ISRCTN13272820 https://doi.org/10.1186/ISRCTN13272820

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

Submission date	Recruitment status
30/04/2012	No longer recruiting
Registration date	**Overall study status**
13/06/2012	Completed
Last Edited	**Condition category**
05/12/2014	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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
NG81 1BB
-
nadina.lincoln@nottingham.ac.uk

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 Questionnaire12 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
c/o Prof Nadina Lincoln
Institute of Work, Health & Organisations
International House
B Floor
Jubilee Campus
Wollaton Road
Nottingham
England
United Kingdom

NG81 1BB
+44 (0)115 846 7523
I-WHO@nottingham.ac.uk

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