Trial Description

Title

**Hiking as a therapy for depressive patients?
Feasibility study for the systematic implementation of hikes into the daily care routine as well as identification of relevant target metrics at the Klinikum Christophsbad Göppingen for people with depression as main diagnosis - pilot study (phase 1)**

Trial Acronym

WaThe

URL of the trial

http://--

Brief Summary in Lay Language

**Hiking as a regular leisure activity has experienced a significant upswing in recent years - there is a real boom in hiking. Many people pursue different motives, such as being physically active, experiencing nature, travelling, slowing down everyday life and generally promoting health. On the other hand, the problem of depression is becoming more and more present in our society: The number of people affected is constantly increasing and more and more people need to be treated therapeutically. At the Klinikum Christophsbad in Göppingen (Germany), the two circumstances mentioned have been combined for several years within the framework of psychiatric and psychosomatic acute treatment in addition to a wide range of forms of therapy: Hikes of about three hours in the surroundings of Göppingen are used to psychologically stabilise the participants, to seek, promote and use personal resources.
This project is sponsored by the Karl and Veronica Carstens Foundation and is scheduled to run for three years. In a first pilot study (prospective uncontrolled study, duration approx. 1 year) interested participants at the Klinikum Christophsbad will be interviewed quantitatively as well as qualitatively in order to check the feasibility of the planned study (especially the identification of barriers). The further aim is to identify potential target measures that might be relevant for a possible modification of psychosocial health and depression severity. The findings of the pilot study will then form the basis for the main study (prospective randomised control trial, duration approx. 2 years), in which the hiking offer will be evaluated with regard to its effectiveness (especially improvement of mental health).
The results will show whether hiking can be recommended for the rehabilitation of mental illnesses in a clinical setting.**

Brief Summary in Scientific Language

Background: Depression disorders are on the rise and fundamentally restrict those affected both in coping with everyday life and in performing their professional and social functions. Physical activity, group and nature experiences play an important role in the clinical treatment of depression due to the many proven positive effects on mental health. These factors are also mentioned by many people as the

basic motives for hiking. Unfortunately, the studies on the effectiveness of hikes for depression are inadequate, which is why the present project takes up this topic. The aim is to contribute to statements about the effectiveness of hiking on symptoms of depression.
Goal: a. Examination of the feasibility of the planned effectiveness study (mainly by identifying barriers and promotion factors); b. Identification of potential target measures that might be relevant in terms of a possible modification of psychosocial health; c. Enable case number estimation for the main study. The planned preliminary study is therefore designed to generate hypotheses and will serve as a basis for the main study (prospective randomised control trial, duration approx. 2 years), in which the effectiveness of the hiking offer (especially improvement of mental health) will be evaluated.
Method: To answer the research question, the project is divided into two study phases. In the pilot study described here, a prospective, non-randomised and non-controlled observational study will be carried out. The participants will be recruited from 3 stations of the Klinikum Christophsbad in Göppingen/ Geislingen and will be mainly diagnosed with depression. For a period of 6 weeks, all participants complete a weekly hiking unit (approx. three hours, 4-10km, moderate intensity) in a natural environment in the area around Göppingen. In order to measure the medium-term effects, the participants are required to make self- and external assessments before and after the entire intervention period (6 weeks) on the severity of the depression, on the state of health, on hedonia/pleasure and on self-efficacy. Short-term effects are to be assessed by self-assessments before, during and after the individual hiking units with regard to potential changes in the tendency to rumination, well-being, arousal and affective reaction as well as subjective exertion. Detailed documentation of the progress of the study and qualitative interviews (n=9-12) at the end of the entire intervention period with the participating staff (psychologists, doctors, nursing staff) and study participants will also be used to identify barriers that stand in the way of an examination of the effectiveness of the hikes in the clinical setting.

Organizational Data

- DRKS-ID: **DRKS00017207**
- Date of Registration in DRKS: **2019/09/12**
- 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.: **F-2019-053 , Ethik-Kommission bei der Landesärztekammer Baden-Württemberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **F33 - Recurrent depressive disorder**

Interventions/Observational Groups

- Arm 1: **Patients from selected stations (depression station, 2 day clinics) in the Klinikum Christophsbad take part in weekly hikes for 6 weeks.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **II**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Identification of suitable target measurands (promotion factors):
- medium-term effects, measurement dates: Pre/post intervention period (6 weeks), measurement method: Self-assessment questionnaires (basic data, BDI-II, SHAPS-D, VR36, SWE); external assessment questionnaires (GRID-HAMD-21, MADRS).
- Short-term effects, measurement times: Pre/post intervention (6x), measurement procedure: Self-assessment questionnaires (RRQ, FAS & FS, RPE, Bf-SR).

Identification of barriers that occurred during a scientific study in a clinical setting at the Klinikum Christophsbad in Göppingen, Germany: Measurement method: qualitative interviews.

Endpoint: reaching 50 participants
Objective: To identify hypothesis generation, suitable target measures and problematic barriers for the main investigation (effectiveness study, RCT).

Secondary Outcome

Enable case number estimation for the main study

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik Christophsbad für Psychiatrie und Psychotherapie , Göppingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/08/19**
- Target Sample Size: **50**
- 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

Inpatient/outpatient treatment in the participating care units;
Main diagnosis: depression;
Age from 18 years;
The patient should, in the opinion of the doctors and nursing staff, be able to walk for three hours outside the station without endangering themselves or others;
At the beginning of the study, the participants are in a physical condition that allows a three-hour hike (absence of injury or physical discomfort);
Consent to voluntary study participation;
Mental condition permitting a three-hour hike outside the clinic

Exclusion criteria

No treatment in the participating wards;
Main diagnosis is not depression;
Age under 18 years;
A mental condition classified by the doctors or nursing staff that does not allow a three-hour hike outside the hospital;
A participant has not reached the age of majority;
Diseases that impair stress capacity and fitness for sport or lead to side effects (e.g. serious cardiovascular diseases, acute infections, acute traumatic injuries);
no interest in participating (refusal);
Lack of knowledge of German;
physical limitations or complaints that are associated with a reduction in the physical ability to work under pressure

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Karl und Veronica Carstens- Stiftung
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Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: **Recruiting ongoing**
- 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.*