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Effectiveness and cost-effectiveness of body psychotherapy in the treatment of negative symptoms of schizophrenia

Submission date
06/04/2010

Recruitment status
No longer recruiting

Registration date
07/04/2010

Overall study status
Completed

Last Edited
15/02/2016

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims.
Schizophrenia is an illness which is largely made up of two different types of symptoms known as positive and negative symptoms. Positive symptoms include things such as hallucinations, delusions and unusual thoughts. Negative symptoms can include things like having low motivation to do anything and being very distant and removed from other people and events. Although people more commonly think of the positive symptoms when they think of schizophrenia, it is the negative symptoms which have been found to have a greater impact on the persons quality of life and ability to function in the community. Negative symptoms have been found to be resistant to current treatments like talking therapies and medication, but there is some evidence that suggests that Arts Therapies, like body psychotherapy, may help improve these symptoms. This has led to research such as this to see whether body psychotherapy can be both an effective and cost effect treatment to treat these types of symptoms. Body Psychotherapy is a type of arts therapy which focuses on the body and movement as a way to help communication and overcome challenges they may experience in day to day life. Many people who suffer severe negative symptoms find it difficult to engage with other people and a large part of the groups involve trying to overcome these communication barriers through non-verbal means. As the groups progress, the participants are encouraged to get involved in a number of structured tasks which are designed to support creativity, explore what the body is physically capable of, and to challenge dysfunctional body disturbances.

Who can participate?
To be able to take part people must:
-Have been diagnosed with schizophrenia for at least 6 months and currently be treated in the community.
-Experience at least moderate levels of negative symptoms (this will be assessed by a member of our team before the groups take place).
-Be aged 18-65.

-Not have any change in the type of antipsychotic medication they take for at least 6 weeks.
-Be able to speak a sufficient level of English to take part in the groups, and be physically able to take part in light activity.

What will the study involve?
In the study one half of the participants will be offered a 20 session Body psychotherapy group, whilst the other half will be offered a Pilates group. We will measure negative symptoms immediately before the groups start, once the 20 sessions are over, and then again six months later to see if there is any difference in negative symptoms between the two groups. The effect of the Body Psychotherapy group is being compared to a Pilates class so we can account for any possible effect of organised group physical activity.

What are the possible benefits and risks of participating?
Early studies have shown that body psychotherapy may help reduce negative symptoms. Even if this is found not to be the case then being involved in a regular group which includes light physical activity may help to improve physical health. It is currently less clear whether the Pilates group will help improve negative symptoms, but as an organised exercise class the benefits of light physical activity should be the same regardless. As with any exercise however, one possible risk of taking part is suffering a slight physical injury.

Where is the study run from?
The study being run by Queen Mary University of London, along with Kings College London and the University of Liverpool. The groups are being held at various community centres in the areas of Liverpool, Greater Manchester and in certain parts of London.

When is the study starting and how long is it expected to run for?
The study started in May 2011, and is expected to run until the beginning of 2015.

Who is funding the study?
The National Institute for Health Research (NIHR) is funding this study as part of its Health Technology Assessment (HTA) programme.

Who is the main contact?
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Study website
http://blizard.qmul.ac.uk/research-generation/319-ness.html

Contact information

Type(s)
Scientific

Contact name
Prof Stefan Priebe

Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 08/116/68

Study information

Scientific Title
Effectiveness and cost-effectiveness of body psychotherapy in the treatment of negative symptoms of schizophrenia: a multicentre randomised controlled trial

Acronym
NESS

Study objectives
To test the effectiveness of manualised and group based body psychotherapy (BPT) on reducing negative symptoms in patients with schizophrenia as compared to an active control (both conditions in addition to treatment as usual).

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0811668
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/52056/PRO-08-116-68.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
East London and the City Research Ethics Committee 1 pending approval as of 07/04/2010

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Patients in the experimental group will receive BPT which will be delivered in groups of 8 patients and 20 sessions over a 10-week period. Each session will take 90 minutes. BPT is manualised with the following components:
1. Overcoming communication barriers through non-verbal techniques
2. Re-focussing cognitive and emotional awareness towards the body (physical reality, coordination and orientation)
3. Stimulating activity and emotional responsiveness
4. Exploring physical potentials
5. Focussing on strength and experiencing the body as a source of creativity, reliability, pleasure and self-expression
6. Modifying dysfunctional self-perception and addressing body-related psychopathological features such as boundary loss, somatic depersonalisation, and body schema disturbances

All therapists will be accredited dance-movement psychotherapists and receive an additional training in applying the manual of body psychotherapy for patients with negative symptoms of schizophrenia as it was used in the exploratory trial. All therapists will receive a three day training at the beginning of the trial and a one day refresher training after each therapist has completed one group (i.e. after completion of two groups at each site). Regular supervision will be provided 3 times within each 10 week treatment period and arranged as a combination of live supervision and web-based conferences. Training and supervision will be provided by the therapist who acted as the therapist in the original exploratory trial. Adherence to the manual will be assessed by the author of the manual based on videotapes of the sessions. He will assess 20% of all sessions and develop a scale to quantify the adherence ratings.

The active control condition of physical activities (PA) will be delivered with the same frequency and length of sessions and overall duration as BPT, i.e. there will be two sessions per week over a 10-week period and each session will last up to 90 minutes. PA will be described to patients as a fitness and physical health intervention so that in the recruitment process patients consent to participate in one of two interventions that share several elements, most importantly the format and physical activities. This is intended to limit the risk of different acceptance rates of the two interventions once patients are informed about their allocation.

The venue for the PA groups will be similar rooms as those used for BPT (usually they will be the same rooms). PA will consist of pilates exercises and follow the established guidelines for such groups. It will be delivered by pilates trainers. A brief manual for the pilates groups will be

written and contain instructions for how to run the groups as well as references to material describing the exercises in detail.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Level of negative symptoms as assessed on the Positive and Negative Symptom Scale of Schizophrenia (PANSS). All outcomes will be measured at pre-treatment baseline, at the end of treatment and again 6 months after treatment.

Secondary outcome measures
All outcomes will be measured at pre-treatment baseline, at the end of treatment and again 6 months after treatment:
1. Levels of general psychopathology and positive symptoms (PANSS)
2. Subjective quality of life (Manchester Short Assessment of Quality of Life)
3. Extrapyramidal symptoms (Simpson-Angus Scale)
4. Treatment satisfaction (Client Satisfaction Questionnaire)
5. Objective social situation (SIX), which combines objective indicators of independent accommodation, employment and having a partner/friend
6. Instrumental Activities of Daily Living Scale (IADL)

Overall study start date
01/09/2010

Completion date
30/06/2014

Eligibility

Key inclusion criteria
1. Aged between 18 and 65 years, either sex
2. An established diagnoses of schizophrenia according to Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV)
3. Having had symptoms of schizophrenia for at least 6 months
4. Scores of greater than 18 on the subscale negative symptoms of the Positive and Negative Syndrome Scale (PANSS)
5. Willingness to participate in groups for BPT or physical activity (PA)
6. Ability to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
256

Key exclusion criteria
1. Severe physical disability preventing patients from participating in groups for BPT or PA
2. Insufficient command of English so that outcomes cannot be reasonably assessed in English
3. A physical condition that makes participation in either BPT or the PA control group impossible or potentially harmful

Date of first enrolment
01/09/2010

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newham Centre for Mental Health
London
United Kingdom
E13 8SP

Sponsor information

Organisation
Queen Mary University of London and Barts and the London NHS Trust (UK)

Sponsor details
c/o Mr Gerry Leonard
Joint Research and Development Office
Queen Marys Innovation Centre
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England
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Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.nhs.uk/research

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/01/2013		Yes	No
Results article	results	01/02/2016		Yes	No