Trial Description

Title
Three-week inpatient energy management education (IEME) for persons with multiple sclerosis-related fatigue. A feasibility study

Trial Acronym
IEME-Study

URL of the trial
http://www.supsi.ch/home/ricerca/progetti/dettaglio.1666.backLink.abd18de2-15f4-4215-8f54-1d9add87bd35.html

Brief Summary in Lay Language
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Brief Summary in Scientific Language
The objective of part 1 is to adapt the existing evidence based energy management education manuals to the inpatient context and to translate and culturally adapt them to a treatment manual for OT’s and a patient handbook, both in German language. After that we will use and evaluat the manuals with a group of patients and OTs in order to improve the program.

Part 2:
The objective of part 2 is to conduct a feasibility study with a small-scale RCT to examine the feasibility of the study protocol in terms of processes, resources, management, and scientific metrics for a future RCT.

Do you plan to share individual participant data with other researchers?
[---]*

Description IPD sharing plan
[---]*

Organizational Data

- DRKS-ID: DRKS00011634
- Date of Registration in DRKS: 2017/02/07
- Investigator Sponsored/Initiated Trial (IST/IIT): yes
- Ethics Approval/Approval of the Ethics Committee: Approved
DRKS-ID: **DRKS00011634**
Date of Registration in DRKS: **2017/02/07**
Date of Registration in Partner Registry or other Primary Registry: *[---]*
Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
Ethics Approval/Approval of the Ethics Committee: **Approved**
(leading) Ethics Committee Nr.: **BASEC Nr. 2016-02147** , **Ethikkommission Ostschweiz (EKOS)**
Kantonspital St.Gallen
Haus 37
9007 St. Gallen

Secondary IDs

Health condition or Problem studied

- ICD10: **G35 - Multiple sclerosis**

Interventions/Observational Groups

- Arm 1: **During the usual rehabilitation program participants follow the inpatient energy management education (IEME) program. IEME consists of one individual and five group sessions with a previously trained OT (total 6x60min).**
- Arm 2: **During the usual rehabilitation program participants follow 6 group sessions of Progressive muscle relaxation (PMR)delivered by a trained physical therapist (total 6 x 60 min.)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: *[---]*
- Allocation: **Randomized controlled trial**
- Blinding: *[---]*
- Who is blinded: **assessor, data analyst**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
Study Type: **Interventional**
Study Type Non-Interventional: [---]*
Allocation: **Randomized controlled trial**
Blinding: [---]*
Who is blinded: **assessor, data analyst**
Control: **Active control (effective treatment of control group)**
Purpose: **Treatment**
Assignment: **Parallel**
Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Part 1:**
We evaluate the satisfaction of patients with the inpatient energy management education (IEME) conducting a focus group (duration 60 min.)
We evaluate the compliance of OTs during the IEME conducting a focus group (duration 60 min.) and the adherence with fidelity checklists.

**Part 2**
We evaluate recruitment, drop out and follow-up rate and document the recruitment process
We use five different self-assessments questionnaires at baseline, at week three (end of interventions) and week 19 (follow up) to calculate meaningful change in outcome measurements.
Modified fatigue impact scale (MFIS),
Occupational self-assessment (OSA),
Health related quality of life (SF36),
Self-efficacy scale (UW-SES),
Self-efficacy for performing energy conservation strategies assessment (SEPECSA).

## Secondary Outcome

**not applicable**

## Countries of recruitment

- **CH Switzerland**

## Locations of Recruitment
Medical Center: Rehabilitationszentrum Valens, Valens

Recruitment

- Planned/Actual: Planned
- (Anticipated or Actual) Date of First Enrollment: 2017/04/01
- Target Sample Size: 55
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

The inclusion criteria for the participants’ eligibility are a minimum three-week inpatient rehabilitation period and definite MS diagnosis. 
- >18 years,
- Fatigue severity scale 6 (FSS) score >4,
- Expanded disability status scale 7 (EDSS) ≤6.5,

Exclusion criteria

- Insufficient knowledge of the project language (German)
- Reduced cognitive capacity; telephone mini-mental state examination (tMMSE) ≥21
- Depression; Beck depression inventory for fast screening (BDI-FS) >4

Addresses

Primary Sponsor

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Sources of Monetary or Material Support

- Private sponsorship (foundations, study societies, etc.)
  Schweizerische MS Gesellschaft
  6000 Luzern
  Switzerland

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  URL: [---]*

- Private sponsorship (foundations, study societies, etc.)
  Ergotherapie Stiftung
  Ettenbergstrasse 58
  8907 Wettswil a.A.
  Switzerland

  Telephone: [---]*
  Fax: [---]*
  E-mail: info at ergo-stiftung.ch
  URL: [---]*

Status

- Recruitment Status: Recruiting planned
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents
* This entry means the parameter is not applicable or has not been set.
*** This entry means that data is not displayed due to insufficient data privacy clearing.