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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

Registration date
16/05/2008

Overall study status
Completed

Last Edited
11/06/2019

Condition category
Nervous System Diseases

[ ] 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

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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 followng 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