Prospective Observational Study Protocol F1J-EW-B041(a) - Development of a web-based tool for the assessment, follow-up and early prognosis of outcomes in depression

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Taking into account the challenges related to treatment of MDD in a PCP setting, a MDD assessment tool for PCPs will be developed with a twofold intent: a) to help PCPs to follow the progress of their MDD patients from the start of the AD treatment...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Observational non invasive

Summary

ID

NL-OMON37874

Source
ToetsingOnline

Brief title
ePOD study

Condition

- Mood disorders and disturbances NEC

Synonym
Depression, Major Depressive Disorder

Research involving
Human

Sponsors and support

Primary sponsor: S.A. Eli Lilly Benelux N.V.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: Anti-depressants, Major Depressive Disorder, Primary Care, Web-based tool

Outcome measures

Primary outcome

The primary objective of this study will be twofold:

A. To assess website feasibility, usability, and data quality of a web-based major depressive disorder assessment tool. Feasibility will be evaluated by means of the inclusion rate of patients starting an antidepressant and the time to patient*s drop out from the web-based tool. Usability will be assessed by means of the patient*s evaluation of the easiness of use, the actual and perceived length of the web-sessions, and the appropriateness of the website as a communication tool with the doctor. Data quality will be evaluated through the completeness of entries.

B. To validate the overall prognostic value of the web-based assessment tool in relation to three targeted outcomes: a) remission, b) non-remission with minimal response, and c) non-response 3 and 6 months after starting the antidepressant monotherapy.

Secondary outcome

The secondary objectives of this study are:

1. To measure and compare the specific prognostic value of the different variables included in the MDD assessment tool in relation to the three targeted

outcomes (remission, nonremission with minimal response and non-response). These variables are the following:

- demographic variables
- disease history
- initiated class of antidepressant - patient-reported adherence to treatment
- improvement and speed of improvement in depressive, anxious, and physical symptoms, as well as degree of disability (i.e. functioning).

2. To measure and compare the prognostic value of the different variables included in the MDD assessment tool in relation to two other targeted outcomes: functional recovery and non-recovery at 3 and 6 months.

3. To analyze the functional and health economic burden of patients in remission, nonremission with minimal response and non-response at 3 and 6 months.

4. To analyze the depressive symptoms as measured by the questionnaires of patients in remission, non-remission with minimal response and non-response at 3 and 6 months.

5. To describe discontinuation rates, reasons for discontinuation of the first prescribed antidepressant, and treatment decisions in relation of patients in remission, non-remission with minimal response and non-response at 3 and 6 months.

6. To explore the possibility to define outcome categories by using the web-based questionnaires as compared to remission, non-remission with minimal response and non-response outcome categories by standard methods at 3 and 6 months.

7. To explore primary care physicians interest in the website assessments

through a descriptive analyses of the access to the patient self-assessments

reports.

Study description

Background summary

Primary care physicians (PCPs) are responsible for the treatment of the majority (~70-80%) of Major Depressive Disorder (MDD) patients. In usual practice, PCPs can rarely conduct a thorough evaluation of a depressive state or of the changes in disease state during follow-up visits. Not only time constraints, but also the lack of validated prognostic models for depressed patients limits the conclusions drawn from follow-up assessments necessary for the treatment strategy. This situation has direct implications for patients* treatment and outcomes, with depressed patients staying on the same antidepressive (AD) treatment for long periods without achieving remission nor gaining functional recovery.

Study objective

Taking into account the challenges related to treatment of MDD in a PCP setting, a MDD assessment tool for PCPs will be developed with a twofold intent:
a) to help PCPs to follow the progress of their MDD patients from the start of the AD treatment, and
b) to calculate, for a given patient, the probabilities of three target outcome measures at 3 and 6 months: remission, non-remission with minimal response and non-response.

Study design

This study is an international, multi-center, 6-month, longitudinal, prospective, observational study to develop and validate a web-based assessment tool for MDD episodes. Potential prognostic factors will be collected by both the physician during 4 clinical visits (at baseline, 4, 12, and 24 weeks) and by the patient through web-based self-assessments (at baseline, week 1, week 2 and at 2 week intervals during the first 8 weeks and monthly thereafter). Cross-validated, prognostic models will be built for three targeted MDD outcome variables: remission, non-remission with minimal response and nonresponse at 3 and 6 months (12 and 24 weeks) after the start of the treatment.

Study burden and risks

The completion of the questionnaires can be experienced as a burden and influence subject's mental state. This, as well as patient's spiritual well-being is checked by the investigator at each study visit. When the completion of the questionnaires for the patient appears to be too burdensome, the physician will take the patient of study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Male or female outpatients aged between 18-64 years
- Meeting criteria for MDD as defined by DSM-IV and about to start antidepressant

monotherapy at the discretion of the primary care physician
- Having personal access to internet and being comfortable with using it (e.g. being a regular user of personal emails) as assessed by the investigator
- Having signed a consent form (and confirming this consent via the website within 48 hours after baseline visit at the doctor)

Exclusion criteria

- Patients having received any antidepressant for a depressive episode during the past 6 months
- Patients about to start combined antidepressant treatment or a combination of an antidepressant with an antipsychotic or mood stabilizer (continuation of an antiepileptic treatment is allowed)
- Have any history of bipolar disorder, psychosis, schizophrenia, or substance dependence (within the last year and with the eception of tobacco or caffeine)
- Have a history of stroke or dementia
- Being Lilly employee

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2012
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO

Date:	07-03-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL39401.028.12