Tablet-based support for older adults with recurrent depressive or bipolar disorder: A feasibility study of the eCare@Home system in routine outpatient practice

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON42131

Source
ToetsingOnline

Brief title
eCare@Home

Condition

- Other condition
- Mood disorders and disturbances NEC

Synonym
recurrent depressive or bipolar disorder, repeated episodes of feeling down or manic.

Health condition

recidiverende depressieve of bipolaire stoornis

Research involving
Human

Sponsors and support

Primary sponsor: GGZ inGeest (Amsterdam)
Source(s) of monetary or material Support: EU (via ZonMW)

Intervention

Keyword: Elderly patients, Mood disorders, Tablet

Outcome measures

Primary outcome

Primary outcome measures include acceptability (for patients), usability (for patients, their informal carers and clinicians) and client satisfaction (for patients).

Secondary outcome

Secondary outcome measures will focus on mood disorder symptom severity, sleep and activity and the correlation with the self-report variables of the HomePad (mood, sleep and activity).

Study description

Background summary

Studies show that depression has an unfavourable prognosis in late life, with a higher risk of relapse and chronicity than in younger populations. Bipolar disorder, though less common, accounts for 8-10% of psychiatric admissions in late life. Elderly patients with these disorders face a number of challenges posed by mental and physical ageing and often a decrease in social interaction and network. The eCare@Home (ECH) project aims to optimize long-term face-to-face treatment for these patients using a user-friendly tablet computer. The system facilitates self-management and relapse prevention, as well as contact with the patient's family, friends and clinician.

Study objective

This study aims to assess the acceptability and usability of the ECH system from the perspective of patients, their informal carers and their clinicians in a routine outpatient setting for patients with recurrent depressive or bipolar disorder. A secondary objective is to obtain an indication of the relation between the self-report scales of the ECH system and changes in depressive symptoms, manic symptoms, activity and sleep. Good feasibility (i.e. adequate system acceptability and usability) will justify and inform a subsequent formal clinical trial of ECH.

Study design

This is a single-group feasibility study with a pre-post design.

Intervention

The ECH system is based on a generic ICT platform for support for older adults, their friends and family, and their clinicians. Before and during the developmental process, patients, their clinicians and informal carers were interviewed about what they would want and expect from the ECH system. These user assessments resulted in a focus on three main tasks: support for monitoring their mood, activity and sleep; support for staying in touch with their family, friends and clinicians; and keeping up with information about their disorder, medication and relapse prevention plan. There will be separate internet portals for the patients' clinicians, informal carers and friends and family.

Study burden and risks

Because participating patients continue their regular treatment, participation in this study entails a negligible additional risk. Potential risks could involve security problems of the ECH server and technical problems, but both are minimized by adhering to common security standards, using professional hosts, and extensive pre-trial alpha testing of the platform. A burden could be filling in questions about mental health issues, although filling in such questions is part of the regular treatment as well.

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

Patients who are eligible:
- are 60 years of age or older;
- are currently treated by GGZ inGeest for recurrent depression (minimally two former depressive episodes including the present episode) or bipolar disorder (as determined by the GGZ inGeest registration records);
- have been in treatment at GGZ inGeest for at least 6 months;
- have sufficient command of the Dutch language, both verbally and in writing;
- provide signed informed consent.
Informal carers who are eligible:
- live together with the patient (e.g. as a spouse) or have contact with the patient at least once a week;
- are 18 years of age or older;
- sign the informed consent form as well.

Exclusion criteria

There are no exclusion criteria.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	29-12-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21312
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50436.029.14
OMON	NL-OMON21312