

# The impact of a decision aid on depressed patients' involvement in shared decision-making

<b>Submission date</b> 30/10/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/11/2014	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patient involvement in decisions regarding their medical treatment has increased in recent years. Shared decision making (SDM) is a process whereby patients and healthcare professionals discuss healthcare options together and come up with a treatment plan. Patient decision aids (DAs) are resources that help people make decisions about their healthcare and encourage them to participate in SDM. Here, we want to develop and test a DA that supports depressed patients in making decisions regarding their treatment and improve the quality of these decisions by getting them more involved in the SDM process.

### Who can participate?

Patients aged 18-60, diagnosed with depression and currently taking at least one antidepressant medication.

### What does the study involve?

Patients are randomly allocated into one of two groups. Those in group 1 (intervention group) use the test DA before participating in a SDM session. Those in group 2 (control arm) are not given access to the test DA before participating in a SDM session.

### What are the possible benefits and risks of participating?

The study was designed to minimize any risks. All patients are given information regarding the security of data collected. They also have the right to withdraw from the study at any time with no effect on the relationship between the patients and health care team.

### Where is the study run from?

The outpatients department in Al Amal Hospital (Saudi Arabia)

### When is the study starting and how long is it expected to run for?

March 2014 to May 2014

### Who is funding the study?

Al Amal Hospital (Saudi Arabia)

Who is the main contact  
Khalaf Aljumah  
khalafaljumaah@yahoo.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
AMC2013-10

## Study information

**Scientific Title**  
The impact of a decision aid on depressed patients' involvement in shared decision-making: a pilot randomized controlled double blind study

**Acronym**  
Shared decision-making (SDM)

**Study objectives**  
Decision aids can improve patient's participation in SDM more than standard counseling.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Al Amal Complex for Mental Health in Riyadh, Saudi Arabia, October 2013, ref: AMC2013-10

**Study design**  
Pilot randomized controlled double blind study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

An information participation sheet was distributed to all patients during recruitment phase.

**Health condition(s) or problem(s) studied**

Major Depressive Disorder

**Interventions**

Arm one : intervention group. Depressed patients used the DA before attending SDM session.

Arm two: control group. Depressed patients attended SDM session without using DA.

The same treatment, drug, doses, frequency and duration of treatment will be used in both groups and the local and international guidelines regarding the doses and duration of treatment followed.

**Intervention Type**

Behavioural

**Primary outcome measure**

Change in observing patient involvement in the decision making scale.

This was collected once during the an interview involving the patient with researcher when attending a routine outpatient clinic appointment. A data collection sheet and OPTION scale was used.

**Secondary outcome measures**

N/A

**Overall study start date**

01/03/2014

**Completion date**

01/05/2014

**Eligibility****Key inclusion criteria**

1. Patients diagnosed with Major Depressive Disorder (MDD) according to the Diagnostic and Statistical Manual of Mental Disorders, 4th Ed. (DSM-IV)

2. Aged between 18-60
3. Using at least one antidepressant medication

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

60 Years

**Sex**

Both

**Target number of participants**

44

**Key exclusion criteria**

1. Patients having a psychosis history
2. Drug dependency history

**Date of first enrolment**

01/03/2014

**Date of final enrolment**

01/05/2014

**Locations****Countries of recruitment**

Saudi Arabia

**Study participating centre**

**Al Amal Hospital**

SHOBAH

PO box 87904

Riyadh

Saudi Arabia

11652

**Sponsor information**

**Organisation**

Al Amal hospital

**Sponsor details**

SHOBAH  
PO box 87904  
Riyadh  
Saudi Arabia  
11652

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.alamal.med.sa>

**ROR**

<https://ror.org/00zszzj16>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Al Amal hospital (South Arabia)

**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