

Evaluation of adjustment groups for people with Multiple Sclerosis: a pilot study

Submission date 30/04/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/06/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 05/12/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A pilot randomised controlled trial to evaluate an adjustment group for people with multiple sclerosis

Study objectives

There is consensus that the prevalence of depression in people with multiple sclerosis is high. Previous studies have mainly used cognitive behaviour therapy for multiple sclerosis patients with low mood or support groups for multiple sclerosis patients in general.

The aim of this study was to assess the effectiveness of a support group, based on cognitive behavioural principles, for patients with multiple sclerosis experiencing low mood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Nottingham Local Research Ethics Committee

Study design

Randomised controlled trial for approximately one year

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Low mood in people with Multiple Sclerosis

Interventions

The study involved 8 male and 32 females recruited from multiple sclerosis outpatient clinics at Queens Medical Centre, Nottingham and by posters at the Multiple Sclerosis Society office and in their Society newsletter Participation will be over a 1-year period.

The sessions were based on a cognitive behavioural and psycho-educational framework. They were designed to teach individuals to identify and deploy skills to reduce current and future distress, thus aiding coping and adjustment. The sessions were also intended to increase awareness of the role of thoughts, emotions and behaviours and their influence on each other.

Participants in the control group received no psychological intervention but had access to all other services as usual. They were offered group treatment after the six-month outcome had been completed.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

By providing the participants with skills to manage mood, it was hoped that they would experience fewer difficulties with their mood in the future.

Secondary outcome measures

1. Hospital Anxiety and Depression Scale
2. General Health Questionnaire 12
3. Multiple Sclerosis Self Efficacy Scale
4. Multiple Sclerosis Impact Scale
5. Short Form 36 administered 3 and 6 months after random allocation

Overall study start date

01/10/2004

Completion date

31/12/2005

Eligibility

Key inclusion criteria

1. All patients with a score of more than 7 on either the anxiety or depression scales on the Hospital Anxiety and Depression Scale or more than 2 on the General Health Questionnaire 12 and who had a diagnosis of multiple sclerosis for more than three months
2. Able to speak and understand conversational English
3. Able to attend the University for the group intervention
4. Not involved in any other intervention study

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

100,000 prevalence in the UK. Unsure of number of people with MS registered in the Nottingham area. 40 patients enrolled.

Key exclusion criteria

1. Unable to speak and understand conversational English.
2. Unable to attend the University for the group intervention
3. Involved in another intervention study.

Date of first enrolment

01/10/2004

Date of final enrolment

31/12/2005

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Institute of Work, Health & Organisations

Nottingham

United Kingdom

NG81 1BB

Sponsor information**Organisation**

University of Nottingham (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/iwho/>

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

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	01/03/2010		Yes	No