

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

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<b>Registration date</b> 28/09/2007	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 23/10/2020	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

## 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

## **Study type(s)**

Treatment

## **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 a 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 first 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(s)**

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)

### **Key secondary outcome(s)**

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](http://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.

### **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

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

Marília

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**Sponsor information****Organisation**

Federal University of Sao Paulo (Brazil)

**ROR**

<https://ror.org/02k5swt12>

## Funder(s)

### Funder type

Other

### Funder Name

Investigator-funded (Brazil)

## Results and Publications

### 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?
<a href="#">Protocol article</a>	protocol	01/02/2009	23/10/2020	Yes	No