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Psycho-Education with Problem Solving (PEPS) therapy for personality disorder

Submission date	Recruitment status	[X] Prospectively registered
30/11/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/12/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/01/2018	Mental and Behavioural Disorders	

Plain English summary of protocol
STUDY SUMMARY tab on http://www.peps-trial.co.uk/

Study website
http://www.peps-trial.co.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

HTA 08/53/06

Study information

Scientific Title
Psycho-Education with Problem Solving (PEPS) therapy for adults with personality disorder: a community-based randomised controlled trial

Acronym
PEPS

Study objectives
The purpose of the trial is to evaluate the effectiveness of PEPS therapy compared with treatment as usual in improving social functioning in community based adults with personality disorder.

Please note, as of 23/06/2011 various updates have been made to this trial and can be found under this date of update in the relevant fields below.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee Panel C approved on 13/11/2009 (ref: 09/WSE03/48)

Study design
Multicentre two-arm parallel group randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
INFORMATION SHEETS tab on http://www.peps-trial.co.uk/

Health condition(s) or problem(s) studied
Personality disorder

Interventions
Psycho-education combined with problem solving (PEPS) therapy is a complex cognitive-behavioural intervention that integrates individual and group therapies. Psycho-education

consists of up to 4 sessions of an individual collaborative dialogue designed to build a rapport with patients, inform them about their personality disorder, discuss its effects on interpersonal relationships and social functioning, and enhance motivation for therapy. Problem solving therapy is a 12-session group intervention designed to teach people strategies for solving interpersonal problems. Throughout the twelve week problem solving therapy group sessions, participants are offered additional, optional fortnightly individual support sessions with a group facilitator.

PEPS therapy will be compared with treatment as usual. (Added 23/06/2011; previous intervention for this point can be found below).

Follow-up assessments for all participants will be completed after the initial treatment phase (weeks 5 - 10), immediately after the second treatment phase (during weeks 24 - 26) and again four and twelve months after the end of the intervention.

Previous intervention:

PEPS therapy will be compared with a standardised form of 'treatment as usual' which will include an initial care planning session with a mental health worker, including plans for future contact with services and details of alternative sources of help and support, with a follow-up session after approximately 4 weeks and a further session approximately 4 months later with additional telephone support.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Social functioning as measured by the Social Functioning Questionnaire (SFQ). This is an 8-item self-report scale, each item scored on a scale from 0 to 3. A reduction (i.e. an improvement) of 2 points or more on the SFQ at 1 year, post-treatment follow-up is the specified clinically significant change.

Secondary outcome measures
1. Receipt and cost of services post-therapy and at one year follow-up measured by the Client Service Receipt Inventory
2. Scheduled and unscheduled service use post-therapy and at one year follow-up measured by the Client Service Receipt Inventory and a service use record check.
3. Quality of life post-therapy and at one year follow-up measured by the EQ-5D
4. Referrer's ratings of functioning post-therapy and at one year follow-up measured by the Global Assessment of Functioning
5. Anxiety and depression post-therapy and at one year follow-up meaured by the Hospital Anxiety and Depression Scale
6. A rating of the client's self-assessment of problems post-therapy and at one year follow-up

Overall study start date
01/08/2010

Completion date

31/01/2014

Eligibility

Key inclusion criteria
1. Living in the community
2. Presence of one or more personality disorder, as identified by the International Personality Disorder Examination
3. Aged 18 years or over, either sex
4. Proficiency in spoken English is necessary for trial participation due to the requirements of the interventions used
5. Capacity to provide valid informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
340

Key exclusion criteria
Current exclusion criteria as of 23/06/2011:
1. Primary diagnosis of major functional psychosis
2. Insufficient degree of literacy, comprehension or attention to be able to engage in trial therapy and assessments
3. Currently engaged in psychological treatment for personality disorder, or likely to start such treatment during the trial period
4. Already enrolled in any other trial

Previous exclusion criteria:
1. Insufficient degree of literacy, comprehension or attention to be able to engage in trial therapy and assessments, as assessed by the Investigator or authorised designee in conjunction with the participants usual care team. This may be a result of psychosis, developmental disability, organic brain disorder, substance use, or any other disorder or disability.
2. Currently engaged in psychological treatment for personality disorder, or likely to start such treatment during the trial period
3. Already enrolled in any other trial

Date of first enrolment
01/08/2010

Date of final enrolment

31/01/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Mental Health
Nottingham
United Kingdom
NG7 2TU

Sponsor information

Organisation
Nottinghamshire Healthcare NHS Trust (UK)

Sponsor details
Duncan MacMillan House
Porchester Road
Mapperley
Nottingham
England
United Kingdom
NG3 6AA

Sponsor type
Hospital/treatment centre

Website
http://www.nottinghamshirehealthcare.nhs.uk/

ROR
https://ror.org/04ehjk122

Funder(s)

Funder type
Government

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	24/08/2011		Yes	No
Results article	results	01/07/2016		Yes	No