HEALTH TECHNOLOGY ASSESSMENT

VOLUME 20 ISSUE 52 JULY 2016
ISSN 1366-5278

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DOI 10.3310/hta20520

NHS
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Health Research

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

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Declared competing interests of authors: Hywel Williams is Deputy Director of the National Institute for Health Research (NIHR) Programme and chairperson of the Health Technology Assessment (HTA) Commissioning Board. From 1 January 2016 he became Programme Director for the HTA programme. The NIHR HTA programme funded this study; however, Professor Williams was not involved in that funding decision.

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

Published July 2016
DOI: 10.3310/hta20520

This report should be referenced as follows:

McMurran M, Crawford MJ, Reilly J, Delport J, McCrone P, Whitham D, *et al*. 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. *Health Technol Assess* 2016;**20**(52).

Health Technology Assessment is indexed and abstracted in *Index Medicus*/MEDLINE, *Excerpta Medica*/EMBASE, *Science Citation Index Expanded* (SciSearch®) and *Current Contents*®/Clinical Medicine.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.058

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the ISI Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

Editorial contact: nihredit@southampton.ac.uk

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 08/53/06. The contractual start date was in February 2010. The draft report began editorial review in November 2014 and was accepted for publication in December 2015. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

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

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Background: If effective, less intensive treatments for people with personality disorder have the potential to serve more people.

Objectives: To compare the clinical effectiveness and cost-effectiveness of psychoeducation with problem-solving (PEPS) therapy plus usual treatment against usual treatment alone in improving social problem-solving with adults with personality disorder.

Design: Multisite two-arm, parallel-group, pragmatic randomised controlled superiority trial.

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

Participants: Community-dwelling adults with any personality disorder recruited from community mental health services.

Interventions: Up to four individual sessions of psychoeducation, a collaborative dialogue about personality disorder, followed by 12 group sessions of problem-solving therapy to help participants learn a process for solving interpersonal problems.

Main outcome measures: The primary outcome was measured by the Social Functioning Questionnaire (SFQ). Secondary outcomes were service use (general practitioner records), mood (measured via the Hospital Anxiety and Depression Scale) and client-specified three main problems rated by severity. We studied the mechanism of change using the Social Problem-Solving Inventory. Costs were identified using the Client Service Receipt Inventory and quality of life was identified by the European Quality of Life-5 Dimensions questionnaire. Research assistants blinded to treatment allocation collected follow-up information.

Results: There were 739 people referred for the trial and 444 were eligible. More adverse events in the PEPS arm led to a halt to recruitment after 306 people were randomised (90% of planned sample size); 154 participants received PEPS and 152 received usual treatment. The mean age was 38 years and 67% were women. Follow-up at 72 weeks after randomisation was completed for 62% of participants in the usual-treatment arm and 73% in the PEPS arm. Intention-to-treat analyses compared individuals as randomised, regardless of treatment received or availability of 72-week follow-up SFQ data. Median attendance at psychoeducation sessions was approximately 90% and for problem-solving sessions was approximately 50%. PEPS therapy plus usual treatment was no more effective than usual treatment alone for the primary outcome [adjusted difference in means for SFQ –0.73 points, 95% confidence interval (CI) –1.83 to 0.38 points; $p = 0.19$], any of the secondary outcomes or social problem-solving. Over the follow-up, PEPS costs were, on average, £182 less than for usual treatment. It also resulted in 0.0148 more quality-adjusted life-years. Neither difference was statistically significant. At the National Institute for Health and Care Excellence thresholds, the intervention had a 64% likelihood of being the more cost-effective option. More adverse events, mainly incidents of self-harm, occurred in the PEPS arm, but the difference was not significant (adjusted incidence rate ratio 1.24, 95% CI 0.93 to 1.64).

Limitations: There was possible bias in adverse event recording because of dependence on self-disclosure or reporting by the clinical team. Non-completion of problem-solving sessions and non-standardisation of usual treatment were limitations.

Conclusions: We found no evidence to support the use of PEPS therapy alongside standard care for improving social functioning of adults with personality disorder living in the community.

Future work: We aim to investigate adverse events by accessing centrally held NHS data on deaths and hospitalisation for all PEPS trial participants.

Trial registration: Current Controlled Trials ISRCTN70660936.

Funding: This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 20, No. 52. See the NIHR Journals Library website for further project information.

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List of abbreviations

CACE	complier average causal effect
CI	confidence interval
CMHT	community mental health team
CONSORT	Consolidated Standards of Reporting Trials
CPN	community psychiatric nurse
CSRI	Client Service Receipt Inventory
DMEC	Data Monitoring and Ethics Committee
DSM	*Diagnostic and Statistical Manual of Mental Disorders*
EQ-5D	European Quality of Life-5 Dimensions
GAF	Global Assessment of Functioning
GP	general practitioner
HADS	Hospital Anxiety and Depression Scale
IPDE	International Personality Disorder Examination
NCTU	Nottingham Clinical Trials Unit
NICE	National Institute for Health and Care Excellence
PD	personality disorder
PEPS	psychoeducation with problem-solving
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SFQ	Social Functioning Questionnaire
SPSI-R	Social Problem-Solving Inventory – Revised: Short Version
STEPPS	Systems Training for Emotional Predictability and Problem Solving
TMG	Trial Management Group
TSC	Trial Steering Committee
WAI-SR	Working Alliance Inventory – Short Revised

Plain English summary

A personality disorder is a pattern of beliefs and behaviour that causes distress and difficulties to both the affected person and others. We conducted a well-designed evaluation of a treatment called psychoeducation with problem-solving (PEPS) to see if it improved social functioning, which is how well people get on in their day-to-day lives. Psychoeducation involves up to four sessions of an individual talking with a mental health professional about their diagnosis of personality disorder and what it means for them. Participants are then offered 12 group sessions to learn a problem-solving approach to overcome some of their difficulties. We recruited 306 adults and divided them randomly (by chance) to receive PEPS plus usual treatment or usual treatment alone. We planned to recruit 340 people but it was noticed that people receiving PEPS had more adverse events, such as hospital admissions, than those who did not and so we stopped recruiting people early. About 12 months after the end of treatment we found no differences in social functioning between those who received PEPS and those who did not. There were no differences on any other measures – cost of services, quality of life, mood or problem severity. There were more adverse events reported in the PEPS group, but this difference could be as a result of chance. We found no evidence to support the use of PEPS therapy alongside standard care within the NHS to improve social functioning of adults with personality disorder living in the community.

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.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Aims

The study aimed to determine if psychoeducation with problem-solving (PEPS) therapy in addition to usual treatment for people with personality disorder (PD) results in improved social functioning 72 weeks after randomisation (approximately 12 months after the end of treatment), compared with treatment as usual alone.

In addition, we intended to:

- assess the costs and cost-effectiveness of PEPS therapy in addition to usual treatment compared with usual treatment alone
- examine the effects on scheduled and unscheduled use of services
- examine the effect on mood, as measured by the Hospital Anxiety and Depression Scale (HADS)
- evaluate referrers' perceived effects of the intervention using the Global Assessment of Functioning (GAF)
- evaluate participants' perceived effects of the intervention in relation to the severity of the self-identified three most important problems
- examine the process of change by testing the hypotheses:
    - that psychoeducation improves the therapeutic relationship
    - that social problem-solving therapy improves social problem-solving skills
- conduct a qualitative investigation of the receipt of PEPS therapy in practice to identify the views of service users.

Scientific background

Personality disorder

Personality disorder is one of the most common mental health problems, and it is associated with substantial health-care costs.[1–3] Compared with those with no PD, people with PD show higher rates of premature mortality,[4] greater engagement in health-compromising behaviours such as substance abuse,[1] greater levels of general health problems[5] and more use of health-care services.[6] PD is also associated with financial difficulties and problems maintaining jobs,[5] marital dissatisfaction and intimate partner violence,[7] crime[8] and poor quality of life.[9] These matters make a strong case for treating people with PD.

Despite this, there is relatively little reliable evidence on the effectiveness of treatments for PD. Systematic reviews of all psychosocial treatments for PD identified only 27 randomised controlled trials (RCTs) published up to 2006[10,11] and only a few trials have been published since then.[12,13] The majority of studies are underpowered and most related to one specific PD – borderline PD. Chambless and Hollon's[14] criterion for a treatment to be considered effective is that there should be at least two independent, well-conducted RCTs or single-case experiments. Only one therapy meets this criterion; dialectical behaviour therapy is more effective than usual treatment for reducing suicide attempts, service use and borderline symptomatology in borderline PD, although positive effects decay over time.[12] However, other cognitive and behavioural interventions are supported by single RCTs.

Many treatments for PD are intensive and of long duration, which limits the number of services that can be provided. Hence, the great majority of people who may benefit from psychological treatments do not receive them. 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 to alleviate the burden on clinical services that can be created if specific types of PD need to be identified for treatment allocation, and if groups of service users with specific PDs need to be gathered for treatment to commence. 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.[15–17] One relatively brief skills-training approach to improving problem-solving that has been evaluated specifically with people with borderline PD is the Systems Training for Emotional Predictability and Problem Solving (STEPPS) programme.[18] STEPPS is a 20-week group treatment programme for individuals with PD and others within that person's system, such as family members, partners, friends and health-care professionals. STEPPS focuses on psychoeducation, emotion management training and behaviour management training. One RCT[19] found that borderline symptoms were significantly more improved in those in a STEPPS group ($n = 65$) than in those who received treatment as usual ($n = 59$); however, this difference was no longer apparent at the 1-year follow-up. Improvements in secondary outcomes (including GAF, negative affectivity, depression, impulsiveness) and symptoms were also significantly greater for the STEPPS group post treatment but not at the 1-year follow-up. In another RCT,[20] those who completed STEPPS ($n = 33$) were compared with those who received treatment as usual ($n = 33$), with no significant group differences in PD or other psychological symptoms at the 6-month follow-up, although the STEPPS group showed a significantly greater improvement in overall quality of life. There are clearly improvements to be made to problem-solving approaches for people with PD in terms of enhancing and sustaining outcomes and, as mentioned, offering a problem-solving approach to people with PDs other than borderline is a more practical prospect. Social problem-solving therapy is one viable and empirically supported alternative.

Social problem-solving therapy

Good social problem-solving is one component of social competence.[21,22] Social problem-solving is defined as 'the self-directed cognitive-affective-behavioural process by which an individual attempts to identify or discover solutions to specific problems encountered in everyday living'[23] (p.11). There is abundant evidence of an association between social problem-solving deficits and problems related to PD.[24–27] People with PD report less desirable scores on all scales of the Social Problem-Solving Inventory – Revised: Short Version (SPSI-R)[28] compared with a sample of mature students,[22] and people high on borderline traits show poorer social problem-solving abilities than those with lower borderline traits, particularly when experiencing negative emotions.[29] This information suggests that social problem-solving therapy may benefit people with PD.

Problem-solving therapy is suited to people with PD because the focus is on improving social functioning and reducing personal distress, which are considered to be of paramount importance in the treatment of PD.[30] The aim in problem-solving therapy is to help people to recognise their strengths and limitations, and to work with these to learn new skills that will enable them to cope more effectively with life's problems. Problem-solving therapy works to decrease the person's negative problem orientation and develop positive orientation, without which therapy is unlikely to be effective.[31]

Engaging people with PD in treatment is a major challenge.[32,33] The social problem-solving approach enhances engagement by offering an accessible framework for change, supporting people in the experience of successful problem-solving and encouraging independence rather than reliance on therapy. Furthermore, the preliminary psychoeducation component of PEPS therapy aims to educate, build rapport and motivate people for problem-solving therapy.[34] PDs and their impact are discussed in a collaborative dialogue and problems that may be worked on in subsequent group sessions are identified. Psychoeducation has shown good effects with people with borderline PD, showing significantly greater declines in general impulsivity and the storminess of close relationships over 12 weeks than in those who did not receive psychoeducation.[35]

Meta-analyses of problem-solving therapy outcome studies document its effectiveness for people with a wide range of mental health problems.[31,36,37] Detained PD offenders were identified as performing poorly in all aspects of social problem-solving compared with offenders with no PD and non-offenders.[38,39] A pilot study of a psychoeducational intervention aimed at clarifying the offenders' PD diagnosis and identifying associated problems led to an increase in patients' knowledge about PD and improved the therapeutic alliance.[34] A brief problem-solving therapy was evaluated with this client group, finding that social problem-solving abilities improved post therapy and that this improvement was sustained at a 6-month follow-up.[40] A social problem-solving intervention has also been evaluated with women in a secure setting, with improvements after treatment in risk and health,[41] and with people at high risk of suicide, showing reduced suicidal ideation over those receiving treatment as usual.[42]

Psychoeducation with problem-solving therapy

A combined PEPS therapy was evaluated with community adults with PD in a Phase 2 exploratory trial.[43] Overall, this sample had the lowest social problem-solving scores in comparison with mature students, prisoners and PD offenders.[44] At the end of treatment, compared with a wait-list control group, those treated with PEPS therapy showed better social functioning, as measured by the Social Functioning Questionnaire (SFQ).[45] Analyses were conducted to examine the hypothesised mechanism of change, namely that improved social problem-solving leads to improved social functioning.[46] These analyses indicated that all aspects of social problem-solving improved over the course of PEPS therapy and, that controlling for baseline level of social functioning, the most important predictor of improvement in social functioning was a reduction in negative problem orientation (i.e. people felt less threatened by problems and more confident in their ability to solve problems). This exploratory study has been identified as important in four ways.[47,48] First, the intervention was brief and, hence, is likely to be more acceptable to patients and services. Second, PEPS therapy was delivered in clinical settings, hence its likely effectiveness in everyday practice was indicated. Third, PEPS therapy was offered to people with any PD or combination of PDs, so it was inclusive rather than exclusive. Finally, non-specialist staff delivered PEPS therapy; hence it would be possible to deliver it relatively cheaply. In addition, a Delphi study of patients' views of PEPS therapy indicated that it was perceived as acceptable and useful.[49]

Overall, PEPS therapy has the potential to contribute to the Department of Health's agenda that PD should no longer be a diagnosis that excludes people from services.[50] It is an intervention in which staff can easily be trained and, thus, has the potential to make a significant contribution to building workforce capacity.[51] Here, we present the results of an adequately powered, multisite RCT.

Chapter 2 Methods

Design

The PEPS trial was a two-arm, parallel-group, pragmatic randomised controlled superiority trial comparing PEPS therapy plus treatment as usual with treatment as usual alone. Participants were individually randomised at a ratio of 1 : 1, and stratified by sex and centre.

An economic analysis was conducted alongside the trial to determine the costs and cost-effectiveness of PEPS therapy compared with treatment as usual (see *Chapter 5*). In addition, a qualitative component sought to explore participants' experiences of PEPS therapy and treatment as usual (see *Chapter 6*).

Study setting and participants

Study participants were recruited from three NHS trusts providing mental health services in central and north-west London, South Wales and the North-East of England.

We recruited participants from mental health services including community mental health teams (CMHTs), crisis resolution teams, primary care liaison teams, psychology services and on discharge from inpatient care.

Eligibility criteria

At the point of randomisation participants were required to have one or more PD, including a PD not otherwise specified, identified through the International Personality Disorder Examination (IPDE) completed as part of the study-specific procedures at the screening visit. In addition, eligible participants were aged ≥ 18 years, living in the community (including residential or supported care settings) and proficient in spoken English and had capacity to provide informed consent.

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.

Identification of participants

Participants were identified by their mental health team. The initial approach about the study was made by a member of the potential participant's mental health team, who sought verbal agreement from the potential participant to meet with the research team to discuss the study. Referral to the research team was made according to local procedures at each site.

All potential participants referred to the research team were recorded on the Participant Screening and Enrolment Log, whether or not they were enrolled in the trial.

Recruitment

Potential participants providing verbal agreement were referred to the research team who assessed eligibility according to the available clinical information, and invited potentially eligible participants to consider taking part in the trial. Potential participants were provided with written and verbal information about the trial and were given a minimum of 24 hours to consider whether or not to participate.

All participants joining the study provided written, informed consent. Participants were free to withdraw from the study at any time without giving a reason. If participants declined to complete follow-up assessments when originally approached, the researcher sought verbal consent to contact them again at a later stage to see if they were willing to complete the assessments.

Recruitment strategy

The identification and recruitment of participants was actively managed at each site to reduce potential delays and group waiting times. Problem-solving group start dates were determined in advance, allowing a time-limited baseline and randomisation period to be specified, based on recommended minimum and maximum waiting times before commencement of treatment and between the individual and group components of PEPS therapy. The specifications were that psychoeducation should be completed a maximum of 4 weeks before the problem-solving group started. The maximum wait between randomisation and the group starting should be 10 weeks and the minimum should be 5 weeks. This enabled completion of the individual treatment sessions and first follow-up prior to the start of the problem-solving group.

Within each recruitment phase there was an approximate 5-week period within which baseline assessments and randomisation were completed for participants in a particular recruitment phase. Randomisation was completed as soon as possible after baseline assessments and in all cases this should have been done within 1 week.

A minimum starting group size of six was recommended. During the randomisation period, local teams aimed to randomise a minimum of 12 participants to ensure an adequate minimum starting group size. It was recommended that starting group sizes should generally be no more than 10 participants. However, local teams could use discretion in determining the appropriate group starting size according to local circumstances, current waiting times and recruitment rates.

Screening

To confirm eligibility for the trial the following screening measures were undertaken before randomisation:

1. The presence of PD was confirmed using the IPDE.[52] The IPDE is a 99-item, semistructured interview that allows both diagnostic and dimensional scores to be extracted for each PD according to either *Diagnostic and Statistical Manual of Mental Disorders* (DSM)[53] or *International Classification of Diseases*[54] criteria. DSM criteria were used in this trial. Each item is scored as the behaviour or trait being absent or normal (score 0), exaggerated or accentuated (score 1), or at the criterion level or pathological (score 2). Diagnostic scores were calculated in accordance with the scoring manual. A minimum of one ‘probable’ score on any diagnostic category including PD not otherwise specified was required to be eligible for the trial.
2. Adequate literacy was required to engage in trial therapies and assessments. In the majority of cases this was assessed by the investigator or authorised designee in conjunction with the participant’s usual-care team. Adequate literacy was determined in discussion with the participant and their clinical team, based on the ability to participate in the trial therapy and assessments. The Basic Skills Agency’s, *Fast Track 20 Questions*[55] was available as an additional screening measure to aid assessment of literacy if required, but was not used. Study recommendations were that a score of ≥ 3 on the literacy component of the *Fast Track 20 Questions* indicated that additional consideration may be required, but did not prohibit further involvement in the trial. The final decision about inclusion or exclusion was made by the therapist in consultation with the referrer, the client and, if necessary, the site coinvestigator or site clinical supervisor.

Interventions

This was a two-arm trial comparing PEPS therapy in addition to treatment as usual with treatment as usual only.

Psychoeducation with problem-solving therapy

Psychoeducation with problem-solving therapy is a complex cognitive–behavioural intervention that integrates individual and group therapies. There are two distinct components – individual psychoeducation and group problem-solving therapy – with optional individual support sessions.

Psychoeducation

Psychoeducation consists of up to four sessions delivered by a mental health worker trained to administer the procedure. The number of sessions depends on the duration of sessions and the speed at which the participant can comfortably work through the session content. Although the guidance is to work in 1-hour sessions, some participants prefer to have longer and less frequent sessions to maintain the flow of the content.

The sessions are conducted as a one-to-one collaborative dialogue and are designed to fulfil both general and specific functions. In general, the aims are to build rapport with participants and enhance their motivation for the subsequent problem-solving therapy. This is done specifically by asking participants their views on how their personality leads to problems in interpersonal relationships and social functioning, introducing them to and discussing their PD diagnoses, and explaining how therapy can help people ameliorate their problems.

Interviewers follow a set procedure described in a facilitator's manual (see *Appendix 1*). Participants are first asked about their understanding of personality and any personality-related problems that they experience in a brief interview consisting of six questions:

1. What does the word 'personality' mean to you?
2. Do you think your personality causes you problems? In what way?
3. Do you think your personality causes problems for other people? In what way?
4. Would you like to change the way you handle problems?
5. Some people are diagnosed as having a PD. Do you know what a PD is?
6. Have you ever been told you might have a PD?

Information on personality and PD is then provided, following an information sheet explaining the concept of personality in terms of it being the way people typically think, feel and behave, and PD being personality styles that persistently cause difficulties and distress. The suggestion that problem-solving therapy can help ameliorate problems is then introduced. Participants are asked to complete a checklist of what problems they experience in relation to their PD. The interviewer completes a checklist that takes the individual through their PD diagnoses, as identified prerandomisation using the IPDE,[52] which is a structured clinical assessment. The interviewer and the participant discuss information about the individual's personality problems from both perspectives. Participants are then guided to identify specific problems that they want to change, and prioritise those to be addressed in the subsequent problem-solving therapy sessions. The interviewer summarises the progress made in psychoeducation and logs the problems to be addressed in problem-solving therapy on a summary pro forma. This summary is used to convey the information to the problem-solving therapy facilitators. The content of psychoeducation is also summarised in a personalised booklet (see *Appendix 2*) that the participant is given to keep.

Problem-solving therapy

Problem-solving therapy is a 12-session manualised (see *Appendix 3*) group intervention designed to teach people a strategy for solving interpersonal problems. Problem-solving therapy is delivered by two mental health professionals trained to administer the therapy. The recommended starting group size was between 6 and 10 participants, but local sites were advised to use discretion so that when trial recruitment was slow, groups could start without undue delay; actual group sizes were between 5 and 12 participants. Sessions lasted approximately 2 hours, divided into 75 minutes of problem-solving work, a 15-minute break and 30 minutes of problem-solving work.

In each session, one participant worked through an actual problem that was identified in collaboration with one of the group facilitators prior to the group session. The problem selected could be an emotional or interpersonal problem, rather than a practical problem, and would be one that was current and important but not excessively distressing or unsuited to sharing in a time-limited group. Participants were then guided to learn the steps of the problem-solving process, based on the work of D'Zurilla and Nezu:[56,57]

(a) orientation – identifying negative feelings and using these as a cue for initiating the problem-solving process
(b) problem definition – defining their problem clearly and accurately, breaking down large problems into smaller, more manageable ones
(c) goal-setting – setting specific goals for change
(d) generating alternatives – generating solution options
(e) decision-making – considering the consequences of each option to themself and others in both the short and the long term
(f) action-planning – selecting potentially effective options and organising these into a means-end action plan.

Participants were then expected to implement the action plan and were offered optional fortnightly individual support sessions throughout the 12-week problem-solving group therapy to help with implementation. Progress with the action plan was reviewed in the next group session.

The problem-solving process is translated into colloquial questions, which are shown in *Table 1*, along with the formal stages of the process and the skills learned in each stage.

TABLE 1 The problem-solving process

Question	Stage	Skills
Feeling bad?	Orientation	Recognition and understanding of feelings countering impulsivity
What's my problem?	Problem definition	Information gathering Assessing the quality and relevance of information Breaking down large problems
What do I want?	Goal-setting	Identification of needs Setting targets
What are my options?	Alternatives	Creative thinking
What's my plan?	Decision-making	Challenging dysfunctional beliefs Challenging antisocial attitudes Anticipation of outcomes Forward planning
How did I do?	Evaluation	Recognise and reward success Recognise and address obstacles

Throughout this process, attention was paid to improving optimism and hope for change, which is identified as of equal importance to problem-solving skills. This was done by helping participants experience success in problem-solving through guiding them through the problem-solving process, giving them support in their efforts to solve problems, identifying their strengths and highlighting problem-solving successes.

The process of problem-solving through addressing the key questions was recorded on a flip chart as the session progressed. The flip chart could be written by a group member or one of the facilitators, depending on the abilities of group members. This material was then transcribed to A4 sheets, which were given to the participant for his or her records, and a copy retained for the facilitators' records. Individual support sessions of 1-hour duration were offered fortnightly to help the individual carry out problem-solving action plans. Additionally, participants were encouraged to work through problems independently outside sessions in order to generalise the new skills. A worksheet was provided to assist with independent working.

Problem-solving therapy was provided in mixed- or single-sex groups, depending on the stage of the trial (described in *Changes to the intervention during the trial*), the number and suitability of referrals received, and participant preference. Participants allocated to PEPS therapy were expected to attend every session, and regular attendance was encouraged in accordance with normal clinical practice. A record of attendance at sessions was maintained for all participants. Participants were not withdrawn from trial therapy for reasons of poor attendance. Owing to variable group attendance rates, a prespecified minimum attendance at group treatments was defined for participants to be considered to have received therapy per protocol. The agreed hypothesis was that attending ≥ 6 of the maximum 12 group sessions of problem-solving therapy would be associated with improved outcomes on the SFQ.

Changes to the intervention during the trial

Within the trial, problem-solving groups were originally intended to be single sex. This was to ensure consistency with the pilot study and in response to preferences expressed by service user representatives advising on the design of the study during protocol development. However, the requirement for single-sex groups was found to cause delays while awaiting the accrual of sufficient participants to form a group. This was a particular issue for male participants because fewer men were referred to the study.

After consulting with the Trial Steering Committee (TSC), the study team took the decision to allow problem-solving therapy to be offered in mixed-sex groups. The reasons for this were:

1. Mixed-sex groups are routine practice in community-based clinical services already offering PEPS therapy.
2. Mixed-sex groups may help to reduce waiting times and delays between recruitment and randomisation.
3. Mixed-sex groups can provide clinical benefits (e.g. helping participants to address issues with relating to people of the opposite sex).

An amendment was submitted to the Research Ethics Committee to introduce this change in August 2011, approximately halfway through the recruitment period. Following implementation of this amendment, allocation to mixed- or single-sex groups was made in accordance with usual clinical practice, incorporating participant preference where possible.

Treatment as usual

Usual treatment was provided by participants' usual-care teams in accordance with normal clinical practice. No restrictions were placed on access to other treatments during the trial period, although engagement in a specific programme of psychological treatment for PD was an exclusion criterion applied at the point of enrolment.

The original protocol included a standardised form of treatment as usual as the control. Shortly after the start of the recruitment period, it became apparent that there was substantial variability in the level and type of care provided to people with PD at each of the participating sites. Many potential participants were being assessed by mental health services and discharged without treatment. To exclude these people would seriously compromise recruitment to the trial. For this reason, the study team could not impose a standardised form of treatment as usual on the referring clinical services. The study team felt that this issue was likely to become more pressing as NHS cuts at the time caused CMHTs to reduce services. As a result, it was agreed that the trial should compare PEPS therapy with treatment as usual in whatever form that took, and the planned requirement for a standardised form of treatment as usual was removed from the protocol in August 2010. The standardised form of treatment as usual, outlined in the original protocol, was recommended as a minimum standard of care but this was not imposed on clinical services referring participants to the trial.

Treatment fidelity

Manualised assessment and treatments

The IPDE schedule, psychoeducation and problem-solving therapy are all comprehensively manualised.

Training and supervision

Therapists were qualified mental health nurses or psychology graduates with clinical experience. All IPDE assessors attended training in administering and scoring the structured interview from a qualified and highly experienced clinician and researcher. Each lead clinician who delivered psychoeducation and problem-solving therapy was trained to conduct the intervention. Problem-solving therapy groups were facilitated by two facilitators. Most cofacilitators also attended training in delivery of the intervention; however, on the rare occasions that this was not possible, groups could be cofacilitated by a facilitator who had not completed the training, provided that they were fully briefed by the lead therapist and were aware of the limitations of their involvement. A minimum of one fully trained and assessed facilitator was present at every group session.

Psychoeducation training was delivered after IPDE training and consisted of informing therapists of the rationale for psychoeducation, explaining the delivery mode of an educational dialogue and familiarising therapists with the materials and their sequence of delivery. Problem-solving therapy training consisted of 3 days in which groups of participants were given the theory, outcome evidence and role-play practice.

In each case (IPDE, psychoeducation and problem-solving), training followed an existing training protocol. Training was conducted centrally by experienced clinicians and researchers. After training, regular supervision was provided, both centrally and locally.

Competence checks

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 (see *Appendices 4–6*). These specified the key activities for conducting the IPDE and delivering psychoeducation and problem-solving sessions according to the intended treatment model. 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. Having assessed the therapists as competent to deliver the treatment according to the model and the protocol, no further checks were made. This was considered to reflect actual clinical practice in which staff are trained in a procedure and, if they meet the standards set by the trainers, they commence practice and the quality of their continued practice is monitored through supervision.

Fidelity checks

Treatment fidelity was assessed in three ways:

1. Measuring adherence to protocol implementation (e.g. frequency and duration of treatment sessions).
2. Assessing adherence to therapy, as specified in the treatment manual.
3. Clinical supervision.

Adherence to psychoeducation was self-rated by the therapist after the end of all psychoeducation sessions, using a standard protocol (see *Appendix 7*). Adherence to problem-solving group sessions was rated by experienced clinicians, based on a sample of audiorecorded sessions.

Outcome measures

Primary outcome

The primary outcome was social functioning as measured by the SFQ.[45] This is an 8-item self-report scale, on which each item is scored from 0 to 3. The total SFQ score ranges from 0 to 24. A reduction (i.e. an improvement) of ≥ 2 points on the SFQ at the 72-week follow-up was the specified clinically significant change.

Secondary effectiveness outcomes

1. Scheduled and unscheduled health-service use collected through a retrospective review of mental health service and general practitioner (GP) records.
2. Mood, measured by the HADS,[58] a 14-item self-report questionnaire with scores in the range of 0 to 42, and on which higher scores are less desirable.
3. The referring clinician's judgement of the participant's overall level of psychosocial functioning assessed by the GAF.[53]
4. The client's assessment of severity, on a scale from not at all distressing (0) to very distressing (10), of the three problems they considered most important (three main problems).

Process measures

The following measures were intended as measures of the processes of change during PEPS therapy:

1. Therapeutic relationship was assessed using the Working Alliance Inventory – Short Revised (WAI-SR),[59] a 12-item scale rated by both client and therapist to assess agreement on the tasks of therapy, agreement on the goals of therapy, and the bond between client and therapist, with a range of scores between 12 (poor) and 48 (good).
2. Social problem-solving abilities were measured by the SPSI-R,[28] a 25-item self-report questionnaire that measures problem-solving orientations and styles, with five items in each of the five subscales: positive problem orientation, negative problem orientation, rational problem-solving, impulsivity/careless style and avoidance style. Effective social problem-solving is indicated by higher scores on positive problem orientation, rational problem-solving and the SPSI-R, and lower scores on negative problem orientation, impulsivity/careless style and avoidance style. A total social problem-solving score ranges from 0 to 25, in which a higher score is more desirable.

Health economic outcomes

1. Receipt and cost of services were collected using the Client Service Receipt Inventory (CSRI).[60]
2. Quality of life was assessed by the European Quality of Life-5 Dimensions (EQ-5D),[61] a health status measure used to generate quality-adjusted life-years (QALYs).

Participants' views and experiences

Qualitative semistructured interviews were completed with participants allocated to PEPS therapy after psychoeducation and after problem-solving therapy to seek participants' views on treatment. Further interviews were completed with all participants after the final follow-up to seek participants' views on the experiences of PEPS therapy and usual treatment.

Safety and tolerability measures

Adverse events occurring in trial participants were recorded and monitored. For the purposes of this trial, a recordable adverse event was defined as any of the following:

- death for any reason
- inpatient hospitalisation for any reason
- any other serious, unexpected adverse event.

Adverse events were reported for all participants from consent to trial completion or early withdrawal from trial follow-up. If a participant withdrew from treatment but agreed to remain in trial follow-up, data collection, including adverse event reporting, continued in accordance with the protocol.

Premature withdrawal from the trial therapies or follow-up was reported, with reasons for withdrawal documented when these were given.

Statistical methods

Statistical analysis

The analysis and reporting of the trial was in accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines.[62–65] Analyses were detailed in a statistical analysis plan, which was finalised prior to completion of data collection and database lock. All analyses were conducted using Stata version 13 (StataCorp LP, College Station, TX, USA).

Preliminary analyses

Descriptive statistics of demographic and clinical measures were used to examine the balance between the randomised arms at baseline.

Primary analysis

The primary analysis compared the mean SFQ score between PEPS and usual treatment at the 72-week postrandomisation follow-up, adjusted for baseline SFQ score and stratification variables (centre and sex), and implemented using maximum likelihood-based generalised linear modelling. The primary analysis compared individuals as randomised, regardless of treatment actually received or if 72-week follow-up SFQ data were observed (intention-to-treat principle). The effect is presented as an adjusted difference in means, 95% confidence intervals (CIs) and *p*-value for the comparison.

Imputation of missing primary outcome data

The pattern of missing data was investigated by examining variables recorded at baseline that were associated with 'missingness' of SFQ score at the 72-week follow-up. Multiple imputation and analysis of multiple imputed data sets were conducted using 'mi' procedures in Stata. The imputation model contained site, age, sex, ethnicity, social status, PD category (simple or complex), SFQ at baseline and 24 weeks, baseline EQ-5D health state score, baseline HADS score, baseline SPSI-R score and baseline three main problems score, and 20 data sets were imputed.

Missing item data

For all outcomes that are a scale comprising a number of items, the following procedure was undertaken when $> 0\%$ and $\leq 15\%$ of items were missing:

- Step 1: calculate the scale mean for each participant (denoted by m1 for those with $> 0\%$ and $\leq 15\%$ of items missing).
- Step 2: calculate the mean of scale means for participants with complete scale data only (denoted by M1).
- Step 3: calculate each item mean for all participants with observed data for that item (denoted by S1).
- Step 4: for each item, calculate $M1 - S1$ (denoted by d).
- Step 5: impute missing item data using $m1 - d$.

When $> 15\%$ of items were missing, the total scale score was regarded as missing and imputed using multiple imputation.

Clustering in psychoeducation with problem-solving arm

In this trial there were two potential sources of clustering in the PEPS arm only: by therapist in the first treatment phase and by the problem-solving therapy group in the second treatment phase. Data for the former were not available for some participants, or else treatment in the first phase was delivered by a single therapist per centre. Furthermore, any clustering effect was expected to be dominated by the latter. Therefore, we obtained clustered sandwich estimates of variance by specifying the 'cluster' option in all regression models, which relaxes the assumption that all observations are independent.

Sensitivity analyses

We conducted the following sensitivity analyses of the primary outcome:

1. Repeated the primary analysis with additional adjustment for any variables displaying marked imbalance between the arms at baseline.
2. Repeated the primary analysis restricted to those participants with observed primary outcome data at 72 weeks.
3. To examine treatment efficacy, complier average causal effect (CACE) estimates[66] were calculated using instrumental variable regression methods for those participants in the PEPS arm who received the intervention in line with the treatment protocol. The definition of treatment received as per protocol was having completed psychoeducation according to the therapist assessment and attended a minimum of six of the group problem-solving sessions.

Subgroup analyses

Although no subgroup analyses were specified a priori, we conducted two exploratory subgroup analyses by including appropriate interaction terms in the regression model for the primary outcome. We investigated whether or not there was any evidence of differential effects of treatment on SFQ score at 72 weeks according to (1) study site (central and north-west London, South Wales and North-East England); (2) PD category (simple, complex); and (3) borderline PD diagnosis at baseline.

Secondary outcomes

Analysis of secondary outcomes was conducted using a similar approach as for the primary outcome, except that missing data were not imputed, and choice of regression model and presentation of the estimated between-group effect was dependent on outcome type (continuous, binary, ordinal, rate). We used proportional odds logistic regression for ordinal data and we checked the goodness-of-fit assumption for the Poisson regression analysis of count data using the Pearson test. Descriptive data are presented for each time point, but formal comparisons were only conducted for 72-week data. The exception to this is the SPSI-R total score, for which a repeated measures analysis was conducted including data at both the 24- and 72-weeks follow-up to examine whether any treatment effects were sustained or emerged later. This was tested formally with an interaction term between treatment group and time in the model, and in the absence of any evidence of a time effect, a repeated measures analysis generates an average effect size over the duration of follow-up.

Between-group differences in health-care service use and adverse events were estimated using binomial/Poisson regression modelling and allow for multiple events per individual.

Interim analysis

No formal interim analyses for effectiveness were planned or undertaken, however, unblinded data were periodically reviewed by the Data Monitoring and Ethics Committee (DMEC) during routine meetings.

Sample size

The sample size calculation for the study was based on the primary hypothesis that those randomised to PEPS therapy in addition to usual treatment would have improved social functioning at 72 weeks after randomisation compared with those randomised to usual treatment only. We powered the trial to detect a difference of 2 points on the SFQ score (standardised effect size of 0.44). This is agreed to be a clinically significant and important difference.[67] We based our sample size estimate on a conservative (i.e. largest) estimate of standard deviation (SD) of 4.53 points.

To detect a difference in mean SFQ score of 2 points with a two-sided significance level of 1% and power of 80%, with equal allocation to two arms, would require 120 patients in each arm of the trial. In anticipation of a 30% loss to follow-up at 72 weeks after randomisation, we planned to randomise 340 participants (170 in each arm).

Randomisation

Following recruitment and completion of screening and baseline assessments, participants were randomly allocated to receive PEPS therapy in addition to usual treatment or usual treatment alone at a ratio of 1 : 1.

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 (NCTU), in accordance with its standard operating procedure and held on a secure server. The randomisation was stratified by recruiting centre and sex. The sequence of treatment allocations was concealed until recruitment, data collection and all other trial-related assessments were complete.

The investigator, or an authorised designee, accessed the treatment allocation for each participant by means of a remote, internet-based randomisation system developed and maintained by the NCTU. Allocation was therefore fully concealed from recruiting staff.

Study procedures

Preparatory phase

Site initiation visits were completed prior to the start of recruitment to ensure that all site staff were trained in the protocol and study-specific procedures.

Visit schedule

The duration of follow-up was 72 weeks post randomisation. The study schedule is shown in *Figure 1*.

Data collection

Follow-up visits were completed in person or by telephone. To improve response rates at the final follow-up, the SFQ was posted to participants who could not be contacted by another means.

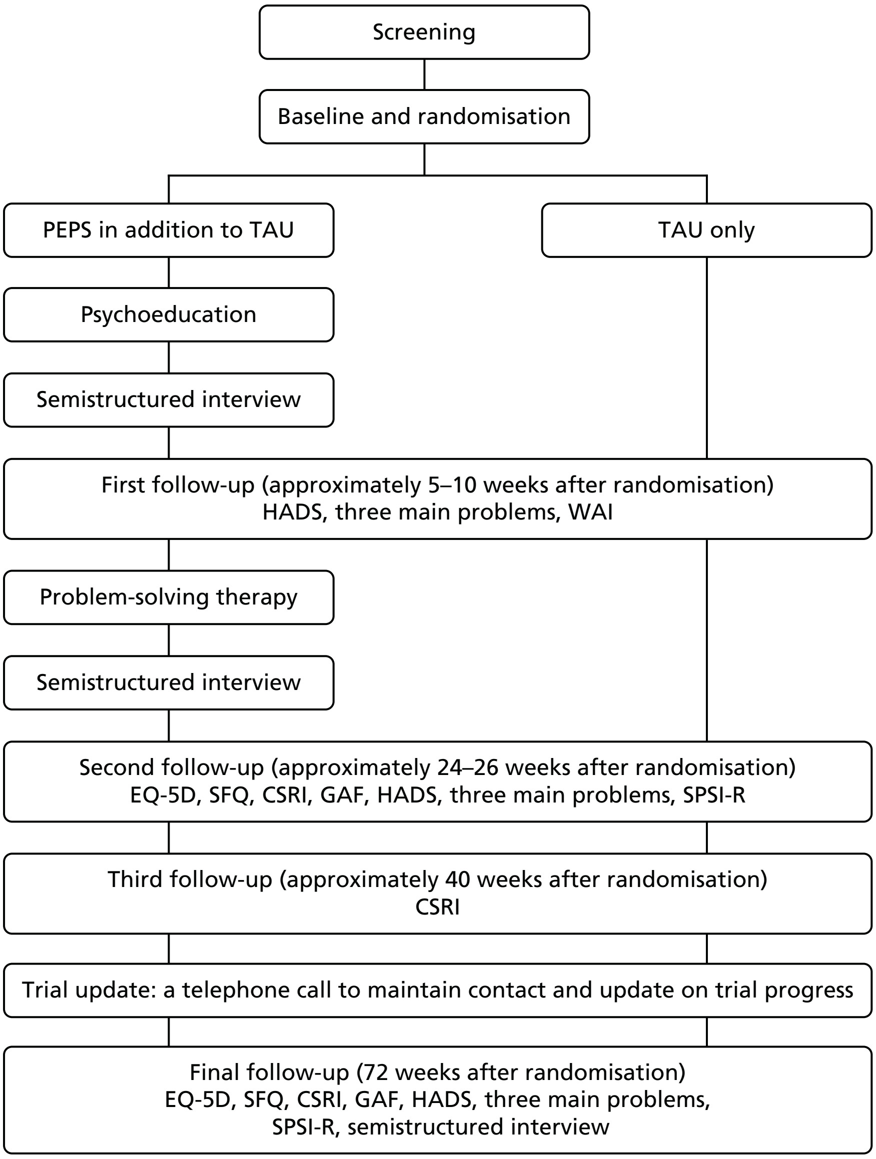

FIGURE 1 Schedule of visits. TAU, treatment as usual.

The majority of data were collected through the use of standardised, self-report assessment measures completed by participants during scheduled follow-up visits. Research staff involved in data collection were provided with guidance on the principles of standardised assessment and on the specific measures employed in the trial. Assessments were self-completed by participants or read aloud to participants by the researcher if required. In this case, questions were read out verbatim and were not reworded. No test feedback was given to participants.

The Service Use Record Check was completed by the research assistants after the final assessment measures had been collected. Service use data were collected from GP and mental health records retrospectively for the duration of the trial, according to a data collection manual that outlined procedures for accessing GP records, procedures for dealing with incomplete or inconsistent data, and definitions of key terms; standardised data collection forms were used (see *Appendix 8*).

Blinding

In pragmatic trials of this type, as in usual clinical practice, it is not possible to blind participants or clinicians to whether they are in the intervention or control arm of the trial; therefore, 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 participants who were not blind to treatment allocation. However, outcome measures were administered by research assistants blinded to treatment allocation in order to reduce assessment bias as far as possible. Data analysts remained blinded to allocation during the study by having access to only aggregate data and no access to data that could reveal treatment arm, such as course attendance. Final analyses were conducted using treatment labels A/B, with allocation decodes released only after completion of analyses. Data that could reveal allocation were analysed following release of allocation decodes.

At the start of each follow-up, participants were reminded of the importance of not disclosing their treatment allocation to the research assistant using a suggested unblinding script (see *Appendix 9*). If the research assistant was inadvertently unblinded to treatment allocation before completing the final follow-up, a record of the incident of unblinding was made. Researchers also reported whether or not they were aware of the treatment allocation at the time of completing the primary end-point assessments. Owing to changes in personnel over the course of the trial, in some cases, end-point assessments were conducted by researchers who were not unblinded. A record was made of the blinding status of the researcher conducting the final follow-up data collection.

Payments to participants

Participants reaching the final follow-up were offered a non-contingent voucher payment in recognition of their contribution to the trial. Contact with the participant at the final follow-up was sufficient for provision of the voucher (i.e. payment was not contingent on completion of the final follow-up assessments). This voucher payment was introduced in an amendment in April 2013, approximately halfway through final follow-up completion.

Reimbursement of travel expenses incurred in relation to attendance at research appointments was offered, and travel expenses incurred by participants in conjunction with the treatments provided in the trial were paid in accordance with normal clinical practice at the local sites.

Patient and public involvement

Two service users were involved in the protocol development and in the preparation of the participant information sheet and consent form. Service user representatives on the Trial Management Group (TMG), TSC and DMEC contributed to the management and oversight of the trial.

Research governance

The study was conducted in accordance with the principles of good clinical practice and the *Research Governance Framework for Health and Social Care*.[68]

Ethics

Ethical approval for the study, including amendments, was given by the South Wales Research Ethics Committee (reference number 09/WSE03/48).

The final approved protocol was version 6.0, dated 3 April 2013. The original approved protocol was version 1.0, dated 18 September 2009. For a summary of amendments implemented during the trial see *Appendix 10*.

Oversight

A number of committees were assembled to ensure the proper management and conduct of the trial, and to uphold the safety and well-being of participants. The general purpose, responsibilities and structures of the committees were described in the protocol, with separate charters developed for the independent oversight committees.

The TMG comprised members of the study team and met regularly throughout the trial to oversee the day-to-day management of the trial. The TMG met approximately once a month for the duration of the trial, with meetings held face to face and by teleconference for those unable to attend in person. The TMG reviewed recruitment and data completion rates, as well as identifying and addressing any issues arising during the course of the trial.

Independent oversight of trial conduct was provided by the TSC and DMEC.

The independent TSC monitored, reviewed and supervised the progress of the trial. The TSC also monitored pooled data to consider safety and efficacy indications, and considered reports from the DMEC.

An independent DMEC was established, with access to unblinded data, to provide independent reviews and recommendations to the TSC regarding continuation of the study in light of potential treatment effect. The DMEC was advisory to the TSC. During routine conduct of the trial, the DMEC was the only group with access to unblinded data. The DMEC reviewed unblinded data at routine meetings held during the course of the trial. The data that were presented included listings of reported adverse events and reported hospitalisations collected from the CSRI.

For the schedule of meetings of the DMEC and TSC see *Appendix 11*.

Safety monitoring

Local procedures were implemented at each site to ensure adverse events were recognised and reported, including asking participants about adverse events during each contact and asking the participant's clinical team to inform the site principal investigator if an adverse event was identified. The participant's responsible clinician was also contacted by letter to request information on adverse events throughout the trial.
In addition, in the event of loss to follow-up, the participant's clinical team and/or GP were contacted to alert the responsible clinician to the participant's loss to follow-up and to request information on any unreported adverse events to ensure that safety data remained accurate and up to date. All adverse events were reported to the trial co-ordinating centre within 24 hours of the study team becoming aware of them.

Adverse event reports were reviewed on receipt at the co-ordinating centre, and were assessed for relatedness and expectedness by the chief investigator in accordance with the National Research Ethics Service guidance on adverse event reporting in trials that do not include medicines. To guide this assessment, the adverse event form collected information on all possible and suspected causes identified from the available clinical information, including clinical notes and participant self-report. A categorical assessment of 'relatedness to the trial' was also made by the person reporting the event.

Adverse events were also classified by the person reporting them according to whether or not there were indications of 'psychological antecedents'. Events that were deemed to have psychological antecedents were defined as mental health-related events. Mental health-related events were further categorised as follows:

- self-harm, including drug or alcohol overdose
- deterioration in mental health
- suicidal ideation
- suicide or attempted suicide
- planned/respite hospital admission
- other (specify).

The primary classification only was recorded. Adverse events were classified by the person reporting the event on the basis of the information available at the time (e.g. through participant self-report or clinical notes). For example, attempted suicide was recorded when this was the reason given by the participant, and it does not necessarily relate to the severity of harm caused or evidence of clear intent (i.e. events recorded as 'attempted suicide' are not necessarily life-threatening).

All adverse events were routinely reported to the Research Ethics Committee, DMEC and TSC as part of the regular reporting requirements. In addition, serious adverse events that were deemed to be both related to administration of any of the trial procedures and that were not identified as expected occurrences were subject to expedited reporting to the Research Ethics Committee, as required by the National Research Ethics Service guidance for studies that are not clinical trials of investigational medicinal products in the UK.

Chapter 3 Early stopping of recruitment and delivery of the trial intervention

The decision to stop recruitment and trial therapy

On 29 October 2012, following the fourth meeting of the DMEC, the DMEC chairperson wrote to the TSC notifying the TSC of a safety alert in the PEPS trial based on an untoward pattern of serious adverse events. The DMEC had done some investigations but had been unable to satisfy themselves of whether this finding might or might not have been treatment related. The DMEC recommended further investigations to clarify the safety and tolerability of the treatment and advised that randomisation to the trial be suspended until this had been further investigated. The DMEC did not recommend stopping the treatment of people currently in the trial, as they considered that the potential risks of harm in discontinuing treatment were not justified at that stage. Following subsequent correspondence and discussions between the two committees, during which the TSC reviewed the recommendations of the DMEC and the unblinded data on which they were based, the TSC agreed that a safety concern could not be ruled out, but made different recommendations to those advocated by the DMEC. The TSC communicated the following decisions to the chief investigator and trial co-ordinating centre in a letter dated 6 November 2012:

- No further patients should be randomised into the PEPS trial.
- Patients who were currently in treatment in the trial should no longer receive trial treatment within the parameters of the trial treatment protocol.
- To fulfil the duty of care to patients who have completed the treatment phase of the trial the trial team should consider how to inform patients of the possibility of harm.
- Trial data should continue to be collected and all patients followed up as per protocol.

A number of clinical concerns were raised by the PEPS trial team between 10 and 12 November 2012, and the study team felt that a challenge to the decision to stop trial treatment was warranted. In the absence of precedent in this situation, the following process was proposed by the trial co-ordinating centre and agreed by all parties, including the funder:

- A joint meeting of TSC and trial team would be held.
- The TSC would explain their decisions and rationale behind them.
- The study team would present their concerns.
- Chaired discussion between all parties.
- The TSC would convene a closed meeting to consider the challenge and agree its response.

These discussions took place at a face-to-face meeting held on 15 November 2012. The meeting was hosted by the NCTU and chaired by a senior member of the NCTU, who was not otherwise involved in the trial. The closed TSC meeting was held on 19 November 2012. Immediately following this meeting, the TSC wrote to the study team to confirm the unanimous decision of the TSC to uphold its original decision. Following this confirmation, the study team took immediate steps to action the implementation plan that had been previously agreed during the meeting held on 15 November 2012 and in subsequent correspondence.

Stopping recruitment and trial therapy

On receipt of the notification of the initial decision from the TSC on 6 November 2012, the following interim actions were taken immediately by the chief investigator and trial co-ordinating centre:

- The online randomisation system was suspended on 6 November 2012 to ensure that no further participants would be randomised.
- The TMG, other coinvestigators, the trial funder and the trial sponsor were notified immediately.
- A holding statement, approved by the TSC and sent on their behalf, was circulated to recruiting sites on 8 November 2012. Site principal investigators were asked to disseminate the holding statement to site staff and to stop any further recruitment of participants with immediate effect on 8 November 2012.

Delivery of the trial therapy was suspended where it was possible to do so without undue disruption (e.g. postponing appointments). At this stage, steps were not taken to permanently discontinue treatment or inform participants until the implications had been fully considered and a clinically appropriate action plan, with support and alternative treatment arrangements, was in place.

A brief search and consultation failed to find any previous examples of cessation of recruitment and treatment because of a safety alert in a trial of this type. Therefore, the process of stopping recruitment and delivery of trial therapy meant that additional, specific procedures were developed in collaboration between the TMG, TSC and NCTU with reference to clinical guidelines and accepted good practice. Regular communication was maintained during the planning and implementation to review progress and agree the next steps.

Informing participants and clinicians of the trial changes

Everyone affected by the trial changes was provided with information by the research team. A written information sheet was provided. Participants who were 'active' in the trial (i.e. recently referred or in the treatment phase) were provided with additional information and support regarding their ongoing care. A separate, simplified version of the information sheet was available for participants in the follow-up period.

Clinical teams and referring clinicians were informed of the trial changes. They received the same information as participants, and were offered additional guidance on 'frequently asked questions' and sources of additional support and advice, should they be required to respond to queries or concerns from participants.

A letter was sent to the responsible clinician within mental health services and the GPs for all participants involved in the trial to inform them of the changes to the trial.

Participants and clinical teams were informed of the changes to the study as a matter of urgency. It was considered essential that all those affected by the changes were informed by the research team first, before this information was in the public domain.

The provision of information to people affected by the trial changes was completed on a staged basis so that the processes used and information provided could be informed by early feedback from participants and clinical teams. However, the process of informing people affected by the trial changes was time limited and all those affected by the changes were notified within a reasonable time scale. Whenever possible, this was within 4 weeks.

Updated consent

No further trial-specific procedures (e.g. continuation of the IPDE, sessions with a PEPS therapist or follow-up assessments) were completed with participants until they had been informed of the trial changes. Participants in the trial were asked to sign an updated consent form to confirm receipt of the new information and indicate their ongoing agreement to participate in the trial. Verbal consent was accepted for continuation of follow-up assessments completed by telephone, although written consent forms were also requested.

Issues relating to participants

When the decision to stop recruitment and delivery of the trial therapy was made, 306 participants had been randomised. The number of participants at each stage of the trial is shown in *Table 2*.

Randomised to psychoeducation with problem-solving therapy and active in the treatment phase of the trial

Participants who had been randomised to receive PEPS therapy and were currently in the treatment phase of the trial were informed of the trial changes as soon as practically possible, and arrangements were made to ensure that the delivery of PEPS therapy was stopped in a clinically appropriate way. The TSC had confirmed that their recommendation to stop trial treatment did not advocate an abrupt stopping. Delivery of trial treatment in accordance with the protocol should cease; however, there was scope to meet with participants to explain the situation and to involve them in decisions about a structured and clinically appropriate end to trial treatment. What was clinically appropriate depended on the stage of PEPS therapy and the needs of individual participants. This was a clinical judgement made by the site principal investigator in consultation with clinicians involved in the trial, the participant's usual clinical team and the participant, as appropriate. To underpin what was clinically appropriate we referred to national guidelines on treatment of PD. There are two National Institute for Health and Care Excellence (NICE) guidelines on the treatment and management of PD: one for borderline PD[69] and one for antisocial PD.[70] Both emphasise the importance of endings and transitions. As a result, the study team identified a need to liaise with clinical teams to identify what support they could offer and how the investigators and trial therapists could assist.

Randomised, active in follow-up

Participants currently in follow-up were informed of the trial changes at their next scheduled follow-up appointment if this was due within 4 weeks. Participants were informed by letter before their next scheduled appointment, if this was necessary, to prevent an undue delay. Participants informed of the trial changes by letter were provided with contact details and invited to contact the study team should they have any queries or wish to discuss this further.

TABLE 2 Number of participants and trial stage at stoppage

Stage of the trial	Number of participants
Randomised to PEPS therapy and active in the treatment phase of the trial	19
Randomised, active in follow-up	210
Randomised, completed trial follow-up	54
Randomised, withdrawn before completion	23
Active in screening phase	38
Referred but not yet started study-specific procedures	42

Active in screening phase

Participants who had not yet been randomised but were active in the screening phase of the trial were also informed promptly. Participants in the middle of the IPDE were given the choice to stop or continue this. Participants who completed the IPDE were offered feedback on the results of the IPDE, in accordance with the existing procedure for doing this at the end of the trial (this is distinct from the provision of psychoeducation).

Referred but not yet started study-specific procedures

There was a number of people who had not completed any study-specific procedures at the time of stopping, although some had given consent to join the trial. The research team contacted these people to thank them for their interest in the study and to inform them that recruitment to the trial had stopped.

Randomised, completed trial follow-up or withdrawn before completion

In addition, participants who were in follow-up and those who had completed their involvement with the trial (completed final follow-up or withdrew before completion) were informed and supported, as appropriate. Arrangements were made to contact participants who had completed their involvement in the trial and those who withdrew before completion. These participants were informed by letter and provided with a written information sheet.

The following people were not directly informed of the trial changes by the research team:

- people who were referred to the PEPS trial, but were excluded before consent or declined to participate
- participants who consented and withdrew before randomisation
- participants who consented, but were not eligible for randomisation following screening.

Additional support for study staff

Study-wide guidance documents were prepared and maintained to ensure that everybody involved in informing participants and clinical teams, and responding to queries, including those responsible for staffing the trial helpline, had access to relevant written information to support them in this role.

Initially, local sites made arrangements for a limited local helpline to address queries and concerns from participants and clinical teams promptly. Arrangements for a trial-wide helpline were made, in the event that demand should exceed local capacity.

A press release was prepared and agreed by all parties so that a clear statement could be made in the event that the media picked up on the trial stoppage.

The national helpline and press statement were not used.

Documentation of the process

The process of informing participants and of stopping the delivery of PEPS therapy was clearly documented. Feedback given by participants was recorded to inform the ongoing process and ensure that lessons could be learned.

In addition to recording what information was provided and when, sites were also asked to document any questions, comments or concerns raised by participants and clinical teams, and to provide feedback to the trial co-ordinating centre on the issues raised.

Participants' views on trial stoppage

Feedback was reviewed to identify learning points and enable reflection on the processes used in the trial and during implementation of the trial changes.[71] Specific feedback was received and documented from 37 participants from all trial stages. A number of recurring views were identified. Among the most frequently reported were that an initial increase in distress was expected when engaging in psychological therapies; stopping PEPS therapy led to a concern over the lack of alternative treatment options; that there were alternative interpretations of the finding that more adverse events were recorded in the PEPS group; and that therapy delivered within the trial could have been improved (e.g. needed to be longer). There were no complaints about how the trial changes were implemented.

Urgent safety measure

A substantial amendment (substantial amendment 08 dated 26 November 2012) sought retrospective approval from the Research Ethics Committee for implementation of the trial changes as an urgent safety measure. The procedure for informing participants and clinical teams, and supporting documents were submitted for ethical review and approval in parallel to implementation. Approval was received in December 2012.

Chapter 4 Results

Recruitment

Study recruitment commenced in August 2010. Between August 2010 and November 2012, 739 people were referred to the trial for assessment of eligibility. Of these, 444 people were initially assessed as eligible and provided consent to join the trial. The reasons for non-participation were not willing to provide consent ($n = 113$), not eligible ($n = 49$), unable to contact following referral to the trial ($n = 106$) and not recruited because of the early stoppage ($n = 27$). The reasons participants were deemed not eligible for enrolment are given in *Table 3*.

One hundred and thirty-eight people provided consent to join the trial but withdrew or were excluded before randomisation. The reasons for withdrawal/exclusion before randomisation are presented in *Table 4*.

Of the participants who consented but were not randomised, 67% were female and the average age was 38 years.

TABLE 3 Reasons for non-enrolment

Not eligible for enrolment in the trial	Total number of participants
Responsible clinician did not consider person had PD	7
Primary diagnosis of psychosis	3
Insufficient spoken English	1
Insufficient literacy, comprehension or attention	3
Receiving other psychological treatment for PD	22
Other	13
Total not eligible for enrolment in the trial	49

TABLE 4 Withdrawal/exclusion before randomisation

Withdrawal/exclusion before randomisation	Total number of participants
PD diagnosis not confirmed by IPDE	32
Insufficient literacy identified at screening	1
Participant withdrew consent	34
Unable to contact	23
Early stopping of recruitment	48
Total withdrawn/excluded before randomisation	138

Participant flow

The CONSORT diagram in *Figure 2* summarises the assessments completed at each time point.

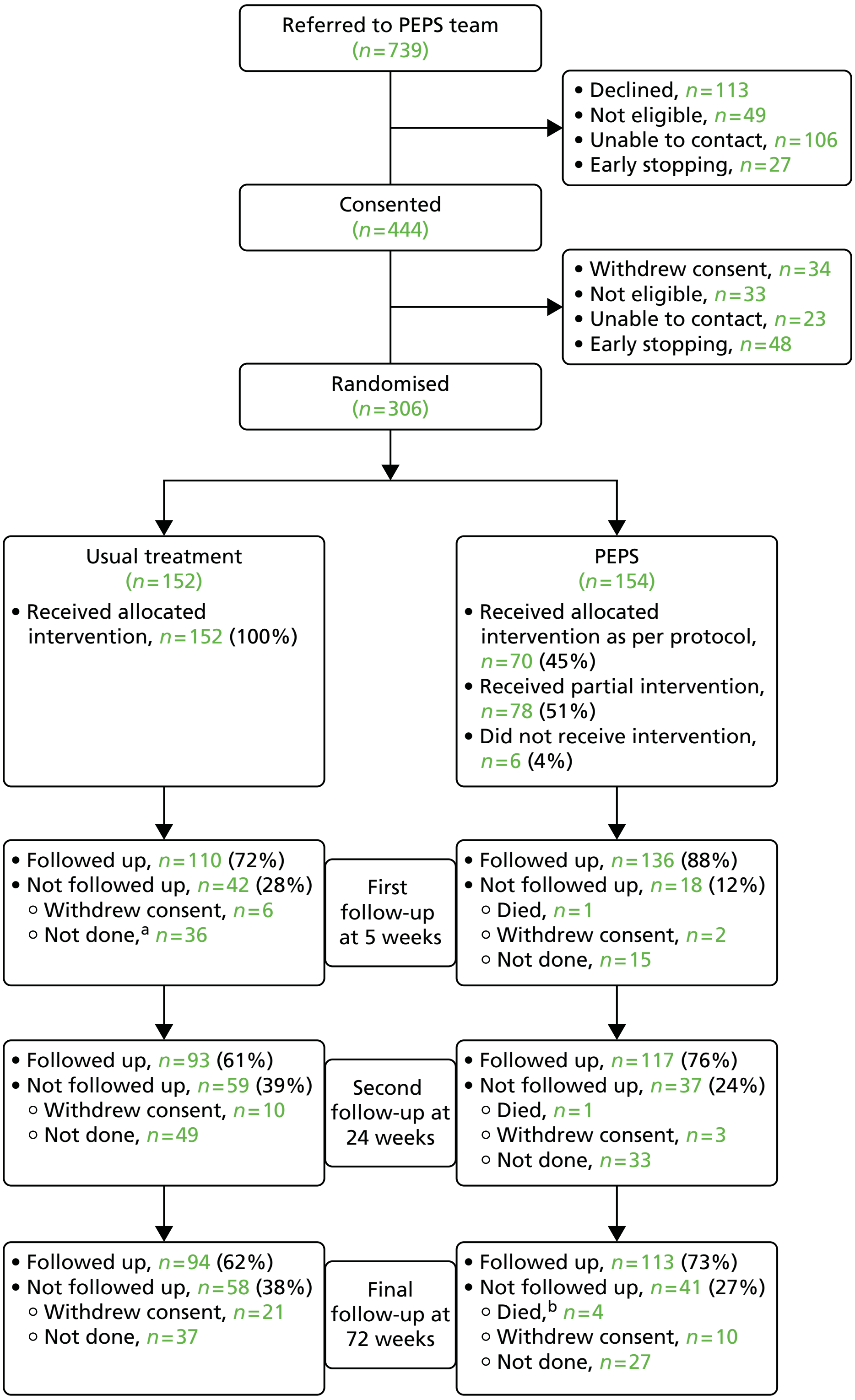

FIGURE 2 The CONSORT diagram. a, Not done is a combination of those participants who did respond to contact and those who chose not to attend the follow-up for that particular follow-up; b, two of the deaths occurred before and two after the trial was stopped.

Follow-up at 72 weeks after randomisation was completed for 62% and 73% in the usual treatment and PEPS arms, respectively. Follow-up rates for each time point by centre were as follows:

- first follow-up: central and north-west London 75%, South Wales 89%, North-East England 80%
- second follow-up: central and north-west London 61%, South Wales 73%, North-East England 74%
- final follow-up: central and north-west London 66%, South Wales 76%, North-East England 62%.

The median (first quartile, third quartile) time between consent and randomisation was 6.1 (2.3, 11.9) weeks, and was 2.0 (1.0, 3.9) weeks between randomisation and first therapy session (PEPS only).

The mean times between randomisation and the first follow-up was 8.0 (SD 5.1) weeks, second follow-up was 28.8 (SD 6.9) weeks and final follow-up was 80.3 (SD 10.1) weeks.

Baseline characteristics of randomised participants

Table 5 summarises the randomised groups at baseline. Of the 306 participants, 230 (75%) were women and the mean age was 38.2 years (SD 10.9 years). The only variable with a notable imbalance between the arms at baseline was type of PD, with a greater proportion in the PEPS arm defined as complex (60% compared with 49% in the usual-treatment arm).

Table 6 shows baseline demographic and outcome variables further categorised by follow-up at 72 weeks and trial arm. Participants who completed the trial were slightly older, more likely to be female and more likely to have never worked or be long-term unemployed. There was no strong suggestion that different types of participants were followed up in the two trial arms, although white participants were over-represented among completers in the usual-treatment arm, while those with PD classified as simple were over-represented among completers in the PEPS arm.

TABLE 5 Summary of participant characteristics at baseline by trial arm

	Treatment arm	
Variable	Usual treatment (*n* = 152)	PEPS (*n* = 154)
Age at randomisation (years), mean (SD)	37.8 (11.0)	38.6 (10.9)
Sex, *n* (%)		
Female	115 (76)	115 (75)
Male	37 (24)	39 (25)
Age left full-time education (years), mean (SD)	16.9 (3.3)	17.2 (3.7)
Highest educational attainment, *n* (%)		
None	29 (19)	24 (16)
GCSE	16 (10)	22 (14)
A-level	45 (30)	35 (23)
Vocational	10 (7)	10 (7)
Degree	32 (21)	36 (23)
Other	20 (13)	25 (16)
Missing	0	2 (1)

continued

TABLE 5 Summary of participant characteristics at baseline by trial arm (*continued*)

Variable	Treatment arm	
	Usual treatment ($n = 152$)	PEPS ($n = 154$)
Ethnicity, *n* (%)		
White	127 (83)	129 (84)
Mixed	9 (6)	6 (4)
Black Caribbean	6 (4)	5 (3)
Black African	0	2 (1)
Black other	2 (1)	0
Asian Indian	1 (2)	0
Asian other	1 (1)	0
Other	6 (4)	12 (8)
Socioeconomic status, *n* (%)		
Never worked and long-term unemployed	96 (63)	105 (68)
Routine and manual occupations	28 (18)	20 (13)
Intermediate occupations	13 (9)	9 (6)
Managerial and professional occupations	15 (10)	20 (13)
IPDE type (definitive), *n* (%)		
Paranoid	16 (11)	13 (8)
Schizoid	1 (1)	4 (3)
Schizotypal	0	0
Antisocial	31 (20)	23 (15)
Borderline	90 (59)	93 (60)
Histrionic	6 (4)	2 (1)
Narcissistic	3 (2)	1 (1)
Avoidant	56 (37)	57 (37)
Dependent	7 (5)	4 (3)
Obsessive–compulsive	20 (13)	14 (9)
PD not otherwise specified	10 (7)	14 (9)
PD,[a] *n* (%)		
Simple PD	77 (51)	61 (40)
Complex PD	75 (49)	93 (60)

A-level, advanced level; GCSE, General Certificate of Secondary Education.

[a] The simple/complex categories are based on Tyrer and Johnson,[72] in which simple refers to one or more PDs in one DSM cluster and complex refers to two or more PDs in two or more clusters.

TABLE 6 Summary of participant characteristics at baseline by trial arm and trial completion status

Variable	Non-completer		Completer[a]	
	Usual treatment ($n = 58$)	PEPS ($n = 41$)	Usual treatment ($n = 94$)	PEPS ($n = 113$)
Age at randomisation (years), mean (SD)	36.2 (10.9)	37.0 (11.3)	38.9 (11.0)	39.1 (10.7)
Sex, *n* (%)				
Female	38 (65)	27 (66)	77 (82)	88 (78)
Male	20 (35)	14 (34)	17 (18)	25 (22)
Age left full time education (years), mean (SD)	17.1 (3.8)	16.4 (2.8)	16.8 (2.9)	17.5 (3.9)
Highest educational attainment, *n* (%)				
None	11 (19)	6 (15)	18 (19)	18 (16)
GCSE	7 (12)	4 (10)	9 (10)	18 (16)
A-level	18 (31)	12 (29)	27 (29)	23 (20)
Vocational	5 (9)	2 (5)	5 (5)	8 (7)
Degree	12 (20)	8 (19)	20 (21)	28 (25)
Other	5 (9)	7 (17)	15 (16)	18 (16)
Ethnicity, *n* (%)				
White	44 (76)	34 (83)	83 (88)	95 (84)
Mixed	6 (11)	4 (10)	3 (3)	2 (2)
Black Caribbean	4 (7)	1 (2)	2 (2)	4 (3)
Black African	0	0	0	2 (2)
Black other	2 (3)	0	0	0
Asian Indian	0	0	1 (1)	0
Asian other	0	0	1 (1)	0
Other	2 (3)	2 (5)	4 (4)	10 (9)
Socioeconomic status, *n* (%)				
Never worked and long-term unemployed	32 (55)	27 (66)	64 (68)	78 (69)
Routine and manual occupations	13 (23)	4 (10)	15 (16)	16 (14)
Intermediate occupations	7 (12)	4 (10)	6 (6)	5 (4)
Managerial and professional occupations	6 (10)	6 (14)	9 (10)	14 (13)
PD, *n* (%)				
Simple PD	28 (48)	13 (32)	49 (52)	48 (42)
Complex PD	30 (52)	28 (68)	45 (48)	65 (58)
Baseline SFQ score				
Mean (SD)	14.9 (4.9)	14.7 (4.1)	14.0 (4.2)	15.1 (4.0)
Median (first quartile, third quartile)	15 (12, 19)	14 (11, 18)	14 (11, 17)	15 (13, 18)

continued

TABLE 6 Summary of participant characteristics at baseline by trial arm and trial completion status (*continued*)

	Non-completer		Completer[a]	
Variable	Usual treatment (*n* = 58)	PEPS (*n* = 41)	Usual treatment (*n* = 94)	PEPS (*n* = 113)
Baseline HADS score				
Mean (SD)	27.1 (8.1)	28.6 (5.7)	27.7 (7.3)	27.0 (7.7)
Median (first quartile, third quartile)	28.5 (21, 33)	28 (24, 33)	28 (23, 34)	28 (23, 32)
Baseline EQ-5D health status score				
Mean (SD)	43.2 (23.9)	44.3 (20.4)	40.4 (23.5)	44.6 (23.0)
Median (first quartile, third quartile)	45 (25, 60)	45 (30, 59)	39.5 (20, 60)	40 (30, 60)
Baseline SPSI-R score				
Mean (SD)	6.8 (3.1)	6.2 (3.1)	6.9 (3.4)	6.5 (3.0)
Median (first quartile, third quartile)	6.2 (4.6, 8.6)	6 (4.2, 8.2)	7.2 (4.3, 9.1)	6.6 (4.4, 8.6)
Baseline three-problem average score				
Mean (SD)	8.7 (1.1)	9.0 (1.0)	8.7 (1.1)	8.6 (1.1)
Median (first quartile, third quartile)	9 (8, 9.7)	9 (8.7, 10)	9 (8, 9.7)	8.7 (8, 9.3)

A-level, advanced level; GCSE, General Certificate of Secondary Education.

[a] Completer is defined as someone who attended final follow-up at 72 weeks after randomisation and had primary outcome available.

Duration of follow-up

Follow-up was greater in the PEPS arm at every time point (see *Figure 2*). Overall, 68% of participants were followed up at the 72-week primary end point. In addition to a greater proportion of completers, duration of engagement with the trial among non-completers was greater in the PEPS arm (*Table 7*). This resulted in a total of 178 and 203 person-years of follow-up in the usual-treatment and PEPS arms, respectively.

Uptake of psychoeducation with problem-solving therapy

Table 8 summarises how much PEPS intervention was offered to, and attended by, trial participants allocated to receive it. Median attendance at the individual psychoeducation sessions was approximately 90%, dropping to around 50% for the problem-solving therapy group sessions. Seventy (45%) participants completed the PEPS intervention as per protocol. The size of PEPS problem-solving therapy groups formed at randomisation and followed up at 72 weeks is reported in *Table 9*, along with estimated intracluster correlation coefficients for primary and secondary outcomes.

TABLE 7 Summary of participation duration by trial arm and trial completion status

	Treatment arm			
	Usual treatment		PEPS	
Time active in PEPS trial	Non-completer (*n* = 58)	Completer (*n* = 94)	Non-completer (*n* = 41)	Completer (*n* = 113)
Mean number of weeks (SD)	30.0 (25.7)	80.2 (9.8)	36.7 (23.4)	80.3 (10.4)

TABLE 8 Uptake of PEPS therapy

Session types	Number offered	Number attended	Proportion offered/attended
Psychoeducation sessions			
Mean (SD)	3.4 (0.7)	3.0 (1.0)	0.9 (0.3)
Median (first quartile, third quartile)	3 (3, 4)	3 (3, 4)	1 (0.8, 1)
Problem-solving group sessions			
Mean (SD)	11.8 (0.8)	5.2 (4.0)	0.5 (0.3)
Median (first quartile, third quartile)	12 (12, 12)	6 (2, 9)	0.6 (0.3, 0.8)
Number of participants offered problem-solving sessions, *n* (%)	133 (100)		
Non-attenders, *n* (%)	20 (15)		
Attended 1–5 sessions, *n* (%)	43 (32)		
High attenders (minimum six sessions), *n* (%)	70 (53)		
Individual support sessions			
Mean (SD)	4.2 (1.9)	2.3 (1.8)	0.5 (0.4)
Median (first quartile, third quartile)	5 (3, 6)	2 (1, 4)	0.5 (0.2, 0.8)

TABLE 9 Intracluster correlation coefficients for outcomes at 72 weeks in PEPS arm according to therapy group

Outcome at 72 weeks' follow-up	Estimated intracluster correlation coefficient (95% CI)
SFQ	0.07 (0 to 0.24)
HADS	0.11 (0 to 0.29)
SPSI-R	0.01 (0 to 0.17)
Three main problems	0.01 (0 to 0.15)
Size of cluster in problem-solving group	
As formed on randomisation	
Number of groups	18
Median (25th quartile, 75th quartile)	6.5 (6, 8)
Minimum, maximum	5, 12
Followed up at 72 weeks	
Number of groups	18
Median (25th quartile, 75th quartile)	5 (5, 6)
Minimum, maximum	1, 10

Primary outcome

Primary analysis

Based on observed data, the mean SFQ score at 24 weeks was 13.5 points (SD 4.5 points), and for usual-care and the PEPS arm was 13.8 points (SD 4.5 points); the corresponding mean scores at 72 weeks were 13.9 points (SD 5.3 points) and 13.5 points (SD 4.8 points), respectively. However, the primary analysis was conducted based on multiple imputation of missing data.

There was no evidence of any clinically important difference between the arms based on the primary analysis (*Table 10*). Across the whole sample, the mean difference in SFQ score between baseline and the 72-week follow-up was –0.94 points (95% CI –1.54 to –0.32 points).

Sensitivity analyses

There was no strong evidence of a between-group difference in the primary outcome from any of the sensitivity analyses (*Table 11*). As expected, the estimated treatment effect of PEPS among compliers was greater than that from the primary analysis, as were analyses based only on participants with observed data at 72 weeks. The lower confidence limits for these analyses exceed the prespecified minimum clinically important difference in SFQ score of two points. Although the primary analysis excludes any effect, a clinically important benefit of treatment cannot, therefore, be completely ruled out, particularly among participants who undertake all of the psychoeducation treatment phase and at least six group problem-solving sessions.

TABLE 10 Primary analysis: SFQ score (points) at 72 weeks' follow-up

	Treatment arm				
SFQ score	Usual treatment ($n = 152$)	PEPS ($n = 154$)	Adjusted[a] difference in means[b]	95% CI	*p*-value
Baseline, mean[c] (SE)	14.3 (0.4)	15.0 (0.6)	–	–	–
24 weeks, mean (SE)	13.9 (0.4)	13.7 (0.4)	–	–	–
72 weeks, mean (SE)	13.8 (0.5)	13.5 (0.4)	–0.73	–1.83 to 0.38	0.19

SE, standard error.

a Adjusted by baseline SFQ score, study centre and sex.

b Estimated difference in means, 95% CIs and *p*-values based on multiple imputation of missing data.

c Based on imputed data.

TABLE 11 Sensitivity analysis of primary outcome

Analysis type	Adjusted difference in means	95% CI	*p*-value
(1) Primary analysis (MI)	–0.73	–1.83 to 0.38	0.19
(2) As (1) with adjustment for baseline PD type	–0.72	–1.78 to 0.34	0.18
(3) As (1), CACE estimate	–1.60	–3.96 to 0.76	0.18
(4) Observed outcome data	–1.07	–2.24 to 0.09	0.07
(5) As (4), CACE estimate	–2.15	–4.39 to 0.09	0.06

MI, multiple imputation.

Blinding

Unblinding of the researcher was reported for 48 (23%) participants who provided SFQ scores at the 72-week follow-up (*Table 12*). Mean scores were similar among participants in both arms whether or not unblinding was reported. This is unsurprising given that the SFQ is self-completed by participants.

Subgroup analyses

There was no evidence that the effect of PEPS compared with usual treatment differed according to study centre, category of PD at baseline or borderline PD diagnosis at baseline (*Table 13*).

TABLE 12 Summary of primary outcome by unblinding status at final follow-up at 72 weeks

	Treatment arm	
SFQ at 72 weeks by unblinding of researcher at final follow-up	Usual treatment (*n* = 94)	PEPS (*n* = 113)
Unblinded		
Mean (SD)	13.9 (4.2)	14.2 (4.4)
n	12	36
Blinded		
Mean (SD)	13.9 (5.4)	13.1 (4.9)
n	82	77

TABLE 13 Subgroup analysis of SFQ score (points) at 72 weeks by site and PD category

	Treatment arm				
SFQ score	Usual treatment	PEPS	Interaction coefficient[a]	95% CI	*p*-value
72 weeks by site					
Central and north-west London, mean[b] (SE)	13.2 (0.8)	13.0 (0.7)			
South Wales, mean (SE)	13.4 (0.9)	13.7 (0.6)	–0.37	–3.19 to 2.45	0.30
North-East England, mean (SE)	14.8 (0.7)	13.9 (0.7)	–1.34	–3.82 to 1.14	
72 weeks by PD category					
Simple, mean (SE)	12.5 (0.6)	13.1 (0.7)	0.03	–0.63 to 0.69	0.93
Complex, mean (SE)	15.1 (0.7)	13.8 (0.5)			
72 weeks by borderline diagnosis at baseline					
Not borderline, mean (SE)	14.6 (0.5)	13.1 (0.5)	–	–	–
Borderline, mean (SE)	12.5 (0.8)	14.1 (0.7)	–0.98	–3.24 to 1.27	0.39

SE, standard error.

a Estimated based on multiple imputation, adjusted for baseline SFQ score, study centre and sex.

b Based on imputed data.

Secondary outcomes

Hospital Anxiety and Depression Scale

Table 14 summarises the HADS total score at all outcome assessment visits, and the estimated between-group difference at 72 weeks. There was no evidence of any difference between PEPS and usual treatment, although the 95% CIs were wide and includes a potentially clinically important effect (i.e. 1.5 points) in either direction.[73]

Three main problems

Table 15 summarises the three main problems mean scores at each time point and the estimated between-group difference at 72 weeks' follow-up. *Table 16* shows reported change at each follow-up time compared with previous assessment, and ordinal logistic regression of rated change at 72 weeks. Mean scores were reduced in both arms over time and overall, 108 (55%) participants reported some improvement at 72 weeks but there was no evidence of any difference between PEPS and usual treatment in either measure.

TABLE 14 Hospital Anxiety and Depression Scale

	Treatment arm				
HADS score	Usual treatment	PEPS	Adjusted[a] difference in means	95% CI	*p*-value
Baseline, mean (SD)	27.5 (7.5)	27.4 (7.2)	–	–	–
5 weeks, mean (SD)	25.4 (9.8)	24.5 (7.9)	–	–	–
24 weeks, mean (SD)	25.1 (8.6)	23.7 (8.7)	–	–	–
72 weeks, mean (SD)	22.3 (11.8)	21.0 (10.9)	–1.2	–4.2 to 1.8	0.44

a Adjusted by baseline HADS score, study centre and sex.

TABLE 15 Three main problems

	Treatment arm				
Three main problems score	Usual treatment	PEPS	Adjusted[a] difference in means	95% CI	*p*-value
Baseline, mean (SD)	8.7 (1.1)	8.7 (1.1)	–	–	–
5 weeks, mean (SD)	7.7 (2.3)	7.8 (1.7)	–	–	–
24 weeks, mean (SD)	7.5 (2.1)	7.1 (2.1)	–	–	–
72 weeks, mean (SD)	6.6 (2.8)	6.3 (2.8)	–0.3	–1.0 to 0.5	0.48

a Adjusted by baseline three main problems score, study centre and sex.

TABLE 16 Three main problems rating change

Three main problems score	Treatment arm		Adjusted[a] odds ratio	95% CI	*p*-value
	Usual treatment	PEPS			
5 weeks, *n* (%)	*N* = 110	*N* = 136			
Very much improved	3 (3)	1 (1)			
Much improved	11 (10)	22 (16)			
Minimal improvement	21 (19)	59(43)			
No change	29 (26)	35 (26)			
Minimally worse	16 (14)	4 (3)			
Much worse	14 (13)	2 (1)			
Very much worse	6 (5)	3 (2)			
24 weeks, *n* (%)	*N* = 93	*N* = 116			
Very much improved	5 (5)	9 (8)			
Much improved	10 (11)	26 (22)			
Minimal improvement	26 (28)	38 (33)			
No change	24 (26)	23 (20)			
Minimally worse	8 (9)	7 (6)			
Much worse	12 (13)	6 (5)			
Very much worse	6 (6)	3 (2)			
72 weeks, *n* (%)	*N* = 90	*N* = 108			
Very much improved	8 (9)	13 (12)			
Much improved	17 (19)	27 (25)			
Minimal improvement	19 (21)	24 (22)			
No change	19 (21)	16 (15)	0.65	0.38 to 1.12	0.12
Minimally worse	3 (3)	3 (3)			
Much worse	10 (11)	11 (10)			
Very much worse	7 (8)	4 (4)			

[a] Adjusted by baseline three main problems score, study centre and sex.

Global Assessment of Functioning

Global Assessment of Functioning was included as a means of collecting data on the referring clinicians' rating of change during the trial. However, during the course of the trial it became apparent that GAF completion rates were poor. The reasons for this were explored with site staff and identified as:

- participants being discharged from secondary care services and therefore there not being a suitable clinician involved in their care to provide this rating
- participants in services may not have a regular care team/care co-ordinator
- even for participants for whom a care co-ordinator/regular clinical team is available, GAF scores are difficult to obtain. One reason for the low returns is resource issues within mental health services generally (e.g. budget cuts and job losses), which make any non-essential activities difficult to complete. Another may be lack of familiarity with the rating tool.

Continued efforts were made to obtain a rating from the original referrer or other member of the participant's clinical team. The TMG agreed in advance that a minimum of 80% completion rate at baseline and 50% completion at follow-up would be required to enable a valid analysis of GAF data to be made. These rates were not achieved.

Mechanism of change

Working Alliance Inventory – Short Revised

The WAI examines the development of treatment alliance and was used to assess the effectiveness of the psychoeducation component in developing treatment alliance. The WAI is intended to be completed by clients and therapists. In the trial, the therapist form was completed by the PEPS therapist for participants allocated to PEPS therapy and a member of the participants' usual-care team for participants receiving treatment as usual only. Participants were asked to complete the WAI client form in relation to the working alliance with the relevant clinician. However, for the same practical reasons as listed above for the GAF, completion rates were poor and did not reach the prespecified level required for a valid analysis.

Social Problem-Solving Inventory – Revised: short version

Table 17 summarises the SPSI-R total score at all outcome assessment visits and the estimated between-group difference in total score based on a repeated measures analysis that includes data from both 24 and 72 weeks' follow-up. There was no evidence of any difference between PEPS and usual treatment. Analyses for each of the five SPSI-R subscales follow the same approach and found no evidence of any treatment effect (data not shown).

Service use

Table 18 summarises participants' use of health services during the trial. Data were available for 140 (91%) and 126 (83%) participants in the PEPS and usual-treatment arms, respectively. There were 2041 contacts with health services from 135 individuals in the PEPS arm, compared with 2064 from 116 individuals allocated to usual treatment. When converted to annual rates, this equated to a mean of approximately 10 contacts per person per year. There was no evidence of any differences between groups in total health-service use, use of emergency or crisis services, or whether classified as scheduled or unscheduled.

When unclassified health service contacts were reassigned as either scheduled or unscheduled, there was a higher proportion of scheduled contacts in the PEPS arm than in the usual treatment arm (*Table 19*). However, 95% CIs were wide and included the null, indicating no strong evidence that participants in the two groups differed in scheduled use of health services.

TABLE 17 Social Problem-Solving Inventory – Revised: short version

	Treatment arm		Repeated measures		
SPSI-R score	**Usual treatment**	**PEPS**	**Adjusted[a] difference in means**	**95% CI**	***p*-value**
Baseline, mean (SD)	6.9 (3.3)	6.4 (3.0)	–	–	–
24 weeks, mean (SD)	8.0 (3.6)	7.7 (3.5)	–	–	–
72 weeks, mean (SD)	8.2 (4.0)	8.0 (4.0)	0.14	–0.53 to 0.82	0.68

a Adjusted by baseline SPSI-R score, study centre, sex and visit.

TABLE 18 Service use

Service use	Treatment arm		Adjusted[a] IRR	95% CI	*p*-value
	Usual treatment (*N* = 126)	PEPS (*N* = 140)			
Overall service use, *n* contacts (*n* individuals)					
Scheduled	921 (87)	970 (106)			
Unscheduled	604 (80)	547 (94)			
Unclassified	539 (93)	524 (118)			
Total	2064 (116)	2041 (135)			
GP contacts, *n* contacts (*n* individuals)	1649 (80)	1521 (98)			
Emergency department, *n* contacts (*n* individuals)	151 (47)	142 (55)			
Hospital admissions, *n* contacts (*n* individuals)	48 (26)	83 (34)			
Hospital outpatient appointment, *n* contacts (*n* individuals)	8 (5)	19 (11)			
Mental health service, *n* contacts (*n* individuals)					
Crisis resolution service	30 (20)	55 (28)			
A&E liaison service	6 (6)	12 (11)			
Other mental health service	172 (106)	209 (120)			
Overall service use for emergency department, hospital admission, crisis resolution and A&E liaison service, *n* contacts (*n* individuals)					
Scheduled	34 (27)	49 (29)			
Unscheduled	195 (54)	230 (65)			
Unclassified	6 (4)	13 (10)			
Total	235 (85)	292 (104)			
Overall service use, *n* contacts (*n* individuals)					
1–9	52 (45)	51 (38)			
10–19	32 (27)	50 (37)			
20–29	10 (9)	20 (15)			
30–39	9 (8)	7 (5)			
> 40	13 (11)	7 (5)			
Overall service use (annual rate) during 72 weeks after randomisation, mean (SD)	10.6 (11.0)	9.9 (14.3)	0.97	0.77 to 1.22	0.81
Overall service use for emergency department, hospital admission, crisis resolution and A&E liaison service (annual rate), mean (SD)	2.5 (3.1)	2.4 (3.2)	0.97	0.66 to 1.41	0.87
Scheduled service use (annual rate), mean (SD)	6.5 (7.4)	6.0 (5.5)	0.91	0.69 to 1.21	0.54
Unscheduled service use (annual rate), mean (SD)	4.4 (6.2)	3.7 (4.3)	0.87	0.60 to 1.26	0.47

A&E, accident and emergency; IRR, incidence rate ratio.

[a] Adjusted by study centre and sex.

TABLE 19 Sensitivity analyses of service use

Assignment of service use type	Treatment arm Usual treatment	 PEPS	Adjusted[a] risk ratio	95% CI	*p*-value
Overall service use if unclassified assigned as scheduled, *n* health service contacts (%) [*n* individuals]					
Scheduled	1460 (71) [117]	1494 (73) [134]			
Unscheduled	604 (29) [80]	547 (27) [94]	0.99	0.93 to 1.06	0.77
Overall service use if unclassified assigned as unscheduled, *n* health service contacts (%) [*n* individuals]					
Scheduled	921 (45) [87]	970 (47) [106]			
Unscheduled	1143 (55) [108]	1071 (53) [125]	1.05	0.92 to 1.19	0.46

a Adjusted by study centre, sex, service type and allowing for multiple events per individual.

Adverse events

Twenty-eight individuals reported a total of 35 adverse events following referral to the PEPS trial and before randomisation. Of these, 14 participants were allocated to each arm, with 14 adverse events occurring in participants allocated to PEPS and 21 in participants allocated to usual treatment. Following randomisation, a total of 76 adverse events were reported by 39 individuals allocated to usual treatment and 117 events were reported by 60 individuals allocated to PEPS (*Table 20*).

Four deaths were reported during the study: two were due to natural causes and two were suicides. All four participants were allocated to the PEPS arm. The nature and circumstances of these deaths did not seem related to the therapy.

During the trial, one serious adverse event was reported that had a suspected relationship to the trial and was not listed in the protocol as an expected occurrence. This was a non-fatal overdose resulting in an overnight hospital admission, which was precipitated by a number of stressors including anxiety about group work in relation to forthcoming PEPS therapy. This event was reported to the Research Ethics Committee, DMEC and TSC. A briefing was issued to all site staff reminding them of the importance of identifying anxiety in relation to group work and supporting participants with this, as appropriate.

Table 20 provides further details of hospitalisations, self-harm, and other mental health-related adverse events.

Table 21 shows the results of between-group analyses of reported adverse events. There were approximately 13% more participants in the PEPS arm who reported at least one adverse event, equivalent to an approximate 50% relative increase. However, when the difference in total follow-up between the arms is accounted for, this figure of 50% was attenuated to approximately 30%, with 95% CIs that span the null. Results of the analysis of total number of adverse events were similar, with an approximately 20% greater reported event rate in the PEPS arm, with a 95% CI that includes the null.

TABLE 20 Adverse event reports summary post randomisation

	Treatment arm	
Adverse event report categories	Usual treatment ($N = 152$)	PEPS ($N = 154$)
Participants with any adverse event, *n* (%)	39 (26)	60 (39)
All adverse event reports,[a] *n* events (*n* individuals)		
Hospitalisation	62 (33)	100 (51)
Death[b]	0	4 (4)
Other	14 (12)	13 (12)
Total	76 (39)	117 (60)
Participants with multiple hospitalisations, *n* (%)		
1	19 (58)	29 (56)
2	6 (18)	13 (26)
3	3 (9)	3 (6)
4	4 (12)	2 (4)
5	0	1 (2)
6	1 (3)	0
7	0	2 (4)
9	0	1 (2)
Mental health-related adverse event reports, *n* events (*n* individuals)		
Planned/respite hospital admission	2 (2)	1 (1)
Self-harm including drug or alcohol overdose	27 (16)	42 (24)
Suicide or attempted suicide	4 (3)	7 (7)
Deterioration in mental health	3 (2)	9 (7)
Suicidal ideation	6 (6)	8 (6)
Other	3 (3)	4 (4)
Total	45 (26)	71 (37)
Participants with multiple self-harm reports, *n* (%)		
1	11 (69)	16 (67)
2	2 (12)	3 (12)
3	1 (6)	1 (4)
4	1 (6)	3 (12)
5	1 (6)	1 (4)

a Some participants reported more than one type of adverse event.
b Two of the deaths were from natural causes and two were suicide.

TABLE 21 Between-group comparisons of number of individuals with at least one adverse event and the total number of reported adverse events

	RD, % (95% CI)		RR (95% CI)		IRR (95% CI)	
Adverse events	Crude	Adjusted[a]	Crude	Adjusted[a]	Crude	Adjusted[a]
Based on number of individuals (usual treatment, *n* = 39; PEPS, *n* = 60)	13.3 (2.9 to 23.7)	13.0 (2.9 to 23.1)	1.52 (1.09 to 2.12)	1.52 (1.09 to 2.13)	1.35 (0.89 to 2.07)	1.37 (0.91 to 2.05)
Based on number of adverse events (usual treatment, *n* = 76; PEPS, *n* = 117)	–	–	–	–	1.35 (1.00 to 1.83)	1.24 (0.93 to 1.64)

IRR, incidence risk ratio; RD, risk difference; RR, relative risk.
a Adjusted by site and sex.

Notes

The total amount of follow-up was unequal between trial arms: usual care = 9279 and PEPS = 10,579 person-weeks (178 and 203 person-years, respectively).

IRR analysis for number of adverse events allows for ≥ 1 adverse event per individual.

Chapter 5 Health economics analysis

Objectives

Any new intervention requires the use of scarce health-care resources and so conducting economic evaluations to assess cost-effectiveness is crucial. Economic evaluations of interventions for PD are few in number, although cost-effectiveness analyses of specific therapies, psychotherapy more generally and whole programmes have been conducted.[74–76] The objectives of the economic evaluation in this study were:

1. to measure and describe the 6-month health-care and societal costs (with a detailed breakdown of care, benefits, lost employment, etc.) of participants in the PEPS trial at randomisation, and their association with clinical and demographic characteristics
2. to measure, describe and compare patterns of service utilisation by participants at second follow-up (post treatment, 24–26 weeks), third follow-up (week 40) and fourth follow-up (week 72) across the two groups (PEPS and usual treatment)
3. to compare care costs (health care and societal) at second, third and fourth follow-up
4. to assess the cumulative cost–utility of PEPs compared with usual treatment at second, third and fourth follow-up.

Methods

Analyses were detailed in an economics analysis plan, which was finalised prior to completion of data collection and database lock.

Use of health services, employment effects and welfare benefits

Comprehensive data were collected on all health, social care and other relevant services used by individual study members using a tailored version of the CSRI.[60] The CSRI was used at baseline and at second, third and fourth follow-ups, with information provided via participant self-report. The baseline interview covered resource use for the previous 6 months, while the subsequent interviews covered resource use since the last interview. The CSRI included the following broad categories of information:

- contacts with health- and social-care professionals
- use of day care services
- use of inpatient care
- contacts with criminal justice/legal services
- medication
- education and time absent from studies
- employment and time off work
- welfare benefits.

Cost calculations

The costs of each resource item were calculated using the best available unit cost estimates (see *Appendix 12*) and reported in 2012/13 prices. 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 (see *Appendix 13*). Costs were calculated using data on the number of therapy sessions received by each participant. Lost employment costs for those in employment will be calculated by combining time off work with daily earnings. The value of benefits received was calculated but these are transfer payments and so were not included with the service or lost employment costs.

Quality-adjusted life-years

The EQ-5D was used to measure health-related quality of life. This consists of five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). Each of these received a score of 1, 2 or 3 corresponding to 'no problems', 'moderate problems' and 'major problems'. Utility scores were attached to each health state based on these scores (a table of utility values has been produced by the Centre for Health Economics, University of York[77]). These utility scores were 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.

Analyses

Cost data are frequently skewed and this can lead to incorrect *p*-values and CIs when making comparisons between groups. To address this, we used a bootstrapped regression model, which makes no assumptions about the data distribution. 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. To construct these, four regression models were run using 10,000 bootstrapped resamples. The models used service costs and QALYs at second and final follow-up as the dependent variables. The independent variables were the group identifier and the baseline measure of cost or utility score. The 10,000 coefficients for the group identifier variable are 10,000 estimates of the cost/outcome differences and these were plotted against each other. The planes show the probability of the PEPS group having (i) lower costs and better outcomes, (ii) higher costs and better outcomes, (iii) lower costs and worse outcomes, and (iv) higher costs and worse outcomes than supportive care alone. 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. There is a theoretical, but unknown, value (represented by the term λ) that society would place on a 1-unit QALY gain as measured by the EQ-5D. Net benefit can be defined as:

$$\mathrm{NB} = (\lambda \times \mathrm{E}) - \mathrm{SC}, \tag{1}$$

where NB is net benefit, E is effectiveness (i.e. QALY gains compared with baseline) and SC is service costs. For example, if for a particular patient the QALY gained during the follow-up period is 0.05 and if their service cost is £400, then we can calculate their net benefit if we know λ. If $\lambda = £0$ then the net benefit is –£400, whereas if $\lambda = £10,000$ then the net benefit is £100. Net benefits for all patients were estimated by assuming different values for λ ranging between £0 and £50,000 in £5000 increments. A regression model was then used to determine the mean difference in net benefit between usual-treatment and PEPS groups for every value of λ. For each model, 10,000 regression coefficients for the group identifier variable were generated using bootstrapping and the proportion of these that were greater than zero indicated the probability that PEPS was cost-effective (i.e. it resulted in a mean incremental net benefit greater than zero). These probabilities were subsequently used to generate the cost-effectiveness acceptability curves.

Results

Service-use data are summarised in *Table 22*. In the 6 months before baseline assessment, over 90% of patients had GP contacts and these occurred approximately every month. Over half also had contacts with psychiatrists and around one-quarter of patients in both groups had inpatient admissions. Most other services were used by relatively few patients. Overall, there were few noticeable differences between the two groups at baseline, although the group randomised to PEPS did have more contacts with home treatment/crisis team members.

TABLE 22 Number (%) of patients using health-care services and mean (SD) number of contacts before baseline assessment, second, third and final follow-up

	Time point															
	6 months to baseline				Baseline to second follow-up				Second to third follow-up				Third to final follow-up			
	Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS	
Service	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]
GP	111 (94)	7.6 (10.4)	122 (90)	6.4 (5.5)	85 (72)	5.9 (5.3)	102 (76)	6.2 (7.7)	86 (73)	5.3 (5.8)	80 (59)	5.6 (6.2)	80 (68)	7.7 (8.1)	91 (67)	8.1 (11.6)
Psychiatrist	79 (67)	3.1 (5.5)	100 (74)	2.7 (3.4)	53 (45)	3.1 (2.8)	55 (41)	2.4 (1.9)	49 (42)	2.4 (2.4)	48 (36)	2.3 (1.5)	49 (42)	4.2 (5.1)	62 (46)	2.7 (3.1)
Other doctor	29 (25)	3.7 (5.1)	35 (26)	3.3 (4.4)	25 (21)	3.6 (8.1)	33 (24)	3.3 (3.7)	16 (14)	2.1 (1.8)	18 (13)	4.1 (4.8)	19 (16)	3.6 (2.8)	27 (20)	4.7 (10.4)
Psychologist	22 (19)	4.0 (5.5)	22 (16)	5.6 (5.6)	15 (13)	8.1 (8.4)	15 (11)	5.3 (5.8)	14 (12)	8.9 (7.3)	8 (6)	8.1 (6.0)	14 (12)	10.4 (11.0)	16 (12)	7.7 (9.1)
Drug and alcohol advisor	12 (10)	5.9 (6.3)	17 (13)	9.4 (9.8)	4 (3)	6.3 (4.6)	11 (8)	20.7 (33.4)	7 (6)	19.9 (19.5)	12 (9)	13.3 (27.9)	6 (5)	16.8 (12.4)	5 (4)	6.6 (6.6)
Other counsellor/therapist	21 (18)	10.1 (8.5)	27 (20)	10.0 (9.9)	13 (11)	9.5 (10.2)	19 (14)	15.3 (26.7)	14 (12)	8.2 (7.0)	17 (13)	9.5 (8.5)	10 (8)	19.6 (17.1)	22 (16)	14.4 (14.2)
Home treatment/crisis team member	34 (29)	7.7 (9.5)	56 (41)	5.3 (6.7)	26 (22)	6.3 (10.5)	32 (24)	7.1 (10.4)	17 (14)	8.0 (19.9)	17 (13)	6.7 (7.2)	18 (15)	5.7 (5.1)	23 (17)	5.3 (4.9)
Assertive outreach team member	2 (2)	25.5 (2.1)	1 (1)	8.0 (–)	1 (1)	10.0 (–)	–	–	1 (1)	10.0 (–)	1 (1)	26.0 (–)	–	–	1 (1)	3.0 (–)
Early intervention team member	3 (3)	7.7 (3.8)	2 (1)	1.0 (0.0)	–	–	–	–	2 (2)	7.0 (4.2)	–	–	–	–	–	–
Social worker	37 (31)	6.4 (8.1)	41 (30)	8.2 (9.8)	20 (17)	14.3 (18.1)	33 (24)	4.9 (4.8)	21 (18)	6.8 (5.8)	26 (19)	6.9 (7.6)	19 (16)	6.7 (5.9)	22 (16)	9.0 (8.7)
Mental health nurse	43 (36)	9.8 (8.2)	53 (39)	10.8 (11.7)	32 (27)	9.9 (8.1)	38 (28)	9.8 (9.3)	27 (23)	10.4 (12.1)	29 (21)	5.4 (4.4)	28 (24)	9.3 (7.3)	30 (22)	14.6 (19.7)
Occupational therapist	20 (17)	7.3 (9.5)	14 (10)	6.1 (6.8)	9 (8)	10.2 (20.7)	9 (7)	5.3 (7.1)	4 (3)	2.8 (1.3)	7 (5)	2.7 (1.3)	4 (3)	11.0 (16.0)	5 (4)	3.0 (1.2)
Accident and emergency service	46 (39)	5.0 (17.5)	56 (41)	1.9 (1.4)	27 (23)	2.2 (2.6)	34 (25)	2.8 (5.9)	22 (19)	2.0 (1.1)	29 (21)	1.8 (1.8)	33 (28)	2.3 (1.8)	28 (21)	2.6 (3.9)
Drug/alcohol service	2 (2)	11.0 (12.7)	7 (5)	25.9 (43.0)	–	–	4 (3)	15.5 (18.1)	2 (2)	42.0 (25.5)	4 (3)	9.5 (4.9)	1 (1)	60.0 (–)	2 (1)	4.0 (2.8)
Community mental health centre	9 (8)	13.4 (11.3)	9 (7)	23.7 (46.8)	4 (3)	15.5 (13.1)	6 (4)	7.0 (7.5)	3 (3)	26.3 (21.5)	3 (2)	6.0 (2.0)	6 (5)	23.7 (20.9)	2 (1)	13.5 (17.7)
Day care centre/day hospital	5 (4)	17.2 (19.2)	6 (4)	18.0 (28.3)	9 (8)	21.4 (26.9)	5 (4)	10.6 (10.7)	7 (6)	16.0 (16.4)	4 (3)	46.0 (51.2)	6 (5)	24.3 (38.1)	4 (3)	27.5 (31.6)
Drop-in centre	9 (8)	31.7 (44.2)	17 (13)	26.7 (38.2)	10 (8)	15.5 (19.1)	18 (13)	10.9 (20.9)	8 (7)	27.1 (25.0)	10 (7)	15.6 (16.8)	7 (6)	33.3 (26.2)	7 (5)	26.6 (35.7)
Self-help/support group	12 (10)	21.0 (36.0)	15 (11)	18.1 (35.9)	7 (6)	9.1 (9.9)	10 (7)	29.0 (46.0)	7 (6)	18.7 (13.7)	7 (5)	12.4 (11.3)	9 (8)	7.7 (8.5)	11 (8)	9.1 (8.6)

continued

TABLE 22 Number (%) of patients using health-care services and mean (SD) number of contacts before baseline assessment, second, third and final follow-up (*continued*)

Service	Time point															
	6 months to baseline				Baseline to second follow-up				Second to third follow-up				Third to final follow-up			
	Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS	
	n (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]
Class/group at a leisure centre	8 (7)	24.5 (17.7)	9 (7)	13.3 (13.4)	8 (7)	26.9 (32.6)	6 (4)	17.2 (22.7)	6 (5)	15.2 (12.7)	5 (4)	9.8 (8.0)	3 (3)	7.7 (4.0)	5 (4)	5.4 (2.3)
Adult education class	10 (8)	8.5 (7.4)	20 (15)	19.0 (24.0)	7 (6)	13.4 (6.8)	9 (7)	22.4 (39.9)	10 (8)	15.6 (15.8)	11 (8)	18.1 (34.6)	10 (8)	11.4 (10.7)	6 (4)	20.5 (16.9)
Other day care activity provided by team	10 (8)	14.8 (13.3)	10 (7)	13.1 (14.8)	3 (3)	25.0 (2.6)	4 (3)	19.0 (11.9)	7 (6)	17.0 (15.8)	5 (4)	17.2 (11.3)	3 (3)	11.3 (12.9)	2 (1)	30.0 (5.7)
Inpatient admission[b]	31 (26)	1.5 (0.9)	35 (26)	1.5 (0.9)	17 (14)	1.4 (0.6)	25 (19)	1.4 (0.9)	13 (11)	1.6 (1.0)	15 (11)	1.3 (0.6)	14 (12)	1.5 (0.9)	20 (15)	1.5 (0.9)

a Number of contacts is only those using each service (i.e. not the whole sample).
b Contacts represent number of admissions.

During the period between baseline assessment and second follow-up, the vast majority of patients again had contact with GPs. In both groups, there was a reduction in contact with GPs, psychiatrists, home treatment/crisis team members, social workers and mental health nurses. Fewer were admitted to hospital. The only key difference between groups was in the use of a social worker, with 24% of patients in the PEPS group having contact, compared with 17% of patients in the usual-treatment group. However, the amount of contact with social workers was much higher in the usual-treatment group than the PEPS group, indicating a greater intensity of use.

Between the second and third follow-ups, there was a continued reduction in contact with home treatment/crisis team members and mental health nurses in both groups. Contact with GPs, psychiatrists and social workers was reduced in the PEPS group, but this trend was not observed in the usual-treatment group. Between the third and final follow-ups, there was a slight increase in contact with GPs, psychiatrists and home treatment/crisis team members in the PEPS group, which also saw a small increase in inpatient care. No noticeable changes in service use were observed in the usual-treatment group.

Mean service costs are presented in *Table 23*. At baseline, mean costs were highest for inpatient care, followed by contact with psychiatrists, GPs and social workers. Inpatient and GP costs were higher for the usual-treatment group, and the psychiatrist and social worker costs were higher for the PEPS group. However, the variation around the means was substantial, as indicated by the SDs. Total health-care costs were significantly higher for women than for men by an average of £2044 and were higher by an average of £5431 if the patient had a non-specified PD.

Between baseline and the second follow-up, mean costs were again highest for the use of inpatient care, contacts with psychiatrists, GPs and social workers. For all of these four services, costs were higher in the usual-treatment group than in the PEPS group; the cost difference was especially high for inpatient care (usual treatment, £1430; PEPS, £847) and contacts with social workers (usual treatment, £658; PEPS, £187). Between the second and third follow-ups, the costs of inpatient care, psychiatrists and GPs were still higher for the usual-treatment group. Costs of social worker contacts were similar between the groups. Finally, between the third and final follow-ups, costs of psychiatrists and GPs were higher for the usual-treatment group, while the costs of inpatient care and social workers were higher for the PEPS group.

The total cost of all health-care services at baseline was £265 higher in the usual-treatment group than in the PEPS group (*Table 24*). This cost difference widened at the second and third follow-ups in favour of PEPS; however, the 95% CI shows the difference to be non-significant. By the final follow-up, the mean costs were £1174 higher for the usual treatment group than for the PEPS group, after adjusting for differences in baseline costs. However, the SDs were large and this difference was also non-significant.

When the cost of the PEPS intervention was considered, the total costs for the PEPS group increased to £7727 per patient for the entire follow-up period, which is still lower than the total cost of the usual-treatment group (£8072 per patient). After adjustment for baseline, the cost for the PEPS group was £182 less than for the usual-treatment group.

At the 72-week follow-up, the SFQ score (the primary clinical outcome) is slightly in favour of the PEPS group, although the difference is not statistically significant ($p = 0.19$). Therefore, in a technical sense, PEPS was seen to be dominant as it resulted in lower service costs and an improved SFQ score. However, this does not take uncertainty around these estimates into account.

The utility values derived from the EQ-5D are shown in *Table 25*. At baseline assessment and at the second follow-up, the mean utility scores were slightly higher in the usual-treatment group. At the final follow-up, the mean utility score was slightly higher in the PEPS group. However, none of these differences was statistically significant.

TABLE 23 Mean (SD) health-care service costs (2012/13 £)

Service	Time point							
	6 months to baseline		Baseline to second follow-up		Second to third follow-up		Third to final follow-up	
	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS
GP	465 (1489)	291 (380)	267 (599)	238 (430)	198 (383)	138 (231)	289 (616)	233 (477)
Psychiatrist	472 (627)	595 (729)	396 (684)	298 (482)	359 (696)	274 (481)	479 (980)	434 (895)
Other doctor	76 (247)	86 (239)	98 (390)	83 (205)	24 (76)	93 (397)	78 (324)	92 (341)
Psychologist	89 (326)	117 (406)	135 (528)	75 (333)	133 (463)	64 (316)	143 (553)	106 (492)
Drug and alcohol advisor	32 (142)	64 (249)	11 (73)	91 (581)	64 (349)	64 (478)	46 (244)	13 (92)
Other counsellor/therapist	107 (335)	140 (445)	62 (267)	146 (725)	61 (235)	79 (309)	103 (446)	150 (510)
Home treatment/crisis team member	52 (167)	52 (145)	39 (260)	44 (197)	17 (100)	17 (69)	22 (78)	20 (74)
Assertive outreach team member	26 (203)	1 (17)	4 (45)	0 (0)	4 (45)	14 (165)	0 (0)	1 (6)
Early intervention team member	4 (28)	< 1 (3)	0 (0)	0 (0)	3 (26)	0 (0)	0 (0)	0 (0)
Social worker	374 (1106)	455 (1296)	658 (2956)	187 (520)	253 (859)	266 (879)	234 (1160)	284 (1189)
Mental health nurse	212 (436)	210 (424)	172 (448)	153 (413)	130 (386)	63 (179)	139 (351)	168 (529)
Occupational therapist	49 (205)	38 (239)	33 (265)	9 (42)	3 (17)	4 (18)	28 (282)	3 (14)
Accident and emergency service	243 (1392)	96 (159)	63 (190)	89 (396)	47 (114)	48 (137)	81 (176)	67 (257)
Drug/alcohol service	< 1 (4)	3 (22)	0 (0)	1 (7)	3 (27)	5 (49)	1 (10)	1 (10)
Community mental health centre	4 (27)	22 (236)	2 (11)	14 (148)	9 (85)	< 1 (1)	41 (319)	1 (6)
Day care centre/day hospital	2 (10)	6 (37)	7 (38)	3 (28)	4 (21)	5 (40)	7 (45)	3 (22)
Drop-in centre	10 (64)	28 (237)	5 (26)	7 (34)	6 (28)	3 (19)	50 (504)	4 (34)
Self-help/support group	6 (39)	59 (387)	1 (7)	4 (24)	37 (378)	1 (6)	5 (32)	4 (20)
Class/group at a leisure centre	3 (18)	8 (70)	2 (12)	2 (12)	24 (252)	5 (50)	4 (37)	4 (39)
Adult education class	2 (7)	31 (251)	3 (16)	4 (23)	13 (100)	18 (121)	3 (20)	5 (29)
Other day care activity provided by team	18 (159)	10 (77)	1 (9)	2 (18)	2 (14)	1 (6)	3 (25)	1 (7)
Inpatient admission	1930 (4662)	1600 (4815)	1430 (5835)	847 (3239)	552 (2262)	413 (2099)	982 (4455)	1314 (8139)

TABLE 24 Total mean (SD) health-care service costs excluding intervention (2012/13, £)

Health-care service use period	Treatment arm		Difference adjusted for baseline (95% CI)
	Usual treatment	PEPS	
6 months to baseline	4178 (5780)	3913 (5834)	–
Baseline to second follow-up	3391 (7255)	2296 (4081)	–1051 (–2470 to 367)
Baseline to third follow-up	5334 (8434)	3870 (5692)	–1391 (–3112 to 331)
Baseline to fourth follow-up	8072 (10,598)	6777 (10,550)	–1174 (–3720 to 1371)

TABLE 25 Mean (SD) utility scores at baseline assessment, second and final follow-up

Assessment time point	Treatment arm, mean utility score (SD)		*p*-value
	Usual treatment	PEPS	
At baseline	0.3647 (0.3664)	0.3422 (0.3505)	0.6194
At second follow-up	0.4050 (0.3529)	0.3731 (0.3709)	0.4868
At final follow-up	0.3825 (0.3718)	0.3895 (0.3668)	0.8802

Quality-adjusted life-years generated using the area under the curve method are shown in *Table 26*. The mean QALY gain between baseline and second follow-up was 0.2161 for the usual-treatment group and 0.2108 for the PEPS group. However, the difference adjusting for baseline utility score was 0.0557 in favour of the PEPS group. By the final follow-up, the QALY gain in the usual-treatment group was 0.5706 and 0.5616 in the PEPS group. The adjusted difference was 0.0148 in favour of PEPS.

In a technical sense, PEPS was seen to be dominant as it resulted in lower total costs and a greater QALY gain, after adjusting for baseline. However, this does not take uncertainty around these estimates into account.

The cost-effectiveness plane showing cost (including service costs for both groups and intervention cost for PEPS group only) and QALY differences at second follow-up is shown in *Figure 3*. At the second follow-up, 62.4% of the resamples showed lower costs and a greater QALY gain for the PEPS group while 30.6% of resamples showed lower costs and a lower QALY gain. Only 4.8% of the resamples showed higher costs and more QALYs for PEPS, and 2.2% showed higher costs and a lower QALY gain. The cost-effectiveness plane for the QALY gain and cost differences by final follow-up is presented in *Figure 4*. The most likely scenario with 36.8% of resamples was that PEPS resulted in lower costs and greater QALYs. Higher costs and more QALYs were revealed in 28.1% of resamples. Lower costs and fewer QALYs were shown by 17.9% of resamples and higher costs and fewer QALYs by 17.2%. Clearly, the level of uncertainty is substantial over the entire follow-up.

TABLE 26 Mean quality-adjusted life-years (SD) gained between baseline and second follow-up, and between baseline and final follow-up

Assessment time point	Treatment arm, mean QALY (SD)		Difference adjusted for baseline utility (95% CI)
	Usual treatment	PEPS	
Baseline and second follow-up	0.2161 (0.1961)	0.2108 (0.2158)	0.0057 (–0.0215 to 0.0328)
Baseline and final follow-up	0.5706 (0.4624)	0.5616 (0.5142)	0.0148 (–0.0622 to 0.0919)

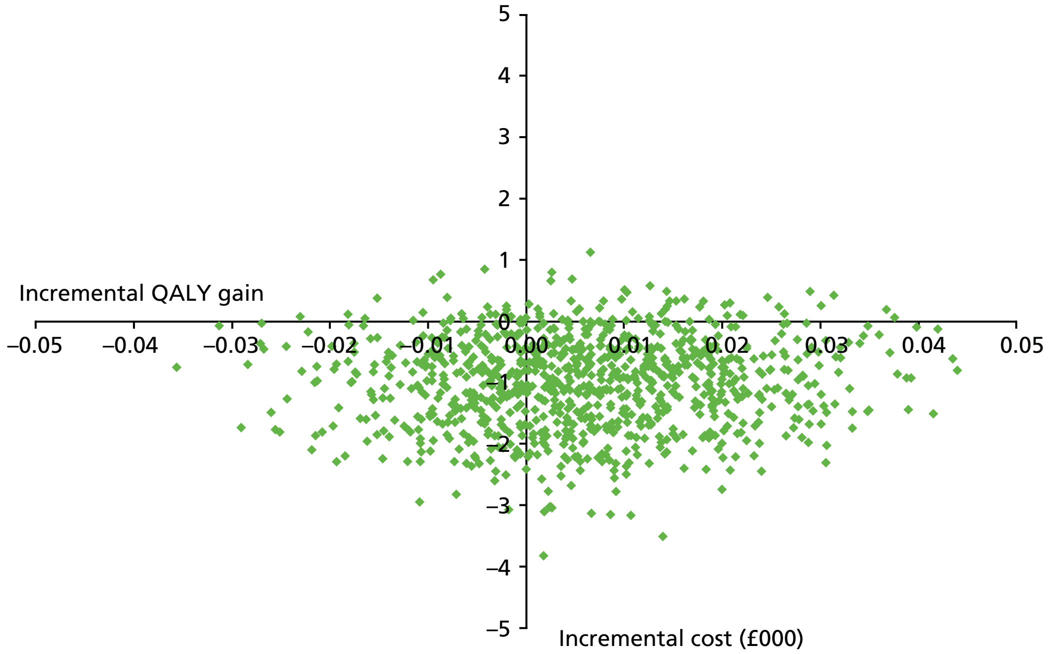

FIGURE 3 Cost-effectiveness plane of cost and QALY differences at the second follow-up.

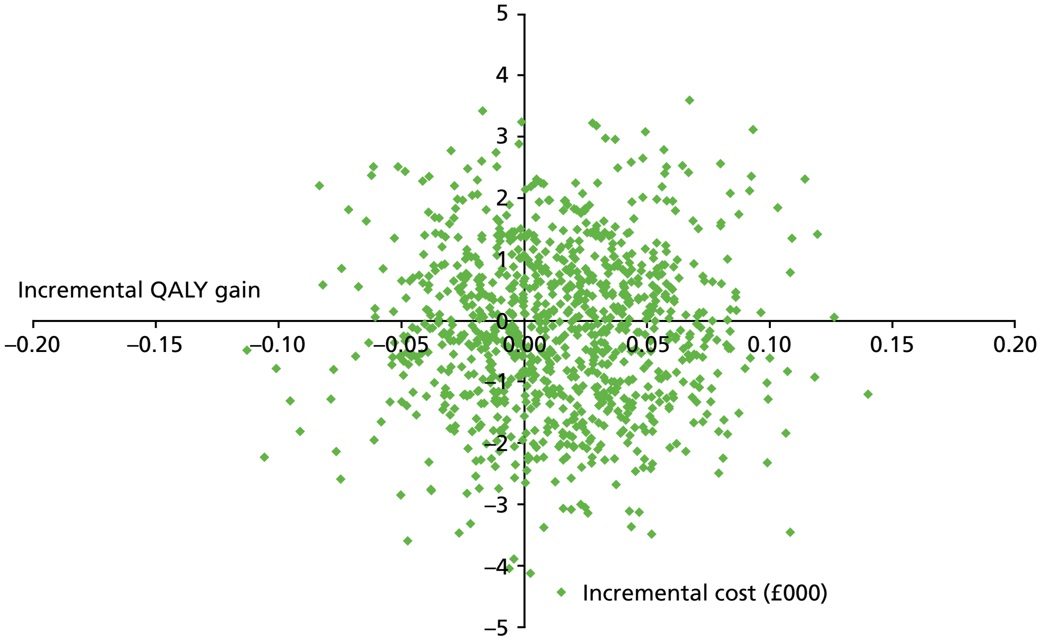

FIGURE 4 Cost-effectiveness plane of cost and QALY differences at the final follow-up.

The cost-effectiveness acceptability curve for the whole follow-up period is shown in *Figure 5*. Even if society was not willing to attach any monetary value to QALY gains there would remain a likelihood of 58% that PEPS is the most cost-effective option. As a unit improvement is valued at higher levels, this likelihood increases. Although we do not know the true societal value that should be placed on a QALY gain, NICE uses a threshold in the region of £20,000–30,000. Between these two levels there is a 63.6–64.2% likelihood that PEPS is the more cost-effective option.

The above analyses focus on health-care costs. However, it is likely that people with PD will incur higher cost of criminal justice service as a result of their condition. Two types of criminal justice service were considered in this analysis: police contact and nights detained in a police cell. The use and costs of both services are shown in *Tables 27* and *28*. Costs of police contact were similar in the two groups. Although relatively few patients spent nights detained in a police cell, the cost was high. It can be seen that the cost was greatest for the PEPS group before baseline assessment (£211 per patient), but this cost was reduced during the follow-up period.

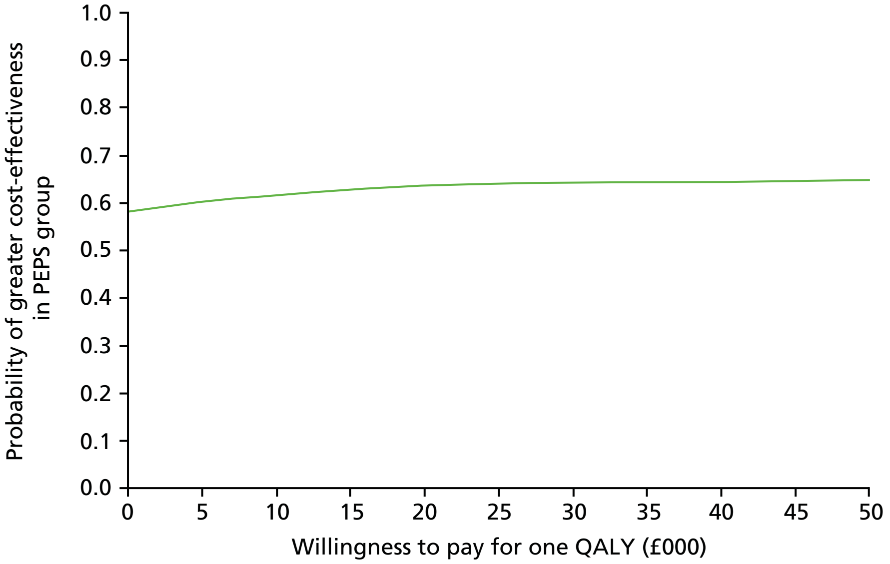

FIGURE 5 Cost-effectiveness acceptability curves showing the probability that PEPS is most cost-effective option.

TABLE 27 Number (%) of patients using criminal justice services and mean (SD) number of contacts before baseline assessment, second, third and final follow-up

	Time point															
	6 months to baseline				Baseline to second follow-up				Second to third follow-up				Third to final follow-up			
	Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS	
Service	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]	*n* (%)	Mean (SD) contacts[a]
Police contact	31 (26)	1.8 (1.2)	45 (33)	3.1 (5.2)	19 (16)	1.9 (1.8)	23 (17)	2.9 (6.1)	13 (11)	3.4 (5.6)	18 (13)	2.6 (3.2)	16 (14)	4.0 (4.8)	22 (16)	2.9 (3.7)
Nights detained in a police cell	4 (3)	1.8 (1.5)	10 (7)	6.9 (18.7)	1 (1)	1.0 (–)	2 (1)	1.0 (0.0)	1 (1)	6.0 (–)	2 (1)	4.0 (4.2)	–	–	2 (1)	5.0 (5.7)

a Number of contacts for those using each service (i.e. not the whole sample).

TABLE 28 Mean (SD) service costs of criminal justice service (2013, £)

	Time point							
	6 months to baseline		Baseline to second follow-up		Second to third follow-up		Third to final follow-up	
Service	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS
Police contact	16 (33)	34 (110)	10 (34)	17 (90)	12 (69)	12 (48)	18 (73)	16 (60)
Nights detained in a police cell	25 (165)	211 (2137)	4 (38)	6 (50)	21 (229)	25 (252)	–	31 (322)

Information on the number of days lost from work as a result of health problems (absenteeism) and the cost impact of absence from work is given in *Tables 29* and *30*. The data relate only to those in employment, the assumption being that, given the level of unemployment in the economy, long-term absence from work does not result in lost output because others are employed instead. Lost work time was experienced by a small number of patients, but the costs were substantial. The lost employment costs were also similar between groups at baseline. These costs then fell for the PEPS group, but remained stable for the usual-treatment group.

Conclusion

The analyses presented in this chapter have focused on costs and cost-effectiveness. Over the follow-up period, costs were slightly lower in the PEPS group. There was substantial uncertainty in this result, as shown by the wide CIs. Utility scores derived from the EQ-5D were very low (average scores were typically around 0.4). The analyses demonstrated that QALY gains were very similar in the two groups, but with a very slight advantage in favour of the PEPS intervention after controlling for baseline differences. Technically, the PEPS intervention was 'dominant' in that it resulted in lower average costs and greater QALY gains. However, the uncertainty around both estimates means that, at a NICE threshold of £20,000–30,000, there is a 64% likelihood that the intervention is the more cost-effective option. Given all the information available, PEPS is somewhat more cost-effective but much caution is required in interpreting this result. We have not considered the logistics of implementation and that may outweigh the benefits from the intervention.

TABLE 29 Number (%) of patients taking days off work as a result of health problems and mean (SD) number of days off work before baseline assessment in the periods leading up to the second, third and final follow-ups

	Time point															
	6 months to baseline				Baseline to second follow-up				Second to third follow-up				Third to final follow-up			
	Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS		Usual treatment		PEPS	
Service	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days	*n* (%)	Mean (SD) lost days
Lost work	19 (16)	39.2 (58.4)	19 (14)	44.2 (56.0)	16 (14)	14.4 (23.7)	13 (10)	40.6 (71.0)	12 (10)	25.6 (41.4)	9 (7)	5.7 (4.9)	12 (10)	22.3 (28.4)	10 (7)	10.1 (7.4)

TABLE 30 Mean (SD) cost of lost employment (2012/13, £)

Cost	Time point							
	6 months to baseline		Baseline to second follow-up		Second to third follow-up		Third to final follow-up	
	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS	Usual treatment	PEPS
Production loss[a]	664 (2848)	654 (2698)	205 (1032)	411 (2567)	274 (1566)	40 (196)	238 (1158)	79 (344)

[a] Lost production cost for whole sample.

Chapter 6 Qualitative analysis

Objectives

The purpose of this analysis was to search for themes across the PEPS qualitative data set, which consisted of reports compiled by researchers of participant responses to semistructured interviews, conducted according to interview schedules developed for the study (see *Appendices 14–17*). These data were gathered at:

- first follow-up (after psychoeducation), on the effects of psychoeducation ($n = 87$)
- second follow-up (after problem-solving therapy), on the effects of problem-solving therapy ($n = 61$)
- final follow-up (at 72 weeks), on experiences of usual treatment ($n = 41$) or PEPS therapy ($n = 47$).

The data were analysed using a thematic analysis.[78] Thematic analysis was chosen because of its ability to richly describe a large number of data by drawing out key points and presenting them in an easily accessible format,[78] and it has been used to investigate engagement issues in people with PD.[79]

Theoretical position

A pragmatic, flexible, inductive, thematic analysis was undertaken to provide largely face-value feedback on participant experience of the interventions, as described above. All semistructured interviews ($n = 236$) were included in this analysis. As the primary aim of the thematic analysis was to meet the objectives of the PEPS study, the focus was to provide a rich and nuanced reflection on participants' experiences of usual treatment and PEPS as well as to explore, in as much detail as the data permitted, their perceived benefits or bad effects of the treatments under investigation.

Method

The interview transcripts were read by two researchers (ML and JD), who familiarised themselves with the entire data set being analysed. 'Best' answers to the research questions were captured in the form of selected excerpts or quotes as an initial step in the analysis. Through an iterative process, these quotes were organised into recurring patterns or themes. Finally, the themes identified separately were merged or differentiated and checked to ensure that there was good evidence for them.

In doing this, the following 'lenses' influenced the selection process: the notion of 'prevalence' (how frequently the idea occurred across the data set was an organising principle, although with the caveat that more instances does not necessarily mean that they are more important); and a notion of 'keyness' (the extent to which a quote or excerpt captured something important to the research question).

Themes

Feedback after psychoeducation

Psychoeducation followed the use of the IPDE to ensure that the individual was eligible for the study, and consisted of up to four sessions of an individual collaborative dialogue designed to build rapport with participants, inform them about their PD diagnosis and discuss its effects on interpersonal relationships and social functioning. The analysis found five themes pertaining to the individual psychoeducation sessions, which are summarised in *Box 1* and then elaborated.

BOX 1 Themes relating to psychoeducation

Themes

1. Collaborative one-to-one process.
2. Provided improved knowledge of traits and understanding of individual relevance and application.
3. Emotional impact and willingness to tolerate this and keep with the process.
4. Positive orientation: optimism, trust and motivation.
5. Barriers to progress: doubts and uncertainties.

Theme 1: a collaborative one-to-one process

In general, participants felt that psychoeducation had been a professional, constructive, well-structured discussion about their diagnosis and its implications for their social functioning and problem-solving.

> *I've found them useful to help me identify some of my patterns, and also enjoyable. Put things into context.*
>
> *01/098*

> *The [psychoeducation] sessions were simple to understand, not overelaborate – using simple down to earth speak. Everyone would benefit from learning.*
>
> *03/080*

> *Although I have been in therapy a long time and inpatient in various institutions and also seen many psychiatrists over the last 16 years this is the first time I've talked to anyone about my diagnosis. In therapy we talked about me and occasionally make reference to it. With psychiatrists it is always about symptoms. This has been reassuring to properly talk to someone about BPD [borderline PD] – a new context. Psychoeducation is definitely the main factor, without that phase the group sessions would not have worked. People would not have returned to the group sessions without the initial one to one.*
>
> *01/099*

> *Being supportive and somebody really listening to your feelings helps me feel secure and worthy as a person, that someone takes the time to listen.*
>
> *02/009*

> *I have become more curious and intrigued about my diagnosis. Finding out more about me. I can recognise and rationalise others' behaviour and personality, so feel more able to understand them. I'm trying to apply this to me where I can.*
>
> *03/024*

> *Good to talk about things and have things explained.*
>
> *01/148*

> *I've got hope that I can deal with some of the things we have discovered in the sessions.*
>
> *02/014*

> *. . . contact with someone who was interested and understood the problems [was helpful]. I learned about PD generally and about the relation to my own problems and how they affect my relationship with others and my reactions to problems.*
>
> *03/27*

> *We learnt that I've got a PD, which has just been categorised as depression – hard to put into words. Found it helpful to breakdown what my problems are.*
>
> *02/099*

Theme 2: increased or new knowledge of the core concept of 'trait' (versus symptom), and a greater understanding of its relevance and application to the individual themselves

Participants had engaged in a meaningful process of self-understanding and were given a specific conceptual framework that made sense to them. This brought relief and a sense that they could apply this knowledge to their recovery:

> *Learned how my past has affected my personality.*
>
> 03/01

> *I don't feel as isolated; I'm not the only one receiving a PD diagnosis.*
>
> 03/60

> *Learnt about my own traits and issues and how it effects me personally.*
>
> 03/041

> *[IPDE] was very thought-provoking . . . as I answered some of the questions, I re-evaluated the scenario, situation.*
>
> 03/04

> *Maybe I had in my mind I had a million problems and I've learnt it's all caused by the need to have things perfect and get everything done. The trait is causing me many problems, I'm being irrational. It seems more manageable looking at it here, in this way.*
>
> 02/046

> *Eye opener, empowering. I learned about my own traits. I am beginning to change . . . I learned that I am overly dependent.*
>
> 03/62

> *I've got hope I can deal with some of the things discovered in the [IPDE] sessions.*
>
> 02/14

> *. . . pin-pointing traits was helpful.*
>
> 01/098

> *It was handy to be informed about other personality disorders.*
>
> 01/099

> *What my traits are, the healthy ones and the not so healthy ones.*
>
> 02/062

> *It's not a specific thing with your personality, it's different things.*
>
> 02/108

> *A lot about myself, established 'triggers' for my behaviours. Learned that I have the skills to help myself.*
>
> 03/04

> *Everyone has a personality and that disorder happens when a person experiences, perceives, copes or manages with issues around their feelings and emotions.*
>
> 03/110

> *More about personality disorder. Interesting to have my personality disorder traits reflected back to me. Reassuring conversation relating to borderline personality disorder.*
>
> 01/099

> *The fact that there are so many different types of personality disorder. I was able to put another perspective on my problems. I always thought it was coming from my depression. I'd never thought about it in relation to personality before.*
>
> 01/120

Theme 3: emotional impact and willingness to keep with the process

Participants described the impact of facing and coming to terms with a diagnosis of PD. They described their own emotional responses to it and their concerns about how others might perceive and treat them.

> *Things had happened in our lives wherein we were let down by the system – and [but] the onus was put back onto ourselves for this . . . being described as having a personality disorder. We had failed in the first instance.*
>
> 01/133

> *Triggered some historical memories about [my] father. I have not 'switched off' like I normally do – I have felt more focused.*
>
> 03/82

> *Session 2 [psychoeducation] made me tearful. It felt like having the truth slapped in my face. Was overwhelming seeing all the boxes I had actually ticked. My mum has been a great support whilst in this study. I have got to spend more time with her, which brought us closer and she understands me better.*
>
> 01/38

> *. . . I've also found it very hard and difficult, especially after sessions dealing with my emotions.*
>
> 02/014

> *It's been emotionally draining, but not negative. Feeling that I am not alone has been the biggest thing. Spending time with the research team and trusting the person doing the psychoeducation.*
>
> 01/42

> *It was emotionally painful at times because it brought up some issues from the past that were painful – but I was able to deal with them.*
>
> 03/027

> *Starting to admit things . . . helping me confront stuff. Helped me pinpoint issues. I have said I didn't want to come but that's only confrontation and I know it's going to be okay.*
>
> 01/47

> *After [psychoeducation] sessions you can feel quite vulnerable and confused about what you've talked about.*
>
> 02/014

> *You are talking about things that are painful, but its part and parcel of working through an issue. No pain, no gain.*
>
> 02/009

> *Has felt intense and hard. Has helped me to see things differently.*
>
> 03/029

> *Daunting at first. I've found it difficult to say about all the bad bits . . .*
>
> 02/029

> *Anxious, frightened initially about the questions. Still anxious but not as frightened.*
>
> 03/093

> *When the truth hit me it made me feel emotional – I find emotions hard to deal with.*
>
> 03/062

> *Overwhelming . . .*
>
> 03/11

Theme 4: positive orientation – optimism, trust and motivation

Overall, the detailed IPDE assessment and psychoeducation sessions helped to prepare people and orient them for the next step. Many speakers articulated a positive motivation to build on their skills:

> *That there is hope, it's not mysterious. What personality disorder is and the common aspects that affect lives. That I can do something about it.*
>
> 03/123

> *When you speak out loud about things it makes it real and it makes you look at it, made me want to change it and make it better. I can make better choices.*
>
> 02/098

> *Started to think about different ways of dealing with problems.*
>
> 03/01

> *Learned that I have the skills to help myself.*
>
> 03/04

> *Helped me really think about what things are a problem for me. Useful having that fed back to me. Some questions make me think of things I haven't thought of before. How my natural personality is holding me back. Become more comfortable that I am not the only one with these problems. [Improved motivation by] showing me what I can get out of the sessions.*
>
> 01/51

> *. . . things aren't so bad as I thought they were.*
>
> 02/056

> *Take a step back and look at what I thought were major problems, aren't at all. Feel confident about sharing that [in problem-solving groups to follow].*
>
> 01/46

> *It's made me less apprehensive about going to somewhere new and talking to new people. It's good I've met you [therapist] before the groups start or you're meeting new people in the group and new therapists at the same time, it can be daunting.*
>
> 02/026

> *I feel more motivated to join the group process.*
>
> 03/39

> *Looking forward to problem-solving.*
>
> 03/01

Theme 5: barriers to progress – doubts and uncertainties

Some participants found the information difficult to assimilate. The psychoeducation had not met their expectations. These misgivings or mismatches in their sense of what constituted meaningful help were barriers to progress.

> *I don't know how it [psychoeducation] is helping me, I don't. It released tension. I put it in my mind in the beginning that I didn't fancy it.*
>
> 02/015

> *I've not really understood them. I thought it was counselling, but it's not really . . .*
>
> 01/094

> *I've been unsure of the structure of the individual sessions, not sure what to expect . . .*
>
> 01/124

> *. . . I thought that the personality statements were badly worded – slightly too open to interpretations – a bit vague.*
>
> 01/099

> *Not really [benefited], just good to get started with some therapy.*
>
> 01/102

> *I didn't learn anything.*
>
> 01/102

> *. . . I am a little confused about whether I learnt anything extra to what I already knew.*
>
> 03/078

> *Can't quite remember.*
>
> 01/117

> *I felt bad at the time. Didn't always agree with what was being said. Hard sometimes to recall the information.*
>
> 03/03

> *Can't remember most things.*
>
> 03/37

> *Going through everything and seeing it in black and white, had feeling of being weak.*
>
> 02/099

> *They weren't long enough. There are just too many things that stress me to discuss in the sessions – need to be longer.*
>
> 01/150

> *Learning more about myself and feeling worried.*
>
> 02/108

It is not known if participants felt these impressions could have been raised and addressed during the course of the individual psychoeducation sessions. These follow-up data suggest that they were not resolved. This early feedback of potential difficulties could have been invaluable in engaging successfully with participants who were having difficulties and helping to address them.

Feedback after problem-solving therapy

Problem-solving therapy was a 12-session group intervention designed to teach people strategies for solving interpersonal problems. In addition, individual support sessions were also made available to participants. Six themes were found in this analysis, which are summarised in *Box 2* and elaborated on below.

Theme 1: positive experience

Many participants found problem-solving therapy to be a structured, positive, relevant intervention for them. They found that it was non-threatening and that by applying it they could take effective action successfully. Several responses evidence the fact that many people had grasped the method and felt encouraged about applying it.

> *It was a good course overall.*
>
> 02/055

> *Just that I really enjoyed it. It helped me a lot, but you only get out what you put into it. You need to remember to use the skills.*
>
> 02/008

> *Not what I expected it to be. First group I've stayed 'switched on' for. I learned how to stand back and think about something rather than just react.*
>
> 03/82

> *I found it very beneficial to use those sessions [problem-solving]. The way it was presented I'll give it 9/10.*
>
> 02/023

> *. . . I think its been the most helpful thing I've had since been involved in mental health services. Pitched well as it doesn't assume too much about the person beforehand.*
>
> 02/026

> *What you're doing is brilliant. I think the course should be longer, like a rolling course or open door. Once a week having an open door for people with problems to talk.*
>
> 02/065

> *I think the group should be available more widely.*
>
> 01/117

> *I really miss the place and coming here.*
>
> 01/150

BOX 2 Themes pertaining to problem-solving therapy

Themes

1. Positive experience.
2. Limited engagement.
3. Learning outcomes.
4. Vulnerabilities triggered – feeling exposed and unsatisfied.
5. Peer support seen as a positive resource.
6. Needed more sessions to master new skills.

Managed to attend groups consistently despite feeling stressed.

03/003

I like the fact that it wasn't about me, the fact anything can be broken down into smaller pieces using the steps.

01/098

Valuable experience, I learnt to mediate my responses, to learn to step back and just listen, not comment or criticise.

01/099

It's reinforced that by going through a process again and again it helps and you can get better at it.

01/110

I've learnt that groups aren't as scary as they seem. And the fact that so many options come up and it is helpful.

02/040

That I can control my impulsivity, that the glass is not always half empty, that I can be my own master, I just need to work on my skills and techniques.

02/008

[I] feel more confident in solving problems and feel capable of managing difficulties in a structured way.

03/039

[I learnt] to solve problems in a different way. Something more structured – easy to follow. I recognise the build up of a problem and can ID [identify] how I'm feeling then stop and work things out.

03/013

If you can stick at it long enough it gets better. Realise how it works and that everyone is there for similar reasons and not feeling like an individual in a group.

01/104

My general opinion is it's something you've got to want to participate in. No use sitting there and having no input. Good to have other's input and I've gained more confidence.

01/033

It was OK – didn't think I'd like it at first but it was OK. Good idea and good to know there are things that can help.

03/020

Had impact on me as it made me use my mind more – thinking of options.

03/029

Absolutely brilliant. Although difficult to participate in some of them, I felt the actual problem-solving process was very, very useful.

02/023

It stopped me overdosing, it made me stop and think about things.

02/027

> *[The process was] helpful, I liked the fact that the group wasn't big and the way we dealt with one thing at a time.*
>
> *02/029*

> *I think it brings a lot of mentally ill people together and gives them a bond in a group. It's a good way to come together to bring experiences together.*
>
> *02/052*

> *It's a lot different than I thought; I was expecting it to more emotional but it's been relaxed and informal and I've got on with people better than I thought.*
>
> *02/064*

This was an encouraging and remarkable endorsement by a clinical population that is frequently challenging to engage. There is also implicit confirmation that the PEPS therapists were providing a valuable treatment that was not already routinely available. It looked as if for some participants it contained a collaborative approach to defining personal problems and setting priorities for intervention that had been identified as lacking in treatment plans, based purely on diagnostic assessments by clinicians.[80]

Theme 2: limited engagement

Another robust finding of this analysis was the theme of limited engagement in problem-solving therapy, which seemed to include timing of the problem-solving therapy, resistance to the group format, sustaining the commitment required to complete the course, sometimes speakers felt that participants could not 'relate' to their problem or vice versa, and a deterioration in mental state.

> *I would have got more out of it at a different time. I wasn't 100% there as I had so much going on in my head. If I had the chance I would like to try it again when all other things aren't going on.*
>
> *02/073*

> *I am lucky that it wasn't a group really, mostly just me who attended so . . .*
>
> *01/84*

> *I have learned a lot about myself, but due to physical health problems I've not got as much as I'd like to due to not being able to attend group often. Helpful in future to keep the six steps in mind. Can use it better when not it crisis – have been using problem-solving in recent separation of marriage.*
>
> *03/01*

> *Groups weren't for me and I feel I'm missing out 'cos I still need help. Didn't like talking about other people – they could listen to me and think I'm a bad character.*
>
> *02/015*

> *All female group can go off on a tangent. Shame that it wasn't better attended – lost people over course of the group.*
>
> *01/57*

> *May not have needed to be 12 weeks as same thing each week and group became smaller with time . . . Useful when people related to your problem as a group. Sometimes if people did not relate to my problem or made certain comments, it didn't help, made me feel alone. But not always.*
>
> *01/49*

> *Maybe just that I found I couldn't work with it over the last couple of weeks as I was in a really 'bad' place and couldn't focus on it. I just couldn't engage in it when I was feeling at my worst.*
>
> *03/13*

> *It was getting to me because I wanted to go, but found it difficult to be around the group and I felt bad then that I wasn't attending.*
>
> 02/068

> *I'm not sure I liked the group. I didn't like that individuals were under the 'spot light' to bring their problems.*
>
> 01/86

> *I could have gained more out of it if it hadn't been at the wrong time and the problems with transport didn't help. Things that were said and done in the group [had a bad effect]. I also felt inferior in the group because they sometimes used big words.*
>
> 02/073

> *I did enjoy coming to the group, but my depression came in the last few weeks and that's why I didn't make it to sessions – wasn't myself.*
>
> 02/053

> *I didn't give it a chance.*
>
> 02/015

> *I didn't like the fact that each week was about one person's problem. I wanted more opportunity to talk about my problems. I did relate to some of the other's problems, but not to all.*
>
> 01/38

> *I found it hard going that there were so many sessions. I think a break in the middle of 2 weeks would have been good.*
>
> 02/014

It seems likely that an obvious implication of this theme of insufficient engagement with a core component of treatment was a lack of mastery of the skills required for independent and effective application of problem-solving therapy to complex real-life problems.

Theme 3: learning outcomes

There was a strongly supported theme that problem-solving therapy did result in learning outcomes that participants could articulate for themselves as evidenced in the following quotations:

> *I'm a lot more calmer, I don't lash out as much now. I learnt to talk about things rather then bottling things up then falling apart. I've now learnt I can talk things through, but I don't always talk them through with the right people.*
>
> 01/94

> *I feel as though I got a new set of tools which I can use on a daily basis – I know I am not a freak!*
>
> 02/830

> *Strategies for my goals and ambitions. Learning alternatives to self-harm. Being reminded of importance of planning sleep and meals. Suggestions to keep diaries was useful. Also indirectly learned from others what they had learned. Printouts helpful so you could remember things. Learned about other resources – Crisis Line.*
>
> 01/124

> *I've got in touch with Gofal [a Welsh mental heath and well-being charity] and other agencies to help me get back into work and have support in place.*
>
> 02/023

> *The way we deconstructed the problem in stages was good, it took the excess away – by breaking it down and intervening gently it made the problem seem more manageable. By looking at things objectively it took away the emotional charge/shit feelings/scariness of the problem. I really benefited from learning this tool, I try to implement it as much as I can.*
>
> *01/78*

> *Even though it has been so hard, by hanging on through that day and letting it run its course, you can turn negative thoughts into positive thoughts. After 54 years I am finally starting to have positive thoughts – even if it's just one to get me through the day. Nobody has given us the tools before. I have hope in my heart.*
>
> *02/52*

> *Really good philosophy and tools. It can be difficult and can fall by the wayside – need self-discipline. I learned about myself and how others perceive things – I was able to work out things logically – learnt a structure [for] soul searching. I realise I am a bit of an attention/reassurance seeker. I recognise I can manipulate to get my own way and how this can affect others. I can use Stop & Think more positively. The more I use Stop & Think, the easier I'll find it. I want to be able to incorporate it into everyday life.*
>
> *03/36*

> *. . . a fusion of individual CBT [cognitive–behavioural therapy] in a group setting, but it wouldn't have worked without the supplementary sessions . . . the group alone does not hold it. By listening to other group member's problems and how they react to them . . . that was a learning curve for me to see myself in others. Hard journey to start a path of acceptance and self-compassion. I learned to mediate my responses, to learn to step back and just listen . . . usually my impulses are very quick and I'm out there without thinking . . .*
>
> *01/99*

> *. . . made me use my mind more – thinking of options. Group was caring and understanding. Good using six steps – put a different light on it. Made me try different things rather than just giving up. Understood more about self and built my confidence to ask questions and challenge others/offer others support. I want to use it more than I do, but that's up to me to practise it so it feels easier to engage automatically.*
>
> *03/29*

These quotes provide convincing indications that adult learners had been engaged actively in meaningful learning with unequivocal signs of skills being brought within the participants' reach. Traits associated with self-direction were being nurtured, including being methodical and disciplined, logical and analytical, collaborative and interdependent, open, as well as increasingly motivated and confident, as is consistent with the work of Candy.[81]

Theme 4: vulnerabilities triggered – feeling exposed and unsatisfied

This theme related to having difficult feelings and negative social interactions, making unfavourable comparisons with others and being unable to reconcile the dissonance between what they expected and what problem-solving therapy actually involved. There were some indications of the socioeconomic or cultural differences in which their own lifestyle seemed far removed from the problems being addressed. For a few, it was too contrived, formal and academic.

> *After [problem-solving therapy] group taking feelings home with you with no one to share them with. Listening to other people's problems, felt overwhelmed. Good to feel not alone, but sometimes it felt too much. Walked away with a lot spinning around in your head. Wanting to forget a lot of it. I felt I*

> *was the one with the problem (like when the psychiatrist wrote an inaccurate report). Nowhere else to go. Still lacked confidence. Some people dropped off. Wondering what happened to them. Concerned they were alright.*
>
> *01/133*

> *I didn't like it at all. I'm a private person and didn't want my dirty laundry to be aired. It was not for me. It blew my mind and I couldn't face it. It benefited me in opening my eyes and knowing it's not for me.*
>
> *02/15*

> *Sometimes I didn't think any one listened to me and I would get upset . . .*
>
> *01/148*

> *Sessions would confuse my head coming from my lifestyle. My lifestyle is quite rough. I also struggle with being a bit quiet. And sometimes people having a laugh and I felt I wasn't part of it. I needed to contribute, express more [but could not].*
>
> *01/150*

> *Groups shouldn't be run over the Christmas months, should start in the new year as Christmas is distressing for people so they might/do miss lots of groups over the weeks due to being unwell. Should have been in a nicer environment, the room was too small. The research is a bit formal like it was a test or too academic.*
>
> *01/104*

> *The intensity of the group [had bad effects]. I started drinking a lot. It consumed my thoughts. I think if I hadn't had other therapeutic [one-to-one] support during this time I would have made suicide attempts.*
>
> *01/099*

> *Made me regress, [I] know you (therapist) were correct, but I couldn't change. Confirmed how I felt already. I felt depressed.*
>
> *01/121*

> *Some emotional factors, practical approach and the steps sometimes means you don't have the facility to talk to a lot about why problems have come about. Would be best to have the groups alongside a more emotional focused group.*
>
> *01/133*

> *. . . as soon as the groups finished things went downhill again.*
>
> *03/072*

> *They were good but I don't think it was good how it was set up. It was too planned with someone bringing a problem the following week, situation of 'it's not my turn' to talk about my problem. So you are thinking of your own problem when someone is talking about theirs. The steps were too long. Sometimes you didn't know your problem or what you wanted so you'd spend a long time on that bit and it dragged it out too much and I lost concentration . . .*
>
> *(01/094)*

Theme 5: peer support seen as a positive resource

The content of this theme related to overcoming negative stereotypes, vicarious learning from peers, being less judgemental, and overcoming social isolation.

> *Realised that others who have this diagnosis and that people with BPD [borderline PD] are not monsters. It was helpful to meet other people with BPD who are employed . . . I had a lot of personality issues at work and it is hard to keep a job. It was useful to meet other people who have personality disorders and can keep a job.*
>
> *01/104*

> *I've enjoyed it. Meeting people who are the same as me.*
>
> *02/027*

> *I feel I got a lot emotionally out of the group. I have been using my skills and I don't feel angry if it doesn't work, I just try something else. I am now part of a support group made up of 'stop and think' group members.*
>
> *03/082*

> *Huge meeting others with personality disorder, having others care, listen, take notice. Learnt to be less judgemental of others.*
>
> *03/011*

> *I found it reassuring that I wasn't alone in the way I dealt with things. Others have problems too and being able to share. Got good helpful ideas off others.*
>
> *03/013*

> *Met a member of the group which developed into a friendship. Good to know I'm not on my own, others could identify with things I was saying, vice versa.*
>
> *03/020*

> *Sharing of info with other group members. Feel less isolated, ability to look at things differently breaking the cycle.*
>
> *03/023*

> *Sharing experiences with others and getting their support. Would feel more confident in engaging in other group work.*
>
> *03/076*

> *I made friends and learnt how to listen and negotiate with other group members.*
>
> *03/083*

> *I liked everyone in the group, I enjoyed it sociably, I liked the people very much.*
>
> *01/098*

> *Being in a group with people helped me be more sociable in my personal life.*
>
> *01/100*

> *Rewarding that when I put in options some people thought they were really good options. And some people came back to the group and said it worked, rewarding to be listened to.*
>
> *01/133*

> *It was nice being with people with different experiences – the social aspects. I feel more comfortable making small talk, having done it in a safe environment. Other people come up with things that you don't think of.*
>
> *02/026*

> *Listening to others stories I can relate to, can put a context into it without needing to talk about it. Having another view point of comparison, having someone say 'yes I can relate to this'.*
>
> *02/064*

> *The main thing I've learnt is that other people are dealing with similar problems and using a technique that works.*
>
> *02/065*

> *[I learnt] that there are options to problems. I was expecting mad people in the group but actually they were all quite normal which made me feel less threatened in a group setting.*
>
> *01/104*

> *Group was understanding, good using the six steps.*
>
> *03/029*

Theme 6: needed more sessions to master new skills

Many participants felt that more opportunities to master social problem-solving skills were needed. They wanted to be able to repeat the course and were worried that, after the course was over, there would be nothing to replace it.

> *What you're doing is brilliant – I think the course should be longer, like a rolling course of open door. Once a week, having an open door for people with problems to talk.*
>
> *02/65*

> *More sessions as just warming up.*
>
> *03/37*

> *If I had the chance, I'd like to try it again when . . . other things aren't going on.*
>
> *02/73*

> *Group could be longer. Just got used to people and was only half-way there when it stopped.*
>
> *03/038*

> *I hope we can have somewhere to go like this along the way in the future.*
>
> *02/52*

> *Found support sessions 1 : 1 valuable.*
>
> *03/01*

> *My only worry is that when this is all gone, I'm left with nothing again and that scares me.*
>
> *02/32*

Themes related to psychoeducation with problem-solving therapy based on feedback at 72-week follow-up

The following six themes were found in the interview data on final reflections by participants on PEPS therapy. They are summarised in *Box 3* and then examples of quotes follow.

Theme 1: psychoeducation with problem-solving is a valid treatment

Participants found PEPS to be credible, to mobilise their own resources, to provide positive, collaborative experiences with staff and peers, and to provide hope of adopting a self-directed approach to improving their lives.

> *Really good, well structured. Different depending on who got [participates] in it. Very useful for me. Skills based versus analysis, analytic introspective based. I think this is better for people with a personality disorder. Skills based model really useful. Differing and varying opinions useful because people had similar disorders, you could compare issues. Strategies for my goals and ambitions. Learning alternatives to self-harm. Being reminded of importance of planning sleep and meals. Suggestions to keep diaries was useful. Also indirectly learned from others what they had learned. Printouts helpful so you could remember things. Learned about other resources – Crisis Line.*
>
> *01/124*

> *I think everyone who was offered the chance to go to PEPS therapy doesn't know how lucky they are. To go there and know what's wrong with you and understand why you're different and that you've got to work towards improving yourself. People don't understand mental health, if you keep it in your head what you've learnt here – remember the people you met here and one part of the program will keep you alive.*
>
> *02/052*

> *[PEPS was] very good, it explained a lot to me.*
>
> *02/058*

> *Living again, not just existing, PEPS saved my life!*
>
> *03/004*

> *I hope it gets rolled out at the end of the study.*
>
> *03/023*

BOX 3 Themes related to PEPS therapy

Themes

1. PEPS is a valid treatment.
2. Both psychoeducation and problem-solving therapy are necessary parts of it.
3. Peer support and not being the only one with difficult problems was reassuring.
4. Barriers to PEPS working.
5. Consistency of staff and process important for security and sustained participation.
6. Lack of 'dose' – needed more sessions and supervised practice.

A lot easier to be in and keep employment when one has tools to manage . . . Also [applies to] everyday life. I've had long history of self-harming. Now when I get these urges, I dismiss them. Before, I felt I had to cut myself. Now I can step back, it's worked for me. When born, not given a handbook. By listening to others [in PEPS] who have same problem and trying what's worked for them, it's helpful. Amazing what a little care and compassion can do. To hear another person say, 'I can understand how you feel' means a lot . . . Helped me be more open with my wife. I feel confident knowing she cares about me. If I have a [bad] day, I can tell her. Before would have bottled that up and would have felt like cutting myself. I used to wear a mask, now more open and honest. Know people care about me. No longer embarrassed about who or what I am.

01/127

I did have a benefit. I was thinking in a different way, stopped putting myself down as much and though more positively.

01/084

Felt like I could help other people who were going through things that I'd been through. It's changed my whole attitude. If I think about all of my overdosing, it just seems like selfishness and not being prepared to deal with what I get myself into.

02/027

More confident dealing with things. Deal with things a lot better now than previously; used to have lots of meltdowns. Confidence to deal with things better and be around strangers.

02/029

Having ill people together, we came up with better answers – I think we need each other. Still need each other, need courses like PEPS, can mend each other, laugh and feel more positive. I think I deal with things much better since the course.

02/052

No longer making the same mistakes again and again, now coming up new counselling/solutions to [my] problems

02/056

Helped with social, recently discovered I have Asperger's.

02/064

They [therapists] were lovely, really patient and understanding. Doctors normally make me feel crap and like they are looking down their nose at me. It was really important that PEPS people didn't make me feel like that.

02/029

It's a way of life now. Thank you for changing my life. It's been an amazing experience and I'm very grateful for everyone who played a part in helping me get better.

02/056

Although I have given Q7 [rate the usefulness of PEPS] as a '1', it is because I've let it slip. I do think it is really useful and works. I just need to find a way of reminding myself.

01/117

Learnt how to talk to people comfortably and overcome paranoia of people judging you.

03/001

These responses demonstrate that participants experienced PEPS therapy as combining interesting knowledge of their difficulties with practical coping skills and positive attitudes towards their future recovery.

Theme 2: both psychoeducation and problem-solving were necessary parts of psychoeducation with problem-solving

This theme demonstrated that many participants had grasped the rationale for PEPS and valued both component parts of it.

> *I think they work together, they complement each other – you need both. Whole structure very helpful.*
>
> 01/098

> *Liked the individual ones – felt I could open up better one to one. Group sessions were fine, liked listening to other problems. I've never been good in large groups, was nice that it was a small group. Both parts useful in different ways, useful to have both, worked well together.*
>
> 02/009

> *Both worked well together both equally useful.*
>
> 02/020

> *Both useful and worked well together.*
>
> 03/004

> *The two come hand in hand. If I had to chose, when everyone works in the group together and sharing our experiences was the best part.*
>
> 02/052

> *Went hand in hand, couldn't have one without the other.*
>
> 02/056

> *Worked well together. The more educated you are the more able you are to deal with your problems.*
>
> 02/062

> *Both worked well. One to one gave me confidence to go into the groups, confidence got me ready for the group.*
>
> 03/001

> *Worked well together. One to one brought me outside myself and helped me understand myself which helped me face going to the groups.*
>
> 03/013

> *I like being one-to-one, more direct and just about me; but then in the group It helps you to see other people's views and hear other people who are worse off. [Both] useful for different things, worked well side-by-side. Also nice to have opportunity for individual support sessions.*
>
> 02/004

> *Preferred the group because you realised you're not the only one that behaves like that. Help each other to deal with things and individual session were alright.*
>
> 02/005

> *Found psych-ed great, therapist was really understanding and non-judgemental, prefer one to one. Not a lot of people in the group was good. More attention to each person and good if nervous around big groups.*
>
> 02/006

> *I think it should incorporate the two. I liked that we met the therapist and had a chance to discuss problems to work on. First day with the group is really hard, much easier when you at least know the therapist.*
>
> 02/008

Theme 3: peer support and not being only one with personality disorder or difficult problems to solve was reassuring

> *[Benefited from] the support factor, wish they were still ongoing.*
>
> 02/078

> *I met a couple of other girls that I'm still in touch with and call them when I'm having a bad day.*
>
> 01/042

> *Had someone to discuss things and plan things with, it was nice to have support.*
>
> 01/050

> *Being around others that knew where I was coming from and didn't judge me. Really appreciated it.*
>
> 03/013

> *Good to know other people's views on problems, see things from different angles. Good way to start discussions and share experiences and let off steam.*
>
> 02/006

> *That I'm not alone was such a huge relief. Even when you've got the same problem as someone, it's not exactly the same but you understand each other better.*
>
> 02/008

Theme 4: barriers

Participants highlighted various reasons why they gave up on PEPS. Group factors were a major reason, the size, composition and 'feel' of groups led many to reject this format. Some people realised that their personal mental health vulnerabilities were triggered by PEPS. Some participants were not yet in a reflective space, they felt caught in a spotlight and drawing attention to any perceived shortcomings was too much for them to cope with.

> *Not saying it didn't work, but drop-outs in the group were unsettling. Changes in the group affected me; maybe a bigger group could have helped with this. More men as largely women group.*
>
> 03/125

> *Didn't attend problem-solving groups, couldn't be in a room with strangers.*
>
> 02/058

> *Only went to half of one group session – didn't feel comfortable.*
>
> 02/015

> *Only attend the individual session, found those helpful. Couldn't attend group session due to other commitments.*
>
> 01/150

> *Sometimes it can be awkward, everyone has different problems. Individual more helpful; didn't find groups helpful.*
>
> 01/063

> *Didn't like the groups – would have been better if had more time to work with the therapist.*
>
> 01/086

> *Might be a good idea to have a service user involved in explaining personality disorder – only they understand what it feels like. Would like refresher sessions of problem-solving and maybe include new information on what helps.*
>
> 02/008

> *I think my weak point is that I let it slip. I don't keep things up I need things put on a plate for me or I don't do it.*
>
> 01/084

> *Sometimes main message was lost. Noticed I was distracted by those who were less confident reading and writing. Wondered if it put people off, unsure if others got as much out of it.*
>
> 03/004

> *I do think I've benefited but I've been really ill lately and I have a bad memory.*
>
> 02/014

> *I struggle with paranoia and found that I couldn't understand how others were finding the sessions useful. I judged myself and them but I have learnt that I shouldn't judge them as it is acceptable that they could find it useful even if I didn't.*
>
> 01/099

> *Group sessions didn't feel comfortable enough and being pushed too far into the deep end, made me want to give up.*
>
> 02/039

> *When you are at your lowest sometimes wish you hadn't gone because you know there isn't a booklet to help you.*
>
> 02/052

> *It drew attention to my bad attributes which meant I would leave group sessions feeling low and negative about myself. Also found that I would take on other people's negative thoughts and start thinking those about myself.*
>
> 01/002

> *Everything all together was overwhelming and I was unwell for a period afterwards. The premise of group was to bring a problem you wanted to work on. That exposure mixed with the immediate finality when the sessions ended was difficult.*
>
> 03/123

> *Only went to one group session as didn't get on with some of the participants.*
>
> 03/118

> *It's a good idea but not the group meetings; I prefer one to one. I don't like talking about my problems in front of other people especially if I don't know them. They might take me the wrong way. I've had bad experiences with this in the past.*
>
> 02/015

> *One to one were very good; didn't like the group session everyone knowing my business.*
>
> 02/039

> *Personally it didn't work, especially the group therapy. Went because the GP told me to but they were a waste of time.*
>
> 01/063

> *Wasn't very impressed with it, it didn't seem to benefit me. I didn't like the way the groups were. I didn't like the way it used different people to talk each week – 'spotlighted you' I didn't feel comfortable opening up to strangers.*
>
> 01/086

Theme 5: consistency of staff and process important for security and sustained participation

Psychoeducation with problem-solving staff were valued for being sensitive and skilled. The format seemed acceptable to many participants:

> *Thought the therapists were really good, the way they explained things – not judgemental.*
>
> 02/005

> *Routine helped me, consistent time and place.*
>
> 02/008

> *Staff helpful and supportive, everyone got the chance to give input.*
>
> 02/008

> *Therapists were very nice and down to earth.*
>
> 02/009

From a workforce perspective, the fact that many people with PDs engaged with the staff and the process suggests that treatment specifically designed for people with PD need not be extremely intensive and costly.

Theme 6: lack of 'dose'

A dominant theme in the feedback received on PEPS therapy was that people had not had sufficient exposure to the method and supervised practice in using it until it became a part of their own skill set that they could apply independently.

> *I think others found it difficult being open and dealing with their problems in front of others. I found it useful but ideally it might be useful to have a short refresher course a few months later.*
>
> 02/014

> *Needed longer than 3 months in the group, worked well together.*
>
> 01/084

> *Once sessions were over, I was like a zombie. I couldn't do anything for a few days.*
>
> 03/82

> *Not long enough – only just got into it and then it's finished.*
>
> 03/024

> *Looking for a short-term intervention to a long-term issue. Could have been better to hold the 12 sessions over 12 months, 12 weekly sessions were too much to process.*
>
> 03/123

> *Better to spread therapy over 12 months, time frame was too short, very intense and full on. If over a longer period may be able to take things in better as remembering was difficult.*
>
> 03/125

> *Didn't last long enough. Waited a long time hear if in the group, then given only 2 weeks' notice. Little follow-up.*
>
> 03/036

> *Not enough time to go through everyone in the group and follow-up every problem. Problems never felt finished – so not solved.*
>
> 03/024

> *It could have been longer, could have used the support for a bit longer.*
>
> 02/009

> *Fabulous staff, could have lasted longer.*
>
> 02/066

> *Pity it's still not going on.*
>
> 02/078

> *Groups felt like going back to school. [The process was] not long enough, needed more weeks.*
>
> 03/024

> *After a while I slipped back into my old ways, would be good if it could keep going for longer maybe once a month.*
>
> 02/006

> *I believe the spike in adverse events was due to the model not sustaining the support. It gave people help and then left them.*
>
> 01/099

> *Ended to soon, only got to work on one problem. Would have been good to have chance to say more.*
>
> 01/100

> *Content was good but not enough time to do everything.*
>
> 03/123

> *12 weeks is not enough, should have been extended for as long as the person needs.*
>
> 01/063

These comments suggest that this intervention was offered as a separate, stand-alone treatment. This is not ideal. Participants missed having maintenance sessions to consolidate and reinforce their acquisition of new skills. There seems to have been no carry over to ongoing mental health services participants were receiving. A probable implication is that as soon as the intervention was over, there was risk of it being eroded because it was not practised and improved. It was expecting a great deal of individuals with severe mental health problems to organise themselves to use a complex method unaided and unsupervised after the problem-solving course had been delivered. These data suggest that some participants floundered when the research intervention was suddenly stopped.

Themes related to usual treatment based on feedback at 72-week follow-up

Treatment as usual was provided by participants' usual-care teams in accordance with normal practice. What constituted treatment as usual in the trial was variable. A summary of services mentioned by respondents in their feedback is given in *Table 31*. This analysis found two themes pertaining to treatments and support received as 'usual treatment':

1. helpful aspects of usual treatment
2. unhelpful aspects of usual treatment.

Theme 1: helpful usual treatment

Participants highlighted the usefulness of the practical help and support, being listened to and believed, and a sense that staff were caring and competent.

> *It's been helpful, they gave me advice on staying positive and keeping my mind occupied.*
>
> *01/34*

> *Psychiatrist and social worker. Treatment from psychiatrist was excellent; [I] thought [the] social worker was very bad.*
>
> *02/03*

> *Floating support worker has been a huge help. Advocate has been hugely helpful in appointments [with] CPN [community psychiatric nurse] and psychiatrist – felt more believed and listened to.*
>
> *03/07*

TABLE 31 Services mentioned by participants describing usual treatment

Service	Qualifiers
Outpatient psychiatry	Regular follow-ups over several years
Inpatient admissions	As required
Art therapy	Weekly
Psychology	As agreed
Psychotherapy	As agreed
Keyworker from CMHT or voluntary agency	Regularly (fortnightly or monthly) as planned or when requested
Drug and alcohol team	Not specified
Counselling	As agreed
Planned meetings with GP	Regularly arranged
Community psychiatric nurse	Usually fortnightly or as agreed
Social worker	In role of keyworker usually fortnightly or as agreed
Day centre	Several days a week over the duration of several years
Crisis or emergency services	As required
Occupational therapy	As agreed
Advice on benefits	As required
Mentalisation groups	Weekly for several months
Mindfulness course	As per referral
Mental health advocacy	As required

> *Felt I could talk to my counsellor and they understood.*
>
> 01/44

> *GP doesn't listen or states the obvious. Mental health team have been great. CPN has brought forward appointments with the psychiatrist – monitoring me closely. Health-care assistant tries to motivate me to do things. They try to help even when I don't think they can – don't feel brushed off.*
>
> 02/07

> *GP, psychiatrist and care co-ordinator – everyone was very kind, everyone was doing their best. I felt like I was being looked after.*
>
> 03/10

> *I don't know [what benefits I have had from treatment as usual] maybe a bit of community support has kept me out of hospital.*
>
> 01/82

> *GP and CPN have been brilliant.*
>
> 03/25

> *Yes, the psychologist I had was very good and understanding. She taught me different techniques and helped me to understand how my mind works.*
>
> 01/87

> *I guess so – I've been quite stable. Art therapy helped me to understand my emotions and control them better.*
>
> 01/93

> *Medication and CPN for past 18 months. CPN doesn't always respond quick enough. Finally got meds [medications] balance right. CPN helps with problem-solving.*
>
> 03/34

> *Mental health team have been really good. I only wish what is on offer now with psychology and psycho-education was available 20 years ago as I might have been a lot better.*
>
> 01/111

There was no mention of specific PD services or care pathways. People valued knowing who was responsible for their care and how to contact them as a minimum.

Theme 2: unhelpful aspects of usual treatment

Individuals whose personal histories include being marred by close relationships picked up on staff attitudes and willingness to take action to help them. Some participants were affected by cut-backs. It was concerning to hear that some people felt that unless they deteriorated or experienced crises they were not taken seriously.

> *Waiting lists for treatment – art therapy are really bad. Also took a long time to see a psychiatrist and the mental health team. Quite scary to be kept waiting, to be left alone in those situations.*
>
> 01/140

> *It's all been very confusing. I was receiving support albeit intermittent[ly], but I moved house about a year ago and now my local GP will not refer me to services as he wants proof that I have previously been given a diagnosis of borderline personality disorder.*
>
> 01/115

> *Only given six sessions with my mental health team. Not enough. Actually it's worse at the end. Just about the time you feel you have developed rapport, the sessions end. Now I don't even want to start. I don't see use in having to keep re-explaining myself, to start building rapport with someone who will stop seeing me in a few sessions.*
>
> *01/131*

> *Don't seem that bothered, seems as if they don't have enough time – suggest things and then it takes ages for anything to happen.*
>
> *02/11*

> *Medication and seeing a professional every 4 months. Had a crisis – told there was no-one available to talk to [me]. Requested a copy of the notes the lead professional had made. They did not corroborate her experience of meetings. Felt 'talked down to' confronted the professional, put in a complaint.*
>
> *03/14*

> *Nothing, no treatment received. Medication – came off it in March this year [2012].*
>
> *01/28*

> *Some counselling through GP, but was stopped as funding was pulled. [GP/CMHT] really bad, not sympathetic, not aware of other services. Not at all bothered – didn't see [my] desperation. Told [my] only hope was the crisis team.*
>
> *02/25*

> *Don't feel I've had much treatment. Sessions with psychiatry. See GP regularly. Psychiatrist hasn't given me suggestions or further support. Feel passed back [and] forth between GP and psychiatrist. Therapist at GP and sessions at 'Workshop and Co' all of which stopped, so I feel abandoned.*
>
> *01/01*

> *Psychologist then discharged and had no one. [It] took my daughter being placed on child protection list to have help.*
>
> *02/30*

> *Nothing since CPN at start of PEPS. Would have liked PEPS. Questionnaires made her think more – raised awareness [was] helpful.*
>
> *03/33*

> *Nothing – psychiatrist every 3 months waiting for psychologist. Bad experience of crisis team – [I felt] intimidated [they] didn't understand. Fear of A&E [accident and emergency] – too many germs. Daughter is my carer. Self-management – felt categorised.*
>
> *02/33*

> *Unsatisfactory at all stages – both GP and CMHT. Difficulty being referred by GP basically told to make my own arrangements. CMHT not at all concerned. Just wanted numbers going through their doors. No longer have hope to speak to my GP. I just can't depend on anyone at the moment. Before I had the feeling in the back of my head I could speak to my GP. Now I don't have that feeling anymore.*
>
> *01/108*

> *I didn't receive any treatment for my mental health.*
>
> *01/40*

> *Struggling for a long time. No service for what she needs help with. Refused psychotherapy as [she was] deemed 'not safe'. But not safe without psychotherapy either. Struggling with change of CPN. No progress. Feels that what she says is acknowledged, but no support or way to deal with it after that [is offered].*
>
> *03/107*

> *Difficult to get care other than when I'm in crisis . . .*
>
> *01/104*

> *None – only see GP for alcohol related problems.*
>
> *03/128*

Discussion

The aim of this analysis was to provide information on participants' experiences of usual treatment and PEPS therapy, with their perceived benefits and limitations. The majority of codes related to feedback on treatment aspects participants valued, as well as on obstacles they encountered. For many participants, having a thorough assessment of their personality traits and receiving detailed feedback on the meaning of the results made them feel valued and helped them to understand the challenges they faced if they were to overcome problems and recover valued roles. Furthermore, they grasped the rationale of the treatment to follow and saw the psychoeducation as pretherapy preparation, which was generally helpful in orienting them to the intervention to follow. Good staff performance emerged with a difficult-to-treat group feeling that they were listened to, cared for, supported and treated reliably and skilfully. The structure, training and supervision adopted by PEPS provide useful feedback to services wishing to develop specific care pathways for people with a PD.

Overall, this analysis provided strong indications that PEPS provided self-knowledge in a way that empowered participants to become agents of change. PEPS had an impact on their attitudes, which changed from frequently being disaffected to being engaged, hopeful and motivated to put effort into acquiring skills.

Several well-supported codes in this analysis related to challenges that needed to have been resolved in order for learning to progress from positive interest to successful acquisition of complex social and cognitive skills. Early signs were present that some people were being lost at the beginning of the process when they did not grasp the notion of how their own clusters of habits interfered with their social functioning and problem-solving. Unfortunately, subsequent learning could not proceed until individuals grasped the rationale. Given their personal experiences of being marred by their relationships, the transition from individual to group format was too difficult for many in this clinical population. Instead of labelling the problem-solving a group, it might have been less threatening to have presented it as a safe, non-invasive course. The analysis harvested important feedback on perceptions influencing motivation to engage or reject involvement in a group intervention including size, composition (including sex), efficiency in completing problem-solving cycles, group norms (arriving late, rejecting some contributions) and cohesion. PEPS did provide positive, even corrective, group experiences where groups were smaller, provided valuable suggestions for problem-solving options and challenged negative stereotypes about people meeting criteria for a PD. Unfortunately many people floundered at this stage and did not engage in group-based problem-solving. Follow-up, providing ongoing feedback on attempts to apply the skills and opportunities to repeat the course, emerged as being essential for the approach to become embedded in services and in people's lives.

Closer links to educational research and knowledge about adult learning might have informed more accurate perceptions of prior learning needed for this quite sophisticated intervention to have met its outcome standards for proven efficacy. Clearly coping with high anxiety in social situations was relevant to many participants, but was not the focus of PEPS therapy.

The limitations of this analysis include the second-hand accounts of participants' accounts captured on semistructured interview sheets. Some questions were repetitive and did not draw out meaningful elaborations or invite participants to provide more individualised responses. Future studies might benefit from using focus groups. These could use interview data to differentiate those people who were enthusiastic about the skills-based approach that they had been offered from those whose experience of PEPS had led them to reject this treatment approach. Focus group data could help us to understand what factors differentiated the groups and what might be done to increase access to clearly structured, evidence-based interventions.

Chapter 7 Discussion

Summary of findings

Clinical effectiveness

The findings of this trial showed that PEPS therapy plus usual treatment was no more effective than usual treatment alone on either the primary outcome or a range of secondary outcome measures. Specifically, no superior effect of PEPS therapy plus usual treatment over usual treatment alone at the 72-week follow-up on the primary outcome of social functioning, measured by the SFQ (adjusted difference in means –0.73 points, 95% CI –1.83 to 0.38 points; $p = 0.19$). The change score on the SFQ required to indicate the minimum degree of clinical significance was a reduction of 2 points. The CI of the difference in means crossed zero and did not include –2; thus, the null finding is unequivocal. Scores on the SFQ reduced in both arms of the trial from baseline to the 72-week follow-up, indicating some overall positive change. This may be attributable to being in a trial, bearing in mind that participants in the usual-treatment arm underwent a number of assessments that are not typical of usual treatment, although this observation can also be explained by regression to the mean. While the CI for the whole sample did not include zero, nor did it include –2 points (95% CI –1.54 to –0.32 points), hence any effect did not reach the requirement for minimum clinical significance.

At the 72-week follow-up, no treatment effects were evident for any of the secondary outcomes, namely scheduled and unscheduled health service use collected from GP records, mood measured by the HADS, or on the client's assessment of change on the three problems they considered most important. The process of change, which was to improve social problem-solving skills as assessed by the SPSI-R, showed no group differences at the post-treatment point of measurement. There was consistency across all measures; there were no significant differences between the PEPS group and the usual-treatment group on any measure. Furthermore, there were no obvious effects at different points in follow-up.

The baseline characteristics of the two groups were similar, apart from a slightly higher proportion of participants with complex PD in the PEPS arm. Subgroup analysis of the SFQ at the 72-week follow-up showed no difference in outcome for complex versus simple PD. There was no difference for people with borderline PD.

About half of the people in the PEPS arm did not receive the full dose of treatment. Analysis of the primary outcome by compliance suggested a better outcome for those who received an adequate amount of treatment.

Cost-effectiveness

Psychoeducation with problem-solving shows slightly lower costs and higher QALYs, but differences are not large or significant and CIs are wide. There is a 64% likelihood that the intervention is cost-effective at the threshold used by NICE.

Adverse events

The stoppage of this trial because of concerns about safety is, to our knowledge, unique in trials of complex psychosocial interventions.[82] The DMEC, after studying unblinded data, alerted the TSC to the higher rate of adverse events in the PEPS arm of the trial. The TSC advised that recruitment to the trial be stopped, that treatment should discontinue and that all participants should be alerted to this safety signal. The TSC also firmly advised that follow-up should continue.

It quickly became apparent that stopping a trial of a complex psychosocial intervention because of reports of adverse events was both unique and potentially harmful to the participants, and would require additional, specific procedures to be implemented. We worked closely with the NCTU, in consultation with the TSC and site coinvestigators, to develop procedures for safe stoppage. These included advising the sponsor, advising clinical teams, writing information sheets for participants, devising clinically safe stopping procedures, contacting all participants and conferring with the research ethics committee.[83]

By the end of the trial, both the number of adverse events, including serious adverse events, and the number of people reporting them were greater in the PEPS arm. Four deaths were recorded in the PEPS arm: two of these were from natural causes and two were suicides. The nature and circumstances of these deaths did not seem related to the therapy. The number of hospitalisations and the number of people hospitalised were greater in the PEPS arm. The majority of this difference is accounted for by incidents of self-harm and drug and alcohol overdose. Although there was a tendency for PEPS participants to report more adverse events, even after allowing for greater follow-up in the PEPS arm, the results are inconclusive (adjusted incidence rate ratio 1.24, 95% CI 0.93 to 1.64). It should also be acknowledged that the assumption underlying this analysis, that the occurrence of adverse events follows a Poisson distribution (that is, equally likely to occur at any time following randomisation), may not hold true.

Participant views

Interpretation of the findings is assisted by what the participants told us about their experiences of PEPS and usual treatment. Participants valued the one-to-one psychoeducation sessions, which built rapport and increased knowledge and understanding of PD, as intended. The problem-solving approach was also seen as helpful. There is, therefore, the important suggestion that service users' perceptions of treatment being helpful may not translate into clinically meaningful effects for this group of people.

There were mixed feelings about group work: some felt supported by working with peers, whereas others felt the group setting to be challenging. There was a consistent view that the treatment was too short and the lack of follow-up support was considered a serious shortcoming. Opinions about usual treatment were variable: some individuals were positive about treatment received, while others felt dismissed and neglected. Worryingly, there was a view that the way to access services was to evidence a decline or bring about a crisis (e.g. harm oneself).

Strengths and limitations

Study design

This was a pragmatic trial with broad inclusion criteria (i.e. any PD). As such, it presents results that are generalisable to regular clinical practice in secondary care mental health services.

Treatment fidelity

Treatment fidelity is the extent to which an intervention is delivered as specified in the protocol. Without a high degree of fidelity, there is no way to determine whether unsuccessful outcomes reflect a failure of the model or failure to implement the model as intended.[84] A number of strategies were in place to maximise treatment fidelity. 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 and individuals were rated on competence checklists. None of the therapists failed to meet the competence criteria on any of the measures.

Measures

Validated outcome and process measures were used in this trial. With regard to secondary outcomes of service usage, the original idea was that service use might not decline as a result of treatment but that better use of the services offered might result. That is, treated individuals might attend scheduled appointments and thereby avoid crises that required emergency, unscheduled appointments. In the event, it was not easy to ascertain which appointments were scheduled and which were not, apart from the most obvious ones such as emergency department visits.

Sample size

The power calculation for this trial was based on a pilot study conducted with a comparable sample. As stated in the trial protocol,[85] to detect a mean difference in SFQ score of 2 points (SD 4.53 points) at the 72-week follow-up with a two-tailed significance level of 1% and power of 80% with equal allocation to two arms, the requirement was 120 patients in each arm of the trial. Allowing for 30% drop-out, the aim was to randomise 340 participants in total (i.e. 170 participants per arm). The study fell marginally short of its target of 70% follow-up, with an overall follow-up at the 72-week end point being 68%. There was a difference in the follow-up rate between the usual-treatment arm (62% follow-up) and the PEPS treatment arm (73% follow-up), with the target being met in the latter. The numbers, however, were somewhat short of the desired 120 participants per arm at 94 in the usual-treatment arm and 113 in the PEPS arm. This was partly because the trial was stopped before 340 people could be randomised, with only 306 randomised before recruitment was halted. Furthermore, although this was one of the largest economic evaluations conducted in PD, the sample size may have been too limited to pick up important effects on the use and cost of specific services. Nonetheless, this trial has demonstrated that it is possible to recruit a large number of difficult-to-engage, community-dwelling individuals into a clinical trial and to retain a large proportion of recruits to an end point 72 weeks after randomisation. Further, the achieved sample size, although smaller than the target, still yielded sufficient precision to exclude a clinically meaningful effect.

Bias

Care was taken to minimise bias through independent randomisation, ensuring as far as possible that researchers collecting follow-up data were blinded to allocation, and conducting data entry and cleaning while blind to intervention status. However, researchers were unblinded in some cases, with more cases in the PEPS arm than in the usual-treatment arm (32% vs. 13%). Nonetheless, in the PEPS arm, the mean 72-week follow-up score on the primary outcome (the SFQ) was higher (i.e. in the undesired direction) for the unblinded cases, indicating no bias in favour of the PEPS group.

On average, non-completers in the PEPS arm remained in the trial for longer than non-completers in the usual-treatment arm. This, combined with the higher overall completion rates in the PEPS arm, contributes to more observed person-years of follow-up in the PEPS arm (203 person-years) than with usual treatment (178 person-years).

Bias in adverse event recording

Adverse event recording may have been subject to bias. Recording of adverse events during the trial depended on self-disclosure or a report by a member of the clinical team. The difference in reports of adverse events between arms could be explained in ways other than PEPS causing harm directly. These include differential reporting, for a number of reasons. Those in the PEPS arm were more in contact with therapists and so had more opportunity to report adverse events, and may also have felt more able to admit adverse events candidly. Similarly, there may be a greater degree of identification by staff of problems experienced by participants in the PEPS arm. In addition, clinicians may have been more likely to advise the research therapists about adverse events for those in PEPS therapy, whereas they managed the usual-treatment participants themselves, and so this may appear as more adverse events in the PEPS arm during the treatment phase. Alternatively, PEPS may encourage help-seeking, increasing the likelihood of hospitalisation, in which case adverse events would not be literally 'adverse'. More systematic and objective recording of adverse events would have been desirable. Advance consent had not been obtained to access Health and Social Care Information Centre records, and gaining consent to do so from participants in the follow-up period proved difficult because of limited contact and availability.

Uptake of the intervention

Of those randomised to the PEPS arm, 4% ($n = 6$) received no intervention at all, 51% ($n = 78$) received a partial intervention (i.e. ≤ 5 group sessions) and 45% ($n = 70$) received the intervention as per protocol (i.e. $\geq$ six group sessions). In the pilot study, of the 87 people allocated to PEPS, 13% ($n = 11$) never attended, 1% ($n = 1$) attended psychoeducation only, 21% ($n = 18$) attended psychoeducation and fewer than five group sessions, and 66% ($n = 57$) attended psychoeducation and five or more group sessions. So, in the definitive study, fewer people received no treatment but also fewer received an adequate quantity of treatment. The planned 12-session group intervention actually lasted, on average, six sessions. That is, most participants did not receive the full treatment. CACE analysis attempts to estimate the effect of the intervention among those in the PEPS arm who adhered compared with those in the usual-care arm who would have adhered had they been allocated to receive it. As expected, when the proportion adherent is around 50%, the CACE estimates are approximately twice that of analyses that take no account of amount of intervention received. However the 95% CIs are wide and none of the sensitivity analyses lend strong support for different conclusions from the primary analysis.

Of the psychoeducation sessions offered (on average 3.4), 90% were taken up. Clearly, individual psychoeducation is far better attended than subsequent group sessions and the overall group non-completion rate is high. This difference may be explained in a number of ways. Participants' enthusiasm for treatment may be stronger at the start of treatment and wane with time, they may prefer individual sessions or the content of psychoeducation may be more relevant to their problems.

To our knowledge, there is no review of treatment uptake and completion specifically in RCTs of psychological interventions. However, reviews of treatment completion of psychological therapies for PD using evaluations of any design indicate non-completion rates as low as zero and as high as 80%, with median or mean non-completion rates of between 29% and 35%.[33,86,87] Although the PEPS therapy non-completion rates appear higher than average, studies of non-completion use many different definitions of what constitutes non-completion of therapy and so comparisons may be misleading.

Personality disorder types

The treatment was offered to people with any type of PD. This was a pragmatic approach in that services often cannot offer separate treatments for different disorders and so treatments are offered only for the most common disorders (typically borderline PD) and people with the less common PDs may not be offered treatment at all. However, it may be that people with certain types of disorder have done better than others. Although the trial was not powered to conduct subgroup analyses, examination of those with borderline PD, which was the most prevalent disorder at baseline, showed no difference on the primary outcome at follow-up.

Non-standard usual treatment

The content of usual treatment was not standardised in this trial. Imposing standard treatment on the large number of services contributing to this trial was not considered a feasible option. Practice varied widely across services, and usual treatment was not a clearly prescribed procedure. Some participants commented that usual treatment could be well planned, holistic and reliably delivered, but in other cases it was unfocused, dismissive and unreliable. This issue (i.e. highly variable usual treatment) affected both those in the PEPS plus usual-treatment arm and those in usual treatment alone. The variability of usual treatment and the unclear treatment pathways for people with PD may have, in part, accounted for the loss to follow-up.

Observations about participants

Overall, participants in this trial were heavy users of health services, costing approximately £8000 per annum (based on the baseline data). This is comparable to the estimated treatment costs for schizophrenia but substantially more than the costs for bipolar disorder.[88] This is reflected in low quality of life, with QALYs of around 0.57 over the entire follow-up (i.e. out of possible 1.5 QALYs). The prevalence of PD in mental health services in England is at least 40%.[89] Coid *et al.*[1] have estimated a population prevalence of 4.4% in those aged 16–74 years and this would imply total health costs of around £16B per year.

Interpretation

We found no evidence to support the use of PEPS therapy alongside standard care within the UK NHS for improving social functioning of adults with PD living in the community. This differs from the pilot study, in which a significant improvement was found in the primary outcome of social functioning, measured, as in this trial, by the SFQ at the end of treatment, which was a mean of 24 weeks post baseline (range 21–28 weeks).[43] The between-group difference on the SFQ at the end point was –1.06 points (95% CI –1.99 to –0.18 points). In the pilot study, there were also significant improvements on the SPSI-R, although no significant improvements in service use.

A number of explanations can be put forward for the lack of significant effects observed in this full-scale trial compared with the pilot study. The full trial 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. Evidence from meta-analyses shows that demonstration projects have larger effects than programmes delivered more widely, and high methodological rigour is related to smaller outcomes.[90] Pilot projects may produce larger effects because they are more manageable in size and they are innovative, hence they may benefit from closer supervision, higher programme fidelity and a greater motivational drive from the closely involved chief investigator.

Evidence for the effectiveness of psychological treatments for PD is marred by methodological weakness. Systematic review authors have concluded that many of the trials of PD treatments are of poor quality, have small sample sizes and use a wide range of non-comparable outcomes with different degrees of clinical importance (e.g. self-reported changes in personality beliefs vs. days in hospital).[11,91,92] This variation makes it difficult to draw firm conclusions about any one treatment, and there is a place for specifying core outcome measures of agreed importance to all.[93]

Most of the treatments for PD that are evidenced as effective are of relatively long duration and are delivered by highly trained personnel, and hence are costly to deliver and are consequently of restricted availability. The question of whether or not brief interventions work for PD has been investigated recently,[94] with insufficient available evidence to provide an answer. The null findings of the PEPS trial suggest that the intervention may have been too brief to have had an effect, at least as a stand-alone treatment divorced from good clinical care. This point of view was articulated by participants in the PEPS trial.

Although social problem-solving was addressed as a common need among people with PD, this may not be the case. Alternatively, this particular aspect of treatment may not have been a priority for all participants. Hence, brief 'one-size-fits-all' treatments appear not to be the way forward, but rather clinicians should base treatment plans on a thorough case formulation. Assessment and case formulation would also reveal who might benefit from group sessions and who might be averse to working in groups. Information from participants tells us that some participants enjoyed the support gained from other group members, whereas others found it difficult to discuss their own problems or to listen to others discussing their problems. This is reflected in the differential attendance rates for individual and group components. However, many interventions for people with PD are group based and it may be that there is a need to offer some pretherapy training in group-work skills so that people find it easier to engage.[95]

Crudely set in the company of similar trials reporting the same outcome, PEPS is the largest and longest trial and, to our knowledge, most methodologically rigorous. A synthesis of these trials is presented in *Figure 6*. Although the synthesis of all trials does still suggest a modest effect, despite the PEPS data, the overall result is dominated by small bias-prone studies. In *Figure 7* the studies are sorted by time, with a real trend across time showing that the more recent the study the less the effect of the intervention. This may be because of improvements in study design and conduct over the past 15 years.

Recently evidence has been accruing from trials that structured clinical management achieves equally good outcomes as specific treatments for PD.[98–101] Commenting upon this, Bateman[102] speculated that in the past general psychiatric treatment, or treatment as usual, may actually have inadvertently been harmful and specialist treatments may have shown benefit primarily by minimising harm, possibly through preventing unco-ordinated care. Service users and providers have also highlighted the importance of co-ordinating and integrating psychological treatments within teams that can provide additional support for patients at times of crisis.[30] In the PEPS trial, treatment was delivered as a stand-alone therapy rather than being integrated into a co-ordinated package of care.

In the PEPS trial, although there was a higher number of adverse events reported in the treatment arm, it is also the case that the number of reported events was high in the usual-care arm: 76 adverse events reported by 39 people (26%) over a period of 72 weeks. One explanation for a higher number of reported events in the treatment arm of the PEPS trial 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 well be more damaging than to have had little or no support in the first place. As reported by participants, some individuals may be driven to dramatic and harmful gestures to access services.

Study or subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, fixed, 95% CI
Up to 6 months								
Evans 1999[96]	9.8	4.9	18	13.1	4	14	8.4%	−3.30 (−6.38 to −0.22)
Huband 2007[43]	12.09	4.54	74	13.74	3.78	72	43.8%	−1.65 (−3.00 to −0.30)
Subtotal (95% CI)			**92**			**85**	**52.3%**	**−1.92 (−3.16 to −0.68)**
Heterogeneity: $\chi^2=0.92$, df=1 ($p=0.34$); $I^2=0\%$								
Test for overall effect: $z=3.03$ ($p=0.002$)								
>6 months to 1 year								
Davidson 2006[97]	11.6	5.8	19	13.2	5.7	20	6.2%	−1.60 (−5.21 to 2.01)
Subtotal (95% CI)			**19**			**20**	**6.2%**	**−1.60 (−5.21 to 2.01)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.87$ ($p=0.39$)								
>1 year								
PEPS 2016[a]	13.5	4.8	113	13.9	5.3	94	41.6%	−0.40 (−1.79 to 0.99)
Subtotal (95% CI)			**113**			**94**	**41.6%**	**−0.40 (−1.79 to 0.99)**
Heterogeneity: not applicable								
Test for overall effect: $z=0.56$ ($p=0.57$)								
Total (95% CI)			**224**			**200**	**100.0%**	**−1.27 (−2.16 to −0.37)**
Heterogeneity: $\chi^2=3.50$, df=3 ($p=0.32$); $I^2=14\%$								
Test for overall effect: $z=2.77$ ($p=0.006$)								
Test for subgroup differences: $\chi^2=2.58$, df=2 ($p=0.27$); $I^2=22.6\%$								

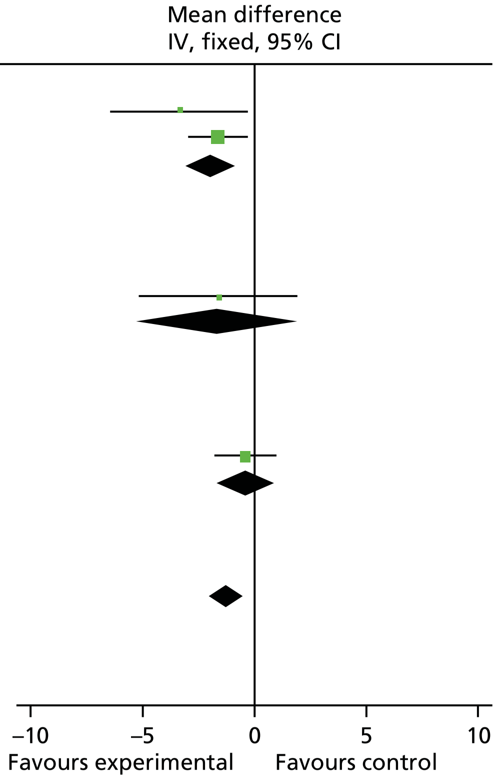

FIGURE 6 Synthesis of studies using SFQ as an outcome. a, PEPS 2016 refers to this report. df, degrees of freedom; IV, inverse variance.

Study or subgroup	Experimental Mean	Experimental SD	Experimental Total	Control Mean	Control SD	Control Total	Weight	Mean difference IV, fixed, 95% CI	Year
Evans 1999[96]	9.8	4.9	18	13.1	4	14	8.4%	–3.30 (–6.38 to –0.22)	1999
Davidson 2006[97]	11.6	5.8	19	13.2	5.7	20	6.2%	–1.60 (–5.21 to 2.01)	2006
Huband 2007[43]	12.09	4.54	74	13.74	3.78	72	43.8%	–1.65 (–3.00 to –0.30)	2007
PEPS 2016[a]	13.5	4.8	113	13.9	5.3	94	41.6%	–0.40 (–1.79 to 0.99)	2014
Total (95% CI)			**224**			**200**	**100.0%**	**–1.27 (–2.16 to –0.37)**	

Heterogeneity: $\chi^2=3.50$, df=3 ($p=0.32$); $I^2=14\%$
Test for overall effect: $z=2.77$ ($p=0.006$)

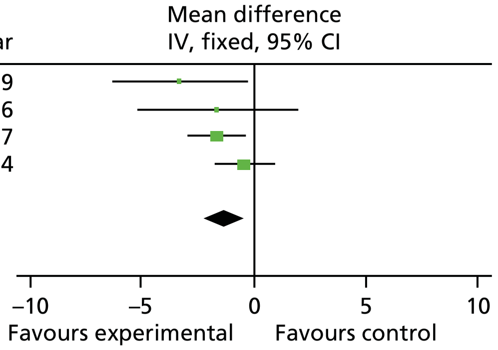

FIGURE 7 Changes over time in studies using SFQ as an outcome. a, PEPS 2016 refers to this report. df, degrees of freedom; IV, inverse variance.

Chapter 8 Conclusions

Implications for health care

The conclusion here is that PEPS therapy should not be promoted for people in secondary 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. However, any use of 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.

It seems reasonable to say that no specific treatment should be delivered to this group of individuals in the absence of good clinical care. This is an important and topical message when the Improving Access to Psychological Therapies initiative is being extended to people with 'severe mental illness', which includes PD.[103] Structured clinical management of people with PDs is an important aspect of treatment, it is not an alternative to specific treatments but rather the bedrock on which these treatments may be offered.

Some participants expressed reservations about group sessions, both in terms of the content being challenging and also concerning anxieties about being with other people. Others found group work to be an informative process and the support of others was deemed helpful. A general message is a greater investment in preparing people for group treatment may be worthwhile to prevent treatment non-completion.[104] The higher costs of group versus individual sessions may make individual preparation sessions cost-effective (£476 vs. £119, respectively).

Psychoeducation with problem-solving was also reported to have equipped a workforce of mental health professionals to offer consistently skilled responses to people presenting with PD. Although this intervention did not achieve the standard for significance, a positive working alliance and a willingness among many people with PD to master well-defined skills suggests that a promising start was made to developing general staff competencies and engaging people with PD in services.

Implications for researchers

Defining and reporting adverse effects of psychological therapies

The issue of defining and recording adverse events in trials of complex psychosocial interventions has been highlighted as of crucial importance. Consideration of potential harms has not been given adequate attention in clinical trials of psychosocial interventions with people with PDs or participants with other types of problems.[82,105,106] Specification of the nature of possible harms and identification of the type of person who may be susceptible to harm is important information to collect to establish risk–benefit balances that ought to be available to clinical services to inform the choice of treatments provided and to patients to help them make decisions about consenting to psychosocial treatment. Linden[107] has offered definitions of a range of unwanted events and adverse treatment reactions and has constructed a checklist for recording the existence, severity and treatment-relatedness of these events that may be of value for systematic observation of harms in clinical trials. Jonsson *et al.*[105] offer suggestions for collecting and reporting adverse effects in RCTs, including providing a plan for how harms will be detected within the protocol for ethical review, using structured assessment methods such as checklists or rating scales, active and regular monitoring, and reporting the absence of harms as well as the occurrence of harms. At the consent stage it is worth asking participants for permission to access official records that may assist in the identification of adverse events, including centrally held NHS data via the Health and Social Care Information Centre.

Processes for stopping trials of psychological therapies

Consideration should be given in advance to procedures for stopping trials of psychosocial interventions, should this be necessary. The difficult and traumatic halting of PEPS was made more challenging by the need for additional, very specific procedures to be implemented. It was important that this was undertaken both swiftly and safely, and the procedure we followed has already been presented.[83] We hope to fully publish this experience to guide funders, sponsors, participants, trial units and triallists.

Recommendations for research

Methodological research

Measuring adverse events in psychological therapies

There is clearly a place for systematic research into the definition and prevalence of adverse effects of psychological therapies. We know of some ongoing work in Sheffield [www.shef.ac.uk/scharr/sections/hsr/mh/mhresearch/adeptproject (accessed 25 April 2016)] and await results of this important initiative.

Procedures for stopping trials of psychosocial interventions

We have discovered that there is not clarity around this issue. We suggest that Delphi work could inform a working party to draw on collective experience and consideration of specific examples in order to inform policy and the design and conduct of trials.

Core outcomes

There is a need to define and gain consensus for a core outcome data set for trials such as PEPS. We think a Core Outcome Measures in Effectiveness Trials initiative (COMET; www.comet-initiative.org), specific to psychological interventions for people with borderline personality difficulties is indicated, or this area of evaluative research will continue to be dogged by use of different measures, used with no agreed consistency.

Service delivery analysis

Pathways of care for people with personality disorder

Service research into defining and implementing pathways of care for people with PD is urgently needed. Given emerging evidence that good clinical care is as effective as 'active' treatments,[95,98–100] more should be done to understand the barriers to, and facilitators of, the implementation of good care. Both qualitative and quantitative investigation is indicated.

Economics

Economic evaluations of interventions for people with personality disorder

Evidence from this study shows that people with PD are heavy users of mental health services and have poor quality of life in comparison with people with other disorders. Overall, participants in this trial had annual costs of around £8000 (based on the baseline data) and QALYs were around one-third of those of people with full health. Evaluations of treatments for people with PD should continue to address both costs and quality of life.

Evaluations

James Lind initiative

There are several ongoing James Lind initiatives in mental health care. It would seem that there could be a priority-setting exercise conducted for questions of relevance to the care of people with borderline-type problems.

Disaggregation of psychoeducation and problem-solving therapy

Although PEPS therapy as a whole was not effective, there were differences in uptake of the individual psychoeducation sessions and the group problem-solving sessions. Individual psychoeducation sessions were well attended, and this component of the intervention may be worth evaluating separately. However, care should be taken to embed this in good clinical care.

Active comparator

As good-quality clinical care has established effectiveness, future trials ought to be a comparison between good-quality routine clinical care versus good-quality clinical care plus the experimental intervention. This would answer the question as to what additional value was conferred by the intervention over and above that from good-quality routine clinical care. This type of design has not been employed, to date, in PD treatment trials. This would require specification and monitoring of good-quality clinical care. In addition, the impact of continuation of care after the end of the experimental treatment could be tested.

Adverse events

We plan to investigate adverse events further by accessing centrally held NHS data on deaths and hospitalisations for all PEPS trial participants. Because we do not have consent from all participants to do this, accessing this information without participant consent requires approval from the Health Research Authority Confidentiality Advisory Group. In light of the trial stoppage for safety reasons, we have a clear justification for requesting approval.

Other interventional research

This is a grossly under-researched area. There is a place for a broad overview of all evaluative studies in this area, to produce a map of where randomised research exists and where it does not. The number and power of studies in this area would then become obvious. In this way, guidance on what systematic reviews are possible can be created and, where relevant to NHS practice, those interventions in everyday practice that have not been fairly tested in trials could then be randomised within the context of routine care.

Final statement

This rigorous trial has established that PEPS therapy is not an effective treatment for improving social functioning in community adults with PD. This is despite PEPS being based on solid theoretical and empirical foundations,[43,56] on therapy components with demonstrated effectiveness in dealing with a range of psychological problems[31,36,37] and which has been deemed helpful by those who have received it.[49] This is not the first psychosocial intervention that has appeared promising – theoretically, empirically and by favourable participant judgement – but has proved in rigorous trials to be ineffective or even harmful.[108,109] Information from this study indicates that people with PD have poor quality of life and are heavy users of health and social services. It is important to continue to seek effective management and treatment for this group of troubled individuals. Good-quality research is the only way to provide evidence of what is genuinely effective, or ineffective, and is the best way to serve patients, their family and friends, and our wider society. Such research is expensive, but the costs of not conducting such research may well be greater.

Acknowledgements

We thank all those who took part in the trial and clinical staff at the participating sites for their support.

The PEPS Trial Collaborative Group acknowledges the support of the National Institute for Health Research, through the Mental Health and Primary Care Research Networks and the National Institute for Social Care and Health Research in Wales.

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The research was supported by the following people: Madeline Dean, Dina Gazizova, Sarah Johnson, Antoinette McNulty, Lesley O’Connell, Lorraine O’Connell, Rosemary Stevenson, Raphael Underwood, Sharmini Rajenthran and Tendai Rushwaya.

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The research was supported by the following people: Tracey Brain, Delyth Braim, Sarah Hunt, Cat Johnston, Sandra Jumbe, Tracey Roberts and Daniel Webb.

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Stewart Mitchell provided local clinical supervision for the PEPS therapists.

The research was supported by the following people: Karen Bibbings, Philippa Bolton, Emily Clare, Gillian Cunningham, Jacqueline Harvey, Lesley Haley, Val Heard, Anthony Jones, Deborah Kemp, Saffra Knox, Sophie Lake, Cameron Martin, Paul Moran, Kerry Stott, Sophie Sultana and Corinne Vaughan.

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Data sharing statement

Data may be obtained from the NCTU according to their policy for sharing individual participant data from clinical trials.

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Appendix 1 Psychoeducation facilitators' manual

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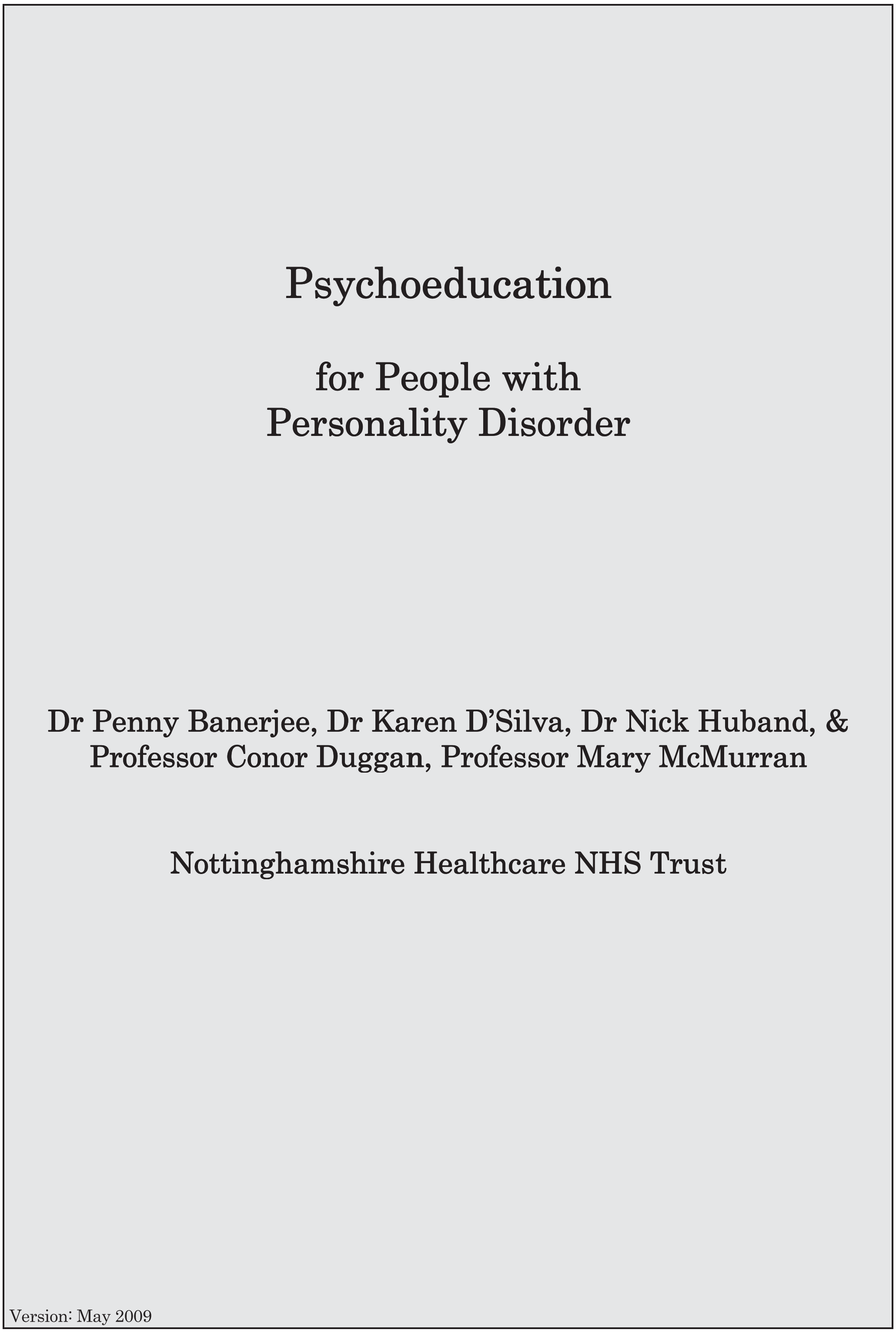

Psychoeducation

for People with
Personality Disorder

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Version: May 2009

Using this Manual

This manual has been designed to be used alongside training in the delivery of psychoeducation. It should not be used without this training.

Contents

Introduction

The psychoeducation programme presented in this manual formed part of a treatment for community-dwelling men and women with personality disorders that was evaluated in a community-based randomised controlled trial (Huband, McMurran, Evans, & Duggan, 2007). In this trial, individual psycho-education sessions preceded *Stop & Think!,* a group social problem solving intervention. Those treated improved in their self-reported social functioning and reduced their anger expression scores significantly more than those who received treatment as usual. The purpose of this manual is to describe the rationale and evidence for using psychoeducation alongside social problem solving therapy for people with personality disorders, as well as to give a detailed description of how to implement the psychoeducation part of this programme.

Psychoeducation

This programme of psychoeducation for people with personality disorders developed from the observation that, among a sample of forensic inpatients with personality disorder, few people actually knew about and understood their diagnoses, and that many of those that did have information had picked this up from reports rather than having been directly informed by a clinician (D'Silva & Duggan, 2002). This shortcoming led to the development of an educational component in which personality disorder diagnosis, traits, and problems in interpersonal functioning were discussed in a collaborative dialogue between the clinician and patient (Banerjee, Duggan, Huband & Watson, 2006; D'Silva & Duggan, 2002). A study of the impact of four sessions of psychoeducation with 34 patients found not only that the patients' knowledge about their disorder improved, but also that the therapeutic alliance was enhanced by the intervention.

This psychoeducation module was included as the first part of the treatment in Huband et al.'s (2007) treatment trial for people with personality disorder. Individual psychoeducation sessions preceded the group social problem solving sessions. The aims of psychoeducation were to provide individuals with information about their personality disorder, to discuss the problems they experienced in relation to their personality disorder, and to identify problems that could be focused upon in the problem solving group sessions that formed the next stage of treatment. Participation in the psycho-education programme was intended to build a therapeutic alliance and enhance motivation for therapy.

The International Personality Disorder Examination

The psychoeducation module was developed to follow administration of the interview version of the International Personality Disorder Examination (IPDE; Loranger, 1999). The IPDE is a structured clinical interview that assesses personality disorder, and the results of this assessment are used in the psychoeducation programme. Use of the psychoeducation module therefore requires a trained clinician to carry out this assessment. Training in the IPDE is available only to appropriately qualified mental health professionals, who will have knowledge about personality disorder and clinical experience of the diagnosis and treatment of people with personality disorder. Thus, this manual assumes a high degree of knowledge and the content does not cover basic personality disorder diagnostic issues.

Format of the psychoeducation programme

The psychoeducation programme described here makes use of the results of the IPDE assessment, which is administered prior to the programme to identify the specific difficulties each person is experiencing. Difficulties are defined as those IPDE items that have been scored as 2, i.e., at the criterion level for diagnosis. The results of the IPDE assessment will be compared with the client’s own view of his or her difficulties and any differences in opinion are discussed. The main focus of the education component is to examine the individual’s persistent recurring patterns of thoughts, feelings and behaviours and the interpersonal consequences of these. By the end of the psychoeducation programme, each individual should be able to identify his or her own personality difficulties and understand how they relate to his or her individual interpersonal style. Participants are also encouraged to define personal goals for change to address in the therapy that follows.

The psychoeducation module is offered in up to four individual one-hour sessions, typically once per week. Some individuals will be comfortable covering the necessary material in fewer but longer sessions, whereas others who find it more difficult to concentrate may benefit from having a greater number of shorter sessions. In our trial, the psychoeducation component was delivered in an average of three sessions (Huband et al., 2007).

Aims of the psychoeducation programme

The aims of the psychoeducation programme are as follows:

1. To provide a basis for establishing rapport between client and clinician, and hence a means of establishing a therapeutic alliance.
2. To provide the client with an understanding of his/her personality problems and how such problems relate to their style of interpersonal functioning.
3. To introduce the client to the concept that personality problems may be ameliorated by acquiring new skills.
4. To provide the client with a focus for areas of change and hence to agree treatment goals.
5. To promote the concept of taking responsibility for behaviour.

The psychoeducation module is presented here in three sessions that follow a structured but flexible format. The first session is used to explain what personality problems are all about, the second to assess and improve the individual's understanding of their own difficulties, and the third to identify what the client wants to change. The content of the psychoeducation sessions is provided below.

Psychoeducation Sessions

Session tasks are listed below. The materials required for each session are highlighted in bold.

Session 1

- Carry out the **Brief Structured Interview**
- Give client the information sheet, **All About Problems and Personality.**
- Talk through this material and introduce the idea of skills training.

Session 2

- Support the client in completing the **Problems Checklist (Client Version)**.
- Draw attention to the interpersonal themes recorded on the list.
- Make a note of which boxes the client has ticked.
- Ask client to complete the worksheet- **What do I want to change about myself?** Use this to list five things he or she wishes to change.

After the session, compare the ticked items with the results of his/her IPDE assessment, focusing on those items that have been scored at the criterion level, i.e., score 2. Mark these onto the **Problems Checklist (Clinician Version)** for discussion with the client in the next session. Note that this checklist has sub-headings that relate to the various PD diagnoses.

Session 3

- Discuss the **Problems Checklist (Clinician Version).**
- Discuss how the client's self-assessment compares with problems identified by the IPDE assessment.
- Discuss how problems can be grouped together and described as personality traits.

- Firm up treatment goals in the list of five things the client wishes to change identified in Session 2. Ensure both parties have these written down.
- Address any anxieties about the forthcoming *"Stop & Think!"* group therapy.

After the sessions, arrange for the preparation of a personalised booklet for each client in which the information from these sessions is stored.

Psychoeducation Session 1.

What is personality and how can it lead to problems?

Session summary

- Carry out the **Brief Structured Interview** with the client.
- Give client information sheet entitled **All About Problems and Personality.**
- Talk through this material and introduce the idea of skills training.

Aims of the session

1. To assess the client's understanding of personality.
2. To introduce the idea that personality is the way we think feel and behave.
3. To start to build rapport/therapeutic alliance.
4. To introduce the idea that you can learn skills that will make it easier to sort out life's problems.

Assess the client's understanding of personality using the **Brief Structured Interview** (see Table 1), which consists of four questions that focus on personal difficulties and how such difficulties affect interpersonal functioning.

Table 1

Brief Structured Interview

1. What does the word 'personality' mean to you?
2. Do you think your personality causes you problems? In what way?
3. Do you think your personality causes problems for other people? In what way?
4. Would you like to change the way you handle problems?

The answers to the Brief Structured Interview questions provide a baseline for the interviewer to discuss personality disorder and its aetiology and also to check the clients understanding of their disorder.

Then give the information sheet, **All About Problems and Personality** (Appendix 2) to the client. Explain the nature of personality and personality difficulties and discuss this with the client. Introduce the concept that personality problems may be ameliorated by acquiring social problem solving skills, with reference to the forthcoming group work.

Psychoeducation Session 2

Identifying your problems

Session summary

- Support the client in completing the **Problems Checklist (Client Version).**
- Draw attention to the interpersonal themes recorded on the list.
- Make a note of which boxes the client has ticked.
- Ask client to complete the worksheet- **What do I want to change about myself?**

After the session, compare the ticked items with their IPDE results (items scored 2). Mark these onto the **Problems Checklist (Clinician Version)** for discussion with the client in the next session. Note that this checklist has sub-headings that relate to the various PD diagnoses.

Aims of the session:

1. To identify aspects of the clients life that cause problems
2. To compare the client's views of their problems with other people's views and with problem areas identified at assessment/by the IPDE.
3. To discuss any differences that arise and why people might see things differently.
4. To help the client to select five realistic difficulties to try to change.

Go through the **Problems Checklist (Client Version)** (Appendix 3) with the client. This summarises personal difficulties. The client is asked to tick which checklist items apply to him or her personally. The list can be taken home for further consideration or to ask the opinion of others. The clinician retains a copy of the checklist. A separate sheet, the **Problems Checklist (Clinician Version)** (Appendix 4) is then used to collate the client's scores into problem areas, which may be used to inform feedback. These problem areas may equate to personality traits or personality disorders.

The client is then helped to identify a maximum of five difficulties that they want to work on in the forthcoming *Stop & think!* group sessions using the worksheet, **What do I want to change about myself?** (Appendix 5). In some cases, a client may choose a problem that is not specified on the checklist. Some people, for example, may chose a long-standing interpersonal problem that is not specified in the list (perhaps a self-defeating or a sadistic trait), or a problem that is not easily summarised by one of the DSM-derived checklist items (such as becoming more assertive when conversing with authority figures). Input from the clinician is advisable, however, to guide the participant towards selecting difficulties and goals that can be defined with reasonable clarity, which are important to tackle, and which are realistic to address in *Stop & Think!* sessions. It would, for example, be unrealistic for someone who has been cutting herself for many years to expect to suddenly stop doing so, or for someone who was chronically avoidant to have as his goal to be able to hold a successful party every weekend.

Psychoeducation Session 3

Prioritising problems for group work

Session summary

- Discuss the **Problems Checklist** (Clinician Version).
- Discuss how client's self-assessment compares with problems identified by the IPDE.
- Discuss how problems can be grouped together and described as personality traits.
- Firm up treatment goals and ensure both parties have these written down.
- Address any anxieties about the forthcoming *"Stop & Think!"* group.

After the session, arrange preparation of personalised booklet for the client in which the information from these sessions is stored.

Aims of the session:

1. To review work from the previous session.
2. To explain how the problems the person experiences relate to their personality traits.
3. To clarify what the client wishes to change.
4. To finalise list of five things the client would like to change.
5. To produce and discuss the personal booklet.

Review work from the previous session. Summarise the identified difficulties under personality traits and discuss in general terms how these might affect the individual or their behaviour. Clarify the client's views on what he or she would most like to change about him- or herself. Firm these up as treatment goals. Reinforce the concept of personality disorder as amenable to amelioration by skills acquisition. It is important that the client retains all materials from these three sessions. Each subsequently receives a booklet summarising his/her own difficulties and goals for change. Finally, address any anxiety about the forthcoming *Stop & think!* group programme.

Finally

Ask clients to provide feedback on their experience of Psychoeducation (Appendix 6).

A report on Psychoeducation may be prepared for referrers and the client's record (Appendix 7).

References

Banerjee, P., Duggan, C., Huband, N., & Watson, N. (2006). Brief psychoeducation for people with personality disorder: A pilot study. *Psychology and Psychotherapy: Theory, Research and Practice, 79,* 385-394.

D'Silva, K., & Duggan, C. (2002). The development of a psycho-educational programme for personality disordered patients. *Psychiatric Bulletin, 26*, 268-271.

Huband, N., McMurran, M., Evans, C., & Duggan, C. (2007). Social problem solving plus psychoeducation for adults with personality disorder: A pragmatic randomised controlled trial. *British Journal of Psychiatry, 190,* 307-313.

Loranger, A.W. (1999). *International Personality Disorder Examination (IPDE).* Odessa, FL: Psychological Assessment Resources.

Appendices

Appendix 1	Brief Structured Interview
Appendix 2	All About Problems and Personality information sheet
Appendix 3	Problems checklist (Client Version)
Appendix 4	Problems checklist (Clinician Version)
Appendix 5	What do I want to change about myself? worksheet
Appendix 6	Participant evaluation form
Appendix 7	Psychoeducation report pro forma

Brief structured interview

(given at beginning of the psychoed sessions)

Name: ______________________________ Date: ______________

I want to ask about you and your personality. There are just six short questions.

Question 1

What does the word ‘personality’ mean to you?

Question 2

Do you think your personality causes you problems? In what way?

Question 3

Do you think your personality causes problems for other people? In what way?

Question 4

Would you like to change the way you handle problems?

Question 5

Some people are diagnosed as having a personality disorder. Do you know what a personality disorder is?

Question 6

Have you ever been told you might have a personality disorder?

All About Problems and Personality

What are personality problems?

We all have problems, and especially problems with other people. These problems crop up from time to time and we all try to deal with them.

Some people seem to find a way of dealing with each new problem they find. They have the knack of getting their problems sorted. Lucky them.

For others, it's more difficult. They try to sort their problems, but their 'personality' seems to get in the way. They find themselves doing things much the same way each time. Perhaps making the same mistakes again. It is like repeating the same patterns of behaviour again and again and their problems don't get sorted properly. They are often unhappy. Those around them are often unhappy as well. If you are one of these people, you will want something to change.

So what is my 'personality' and how does it mess things up?

Personality is just the way you usually <u>think</u>, <u>feel</u> and <u>behave</u>. It's just how you are.

Your personality may get in the way of getting your problems sorted. You find you think, feel and behave much the same way every time. And because of how you think, feel and behave, things continue to go wrong.

Why does this happen?

We think some people just haven't been given the **<u>skills</u>** to get things sorted. Not really their fault.

Maybe nobody gave them the right skills. Maybe they were unable to learn the skills. So their personality (their usual way of thinking, feeling and doing) takes over. And it doesn't work too well. So problems don't get sorted out. And the problems keep coming back.

This project is all about learning new skills that can help stop this happening. Breaking the cycle.

What is personality disorder?

A person is said to have a personality disorder if their personality causes distress or difficulties for themselves or others, and this happens over and over again.

A personality disorder must have the three **P**s. It must be:

Problematic	It causes distress or difficulties for the person or for other people. It can lead to problems with relationships, with employment, and with the law.
Persistent	This way of thinking, feeling and behaving is long-standing. The difficulties tend to appear in late childhood and teenage years and continue into adult life.
Pervasive	This way of thinking, feeling and behaving occurs in many situations.

What can be done to help?

You have agreed to take part in the *"Stop & Think!"* treatment. This can help you to change some of your ways of thinking, feeling and behaving. But only if that is what you want.

These changes can allow a person to have a better quality of life. These changes can allow them to function better with other people. At the end of the day, it's up to you.

What do I have to do to make this work?

First, you need to be clear about what bits of your thinking, feeling and behaving you really want to change. The *Stop & Think!* worker will help you decide.

In the next session, you'll look at a list of problems. You'll tick those problems that apply to you. Then you'll go away and pick the 5 you most want to change.

Once you've chosen these, you can go ahead and join the group. The *Stop & Think!* worker will explain what the group work involves. We don't pretend it'll be easy – changing and learning new things never is. But it might be worth a bit of effort.

It's all about you learning new skills to help yourself get a better quality of life.

Problems Checklist (Client Version)

Do you have any of these problems?

If you do, which of them would you most like to change?

(1) Problems making it hard to want any close relationships

☐ Finds it hard to trust people - sometimes finds it hard to trust friends
☐ Often thinks: *"that person is out to get me"*
☐ Doesn't like confiding in others in case they can't be trusted
☐ Often notices other people's casual comments; thinks *"they're having a go at me"*
☐ Finds it hard to forgive people - often bears a grudge
☐ Gets annoyed if others are critical or make comments
☐ Quick to be suspicious that a loved-one is not being faithful
☐ Believes strongly in magic and supernatural forces
☐ Sees and notices things that most other people don't see and notice
☐ Has very few close friends
☐ Gets uncomfortable with people - worries that they might be a threat
☐ Experiences things that other people often don't seem to know about
☐ Has thoughts that other people don't seem to have
☐ Says things that other people regard as strange
☐ Does things that seem sensible, but which others think rather unusual
☐ Dresses in a way that others think is odd
☐ Is suspicious - feels that others are out to get them
☐ Doesn't want close relationships and doesn't like them
☐ Usually prefers doing things alone
☐ Doesn't have much interest in sex
☐ Finds it hard to enjoy anything
☐ Has very few close friends
☐ Isn't impressed by other people's praise
☐ Isn't bothered by other people's critical comments
☐ Sometimes seen by others as rather cold and unemotional

(2) Problems making it hard to keep close relationships

☐ Often has a need to flirt - can be seductive
☐ Worries a lot about own appearance and whether people notice
☐ Has a way of showing feelings that people say is very dramatic
☐ Unhappy if not the one who stands out in the crowd
☐ Has feelings that often change suddenly and unexpectedly
☐ Tends to talk dramatically - doesn't bother with the details
☐ Easily influenced by people and situations
☐ Often feels very close to new people after spending very little time with them
☐ Often skipped school *(before age 15)*
☐ Ran away from home overnight more than once *(before age 15)*
☐ Often started fights *(before age 15)*
☐ Used a weapon more than once *(before age 15)*
☐ Was sometimes cruel to animals or was cruel to people *(before age 15)*
☐ Sometimes destroyed other people's property or started fires *(before age 15)*
☐ Often lied *(before age 15)*
☐ Stole from people *(before age 15)*
☐ Finds it hard to hold down a steady job
☐ Finds it hard to stay out of trouble
☐ Often gets into fights
☐ Not good at paying bills or debts
☐ Often lies or cons people
☐ Often takes chances - does reckless things
☐ After breaking the law, feels there was good reason for the crime - is not sorry
☐ Finds it hard to plan ahead
☐ Often uses people - takes advantage of them
☐ Sees self as important - gets annoyed when people don't respect this
☐ Has problems that are different from those other people have
☐ Thinks a lot about being famous, powerful or attractive
☐ Feels a real need to be treated as a special person
☐ Needs to be admired - much happier when the centre of attention
☐ Finds it hard to be concerned about how other people feel
☐ Often feels jealous of others – or that others are jealous
☐ All relationships seem to be intense - lots of ups and downs
☐ Sometimes acts suddenly - doesn't care that this might be self-damaging
☐ Can experience sudden mood swings - these can be very powerful

- ☐ Has angry outbursts - things can get smashed, sometimes people get hit
- ☐ Often behaves as if suicidal - has episodes of self-harm
- ☐ Finds it hard to decide what's important in life
- ☐ Uncertain about self-image - often thinks *"Who am I?"*
- ☐ Finds it hard to control angry outbursts
- ☐ Usually feels empty - often feels bored
- ☐ When stressed, finds people and surroundings don't seem real anymore
- ☐ Can make frantic efforts to stop someone close from leaving
- ☐ When stressed, can feel very paranoid
- ☐ Finds it hard to plan ahead

(3) Problems making it hard to form close relationships

- ☐ Finds it hard to make decisions - needs reassurance and advice from others
- ☐ Likes others to make important decisions and take responsibility
- ☐ Finds it hard to disagree with someone - scared of losing their support
- ☐ Lacks self-confidence - finds it difficult to do things without others helping
- ☐ Offers to do unpleasant things for other people - to make sure of their support
- ☐ When alone, feels helpless and unable to care for self
- ☐ If a close relationship ends, quickly seeks another relationship for care and support
- ☐ Worries a lot about being left to manage alone
- ☐ Feels inferior to others
- ☐ Won't get involved with people unless sure of being liked
- ☐ Avoids mixing with others - scared they will criticise or disapprove
- ☐ Very careful and guarded in close relationships
- ☐ Worries a lot about being rejected by others
- ☐ Doesn't function well with new people - feels very inadequate
- ☐ Avoids new social situations - worries about being embarrassed
- ☐ Thinks too much about rules, details and lists
- ☐ Finds being a perfectionist makes it very difficult to get things done
- ☐ Needs to concentrate on work all the time - enjoys being very productive
- ☐ Has definite ideas about right and wrong - feels things must always be correct
- ☐ Unable to throw away objects that others might see as useless or worthless
- ☐ Finds it hard to work with others, especially if they want to do things a different way
- ☐ Doesn't like spending money unnecessarily - or wasting it on gifts
- ☐ Doesn't like change - sometimes seen as inflexible and stubborn
- ☐ Sometimes does things slowly or badly on purpose
- ☐ Feels other people don't understand and don't appreciate

☐ Gets out of doing things by pretending to have forgotten they need doing

☐ Doesn't like people in authority - often criticises them

☐ Often grumpy and argumentative

☐ Gets annoyed and envious when others seem to get a better deal out of life

☐ Complains about having bad luck and often blames others for this – then changes and blames self

Problems Checklist (Clinician Version)

Do you have any of these problems?

If you do, which of them would you most like to change?

Paranoid problems - make it hard to want any close relationships

- ☐ Finds it hard to trust people - sometimes finds it hard to trust friends
- ☐ Often thinks: *"that person is out to get me"*
- ☐ Doesn't like confiding in others in case they can't be trusted
- ☐ Often notices other people's casual comments; thinks *"they're having a go at me"*
- ☐ Finds it hard to forgive people - often bears a grudge
- ☐ Gets annoyed if others are critical or make comments
- ☐ Quick to be suspicious that a loved-one is not being faithful

Schizotypal problems - make it hard to want any close relationships

- ☐ Believes strongly in magic and supernatural forces
- ☐ Sees and notices things that most other people don't see and notice
- ☐ Has very few close friends
- ☐ Gets uncomfortable with people - worries that they might be a threat
- ☐ Experiences things that other people often don't seem to know about
- ☐ Has thoughts that other people don't seem to have
- ☐ Says things that other people regard as strange
- ☐ Does things that seem sensible, but which others think rather unusual
- ☐ Dresses in a way that others think is odd
- ☐ Is suspicious - feels that others are out to get them

Schizoid problems - make it hard to want any close relationships

- ☐ Doesn't want close relationships and doesn't like them
- ☐ Usually prefers doing things alone
- ☐ Doesn't have much interest in sex
- ☐ Finds it hard to enjoy anything
- ☐ Has very few close friends

- ☐ Isn't impressed by other people's praise
- ☐ Isn't bothered by other people's critical comments
- ☐ Sometimes seen by others as rather cold and unemotional

Histrionic problems - make it hard to <u>keep</u> close relationships

- ☐ Often has a need to flirt - can be seductive
- ☐ Worries a lot about own appearance and whether people notice
- ☐ Has a way of showing feelings that people say is very dramatic
- ☐ Unhappy if not the one who stands out in the crowd
- ☐ Has feelings that often change suddenly and unexpectedly
- ☐ Tends to talk dramatically - doesn't bother with the details
- ☐ Easily influenced by people and situations
- ☐ Often feels very close to new people after spending very little time with them

Antisocial problems *(before age 15)* - make it hard to <u>keep</u> close relationships

- ☐ Often skipped school
- ☐ Ran away from home overnight more than once
- ☐ Often started fights
- ☐ Used a weapon more than once
- ☐ Was sometimes cruel to animals or was cruel to people
- ☐ Sometimes destroyed other people's property or started fires
- ☐ Often lied
- ☐ Stole from people

Antisocial problems *(since age 15)* - make it hard to <u>keep</u> close relationships

- ☐ Finds it hard to hold down a steady job
- ☐ Finds it hard to stay out of trouble
- ☐ Often gets into fights
- ☐ Not good at paying bills or debts
- ☐ Often lies or cons people
- ☐ Often takes chances - does reckless things
- ☐ After breaking the law, feels there was good reason for the crime - is not sorry
- ☐ Finds it hard to plan ahead

Narcissistic problems - make it hard to keep close relationships

☐ Often uses people - takes advantage of them
☐ Sees self as important - gets annoyed when people don't respect this
☐ Has problems that are different from those other people have
☐ Thinks a lot about being famous, powerful or attractive
☐ Feels a real need to be treated as a special person
☐ Needs to be admired - much happier when the centre of attention
☐ Finds it hard to be concerned about how other people feel
☐ Often feels jealous of others – or that others are jealous

Borderline problems - make it hard to keep close relationships

☐ All relationships seem to be intense - lots of ups and downs
☐ Sometimes acts suddenly - doesn't care that this might be self-damaging
☐ Can experience sudden mood swings - these can be very powerful
☐ Has angry outbursts - things can get smashed, sometimes people get hit
☐ Often behaves as if suicidal - has episodes of self-harm
☐ Finds it hard to decide what's important in life
☐ Uncertain about self-image - often thinks *"Who am I?"*
☐ Finds it hard to control angry outbursts
☐ Usually feels empty - often feels bored
☐ When stressed, finds people and surroundings don't seem real anymore
☐ Can make frantic efforts to stop someone close from leaving
☐ When stressed, can feel very paranoid
☐ Finds it hard to plan ahead

Dependent problems - make it hard to form close relationships

☐ Finds it hard to make decisions - needs reassurance and advice from others
☐ Likes others to make important decisions and take responsibility
☐ Finds it hard to disagree with someone - scared of losing their support
☐ Lacks self-confidence - finds it difficult to do things without others helping
☐ Offers to do unpleasant things for other people - to make sure of their support
☐ When alone, feels helpless and unable to care for self
☐ If a close relationship ends, quickly seeks another relationship for care and support
☐ Worries a lot about being left to manage alone

Avoidant problems - make it hard to form close relationships

☐ Feels inferior to others
☐ Won't get involved with people unless sure of being liked
☐ Avoids mixing with others - scared they will criticise or disapprove
☐ Very careful and guarded in close relationships
☐ Worries a lot about being rejected by others
☐ Doesn't function well with new people - feels very inadequate
☐ Avoids new social situations - worries about being embarrassed

Obsessive-compulsive problems - make it hard to form close relationships

☐ Thinks too much about rules, details and lists
☐ Finds being a perfectionist makes it very difficult to get things done
☐ Needs to concentrate on work all the time - enjoys being very productive
☐ Has definite ideas about right and wrong - feels things must always be correct
☐ Unable to throw away objects that others might see as useless or worthless
☐ Finds it hard to work with others, especially if they want to do things a different way
☐ Doesn't like spending money unnecessarily - or wasting it on gifts
☐ Doesn't like change - sometimes seen as inflexible and stubborn

Passive-aggressive problems - make it hard to form close relationships

☐ Sometimes does things slowly or badly on purpose
☐ Feels other people don't understand and don't appreciate
☐ Gets out of doing things by pretending to have forgotten they need doing
☐ Doesn't like people in authority - often criticises them
☐ Often grumpy and argumentative
☐ Gets annoyed and envious when others seem to get a better deal out of life
☐ Complains about having bad luck and often blames others for this – then changes and blames self

What do I want to change about myself?

On the checklist, you will probably have ticked quite a few of the boxes.
Have a close look at all the problems you have ticked.
Which are the ones you most want to change?
(pick the 5 most important and write them below)

I want to change the following things about myself:

1)

2)

3)

4)

5)

Psychoeducation
End of course feedback form

In order for us to make Psychoeducation as useful as possible to future participants we would like you to give us your opinions on your experience

1. Please list the main things you have learnt:

2. Overall how useful was Psychoeducation to you? (Please circle the most appropriate number.)

1 2 3 4 5 6 7 8 9 10
not at all fairly very

3. How interesting was Psychoeducation to you?

1 2 3 4 5 6 7 8 9 10
not at all fairly very

4. How enjoyable was Psychoeducation to you?

1 2 3 4 5 6 7 8 9 10
not at all fairly very

5. What changes would make Psychoeducation better?

6. What were the most useful bits?

Thank you

Psychoeducation - end of course summary

Name	Date of Birth	ID no
Start date / / end / /	Course competed Yes/No	
Therapist.	signature	

Diagnosis	? IPDE score ? agreed diagnosis
Clients view of diagnosis (include a statement of whether the client agrees with the diagnosis and if they do not agree list which aspects they do not agree with and why)	

Aims of Psychoeducation

1. To provide a basis for establishing rapport between client and clinician, and hence a means of establishing a therapeutic alliance.
2. To provide the client with an understanding of his/her personality problems and how such problems relate to their style of interpersonal functioning.
3. To introduce the client to the concept that personality problems may be ameliorated by acquiring new skills.
4. To provide the client with a focus for areas of change and hence to agree treatment goals.
5. To promote the concept of taking responsibility for behaviour.

Overview of psychoeducation (provide a brief summary of the psychoeducation sessions; you might like to relate it to the aims above.)

Name	Date of Birth	ID no

Summary of problems (expand on the list of agreed problems taking into account the discussion you have had around the problems using examples if necessary to show the effect that the problems have on the clients lifestyle and interpersonal functioning.)

Problems the client has identified that they want to change

1.

2.

3.

4.

5.

Other problems the client would like to change but not included as treatment goals

Appendix 2 Psychoeducation participant booklet

Reproduced with permission from Banerjee P, D'Silva K, Huband N, Duggan C. *Psychoeducation for People with Personality Disorder*. Unpublished manual. Nottingham, UK: Nottinghamshire Healthcare NHS Trust; 2009.

Psychoeducation Information Booklet

Personal Information Summary Prepared for

Name ___________________________________

Psychoeducation Information Booklet developed by:

Contents

Confidential Summary

Notes...

My Problems – What I want to change

You identified the following things that you wished to change:

1.

2.

3.

4.

5.

All about problems and personality

What are personality problems?

We all have problems, and especially problems with other people. These problems crop up from time to time – and we all try to deal with them. Some people seem to find a way of dealing with each new problem they find. They have the knack of getting their problems sorted.

For others, it's more difficult. They try to sort their problems, but their 'personality' seems to get in the way. They find themselves doing things much the same way each time. Perhaps making the same mistakes again. And their problems don't get sorted properly. They are often unhappy. Those around them are often unhappy as well. If you are one of these people, you will want something to change.

.

All about problems and personality

So what is my 'personality' and how does it mess things up?

Personality is just the way you usually **think**, **feel** and **behave**. It's just how you are. Your personality may get in the way of getting your problems sorted. You find you think, feel and behave much the same way every time. And because of how you think, feel and behave, things continue to go wrong.

Why does this happen?

We think some people just haven't been given the **skills** to get things sorted. Not really their fault. Maybe nobody gave them the right skills. Maybe they were unable to learn the skills. So their personality (their usual way of thinking, feeling and doing) takes over. And it doesn't work too well. So problems don't get sorted out. And they keep coming back.

Confidential Summary

My Problems Checklist Summary

My Problems Checklist Summary

Confidential Summary

Information about personality disorder

What is personality disorder?

A person is said to have a personality disorder if their personality causes distress or difficulties for themselves or others, and this happens over and over again.

Note: a personality disorder must have the three **P**s. It must be:

Problematic	It causes distress or difficulties for the person or for other people. It can lead to problems with relationships, with employment, and with the law.
Persistent	This way of thinking, feeling and behaving is long-standing. The difficulties tend to appear in late childhood and teenage years and continue into adult life.
Pervasive	This way of thinking, feeling and behaving occurs in many situations.

Information about personality disorder

What can be done to help?

The aim of treatment is to try to change or adapt this problematic way of thinking, feeling and behaving so that the problems it causes (e.g. in relationships, employment and with the law) are reduced.

These changes can allow a person to have a better quality of life. These changes can allow them to function better with other people.

What do I have to do to make this work?

First, you need to be clear about what bits of your thinking, feeling and behaving you really want to change. On the next three pages there is a list of problems you have identified and agreed with your key worker.

On the last page is a list of things you want to change. These are things you can look at in the group. Now you can go ahead and join the group. The *Stop & Think!* worker will explain what the group work involves. We don't pretend it'll be easy – changing and learning new things never is. But it might be worth a bit of effort.

It's all about you learning new skills to help yourself get a better quality of life.

Confidential Summary

My Problems Checklist Summary

When you completed the Problems Checklist, you identified and we agreed upon the following difficulties

Appendix 3 Problem-solving therapy manual

Stop & Think!

Problem solving therapy for people with personality difficulties

Mary McMurran PhD
University of Nottingham

Version: May 2009

Contents

Section

About This Manual

This manual is for use only by those who have received ***Stop & Think!*** training. It should not be altered, copied, or electronically distributed.

Acknowledgement

Thanks are owed to Stephen Coupe, Consultant Clinical Psychologist, who has co-facilitated many ***Stop & Think!*** training courses. In the course of this joint training, Steve has helped clarify many issues and made a significant contribution to the development of this treatment manual.

Section 1.

Introduction

Stop & think! is a form of social problem solving therapy that may be used with people with personality difficulties to help them improve their social functioning. Based upon the work of North American psychologists Thomas D'Zurilla, Arthur M. Nezu, and Christine Maguth Nezu, my colleagues and I have developed ***Stop & think!*** in the UK for people with personality disorders or difficulties. Here, ***Stop & think!*** is presented as an intervention for people with personality difficulties; that is, they may or may not have a formal personality disorder diagnosis. The purpose of this manual is to describe the rationale for using social problem solving therapy with people with personality difficulties, including evidence for the effectiveness of ***Stop & think!***, and then to describe the principles of ***Stop & think!*** practice.

The essential purpose of ***Stop & think!*** is to teach participants a method for solving problems that, once learned, they can use independently. ***Stop & think!*** does this by working on people's current concerns. People's current concerns are 'hot' topics, and working towards a solution has real meaning in the here and now. If ***Stop & think!*** proves effective in ameliorating current problems, then not only has a real problem been addressed, but the effectiveness of the ***Stop & think!*** approach to solving problems has been demonstrated to the participant. This should encourage the participant to try ***Stop & think!*** with other problems he or she is facing. ***Stop & think!*** is therefore designed not only to help people tackle problems that they are currently experiencing, but also to help them practise and assimilate the skills of problem solving so that they can use these independently, without professional help.

The ***Stop & think!*** manual is less highly structured than some other treatment manuals; it does not describe a series of discussions, exercises, and role-plays that make up a session. Because the programme works on people's current concerns rather than tackling problems in the abstract, the programme uses a semi-structured approach. There is a prescribed sequence, but within this there is considerable latitude regarding how facilitators might respond to participants' problems. Because of this, facilitators need to be both experienced professionals and adequately trained to implement ***Stop & think!***

Supervision and support are also highly important with ***Stop & think!*** As with all interventions addressing people's problems, the professional approach is to have regular supervision and support to permit reflection on what is happening in sessions and to address any problems that may be arising. The less structured approach of ***Stop & think!*** makes supervision and support all the more relevant to prevent programme drift and to deal with any practitioner anxieties. This has been taken into account in the development of training for ***Stop & think!*** facilitators, where there is an expectation that supervision is provided to enable staff skill competencies evidenced during training to be developed further as their experience of delivery extends.

Section 2.

Personality disorder and personality difficulties

Personality disorder is defined in the American Psychiatric Association's (1994) *Diagnostic and Statistical Manual of Mental Disorders* as 'an enduring pattern of inner experience and behavior that deviates markedly from the expectations of the individual's culture, is pervasive and inflexible, has an onset in adolescence or early adulthood, is stable over time, and leads to distress or impairment' (p. 629). The personality disorders and their key characteristics are listed in Table 1.

Table 1.

Personality disorders

Personality disorder	Key characteristics
Cluster A	
Paranoid	Distrust, suspiciousness
Schizoid	Socially and emotionally detached
Schizotypal	Unusual perceptions, odd beliefs, socially anxious
Cluster B	
Antisocial	Disregards the rights of others
Borderline	Unstable mood, relationships, and self-image
Histrionic	Excessively emotional, attention-seeking
Narcissistic	Grandiose, lacks empathy, needs admiration
Cluster C	
Avoidant	Socially inhibited, feels inadequate, oversensitive
Dependent	Clinging, submissive
Obsessive-compulsive	Perfectionist, inflexible

In psychiatric diagnostic systems, if these features are present to a certain degree, then a personality disorder diagnosis may be made. However, this diagnostic cut-off point is somewhat arbitrary and often excludes people who have difficulties. Instead of diagnostic cut-offs, personality difficulties can be looked at as existing on a continuum, where the problems are experienced by the person concerned, or others in his or her social world, to a greater or lesser degree. So, personality difficulties would be said to exist where a person has ‘a history of emotional problems and problematic behaviour that leads to distress, difficulties in relating to other people, and poor social functioning’.

How might someone with personality difficulties that could benefit from ***Stop & think!*** present him- or herself? Some examples are presented in Box 1.

Box 1. Examples of how people with personality difficulties may present themselves

¤ When criticised or challenged, they may lose their temper quickly, even to the point of violence. Your point of view will be dismissed as worthless.

¤ They will say they want to change antisocial ways, settle down, and lead a trouble-free life. However, they show a lack of depth and persistence at working towards new life goals and become easily frustrated when things don’t go their way. This can lead to repeated relapses to behaviours that either express or blot out the frustration (e.g., substance use, aggression).

¤ A passive approach to life’s problems may be evident. They may seem to take advice about tackling their problems, but when encouraged to become independent they are likely to react in ways that show they still have serious problems. This may include self-harm, substance use, and threatening harm to others.

Section 3.

Social problem solving

Definitions

What is social problem solving? Social problem solving is: "*the self-directed cognitive-affective-behavioral process by which an individual attempts to identify or discover solutions to specific problems encountered in everyday living"* (D'Zurilla & Nezu, 2007, p. 11). Social problem solving involves thoughts, feelings and behaviour.

What is an effective solution? An effective solution is: *"one that achieves the problem-solving goal (i.e., changes the situation for the better and/or reduces the distress that it produces), while at the same time maximizing other positive consequences and minimizing negative consequences .. to others as well as oneself"* (D'Zurilla & Nezu, 2007, p. 13). Thus, a solution that disregards the welfare of other people is not an *effective* solution.

Good problem-solving skills consist of the ability to recognise problems when they arise, define the problem clearly, set goals for change, produce a diversity of possible solutions, anticipate outcomes, devise effective actions plans that have stepwise stages, and carry out those action plans to solve problems effectively.

Theoretical roots

Social problem solving therapy has its roots in a stress-coping model (Lazarus & Folkman, 1984). In this model, stressors are seen as part of everyday life. The level of an individual's stress response (i.e., psychological and even physical distress) is determined not only by the seriousness of the stressor but also by how the individual appraises the stressor and the skills the individual possess to enable him or her to cope with the stressor. So, an everyday problem, such as a car breakdown, will affect people differently depending on how they *appraise* the problem and how they are able to *cope with* the problem. Consider how people with personality problems might appraise a car breakdown: Someone tampered with it (paranoid); I can't cope with it (dependent); The damned car is a useless piece of tin (antisocial). Also consider how a person's abilities to cope impact upon the stress response. Coping depends in part upon the individual's ***social competence***, that is the ability to interact effectively with others. Social competence is a personal resource that protects against psychological distress. In the car breakdown example, a socially competent person will be able to summon and ask for help effectively.

There is no doubt that a person's physical capital, human capital, and social capital also play a part in determining the stress response. For instance, a person who can afford to be a member of a breakdown service (physical capital), or who knows how to fix cars (human capital), or has a friend who is a mechanic (social capital) is likely to be less stressed by a car breakdown. However, here we focus on social problem solving as it contributes to social competence.

Is poor social problem solving associated with personality disorders?

Poor problem-solving skills are associated with a range of psychological and behavioural problems, including anxiety and depression (Cassidy & Long, 1996; Kant & D'Zurilla, 1997), substance abuse (Herrick & Elliott, 2001), and hostility and aggression (Keltikangas-Järvinen & Pakaslahti, 1999; Matthys, Cuperus, & van Engeland, 1999). These are common problems amongst people with personality problems.

Poor social problem-solving is also associated with personality disorders. We have used the Social Problem Solving Inventory – Revised (SPSI-R; D'Zurilla, Nezu, & Maydeu-Olivares, 2002 – see Section 4 for more details) to compare the problem solving abilities of personality disordered adults, personality disordered offenders, prisoners and mature students (Hayward, McMurran, & Sellen, 2008; Huband, McMurran, Evans, & Duggan, 2007; McMurran, Blair, & Egan, 2002; McMurran, Egan, Blair, & Richardson, 2001). The data presented in Table 2 show that people with personality disorders are more negative, impulsive, and avoidant and less rational in their approach to problems compared with better functioning groups. Herrick and Elliott (2001) found poor problem solving in personality disordered substance abusers, especially in Cluster A, the so-called 'eccentric' personality disorders (i.e., paranoid, schizoid, and schizotypal) and Cluster C, the 'anxious' personality disorders (avoidant, dependent and obsessive-compulsive). Furthermore, vulnerable prisoners are poor at social problem solving (Hayward et al., 2008) and poor social problem solving has been shown to be associated with distress and depression in people detained in a secure setting (Biggam & Power, 1999a,b).

Table 2.

Mean scores and standard deviations on the Social Problem Solving Inventory-Revised for UK male samples

SPSI-R	Personality disordered offenders (N=72)	Personality disordered community adults (N=80)	Vulnerable prisoners on special location (N=68)	Prisoners on normal location (N=47)	Mature students (N=70)
Positive Problem Orientation	9.29 (4.63)	6.36 (4.38)	10.30 (5.43)	12.26 (5.03)	12.82 (4.14)
Negative Problem Orientation	22.33 (8.65)	25.35 (8.34)	23.48 (11.07)	15.53 (12.22)	10.95 (6.79)
Rational Problem Solving	29.19 (18.08)	24.20 (17.53)	38.43 (20.33)	37.49 (17.17)	44.78 (12.60)
Impulsive/ Careless Style	23.32 (8.88)	19.64 (9.00)	21.65 (10.44)	15.02 (10.03)	10.97 (5.84)
Avoidant Style	15.25 (6.48)	14.56 (6.31)	14.73 (7.27)	10.45 (7.62)	8.25 (5.42)
Social Problem Solving	8.52 (3.57)	7.92 (3.41)	9.36 (3.83)	11.78 (4.11)	13.39 (2.51)

Evidence exists to suggest that poor social problem solving mediates the relationship between personality traits and psychological and behavioural problems. A mediator is a variable that explains how one thing has an effect on another. In this case, certain personality traits are more likely to lead to psychological or behavioural problems in people who have poor social problem-solving abilities. In our research, we have found social problem solving to mediate between trait impulsivity and aggression in both men and women (McMurran, Blair, & Egan, 2002; Ramadan & McMurran, 2005). That is, impulsive people are more likely to be aggressive if they have poor social problem solving skills. Social problem solving also mediated between trait impulsivity and heavy drinking in men (McMurran, Blair, & Egan, 2002). This suggest to us that improving social problem solving through therapy might lead to reduced aggression and heavy drinking in impulsive people for whom these behaviours are problematic.

Other research that we have conducted shows that an impulsive/careless problem solving style is associated with borderline, histrionic, and narcissistic personality traits, and a negative approach to problems is associated with avoidant and dependent personality traits (McMurran, Duggan, Christopher, & Huband, 2007). Based upon this research, we have proposed a model of personality difficulties in which the concept of social problem solving is central to adaptive functioning (McMurran, Egan, & Duggan, 2005). This is outlined in Figure 1. We postulate that innate temperament is the developmental start-point for behavioural patterns. Certain temperaments limit and bias information processing, interfering with the acquisition of good social problem solving skills and consequently lead to dysfunctional ways of operating in everyday life. Interpersonal dysfunction causes distress, experienced affectively in a number of ways including anxiety, depression, and anger. Distress further impairs problem solving abilities and may also lead to problematic stress-relieving behaviours, such as substance use, which still further impair social problem solving abilities and also potentially create additional interpersonal problems. Persistent dysfunction leads to a negative approach to life's problems and the development of maladaptive self-schemas that have a further deleterious effect on information processing and social problem solving.

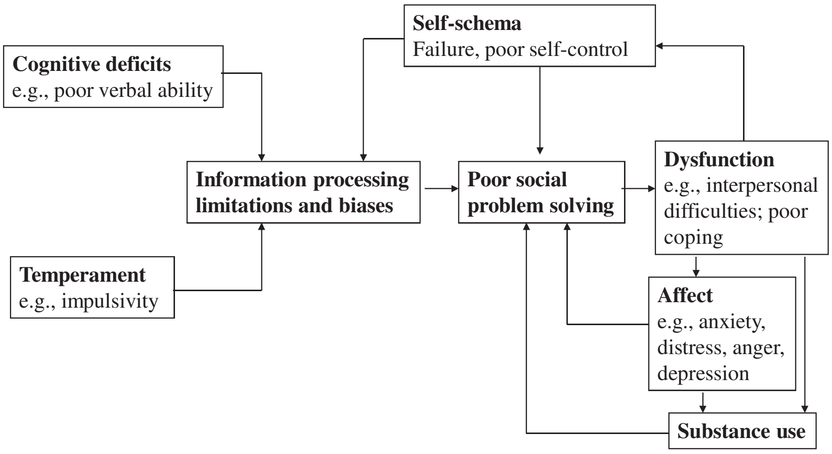

Figure 1. *Social problem solving model of personality difficulties*

In summary, this proposed model indicates the importance of targeting social problem solving skills, not only to assist in finding solutions to current problems, but also as an important means of tackling other emerging difficulties that an individual might experience.

Poor social problem solving may be at the root of interpersonal difficulties and poor coping in the social world, but, furthermore, the distress caused by these problems can be debilitating. Dysfunction and distress can lead to damaging coping behaviours, e.g., substance use. If this maladaptive pattern persists over time, then the person's builds up negative beliefs about him or herself (see Box 2). Distress, damaging coping behaviours, and negative self-beliefs, all interfere with social problem solving in a negative feedback loop.

Box 2. Expressions that indicate negative beliefs about the self

"We've had another argument. It was all my fault. I always screw up in relationships."

"I just cannot control my temper – never could, never will."

"There's no point discussing problems with people – it gets you nowhere."

"People will take the piss if you let them. It's human nature. You have to get them before they get you."

"I'm an easy-going person. It's so much easier to let other people have their own way than to argue about things or get into debates."

Section 4.

Does *Stop & think!* work?

The model described in the previous chapter suggests that social problem solving deficits may contribute to problems that typify personality disorder. The next step is to see if there is evidence to suggest that problem solving therapy might benefit people with personality difficulties.

Problem solving therapy (or problem solving skills training) aims to teach people the skills for solving life's problems, and has been used successfully in the treatment a range of problems, including depression (Biggam & Power, 2002; Townsend et al., 2001), aggressiveness in children (Frey et al., 2000), self-harm (Salkovskis , Atha, & Storer, 1990), and offending (Friendship, Blud, Erikson, Travers, & Thornton, 2003). A meta-analysis of 31 randomised controlled trials of problem solving therapy for a range of psychological and health problems found that overall problem solving therapy was more effective than no treatment or treatment as usual, and as effective as other active treatments (Malouff, Thorsteinsson, & Schutte, 2007). Problem solving therapy may have advantages over other therapies in its acceptability, brevity, and relative ease of implementation. Two important findings in this meta-analysis were that problem solving therapy was more effective when: *a) It included problem-orientation training, and b) homework exercises were assigned.* These findings have been incorporated into the delivery of ***Stop & think!***

Given that people with personality disorders show social problem solving deficits, and given that problem solving therapy is effective with problems relevant to personality disorder, it is reasonable to suppose that problem solving therapy could benefit people with personality difficulties (McMurran, Nezu & Nezu, 2008). We have begun to test this out.

The Social Problem Solving Inventory-Revised

In our research, the measure we used to examine social problem solving skills was the Social Problem-Solving Inventory -Revised (SPSI-R; D'Zurilla, Nezu, & Maydeu-Olivares, 2002). Because we need to refer to this, a description of the scale is useful here. The SPSI-R is a self-report questionnaire where respondents rate their adherence to items on a 5-point scale, with values from 0 to 4. This provides scores on five scales as well as a total score. There are long (L = 52 items) and short (S = 25 items) of this questionnaire, but both measure the same scales. The scales of the SPSI-R are as follows:

Positive Problem Orientation (PPO; L, S = 5 items). This is a 'cognitive set' (i.e., a person's perspective) where there is a constructive approach to problems, with problems seen as a challenge rather than a threat. There is optimism about the solvability of problems and a belief in one's own personal ability to solve problems. There is an understanding that problems take time and effort to solve.

Negative problem orientation (NPO; L = 10 items, S = 5 items). This is a cognitive-emotional set where problems are viewed as a threat to well-being. Problems are viewed as unsolvable and there is a low expectation of one's own ability to solve problems. When confronted with problems, people become frustrated and upset.

Rational Problem Solving (RPS; L = 20 items, S = 5 items). This is a systematic approach to solving problems that includes problem definition, goal setting, generation of alternatives, thinking o the consequences, and forming an action plan.

Impulsivity/Carelessness Style (ICS; L = 10 items, S = 5 items). This is where attempts to solve problems are impulsive, hurried, and careless. Insufficient information is gathered in defining the problem, achievable goals are not set, only a few options are generated, the consequences of each option are incompletely thought through, and the effectiveness of the action plan is not monitored.

Avoidance Style (AS; L = 7 items, S = 5 items). This is where problem-solving is deferred. There is a hope that the problem will solve itself or that other people will solve it.

Social Problem Solving (SPS). This is a total score derived by averaging each scale and reversing the scores of the negative scales (NPO, ICS, and AS).

Stop & think! groups were first piloted with nine mentally disordered male patients (six with a classification of mental illness but also with personality problems, and three classified as personality disordered) in a regional secure unit for mentally disordered offenders (Arnold Lodge, Leicester, UK). Using the SPSI-R, we found that only six weekly sessions of 1½ hours' duration produced statistically significant improvements in patients' overall problem solving scores, and significant reductions in impulsivity and negative problem orientation (McMurran, et al., 1999).

The effectiveness of ***Stop & think!*** was then examined further with personality disordered offenders treated in Arnold Lodge's Personality Disorder Unit (PDU). After three months in treatment, personality disordered offenders (N=14) showed positive change on all scales of the SPSI-R except PPO (McMurran, Fyffe, McCarthy, et al., 2001). More recent data show that these changes are sustained, even after discharge (see Figure 2).

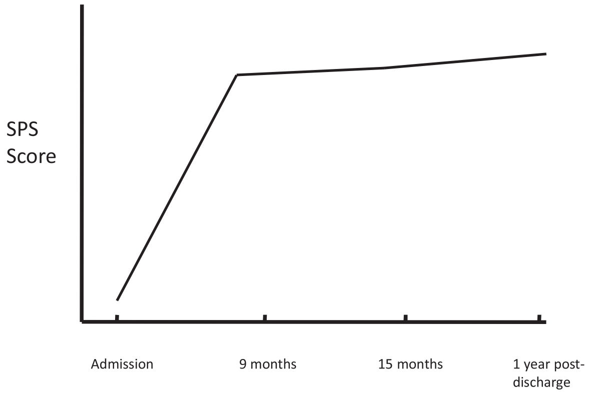

Figure 2*. SPSI-R total SPS scores over time for 11 PDU patients (data from annual report).*

More recently, the effectiveness of a combination of ***Stop & think!*** along with a psychoeducation component, which teaches participants about their personality problems, was examined in a randomised controlled trial (Huband, McMurran, Evans, & Duggan, 2007). Participants were 176 community-dwelling men and women with personality disorder in several sites across the East Midlands of England, who were randomly allocated to either treatment or a wait-list control. The treated group received, on average, 9 group sessions and a further 3 individual support sessions. The primary outcome measure was the Social Functioning Questionnaire (SFQ; Tyrer et al., 2005), which measures functioning in the domains of home, work, leisure, and relationships. Social functioning has been empirically identified in several studies as integral component of personality disorder (Nur, Tyrer, Merson, & Johnson, 2004; Seivewright, Tyrer & Johnson, 2004; Skodol et al., 2005). Hence, improving social functioning is an important aspect of treating personality disorder *per se.* In the trial, there was a significant difference between the treatment and wait-list controls on the SFQ, with the treated group scoring better ($d = 0.25$). The treated group also scored better on the SPSI-R ($d = 0.56$) and on anger expression, as measured by the State-Trait Anger Expression Inventory (STAXI-2; Spielberger, 1999).

Further examination of the data revealed that, for 93 people who completed treatment (i.e., including some of the wait-list controls), pre- and post-treatment changes were positive on all SPSI-R scales and on the SFQ (McMurran, Huband, & Duggan, 2008). In regression analysis, after controlling for pre-treatment SFQ scores, change on the SPSI-R total score predicted change on the SFQ. Of the SPSI-R subscales, change in Negative Problem Orientation was the sole predictor of change on SFQ. This study supports the hypothesis that, when social problem solving therapy for people with personality disorder works, it does so by improving social problem solving ability. Specifically, social problem solving therapy may be effective by reducing Negative Problem Orientation and thereby improving social functioning.

Comments on the psychoeducation plus ***Stop & think!*** treatment trial expressed support for its inclusiveness (i.e., people with any personality disorders were eligible), its delivery by non-specialist staff, and its brevity (Crawford, 2007; Paris, 2007). In addition, a survey of patients' views about ***Stop & think!*** showed that the intervention was perceived as useful (McMurran & Wilmington, 2007). Here are some of their observations: *Very relevant; It's been very useful;* ***Stop & think!*** *helps people realise that there is a solution to problems; The more you do it, the better you get.*

Section 5.

Stop & think! assessment

All services should design an assessment protocol. In doing this, the various purposes of assessment need to be considered:

- Client selection
- Measuring treatment outcomes
- Measuring progress in treatment
- Service audit

Preparing the client for *Stop & think!*

The client assessment process must be linked to the treatment offered and indeed should be part of the preparation of the client for commencing groupwork sessions. In the evaluation by Huband et al. (2007), ***Stop & think!*** was preceded by individual psychoeducation sessions, in which personality assessments were conducted, feedback was given, and a discussion about problems was held. Importantly, the problems clients wanted to work on in ***Stop & think!*** groups were identified.

At the start of the assessment stage, the potential participant will need to know what he or she is being assessed for. An information leaflet about ***Stop & think!*** is presented in Appendix 1. The assessments should be described and, when the results are available, feedback should be given. This will form the basis of a dialogue aimed at identifying the problems the client could focus upon in the ***Stop & think!*** groups. Further information on pre-group preparation is given in Section 8.

Client selection: personality disorder

One selection criterion is that the person should have personality difficulties. This raises the question of whether a formal assessment of personality required. Assessing personality is a complex business, often using tests or interview schedules that require specialist training. The advice given here is to conduct a common-sense assessment of personality difficulties. However, if you think assessing personality is important, then you should involve a chartered psychologist or a psychiatrist in selecting people for your service.

Assessing change in personality as a result of treatment is not appropriate. ***Stop & think!*** does not purport to change personality, but rather to teach people how to cope better with life's problems and to improve functioning with regard to relationships, work, and employment.

You may decide to select men and women with personality difficulties who are not formally diagnosed. Personality difficulties are usually detected by the types of problems people present, including aggressiveness, antisocial behaviour, drinking and drug use, emotional instability, self-harm, and overdosing. Less obvious are the problems of people who are socially withdrawn, avoidant or dependent, since they are less likely to complain or be complained of by others, however such people are eligible for ***Stop & think!***

How do we know that these problems relate to personality difficulties and not to other kinds of difficulties? The first step is to eliminate other obvious problems. If the person has an acute mental illness, has serious drug or alcohol dependency, is suffering from the effects of brain injury, or has a developmental disability, then he or she is not suitable for ***Stop & think!*** groups. This is not to say that such people could not benefit, but their particular needs make them unsuited to a group intended for people with personality difficulties. Also, there is no clear evidence that people with Cluster A personality disorders (i.e., paranoid, schizoid, and schizotypal) respond to ***Stop & think!*** – they have not presented in sufficient numbers in our treatment trial for us to be sure that they benefit.

Those whose problems are related to personality difficulties will have had these difficulties from an early age, including: impulsive behaviour and conduct disorder; difficulties getting along with other people by being either dominant and hostile, or submissive and passive; low self-esteem and poor sense of identity; having fixed, inflexible views of the world; or having difficulties seeing matters from another's perspective.

Measuring treatment outcomes

Using validated psychometric tests, two areas of functioning can be measured both at the start and the end of ***Stop & think!*** to see if changes are evident: (1) Social problem solving, and (2) Social functioning.

Social Problem Solving. ***Stop & think!*** aims to improve social problem solving. We use the Social Problem-Solving Inventory-Revised (SPSI-R; D'Zurilla et al., 2002), a test which was described in the previous chapter. This test is helpful in examining change over the course of treatment, but two issues must be considered: (1) user qualifications, and (2) cost. The SPSI-R is under copyright, and so it cannot be reproduced here. It is available to appropriately qualified professionals (i.e., those who have completed a graduate level course in tests/measurements) from :

The Cognitive Centre Foundation, 1st Floor, 34 Cardiff Road, Dinas Powys, Vale of Glamorgan,
Wales, CF64 4JS www.cognitivecentre.com

The SPSI-R gives an indication of the person's strengths and weaknesses. Mean scores for UK populations against which an individual's scores may be compared were presented earlier in Table 2. Remember, that good functioning is indicated by ***higher*** PPO, RPS, and SPS scores, and ***lower*** NPO, ICS, and AS scores.

Social functioning. ***Stop & think!*** aims to improve social functioning. In the randomised controlled trial of ***Stop & think!*** (Huband et al., 2007), we used the Social Functioning Questionnaire (SFQ; Tyrer et al., 2005). This is reproduced, with permission, in Appendix 2. This short questionnaire, which is in the public domain, asks respondents to rate how they have been recently in 8 areas: I complete my tasks at work and home satisfactorily; I find my tasks at work and home very stressful; I have no money problems; I have difficulties in getting and keeping close relationships; I have problems with my sex life; I get on well with my family and other relatives; I feel lonely and isolated from other people; I enjoy my spare time. Each item is scored 0 to 3, with a total score in the range 0 to 24, the higher the score indicating *poorer* functioning. A score of 10 or more indicates poor social functioning, and a reduction of 2 points on this scale is likely to be clinically significant.

Measuring progress in treatment

Assessment is also important for monitoring progress in treatment. There are several ways to do this. First, over the course of treatment, it would be expected that the participant would show improvements in his or her willingness and ability to use the ***Stop & think!*** procedure. The paperwork associated with the process contains a wealth of information that may be used to assess engagement and progress. This may be used to garner the following information:

- A simple count of the number of problems tackled using the process (both in groups and independently)
- Change in the number of options generated as possible solutions to a problem (participants usually become more creative over time);
- Change in the quality of the action plans produced (participants' plans usually become more appropriate and realistic over time); and
- An assessment of the implementation of the action plan and its constituent parts.

Second, a staff rating scale could be of value in measuring change. A rating scale that could be used in the early days of treatment and again at the end of treatment is given in Appendix 3. Finally, it is important to find out the participant's opinion of ***Stop & think!*** A post-intervention interview is given in Appendix 4.

Final report

At the end of ***Stop & think!***, even with no specialist input, you will be able to report changes on the SFQ, changes in the problem solving process, changes in staff ratings, and the participant's self-evaluation.

Service audit

Additionally, client data can be aggregated to give information about the effectiveness of the service overall (see Box 3 for suggestions).

Box 3. Service evaluation suggestions

How many people are referred?

What is the profile of people referred (e.g., sex, age, type of problem)?

What proportion is selected?

What is the profile of those selected (e.g., sex, age, type of problem)?

How many complete the treatment?

What reasons do non-completers give for leaving?

What improvements are made by completers?

What are clients' opinions of the treatment?

Section 6.

The principles of problem solving therapy

Problem-solving therapy is not a way of changing personality; it is a way of teaching people to deal effectively with problems. The task is to introduce systematic problem-solving skills to those who have never learned them, or retrain people who have fallen out of the habit of systematic problem solving. Teaching people social problem-solving skills can be compared to teaching people to drive a car. Some have never learned, and need to start from scratch. When learning to drive, they have to think about every move, which is laborious. As drivers become more experienced, their driving becomes more automatic. This makes them more efficient, as long as they are using the safest techniques. If they are not, then they have to start thinking again about what they are doing and correct bad habits. Re-training requires us to bring skills back temporarily from automatic processing into conscious processing for correction. In problem solving therapy, people are taught to address their problems systematically in an explicit step-by-step approach. If repeated often enough, this systematic approach will become automatic, and people will become effective problem-solvers. Facilitators do not solve people’s problems, but rather they teach people a strategy by which they can solve their own problems independently.

Social problem solving skills

Social problems solving consists of a range of skills, including:

- Problem awareness
- Problem definition
- Information gathering
- Distinguishing fact from opinion
- Goal setting
- Alternative solutions thinking
- Consequential thinking
- Decision-making
- Formulating an action plan in means-end steps
- Behavioural enactment of the plan

These skills are contained within the problem-solving approach of Thomas D'Zurilla and colleagues (D'Zurilla & Goldfried, 1971; D'Zurilla & Nezu, 1999, 2007), who describe seven separate steps for successful problem solving. These seven steps, along with a brief description, are:

1. Orientation. Problem recognition is the first step to effective problem solving. This consists of recognising unpleasant feelings and seeing these as a cue to begin the problem-solving process, rather than as an unpleasantness to be endured. This requires a positive problem orientation, that is the understanding that problems are a normal part of life and that problems can be solved with a bit of effort.

2. Problem definition. The ability to define a problem clearly and accurately is important to effective problem solving. An accurate definition requires information gathering and an ability to get the facts straight, not relying on inferences or suppositions. The ability to disentangle large, unmanageable problems into smaller, manageable ones is also important.

3. Goal setting. The next step is to decide upon the desired outcome. If you do not know what you want, you cannot work out a plan to achieve it and you won't know when you have got it!

4. Generation of alternatives. The creative generation of multiple possible ways of achieving the goal is important. Among the list of potential solutions is likely to be one or two that will work. It is important not to censor potential solutions at this stage, but instead to encourage creativity. Weeding out the imprudent, antisocial, and illegal options comes later.

5. Decision-making. Each potential solution is examined in relation to its likely consequences -- the advantages and disadvantages. This enables a decision about which options to choose as potentially effective, and which to reject as ineffective or too costly in terms of harm to self or others.

6. Action. One or more of the viable options are selected into an action plan. This action plan should consist of specific tasks that can actually be carried out. Vague intentions are not helpful here. Each solution should be arranged in a logical means-end sequence leading up to the specified goal. Then, of course, the action plan has to be carried out.

7. Evaluation. After the action plan has been attempted, the outcomes should be evaluated. If the goals have been met, then praise is due. It is important to recognise success in shaping behaviour. If the plan was not successful, then the reasons for this need to be identified. What were the obstacles? How can these be overcome? Would it be useful to try the problem-solving process again with a different focus? Would skills training help?

Addressing negative problem orientation

The main challenge of social problem solving therapy is to encourage people to adopt a positive approach to solving life's problems. Instead of viewing problems as insurmountable obstacles that get in the way of happiness, problems are to be seen as a normal part of life and, with a bit of effort, they can be tackled successfully. **This is important.** In the meta-analysis of treatment trials by Malouff and colleagues (2007), encouraging people to become less negatively oriented and more positively oriented to problem solving was a strong predictor of positive outcome in treatment. In our own research, a reduction in SPSI-R scores on Negative Problem Orientation was the significant predictor of improvements on the Social Functioning Questionnaire.

In addressing problem orientation, it is important to know what you are aiming to change. A **negative problem orientation** is a cognitive-emotional set where problems are viewed as a threat to well-being, they are viewed as unsolvable and there is a low expectation of one's own ability to solve problems. Hardly surprising, then, that people become frustrated and upset when confronted with problems. By contrast, a **positive problem orientation** is a cognitive set (i.e., a person's perspective) where problems are seen as a challenge rather than a threat, there is optimism that problems can be solved, there is a belief in one's own personal ability to solve problems, there is a constructive approach to problem-solving, and a willingness to devote time and effort to solving problems. A positive problem orientation is realistic: you don't expect people to be *glad* that they have problems or feel *pleased* that they need to buckle down and solve problems. Think of it more as a kind of "Damn this problem .... Oh well, I suppose I'd better crack on and do something about it".

How do you change a person's orientation from positive to negative? A person should be encouraged to realise that **problems are normal** – we all have them a lot of the time – and that **problems can be solved if you tackle them constructively**.

Helping a person to **experience success in problem solving** is important. A person may be helped to tackle less difficult problems first to give them a good chance of experiencing success. Alternatively, he or she could tackle a big problem which would be very rewarding to solve. In therapy, can the person be supported in the problem solving process to the point of solving a problem and feeling better about it? This will require giving the person **support in persisting with efforts to solve problems.** In ***Stop & think!*** participants are offered optional individual support sessions about once a fortnight. These sessions focus on helping people carry out their problem-solving action plans. Throughout therapy, **identify the client's strengths.** Some people just do not know when they are good at something; if you point out and reward a person's strong points, they will feel more competent and will likely use this skill more often. It is important to **identify problem-solving successes.** Often people do not take time to recognise when they have achieved something – successes just kind of slip by. Also, it is important to **praise approximations to success**; if a person gets one step nearer his or her goal, that's worth noting. Recognising success when you get there is important reinforcing feedback. When problem-solving has not been successful, **frame lack of success as a learning opportunity.** The aim is to steer people away from self-criticism and feelings of failure into a more positive approach of enquiry: Why did that not work? How can I do it differently? All of this means that you must **follow up the problem solving action plans** – do not fail to do this, or your clients will think you are not really interested in whether or not they solve their problems.

Encouraging a positive mind-set is important, but people also need to improve their specific problem solving skills. There are variations in the way that problem-solving therapy or skills training may be applied (McGuire, 2001). The method described in the next chapter is called ***Stop & think!***

Section 7.

Stop & think!

Stop & think! is a semi-structured treatment programme, which means that there is a prescribed procedure for each session but the content of the session varies depending upon the particular problem the participant chooses to work on. This semi-structured nature of ***Stop & think!*** provides an important level of flexibility to allow a focus on participants' current problems, thus potentially enhancing the relevance and usefulness of the treatment programme as a whole. However, this flexibility comes with the risk of drift away from the original objectives of the treatment, and so training and supervision are crucial to good quality delivery and its maintenance over time.

The steps identified by D'Zurilla and his colleagues can be translated into six key questions that guide the problem-solving process in clinical practice. The six key questions are:

Feeling bad?
What's my problem?
What do I want?
What are my options?
What is my plan?
How did I do? or How am I doing?

The six questions fit in with the seven steps as outlined in Table 3. This Table also shows the range of issues targeted in the problem-solving process.

In practice, the six key questions are used every time, without variation. The aim is to teach people a ***strategy*** for solving problems. By using the procedure repeatedly, it is more likely to stick in a person's mind, and thus it becomes more likely that that person will use the strategy him/herself when problems arise. Working through the questions may seem contrived and repetitive for a while, but once the new style of problem-solving is learned it should become automatic.

Table 3.

The problem-solving process

Question	*Stage*	*Skills*
Feeling bad?	Orientation	Recognition and understanding of feelings Countering impulsivity
What's my problem?	Problem definition	Information gathering Assessing quality & relevance of information Breaking down large problems
What do I want?	Goal setting	Identification of needs Setting targets
What are my options?	Alternatives	Creative thinking
What's my plan?	Decision making	Challenging dysfunctional beliefs Challenging antisocial attitudes Anticipation of outcomes Forward planning
	Action	Interpersonal skills
How did I do?	Evaluation	Recognise and reward success Recognise and address obstacles

The six key questions

Feeling bad?

Recognition of an unpleasant feeling is the cue to start the problem solving process. At first, identifying the experience of an unpleasant feeling is more important than giving the feeling a precise label, and expressing feelings in the vernacular is acceptable, e.g., fed up, pissed off, gutted. Once a feeling has been identified, it can be helpful to examine the physical and psychological experiences in greater depth so that people begin to learn to attend to their feelings. For example, anger may be associated with agitation, sweating, muscle tension, and an inability to focus on anything other than the source of anger. Depression may be associated with lethargy, lack of appetite, and an inability to concentrate. Feelings are important as the signal that there is a problem and that thinking and planning needs to begin. In the next stage, feelings can be analysed more precisely to inform the problem definition.

What's my problem?

An accurate and workable definition of the problem is important. First, it is important to dismantle large, overwhelming problems. "Life is awful" is too large to handle, and the component problems should be disentangled, for example no relationship, no job, and a horrid flat. Each may then be tackled separately. Second, it is useful to recognise the feeling and own the current problem. This is not to say that other people have not contributed to the client's problems, but it helps the client to focus upon how he or she can take action to change any problematic situation. Examples are: "I feel angry and neglected because she has not written" as opposed to "She is a selfish cow who has not written to me" and "I am scared of men and angry with everyone because of my abuse" rather than "He was a bastard and he's ruined my life".

What do I want?

Without a goal it is impossible to devise an action plan. One analogy is baking. Unless you decide what you are going to bake, you cannot make a shopping list, buy the appropriate ingredients, mix them in the right proportions, choose what baking tins to use, and bake the at the correct heat for the optimum length of time. Also, without a goal you will never know if you have reached it or not. This can be very depressing because you never seem to achieve anything at all (even though you do achieve things really).

What are my options?

Creative thinking is a vital component of ***Stop & think!*** Rather than persevering with one or two ineffective solutions, a whole range of possibilities is generated. Although some of these may be impractical, imprudent, or illegal, it is important at this stage to reward the creative generation of options. The more options generated, the more likely the list is to contain useful and effective solutions. Each option must be analysed to determine the likely consequences. The 'pros and cons', 'fors' and 'againsts', 'positives and negatives', or 'good and bad outcomes' are thoroughly examined (pick your preferred words to describe the 'advantages' and 'disadvantages'). Then each option is reviewed and either selected or eliminated. Those selected form the action plan.

What is my plan?

It is important to realise that the ultimate aim of ***Stop & think!*** is the formulation of an ***action plan***. That is, we are aiming to help people move on from expressing concern to taking action to solve problems. Although ***Stop & think!*** teaches thinking skills, the only way that the effectiveness of rational problem-solving can be tested is by checking if the action plan derived through ***Stop & think!*** actually works. The key question "What's my plan?" should lead to an action plan consisting of specific (not vague) tasks; that is, action plans should consist of items that people can actually ***do.*** Several items may be chosen from those generated in response to the question "What are my options?", and these should be listed in a logical sequence, for example, the goal 'To make contact with someone' may have the following steps: (1) Think about what I want to say in a letter, (2) Write a rough version, (3) Ask John to look it over, (4) Write it out properly, (5) Send it first class, (6) Phone after three days to see what the reaction is.

Items on the action plans must be SMART:

S - specific and significant

M -measurable and meaningful

A - attainable, acceptable, and action-oriented

R - realistic, relevant, and rewarding

T - time-based and trackable

It is worth checking the action plant against the original problem and the original feelings. Will this plan solve that problem and make you feel better?

Action

Taking action is important. Obviously, problems don't get solved by just thinking about them; action needs to be taken. Also, in the meta-analysis of treatment trials by Malouff and colleagues (2007), assigning 'homework' was a strong predictor of positive outcome in treatment. Action plans can be supported in extra individual sessions. The input in individual sessions may be to help people cope with feelings of anxiety, giving practical advice on taking the actions, or helping a person break the plan down into even smaller steps.

How did I do?

Reviewing the action plan is important for knowing whether the problem has been successfully dealt with or not. If it has, then praise and satisfaction are due, both of which raise self-esteem and self-efficacy. If the problem has not been solved, then it is important to approach this with a spirit of enquiry: Was the action plan actually carried out? If not, why not? Identifying and addressing obstacles to implementing change is crucial. If the plan was carried out, why was it not effective? Has a new problem been identified in the process? Does a new problem solving procedure need to be implemented? Is skills training or other therapy required?

In this section, the process of ***Stop & think!*** has been described. Next, some of the practicalities of running ***Stop & think!*** groups will be addressed.

Section 8.

Running *Stop & think!* groups

Pre-group preparation

Prior to starting ***Stop & think!*** sessions, participants are individually introduced to the principles of problem solving and the rationale behind ***Stop & think!*** (see Assessment section). The duration and number of pre-group meeting(s) will be dependent upon the person's cognitive abilities. The person is introduced to the problem-solving process, specifically the six key questions and the paper work, in order that they become familiar with the principles of ***Stop & think!***

The following issues need to be addressed during preparation:

1. What are the person's personal aims and perceived gains in attending ***Stop & think!*** Make sure these are consistent with the aims of the therapy.
2. Has the person had previous experience of problem solving therapy, either in groups or individually? If so, care should be taken to assess any differences in approach between previous therapies and this one to avoid confusion.
3. Provide the person with an overview of the ***Stop & think!*** rationale, the operation of sessions, the paperwork involved, and reporting procedures.
4. Show the patient the six key questions and work through an example.

Stop & think! groups

Stop & think! should be run with groups of 6-8 participants. Sessions are 2 - 2½ hours long and the recommended frequency of delivery is that sessions are held once or twice a week. Evidence tells us that people experience the benefits within 12 sessions/3 months. The ***Stop & think!*** work-through is written on a flip chart in the session, and the content of this should be transcribed onto a worksheet (Appendix 5 – see worked example in Appendix 6) either by the participant after the session or by a co-facilitator during the session. Some facilitators take laptops into sessions and type up the ***Stop & think!*** work-through ready for printing out at the end of the session. Participants are expected to keep all written work together in a file.

Individual support sessions

In addition to groupwork, individual support sessions may be offered. In the randomised controlled trial (Huband et al., 2007), individual support sessions were optional. These individual sessions should augment group sessions, assisting participants to complete any unfinished work on their problems, using the ***Stop & think!*** procedure, or offering support in carrying out action plans. Frequency can be decided dependent on participant need, but a recommended frequency is one individual session for every two group sessions. Group facilitators may also wish to review a person's work from time to time, to ensure that action plans are realistic and achievable, and that participants do not accumulate too many different plans to work on.

Independent working

Participants should also be encouraged to work independently on their problems, using worksheets (Appendix 5). This fosters generalisation of the procedure.

Stop & think! some practical tips

- **Set non-negotiable group rules in the first session.** These rules will relate to confidentiality, respect, and attendance. Pin these up at all sessions so that a person may be called to account for any rule deviations.
- **Set non-negotiable group rules in the first session.** They may also cover domestic matters, such as the provision of breaks and refreshments.
- **Start on time.** Do not wait for latecomers before starting the group. Those who have come on time simply get bored hanging around, and waiting does not encourage punctuality.
- **Keep an up-tempo pace.** It helps to keep a brisk pace, involve participants in discussion with each other, and have a laugh occasionally.
- **Reward, reward, reward.** When people participate well, remember the key questions, present prosocial views, and give advice to others, make something of it. We want to encourage the desired behaviours.

- **Involve everyone.** Make sure everyone in the group is involved in discussion. Ask questions of named people, e.g., “What do you think, Bob?”, “Do you ever feel like this, Bill?”, “What would you do, Barbara?”
- **Defining the problem.** Sometimes it is hard to capture a person’s problem in so many words. Ask group members to have a go. Agree the best brief definition.
- **Flipping charts!** Get the participants to do the writing on the flip charts. This keeps them involved (and improves spelling!).
- **Watch out for the chatty one.** Avoid an exclusive one-to-one dialogue with the most vocal group member. Be aware of this as a trap that is easy to fall into -- it can be easier for a group leader to talk to the chattiest person to the exclusion of others.
- **Participants as teachers.** When a visitor or newcomer joins the group, ask the participants to explain the ***Stop & think!*** process. Explaining what it is about will help the participant learn.
- **Normalise.** It helps if participants learn that problems are the stuff of everyday life for all of us not just a symptom of a mental health problem. We can let participants know that sometimes we fall out with people, lack confidence, or screw things up.
- **Concrete examples.** It helps to illustrate points by using concrete examples. Baking, for example, illustrates the importance of goal-setting. You need to know what you want to make in order to devise an effective action plan. For instance, you need to know you want to make pancakes in order to buy the right ingredients, mix them in the right proportions, and cook them in the right way.
- **Group problems.** Problems experienced in the group can be the focus of ***Stop & think!*** For example, if people are reluctant to speak for fear of others breaching confidentiality, this can be worked through by the group.
- **Big problems are lots of little problems wrapped up in one.** Some problems are too big to handle in one go. They need to be broken down into manageable chunks.
- **“Talk to someone” is not the solution to every problem!** We are trying to encourage independent thinking, and so we discourage over-reliance on “talk to someone” as the universal solution to all problems. We ask people to be more precise about what they need from their helper, e.g., assistance with writing a letter, a friendly critic who will allow you to rehearse a difficult conversation, or someone to provide some information about a subject.

- **Please expand on that.** Ask people to expand their reasoning. After all, we are trying to teach people *thinking* skills.
- **Recognising emotions.** You may have to work on getting participants to identify unpleasant feelings and so cue in to the problem-solving process. Try focusing on a specific unpleasant feeling and asking for a description of the feeling. Depression, for example, may make people tearful, sleepy, apathetic, and grumpy.
- **Anxiety and worry.** Having a problem and not knowing what to do about it is a worry in itself. Having an action plan for solving a problem can reduce anxiety and worry.

The biggest threat

The biggest threat to the integrity of ***Stop & think!*** is applying it in a mechanistic fashion. Remember, you are working on real problems that deserve serious consideration. It is important to give time and attention to the problem. Using the ***Stop & think!*** procedure does not make clinical and interpersonal skills redundant.

Suggested timing

Time (in minutes)	**Activity**
0 – **15**	Ask 'How did I do?' - take feedback from last week's action plan
16 – 25	Ask person briefly to summarise this week's problem
26 – 35	Ask 'Feeling bad?' - link this with the problem
36 – 55	Ask 'What's my problem?' – get a clear definition of a specific problem. Use the group to help with the definition
56 – 60	Ask 'What's my goal?' – get a clear goal
61 – 75	Ask 'What are my options?' – get the person and the rest of the group to generate a list of options. In the early stages, the list is likely to be sparse. Later on, you will need to streamline the list by putting similar options together. (Break in the middle of this.)
76 – 90	Break
91 – 95	Finish 'What are my options?'
96 -105	Work through the 'pros' and 'cons' of each option. If the list is very long, discuss all pros and cons but write only one in each box. (Note –if there are no pros or cons to an option, you do not need to fill the box.)
106 -110	Review all the options and make a selection of the most suitable options.
111-120	Ask 'What's my plan?' – reconfigure the options into a logical means-end action plan

Session 9.

Getting started

Starting a new group requires the usual introductions.

- Introduce staff and group members to each other
- Use a simple ice breaker exercise, for example ask people in pairs to prepare a poster (flip chart) with their name and some key features about themselves on it. Use words, or drawings, or a mixture of both.
- Explain housekeeping issues, for example where the facilities are, when there will be breaks, the arrangements for smoking and drinks.
- Explain any non-negotiable 'ground rules' relating to safety, security, and confidentiality and then ask the group to generate any 'local rules' that they want to agree to work to.
- Give a brief introduction to ***Stop & think!*** along with some examples to illustrate how *avoiding* problems or *acting rashly* can make matters worse rather than better.

Introducing *Stop & think!*

> "Some people have difficulties recognising unpleasant feelings, being clear about the problem that is causing those feelings, analysing the problem carefully, and coming up with a solution that will solve the problem. As a result, people either do nothing, or do something without thinking. Often this can make matters worse rather than better. Here are a couple of examples."

Providing examples

Present the following examples, one at a time, written in advance on a flipchart, handout, or slide. Discuss each example, using the questions provided as prompts.

Example 1 ~

Kerry's brother Lee takes advantage of their mum by treating her like a slave and cadging money off her. Kerry say nothing, buts get more and more annoyed with Lee. Kerry won't speak to her brother, but she does criticise him to their mum. Kerry's mum gets fed up with this and loses her temper with Kerry.

What is Kerry's problem?

Has Kerry solved the problem?

What do you think she could have done instead?

Example 2 ~

Terry loves his girlfriend Vicky, but they are not getting on too well right now. Vicky goes out for a night with her mates. Later in the week, Terry hears that she was flirting with a bloke in the nightclub. Terry accuses Vicky of being unfaithful. Vicky denies it and gets very angry with Terry for having accused her. Terry then loses his temper, roughly shoves Vicky out of his way, and walks out of the house.

What is Terry's problem?

Has Terry solved the problem?

What do you think he could have done instead?

Devise your own examples if you want to make these more relevant to your participant demographic.

Explain *Stop & think!*

"Stop & think! helps people recognise when they are feeling bad; helps people be clear about the problem that is causing them to feel bad; helps people think about possible solutions to the problem; and helps them come up with an action plan."

> ***"Stop & think!*** follows six key questions ~
>
> Feeling bad?
>
> What's my problem?
>
> What do I want?
>
> What are my options?
>
> What's my plan?
>
> How am I doing?/How did I do?"

These questions are the core of ***Stop & think!*** and it helps to pin the questions around the room, or give participants reminder cards, or both. Here is an opportunity to be creative!

Feeling bad

Explain the importance of the first question, 'Feeling bad?'

> "The first question, 'Feeling bad?' requires people to notice their feelings and label these feelings. Some people have difficulty even realising that they feel bad. Recognising when you feel bad is important because this acts as a cue to start problem solving."

The next step is an exercise to start attuning people to recognising unpleasant feelings. This is essentially a brainstorming exercise, but with fun and creativity added. Draw an outline diagram of a body on a flipchart. Ask group members to name unpleasant feelings, and ask them to draw something on the body that represents the physical sensation of these feelings, for example a butterfly in the stomach (anxiety), a bead of sweat on the forehead (fear), redness on the face (anger), a tear in the eye (sadness). Participants may be given the 'Feeling bad?' worksheet (Appendix 5) for independent work.

In moving through the ***Stop & think!*** problem solving procedure, participants should briefly outline their problem first. Facilitators should then invite the participant to take one step back and ask, 'What were the unpleasant feelings?' The purpose of doing this is to indicate to participants that in future they need to be alert to unpleasant feelings so that they can trigger the problem solving process early on in a potentially problematic situation.

Problem solving

The next step is to work through the problem solving procedure for the first time, using an example. We have found that using a current problem of a soap opera character is both engaging and useful. Alternatively, an example of a commonly experienced problem may be chosen. Again, creativity can be used as to how to present a clear example of an inter-personal problem situation through which the problem solving procedure can be illustrated.

Examples of problems

Angry – Partner doesn't help with the housework

Lonely – No friends

Sad – Fell out with best mate

Worried – Workmate steals from the firm and I might get implicated

Frustrated – My partner won't let me discipline her children

The questions should be worked through in turn right up to 'What's my plan?' At this point, ***Stop & think!*** will end, just as it will in real sessions. The sessions are where the planning takes place, but it is outside of sessions that the action plan is carried out. This is ***crucial***: problems mostly cannot be solved on paper without follow-up action. Feedback on action plans – 'How am I doing? – needs to be presented the following week.

Take any questions and then prepare for the next session when a real problem will be tackled. It is important to identify in advance the problem to be addressed in the next session, otherwise you may face an uncomfortable silence. Problem identification may be done in the group, or by facilitators in the individual support sessions.

***Stop & think!* – session 2 onwards**

In the first session that deals with a participant's problem, the ***Stop & think!*** procedure will start at question 1, 'Feeling bad?' and proceed from there. From session 2 onwards, the session will start with feedback from the participant whose problem was the focus in the previous week, that is, 'How am I doing?' or 'How did I do?' Some catch up of action plans from previous weeks may also be appropriate. About 20 minutes of the session should focus on feedback, and the remainder on new problem solving. Facilitators should be mindful of time, ensuring that the feedback part of the session does not run over and encroach upon the problem solving time.

Types of problem for *Stop & think!*

In theory, all kinds of problems can be processed using the ***Stop & think!*** approach. In therapy, however, we wish to concentrate on personal and interpersonal problems, rather than practical problems. Problems with anxiety, depression, interpersonal friction, family relationships, and offending are all grist to the mill. Practical problems such as finding accommodation, accessing benefits, and looking for work need not be ruled out, since they frequently have an interpersonal component, but they should not form the main diet of group sessions.

Group facilitators' problems

Group facilitators may very occasionally wish to work through issues relevant to a ***Stop & think!*** as a problem of their own. For example, a useful strategy when a group is not going well is for the facilitator to bring this to the group as his or her problem, for example "I'm feeling worried because the group does not seem to be bringing problems up for discussion". This illustrates that everyone can experience problems and ***Stop & think!*** procedure can help solve them, while also getting the group to address its own problems.

Skills training

Stop & think! does not include interpersonal skills training, such as assertiveness or negotiation skills. ***Stop & think!*** can, however, include brief, ad hoc skills training exercises relevant to an individual's action plan e.g., rehearsing a conversation, practising assertiveness, or learning relaxation. More in-depth skills training should be dealt with in other groups dedicated to the purpose. ***Stop & think!*** should be linked with such skills training groups.

Good practice guidelines

Finally, feedback from services that we have worked with has enabled us to draw up good practice guidelines. These are:

Stop & Think! Good Practice Guidelines

- The purpose of *Stop & Think!* is to teach participants a strategy for solving life problems. *Stop & Think!* groups are not for the purpose of introducing patients to working in group
- All *Stop & Think!* staff should operate the same approach.
- Three trained staff should be allocated to each group, of whom two will attend any one session.
- Clients should be referred to *Stop & Think!* group facilitators for suitability assessment.
- Suitability will be determined by motivation to attend groups, ability to benefit from *Stop & Think!* group work, and current group constitution.
- Clients will be informed of the aims, content, and process of *Stop & Think!*
- The optimum is 6 participants per group.
- Sessions to be a minimum of 2 hours duration (including break).
- Groups to run in blocks of 12 sessions.
- Prior to the block of sessions, staff will meet individually with patients to identify problems to be worked on in group and prepare patients for working on those problems in a group. The focus may be on current problems or on more fundamental psychological issues
- Prior to each session, co-facilitators will meet to agree the session agenda.
- The facilitator leads the group, the scribe focuses on writing the flip charts and should not be the lead facilitator.
- The flip charts should be written up after each session and copies made for patient and staff.
- After each session, co-facilitators will meet for debriefing.
- Issues identified in the group session will be taken forward as appropriate.
- Between group sessions, staff will support individuals with action plans in individual sessions.
- After each block, staff will review and rationalise all action plans for each individual.
- After each block, staff will summarise the problems worked on, problem themes, and unmet need identified during the block and write a report for each client's referrer or CPA meeting.
- If appropriate, after each block, staff will identify problems to address in next block of *Stop & Think!*
- All staff will receive supervision specifically related to *Stop & Think!* for a minimum of one hour per block of sessions , e.g., peer supervision, group supervision, expert supervisor.

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Appendices

Appendix 1.

Stop & Think!

Stop & Think! is a group programme for people who have problems controlling their emotions or behaviour, to the extent that this makes them unhappy or causes problems with other people in their lives. The problems of people who are eligible for ***Stop & Think!*** relate to personality difficulties. That means that they have traits that sometimes make life difficult. Traits that can cause problems include impulsivity, irritability, aggressiveness, and poor self-worth. ***Stop & Think!*** aims to help people cope with these difficulties and solve life's problems more effectively.

Stop & Think! teaches people a strategy for solving problems. ***Stop & Think!*** involves answering six key questions:

Feeling bad?

Some people have difficulty recognising unpleasant feelings such as anger, depression, and boredom. Either they react without thinking to the unpleasant feelings or they just put up with them. What they don't do is try to identify what the problem is and work out an effective action plan. ***Stop & Think!*** helps you recognise unpleasant feelings and start problem solving.

What's my problem?

You can't solve a problem unless you can say what it is. Some people have difficulty defining their problems clearly and breaking down big problems into smaller, manageable ones. ***Stop & Think!*** teaches you to define your problems clearly and break big problems into smaller chunks.

What's my goal?

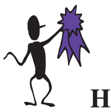
To solve a problem, you need to know what you're aiming for, otherwise you'll never know if you've arrived! ***Stop & Think!*** teaches you to set clear, achievable goals.

What are my options?

There are usually a number of ways of achieving a goal. Be creative and think of a lot of options. This gives you more than one way to solve a problem. Creativity is good, but you also need common sense. ***Stop & Think!*** teaches you to be creative in thinking of possible solutions to a problem. Then you learn to think of what would likely happen if you took action, and you weed out the bad ideas.

What's my plan?

The good ideas that you are left with are then put into order as an action plan. This action plan isn't going to be effective if it stays on paper, so you need to carry out this plan.



How am I doing?

Action plans need to be checked to see if they are working. Have you achieved your goal? If so, well done! If not, what got in the way? What can you do next?

Appendix 2.

Social Functioning Questionnaire (Reproduced with permission)

Please look at the statements below and tick the reply that comes closest to how you have been recently.

I complete my tasks at work and home satisfactorily

Most of the time ☐
Quite often ☐
Sometimes ☐
Not at all ☐

I find my tasks at work and at home very stressful

Most of the time ☐
Quite often ☐
Sometimes ☐
Not at all ☐

I have no money problems

No problems at all ☐
Slight worries only ☐
Definite problems ☐
Very severe problems ☐

I have difficulties in getting and keeping close relationships

Severe difficulties ☐
Some problems ☐
Occasional problems ☐
No problems at all ☐

I have problems in my sex life

Severe problems ☐
Moderate problems ☐
Occasional problems ☐
No problems at all ☐

I get on well with my family and other relatives

Yes, definitely ☐
Yes, usually ☐
No, some problems ☐
No, severe problems ☐

I feel lonely and isolated from other people

Almost all the time ☐
Much of the time ☐
Not usually ☐
Not at all ☐

I enjoy my spare time

Very much ☐
Sometimes ☐
Not often ☐
Not at all ☐

Scoring:

I complete my tasks at work and home satisfactorily

Most of the time	0
Quite often	1
Sometimes	2
Not at all	3

I find my tasks at work and at home very stressful

Most of the time	3
Quite often	2
Sometimes	1
Not at all	0

I have no money problems

No problems at all	0
Slight worries only	1
Definite problems	2
Very severe problems	3

I have difficulties in getting and keeping close relationships

Severe difficulties	3
Some problems	2
Occasional problems	1
No problems at all	0

I have problems in my sex life

Severe problems	3
Moderate problems	2
Occasional problems	1
No problems at all	0

I get on well with my family and other relatives

Yes, definitely	0
Yes, usually	1
No, some problems	2
No, severe problems	3

I feel lonely and isolated from other people

Almost all the time	3
Much of the time	2
Not usually	1
Not at all	0

I enjoy my spare time

Very much	0
Sometimes	1
Not often	2
Not at all	3

Appendix 3.

Stop & Think! Rating Scale

This rating scale should be used to assess an individual's performance in applying the *Stop & Think!* procedure to a specific problem. The individual's performance in each stage should be rated. This will identify the person's strengths and weaknesses. Rating the procedure at different stages in therapy permits the assessment of changes over time. The problem that was addressed should be recorded and a copy of the *Stop & Think!* worksheet pertaining to that problem should be appended to this rating sheet.

CLIENT'S NAME:______________________________ ASSESSOR'S NAME:__________________________ DATE:________________________

PROBLEM ASSESSED: ____

____

UNDER DEVELOPED		WELL DEVELOPED
Feeling bad? An under-developed response shows a lack of awareness of emotions (e.g., 'I don't know'). There is an inability to name (e.g., 'I just feel bad') and own emotions (e.g., 'It's him that makes me feel like this'). A limited range of emotions is expressed. Emotions are not linked to physical sensations or cognitive changes. The focus is on behaviours rather than emotions or feelings, and feelings are described as behaviours (e.g., 'I felt like punching someone').	**0 1 2 3 4 5 6 7 8 9 10**	**Feeling bad?** A well-developed response clearly identifies and owns difficult emotions. This is signified by statements of 'I feel ……'. Emotions (e.g., angry, sad, anxious) are clearly identified and are linked with physical sensations (e.g., tense, heart racing, feeling a lump in stomach) and cognitive changes (e.g., mind racing, focus only on one thing, confusion). There is recognition that these emotions and feelings are linked to the problem. There is recognition that 'feeling bad' is a cue to initiate problem solving.

What's my problem? An under-developed response is a vague, unfocused or global problem (e.g., 'My relationships are terrible'); or a list of problems; or a problem that is historical, although expressing current difficult emotions relating to a past problem is acceptable. Responsibility for the problem is placed elsewhere (e.g., 'They don't treat me fairly'). The problem is not related to the emotions identified. The problem is based on assumptions (e.g., 'I am singled out for unfair treatment').	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**What's my problem?** A well-developed response is a description of a specific current or anticipated problem that relates to feeling bad. The description is clear and concise while identifying the crux of a problem. It does not focus on the superficial aspects of a problem, but rather the focus is on problematic issues that are part of a pattern for the individual (e.g., rather than focus on a minor altercation, the focus might be upon a pattern of angry responding when thwarted).
What do I want? An under-developed response is unclear (e.g., 'I want to be better'), unspecific (e.g., 'I want to be happy') and unrealistic (e.g., 'I want to stop feeling angry'). The focus is on what other people should do rather than what the person him/herself should do. The goal is not related to the problem expressed hence it will not solve the problem or ameliorate unpleasant feelings.	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**What do I want?** A well-developed response is an important, specific and realistic goal (e.g., 'I want to learn ways to control my anger better'). The goal should focus on changing one's own behaviour and not on the expectation that others will change. When achieved, the goal should ameliorate the identified problem and hence reduce the frequency or intensity of unpleasant feelings.
What are my options? An under-developed response shows few options or options that are all variations of the same thing. The options may be a rehearsed set, with no real thought given to the specific problem under discussion (e.g., 'Speak to staff'). The options are vague (e.g., 'Relax'). There is a predominance of unreasonable options. The options do not relate to the expressed problem. The balance of advantages and disadvantages is not addressed and the effects on other people are not acknowledged.	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**What are my options?** A well-developed response shows a diverse range of options. The list can include options that may not be advisable to act upon (e.g., self-harm, violence to others), but most will be potentially useful options. The options will relate to the expressed problem. The major advantages and disadvantages to self and others of each option are identified.

What is my plan? An under-developed action plan is an uncoordinated list of actions that have no clear progression. The plan is a repeat of the list of options generated. The items on the plan are vague (e.g., 'I will improve my self confidence') and outcomes are not measurable. The plan does not include immediately actionable coping strategies or the plan focuses only on immediate coping strategies. There is no reference to the resources needed for supporting the plan. The plan does not relate to the expressed problem. The actions are antisocial or damaging.	**0 1 2 3 4 5 6 7 8 9 10**	**What is my plan?** A well-developed action plan focuses upon a small list of themed actions (e.g., prevention, coping, negotiation). In each theme, a small number of actions should be listed. These should be SMART, i.e., specific, measurable, achievable, realistic, and time-limited. There should be actions with immediate, short-term, and longer-term outcomes. Any support needed to enact the plan is specified. Some plans should be challenging and aim to address the problem's causes. The action plan relates to the expressed problem. There are no antisocial or damaging actions.
How am I doing? An under-developed appraisal is rushed, superficial, and unclear. The plan has not been tackled and no good reasons are given for inaction. Alternatively, there is claim to an immediate and complete success (e.g., 'The first step solved all my problems'). Successes may have been achieved but are not recognised. Failures are viewed as a shortcoming of the plan and there is no commitment to persist with the plan, examine the reasons for lack of success, or find alternative strategies.	**0 1 2 3 4 5 6 7 8 9 10**	**How am I doing?** A well-developed appraisal is honest. It reports on all aspects of the plan and indicates which actions have been carried out and which have not. The success or otherwise of each action is assessed and the obstacles to implementation of the plan are identified. The reasons for lack of success with aspects of the plan are identified and alternative strategies are considered. Success is acknowledged in terms of incremental achievement towards the identified goal. A clear intent is expressed to continued work on the plan.

Appendix 4.

Client Post-Intervention Interview Schedule for *Stop & Think!*

Participant Identification .... Date ....

The purpose of this interview is to gather your views on the *Stop & Think!* group sessions. The *Stop & Think!* sessions were those where you learned a way of tackling and solving problems.

1. **First, I am interested in hearing your general opinions of the *Stop & Think!* sessions. So, before I ask you any questions that might get you thinking about specific things, would you please give me your general opinions of the *Stop & Think!* sessions?**

2. **Please tell me the main things you learned in the *Stop & Think!* sessions:**

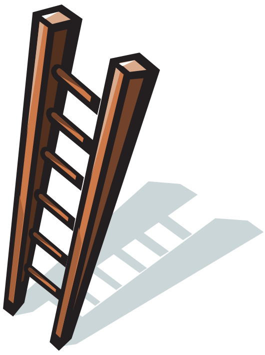
3. **Besides gaining knowledge, I am interested in whether you got anything else out of the *Stop & Think!* sessions. Did you benefit in any way?**

   3a. If you did benefit, could you please try to tell me how *Stop & Think!* had this good effect?

4. **Do you think *Stop & Think!* had any bad effects?**

   4a. If so, could you please try to tell me how *Stop & Think!* had a bad effect?

5. May I ask you to rate how useful you found the Stop & Think! sessions overall?



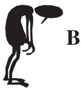
10	**Very useful indeed**
9	
8	
7	
6	
5	
4	
3	
2	
1	
0	**Not at all useful**

6. Do you have any other comments?

Thank you for your help.

Appendix 5. (*Note:* Your version of this will need to offer more space for clients to write in).

Stop & Think!



Bad feelings?

What's my problem?

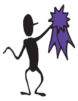
What do I want?

What are my options?

	Good outcomes	*Bad outcomes*

What's my plan?

Action	*Date*	*Helper*



How am I doing?

Appendix 6.

Stop & think! example

Feeling bad?

Sad, lonely

What's my problem?

My wife dumped me and I can't see the kids

What do I want?

To see my children

What are my options?

Options	**Positives**	**Negatives**
Kidnap the kids	I'd see lots of them.	Would distress the kids. She'd get the law onto me.
Speak to my wife and negotiate access	Maybe we could work something out. I could tell her I'm doing something about my problems.	She'd not listen because she thinks I'm unreliable and aggressive.
Write to my wife to negotiate access	Wouldn't have to listen to her criticising me.	She'd tear the letter up.
Ask Social Services if they can arrange access.	Might get a result.	I got banned from seeing the kids because of my drinking and aggression.

What's my plan?

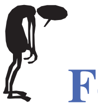
Speak to Social Services. Tell them I'm doing something about my drinking and aggression. Ask them to help me negotiate access with my wife.

Continue to work on my problems. Phone up the Alcohol Counselling Service to make an appointment.

Appendix 7.

Stop & Think!

* * *



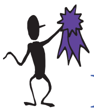
Feeling bad?

What's my problem?

What do I want?

What are my options?

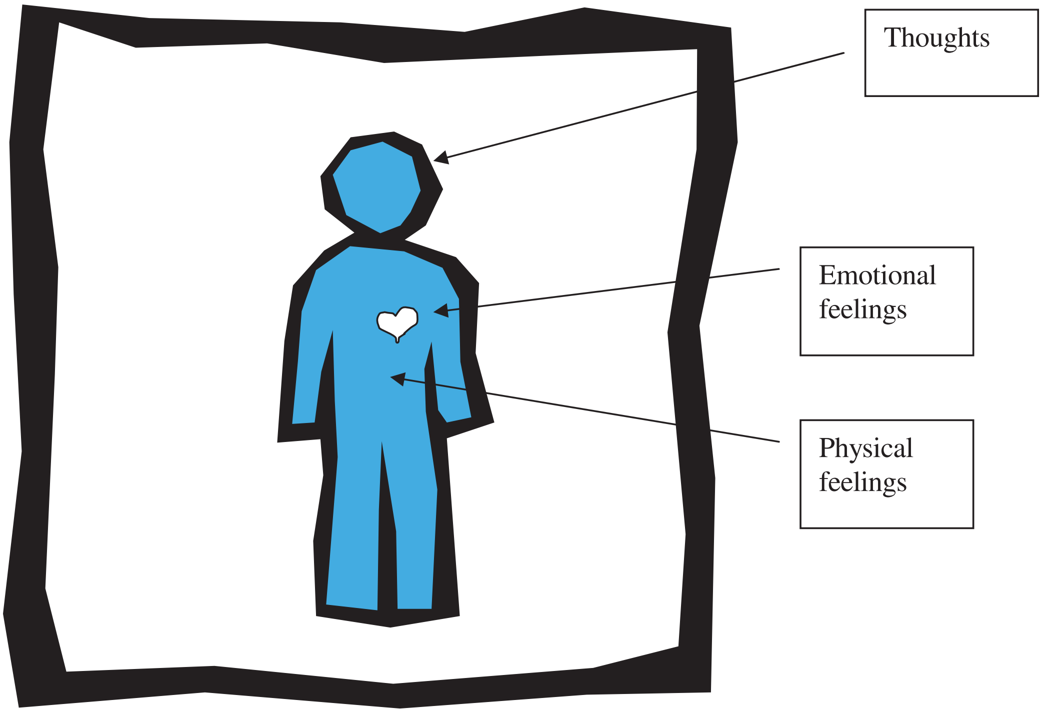
What's my plan?



How am I doing?

Appendix 8.

Feeling bad?



Appendix 4 Competence rating scale: International Personality Disorder Examination

IPDE Interview Technique
Competence Rating Scale

Site		**Therapist**	

IPDE administration competence is rated on a scale of 0 to 6 where:

0 = poor 1= barely adequate 2 = mediocre 3= satisfactory 4 = good 5 = very good 6 = excellent

Task	Competence 0 – 6	Comments
Rapport: Interviewer has built a rapport with the client so that the interview takes place fluently and conversationally. There are no over-long silences, signs of irritability, or criticisms. Rather, the interview flows well, with the questions being asked sympathetically by the interviewer and answered reasonably by the interviewee.		
Sticking to the IPDE questions: The interviewer sticks to the questions as listed in the IPDE. Rewording makes the question clearer without deviating from the meaning of the IPDE question. Prompts relate to the question that was asked.		
Maintaining focus: The interviewer keeps the focus on the question that was asked. If the interviewee drifts off topic, the interviewer draws the focus back to the relevant question. The interviewer does not pursue tangential or irrelevant topics. The interviewer reminds the interviewee that this is an assessment and that time does not allow for all topics of interest or importance to be covered.		
Moving on: The interviewer moves on to the next question as soon as enough information has been elicited to answer the current question. The interviewer does not permit unnecessary, lengthy elaborations. Curtailing the interviewee is done sensitively.		

Acceptable competence is defined as follows:
Competence: Minimum score of 16, no item below a 3

PEPS Trial IPDE Administration Competence Rating Scale v1.0 – 19 July 2011

Appendix 5 Competence rating scale: psychoeducation

Psycho-Education
Adherence & Competence Rating Scale

Site		**Therapist**	

The items below define a good psycho-education programme. In the first section, you rate *if* the therapy tasks were done in sessions (adherence). Adherence is a simple yes/no rating, identifying whether or not the task was done. There is also a section for comment. In the second section, you rate *the degree* to which the therapy goals were evident by the final session.

Adherence

Task	**Adherence Yes/No**	**Comments**
1 Complete the Brief Structured Interview		
2 Discuss the contents of the information sheet, All About Problems and Personality		
3 Support the client in completing the Problems Checklist (Client Version)		
4 Help the client to complete the worksheet- What do I want to change about myself?		
5 Discuss the Problems Checklist (Clinician Version)		
6 Help the client list five things s/he wishes to change		
7 Prepare a personalised booklet for each client		
Total		

PEPS Trial Psycho-Education Competence Rating Scale v1.0 – 19 July 2011

Competence

Now, please rate the degree to which the therapy goals were evident by the final session on a scale of 0 to 6 where:

0 = poor 1= barely adequate 2 = mediocre 3= satisfactory 4 = good 5 = very good 6 = excellent

	Task	Competence 0 - 6	Comments
1	**Rapport:** Rate the degree to which the relationship between the therapist and the client was easy, interactive (i.e., client spoke freely; therapist did not lecture), and positive (i.e., lots of agreements, few confrontations).		
2	**Knowledge:** Rate the degree to which the client shows an understanding of personality problems and insight into the effect these have on his/her interpersonal functioning.		
3	**Optimism about change:** Rate the degree to which the client appears to feel optimistic that treatments can help with personality problems and that new skills can be learned to improve interpersonal functioning.		
4	**Motivation for *Stop & Think!* group:** Rate the degree to which the client appears to be motivated to participate in forthcoming group work.		
	Total		

Acceptable adherence and competence is defined as follows:

Adherence: 7 / 7

Competence: Minimum score of 16, no item below a 3

PEPS Trial Psycho-Education Competence Rating Scale v1.0 – 19 July 2011

Appendix 6 Competence rating scale: problem-solving therapy

Stop & Think!
Adherence & Competence Rating Scale

Site		**Session**		**Therapist**		**Co-Therapist**	

The list of items below defines a good problem solving session. The task is to rate *if* these tasks are done in the session (adherence) and *how well* these tasks are done in the session (competence). There are two therapists in each session and the focus here is on the *task* rather than the therapist. Each task should be rated twice – once for adherence and once for competence. Adherence is a simple yes/no rating, identifying whether or not the task was done. Competence is rated on a scale of 0 to 6 where:

0 = poor   1= barely adequate   2 = mediocre   3= satisfactory   4 = good   5 = very good   6 = excellent

	Task	**Adherence** **Yes / No**	**Competence** **0 – 6**
1	How did I do?		
2	Feeling bad?		
3	What’s my problem?		
4	What do I want?		
5	What are my options?		
6	What’s my plan?		
7	Therapy is well-paced and engaging and positive problem orientation is encouraged		
	Total		

Acceptable adherence and competence is defined as follows:
Adherence: 7 / 7
Competence: Minimum score of 28, no item below a 3

PEPS Trial Stop & Think Competence Rating Scale v1.0 – 19 July 2011

Definitions

	Task	Definition Score 6	Score 0
1	How did I do?	Asks client who developed an action plan in last session to feedback on progress. Reminds group about the problem investigated. Asks client what action plan items have been undertaken. Praises completion of tasks. Asks client to identify obstacles to action plan items that have not been undertaken. Offers individual support session to address obstacles. Asks client if s/he believes the problem is solved or on the way to being solved. Asks client if s/he feels any better about this problem. Ends with praise for positive action.	Forgets who developed an action plan in last session. Does not remind group about the problem investigated. Asks client only for general feedback. Does not praise completion of action plan items or identify obstacles to tasks that were not undertaken. Does not ask the client if s/he believes progress has been made towards solving the problem or if s/he feels any better about this problem. Does not end with praise for positive action.
2	Feeling bad?	The therapist asks the group to name the question – *Feeling bad?* The therapist asks the client to identify the unpleasant feelings associated with the problem. The therapist asks the client to identify physical sensations associated with the emotions. The therapist explains that it is important to attend to unpleasant feelings and use them as a trigger to start the problem solving process.	The therapist names the question instead of asking the group what this is. The therapist accepts the naming of unpleasant feelings without asking the client to relate these to physical sensations. The therapist does not explain why it is important to attend to unpleasant feelings.

PEPS Trial Stop & Think Competence Rating Scale v1.0 – 19 July 2011

	Task	Definition	
		Score 6	Score 0
3	What’s my problem?	The client is asked to briefly introduce the problem s/he wishes to work on in this session. The client is allowed to describe the problem in his/her own words. The therapist prompts for further information as necessary or politely curtails a lengthy description. The client is thanked for describing the problem. The therapist summarises the main aspects of the problem. Group members are asked if they have any comments or questions. The therapist then turns to the question *Feeling Bad?* After this has been addressed, the therapist asks the group to name the second question – *What’s my problem?* The client is invited to revisit the problem already mentioned and add any information. The client is asked specifically about what makes him/her feel bad. The client is allowed time to talk about the problem, with the aim of specifying an important and manageable aspect on which to focus for the rest of the process. Group members are asked to comment (e.g., on similar experiences, to ask for clarification, etc). The therapist aims to capture the problem succinctly in a few words. The therapist asks group members for suggestions about the best way to word the problem. The therapist chooses the best words and phrases and produces a succinct definition. The therapist checks with the client that the wording captures the actual problem. Amendments are made as necessary. The problem is then written on the flip chart.	The therapist allows too lengthy a description of the problem. The therapist does not appear interested in the problem. The therapist does not thank the client for describing the problem, does not summarise, and does not ask the group for comments. The therapist then turns to the question *Feeling Bad?* After this has been addressed, the therapist names the second question or simply writes it on the flipchart instead of asking the group what this is. The therapist does not ask what it is about the problem that makes the client feel bad. The client’s problem is barely explored at all. The client is not helped to break down a large problem into more manageable constituent problems. Group members are not brought in to the discussion. The therapist defines the problem without involving group members. The therapist does not check the accuracy of the wording with the client before writing the problem on the flip chart.
4	What do I want?	The therapist asks the group to name the third question – *What do I want?* The therapist asks the client to identify a primary goal for change. The therapist checks that this will address the identified problem and lead to the client feeling better.	The therapist names the third question or simply writes it on the flipchart instead of asking the group what this is. The therapist asks the client to identify a primary goal for change but does not check that this will address the identified problem or lead to the client feeling better.

PEPS Trial Stop & Think Competence Rating Scale v1.0 – 19 July 2011

	Task	Definition	
		Score 6	Score 0
5	What are my options?	The therapist asks the group to name the fourth question – *What are my options?* The therapist asks all group members to contribute options. Where few options are generated, the therapist challenges group members to think of 'just one more'. Where numerous options are generated, similar ones are merged (e.g., play tennis, play football, go running might be summarised as 'take up a sport'). Options are not censored. Options are listed on the flip chart. Pros and cons of each option are discussed with nothing being written. The main pros and cons are then written on the flip chart. The pace is relatively brisk and repetition is avoided. The client is asked to run through the list of options and identify each as definitely 'yes' , 'maybe', or definitely 'no'. The client may be asked to consider an item carefully, but is given free choice.	The therapist names the fourth question or simply writes it on the flipchart instead of asking the group what this is. The therapist does not encourage the group to think creatively. The therapist censors suggestions. The therapist allows the list to grow too long (i.e., more than 10). All pros and cons for each option are written on the flip chart as the discussion takes place. The pace is slow and the content repetitive. The client is urged to adopt non-preferred options.
6	What's my plan?	The therapist asks the group to name the fifth question – *What's my plan?* The preferred options are operationalised and put in a logical sequence (e.g., chronological). The end product is a SMART action plan, i.e., items are specific, measurable, actionable, realistic, and timed. Helpers are identified if needed. The client is asked if the action plan is acceptable. The client is asked if the action plan is likely to help him/her attain the specified goal, solve the problem, and make him/her feel better. The client is thanked for working on the problem in the group. The therapist asks the group to name the sixth and final question – *How am I doing?* The client is reminded that feedback on progress will be taken in the next session. The problem solving process is immediately put into a format that is easy for the client and the therapist to retain and refer to.	The therapist names the fifth question or simply writes it on the flipchart instead of asking the group what this is. Options are left vaguely stated. The order is not logical. No deadlines are set. Help needed is not identified. The therapist does not check if the client accepts the action plan. The therapist does not relate the plan to the goal, the problem or the unpleasant feelings. There is no reminder the final question and next session's feedback. The client receives only the flip chart. There is a substantial delay before the client before the client receives the problem solving record. The therapist does not retain a copy.

PEPS Trial Stop & Think Competence Rating Scale v1.0 – 19 July 2011

	Task	Definition	
		Score 6	Score 0
7	Therapy is well-paced and engaging ,and positive problem orientation is encouraged	The therapy is appropriately paced. The therapist shows warmth, empathy, and understanding. Humour is used appropriately. Group members are encouraged to contribute to the client's problem solving process. The therapist ensures that quieter group members are invited to contribute. The therapist identifies the client's strengths and comments on these. Participation in the problem solving process is praised. Problems are normalised by identifying other group members who have experienced similar difficulties. Problem solving successes are recognised and praised. Approximations to success are praised. Lack of problem solving success is reframed as a learning opportunity. The session times and the duration of the break are specified in advance and the timings are adhered to. There is a break at a suitable juncture.	The therapy is too slow or too fast. The therapist shows aloofness, lack of concern, or lack of understanding. The session is dull and boring. The focus is too concentrated on the client who is working through a problem, and as a result other group members switch off from the process. More talkative group members are allowed too much air time. Quieter group members are ignored. The client's strengths are not comment upon. Participation is not praised. Successes are not praised. The session times are not clear. The session ends significantly early or late. There is no break or the break occurs at an inappropriate time.

Appendix 7 Psychoeducation therapist fidelity rating

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PSYCHO-EDUCATION

THERAPIST RATING OF TREATMENT ADHERENCE

The checklists below guide you to rating fidelity to the psycho-education session programme. In the first section, you rate *if* the therapy tasks were done in sessions (adherence). Adherence is a simple yes/no rating, identifying whether or not the task was done. There is also a section for comment. In the second section, you rate *the degree* to which the therapy goals were evident by the final session.

Task	Adherence	Comments
1. Complete the Brief Structured Interview.	Yes ☐ No ☐	
2. Discuss the contents of the information sheet, All About Personality Problems and Personality.	Yes ☐ No ☐	
3. Support the Client in completing the Problems Checklist (Client Version).	Yes ☐ No ☐	
4. Help the client to complete the worksheet – What do I want to change about myself?	Yes ☐ No ☐	
5. Discuss the Problems Checklist (Clinician Version).	Yes ☐ No ☐	
6. Help the client list five things s/he wishes to change.	Yes ☐ No ☐	
7. Prepare a personalised booklet for each client.	Yes ☐ No ☐	

Now, please rate the degree to which the therapy goals were evident by the final session on a scale of 0 to 6 where:

0 = poor 1 = barely adequate 2 = mediocre 3 = satisfactory 4 = good 5 = very good 6 = excellent

Goal Attainment	Rating (0 – 6)	Comments
1. Rapport: *Rate the degree to which the relationship between you and the client was easy, interactive (i.e., client spoke freely; you did not lecture), and positive (i.e., lots of agreements, few confrontations).*	☐	
2. Knowledge: *Rate the degree to which the client shows an understanding of personality problems and insight into the effect these have on his/her interpersonal functioning.*	☐	
3. Optimism about change: *Rate the degree to which the client appears to feel optimistic that treatments can help with personality problems and that new skills can be learned to improve interpersonal functioning.*	☐	
4. Motivation for *Stop & Think!* group: *Rate the degree to which the client appears to be motivated to participate in forthcoming group work.*	☐	

PEPS Psycho-Education Adherence Rating Final v1.0 – 16 June 2010
ISRCTN70660936

Appendix 8 Record check data collection forms

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

CMHT RECORD CHECK: MENTAL HEALTH SERVICE CONTACTS

Review Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

Page ☐☐ of ☐☐

Service Type	Date of First Contact	No. of Contacts*	Discharge Date	Reason for Discharge
☐☐ If other, specify: ______	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or before trial entry ☐	☐☐☐ No. DNA ☐☐☐	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or ongoing ☐	☐ Planned ☐ Unplanned ☐ N/K Details (if relevant): ______
☐☐ If other, specify: ______	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or before trial entry ☐	☐☐☐ No. DNA ☐☐☐	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or ongoing ☐	☐ Planned ☐ Unplanned ☐ N/K Details (if relevant): ______
☐☐ If other, specify: ______	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or before trial entry ☐	☐☐☐ No. DNA ☐☐☐	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or ongoing ☐	☐ Planned ☐ Unplanned ☐ N/K Details (if relevant): ______
☐☐ If other, specify: ______	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or before trial entry ☐	☐☐☐ No. DNA ☐☐☐	☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y Or ongoing ☐	☐ Planned ☐ Unplanned ☐ N/K Details (if relevant): ______

Service Type:
1 = Community mental health team
2 = Psychology / psychotherapy service
3 = Psychiatrist (outpatient)
4 = Day hospital
5 = Crisis resolution
6 = Home treatment
7 = Drug and alcohol services
8 = Specialist PD service
9 = Rehab / recovery team
10 = Assertive outreach service
11 = Intensive Community Support / Community Support Service
12 = Assessment and Brief Treatment / Primary Care Liaison Team / Access Teams
13 = A&E liaison / Liaison Psychiatry
14 = Eating disorders services
15 = Learning disabilities services
16 = Psychosis service
17 = Other, specify.

** Record contacts since entry to the trial only.*

PEPS Record Check Mental Health Service Contacts Final v1.0 – 10 February 2014
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

GP RECORD CHECK: HOSPITAL OUTPATIENTS

Review Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

Page ☐☐ of ☐☐

Since entry to the trial has the participant had a hospital outpatient appointment? Yes ☐ No ☐

Record the details of each hospital outpatient appointment since entry to the trial.

Date of Appointment	**Medical Specialty**	**Reason** *(tick all that apply)*	**Attended?**
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐☐ If other, specify: ____________	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Other (specify) ____________	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐☐ If other, specify: ____________	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Other (specify) ____________	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐☐ If other, specify: ____________	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Other (specify) ____________	☐ Yes ☐ No ☐ Not Known

Medical Speciality
1 = Audiology
2 = Acute / Emergency Medicine
3 = Cardiology
4 = Dermatology
5 = Gastroenterology
6 = Genitourinary Medicine
7 = Oncology
8 = Ophthalmology
9 = Neurology
10 = Respiratory
11 = Obstetrics & Gynaecology
12 = Other, specify

PEPS Record Check Hospital Outpatients Final v1.0 – 10 February 2014
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

GP RECORD CHECK: HOSPITAL ADMISSIONS

Review Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

Page ☐☐ of ☐☐

Since entry to the trial has the participant been admitted to hospital as an inpatient? Yes ☐ No ☐

Include both general and psychiatric hospital admissions and any secure hospital stays.

Record the details of each admission since entry to the trial.

Date of Admission	Reason *(tick all that apply)*	Length of Stay (Nights)	Planned Admission?
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical care ☐ Mental health care ☐ Social care / respite ☐ Self-harm / overdose ☐ Other (specify) ________________ ________________	☐☐☐	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical care ☐ Mental health care ☐ Social care / respite ☐ Self-harm / overdose ☐ Other (specify) ________________ ________________	☐☐☐	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical care ☐ Mental health care ☐ Social care / respite ☐ Self-harm / overdose ☐ Other (specify) ________________ ________________	☐☐☐	☐ Yes ☐ No ☐ Not Known

PEPS Record Check Hospital Admissions Final v1.0 – 10 February 2014
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

GP RECORD CHECK: GP CONTACTS

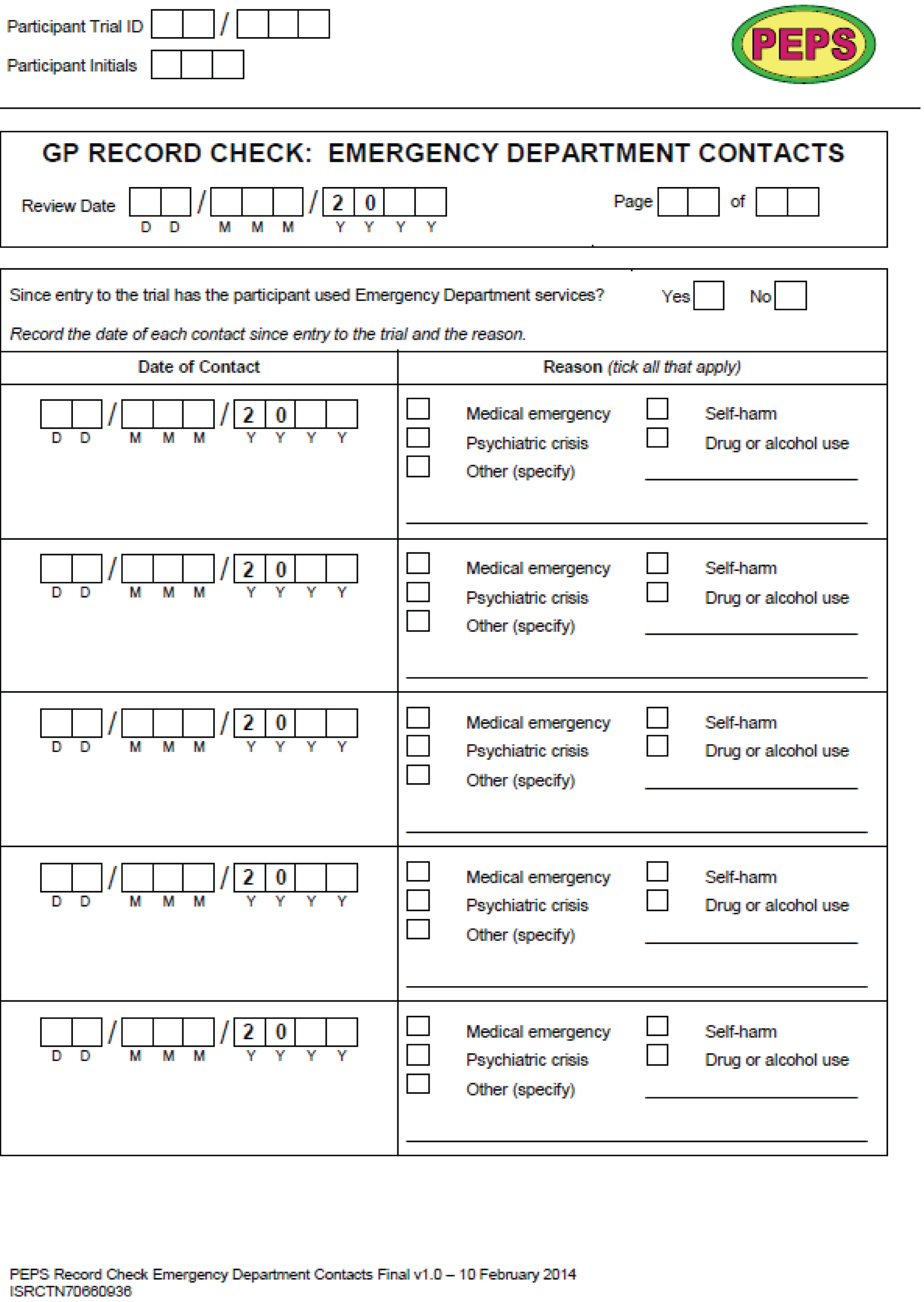
Review Date ☐☐ / ☐☐☐ / 2 0 ☐☐ Page ☐☐ of ☐☐
D D M M M Y Y Y Y

Since entry to the trial has the participant attended an appointment at the GP surgery (including telephone contacts)? Yes ☐ No ☐

Record the details of each GP attendance or contact since entry to the trial.

Date of Attendance or Contact	Reason *(tick all that apply)*	Scheduled / Pre-Booked Appointment?
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y ☐ Tick if telephone contact	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Attendance with / for other ☐ Other (specify) ____________________ ____________________	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y ☐ Tick if telephone contact	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Attendance with / for other ☐ Other (specify) ____________________ ____________________	☐ Yes ☐ No ☐ Not Known
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y ☐ Tick if telephone contact	☐ Medical care ☐ Mental health care ☐ Screening or assessment ☐ Routine review or follow-up ☐ Attendance with / for other ☐ Other (specify) ____________________ ____________________	☐ Yes ☐ No ☐ Not Known

PEPS Record Check GP Contacts Final v1.0 – 10 February 2014
ISRCTN70660936



Participant Trial ID ☐☐☐ / ☐☐☐

Participant Initials ☐☐☐

GP RECORD CHECK: EMERGENCY DEPARTMENT CONTACTS

Review Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

Page ☐☐ of ☐☐

Since entry to the trial has the participant used Emergency Department services? Yes ☐ No ☐

Record the date of each contact since entry to the trial and the reason.

Date of Contact	Reason *(tick all that apply)*
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical emergency ☐ Self-harm ☐ Psychiatric crisis ☐ Drug or alcohol use ☐ Other (specify) ____________
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical emergency ☐ Self-harm ☐ Psychiatric crisis ☐ Drug or alcohol use ☐ Other (specify) ____________
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical emergency ☐ Self-harm ☐ Psychiatric crisis ☐ Drug or alcohol use ☐ Other (specify) ____________
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical emergency ☐ Self-harm ☐ Psychiatric crisis ☐ Drug or alcohol use ☐ Other (specify) ____________
☐☐ / ☐☐☐ / 2 0 ☐☐ D D M M M Y Y Y Y	☐ Medical emergency ☐ Self-harm ☐ Psychiatric crisis ☐ Drug or alcohol use ☐ Other (specify) ____________

PEPS Record Check Emergency Department Contacts Final v1.0 – 10 February 2014
ISRCTN70660936

Appendix 9 Unblinding script

Final version 2.0: 3 December 2010

At the start of the study, the following information should be given:

> *The study involves looking at two different treatments for personality disorder. To find out which treatment is best we are asking you to complete some questionnaires and interviews with me. Both you and your mental health team will know what treatment you are receiving, but to make sure the results are fair, it is important that I don't know which treatment group you are in until you have finished taking part in the research. I will remind you not to tell me this information each time I contact you about the research.*

Each time the research assistant assesses the participant, a reminder about the need for blinding should be issued.

There is a particular risk of unblinding at the administration of the CSRI at the second follow-up. A specific instruction is recommended at this point:

> *I am going to ask you about the services you have received in the past 6 months. Remember, it is important that I don't know which treatment group you were in. So, you should not tell me whether or not you received PEPS sessions (i.e. psychoeducation and Stop & Think sessions). Just don't mention these and tell me only about your use of other services.*

Appendix 10 Summary of trial amendments

Stage of the trial	Amendment reference	Protocol version and date	Summary of changes
Amendments implemented before recruitment started	Substantial amendment 1 (15 June 2010)	Version 2.0, dated 15 June 2010	The protocol was amended to include revised eligibility criteria, clarification of arrangements for the trial DMEC, a change to the follow-up schedule and addition of the service use record check as a secondary outcome measure
Amendments implemented during the recruitment phase	Substantial amendment 2 (17 August 2010)	Version 3.0, dated 17 August 2010	The planned requirement for a standardised form of treatment as usual was removed from the protocol
	Substantial amendment 3 (4 October 2010)	Version 4.0, dated 4 October 2010	The protocol was amended to include additional competence checks for the IPDE and delivery of psychoeducation, and to clarify the publication policy. In addition, the amendment included a procedure for providing feedback of the participants' IPDE results at final follow-up and to allow provision of a summary of the trial results after the final report
	Substantial amendment 4 (1 April 2011)	Version 5.0, dated 1 April 2011	In response to advice from the TSC and DMEC the definition of recordable adverse events was expanded and simplified to ensure that all potentially relevant adverse events were recorded. The reporting procedure was also clarified
	Substantial amendment 5 (17 August 2011)	N/A	The decision was taken to allow problem-solving therapy to be offered in mixed-sex groups. The participant information sheet was updated to remove the reference to single-sex groups
	Substantial amendment 6 (02 February 2012)	N/A	The interview schedule at final follow-up for participants in the treatment as usual arm was updated to remove references to standardised treatment as usual as per the changes implemented in Substantial amendment 2
	Substantial amendment 7 (5 July 2012)	N/A	Following the decision to provide IPDE feedback to participants who requested this, at the end of their involvement in the trial the study team developed a procedure and supporting documents to ensure that this feedback was provided sensitively and within an appropriate context to avoid causing distress or worry to participants. The procedure, letters and report template for the provision of IPDE results were submitted for review
	Substantial amendment 8 (26 November 2012)	N/A	Retrospective approval was sought from the Research Ethics Committee for implementation of the trial changes as an urgent safety measure, following the decision to stop recruitment and delivery of the trial intervention
Amendments implemented during the follow-up phase	Substantial amendment 9 (3 April 2013)	Version 6.0, dated 3 April 2013	This amendment included proposals for a number of measures to improve follow-up completion, including the introduction of payments to participants, the facility to post the SFQ to participants for completion and submission of a participant newsletter

N/A, not applicable.

Appendix 11 Schedule of Data Monitoring and Ethics Committee and Trial Steering Committee meetings

DMEC meetings	TSC meetings
2010	
19 October 2010	17 March 2010
2011	
15 February 2011	23 March 2011
	22 June 2011
	16 September 2011
2012	
28 February 2012	13 January 2012
15 October 2012	16 March 2012
	15 August 2012
	1 November 2012
Plus subsequent joint TSC/TMG meetings regarding early stopping	
2013	
	9 January 2013
	20 March 2013
	6 December 2013

Appendix 12 Unit costs used in economic evaluation

Service	Unit cost	Source
GP	£4 per minute of patient contact	Curtis (2013)[110]
Psychiatrist	£362 per face-to-face contact	
Other doctor	£135 per 30 minutes of patient contact	
Psychologist	£134 per hour of client contact	
Drug and alcohol advisor	£54 per clinic consultation	
Other counsellor/therapist	£63 per hour of client contact	
Home treatment/crisis team member	£37 per hour per team member	
Assertive outreach team member	£49 per hour of patient contact	
Early intervention team member	£37 per hour	
Social worker	£226 per hour of face-to-face contact	
Mental health nurse	£74 per hour of face-to-face contact	
Occupational therapist	£44 per hour	
Accident and emergency service	£125 per attendance	
Drug/alcohol service	£38 per user session	
Community mental health centre	£38 per user session	
Day care centre/day hospital	£38 per user session	
Drop-in centre	£38 per user session	
Self-help/support group	£38 per user session	
Class/group at a leisure centre	£38 per user session	
Adult education class	£38 per user session	
Other day care activity provided by team	£38 per user session	
Inpatient admission	£345 per day (psychiatric); £577 per day (other)	Department of Health (2012)[111]
Contact with police	£1 per minute	Bedfordshire Police Authority (2009)[112]
Night detained in a police cell	£414 per night	Heslin *et al*. (2016)[113]
National average wage	£26,500 per year	Office for National Statistics (2013)[114]

Appendix 13 Intervention costs

Individual psychoeducation sessions

Delivered by a band 6 mental health nurse, psychology graduate or other mental health professional.

1-hour session.

Unit cost = £119 per session.

Problem-solving group session

Delivered by two band 6 mental health nurses, psychology graduates or other mental health professionals.

2-hour sessions.

Average of 7.5 participants.

Unit cost = £63 per session.

Individual support as part of group therapy

Delivered by a band 6 mental health nurse, psychology graduate or other mental health professional.

1-hour session.

Unit cost = £119 per session.

Appendix 14 Qualitative interview schedule: post intervention – psychoeducation

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

Post-Intervention Interview Schedule
Psycho-Education

Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

The purpose of this interview is to gather your views on the psychoeducation sessions that you did with [NAME OF CLINICIAN]. The psychoeducation sessions were those where you looked at your personality and related problems.

Your views are being gathered as part of a research study investigating psychoeducation. We are asking for your views because you consented to participate in this research, however, if you do not want to give us your views, that's OK.

Ask the client for permission to proceed. If the client declines, thank them for their time and conclude the interview.

1. **First, I am interested in hearing your general opinions of the psychoeducation sessions. So, before I ask you any questions that might get you thinking about specific things, would you please give me your general opinions of the psychoeducation sessions?**

2. **Please tell me the main things you learned in the psychoeducation sessions:**

3. **Besides gaining knowledge, I am interested in whether you got anything else out of the psychoeducation sessions. Did you benefit in any way?**

PEPS Trial Client Post-Intervention Interview Psycho-Education Final v1.0 – 20 May 2009
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PEPS

3a. **If you did benefit, could you please try to tell me <u>how</u> psychoeducation had this good effect?**

4. **Do you think psychoeducation had any bad effects?**

4a. **If so, could you please try to tell me <u>how</u> psychoeducation had a bad effect?**

5. **May I ask you to rate how motivated you now feel about attending the *Stop & Think!* group sessions?**

10 Very motivated

9

8

7

6

5

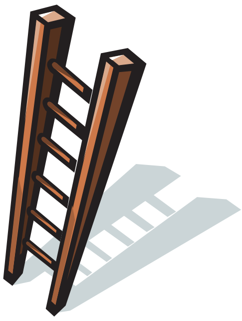
4

3

2

1

0 Not at all motivated



PEPS Trial Client Post-Intervention Interview Psycho-Education Final v1.0 – 20 May 2009
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

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PEPS

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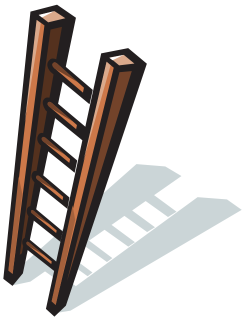
6. The psychoeducation sessions were meant to improve your motivation for *Stop & Think!* group sessions. Do you think the sessions did anything to help become more strongly motivated?

6a. If yes, can you think of what effect the psychoeducation sessions had that made you more motivated?

6b. If no, can you think of why the psychoeducation sessions had no effect on your level of motivation?

7. May I ask you to rate how useful you found the psychoeducation sessions overall?

10 Very useful indeed



9

8

7

6

5

4

3

2

1

0 Not at all useful

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PEPS

8. Do you have any other comments?

Thank you for your help.

PEPS Trial Client Post-Intervention Interview Psycho-Education Final v1.0 – 20 May 2009
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Appendix 15 Qualitative interview schedule: post intervention – problem-solving therapy

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PEPS

Post-Intervention Interview Schedule
Problem Solving Therapy

Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

The purpose of this interview is to gather your views on the *Stop & Think!* group sessions. The *Stop & Think!* sessions were those where you learned a way of tackling and solving problems.

Your views are being gathered as part of a research study investigating *Stop & Think!* We are asking for your views because you consented to participate in this research, however, if you do not want to give us your views, that's OK.

Ask the client for permission to proceed. If the client declines, thank them for their time and conclude the interview.

1. **First, I am interested in hearing your general opinions of the *Stop & Think!* sessions. So, before I ask you any questions that might get you thinking about specific things, would you please give me your general opinions of the *Stop & Think!* sessions?**

2. **Please tell me the main things you learned in the *Stop & Think!* sessions:**

3. **Besides gaining knowledge, I am interested in whether you got anything else out of the *Stop & Think!* sessions. Did you benefit in any way?**

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PEPS

3a. If you did benefit, could you please try to tell me <u>how</u> *Stop & Think!* had this good effect?

4. Do you think *Stop & Think!* had any bad effects?

4a. If so, could you please try to tell me <u>how</u> *Stop & Think!* had a bad effect?

5. May I ask you to rate how useful you found the Stop & Think! sessions overall?

10 Very useful indeed

9

8

7

6

5

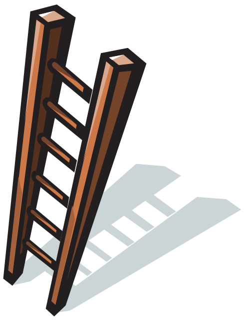
4

3

2

1

0 Not at all useful



PEPS Trial Client Post-Intervention Interview Problem Solving Final v1.0 – 17 September 2009
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Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PEPS

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6. How much would you say you actually use the *Stop & Think!* procedure when you have problems?

10 Almost always

9

8

7

6

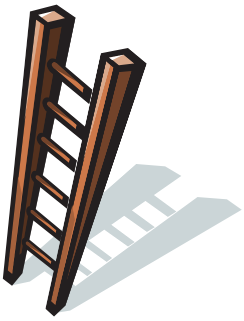
5

4

3

2

1 Never



7. Do you have any other comments?

Thank you for your help.

PEPS Trial Client Post-Intervention Interview Problem Solving Final v1.0 – 17 September 2009
ISRCTN70660936

Appendix 16 Qualitative interview schedule: 72-week follow-up – psychoeducation with problem-solving therapy

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

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72 Week Follow-Up Interview
PEPS Therapy

Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

The purpose of this interview is to gather your views on PEPS therapy, that is the individual psychoeducation sessions and the Stop & Think! group sessions.

Your views are being gathered as part of a research study investigating PEPS therapy. We are asking for your views because you consented to participate in this research, however, if you do not want to give us your views, that's OK.

> *Ask the client for permission to proceed. If the client declines, thank them for their time and conclude the interview.*

1. **First, I am interested in hearing your general opinions of the PEPS therapy. So, before I ask you any questions that might get you thinking about specific things, would you please give me your general opinions of the PEPS therapy?**

2. **Please tell me the main things you learned in the PEPS therapy:**

3. **Besides gaining knowledge, I am interested in whether you got anything else out of the PEPS therapy. Did you benefit in any way?**

PEPS Trial Client Post-Intervention Interview PEPS Final v1.0 – 17 September 2009
ISRCTN70660936

Participant Trial ID	☐☐ / ☐☐☐
Participant Initials	☐☐☐

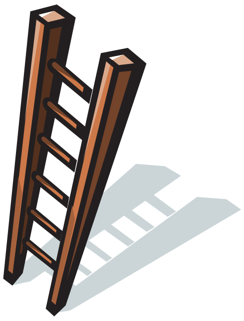
3a. If you did benefit, could you please try to tell me how PEPS therapy had this good effect?

4. Do you think PEPS therapy had any bad effects?

4a. If so, could you please try to tell me how PEPS therapy had a bad effect?

5. May I ask you to rate how useful you found the PEPS therapy overall?

10	**Very useful indeed**
9	
8	
7	
6	
5	
4	
3	
2	
1	
0	**Not at all useful**



PEPS Trial Client Post-Intervention Interview PEPS Final v1.0 – 17 September 2009
ISRCTN70660936

Participant Trial ID ☐☐ / ☐☐☐

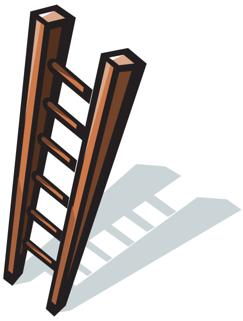
Participant Initials ☐☐☐ Date of Birth ☐☐ / ☐☐☐ / ☐☐☐☐
D D M M M Y Y Y Y

PEPS

6. There were two main components in PEPS therapy – psychoeducation and problem solving. We would like your opinion on whether one is more useful than the other and how they work together.

7. How much would you say you actually use the *Stop & Think!* procedure when you have problems?

10 **Almost always**
9
8
7
6
5
4
3
2
1 **Never**



8. Do you have any other comments?

Thank you for your help.

PEPS Trial Client Post-Intervention Interview PEPS Final v1.0 – 17 September 2009
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Appendix 17 Qualitative interview schedule: 72-week follow-up – usual treatment

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PEPS

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72 Week Follow-Up Interview
Treatment as Usual

Date ☐☐ / ☐☐☐ / 2 0 ☐☐
D D M M M Y Y Y Y

The purpose of this interview is to gather your views on the treatment or care that you received from your mental health team and / or GP. We are interested in what you think about the treatment that you have received for mental health problems.

Your views are being gathered as part of a research study looking at treatments for people with personality difficulties. We are asking for your views because you consented to participate in this research, however, if you do not want to give us your views, that's OK.

Ask the client for permission to proceed. If the client declines, thank them for their time and conclude the interview.

1. **First, would you please tell me what treatment or care you have received in the past XX months?**

2. **I am interested in hearing your general opinions of the treatment or care you received from your mental health team / GP for mental health problems. So, before I ask you any questions that might get you thinking about specific things, would you please give me your general opinions of the treatment or care you have received?**

PEPS Trial Client Post-Intervention Interview – TAU Final v2.0 – 02 February 2012
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Participant Trial ID ☐☐ / ☐☐☐

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3. **I am interested in what benefits you got from the treatment or care you received. Did you benefit in any way?**

a. If you did benefit, could you please try to tell me how the treatment or care you received had this good effect?

4. **Do you think the treatment or care you received had any bad effects?**

a. If so, could you please try to tell me how the treatment or care you received had a bad effect?

Participant Trial ID ☐☐ / ☐☐☐

Participant Initials ☐☐☐

PEPS

5. **May I ask you to rate how helpful you found the treatment or care you received overall?**

10	**Very helpful indeed**
9	
8	
7	
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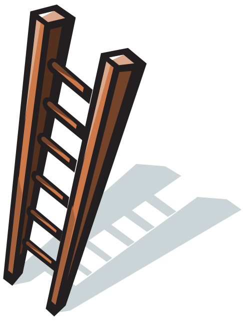
5	
4	
3	
2	
1	
0	**Not at all helpful**



6. **Do you have any other comments?**

Thank you for your help.

PEPS Trial Client Post-Intervention Interview – TAU Final v2.0 – 02 February 2012
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