PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Stepped movement-oriented rehabilitation and aftercare in patients with inflammatory and non-inflammatory diseases of the musculoskeletal system

Trial Acronym

boRN

URL of the trial


Brief Summary in Lay Language

People with back pain, rheumatoid arthritis (chronic polyarthritis) or an inflammation of the spinal column often feel bad healthwise: They suffer from severe pain, are exhausted and unable perform their daily tasks like they used to. Some of them are on sick leave a lot, can't handle their workload or have difficulties caring for their home and families. A way for these people to feel better and manage their chores again can be to do sports regularly. Unfortunately, most patients with those conditions don’t exercise much. If the patient’s situation keeps getting worse, they can attend a rehabilitation clinic. Rehabilitation usually takes about three weeks during which patients take part in treatment and courses daily.

Throughout rehabilitation, patients are also encouraged to try out different kinds of sports. At the end of rehabilitation they often get a prescription for sport courses for their time afterwards. But these prescriptions only remain valid for a short amount of time, which means the patients should care for their sport activities on their own after that. Although most want to, they are hindered by problems with their available time and motivation. Therefore, it is indeed pivotal to show different possible sport activities and their positive effect on one's wellbeing to the patients. However, making concrete plans with them on how to exercise more in their daily life and how to support them in actually realising them is just as important.

For our project we formed two groups. One group of patients received the normal treatment during their rehabilitation which meant changing therapists and fellow patients. At the point of starting and finishing rehabilitation, the patients were completing a fitness test we tried out with them. If this test hasn’t worked well, we changed it to let the second group do the improved test. We wanted to examine how the patients developed throughout the exercises during rehabilitation.

During rehabilitation, the second group exercised in a training group eight times a week with the same therapists and fellow patients. In that way, everybody could get to know each other better and motivate one another. Together, the importance of sports and exercise could be discussed. Everyone could share their own experiences and exchange with others. Additionally, everyone got a little
notebook to write down their own ideas on which sport they would like to continue after rehabilitation. This plan was shared with the patient’s family doctor, who supported them in the realisation of their plans. We want to keep in contact with the patients and get to know how they are even after they have finished rehabilitation. The patients themselves decided the way in which we could contact them: for half a year, we either wrote text messages or emails, called the patients or sent a letter from time to time. In that way we also wanted to remind the patients of their plans for exercising back at home.

When starting rehabilitation, all patients filled out a questionnaire about their health, sports activities, their work and several other things. Six months and one year after discharge the patients again received questionnaires to fill out and send back to us. This gave us information on how these things (health, exercise, work) developed over the time. We assumed that patients in the group with the improved fitness test, stable training groups, exercise plans and messages after the end of rehabilitation would feel better after one year than patients in the group with standard treatment.

**Leading Questions:**

Can intensified stepped exercise therapy units with systematic motivational work in in-patient rehabilitation and continuous follow-up care after discharge improve the health-related quality of life as well as the physical and psychological health of patients with the most common inflammatory and non-inflammatory chronic conditions of the musculoskeletal system in the long run?

Can the rehabilitants’ motivation concerning the realisation of physical activities be furthered in the long run and the sociomedical progression be improved?

**Background:**

Making up about a third (inpatient) respectively two thirds (semi-residential) of rehabilitants, chronic musculoskeletal conditions are currently the main cause for medical rehabilitation measures funded by the German Pension Insurance with the most frequent condition being chronic non-inflammatory back pain (BP). Like the most common inflammatory diseases (chronic polyarthritis (cP) and ankylosing spondylarthritis (AS), this diagnosis comes with massive restrictions of physical and psychological health. Chronic pain and sometimes severe limitations of productivity lead to a diminished quality of many aspects of life. To prevent chronification and/or a progression of disease, an early diagnosis and adequate medical care (i.a. medication) are of utmost importance. Activating exercise therapy units serve as important interventions to support the patients in changing their routine into a more active and healthy lifestyle. In the process, the (exercise) therapy must be adapted to serve the rehabilitants’ needs and introduce them to various forms of sports and exercise. Up until now, most studies could only show a positive effect of medical rehabilitation on a short- or medium-term-basis. Motivational intervention modules are intended to encourage the rehabilitants to implement and keep up their exercise program even after leaving rehabilitation. Continuous aftercare going beyond the hospitalisation and the use of new media to keep up the contact with the rehabilitants have shown promising successes in newer studies.

**Study Design:**

The boRN-study was a multicentric intervention study with continuous observations over the course of one year for a participatory organisation of the musculoskeletal rehabilitation and aftercare between the rehabilitants and the rehabilitating team involving the doctor(s) responsible for further treatment. Test persons with chronic back pains, chronic polyarthritis or ankylosing spondylarthritis in the employable age (18 to 65 years) were surveyed in
questionnaires at four time points of measurement (t1=rehabilitation onset, t2=discharge, t3= 6-months-follow-up, t4= 12-months-follow-up).

Method:
The realisation and efficacy of the complex boRN-intervention were analysed prospectively at the end of rehabilitation (t2), and after six (t3) and 12 months (t4) in comparison to the starting condition at the onset of rehabilitation (t1). Compared to the control group (UC: n=266), improvements of the intervention group (IG: n=180) regarding the primary and secondary outcomes were evaluated.

Data sources:
-self-reporting of patients (questionnaires at 4 measurement time points)

Do you plan to share individual participant data with other researchers?
[---]*

Description IPD sharing plan
[---]*

Organizational Data
- DRKS-ID: DRKS00007920
- Date of Registration in DRKS: 2015/04/08
- 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.: [---]*, Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg

Secondary IDs
- ICD10: M51 - Other intervertebral disc disorders
- ICD10: M53 - Other dorsopathies, not elsewhere classified
- ICD10: M54 - Dorsalgia
- ICD10: M05 - Seropositive rheumatoid arthritis
Arm 1: After a screening of physical fitness at the onset of rehabilitation, the participants in the intervention group were referred to one of two performance graduated closed training groups (moderate/intense) with mixed principal diagnosis groups (BP, cP, AS) and integrated motivational work. During the three-week stationary rehabilitation the participants in their closed training groups completed eight units of 60 minutes with exercise elements to advance flexibility, strength, stamina and coordination, which each exceeded the conventional rehabilitation units in their intensity. The screening of physical fitness for the group was repeated at the time of discharge. Individual aftercare-counselling was realised in the clinic. After discharge the rehabilitants receive 20-week-aftercare through a medium of communication technology they chose (letter/telephone call or text messages/e-mail), which is organised and carried out by the aftercare-representative of the clinic. The doctor(s) responsible for further treatment were asked for their assistance in the implementation of the patients’ exercise plans.

Arm 2: The control group received conventional musculoskeletal rehabilitation.

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Non-randomized controlled trial
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Active control (effective treament of control group)
- Purpose: Treatment
- Assignment: Other
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

physical role function of the Short-Form 36-Item Health Survey (Bullinger & Kirchberger, 1998): comparison between control group and intervention group at t4 (12 months after discharge) while controlling for the initial value at t1
**Secondary Outcome**

- Physical and mental component score of the short-form 36-Item Health Survey (SF-36) (Bullinger & Kirchberger, 1998)
- Pain in the last 4 weeks: numeric rating scale (0 = no pain to 10 = unbearable pain)
- Fatigue in the last 4 weeks: numeric rating scale (0 = no fatigue to 10 = total fatigue)
- Function status: Physical Fitness Questionnaire (FFb-Mot) (Bengel, Wirtz, & Zingmann, 2008; Bös et al., 2002)
- Participation: index for measurement of the limitations of participation (IMET) (Deck, Mittag, Hüppe, Muche-Borowsk, & Raspe, 2007)
- Anxiety and Depression: Hospital Anxiety Despression Scale -german version (HADS-D) (Herrmann-Lingen, Buss & Snaith, 2005)
- Physical activity in daily life, leisure time and sports activity: Freiburg Questionnaire of physical activity (FFkA) (Frey, Berg, Grathwohl, & Keul, 1999)
- Perceived advantages and disadvantages of physical activity: decision balance concerning physical activity (Basler, Quint, & Wolf, 2004)
- Sports-related HAPA-scales (Schwarzer, 2008): risk perception, self-efficacy expectations, action outcome expectations, intention of exercising, behavior change planning, barriers and resources of physical activity per questionnaire for assessment of health-related behavior (FEG) (Bengel et al., 2008)
- Sick leave in the last 12 months
- Application for disability benefits

All secondary outcomes were analysed through a group comparison between control- and intervention group at t4 (12 months after discharge) while controlling for the initial value at t1 (rehabilitation onset) as well.

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- Medical Center Rehazentrum, Bad Eilsen
- Medical Center Fachklinik Blankenburg, Teufelsbad

**Recruitment**

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2011/05/02
- Target Sample Size: 630
- 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**

- ICD-10-diagnosis of inflammatory-rheumatic diseases: back pain (M51-M54), chronic polyarthritis (M05-M07) or ankylosing spondylarthritis (M45-M46)
- medical rehabilitation after the Allgemeinem Antragsverfahren or expedited procedure
- sufficient language proficiency
- written agreement of participation in the study

**Exclusion criteria**

- follow-up treatment
- surgery in the last three months
- severe cardiopulmonary condition (contraindication for intense physical exercise)
- insufficient proficiency in german (for filling out questionnaires)
- ongoing application for disability pension benefits
- inability to train in groups, contingent upon insufficient health

**Addresses**

**Primary Sponsor**

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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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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2013/12/31

Trial Publications, Results and other documents


- Abstract: Golla, A. (2013). Patientenorientierte systematische Motivation zur langfristigen Bewegungsförderung während und nach orthopädisch-


* 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.