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Cluster randomized clinical trial to evaluate the effectiveness of a diagnosis recognition and treatment guide for depressive disorders in primary care

Submission date
17/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
23/10/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N/A

Study information

Scientific Title
Cluster randomized clinical trial to evaluate the effectiveness of a diagnosis recognition and treatment guide for depressive disorders in primary care

Study objectives
Is the use of a depression recognition and treatment guide by clinicians in a primary care setting effective in the treatment of patients known to have depression? An evaluation of the effectiveness of implementation and dissemination of a guideline for the treatment of depression disorders in primary care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethical Committee of Federal University of Sao Paulo (Universidade Federal de Sao Paulo, Escola Paulista de Medicina), Sao Paulo City, State of Sao Paulo, Brazil. Approved on September 4th 2002 (ref: 0588/02)
2. Research Ethical Committee of Faculty of Medicine of Marilia (Faculdade de Medicina de Marilia), Marilia City, State of Sao Paulo, Brazil. Approved on June 24th 2002.
3. Research Ethical Committee of the Primary Care Department of Marilia City (Secretaria Municipal de Higiene e Saude de Marilia) State of Sao Paulo, Brazil. Approved on June 5th 2002.

Study design
Multicentric cluster randomized 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
Depression

Interventions
There were 4 control clusters and 4 intervention clusters. Each cluster had 8 participating clinicians and 30 participating patients (8 clinicians and 240 patients in total).

All patients recruited by the principal researcher, after clinical interview and baseline application of HAM-D scale by the research assistant, received a card with their appointment date and the name of primary care clinician that they would be seeing, and an unique patient identifier that would allow the clinician to access the appropriate patient information. Patients were scheduled for follow-up visits to the clinician at 2, 4, 8, 12 and 16 weeks after the fist appointment in primary care.

For each patient, a package was sent to the assigned clinician containing the particular diagnosis of depression, the initial patient HAM-D severity score, and a checklist for monitoring patient compliance and response at each visit. The checklist included symptoms of depression, dose and side effects of medications, and treatment compliance. Clinicians in the experimental intervention group also received a depression-specific guide, adopted from rigorous, previously published guidelines, which provided brief and objective educational information regarding the effects of depression on patient's daily living, the importance of recognizing the patient's mental state, the association of the patient's mental state with related signs and symptoms, depression types that can be treated by clinicians, treatment stages, strategies for improving adherence to treatment, and guidelines for the therapeutic management planning using standardized antidepressants in primary care. Clinicians in the intervention group prescribed medications to patients according to the guide for 16 weeks. Control intervention clinicians received patients to treat with usual care.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
At 16 weeks, depression severity as measured by the HAM-D scale, was evaluated at a mental health facility by two independent evaluators who were blind to treatment allocation. Differences in score were resolved by consensus between evaluators. The primary outcomes were:
1. Appropriate treatment rate, through the prescription of an antidepressant at the first appointment with the clinician
2. Clinical remission rate (16 week depression severity of less than 8 points on the HAM-D scale)

Secondary outcome measures
1. Cost of treatment during the 16 weeks of follow-up was calculated in US dollars using the lowest posted January 2007 price of medications (www.consultaremedios.com.br).
2. Withdrawals in the two treatment groups were compared. Patients refusing treatment after referral to the primary care clinician or not attending the three consecutive appointments were defined as patient withdrawals. Patients whose depression worsened and were referred for an urgent or emergency psychiatric assessment were withdrawn by the primary care clinician and referred to treatment in secondary mental health facility.

Overall study start date
16/06/2003

Completion date
30/06/2006

Eligibility

Key inclusion criteria
Clinicians:
All general clinicians working at the basic healthcare units of primary care setting were eligible to participate in the study regardless of age, gender, year of graduation and activity in primary care.

Patients:
1. Patients living within the geographical area of the clinician
2. Aged more than 18 years
3. Both gender
4. Clinical diagnosis of depression according to the Diagnostic and Statistical Manual of Mental Disorders - Fourth Edition (DSM-IV) criteria and with a baseline score of 8 to 22 points in the Hamilton Rating Scale for Depression (HAM-D)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
8 clinicians and 240 patients

Key exclusion criteria
Clinicians:
1. Refused to participate in the study
2. Where there were two clinicians working at the same practice, one of them was excluded to avoid the risk of cross contamination

Patients:
1. Already using antidepressant
2. Psychiatric co-morbidity and/or a severe medical condition

Date of first enrolment
16/06/2003

Date of final enrolment
30/06/2006

Locations

Countries of recruitment

Brazil

Study participating centre
Avenida Monte Carmelo
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Sponsor information

Organisation
Federal University of Sao Paulo (Brazil)

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Sponsor type
University/education

Website
http://www.unifesp.br

ROR
https://ror.org/02k5swt12

Funder(s)

Funder type
Other

Funder Name
Investigator-funded (Brazil)

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	01/02/2009	23/10/2020	Yes	No