Nadina Lincoln
Nadina.Lincoln@nottingham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Nadina Lincoln

Contact details
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Additional identifiers

Protocol serial number
5790

Study information

Scientific Title

Acronym

AIMS

Study objectives

Evaluation of psychological support groups based on cognitive behavioural principles for people with multiple sclerosis (MS) and low mood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 04/Q2404/105)

Study design

Randomised interventional treatment trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Neurological, Mental Health Research Network; Subtopic: Neurological (all Subtopics), Service Delivery; Disease: Anxiety, Nervous system disorders

Interventions

Group intervention based on cognitive behavioural therapy (CBT) principles versus usual care.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Mood measured by the general health questionnaire (GHQ-12), follow up at 4 months and 8 months post-randomisation

Key secondary outcome(s)

Hospital anxiety and depression questionnaire and Beck Depression Inventory (BDI-II) to measure mood.

Completion date

30/09/2009

Eligibility

Key inclusion criteria

Inclusion criteria added as of 19/11/2012:

1. Give informed consent

2. Have a diagnosis of multiple sclerosis
3. Have a score of 3 or more on the General Health Questionnaire 12 or 8 or more on the Hospital Anxiety and Depression Scale depression or anxiety sub-scales i.e. they have low mood

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Exclusion criteria added as of 19/11/2012:

1. Less than 12 months has elapsed since diagnosis
2. Not able to speak and understand conversational English
3. Unable to attend the hospital or university for group treatment sessions if offered group treatment
4. Taking part in other psychological intervention studies

Date of first enrolment

02/06/2008

Date of final enrolment

30/09/2009

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Institute of Work, Health & Organisations

Nottingham

United Kingdom

NG8 1BB

Sponsor information

Organisation

University of Nottingham (UK)

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

Charity

Funder Name

Multiple Sclerosis Society (UK)

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?
Results article	results	01/10/2011		Yes	No