User-friendly ICT Tools to Enhance Self-Management and Effective Treatment of Depression in the EU

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

Summary

ID

NL-OMON37241

Source
ToetsingOnline

Brief title
Moodbuster

Condition

- Mood disorders and disturbances NEC

Synonym
down, mood disorder

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: Depression, Internet, Primary Care, Selfhelp

Outcome measures

Primary outcome

Feasibility of Moodbuster:

Time needed to include the participants

Willingness of participants to cooperate with the study after being informed by the assistent of the GP

Compliance to the protocol of Moodbuster

Usibility of Moodbuster:

System Usability Scale (SUS; Brooke, 1996)

Client Satisfaction Questionnaire-8 (CSQ-8: De Brey, 1983).

Clinical outcome:

Depressive symptoms: Beck Depression Inventory II (BDI-II).

In order to explore the experiences of patients with Moodbuster in a more qualitative way, we also will perform semistructured interviews with patients and assistents of the GP.

Secondary outcome

Expectations toward the intervention:

Credibility/Expectancy Questionnaire (CEQ) of Devilly en Borkovec (Devilly & Borkovec, 2000)

Anxietysymptoms: Hospital Anxiety Depression Scale (HADS-A) (Zigmond & Snaith,

1983).

Mastery: Mastery-scale (Pearlin, 1978)

Quality of life: EuroQol (EuroQol Group, 1990)

Study description

Background summary

Depressive disorders are highly prevalent in the general population (Kessler et al., 1994; ESEMED, 2004) and have a serious impact on the quality of life of patients and their family (Ustun et al., 2004; Saarni et al., 2007). Also, depression is associated with a large economic burden to society (Berto et al., 2000; Greenberg & Birnbaum, 2005; Smit et al., 2006). Most patients with depressive disorders are treated in primal health care (Bijl & Ravelli, 2000). Although effective treatment excist, such as medication and psychotherapy (Cuijpers et al., 2009), further improvements remain necessary.

ICT4Depression (ICT4D) is an European project, in which an innovative programme called Moodbuster is being designed. Moodbuster is an online selfhelp programme, consisting of internet interventions, as well as the use of a smartphone and a wireless pillbox. Patients are able to monitor their symptoms on a daily basis by use of the smartphone. The use of the wireless pillbox, for those patients that already use medication, reminds the patients of proper intake.

Particiating members to the project are the Free University Amsterdam, GGZinGeest (Netherlands), University of Linköping (Sweden), INESC and Plux (Portugal), de University of Limerick (Ireland) and the Aardexgroup (Swiss).

Study objective

The primary aim of ICT4D is to design an intelligent monitoring and selfhelpsystem for use in Primary Care (Moodbuster). In this pilot study the feasibility and the usability if this intervention is tested among patients suffering from minor and major depressive disorder who are being treated in

Primary care.

Study design

To evaluate the feasibility and usability of Moodbuster, a pilot study consisting of one sample of 25 patients will be performed. These patients are invited for a screening interview, followed by a baseline assesment and follow-up measurements after 6 weeks and 3 months. Also, semistructured interviews will be carried out in order to inventarisise the expectations and experiences of the participants.

Study burden and risks

De burden for participants consists of the following tasks:

* Wearing sensor devices (glove and heart rate strep) for two parts of a day during 6 weeks.
* Telephonic diagnostic interview which takes about 45 minutes
* Three measurements: at baseline, after 6 weeks and after 3 months.
* For some participants a face-to-face interview which takes about 1 hour about their experiences with Moodbuster.
* Daily measurement (7 times per day) of mood, sleep and anxiety via the mobile phone during 6 weeks.

The risks associated with participation are small. De safety of the sensor devices is garanteed. However, as the devices don't have a CE-quality mark, a contract will be made with an insurance company.

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

1) Patients of GP with a DSM-IV minor or major depression
2) 18 years or older
3) acces to internet
4)motivated to use bio sensors

Exclusion criteria

suicidal risk
bipolar of psychotic disorder

Study design

Design

Study phase:	2
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2013
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	09-01-2013
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL41822.029.12