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Effectiveness of collaborative care for depressed Chinese people in primary care

Submission date	Recruitment status	[X] Prospectively registered
05/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
04/02/2019	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
NHRI-EX97-9706PI

Study information

Scientific Title
Effectiveness of culturally sensitive collaborative treatment of depressed Chinese people in primary care: a randomised controlled trial

Study objectives
1. Depressed patients who receive intervention have improved treatment outcomes compared to patients who receive usual care
2. Depressed patients who perceive biomedical causes of depression have improved treatment outcomes compared to patients who perceive non-medical causes of depression
3. Depressed patients with history of seeking medical treatment have improved treatment outcomes compared to patients with history of seeking non-medical treatment
4. Depressed patients with low stigmatisation have improved treatment outcomes compared to patients with high stigmatisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Mackay Memorial Hospital Institutional Review Board. Date of approval: 24/04/2007 (ref: MMH-I-S-241 [2])

Study design
Randomised controlled trial.

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
The intervention includes consultation to depressed patients by a psychiatrist, treatment of depression by general medical doctors based on established guidelines, and Care Management by a Care Manager under the supervision of a psychiatrist.

The control group of participants will receive the "standard care."

Duration of interventions: 24 weeks

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Rate of adherence to treatment initiation, assessed by blind assessors at baseline and every four weeks from week 2 until week 26 or end point.

Secondary outcome measures
The following will be assessed by blind assessors at baseline and every four weeks from week 2 until week 26 or end point:
1. Rate of adherence to medication treatment
2. Rate of treatment completers
3. Rate of responders
4. Overall life satisfaction

Overall study start date
01/05/2008

Completion date
31/07/2012

Eligibility

Key inclusion criteria
1. Patients who attend non-psychiatric clinics
2. Patients with Major Depressive Disorder (MDD), defined as a positive screen using the Patient Health Questionnaire (PHQ-9), confirmed with the Schedules of Clinical Assessment in Neuropsychiatry (SCAN) interview
3. Men or women aged 18 or older
4. Able to participate in a clinical diagnostic interview in either Mandarin or Fukienese dialects
5. Individuals who are willing to be followed up concerning their depression symptoms
6. Individuals who have completed a written consent form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Women who are pregnant, breast-feeding or planning pregnancy within the next year
2. Patients with serious suicidal risk
3. Patients with unstable medical illnesses
4. Clinical or laboratory evidence of hypothyroidism
5. Patients with comorbid severe mental disorders including:
5.1. Organic mental disorders
5.2. Alcohol or substance abuse disorders active within the last year
5.3. Schizophrenia
5.4. Delusional disorder
5.5. Psychotic disorders not elsewhere classified
5.6. Bipolar disorder
5.7. Mood congruent or mood incongruent psychotic features
6. Patients with history of treatment by a psychiatrist in the past 4 months

Date of first enrolment
01/05/2008

Date of final enrolment
31/07/2012

Locations

Countries of recruitment
Taiwan

Study participating centre
Department of Psychiatry
Taipei County
Taiwan
25115

Sponsor information

Organisation
National Health Research Institutes (Taiwan)

Sponsor details
35 Keyan Road
Zhunan

Miaoli County
Taiwan
350

Sponsor type
Government

Website
http://english.nhri.org.tw

ROR
https://ror.org/02r6fpx29

Funder(s)

Funder type
Government

Funder Name
National Health Research Institutes (Taiwan)

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	01/01/2018		Yes	No