ISRCTN34879893 https://doi.org/10.1186/ISRCTN34879893

Impact of pharmacist interventions on adherence and patient outcomes among depressed patients.

Submission date
22/11/2014

Recruitment status
No longer recruiting

Registration date
30/12/2014

Overall study status
Completed

Last Edited
22/03/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Making sure major depressive disorder (MDD) patients take their antidepressant treatment (adherence to medication) is essential in managing their condition. Adherence to medication is a dynamic decision-making process, and pharmacists play an important role in improving adherence to antidepressant treatment in different settings within the health care system. Shared decision making (SDM) is a conversation between a patient and a healthcare professional whereby decisions are made about a patients treatment, taking into account what is important to both parties. Here, we want to test a pharmacist intervention (programme) based on SDM to see whether it improves adherence to medication and, ultimately, how successful the treatment is at treating MDD.

Who can participate?
Adults (aged between 18-60) newly diagnosed with MDD.

What does the study involve?
Patients are randomly allocated into one of two groups. Those in group 1 (intervention group) attend a SDM session with a pharmacist which focused on improving the patients involvement in decision making, their beliefs towards antidepressants and their knowledge about antidepressants. Those in group 2 do not attend a SDM session. Adherence to medication, severity of depression, health-related quality of life, patient satisfaction and the patients beliefs about medicine is assessed for all participants at the start of the study, 3 months after the study begins and then again at 6 months.

What are the possible benefits and risks of participating?
The study was designed to minimize any potential risks to the patients. Participants may benefit from intervention conducted in this study.

Where is the study run from?
Al Amal Hospital (Saudi Arabia)

When is the study starting and how long is it expected to run for?
February 2014 to July 2014

Who is funding the study?
Investigator initiated and funded (Saudi Arabia)

Who is the main contact?
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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
Impact of pharmacist interventions on adherence and measurable patient outcomes among depressed patients: a randomised controlled study

Study objectives
The evidence relating to patients' active participation in depression treatment decision making supports the hypothesis that this will result in improved adherence, satisfaction, and improved clinical outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)

AM2013-12

Study design
Interventional prospective randomised controlled study with a 6-month follow-up

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients diagnosed with major depression disorders

Interventions
The intervention focused on the enhancement of the patients' involvement in decision making, their beliefs towards antidepressants and their knowledge about antidepressants.

Pharmacists followed the SDM competency framework proposed by Simmons et al, which was designed specifically for depressed patients, to ensure the coverage of all aspects of SDM for each patient. Before the SDM session started, the research team distributed a decision aid, which was developed and validated by Aljumah et al. and was specified for Arabic-speaking patients, to patients in the intervention group (IG). The intervention focused on the enhancement of the patients' involvement in decision making, their beliefs towards antidepressants and their knowledge about antidepressants. The average time for the first SDM session (at baseline) was 15 minutes and 10 minutes for the remaining SDM sessions.

Randomisation:
A simple randomisation process was used. Study participants were individually randomised to one of two parallel groups with an allocation ratio of 1:1 using a computer-generated list. The computer-generated allocation was done by a research assistant with no clinical involvement in the trial. Pharmacists and psychiatrists were not blinded to the patients' distribution between groups. The research assistant who collected all the data was blinded to the distribution of patients

Intervention Type
Behavioural

Primary outcome measure
Adherence measured by Medication Adherence Scale (MMAS) at baseline, 3 months and 6 months

Secondary outcome measures
1. Patients' beliefs about medicine measured by Beliefs About Medicine Questionnaire (BMQ)
2. Severity of depression measured by MADRS scale
3. Patients' involvement in decisions
4. Health-related quality of life - measured by EuroQOL-5D
5. Patient satisfaction with treatment
Measured at baseline, 3 months and 6 months.

Overall study start date
10/02/2014

Completion date
29/07/2014

Eligibility

Key inclusion criteria
1. Patients within the age range of 18 to 60 years
2. Patients newly diagnosed with a MDD, according to the scales in the Diagnostic and Statistical Manual of Mental Disorders, 4th Ed (DSM-IV)
3. Patients having no psychotic or bipolar history
4. Patients having no drug or dependency history
5. Patients having no cognitive impairment that may hinder the assessment

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
195 patients

Key exclusion criteria
1. Patients having a psychiatric or bipolar disorder history
2. Patients having drug or dependency history.
3. Patients suffering from any cognitive impairment that may hinder the assessment
4. Patients not responding at any level to the antidepressant within 8 weeks of recruitment

Date of first enrolment
10/02/2014

Date of final enrolment

29/07/2014

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 Psychiatric Hospital

Sponsor details
Alkozam Aria
Riyadh
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00996

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00zszzj16

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded (Saudi Arabia)

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/09/2015		Yes	No