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Problem Solving Treatment (PST) Project

Submission date	Recruitment status	[ ] Prospectively registered
13/07/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/05/2013	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.pstproject.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
42.00.0001; NTR607

Study information

Scientific Title

Acronym
PST

Study objectives
There is a need for assistance by primary care mental health workers in general practice in the Netherlands. General Practitioners (GPs) experience an overload of frequent attenders suffering from (co-morbid) psychological problems. For most GPs these problems are complicated to recognise and to refer. PST is a brief and practical skill-building psychological treatment. The treatment has a strict protocol and is based on the principles of cognitive behavioural therapy. PST delivered by nurses seems to be an effective treatment for patients with psychological problems in primary care. This treatment increases the patients skill of structured problem solving and gives back a sense of control. However, research outcomes differ and no systematic review is available. This protocol describes a randomised clinical trial on the effectiveness of PST delivered by nurses for patients in general practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Psychological problems

Interventions
PST versus care as usual.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Reduction of symptoms, measured using the Hospital Anxiety and Depression Scale (HADS) to monitor symptom levels of anxiety and depression.

Secondary outcome measures
1. Social problem-solving skills, measured using a questionnaire designed by DZurilla
2. Psychological and physical well-being using the 36-item short form health survey (SF-36)
3. Social support, using the Social Support Inventory
4. Coping-styles by the VOMS (Vragenlijst over Omgaan met Situaties) is the Dutch adaption of the ways of coping questionnaire (WAYS) which is based on the transactional coping theory of Lazarus and Folkman
5. Rumination: actual scientific reports suggest rumination as a significant, and probable prognostic, factor for depression. The ruminative response scale (RRS) wil be used to measure this.
6. Problem evaluation
7. Health care utilisation. We used the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (Tic-P) to measure the amount health care patients consume and to register sick days from work. Furthermore, the EQ-5D was used.

Overall study start date
01/11/2002

Completion date
01/11/2006

Eligibility

Key inclusion criteria
Patients of 18 years and older, who present psychological problems and are frequent attenders of general practice are recruited by the research-assistant.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Patients who are treated in last year in the GGz, for example with cognitive behaviour therapy
2. Patients who suffer from a serious medical sickness, psychotic impairment, primarily organic-mental impairment or serious individuality problems
3. Patients who are multiple visitors of the general practitioner because of chronic disease or hypochondria
4. Patients who are indicated for anxiolytic or antidepressant treatment, or patients who used these drugs less than 12 weeks ago, or those without constant treatment dose in the following 10 weeks
5. Patients with serious addiction problems
6. Patients who are suicidal
7. Patients who are not able to fill in the questionnaire (General Health Questionnaire [GHQ])
8. Patients with insufficient knowledge of the Dutch language

Date of first enrolment
01/11/2002

Date of final enrolment
01/11/2006

Locations

Countries of recruitment
Netherlands

Study participating centre
van der Boechorststraat 7
Amsterdam
Netherlands
1081 BT

Sponsor information

Organisation
Ministry of Mental Health Care (Geestelijke Gezondheidszorg [GGZ]) (The Netherlands)

Sponsor details
van der Boechorststraat 7
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Netherlands
1081 BT

Sponsor type
Government

Website
http://www.ggznederland.nl/

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

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	12/10/2005		Yes	No
Results article	results	10/10/2012		Yes	No