Primary care evidence-based psychological interventions collaboration (PEP)

Submission date 30/11/2005	Recruitment status No longer recruiting	Prospectively registered
		☐ Protocol
Registration date 22/03/2006	Overall study status Completed	Statistical analysis plan
		[X] Results
Last Edited 02/05/2019	Condition category Mental and Behavioural Disorders	[] Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Primary care evidence-based psychological interventions collaboration (PEP)

Acronym

PEP

Study objectives

The objectives of this study are to examine whether general practitioners (GPs) who have completed training in cognitive behavioural therapy (CBT) demonstrate:

- 1. An increased knowledge of CBT
- 2. An increase in confidence and reported feasibility of delivering CBT in general practice
- 3. An improvement in the quality of CBT they deliver in simulated role-plays
- 4. Improved clinical outcomes for depressed patients

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval has been obtained from the Monash University Standing Committee on Ethics in Research Involving Humans, reference numbers: 154 and 544

Study design

This study is a randomised controlled trial of CBT training with general practitioners randomised to training and waitlisted (control) groups

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Depressive disorder

Interventions

Pre and post measures of knowledge, attitudes and practices (KAP) will be measured with questionnaires, as well as videotaped simulated consultations rated with standardised instruments to measure competence. Enrolled GPs will each recruit depressed patients who will

be followed up for six months during the course of the study using a suite of quantitative outcome measures (PEP pack patient survey). A subset of these patients will be recruited for more in-depth qualitative interviews to assess consumers' and carers' experience of care.

The intervention group receive the CBT program which is a 20-hour face to face skills based program facilitated by specialist mental health care providers or GPs with independent mental health qualifications. Groups of 10-14 GPs per group participate in multiple role-play exercises guided by video-based skills demonstrations, and detailed GP or patient workbooks. The program specifically covers process issues such as integrating psychological skills into general practice, engaging the patient and structuring consultations, as well as specific content issues. The CBT program is an accredited level 2 training program with the Australian general practice mental health standards collaboration.

The control group receive no training initially but are waitlisted to subsequently receive the same training.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

GPs:

- 1. Improvement in knowledge
- 2. Attitudes and performance in simulated consultations

Patients:

- 1. Improvement in depressive symptoms
- 2. Quality of life and disability

Secondary outcome measures

Comparison of pre-training GP knowledge and attitudes with performance in simulated consultations will be undertaken

Overall study start date

01/06/2004

Completion date

31/12/2006

Eligibility

Key inclusion criteria

GPs:

1. Registered GPs in the state of Victoria, Australia

Patients:

- 1. 18-65 years old
- 2. Adequate English skills
- 3. Regular patient of the GP

- 4. GP diagnosis of depression
- 5. Patient health questionnaire (PHQ-9) score >10
- 6. GP intends to manage the patient's depressive illness

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

65 Years

Sex

Both

Target number of participants

40 GPs; 100 Patients

Total final enrolment

55

Key exclusion criteria

Patients:

- 1. Psychotic disorder
- 2. Personality disorder
- 3. Moderate or high suicide risk

Date of first enrolment

01/06/2004

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Australia

Study participating centre 200 Berkeley Street

Victoria Australia 3053

Sponsor information

Organisation

The beyondblue Victorian Centre of Excellence in Depression and Related Disorders (Australia)

Sponsor details

PO Box 6100 West Hawthorn Australia 3122 +61 (0)3 9810 6100 bb@beyondblue.org.au

Sponsor type

Government

Website

http://www.beyondblue.org.au

ROR

https://ror.org/05mwvz623

Funder(s)

Funder type

Government

Funder Name

The beyondblue Victorian Centre of Excellence in Depression and Related Disorders

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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults16/06/200802/05/2019YesNo