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Pilot study for the evaluation of a combined psycho- and physiotherapeutic treatment program for patients with chronic pelvic pain syndrome (CPPS)

Submission date
14/03/2016

Recruitment status
No longer recruiting

Registration date
10/05/2016

Overall study status
Completed

Last Edited
16/12/2021

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Although Chronic Pelvic Pain Syndrome (CPPS) is a severe illness suffered by a notable amount of patients, little is known about its causes. Two new treatments have recently been developed - in the USA and Canada – both having psychological and physiotherapeutic elements. Results for both have been promising so far. However, until now, both methods have only been tested separately and only with male patients. In this study, the feasibility of both approaches will be examined together and with both female and male patients. The researchers also want to find out whether there are things than can be improved upon.

Who can participate?
Patients who suffer from CPPS, have visited the specialized outpatient clinic for CPPS at the University Medical Center Hamburg, and whose quality of life is impaired.

What does the study involve?
Participants are randomly allocated to one of 4 same-sex groups.. One group of female patients and one group of male patients first receive psychotherapy followed by physiotherapy. The other two groups receive physiotherapy only. The psychotherapeutic module involves 9 group sessions led by two experienced therapists. In these sessions, patients learn how to reduce catastrophizing thoughts, how to deal with behavioral and social aspects of CPPS and how to improve everyday activities. In the course of this module, they get to know and try out new coping strategies. The physiotherapeutic module involves 9 sessions in both single and group settings. It includes techniques for self-perception and relaxation as well as elements of respiratory and heat therapy. All participants are asked to fill out questionnaires regarding their physical and emotional well-being therapy at 6 time points. Participants are also investigated by a physiotherapist before each module and four weeks after the last module. Furthermore, the researchers will assess a group of patients that act as controls that cannot take part in the therapy due to their places of residence.

What are the possible benefits and risks of participating?
Participation in this study may increase the quality of life of participants and reduce their pain. There are no significant risks of taking part; some participants may find the therapy distressing or the therapy may not work for them. In these cases, they can approach the experienced therapists who accompany the study.

Where is the study run from?
Department of Psychosomatic Medicine and Psychotherapy , University Medical Center Hamburg (Germany).

When is the study starting and how long is it expected to run for?
January 2015 to January 2018

Who is funding the study?
The PRANA Foundation

Who is the main contact?
Dr Christian A. Brünahl

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Pilot study for the evaluation of the feasibility and the efficacy of a combined cognitive-behavioral and physiotherapeutic treatment program for patients with chronic pelvic pain syndrome (CPPS) within the context of the "Interdisciplinary Research Platform, Chronic Pelvic Pain Syndrome (CPPS)“

Acronym
COMBI-CPPS

Study objectives
Hypothesis 1: Health-related quality of life as measured by the SF-12 will have improved after treatment, either in the physical or the mental domain.
Hypothesis 2: Symptom severity as measured by the NIH-CPSI will have decreased after treatment.
Hypothesis 3: Catastrophizing cognitions concerning pain as measured by the PCS, depressiveness (PHQ-9), anxiety (GAD-7), general somatic symptoms (PHQ-15), perceived stress (PSQ), as well as the number of trigger points will have decreased.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board of the Medical Association of Hamburg, 02/12/2014, ref: PV4801

Study design
Interventional single-centre crossover design with a control group

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Chronic pelvic pain syndrome (CPPS) .

Interventions
Based on the “Cohort Multiple Randomized Controlled Trial” design, patients will be recruited from an interdisciplinary outpatient clinic for CPPS at the University Medical Center Hamburg. Assignment to the treatment and control groups will not be randomized, but will be defined by the ability to participate regularly at the place of treatment.

The treatment group will receive two successive treatment modules, each comprising nine weeks. The psychotherapeutic module is based on the preliminary work of a Canadian research group and consists of a cognitive-behavioral short-term intervention in groups. The physiotherapeutic module is based on the preliminary work of a work group from the USA and will take place both in individual and group settings. Following a cross-over design, one female and one male patient group each will be assigned to one of two sequences of the treatment modules.

The control group will consist of 18 patients who will not be able to participate in the therapy due to their place of residence and who will receive treatment as usual.

Data from 7 points of time before, during and after treatment as well as in comparison to the control group will be analyzed.

Intervention Type
Mixed

Primary outcome measure
Health-related quality of life (SF-12); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment

Secondary outcome measures
1. Symptom severity (National Institutes of Health Chronic Prostatitis Symptom Index, NIH-CPSI); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
2. Pain perception (Short-Form McGill Pain Questionnaire, SF-MPQ); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
3. Pain-related disability (Pain Disability Index, PDI); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
4. Catastrophizing cognitions (Pain Catastrophizing Scale, PCS); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
5. Depressive symptom severity (Patient Health Questionnaire depression module, PHQ-9); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
6. Generic somatic symptom severity (Patient Health Questionnaire Somatization module, PHQ-15); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
7.Anxiety symptom severity (Generalized Anxiety Disorder 7-item scale, GAD-7); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
8. Perceived stress (Perceived Stress Questionnaire, PSQ); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
9. Utilization of the health care system (proprietary questionnaire); 7 times of measurement: at the time of visiting the outpatient clinic, at the time of inclusion, before and after each treatment module as well as four weeks after the overall treatment
10. Physiotherapeutic examination of trigger and tender points; prior to the first and prior to the

second treatment module as well as four weeks after the overall treatment
11. Goal attainment (GAS): directly after the physiotherapeutic module and four weeks after overall treatment (added 13/05/2016)
12. Satisfaction with the treatment (proprietary questionnaire); before the second module as well as four weeks after the overall treatment

Removed outcomes:
11. Goal attainment (GAS): after each module and four weeks after overall treatment
13. Selective attention on pain-related stimuli, measured by a computer-based dot-probe-task; 3 times of measurement: before the psychotherapeutic module, directly after the psychotherapeutic module and 4 weeks after the psychotherapeutic module (added 13/05/2016)

Overall study start date
01/01/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. A diagnosis of CPPS
2. A score ≤ 40 either in the mental or the physical scale of the SF-12
3. Sufficient knowledge of the German language

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
54

Total final enrolment
60

Key exclusion criteria
1. Substance dependence
2. Delusional disorder

Date of first enrolment
23/05/2016

Date of final enrolment
15/07/2017

Locations

Countries of recruitment
Germany

Study participating centre
University Medical Center Hamburg
Martinistraße 52
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Sponsor information

Organisation
University Medical Center Hamburg

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/01zgy1s35

Funder(s)

Funder type
Charity

Funder Name
PRANA Foundation/ PRANA-Stiftung im Stifterverband für die Deutsche Wissenschaft

Results and Publications

Publication and dissemination plan
1. A study protocol will be disseminated in an international peer reviewed scientific journal and presented in national and international conference talks
2. The results will be presented in an international peer reviewed scientific journal and presented in national and international conference talks
3. The results will be used to plan and conduct a randomized controlled trial (RCT)

Intention to publish date
31/07/2018

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	09/01/2018		Yes	No
Results article		14/12/2021	16/12/2021	Yes	No