Psychoeducation with problem-solving (PEPS) therapy for adults with personality disorder: a pragmatic randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of a manualised intervention to improve social functioning

Mary McMurran,[1]* Mike J Crawford,[2] Joe Reilly,[3,4] Juan Delport,[5] Paul McCrone,[6] Diane Whitham,[7] Wei Tan,[7] Conor Duggan,[1,8] Alan A Montgomery,[7] Hywel C Williams,[7] Clive E Adams,[1] Huajie Jin,[6] Matthew Lewis[5] and Florence Day[7] on behalf of the PEPS Trial Collaborative Group

[1]Institute of Mental Health, University of Nottingham, Nottingham, UK
[2]Centre for Mental Health, Imperial College London, London, UK
[3]School of Medicine, Pharmacy & Health, Centre for Integrated Health Care Research, Durham University, Durham, UK
[4]Tees, Esk & Wear Valleys NHS Foundation Trust, Middlesbrough, UK
[5]Centre for Psychological Therapies, Cwm Taf University Health Board, Mountain Ash, UK
[6]Institute of Psychiatry, King's College London, London, UK
[7]Nottingham Clinical Trials Unit, University of Nottingham, Nottingham, UK
[8]Partnerships in Care, Nottingham, UK

*Corresponding author

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

Psychoeducation with problem-solving

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Scientific summary

Background

Personality disorder (PD) is one of the most prevalent forms of mental health problem, and is associated with substantial health-care and social costs. Despite this, there is relatively little reliable evidence on the effectiveness of treatments for PD.

Many treatments for PD are intensive and of long duration, which limits the amount of services that can be provided. Testing the clinical effectiveness and cost-effectiveness of shorter interventions is important if more people with PD are to be treated. Additionally, interventions that can be used with any PD have the potential for more efficient service delivery. In treating groups of people with mixed PDs, the treatment target necessarily needs to be a problem common to all. One core feature of all PDs is the experience of problems with social and interpersonal functioning. Social problem-solving therapy is one viable and empirically supported approach. Meta-analyses of problem-solving therapy outcome studies document its effectiveness for people with a wide range of mental health problems.

A combined psychoeducational intervention aimed at clarifying the PD diagnosis, identifying associated problems and leading into group problem-solving therapy has been developed. Psychoeducation with problem-solving (PEPS) therapy was evaluated with adults with PD in the community, in an exploratory trial. In this trial, those treated with PEPS therapy showed better social functioning, as measured by the Social Functioning Questionnaire (SFQ), at the end of treatment than those in a wait-list control group. Here, we present the results of a multisite randomised controlled trial of PEPS therapy.

Objectives

The study aimed to determine if PEPS therapy in addition to usual treatment compared with usual treatment alone for people with PD resulted in improved social functioning at follow-up 72 weeks after randomisation.

In addition, we planned to:

- assess the costs and cost-effectiveness of PEPS therapy compared with usual treatment alone
- examine the effects on scheduled and unscheduled use of services
- examine the effect on mood
- evaluate participants' perceived effects of the intervention
- evaluate referrers' perceived effects of the intervention
- examine the process of change by testing the hypotheses:
    - that psychoeducation improves the therapeutic relationship
    - that social problem-solving therapy improves social problem-solving abilities
- conduct a qualitative investigation of the receipt of PEPS in practice to identify the views of service users.

Methods

Setting

Community mental health services in three NHS trusts in England and Wales.

Participants

Eligible participants were aged ≥ 18 years, living in the community and proficient in spoken English and had capacity to provide informed consent. At the point of randomisation, participants were required to have one or more probable PDs identified through the International Personality Disorder Examination completed at screening. Exclusion criteria were a primary diagnosis of major functional psychosis, insufficient degree of literacy, comprehension or attention to be able to engage in trial therapy and assessments, engagement in a specific programme of psychological treatment for PD or likely to start such treatment during the trial period, and participation in any other trial.

Interventions

This was a two-arm trial comparing PEPS therapy in addition to usual treatment with usual treatment only. PEPS therapy is a combination of individual psychoeducation followed by group problem-solving therapy. Psychoeducation consists of up to four sessions of information and dialogue about PDs, as experienced by the individual and as assessed by the clinician. The aims are to build rapport, improve knowledge and motivate participants for problem-solving therapy. Problem-solving therapy is a 12-session group intervention designed to help people learn a strategy for solving interpersonal problems. Usual treatment was not specified.

Training

The PEPS intervention was specified in treatment manuals, containing information about the theory underpinning the treatment, the content of sessions, and the duration and frequency of sessions. Therapists were qualified mental health nurses or psychology graduates with clinical experience. Therapists were centrally trained by experienced clinicians, and regular supervision was provided. Audiotapes of treatment delivery were scrutinised by the trainers to ensure that each therapist was adhering to the treatment specification. Competence checklists were constructed for this assessment. Cut-off scores for competence were agreed in advance and therapists were assessed for competence in delivering the treatment. None of the therapists failed to meet the competence criteria on any of the measures.

Randomisation

Randomisation was based on a computer-generated pseudo-random code using random permuted blocks of randomly varying size, created by the Nottingham Clinical Trials Unit in accordance with their standard operating procedure and held on a secure server. Allocation was stratified by recruiting centre and sex.

Blinding

Participants, mental health workers delivering the interventions and participants' usual-care teams were aware of the treatment allocation. Most of the outcome data were obtained from self-report questionnaires from patients who were not blind to treatment allocation. However, outcome measures were administered by research assistants blinded to treatment allocation, and data entry and analyses were conducted blind to allocation.

Outcomes

- The primary outcome of social functioning was measured by the SFQ, an eight-item self-report questionnaire with scores ranging from 0 to 24. A lower score is more desirable.
- Costs and cost-effectiveness were based on the Client Service Receipt Inventory and the European Quality of Life-5 Dimensions (EQ-5D) questionnaire, a health status measure used to generate quality-adjusted life-years (QALYs).

- Scheduled and unscheduled use of services was based on information in general practitioner records, with emergency department visits and attendances at crisis resolution teams designated unscheduled.
- Mood was measured by the Hospital Anxiety and Depression Scale (HADS), a 14-item self-report questionnaire with scores ranging from 0 to 42. Higher scores are less desirable.
- Referrers' perceived effects of the intervention were assessed using the Global Assessment of Functioning (GAF), a rating scale used to rate the social, occupational and psychological functioning of adults from low (score 1) to superior (score 100).
- Participants were asked to specify three main problems they wished to change and rate these on severity on a scale from not at all distressing (0) to very distressing (10).
- Therapeutic relationship was assessed using the Working Alliance Inventory – Short Revised (WAI-SR), a 12-item scale rated by both client and therapist to assess agreement on the tasks and goals of therapy, and the bond between client and therapist, with a range of scores between 12 (poor) and 48 (good).
- Social problem-solving abilities were measured by the Social Problem-Solving Inventory – Revised: Short Version (SPSI-R), a 25-item self-report questionnaire that measures problem-solving orientations and styles. A total social problem-solving score ranges from 0 to 25, with a higher score being more desirable.

Sample size

Allowing for 30% attrition, we estimated that 340 participants would be needed to detect a 2-point difference (standardised effect size of 0.44) on the SFQ with 80% power and 1% two-sided alpha.

Analysis plan

Clinical effectiveness

The primary between-group comparison for the primary outcome was implemented using a multivariable linear regression model following the intention-to-treat principle with multiple imputation of the missing data. The analysis was adjusted by outcome at baseline and stratification variables and allowed for potential clustering by problem-solving group in the PEPS arm. Sensitivity analyses were conducted as follows: (1) intention to treat without imputation of missing data; (2) further adjustment of baseline variables with marked imbalance between arms; and (3) estimating the impact of adherence to intervention on treatment effect.

Analysis of secondary outcomes, health-service use and adverse events was conducted using a similar approach as for the primary outcome, dependent on the outcome type and without imputation of missing data. The exception to this was the SPSI-R total score, which was analysed using repeated measures by including both SPSI-R score at 24 and 72 weeks.

Cost-effectiveness

The cost of the PEPS intervention was estimated using information on the core resources required to deliver the individual and group sessions, and estimating specific costs for those inputs. Health service use was measured using the Client Service Receipt Inventory. Cost data are frequently skewed; therefore, bootstrapped estimates were planned so that mean costs could be compared while imposing no prior assumptions regarding the data distribution. The EQ-5D was used to measure health-related quality of life, with utility scores attached to each health state used to generate QALY gains over the follow-up period (using area under the curve methods and assuming a linear change between any two adjacent time points). Baseline data were analysed using a regression model to identify variables significantly associated with cost. If PEPS resulted in higher costs and better outcomes, then incremental cost-effectiveness ratios were to be computed. Uncertainty around these was explored using cost-effectiveness planes. In addition, cost-effectiveness acceptability curves were generated using the net benefit approach in order to determine the likelihood that the intervention was the most cost-effective option. These probabilities were subsequently used to generate the cost-effectiveness acceptability curves.

Results

A difference in the number of reported adverse events caused concern about the safety of PEPS therapy and led to an early cessation of recruitment after 306 people had been randomised: 154 in the PEPS arm and 152 in the usual-treatment arm.

Follow-up at 72 weeks after randomisation was completed for 62% and 73% in the usual-treatment and PEPS arms, respectively. In addition to a greater proportion of completers, duration of follow-up among non-completers was also greater in the PEPS arm, which resulted in a total of 178 and 203 person-years of follow-up in the usual-treatment and PEPS arms, respectively.

Median attendance at the individual psychoeducation sessions was approximately 90% and for problem-solving group sessions was around 50%. Regarding group sessions, 47% ($n = 63$) received a partial intervention (i.e. ≤ 5 group sessions) and 53% ($n = 70$) received the intervention as per protocol (i.e. ≥ 6 group sessions). Complier average causal effect (CACE) analysis suggests that compliance increases the effect, but none of the sensitivity analyses supports different conclusions from the primary analysis.

Psychoeducation with problem-solving therapy plus usual treatment was no more effective than usual treatment alone on the primary outcome [adjusted difference in means for SFQ –0.73 points, 95% confidence interval (CI) –1.83 to 0.38 points; $p = 0.19$]. No difference was found in scheduled service use (adjusted incidence rate ratio 0.91, 95% CI 0.69 to 1.21; $p = 0.54$), unscheduled service use (adjusted incidence rate ratio 0.87, 95% CI 0.60 to 1.26; $p = 0.47$), HADS score (adjusted difference in means –1.2, 95% CI –4.2 to 1.8; $p = 0.44$) or on severity ratings of three main problems (adjusted difference in means –0.3, 95% CI –1.0 to 0.5; $p = 0.48$). Insufficient data precluded analyses of the GAF. There was no difference in the total SPSI-R score (adjusted difference in means 0.14, 95% CI –0.53 to 0.82; $p = 0.68$) or on any of the subscales. Insufficient data precluded analyses of the WAI. By the final follow-up, the mean costs for the usual-treatment group were £182 higher than for the PEPS group, but the difference was not significant. Similarly, the PEPS group had higher QALYs (adjusted difference in mean gains from baseline to end point 0.015), but the difference was not significant.

By the end of the trial, both the number of reported adverse events, including serious adverse events, and the number of people experiencing them were greater in the PEPS arm. Statistical analysis that allows for the higher follow-up in the PEPS arm shows a tendency for PEPS participants to experience more adverse events, although the results are inconclusive (adjusted incidence rate ratio 1.24, 95% CI 0.93 to 1.64).

Discussion

We found no evidence to support the use of PEPS therapy alongside standard care for improving the social functioning of adults with PD living in the community. This differs from the pilot study, in which significant improvement was found in the primary outcome of social functioning, measured, as in this trial, by the SFQ. The trial reported here was superior in its design and methods: it was multisite, there was a larger number of participants providing greater precision of estimated between-group differences, the follow-up period was considerably longer and the methods of imputing missing data were more sophisticated. Hence, greater confidence can be placed in these results. More adverse events, mainly incidents of self-harm, occurred in the PEPS arm but the difference was not significant. There may have been bias in recording adverse events because more people in the PEPS arm were followed up and for longer.

Recently, evidence has been accruing from trials that structured clinical management achieves equally good outcomes as specific treatments for PD. It may be that specialist treatments benefited primarily by minimising harm, possibly through preventing unco-ordinated care. In the PEPS trial, treatment was delivered as a stand-alone therapy rather than being integrated into a co-ordinated package of care. This may have been a serious shortcoming. One possible explanation for the higher number of reported adverse events in the treatment arm is that the treatment stopped without any structured follow-up, thus leaving participants unsupported after a period of treatment. To have one's support withdrawn may be more damaging than to have had little or no support in the first place.

Conclusion

Psychoeducation with problem-solving therapy should not be promoted for people in mental health services who are diagnosed with PD, at least not in the absence of a structured, comprehensive clinical care package. Harm is most likely to be caused by leaving people unsupported after the conclusion of brief interventions rather than by PEPS itself, with some evidence for this being the CACE analysis showing that more uptake of treatment leads to better outcomes. Use of any brief problem-solving interventions in practice should be conducted only with rigorous collection of data on adverse effects, in the context of the need for better awareness and measurement of adverse events in psychotherapy practice as a whole.

Overall, participants in this trial were heavy users of health services, costing approximately £8000 per annum (based on baseline data). This is reflected in low quality of life, with QALYs of approximately 0.57 over the entire follow-up (out of a possible 1.5 QALYs). It is important to continue to seek effective management and treatment for this group of individuals.

Trial registration

The trial is registered as ISRCTN70660936.

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Editorial contact: nihredit@southampton.ac.uk

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