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Media-supported music therapy in the integrative pain therapy of chronic back pain

Submission date
11/05/2012

Recruitment status
No longer recruiting

Registration date
08/06/2012

Overall study status
Completed

Last Edited
29/09/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Chronic pain is one of the most serious quality-of-life impairing and difficult to treat diseases. Usually, affected patients have been through a wide range of treatments with insufficient improvement. For the affected patients, the pain impairs all aspects of daily life. Against this background, the development and evaluation of treatment methods that go beyond conventional pain therapy is urgently required. By modifying the focus of pain perception, music therapy is likely to be an appropriate treatment method. A special receptive music therapy approach has been developed within the MusicMedicine Research Program of the Paracelsus Medical University of Salzburg, containing audio programs composed on the basis of neurophysiological and psychological aspects of music. These programs are applied by listening twice daily for 30 minutes via headphones played from a special audio device. The efficacy of this treatment was demonstrated in a controlled study including outpatients with depression. The aim of this study is to find out about the effectiveness of receptive music therapy during the rehabilitation of patients with chronic low back pain.

Who can participate?
Patients aged 18 65 who have had chronic back pain for over 6 months.

What does the study involve?
Participants will be randomly allocated to be treated with either receptive music therapy in addition to standard treatment, or standard treatment only. The extent of pain reduction will measured by completing a questionnaire before and after treatment and at the 6-month follow-up.

What are the possible benefits and risks of participating?
The possible benefits are relief from pain and depression. There are no risks involved in this study.

When is the study starting and how long is it expected to run for?
It is anticipated that recruitment will start in October 2011. Participants will be enrolled on the study consecutively for a period of 2 years.

Where is the study run from?
Research Program MusicMedicine, Paracelsus Medical University Salzburg (Austria); Klinik Roseneck, Prien am Chiemsee; Orthopaedie-Zentrum, Bad Fuessing; Schoen Klinik Staffelstein; Schoen Klinik Harthausen; Orthopaedische Klinik Tegernsee.

Who is funding the study?
Deutsche Rentenversicherung Nordbayern (German statutory pension insurance of Northern Bavaria).

Who is the main contact?
Vera Brandes, vera.brandes@pmu.ac.at
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Media-supported music therapy in the integrative pain therapy of chronic back pain: a randomized controlled trial

Study objectives
In what way is receptive music therapy effectively applicable in chronic pain patients, particularly in rehab clinic inpatients with chronic low back pain?

We suppose that combination therapy (receptive music therapy and clinical standard treatment) of chronic low back pain patients is more effective than clinical standard therapy alone regarding symptom reduction (measured by the German pain questionnaire) and subjective disability immediately post treatment as well as after 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Commission of Bavarian Chamber of Physicians [Ethik-Kommission der Bayerischen Landesärztekammer (BLAEK)], Germany, 10/17/2011, ref: 11090

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic back pain

Interventions
During their inpatient rehabilitation treatment (3-4 weeks), the intervention group will be treated with receptive music therapy (i.e., specially developed audio programs, 5 to 7 days per week, each day 2 x 30 minutes) in addition to standard clinical pain treatment, whereas the control group will undergo only standard clinical pain treatment.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Short- and long-term (pre-, post-treatment and 6-month follow-up) difference between intervention and control group:
1. Regarding the extent of pain reduction (measured by the German pain questionnaire [Deutscher Schmerzfragebogen])
2. Regarding subjective disability (measured by the Hannover Functional Ability Questionnaire [Funktionsfragebogen Hannover zur alltagsnahen Diagnostik der Funktionsbeeinträchtigung durch Rückenschmerzen, FFbH-R]
3. Documentation of sociodemographic data (Bado)
4. German Pain Questionnaire (DSF)
5. Hannover Functional Ability Questionnaire for the diagnosis of near-daily functional impairment by back pain (FFbH-R)
6. Beck Depression - Inventory (BDI-II)
7. Questionnaire for acceptance of receptive music therapy at enrollment MT Primary Questionnaire and to 'hear the inner music' (Brandes and Hillert)

Key secondary outcome(s)
1. Exploration of mode of action (mediation vs moderation): To what extent will comorbid depression symptoms ameliorate during the intervention (mediation)? Do patients with comorbid depression show more response to the intervention (moderation) than non-depressed patients? Depressive symptom severity will be measured by the Beck Depression Inventory II (BDI II) and the Quick Inventory of Depressive Symptomatology, clinician rating (QIDS-C).
2. To what extent does receptive music therapy affect recreational ability, reaction to stressful situations and subjective life quality?
3. Treatment adherence and compliance will be assessed by a questionnaire (music therapy acceptance questionnaire) as well as an analysis of dates, times and frequencies of listening,

which will be automatically recorded by the audio devices.
4. Patients will be asked for their subjective appraisal of the intervention

Completion date
31/03/2013

Eligibility

Key inclusion criteria
1. Main diagnosis: chronic back pain (highest degree of chronification according to Gerbershagen) of non-specific origin pain symptom duration > 6 months
2. Age: 18 65 years
3. Adequate knowledge of the German language
4. Written consent for study participation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pain of specific origin
2. Surgical indication (e.g., radicular deficits, spondylolisthesis)
3. Acute inflammation of the musculoskeletal system
4. Severe acute psychiatric conditions (e.g., psychosis, severe depression)
5. Alcohol or drug addiction
6. Clinically relevant hearing loss

Date of first enrolment
01/10/2011

Date of final enrolment
31/03/2013

Locations

Countries of recruitment
Austria

Germany

Study participating centre
Waehringer Strasse 115/19
Vienna
Austria
1180

Sponsor information

Organisation
German Statutory Pension Insurance of Northern Bavaria (Deutsche Rentenversicherung Nordbayern) (Germany)

ROR
https://ror.org/05am9gt90

Funder(s)

Funder type
Government

Funder Name
German Statutory Pension Insurance of Northern Bavaria (Deutsche Rentenversicherung Nordbayern) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration