Trial Description

Title

MiSpEx-Network [National Research Network for Medicine in Spine Exercise] National Research Network for Diagnosis, Prevention and Therapy of back pain in elite Sports and general population - MiSpEx-Multicenter-Interventionstudy

Trial Acronym

MiSpEx - Intervention Study

URL of the trial

http://www.mispex.de/

Brief Summary in Lay Language

Purpose of the study is the validation of preventiv and therapeutic interventions to reduce risk of back pain and and medical condition in elite sports and the general population. Training intervention for the trunk (unimodal) and in Kombination with behavioural therapy (multimodal) are evaluated to a control group (no intervention). Intervention phase is 12 weeks and a total of 24 weeks are screened to assess sustainability. Subjects between 18 and 65 years with/without back pain out of the general population and elite athletes will be recruted.

Brief Summary in Scientific Language

Background: Back pain is a central health issue in industrial countries. The lifetime prevalence is reported with about 90%. In most of the cases, back pain is accompanied with a reduced load bearing capacity in elite sports and it is one major reason for absenteeism at the workplace. This results in a high burden for the health system. The clinical problem is in high loading situations in sport and for subjects with insufficient trunk muscles especially distinct. For development and persistence of medical condition, predominantly deficits on a neuronal, muscular and/or structural level are seen as relevant. Additionally, psycho-social factors are evident. Exercise intervention showed a high efficiency in the prevention and rehabilitation of structural and functional conditions. In contrast, for individual cases the dose-effect relationship to produce adaptation on a structural and functional level resulting in reduced back pain are uncertain. Methods for differential diagnostics in elite sports or the general population need further validation. Due to this lack of evidence, currently an specific and targeted recommendation for back pain treatment is not possible. Therefore, the purpose of the study is the validation of preventiv and therapeutic interventions to reduce risk of back pain and and medical condition in elite sports and the general population. Method: efficacy of excercise intervention will be parameterized by (isolated/combined) adaptations of muscular and neuronal structures as well as pain perception. Training intervention for the trunk (unimodal) and in Kombination with behavioural therapy (multimodal) are evaluated to a control group. Intervention phase is 12 weeks and a total of 24 weeks are screened to assess sustainability. Subjects between 18 and 65 years with/without back pain out of the

general population and elite athletes will be recruted.

Organizational Data

- DRKS-ID: **DRKS00004977**
- Date of Registration in DRKS: **2013/05/16**
- 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.: **36/2011 , Ethikkommission der Universität Potsdam**

Secondary IDs

Health condition or Problem studied

- ICD10: **M54 - Dorsalgia**

Interventions/Observational Groups

- Arm 1: **control group: no intervention**
- Arm 2: **intervention group 1 (unimodal): sensorimotor-/strengthening Training of the trunk (interventiontime:12 weeks; 3 session/week; 45min. each session)**
- Arm 3: **intervention group 2 (mulitmodal): sensorimotor-/strengthening Training of the trunk + educational therapie (interventiontime: 12 weeks; 3 session/week; 45min. each session)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group), Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Parallel**
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Purpose: **Treatment**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

Back pain: assessment by Korff pain questionaire. Measurements: before intervention, after 3, 6, 12, 24 weeks

Secondary Outcome

1. back pain frequency in the last 3 month
2. postural control: center of pressure (COP) for a one-legged stance (force plate)
3. trunk strength: isokinetik trunk extension/flexion peak torque (Nm)
4. fatigue: jumping performance change pre/post fatigue test
Measurements: before intervention, after 3, 6, 12, 24 weeks

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Hochschulambulanz der Universität Potsdam, Potsdam**
- University Medical Center **Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden, Dresden**
- University Medical Center **Universitätsklinikum Heidelberg, Heidelberg**
- University Medical Center **Klinikum der Johann Wolfgang Goethe-Universität Frankfurt am Main, Frankfurt a.M.**
- Medical Center **Schön Klinik Rückeninstitut, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/21**
- Target Sample Size: **600**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

18-65 years of age; subject understand german language; subject is capable to answer a questionnaire without help

Exclusion criteria

acute infection; pregnancy; not able to stand allone; not able to get up from a lying position; disease that contra-induced excercise; acute back pain occured in the last 7 days; additional participation in a parallel MiSpEx study

Addresses

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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URL: **www.bisp.de**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/10/26**

Trial Publications, Results and other documents

- Paper **[---]***

** 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.*