

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

Submission date 30/10/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/11/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/11/2014	Condition category 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
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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11458

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