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Trial of problem-solving by community psychiatric nurses (CPNs) for anxiety, depression and life difficulties among general practice patients

Submission date	Recruitment status	[ ] Prospectively registered
25/04/2003	No longer recruiting	[ ] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
25/04/2003	Completed	[X] Results
Last Edited	Condition category	[ ] Individual participant data
03/09/2009	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 97/43/09

Study information

Scientific Title

Study objectives
The proposed study seeks to evaluate two treatments for anxiety and depression and reactions to life difficulties in general practice patients: a) generic CPN care, i.e.. non-specific support, and b) problem-solving therapy given by a specially trained CPN, each being compared with general practitioners' usual treatment as a control. The study has three specific aims: i) to determine the effectiveness of each of the two treatment in reducing symptoms and alleviating psychosocial problems, ii) to determine the cost-utility, cost-effectiveness, or cost-minimisation of the two treatments, depending on whether or not they prove effective, evaluating not only direct costs of treatment but also indirect costs, including time off work, and iii) to explore whether rapid self-complete tests might predict which patients could benefit from CPN treatment. The primary null hypothesis to be tested is that problem-solving by trained CPNs is no more effective for anxiety, depression and life difficulties than usual GP care. The second null hypothesis is that generic CPN care is no more effective than usual GP care, which would serve to confirm the findings of the one previous trial in this area.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added as of 27/07/2007: Ethical approval for the study was granted by the four local NHS research ethics committees covering the trusts catchment areas:
1. Southampton and South West Hampshire
2. East Dorset
3. North and Mid Hampshire
4. Isle of Wight, Portsmouth and South East Hampshire

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
Mental and behavioural disorders: Depression, anxiety, neuroses

Interventions
A randomised controlled trial with three arms: usual GP care, generic CPN care, and CPN problem-solving. A sample of 20 CPNs will be recruited to receive the problem-solving training, with 20 untrained CPNs from the same Trusts providing generic care.
Health technologies being assessed: Problem-solving includes 7 stages: (i) explanation of the treatment and its rationale, (ii) clarification and definition of the problems, (iii) choice of achievable goals, (iv) generation of alternative solutions, (v) selection of a preferred solution, (vi) clarification of the necessary steps to implement the solution, and (vii) evaluation of progress. Training will be in one-week blocks, of 10 CPNs at a time, followed by supervised treatment, specified in a detailed training manual, of at least 5 patients per nurse. Treatment will comprise an initial one-hour session and 3 or 4 half-hour follow-up sessions. Video-taped recordings will be made in each treatment session during the training period, for use in supervision sessions to give the nurses detailed feedback (in pairs) about their problem-solving skills.

Problem-solving treatment sessions will be audiotaped and a 1 in 10 sample checked for integrity of treatment. Nurses in the generic CPN care arm will be asked to get patients well as quickly as possible using the range of treatments they are experienced in giving, which will usually include non-specific counselling and support. All three groups of patients will be free to consult their GPs throughout the course of the study, and may be prescribed psychotropic drug treatment. Participating GPs will be asked not to refer patients in the routine GP care arm to a therapist during the study period, unless absolutely necessary.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The main outcome measure will be psychological symptoms measured using the revised CIS-R, analysed on an intention-to-treat basis. Social outcome will be measured using the modified Social Adjustment Scale and health-related quality of life using the Euroquol. Patient satisfaction will be measured using a specially designed self-report questionnaire.

The economic analysis (cost-utility, cost-effectiveness, or cost-minimisation depending on the outcomes found) will take into account the cost of CPN training, treatment and supervision, GP consultations, medication prescribed, the number of days off work for patients in paid employment, and other costs incurred by the patient or their family in attending treatment. Patients will be assessed at baseline, at 8 weeks (after the problem-solving therapy has been completed), and at 26 weeks. At baseline patients will be interviewed using the revised Clinical Interview Schedule (CIS-R) to provide total symptom scores and an ICD-10 diagnosis, and will also complete the General Health Questionnaire and Hospital Anxiety and Depression Scale (to explore the usefulness of these scales in predicting which patients benefit from treatment).

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2000

Completion date
30/04/2003

Eligibility

Key inclusion criteria
Patients aged 18 to 65 with a new episode of anxiety, depression or reaction to life difficulties, lasting at least four weeks.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Added as of 27/07/2007: 247

Key exclusion criteria
Already receiving psychological treatment, severe mental illness, actively suicidal, severe substance misuse, housebound, illiterate, temporary residents.

Date of first enrolment
01/05/2000

Date of final enrolment
30/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Primary Medical Care
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Sponsor information

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Sponsor type
Government

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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?
Results article	results	01/09/2005		Yes	No