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

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Scientific summary

Body psychotherapy to treat negative symptoms of schizophrenia

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Background

The negative symptoms of schizophrenia refer to expressive deficits, such as impoverished speech and blunted affect, and experiential/pleasure deficits, such as anhedonia, avolition and asociality. These negative symptoms have been found to be largely resistant to antipsychotic medication and conventional psychotherapeutic interventions, and significantly impact on quality of life and social functioning. There is some evidence to suggest that arts therapies could be effective in the treatment of these symptoms; however, the current data are limited and full-scale trials are required.

In a review by the National Institute for Health and Care Excellence (NICE), arts therapies – which is a label covering all creative therapies, such as music therapy, art therapy, body psychotherapy (BPT), dance movement psychotherapy and drama therapy – were the only type of intervention found to demonstrate consistent efficacy in the amelioration of negative symptoms. However, given that the findings were based on only six small-scale studies, the recommendations for further research recognised the need for larger trials. In addition, it was recommended that trials include an active control group in order to control for any non-specific effects of taking part in group activities.

The aim of this trial is to assess the clinical effectiveness and cost-effectiveness of a manualised form of group BPT that was designed to treat the negative symptoms of schizophrenia in outpatients, comparing outcomes with those from outpatients attending Pilates classes. Pilates is a type of structured physical fitness programme involving stretching and controlled movement, which will control for the effects of therapist attention and group-structured physical activity. In comparing BPT with a physically active control, the aim of the trial was to evaluate the specific components of BPT, which includes the focus on body experience at a cognitive and emotional level, the facilitation of emotional group interactions and the link between movement and emotion.

Objectives

The objectives were to:

1. test the effectiveness of a manualised group BPT intervention in reducing negative symptoms of schizophrenia compared with an active control
2. test the effectiveness of a manualised group BPT intervention in general psychopathology, quality of life, daily activities, objective social situation and treatment satisfaction in participants who were experiencing negative symptoms of schizophrenia compared with an active control
3. test whether or not any effects on primary and secondary outcomes are maintained at 6 months' follow-up
4. assess the cost impact, cost-effectiveness and cost–utility of BPT.

Method

The study was a two-arm, parallel-group, multisite randomised controlled trial (RCT). Patients with schizophrenia [*International Classification of Diseases*, Tenth Edition (ICD-10) codes F20.0–F20.9] experiencing at least moderate levels of negative symptoms [score of ≥ 18 on the Positive And Negative Syndrome Scale (PANSS) negative subscale] were randomised into a 20-session (10-week) BPT group, or a 20-session (10-week) Pilates class. Randomisation was conducted by a statistician from the Clinical Trials Unit through a computer-generated sequence. Participants were randomly allocated, with equal probability, to the intervention or control group, stratified by study centre, in batches using randomly permuted blocks of 4 and 6, starting each batch at the start of a new block in order to preserve balance. Assessors and statisticians were blinded to treatment allocation until the analysis plan was signed off. Analysis was conducted following intention-to-treat principles.

Participants

Participants were recruited from the UK NHS mental health community services in five different Trusts. The eligibility criteria included ages 18–65 years; ICD-10 diagnosis of schizophrenia, with symptoms present for at least 6 months; score of ≥ 18 on PANSS negative symptoms subscale; no change in medication type in the past 6 weeks; willingness to participate; ability to give informed consent; and community outpatient. The exclusion criteria included inability to participate in the groups because of physical disability or condition and insufficient command of English. All groups took place in local community spaces.

Procedures

Potentially eligible participants were approached by their clinicians for their consent to be contacted by a researcher. If they agreed, the researcher arranged a meeting during which a detailed explanation of the study was provided, and, presuming that they were interested in taking part, informed consent was obtained. An eligibility assessment using the PANSS scale was then conducted to ascertain whether or not they had a rating of at least 18 on the negative symptoms subscale, in accordance with the inclusion criterion. Once approximately 16 eligible participants at each site were recruited, a full baseline assessment – which included a second PANSS assessment – was undertaken 1 month prior to the group start date. The assessments were typically conducted in the participants' homes or at their local community mental health team base.

On completion of the groups, the researchers contacted the participants again for the end-of-treatment assessment, which included all of the structured interviews and questionnaires obtained in the baseline assessment, in addition to the Client Satisfaction Questionnaire (CSQ) which was used to measure the participants' satisfaction with treatment. Six months after intervention completion, patients were contacted a final time to arrange the follow-up assessment, which, again, included all of the interviews and questionnaires of the baseline assessment.

The treatment under investigation was BPT, as outlined in an updated version of the manual used in the 2006 exploratory trial. Both BPT and the Pilates groups were delivered twice per week on non-consecutive days for 10 weeks, with each session lasting 90 minutes. A maximum of 10 participants were assigned to each group or class. To limit the impact of any one body psychotherapist or Pilates instructor on outcomes, each one was permitted to run a maximum of two groups.

The BPT group was facilitated by an Association of Dance Movement Psychotherapy (ADMP) accredited therapist, who had attended an additional 2-day training course in delivering the intervention in its manualised form. In each group, the therapist was supported by a volunteer as cofacilitator. Each therapist received a minimum of three 90-minute supervision sessions held by a senior therapist for each group, either in person or via a videoconference.

Each of the 20 sessions comprised five discrete sections. The first was the opening circle, which is used to describe feelings and energy levels; the second was a warm-up section, for which the participants stand in a circle and warm up using different body parts and movements; the third was a structured task section with exercises, such as mirroring each other's movements and creating body image sculpture in partners; the fourth consisted of creative movements, with exercises such as creating group sculptures and reflecting on perceptions and emotions; and finally, the fifth was a closing circle, which was used to reflect on the group experience and to refocus on the self with body-orientated exercises.

The Pilates classes were held in the same venues as the BPT groups. All classes were facilitated by a Register of Exercise Professionals (REPS) level 3-qualified Pilates instructor, and assisted by a cofacilitator. Prior to the classes starting, a brief training session was arranged between the instructor and an experienced clinician.

Outcomes

The primary outcome was the PANSS negative symptoms subscale score, which was assessed at the end of treatment. Secondary outcomes included the PANSS negative subscale score at 6 months post treatment, in addition to general psychopathology and positive symptoms (PANSS), subjective quality of life (Manchester Short Assessment of Quality of Life; MANSA), level of activity (items from the Time Use Survey; TUS), objective social situation (SIX), extrapyramidal symptoms resulting from antipsychotic medication (Simpson–Angus Scale; SAS), emotional experience and expression (Clinical Assessment Interview for Negative Symptoms; CAINS), depression (Calgary Depression Scale) and social contacts (Social Network Scale; SNS), measured both at end of treatment and at 6 months' follow-up. Satisfaction of treatment was measured at the end of the treatment phase (Client Satisfaction Questionnaire; CSQ). In addition, cost impact, cost-effectiveness and cost–utility were assessed using the European Quality of Life-5 Dimensions (EQ-5D) and the Client Service Receipt Inventory (CSRI).

Statistical methods

A 20% reduction in the PANSS score was used as an indicator of clinically significant improvement, which would be a difference of approximately 3 points, given the eligibility criteria. To detect this difference with a standard deviation (SD) of 5, with 90% power for 5% significance, 58 patients were required in each arm. To allow for clustering by group, an intraclass correlation coefficient (ICC) for treatment group of 0.1, and seven patients per group with analysable data at the end of treatment, gives an inflation factor of 1.6, meaning that 93 participants in each arm were required. At 6 months we anticipated a loss to follow-up of 31%, so recruiting 256 participants would leave 88 per arm at 6 months, and 91% power to detect a difference of 3 points at this time point.

The primary analysis was of available cases of the PANSS negative subscale at end of treatment, following intention-to-treat principles. We used a mixed-effects model, fitted by restricted maximum likelihood with fixed effects for the intervention, baseline PANSS negative subscale scores, and centre (because it was used to stratify the randomisation), and random effects for therapy groups to allow for clustering by group. Secondary outcomes were analysed using the same approach. To evaluate the impact of missing data, multiple imputation of the data set was performed and the analysis was replicated. A simple complier-average causal effect analysis (CACE) was completed. In this analysis, compliance was defined as attending at least five sessions, following the results of a recent study that evaluated the effectiveness of BPT for chronic depression. Planned subgroup analyses examining whether or not there were differences in response between those with higher negative symptoms at baseline and a longer duration of illness were also conducted. All analyses were completed using Stata version 12 (StataCorp LP, College Station, TX, USA).

Results

In total, 275 participants were randomised: 140 to the BPT group and 135 to the Pilates group. Each group comprised between 7 and 10 participants. Attendance was relatively high in both groups; however, participants attended significantly more sessions in the BPT arm than in Pilates group [BPT median = 11, interquartile range (IQR) = 5–17; Pilates median = 8, IQR = 1–15; $p = 0.01$]. In the BPT arm, 106 participants (75.7%) attended at least 5 of the 20 sessions, thus fulfilling the minimum attendance threshold required to be defined as a treatment complier in the CACE analysis.

In the primary outcome, no significant difference between the experimental and control condition was detected [adjusted difference in the means = 0.03, 95% confidence interval (CI) –1.11 to 1.17; $p = 0.959$, model-based ICC = 0.099 after controlling for baseline scores, study centre and therapy group]. In the secondary outcomes at the end of treatment, a significant mean difference reduction in the SAS (–0.65, 95% CI –1.13 to –0.16; $p = 0.009$, ICC < 0.001) and the CAINS expression subscale (–0.62, 95% CI –1.23 to 0.00; $p = 0.049$, ICC = 0.022) was detected in favour of the BPT arm in comparison with the Pilates group at the end of treatment. No other significant differences were found in the secondary outcomes at this stage. At the 6-month follow-up, a significant mean difference in the SAS was detected (–0.50, 95% CI –0.97 to –0.07; $p = 0.028$, ICC < 0.001); however, no other differences were detected.

In the CACE analysis, a significant difference was found in the SAS at end of treatment (–0.82, 95% CI –1.51 to –0.12); however, no other differences were detected, including in the primary outcome of negative symptoms. No significant differences in negative symptoms were detected in the subgroup analysis, which compared those with high and low negative symptoms, and long and short duration of illness. There were no serious adverse events related to the intervention.

The total mean costs per participant in the BPT over the whole follow-up period were £2297 (SD = £2835) in comparison with £2442 (SD = £3278) for Pilates. After adjusting for baseline, the total costs were slightly lower for BPT; however, the difference was non-significant (£25; bootstrapped 95% CI –£671 to £721). No significant differences were detected in the sensitivity analysis, for which the costs of Pilates were changed to zero (–£55, 95% CI –£630 to £706). No significant differences were detected in quality-adjusted life-years (QALYs) between BPT and Pilates (adjusted difference in means = 0.01; 95% CI –0.02 to 0.04). At £20,000 per QALY, it was found that there is approximately a 65% likelihood that BPT is a more cost-effective option than Pilates.

Conclusions

No significant differences between BPT and Pilates were detected in the PANSS negative symptoms subscale, both at the end of treatment and 6 months later. A statistically significant improvement in the BPT group in comparison with the Pilates group was detected in the CAINS expression subscale at the end of treatment, and, in movement disorder symptoms, both at end of treatment and 6 months later. However, the small effect sizes mean these are unlikely to reflect relevant clinical benefits. There was no significant difference on any other outcome. Given the results and the high statistical power, these findings support the conclusion that BPT is not an effective treatment for patients with negative symptoms of schizophrenia compared with Pilates as an active control.

Implications for health care

In comparison with an active control, group BPT does not have a clinically relevant beneficial effect in the treatment of patients with negative symptoms of schizophrenia. These results are consistent with an earlier RCT [Multicenter evaluation of Art Therapy in Schizophrenia: Systematic Evaluation (MATISSE)] evaluating the effectiveness of art therapy as a treatment for schizophrenia and, together, contradict current NICE guidelines, which suggest that arts therapies are an effective treatment for negative symptoms.

Trial registration

This trial is registered as ISRCTN842165587.

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