Title: Effects of an individually tailored therapy by patients with non-specific chronic back pain: study protocol of a pragmatic controlled clinical trial

Background

Low back pain is a leading global health problem. In particular, patients suffering from non-specific chronic low back pain (NSCLBP) are a persisting challenge for treatment strategies. Detecting relevant subgroups of patients in regard with their risk of further chronification or preferences for exercise programs is a priority area for clinical research.

Method/Design

This paper describes a study protocol of a pragmatic controlled clinical trial, which will separately evaluate a risk- and preference-orientated therapy. We will recruit 160 participants with non-specific low back pain from two clinics, located in Bavaria (Germany). Whereas the risk-orientated therapy mainly focus on a stratified approach concerning measured symptoms as depression and anxiety, the preference-orientated approach will directly ask patients which exercise-program fits best.
The primary outcome is self-reported functional status measured 6 months after rehabilitation. Secondary outcomes include pain intensity, work ability, anxiety, depression and patient satisfaction. Data will be collected at the beginning, the end and 6 months after in-patient treatment. To enhance clinical implementation of the risk- and preference-orientated approach, the trial will not extend therapeutic services or change any clinical practice during treatment. Problems arising from non-randomization will be statistically addressed.

Discussion:

This paper presents detail on the design, methods and clinical benefits of the study.

Trial registration:

Germanctr.de identifier DRKS00008831, registered on July 2015

Keywords: non-specific low back pain, stratified therapy, inpatient rehabilitation

Background

Low back pain is recognized as a worldwide health problem regarding its medical and economic impact on patients and society [1, 2]. In Germany people who are suffering from chronic back pain can apply for a medical rehabilitation therapy, which usually takes three weeks with therapies in accordance with the biopsychosocial model of health [3].

Despite the relevance of low back pain and especially of the so called non-specific low back pain [NSLBP], therapeutic interventions showed weak effectiveness [4], which already has led to the implementation of a range of newly developed interventions. One promising approach is the functional restoration which combines intensive exercise therapy alongside with behavioral therapy and vocational therapy [5]. Some systematic reviews have shown moderate evidence for improved functioning by applying programs following the principles of functional restoration (FR) or more general by multidisciplinary biopsychosocial rehabilitation (MBR) [6-8]. These findings were not uniformly confirmed by other studies [9-11] and these therapies required higher expenses due to a minimum of 100 hours therapeutic services, which is above the amount of care usually applied in rehabilitation clinics [12]. Despite some reviews showed moderate evidence in favor for these newly implemented therapeutic strategies it requires additional cost-benefit analysis [6, 8] to justify the higher costs.

A few studies implicate, that programs focusing on psychological interventions could improve effectiveness [13]. These studies are motivated by theoretical frameworks such as the fear-avoidance model [FAM], which was originally introduced by Lethem et al. [14] and divided the reactions on a pain event in two paths. On the one hand the confronters, who response to pain with continued exercise and therefore will recover. On the other hand the avoiders, which reduce physical activities due to fear

of pain and hence show further deteriorations as catastrophizing, pain-related disability and depression. Since then, the FAM was further developed and can be seen today as state of the art [15, 16]. But up to date, it is still unknown what type of patients benefit most from which type of psychological intervention [17].

One reason for the repeatedly confirmed lack of effectiveness of medical rehabilitation of back pain is seen in the insufficient individualization in terms of a risk- and preference orientated therapy [18, 19]. Signs of mental disorders such as depression or anxiety should consequently lead to a behavioral therapy [20]. Whereas a preference tailored exercise therapy is applied to improve the adherence to therapies during the rehabilitation therapy and will therefore help to increase everyday activities afterwards [21].

Although the medical rehabilitation in Germany can be characterized as a multidisciplinary biopsychosocial treatment [22, 23] a standardized measurement of risks with a stratified distribution of therapeutic services as recommended by national guidelines [24] and therapeutic standards of the German Pension Fund [25] is not yet established.

Aims of the study

The aim of the study is to evaluate a need-orientated, tailored therapy for patients with NSCLBP. Depending on the extent of individual risks and preferences an appropriate therapeutic regime is recommended. The interventions will be implemented at two rehabilitation centers with a different focus, each:

Focus I: Development of screening-based evaluation of symptoms upon entry with a theory-based and empirically coherent matching to increase functional status..

Focus II: Adapting the subjective preferences for exercise therapy to the inpatient

rehabilitation program in order to improve functional status as well and to facilitate an increased outcome of everyday exercises.

Study design

To evaluate how a risk or preference stratified therapy affects the effectiveness of inpatient rehabilitation a controlled clinical trial is conducted in two inpatient rehabilitation centers in Germany. These clinics implement either the screening of risks or the preference-based approach. The control group will get the conventional therapy and data will be collected purely via paper-pencil. The control group will be carried out before the intervention starts. The subsequent recruitment of the intervention group will use the before mentioned approaches (Figure 1).

Due to the non-randomized design the TREND Statement serves as a guideline for the study reporting [26]. While several randomized trials were already conducted in the setting examined here, none of them could realize an adequate blinding of the treatment or a proper allocation concealment. Furthermore, compared to the conventional therapy, services in subsequent studies were significantly extended during the intervention and hence conclusions concerning the treatment efficacy are difficult to draw. In consequence to this, the German Advisory Council on the Assessment of Developments in the Health Care System concludes that the majority of randomization trials are biased and show as weak internal validity as non-randomized controlled trials [4].

All Patients invited to rehabilitation are already assessed with respect to their medical condition by the German Pension Fund [27]. Therefore, the target population is well defined and a selection effect, which is defined by a lack of representativeness of the sample is reduced. The advantage of the here chosen pragmatic non-randomized design is expected to lead to a higher external validity of the results for the clinical

setting [28, 29]. Finally, a pragmatic study fitting to the existing clinical procedures without extending therapeutic services will have a higher chance of being permanently implemented into routine clinical practice.

Nevertheless, the risk of biased results occurring from a lack of internal validity will be assessed by a data driven approach.

The trial registration was done in the German Clinical Trials Register (DRKS-ID: DRKS00008831). Ethical approval was obtained by the ethics committee - Charité - Universitätsmedizin Berlin (EA1/097/15).

The primary and secondary outcomes will be measured by self-administered questionnaires at the beginning, the end, as well as six months after rehabilitation. Additionally, information from the discharge letters about the applied therapies, comorbidities and aftercare recommendations are used to gather additional information for further analysis. Despite different intervention strategies the primary outcome is the same for both rehabilitation centers.

Theory and Hypothesis

The screening approach focuses on the measurement of pain disability and psychological symptoms as a measure of anxiety and depression and if a certain threshold is reached a therapeutic program will be recommended. To stratify therapy according to the mentioned risk factors is motivated by the FAM.

According to this theoretical framework our primary hypothesis is, that a better symptom-orientated allocation of therapeutic services will lead to an improved functional status six months after rehabilitation.

A pronounced orientation towards patient-preferences in the exercise therapy will not use a single theory. But understanding and improving adherence to exercises is object of a number of models and theories. Among them the theory of planned

behavior is perhaps the most useful here [30, 31]. Nevertheless, since adherence implies that people freely choose to undertake behavioral plans, a preference tailored exercise therapy is thought to increase motivation for therapy and hence trigger a sustainable change in behavior with beneficial effects on the health state.

Therefore, our primary hypothesis is identically formulated to the screening approach hypothesis. Thus a preference orientated exercise therapy will increase functional status measured at six months after rehabilitation.

Due to the questionnaires used a set of secondary hypothesis will be evaluated. Concerning the screening approach not only the functional status but also pain intensity, depression, anxiety and working ability should be improved. Whereas an exercise programs matching better to individually preferences should lead to increased physical activity in everyday life and is thought to reduce pain intensity. Furthermore, both approaches should indicate that a stratified therapy will be perceived more satisfactory, which will be measured with direct questions at the end as well as 6 months after rehabilitation.

Finally, we use the discharge letters for extracting information about the therapeutic services and the aftercare recommendations.

A detailed overview of the used assessments with respect to their course in time and measured construct will find in table 1.

Methods

Study Participants and Eligibility

All patients who are assigned to the rehabilitation clinics with a fitting diagnosis will be informed via a written information about the aim of the study and enrolled to a patient list. After enrollment the inclusion diagnosis and the exclusion criteria (see table 2) will be examined by a physician, who finally decides whether the patient is

eligible or not. All eligible patients will be informed about the aims of the study and asked to sign a written informed consent in order to become a participant.

The prospective controlled clinical trial will be carried out in two orthopedic inpatient clinics both located in the federal state of Bavaria. The “Orthopädie-Zentrum Bad Füssing” implements the preference-orientated approach concerning exercise therapy whereas the “Klinik Höhenried” evaluates the screening-approach.

Interventions

Control

Participants in both control groups receive the conventional biopsychosocial rehabilitation according to the therapeutic standards defined by the German Pension Fund [25]. In average this inpatient rehabilitation program last 3 weeks and includes components from exercise, psychological and occupational therapy which adds up to a total of 60 hours. Whereas exercise therapy, as the main therapy module in general rehabilitation, is applied to all patients, the others are allocated to requirements. Study patients will be asked to fill out a self-administered questionnaire at the beginning, the end and six months after rehabilitation. Additionally, the discharge letters will be collected for each patient.

Intervention

The procedure of enrollment and proof of eligibility will be the same as in the control group but the self-administered questionnaires at the beginning will be entered in a computer, which generates a printout with the results and the recommended therapies. In case of the preference orientated approach the patients will choose one out of three of the following therapeutic programs:

(1) Module “Play and Fun”, e.g. table tennis, game-oriented water based exercises

(2) Module “endurance e.g. nordic walking, swimming

(3) Module “strengthening”, e.g. therapeutic climbing, strength training

The intensity of the chosen approach will be adjusted depending on the severity of pain graded according to van Korffs pain scale [32].

In addition to the chosen exercise module, which lasts approximately 30 hours, patients will receive psychological, educational or occupational therapies, when it seems necessary.

For the screening based approach printouts were generated as well. But in contrast, the results of the self-reported questionnaires will be directly translated into therapeutic recommendations without asking patients about their preferences. All recommendations will be in accordance with the therapeutic standards of the Germen Pension Fund [25]

Based on the described instruments (see table 1) the algorithm is as follows:

(1) Increased pain disability (PDI) [33]: pain management program of at least 200 minutes, if the score is greater than 32 points [34].

(2) Symptoms of depression or anxiety (PHQ-4) [35]: at least one psychological single-session with a duration of 60 minutes, if the score is greater than or equal 6 points.

(3) Increased pain intensity (NRS): relaxation training to an extent of at least 180 minutes, if the average score is greater than 5 points [36].

(4) Reduced work ability (SPE) [37]: occupational therapy of at least 75 minutes will be recommended, if the score is greater than 1 point. In addition, patients with a self-reported poor working ability and with thoughts on a disability pension should intensively informed about further options of an intensified vocational rehabilitation.

In both orthopedic centers the printouts, which display visually the results of the measurements, should be used for communication and motivation of the patients throughout their stay.

Follow up/Drop-outs

Dropouts are defined as patients who withdraw their written consent during the study period. All recorded data will be deleted and no further contact will be made. Otherwise, all patients who are not withdrawing their consent will be contacted at all time points.

Lost to follow up is defined by not filling out a questionnaire at a time point due to any reasons. It is assumed that only a small number of patients will be lost to follow up or withdraw their consent between baseline and discharge. We expect a substantial increase of drop out and lost to follow up (up to 40%) in following period regardless of postal reminders, which will be send after four weeks if questionnaires haven't been sent back. Non responders will be analyzed with respect to their age, gender and baseline measures.

Statistics and Sample Size

Sample size calculation for the primary outcome is done for an analysis of covariance (ANCOVA) according to Borm et al. [38]. They propose to multiply the sample size for the two sample t-test by a design factor, which incorporates the correlation coefficient between the outcome and the covariate. Depending on the magnitude of the correlation a reduced sample size is needed.

In accordance with empirical results [22] we assume a moderate effect size of cohen's d = 0.5 and a correlation between measurements of p=0.5. Finally, we test *H0: equal population means between groups six months after rehabilitation adjusted for covariates* at a significance level alpha=0.05 with a power of 0.8. The sample size

approximation was done with G-Power 3.1.2 [39] and results showed that the recruitment of 48 Patient in each group is sufficient. Allowing for a 40% loss to follow-up and drop outs, we aim to recruit a total of 160 patients in each clinic, 80 per study arm, at the beginning.

Since the ANCOVA is a complete case approach, lost to follow-up at any time lead to a full exclusion of all measurements. Mainly therefore we will also fit an individual growth model for the primary outcome as well as for other metric secondary outcomes [40]. Patient satisfaction will be analyzed by contingency tables and dichotomous outcomes by log-linear models [41]

Compared to randomized trials our design lacks internal validity. Therefore we will run propensity-score matching using a nearest neighbor algorithm with a caliper width of 0.2 of the standard deviation of the logit of the propensity score [42].

All analysis will be performed according to the intension-to-treat principle and the per-protocol principle.

Discussion

Whereas a screening based, stratified approach is already successfully developed for primary care [43] combining risk measurement with therapeutic pathways is not yet evaluated for patients in settings as inpatient rehabilitation. Therefore, the results of the presented study will clarify whether a risk and preference stratified therapy approach can also improve functional status of patients with already chronic low back pain.

During the interventions, there will be no additional therapy implemented compared to care as usual, thus the study can contribute to cost effective therapies of rehabilitation services as well. That is an important point since new treatments which extend therapeutic services during the intervention are already in use in the German

rehabilitation system [44]. Therefore, findings that support a comparable effectiveness without increasing costs could lead to a better use of financial resources [45].

In order to permanently establish the risk and preference stratified treatment in clinical routines a pragmatic study design was chosen and only license-free and short forms of self-reported questionnaires are used.

The results will also contribute to the ongoing debate about adequate clinical management options by patients with non-specific back pain [46].

From a theoretical point of view, the implications of the FAM will be proven for patients with already chronic low back pain, which are assumed to have a poorer general health status than patients with acute pain for whom the model originally was derived.

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Table 1: Outcome measures and collected data

Outcome	Questionnaire	time points		
Primary Outcome (equal for both interventions)		t1	t2	t3
Functional Status	Hannover Functional Ability Questionnaire Back Pain (FFbH-R): measures restrictions in ADL through 12 items range from 0-2 each. 0 means “can’t do”, 1 “can do but with trouble”, 2 “not restricted”	x	x	x
Secondary Outcome Screening based approach				
Pain Disability	Pain Disability Index (PDI) (0-70): constructed on 7 NRS with range 0 to 10 each. 0 means “no disability” and 10 “maximum disability”.	x		x
Pain intensity	NRS Pain: 3 items range from 0-10, each. 0 means “no pain” and 10 “maximum pain”.	x		x
Depression & Anxiety	Patient Health Questionnaire (PHQ-4) (0-12): 4 items, 2 items covering general anxiety and 2 asked for depression symptoms. All items range from 0 to 3, 0 means “not at all” and 3 “almost every day”.	x	x	x
Ability to Work	Subjective Prognosis of gainful Employment (SPE). 3 items asking current and expected work ability as well as plans for early retirement. All items are analyzed dichotomous, where 0 respectively indicate no negative sign.	x	x	x
Treatment Satisfaction	Questions are in accordance with the quality-assurance program of the German Pension Fund The four items asked satisfaction with treatment (e.g. “Overall, how do you rate the rehabilitation process?”) on a five-point ordinal scale (1 "very poor"... 5 "very good")		x	x
Secondary Outcome Preference based approach				
Pain Status	Graded Chronic Pain Status (GCPS) according to Korff	x		x
Treatment Satisfaction	as mentioned above		x	x
Physical Activity	The two items asked for physical activity in days a week and how long in terms of minute activity last.			x
Data not gathering by questionnaires				
Demographic Charactieristics	sex, age, nationality, marital status, education			
Discharge Letters	social medical characteristics, therapeutic applications and aftercare recommendations			

Table 2: Inclusion diagnosis and exclusion criteria

Inclusion diagnosis (ICD-10):
-M51.2-M51.9 (other intervertebral disc disorders), -M53.8, M53.9 (other specified/unspecified dorsopathies), -M54.4-M54.9 (lumbago with sciatica, low back pain, pain in thoracic spine, other/unspecified dorsalgia),
Exclusion criteria
-specific underlying diagnosis of the back pain "red flags"(e. g. rapidly progressive neurologic deficit) -poor health status (e.g. comorbidities) -age below 18 or above 65 -insufficient German

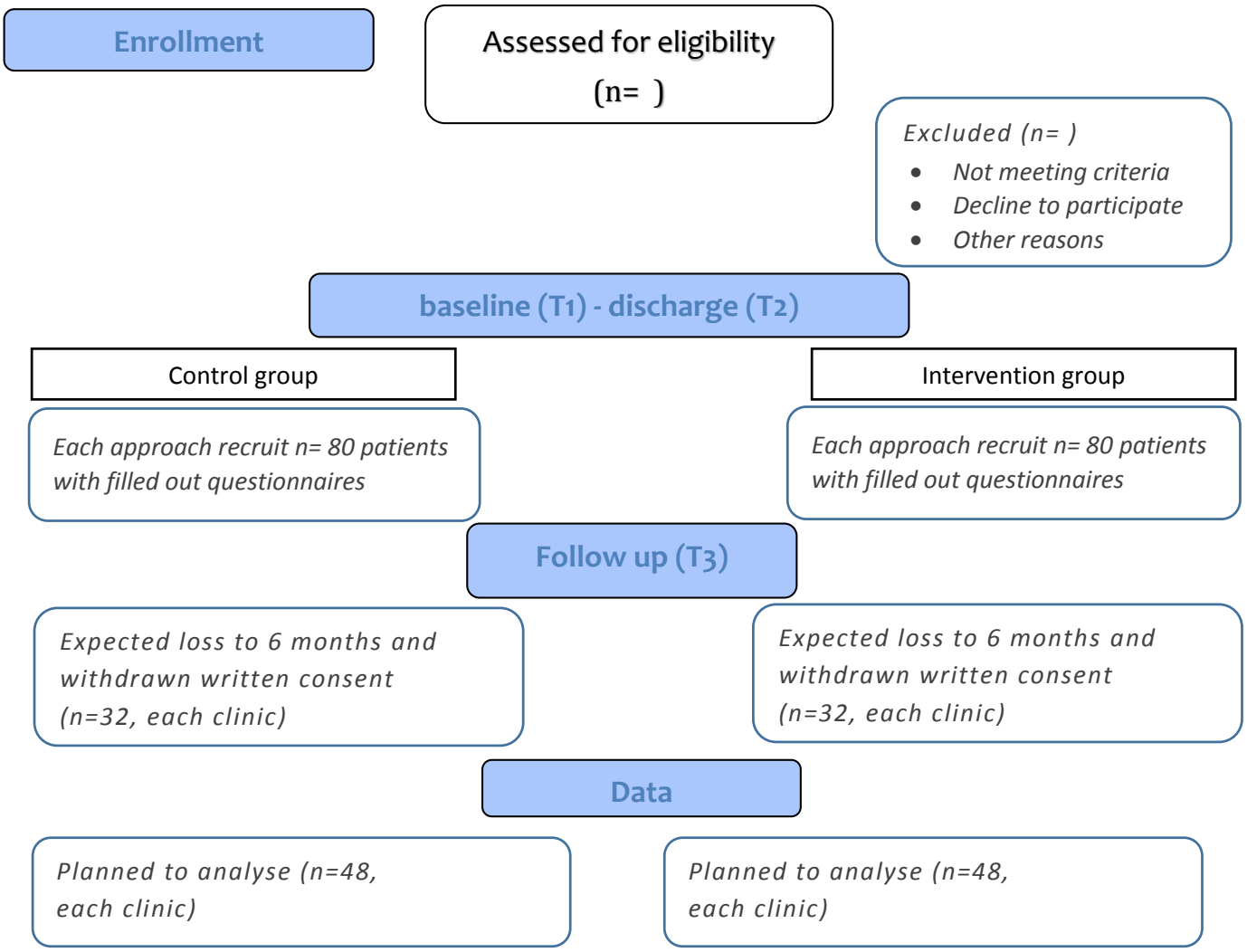

Figure 1: Study Flow Diagram