

# Online therapy programme for fatigue in multiple sclerosis

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<b>Registration date</b> 06/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/03/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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  
heesen@uke.de

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Christoph Heesen

### Contact details

Martinistr. 52  
Hamburg  
Germany  
20246  
-  
heesen@uke.de

## Additional identifiers

**Protocol serial number**  
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

## **Study type(s)**

Treatment

## **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  $\geq 2$  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](http://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(s)**

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.

## **Key secondary outcome(s)**

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 (Skerrett & 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)

**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  $\geq 43$
4. Internet equipment at home (PC with internet access)
5. Interest to attend (agreement)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**  
Hamburg  
Germany  
20246

## Sponsor information

### Organisation

Hertie Foundation (Germany) (Gemeinnützige Hertie Stiftung)

### 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

### 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?
<a href="#">Results article</a>	results	01/09/2018		Yes	No