ISRCTN12277345 https://doi.org/10.1186/ISRCTN12277345

Group body psychotherapy for somatoform disorder

Submission date
16/05/2018

Recruitment status
No longer recruiting

Registration date
27/03/2019

Overall study status
Completed

Last Edited
04/03/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Patients frequently report persistent physical symptoms (PPS) despite the fact that doctors did not identify a specific organic disease to explain those symptoms. Those symptoms are of great concern for patients, they can cause significant distress and often have negative consequences on patient's quality of life. Despite developments for better access to integrated health care a substantial proportion of patients with those conditions are not responding to standard treatments. This is partially a result of the fact that patients often feel their symptoms are misunderstood as if the complaints are "all in the mind". Research established that these physical complaints are complex in nature and that many factors are relevant for the development of these persistent physical symptoms.
PPS (also labelled as "Medically unexplained symptoms", or "Somatic distress disorder") are often characterised by multiple complaints in different locations of the body and patients present not only to primary care but in multiple medical specialist settings. Patients with PPS often experience their bodies as problematic and lack confidence in their normal bodily functions. The symptoms pose challenges to clinicians and patients alike, resulting in significant cost pressure on health care systems.
Talking therapies, predominantly those with a Cognitive Behaviour Therapy background, have been tested in various studies and were found to be effective mainly for some specific PPS conditions such as 'fibromyalgia' and 'irritable bowel syndrome'. Only few studies were carried out in patients with more general PP and a systematic review of findings concluded that the effects of talking therapies tested in those studies was small.
For those reasons and in order to achieve better outcomes for patients, new effective treatments are required that are also better accepted by patients. Previous research findings demonstrated that so-called body-oriented therapies (BPT) can be effective; those treatments – as tested in this study - offer interventions where the body remains the main focus, aiming to improve patients' understanding of bodily functioning and their coping with persistent physical symptoms to alleviate stress and improve the quality of life of patients. Description of what happened to the participants taking part in the study
Patients who have been diagnosed as suffering from PPS by their physicians were contacted by those and offered to participate in this study. They received study information including a description of the treatment that the study was aiming to test. Half of the patients referred at the beginning received the body oriented treatment and the other half after they waited for the

duration of the treatment (so called randomised-controlled study design). Another group of patients was offered to undergo treatment immediately after they had been referred.
This study was aiming to assess the acceptability, the potential benefits, and associated change processes of the BPT therapy for outpatients with PPS.

Who can participate?
Patients with over 6 months persistent bodily complaints without sufficient explanatory organ pathology.

What does the study involve?
We used specific questionnaires on physical symptoms, health-related subjective quality of life and also in respect of patients' acceptance of treatment pre and post therapy participation.

What are the possible benefits and risks of participating?
This study and previous research suggests that patients participating in group body psychotherapy might benefit through a significant reduction of the severity of persistent physical symptoms and experience an increase in their subjective quality of life; participating in group body psychotherapy does not appear to pose any risks to participant.

Where is the study run from?
Department of Psychosomatic Medicine and Psychotherapy, Rechts der Isar Hospital, Munich

When is the study starting and how long is it expected to run for?
January 2011 to December 2015

Who is funding the study?
German Association of Body Psychotherapy (DBK)

Who is the main contact?
Prof. Frank Röhricht, frank.rohricht@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1.0

Study information

Scientific Title
Group body psychotherapy for the treatment of somatoform disorder - a partly randomised-controlled feasibility study

Study objectives
Clinical outcomes for patients with heterogeneous somatoform disorder (bodily distress disorder, including medically unexplained symptoms) are suboptimal, new treatments are required to improve acceptance. Body-oriented psychological therapy approaches have been identified as potentially beneficial additions to the portfolio of treatments.
This study aims to assess the acceptability, the potential benefits, and associated change processes of manualised group body psychotherapy (BPT) for outpatients with Somatoform Disorder.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2009, Ethics committee of the Technische Universität München (Ismaninger Straße 22
81675 München; ethikkommission@mri.tum.de), ref: 2268-08

Study design
Randomised controlled feasibility pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Somatoform disorder (ICD–10 (F45.x) (compatible with diagnosis of somatic symptom disorder DSM-5 (300.82)

Interventions

1. The manualised group body psychotherapy intervention for somatoform disorder (BPT-SD)
The group body psychotherapy manual for somatoform disorder (BPT-SD) was developed based upon aethio-pathogenetic models of the disorder [e.g. 3], taking into account the specific phenomenological presentation and health beliefs of this group of patients, by addressing the complex phenomena in Somatoform Disorders simultaneously across the interacting symptom domains: emotional (worrying, fear, negative cathexis), physiological (hyperarousal, somatic amplification), perceptive (bodily distress as disorder of perception) and cognitive (misinterpretation, negative cognitions). The manual includes interventions aiming to activate resources (capabilities, bodily strength and creativity) and to strengthen (bodily, autonomic) self-regulation. Gradually, a range of alternative motor responses in relation to unpleasant mental states and or psychologically relevant events/conflicts is introduced in therapy, directly addressing the habituated, amplifying somatic reinforcement styles, shifting the attention away from dysfunctional aspects of the body image (constant checking, stimulus entrapment).
The central guiding principle in BPT for somatoform disorder patients is that the body remains the main focus of the therapeutic work throughout. The therapist will not address directly any psychological processes involved in bodily experiences, unless the patient specifically brings them up first.
BPT-SD is delivered as a group therapy with up to 10 participants over a period of 20 weeks (4-6 months) with one session weekly a 90 mins. Pre-therapy each participant is seen individually for one hour to conduct a specific preparation session, outlining the specific body-oriented nature of the intervention.
The first group therapy session facilitates basic group cohesion, familiarization with therapeutic environment and materials. Sessions 2-20 follow a systematic structure with repetitive session elements (opening circle, warm-up and mobilization movement section, structured embodied task section, creative enactments and movement section, closing circle and narratives). For the group process in BPT-SD three distinct phases can be distinguished as follows:
The first phase of the therapy (session 2-5) concentrates on the therapeutic relationship and on achieving a fundamental shift towards a more positive body cathexis: focusing on bodily awareness and perceptions and supporting the verbalising of these experiences. Concurrent with the body oriented exercises in the beginning phase the therapist aims to foster therapeutic alliance whilst working with and through bodily sensations (somatisation) without challenging patient's explanatory beliefs. Psychological processes are only addressed in the context of body based experiential work in therapy and as they emerge in relation to patient's direct accounts.
The main/middle phase (sessions 6-13) will aim to emphasise the contextual factors in relation to perceived bodily sensations, the patient will be gradually supported in understanding the situational nature of bodily sensations and how these change according to external and internal stimuli. Moreover, patients are also likely to remember and clarify their conflicts and traumatic experiences through bodily experiences. Invariably, this occurs when reconstructing memory through expressive behaviour, movements, mimic, and the various aspects of nonverbal communication.
Further intensive exploration of the bodily experiences in the context of interpersonal interactions with both participants and therapists aims to foster an awareness and understanding of the bodily existence as a diverse source of neutrally, positively and negatively evaluated impacts on self-experiences. The role of the therapist here is to help the patients to develop an alternative conceptualization of the body, shifting from a judgemental perspective (body being perceived as a mere hostile object, causing trouble and controlling the self) to a more holistic perspective of self-respect and acceptance. The final phase (session 14-20) of therapy is characterised by narrative re-configuration. Patients are trained/guided to reduce the catastrophic effects of somatic sensations and to increase the acceptance of psychosocial causal attributions. In this way, they gradually shift the discussion from somatic symptoms to related personal issues.
BPT-SD was delivered by a body psychotherapist with a specific training background in one body

psychotherapy modality, Concentrative Movement Therapy [18]; the therapist received training to use the manual and adherence to the manualized intervention strategy was tested through regular supervision provided by the authors of the manual (after sessions 4, 8, 12, and 16).
2. The waiting control arm:
Patients received treatment as usual, consisting of medical appointments as required with their primary care physician; no other specific therapies
Recruitment and randomisation procedures:
Following identification by clinicians all potentially suitable patients were contacted by a research assistant via telephone and invited to attend a baseline assessment. At the first appointment a research assistant (doctor in training) provided potential participants with detailed information about the study, obtained written consent and asked those who agreed to participate to complete the baseline questionnaires. 16 initially recruited patients were then randomly assigned to BPT or Treatment As Usual (TAU), using a computer-generated randomization table. Another group of 8 patients was consecutively recruited and directly allocated to BPT.
Duration of treatment:
After randomization, all patients received the questionnaires to assess baseline characteristics. All patients participating in the trial were asked to complete the questionnaires at baseline, at the end of the intervention (at ~3 months) and at 6 months. The number of patients identified and recruited as well as retention and attrition rates, the number of patients who completed the questionnaires and the clinical outcomes were systematically evaluated. Both the Group Therapy and the waiting list condition for those receiving TAU lasted 20 weeks (4-6 months).

Intervention Type
Other

Primary outcome(s)
1. Mental health is assessed using the Primary Health Questionnaire (PHQ) at baseline, 3-months and 6-months
2. Somatic symptom burden is assessed using the Somatic Symptom Screening Scale (SOMS-7) at baseline, 3-months and 6-months

Key secondary outcome(s))
1. Quality of life is assessed using the Short-Form Health Survey-36 (SF-36) at baseline, 3-months and 6-months
2. Body image is measured using the Dresden Body Image Questionnaire at baseline, 3-months and 6-months
3. Acceptance and satisfaction with treatment: The Helping Alliance Scale [range 0-10] at baseline, 3-months and 6-months

Completion date
31/12/2016

Eligibility

Key inclusion criteria
1. Persistent (>=6 months) bodily complaints without sufficient explanatory organ pathology
2. Diagnosis of any somatoform disorder ICD–10 (F45.x) (compatible with diagnosis of somatic symptom disorder DSM-5 (300.82))

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
24

Key exclusion criteria
1. Somatic symptoms attributable to identified physical disease (nature and degree)
2. Primary diagnosis of anxiety or depressive disorder, psychosis, substance misuse, psychoorganic disorder and patients considered actively suicidal
3. Insufficient language skills leading to inability to complete the questionnaires

Date of first enrolment
01/01/2011

Date of final enrolment
31/12/2015

Locations

Countries of recruitment
Germany

Study participating centre
Rechts der Isar Hospital
Department of Psychosomatic Medicine and Psychotherapy
Klinikum rechts der Isar
Langerstr. 3
Munich
Germany
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Sponsor information

Organisation
Department of Psychosomatic Medicine and Psychotherapy, Klinikum rechts der Isar,

ROR
https://ror.org/04jc43x05

Funder(s)

Funder type
Research council

Funder Name
German Association of Body Psychotherapy (DBK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/04/2019	04/03/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes