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Evaluation of adjustment groups for people with Multiple Sclerosis

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/12/2012	Nervous System Diseases	

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
Institute of Work, Health & Organisations
University of Nottingham
International House
B Floor
Jubilee Campus
Wollaton Road
Nottingham
United Kingdom
NG8 1BB

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5790

Study information

Scientific Title

Acronym
AIMS

Study objectives
Evaluation of psychological support groups based on cognitive behavioural priniciples 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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) priniciples versus usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

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

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

Overall study start date
02/06/2008

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Planned Sample Size: 160

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
England

United Kingdom

Study participating centre
Institute of Work, Health & Organisations
Nottingham
United Kingdom
NG8 1BB

Sponsor information

Organisation
University of Nottingham (UK)

Sponsor details
University Park
Nottingham
England
United Kingdom
NG7 2RD

Sponsor type
University/education

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

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Charity

Funder Name
Multiple Sclerosis Society (UK)

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?
Results article	results	01/10/2011		Yes	No