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Online therapy programme for fatigue in multiple sclerosis

Submission date
08/04/2014

Recruitment status
No longer recruiting

Registration date
06/06/2014

Overall study status
Completed

Last Edited
21/03/2018

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
We intend to study the effectiveness of a psychotherapy-based online program to treat tiredness (fatigue) (ELEVIDA). It is based on a conceptualized model of fatigue and consists of eight modules. The programme will last for 8 weeks. The major aim is to reduce fatigue symptoms in patients with multiple sclerosis.

Who can participate?
Patients with multiple sclerosis who have access to internet

What does the study involve?
Patients will be randomly allocated to two groups: one group will receive the training right away and the other group (wait-list) will receive the training after the study is completed. The study involves psychological and nervous-response-related assessment before and after the training programme, and includes participation in a modern web-based intervention to treat fatigue over 8 weeks. The programme is developed in line with internationally accepted psychological therapy concepts.

What are the possible benefits and risks of participating?
The benefits would be a reduction of fatigue symptoms and to find ways to cope better with fatigue impairment. Risks are not expected.

Where is the study run from?
The study runs via the internet and is managed in University Medical Centre Eppendorf, Hamburg, Germany

When is the study starting and how long is it expected to run for?
The study starts in July 2014 and runs until May 2016

Who is funding the study?
Hertie Foundation (Gemeinnützige Hertie Stiftung) (Germany)

Who is the main contact?
Prof Christoph Heesen
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P1130079

Study information

Scientific Title
Effectiveness of a fatigue management programme for patients with Multiple Sclerosis (MS)

Acronym
ELEVIDA

Study objectives
The study follows 3 major aims:
1. To show effectiveness of an online program to treat fatigue in MS with a cognitive behavioural therapy (CBT) approach based on the concept of Van Kessel (2009).
2. To show that improvement of fatigue will also improve cognitive performance (attention) as well as anxiety and depression.
3. To show that Magnetic Resonance Imaging (MRI) connectivity measures (i.e. DTI and resting state fMRI) will change by the intervention.

We will further try to explore predictors and mediating factors of the intervention by the following hypotheses:
1. The intervention will change avoidance behavior and cognitive variables of illness perception (e.g.. symptom focussing).
2. Personality traits are predictive for treatment success.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Hamburg Chamber of Physicians, July 2014, PV 4772

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Multiple Sclerosis (MS)

Interventions
A pure online randomised-wait-list-control study with a subgroup undergoing clinical examination and MRI. Screening of suitable patients will be performed by checking fatigue scores in the Hamburg Quality of Life in MS fatigue subscale (HAQUAMS, Gold 2001) in the database of the UMC. Patients scoring >= 2 will be contacted. Patients have to apply for the study via a web-based tool provided by the University of Hamburg (see www.unipark.com) which we also applied in the depression study.
Patients fulfilling inclusion criteria based on data-input on the website will be randomised to the intervention group (IG) and the wait-list control group (CG).
1. IG participants will get a personal access code to the training tool.
2. Participants in the waiting list group will get information about their option to enter the FATIMA programme after the study. They will also get a brief explanation about the need for control groups in randomized controlled trials.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Fatigue as measured by the Chalder Fatigue Scale (Cella & Chalder et al., 2010). Pre-post training comparisons immediately after the training and 3 months later will be calculated.

Secondary outcome measures
1. Fatigue: FSMC (Penner et al., 2009)
2. Anxiety and depression: Hospital Anxiety and Depression Scale (HADS, Zigmond & Snaith, 1983)
3. Quality of life: Hamburg Quality of Life Questionnaire in MS (HAQUAMS, Gold et al., 2001)
4. Cognitive self assessment: Multiple Sclerosis Neuropsychological Screening Questionnaire (MSNQ, Benedict et al., 2003)
Exploratory:
5. Cognitive and behavioural responses to symptoms questionnaire (Skerett & Moss-Morris, 2006)
6. Brief Illness Perception Questionnaire (Broadbent et al., 2006)
7. Coping Self Efficacy Scale (CSES, Chesney et al., 2006)
8. Activity of daily life: Frenchay Activity Index (Turnbull et al., 2000)
9. Personality: Revised NEO Personality Inventory (Costa & McCrae,1992)

Overall study start date
01/07/2014

Completion date
26/05/2015

Eligibility

Key inclusion criteria
1. Definite MS according to McDonald criteria (Polman et al., 2010), relapsing-remitting (RR), primary and secondary-progressive (SP) MS course
2. Ability to answer read texts and to answer questionnaires via the internet
3. Fatigue-Scale-Motor-Cognition (FSMC) total fatigue score >= 43
4. Internet equipment at home (PC with internet access)
5. Interest to attend (agreement)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
204

Key exclusion criteria
1. Unclear diagnosis
2. Neuromyelitis optica
3. Major psychiatric disease (f.e. psychotic disease, but we will allow depressive disorders)

Date of first enrolment
01/07/2014

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
Germany

Study participating centre
Martinistr. 52
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Sponsor information

Organisation
Hertie Foundation (Germany) (Gemeinnützige Hertie Stiftung)

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Sponsor type
Research organisation

ROR
https://ror.org/03ak9vt35

Funder(s)

Funder type
Research organisation

Funder Name
Hertie Foundation (Germany) (Gemeinnützige Hertie Stiftung) Ref: P1130079

Alternative Name(s)
Hertie-Stiftung

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

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	01/09/2018		Yes	No