Trial Description

Title

Relational world of chronic pain patients in the course of an inpatient multimodal pain treatment focusing on psychosomatic interventions

Trial Acronym

BECSPIN

URL of the trial

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Brief Summary in Lay Language

In this study we examine the context of chronic pain and the relational world of persons with chronic pain. "Relational world" means the relation and perception of the own body, relations to other persons and, eg. also to the medical system. Body perception or bodily changes play a major role for many medical syndromes. Therefore the treatment of chronic pain under a relational aspect and within a bio-psycho-social model is especially important. The treatment "multimodal pain treatment" stands for a bodily, kognitive, social and behavioural reflection and practice with medical-psychotherapeutic support and guidance. All therapists work with the same concept. The name derives from many (lat. multi) kinds of (lat. modi) of treatment. The study results in evaluating a clinical offer and also has impact on applied sciences.

Brief Summary in Scientific Language

The improvement of the quality of life (QoL) of chronic pain patients is the primary goal of treatment. There is only little data about how a multimodal inpatient treatment with focus on psychotherapy has impact on salutegenetic processes via changes in pain detection and interoception. Especially in groups social issues can be made perceivable and being changed. Thus outpatient disorder-specific group therapy has been described and its promising outcomes has been reported on case-report level. So far, there are very little data on on group-process and outcome variables in the course of a treatment. The results of this study on interoception should have impact on models of pain syndromes and the concept of perceived chronic pain. Moreover they serve the evaluation of an existing clinical offer and the exploration of clinical impact factors with a direct benefit on disorder-specific diagnostic assessments and treatment planning.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00010256**
- Date of Registration in DRKS: **2016/04/01**
- 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.: **77/16 , Ethik-Kommission der Universität Ulm**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1181-4249**

Health condition or Problem studied

- ICD10: **F45.41 - [generalization F45.4: Persistent somatoform pain disorder]**
- ICD10: **F45.40 - [generalization F45.4: Persistent somatoform pain disorder]**
- Free text: **Chronic pain**

Interventions/Observational Groups

- Arm 1: **Patients who meet the criteria for the multimodal pain treatment and who decided to do the therapy after visiting an information group.**

  The criteria are written down by the German Institute for medicial documentation and information (DIMDI) and comprise:

  A patient has to suffer from chronic (> 6 month) pain and has to meet additionally 3 criteria of the following list:
  mental comorbidity that is supportive to the pain disorder, severe physical comorbidity, already existing or imminent impairment of quality of life and/or sickness absence, failure of a previous unimodal pain therapy, of a pain related surgical intervention or a withdrawal intervention, drug misuse

  Data will be assessed via self-report questionnaires and electrocardiogram (ECG).

Characteristics

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

Primary Outcome

Dimensions of interoception: interoceptive accuracy, interoceptive sensibility and interoceptive awareness, as well as autonomous processes measured as (change in) vagal activity (via heart rate variability, HRV) (measured only in T1, T2, T3, T5). HRV and interoceptive accuracy are assessed via ECG with electrodes on the upper body (BIOPAC enhancer). This definitely is a non-invasive procedure. Interoceptive sensibility and awareness are assessed via body perception questionnaire (self-report).
Timetable measures:
T0-baseline, T1 start of the 5-week intervention, T2 2 weeks after start of the 5-week intervention, T3 end of 5-week intervention, T4 3 month after end of intervention, T5 12 month after end of intervention.

Secondary Outcome

All measures are assessed via self-reported questionnaires.
Assessment baseline/T0: Pain history, utilisation (items adapted from the German Pain Questionnaire) and childhood trauma (Childhood Trauma Questionnaire).
Assessment all measuring times T0-T5:
Quality of life (SF-12), pain intensity and frequency (items adapted from the German Pain Questionnaire), clinical mental health (PHQ-9,-15-,-7).
Assessment T1, T3, T4, T5:
Empathie (Levels of emotional awareness scale & Empathy Quotient , Progredienzangst).

During the 5-week intervention quality of therapeutic relationships within small groups will be assessed weekly as process variable with the Group Questionnaire (GQ-D).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Psychosomatische Medizin und Psychotherapie, Ulm**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/04/06**
- Target Sample Size: **30**
- 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

Diagnosis of F45.41 or F45.40, having had a consultation in the outpatient unit and having taken part in the information group before deciding to take part in the treatment program.

Exclusion criteria

not taking part in the treatment program

Addresses

- **Primary Sponsor**

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  Germany

  Telephone: **[---]***
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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*