

Effects of a cognitive-behavioural mindfulness intervention upon quality of life, depression and fatigue among multiple sclerosis (MS) patients

Submission date 11/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 16/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/06/2019	Condition category Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

3200B0-112604

Study information

Scientific Title

Effects of a cognitive-behavioural mindfulness intervention upon quality of life, depression and fatigue among multiple sclerosis (MS) patients

Study objectives

In comparison to conventional optimal medical management, multiple sclerosis (MS) patients assigned to a mindfulness-based stress-reduction (MBSR) intervention will manifest greater improvements in quality of life and reductions in depression and fatigue.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Ethics Committee of Basel (EKBB) on the 21st March 2007 (ref: 32/07)

Study design

Single-centre, randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Multiple sclerosis

Interventions

Intervention:

Mindfulness-based stress reduction. 8-week group (10 - 15 participants) intervention, 2.5 hours per week with one additional whole-day session and optimal conventional medical care.

Control:

Optimal conventional medical care alone.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Quality of life: Hamburg Quality of Life Questionnaire in Multiple Sclerosis and Profile Quality of Life in Chronic Disorder
2. Modified Fatigue Impact Scale
3. Center for Epidemiological Studies Depression Scale

Timepoints of assessment: pre-Intervention, post-intervention and 6-month post-intervention.

Key secondary outcome(s))

1. Multiple Sclerosis Inventory of Cognition
2. Personal Goal Attainment Scale
3. Visual Analogue Quality of Life Scale
4. Spielberger Trait Anxiety Scale
5. Expanded Disability Status Scale
6. 25-foot walk test

Timepoints of assessment: pre-Intervention, post-intervention and 6-month post-intervention.

Completion date

30/06/2009

Eligibility

Key inclusion criteria

1. Both males and females, aged 18 - 70 years
2. Verified diagnosis of MS with an expanded disability status scale score of less than or equal to 6.0 (from no disability to moderately severe disability MS) and no more than one step increase within the last year. We include patients with the following types of disease:
 - 2.1. Relapsing-remitting MS and no more than two exacerbations within the last year, with at least three months since start of last relapse; or
 - 2.2. Secondary progressive disease
3. Patients who have not initiated or changed treatment with a disease-modifying drug within the past three months
4. Patients who have not been treated with corticosteroids within the previous 30 days
5. Time since onset of disease will be evaluated and considered in statistical analyses but will not form a criterion for enrolment into the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

150

Key exclusion criteria

1. Serious psychological disorders other than depression and anxiety syndromes, such as psychotic disorders, bipolar disorders, borderline personality disorders or active substance abuse disorders

2. Evidence of dementia as indicated by testing below the fifth percentile in at least three of six dimensions of neuropsychological functioning (i.e. attention and concentration, processing speed, executive function, verbal memory, and verbal processing)
3. Suicidality
4. Other life-threatening or severely disabling physical disorders
5. Current MS exacerbation
6. Other disorders of the central nervous system (CNS) besides MS
7. Symptomatic medication has been altered within the past three months
8. Pregnancy
9. Inability to understand written and spoken German

Date of first enrolment

01/04/2007

Date of final enrolment

30/06/2009

Locations

Countries of recruitment

Germany

Switzerland

Study participating centre

Department of Psychosomatic Medicine

Basel

Switzerland

4031

Sponsor information

Organisation

University Hospital Basel (Switzerland)

ROR

<https://ror.org/04k51q396>

Funder(s)

Funder type

Government

Funder Name

Swiss National Science Foundation (ref: 3200B0-112604) (Switzerland)

Alternative Name(s)

Schweizerischer Nationalfonds, Swiss National Science Foundation, Fonds National Suisse de la Recherche Scientifique, Fondo Nazionale Svizzero per la Ricerca Scientifica, Fonds National Suisse, Fondo Nazionale Svizzero, Schweizerische Nationalfonds, The Swiss National Science Foundation (SNSF), SNF, SNSF, FNS

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Switzerland

Funder Name

St. Johnson Foundation (Switzerland)

Funder Name

Swiss MS Society (Switzerland)

Funder Name

Merck Serono (Switzerland)

Funder Name

Sanofi Aventis (France)

Funder Name

Biogen Dompe (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	28/09/2010	11/06/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes