Trial Description

Title

Long-term effects of multimodal pain therapy

Trial Acronym

MMT Longterm

URL of the trial

[---]*

Brief Summary in Lay Language

Interdisciplinary multimodal pain therapy is based on the bio-psychosocial pain model and has been established in the treatment of chronic pain in recent years. With the present study, it shall be examined whether, respectively, to which extent there are effects of multimodal pain therapy beyond a time interval of one year after therapy.
For the study, all patients, who had been treated in the Interdisciplinary Pain Center, (University Hospital Freiburg) with a multimodal pain therapy of at least four weeks duration within a timeframe of six years are eligible.
With a questionnaire, data on pain scores (mean, lowest and highest pain score during the preceding two weeks, pain score regarded as a bearable), depression, anxiety, stress, pain related disability and the current employment status. The data shall be compared to data prior to treatment taken from the patient's charts. With this study, it should be elucidated whether there is a long term therapeutic effect. Moreover, possible prognostic factors for the long-term effects should be identified.

Brief Summary in Scientific Language

Interdisciplinary multimodal pain therapy is based on the bio-psychosocial pain model and has been established in the treatment of chronic pain in recent years. The efficiency of multimodal pain therapy has been shown in a variety of studies. Systematic reviews showed that regarding pain reduction, the effect sizes of multimodal pain therapy are relatively modest. Larger effect sizes can be reached regarding functionality, and particularly regarding the return to work rate.
To date there are only few long term observations with a follow-up of more than one year after multimodal pain therapy. Most studies on multimodal pain therapy do not examine intervals of more than one year after therapy. Already within this timeframe, in some studies, a reduction of the effects induced by multimodal pain therapy was observed.
With the present study, it shall be examined whether respectively, to which extent there are effects of multimodal pain therapy beyond a time interval of one year after therapy.
For the study, all patients, who had been treated in the Interdisciplinary Pain Center, (University Hospital Freiburg) with a multimodal pain therapy of at least four weeks duration within a timeframe of six years are eligible.
With a questionnaire, data on pain scores (mean, lowest and highest pain score during the preceding two weeks, pain score regarded as a bearable), depression,

anxiety, stress, pain related disability and the current employment status. The data shall be compared to data prior to treatment taken from the patient's charts. With this study, it should be elucidated whether there is a long term therapeutic effect. Moreover, possible prognostic factors for the long-term effects should be identified.

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

Yes

Description IPD sharing plan

All study data will be published. Raw data will be published as supplementary data.

Organizational Data

- DRKS-ID: **DRKS00017685**
- Date of Registration in DRKS: **2019/08/07**
- 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.: **517/18 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F45.41 - [generalization F45.4: Persistent somatoform pain disorder]**

Interventions/Observational Groups

- Arm 1: **With a questionnaire, data on pain scores (mean, lowest and highest pain score during the preceding two weeks, pain score regarded as a bearable), depression, anxiety, stress, pain related disability and the current employment status.**

Characteristics

- Study Type: **Non-interventional**

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- Study Type Non-Interventional: **Observational study**
- 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

Mean, highest, lowest and acceptable pain strength on the NRS (numerical rating scale) at time of follow-up

Secondary Outcome

Depression/anxiety/stress, quality of life, pain related invalidity, employment status

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Interdisziplinäres Schmerzzentrum, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/21**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Day hospital multimodal pain therapy in the ISZ between 1.1.2013 and 31.12.2018.

Exclusion criteria

Incompleteness of questionnaire, severe psychiatric comorbidity, missing language skills to understand questionnaire

Addresses

■ **Primary Sponsor**

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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 ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

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.*