

## Trial Description

### Title

**The treatment of chronic back pain through non-pharmacological intervention procedures:  
Comparison of efficacy of eurythmy therapy, yoga and standard physio therapy**

### Trial Acronym

**YES**

### URL of the trial

**[---]\***

### Brief Summary in Lay Language

**The effectiveness of physiotherapy in the treatment of chronic back pain treatments is generally accepted. We intend to investigate whether also physical interventions which included elements of 'meditation', such as yoga or therapeutic eurythmy, might be beneficial.**

**The purpose of the study is thus to investigate whether these methods in fact have beneficial effects on chronic back pain, whether or not these interventions differ with respect to the outcomes, and which variables may have a significant impact.**

**Chronic pain syndromes, particularly chronic back pain, represent a dramatically increasing problem in medical care. Apart of direct effects of chronic pain such as decreased functioning, mobility and working ability, the continued experience of pain results in significant experience of stress and impairment of quality of life. Conventional treatment options are limited. Analgesics and pain medication are not optimal for long term application because of their well-known side effects. Since several years, non-pharmacological treatment options enrolling different movement methods were investigated. These include standard physical therapy with exercise and walking, as well as yoga exercises from Indian medicine, and therapeutic eurhythmy from Anthroposophic Medicine. In Integrative Medicine, yoga was meanwhile evaluated in randomized controlled studies as a complementary holistic movement intervention. However, there are currently no data from comparative studies which would allow an assessment of the respective treatment effects.**

### Brief Summary in Scientific Language

**Chronic pain syndromes, particularly chronic back pain, represent a dramatically increasing problem in medical care. Apart of direct effects of chronic pain such as decreased functioning, mobility and working ability, the continued experience of pain results in significant experience of stress, impairment of quality of life, and various vegetative affections. Conventional treatment options are limited.**

**Analgesics and pain medication are not optimal for long term application because of their well-known side effects. Non-pharmacological therapies are well established and include physical therapy, physiotherapy, and psychosomatic therapy. In Anthroposophic Medicine, on the basis of data from uncontrolled**



**studies and also expert recommendations, the application of therapeutic eurythmy is encouraged as an effective intervention to treat chronic back pain. However, reliable data from randomized controlled trials are still lacking. In Integrative Medicine, yoga was meanwhile evaluated in randomized controlled studies as a complementary holistic movement intervention. With respect to the overall positive study outcomes when compared to standard exercise therapy, in the Anglo-American region yoga is implemented in guidelines recommendations first. Within the intended three-arm randomized controlled trial, 270 patients with chronic back pain will be examined for 16 weeks. Patients will be treated actively for 8 weeks either with therapeutic eurythmy, yoga or standard physiotherapy. At the start of the intervention, at the end of the 8 week active phase, and after a further 8 week observation period, patients will be investigated with internationally validated and clinically relevant parameters (primary outcome variable: functional disability due to pain, week 8; secondary outcome variables: intensity of pain, quality of life and well-being, perceived stress, etc.). We suggest therapeutic eurythmy and yoga as equally effective, more effective when compared to standard physiotherapy. The results of the project are intended to provide evidence that yoga and therapeutic eurythmy might be a rationale in the regular treatment of patients with chronic pain conditions. Aim of the project is thus the international establishment of therapeutic eurythmy and yoga as optional interventions in the treatment of chronic pain syndrome.**

## Organizational Data

- DRKS-ID: **DRKS00004651**
- Date of Registration in DRKS: **2013/03/22**
- 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.: **EA4/074/12 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

## Secondary IDs

## Health condition or Problem studied

- ICD10: **M54.5 - Low back pain**

## Interventions/Observational Groups

- Arm 1: **Therapeutic eurythmy**  
-> **once a week for 75 minutes during 8 weeks (=8x) (=10h)**
- Arm 2: **Therapeutic yoga**  
-> **once a week for 75 minutes during 8 weeks (=8x) (=10h)**
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Arm 3: **physiotherapy**-> **once a week for 75 minutes during 8 weeks (=8x) (=10h)**

## Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]\*
- Allocation: **Randomized controlled trial**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

**Evaluation of the efficacy of three interventions, i.e., yoga, therapeutic eurythmy and standard physiotherapy within a randomised controlled study enrolling 270 patients with back pain for 8 weeks plus an 8 observation phase) with standardized questionnaires:**  
**Roland-Morris-Disability Score (functional disability due to chronic pain) at baseline, end of intervention (after 8 weeks), and at the end of the observation period (16 weeks)**

## Secondary Outcome

- **Pain intensity (visual analogue scale, VAS, rating scale)**
- **affections by pain (VAS, "Bothersomeness")**
- **Quality of life (SF-12)**
- **Life satisfaction (BMLSS)**
- **Well-Being (ASTS) -> positive mood subscale**
- **Stress perception (Cohen's Perceived Stress Scale)**  
**at baseline, end of intervention (after 8 weeks), and at the end of the observation period (16 weeks)**
- **Usage of analgesic medication (Diary documentation)**  
**=> recorded during the whole observation period (16 weeks)**

## Countries of recruitment

- **DE Germany**



## Locations of Recruitment

- Medical Center **Gemeinschaftskrankenhaus Herdecke, Gerhard Kienle Lehrstuhl für Medizientheorie, Forschungs- und Lehrzentrum Herdecke, Witten - Herdecke**
- Medical Center **Gemeinschaftskrankenhaus Havelhöhe, Forschungsinstitut Havelhöhe, Berlin**
- University Medical Center **Charite Universitätsmedizin Berlin und Immanuel Diakonie Group Berlin, Berlin**

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/02/27**
- Target Sample Size: **270**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

## Additional Inclusion Criteria

- **Duration of back pain > / = 3 months**
- **Intensity of back pain > / = 40mm to 100mm VAS**
- **Legal capacity**
- **Consent to participate and questionnaire filling**

## Exclusion criteria

- **acute herniated disk (<3 months) or herniated disc with surgical indication**
- **tumors with bone metastases**
- **other currently active, non-pharmacological treatments (Inclusion only if 3 months previously), excepted back therapy training**
- **participation in other clinical trials or observational study within the last 4 weeks**
- **acute psychiatric disorders (depression, psychosis, etc.) which may limit the study validity**

## Addresses

■ **Primary Sponsor**

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## Status

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

■ Study Closing (LPLV): [---]\*

## Trial Publications, Results and other documents

DRKS-ID: **DRKS00004651**

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Deutsches Register  
Klinischer Studien

German Clinical  
Trials Register

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*\* 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.*