Pilot in The Netherlands

1.1 Background

The reach and uptake of depression treatment have increased since the availability of Internet-based interventions over the last decade (Riper et al. 2007, Riper et al. 2013). Meta-analyses showed that these Internet interventions are effective for the treatment of depression (Andersson & Cuijpers 2009, Andrews et al 2010; Richards & Richardson 2012).

Despite these promising results studies have also indicated a low implementation rate of Internet interventions in primary and secondary mental health care, low therapy adherence rates by users of Internet interventions, and users have lacked motivational and personalized support, especially in unguided self-help treatments (Nijland et al. 2010). Currently, a number of innovative strategies are being explored to overcome these problems.

Moodbuster is an innovative intervention for depression treatment that makes use of mobile and Internet technologies. Moodbuster is developed within the ICT4Depression project. Moodbuster aims self-help depression treatment via (1) smartphones and pc for (2) adult patients in primary care by making use of (3) ecological momentary assessment techniques (EMA) including the assessment of physiological symptoms in an integrated manner (4) which enables timely interactive feedback and treatment adaptation if needed for patients and professionals alike (Warmerdam et al 2012). The goal of the current pilot study was to evaluate the feasibility and the usability of Moodbuster for patients with depression in primary care. The study followed in time the pilot study in Sweden and incorporated some of the lessons learned in that pilot.

1.2 Research questions

1. What is the feasibility of Moodbuster in terms of willingness to participate and compliance of patients?
2. What is the usability of Moodbuster in terms of satisfaction and acceptation according to patients?
3. What is the feasibility and usability of Moodbuster in terms of satisfaction and acceptation according to primary care takers?
4. What is the clinical progress in depressive symptoms?

2. Methods

2.1 Design and sample size

This study concered a pilot study consisting of one group patients which received Moodbuster+. Measurements were taken at baseline and at post treatment (after 6 weeks). Based on feasibility, the sample size was determined at 25 patients.

2.2 Procedure

GGZinGeest and the VU University Amsterdam worked closely together for the conduct of this pilot. GGZinGeest is a mental health care organisation where specialized nurses work also in primary care and support GP's with the provision of low intensity depresseion care. Recruitment of participants took place in two ways: 1. In primary care via these specialized nurses and 2. In the general population through press releases and advertising in national media.

Interested patients subscribed themselves for the study via a website. After signing in they received a screening questionnaire for depressive symptoms by email (Kessler Psychological Distress Scale: K10; Kessler et al., 1992), and an information brochure and informed consent form by post. Participants who scored above the cut-off score of 20 on the K10 were contacted for a telephonic diagnostic interview. Inclusion criteria involved a major or minor depression according the DSM-IV criteria, aged 18 years and older, willingness to wear sensor devices and having a pc with Internet connection. Participants with a high risk on suicide were excluded. After inclusion, participants received the baseline questionnaire by email. In a face-to-face consult participants received the sensor devices and instructions about the use of Moodbuster. During the study participants could use a smartphone from the University. Participants received a gift certificate of 50 Euro at the end of the study.

2.3 Instruments

An overview of the instruments is presented in Table 1. Instruments are divided into screening, feasibility and usability, and clinical progress.

Table 4. Overview measurement instruments

	Screening	Baseline(T0)	Posttreatment(T1)	Follow-up (T2)
Screening				
K10	x			
CIDI	x			
Feasibility				
Willingness		x	x	
Compliance			x	
Usability				
Interview patient			x	
Interview caretaker			x	
SUS			x	
CSQ-8			x	
Clinical progress				
BDI, HADS-A		x	x	x

Screening

Screening. The 10-item Kessler psychological distress scale (K10; Kessler and Mroczek, 1992) is a measure of non-specific psychological distress in the anxiety-depression spectrum. This screening questionnaire was used to screen people for depression. Item responses are on a five-point Likert scale (5= "all of the time" to 1= "none of the time"), total score ranges from 10 (no distress) to 50 (severe distress). Participants with a score of 20 or higher on the K10 were eligible for this study. With this cut-off the K10 shows good sensitivity to capture people with different kind of depressive disorders (Donker et al. 2009).

Diagnostic interview. Study participants were asked to participate in a telephone diagnostic interview before the start of Moodbuster. To establish a diagnosis we used the Composite International Diagnostic Interview (CIDI). The CIDI (version 2.1), a structured interview developed by the World Health Organisation (WHO, 1990), enables trained interviewers to assess psychiatric diagnosis defined in the Diagnostic and Statistical Manual of the American Psychiatric Association, 4th edition (2001). The assessment typically lasts 30-75 minutes, depending on the mental state of the respondents. In this study, current mental statuses within the last two months were considered.

Feasibility and usability

Feasibility. To determine the feasibility of Moodbuster the following aspects were studied:

1. Required time to include patients.
2. Willingness of patients to participate in the study after referral by the primary care taker.
3. Compliance
    a. With regard to the sensor devices; how often do patients wear the handglove and the chest strep?
    b. With regard to the ecological measurements; how many measurements did patients fill in on their smartphone?
    c. With regard to the pill box; in how far do patients who are on medication use the pill box?
    d. With regard to the self-help modules; how compliant are patients regarding the modules?

Usability according to patients. To determine the usability of Moodbuster the System Usability Scale (SUS; Brooke, 1996) was used at post-treatment. The SUS consist of 10 questions (e.g. "I can image that many people quickly learn how to use Moodbuster") with 5 response options (ranging from 1 'strongly disagree' to 5 'strongly agree'). The scores on the SUS range from 0 till 100 with higher scores representing a higher usability. The SUS has proven to be a reliable and valid instrument (Brooke, 1986). A SUS score above 68 is considered above average and anything below 68 is below average. We evaluated the usability for four different components of Moodbuster; the website, the mobile application, and the sensor devices. Therefore, the SUS was administered three times to evaluate the three components.

To measure the satisfaction about Moodbuster, the Client Satisfaction Questionnaire-8 (CSQ-8: De Brey, 1983) was used. The CSQ consists of 8 questions inquiring about respondents' opinions and conclusions about services they have received. Response options differ from item to item, but all are based on a four-point scale. Scores range from 8 to 32, with higher values indicating higher satisfaction.

Usability according to primary care takers. Semi-structured interviews were held with primary care takers to explore their experiences with using Moodbuster in primary care.

Clinical progress

Questionnaires to measure symptoms were taken at two moments; at baseline (T0: before the start of the treatment), and after six weeks at posttreatment (T1). At baseline, socio-demografic characteristics were also measured like age, gender, education and work situation.

Depressive symptoms. The Beck Depression Inventory – second edition (BDI-II) is used to measure depressive symptoms (Beck et al., 1961). The BDI-II is developed to measure the severity of the depressive symptoms and is one of the most used self-report questionnaires in this area. The BDI-II contains 21 items with answer categories ranging from 0 till 3. Total

scores varies between 0 and 63 with higher scores representing more severe symptoms. Internal consistency is high with Cronbach's alpha around 0,92 (Van der Does, 2002).

Anxiety symptoms. The 7-item anxiety subscale (Dutch version) of the Hospital Anxiety and Depression Scale (HADS) is used for identifying anxiety symptoms (Zigmond & Snaith 1983). Cronbach`s alpha ranged between 0.81 to 0.84, in different normal and clinical Dutch samples (Spinhoven et al. 1997). Item-responses are on a 0 to 3 scale, total score range is 0-21 with higher scores indicating more anxiety.

2.4 Analyses

Descriptive statistics were used to analyse the data from the SUS and the CSQ. Interviews were written out and text fragments were labeled and categorized. The combination of descriptives statistics and information from the interviews give an indication of the feasibility and the usability of Moodbuster.

Paired t-tests were used to analyse data from the BDI, the HADS and the EQ-5D. Cohen's d was used to calculate effect-sizes (Cohen, 1988). Data from all questionnaires were analysed according to the completers-only principle.

3. Results

3.1 Patients

Recruitment via GP. In total, 43 general practices in primary care were willing to participate in this study, all located in the Amsterdam region. Information brochures about this study (n = 430) were spreaded over these 43 practices. Specialized nurses informed potential patients about this study by giving them these information brochure during a regular consult. Each nurse had 10 information brochures to give to their patients. Via this way, only 1 patient was included in the study.

Recruitment via media. We advertised in daily newspapers, digital media (mainly websites) and sent out a press release to recruit patients. This recruitment strategy appeared more successful. Within a two months period, 49 potential patients subscribed themselves via a website. Of these people, 36 filled in the screener for depression and all of them scored above the cut-off of 20 on the K-10. Eventually, 23 patients were included in the study and started with Moodbuster 9.

Demographic characteristics of patients are displayed in Table 2. The mean age was around 43 years. Most patients were female (68.2%) and highly educated (72.7%). The majority lived alone (36.4%) or with a partner (27.3%). Almost two third had a diagnosis of a major depression according to DSM-IV criteria. As the recruitment of patients took more time than expected and we did not want to delay any longer, we decided to include also patients who had no diagnosis of depression but who did experience depressive complaints. Therefore, 8 patients with no diagnosis were included. However, they had elevated symptoms as was shown by their high scores on the depression screener.

Table 5. Demographic Characteristics at Baseline

	All (n = 23)
Age (years)	42.9
Female	15 (68.2)
Living situation	
alone	8 (36.4)
With a partner	6 (27.3)
With children	1 (4.5)
With partner and children	4 (18.2)
other	3 (13.6)
Education*	
lower	1 (4.5)
middle	5 (22.7)
higher	16 (72.7)
Diagnosis major depression	15 (65.2)

Note. Data are presented as n (%) of participants unless otherwise indicated.
*lower = Primary Education or Lower General Secondary Education, middle = Intermediate Vocational Education or High School, high = Higher Vocational Education or University.

3.2 Feasibility

Three aspects were evaluated to assess feasibility; 1. Required time to include patients, 2. willingness of patients to participate in the study after referral by the primary care taker and 3. Compliance with regard to Moodbuster.

1. *Required time to include patients.* In primary care, 1 patient was included in the study in a period of six weeks, which is less than we expected. Most patients (n=22) were recruited in the general population through the media. In comparison with other Internet-based studies it took more time and much effort to include such a relative low number of patients. This may be due to the extensive screening procedure of participants, they needed to fill out a screener, comply with a diagnostic interview and obtain the smartphone and sensors by visiting the research venue or home visit.
2. *Willingness of patients to participate in the study after referral by the primary care taker.* We do not know exactly how many patients received an information brochure from their nurse. Some nurses gave all their information brochures to potential patients and others gave a part. Given the fact that only 1 patient was included in this way, we could say that the willingness to participate among primary care patients was low.
3. *Compliance with regard to Moodbuster.* Participants used the system as instructed. On average, exposure to the treatment material was 51%. In the six-week period, participants completed approximately three out of six of the available treatment modules. This indicates that they were able to follow instructions, which were to complete one module every two weeks. Good acceptance was also observed with regard to the EMA ratings (in total, 2568 ratings were made), and with regard to sensor usage

(2347 sensor periods). Further details on the participants' use of the system components are provided in Deliverable 4.7 (the final evaluation report).

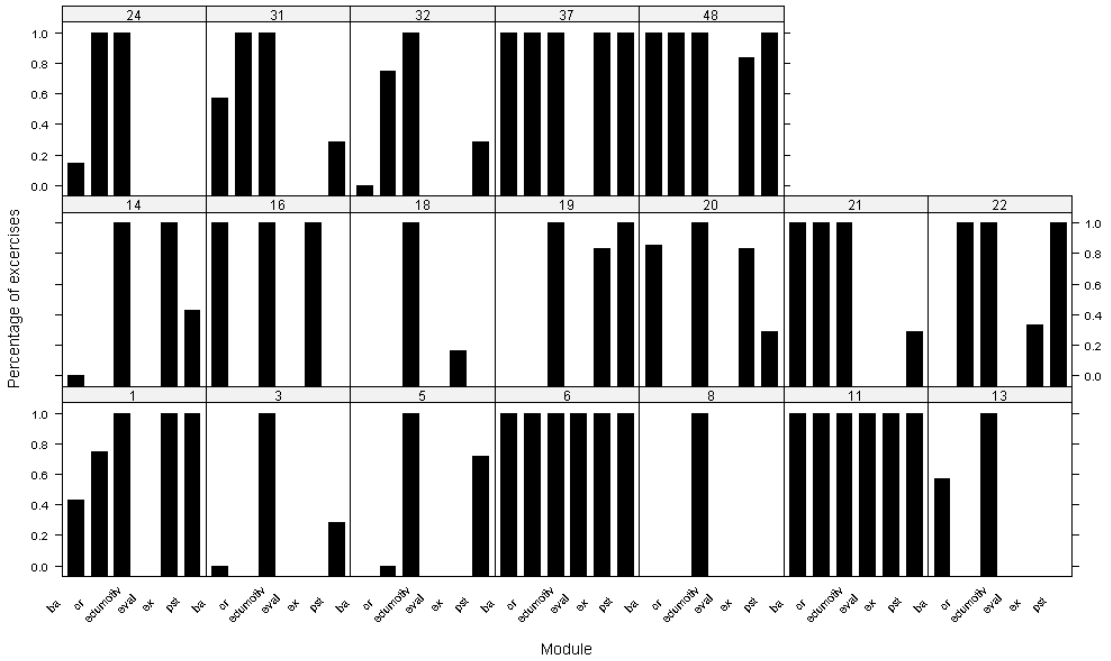

Figure 3: Moodbuster treatment module usage of the participants of the moodbuster pilot trial. Module completion is depicted as a percentage of the total number of exercises in each module (ba: behavioral activation; cr: cognitive restructuring; edumotiv: psycho-education; pst: problem solving therapy; ex: physical exercise; eval: relapse prevention).

3.3 Usability according to patients

Usability of the system was evaluated with the SUS. Mean scores on the SUS for the website of Moodbuster, the mobile application, and the sensor devices were, respectively, 55.3, 50.5 and 40.5. Usability of these three components is below the average of 68.

Mean scores on the different items are reported in Table 3. The website and the mobile phone scored relatively positive on 'need for support' (item 4) and 'inconsistency' (item 6). Aspects that received a relatively negative rating were 'complexity' (item 2), 'easiness to use' (only mobile phone) and 'cumbersome' (item 8).

Table 6. Mean item scores on the System Usability Scale for respectively the website of Moodbuster, the mobile phone, the sensor devices and the medication adherence system (n = 19).

	The website of Moodbuster.	Moodbuster on the mobile phone.	The sensors (n = 15)
1. I think that I would like to use … frequently.	2.7	2.3	1.8
2. I found … unnecessarily complex.	2.8	3.1	3.4
3. I thought … was easy to use.	3.1	2.8	2.7
4. I think that I would need the support of a technical person to be able to use…	2.0	2.2	2.5
5. I found the various functions in … were well integrated.	3.0	2.7	2.2
6. I thought there was too much inconsistency in …	2.8	2.7	3.2
7. I would imagine that most people would learn to use … very quickly.	3.3	3.1	2.5
8. I found … very cumbersome to use.	2.8	3.0	3.6
9. I felt very confident using …	2.7	2.6	2.5
10. I needed to learn a lot of things before I could get going with …	2.2	2.5	2.8

Client satisfaction with the system was assessed with the CSQ. the mean score on the CSQ was 21.1(SD: 5.2), which may be interpreted as a 'fair' score. Mean scores on the different items of the CSQ are reported in Table 4. Scores on the items can range from 1 till 4 with higher scores representing more satisfaction. It can be seen that the system was rated lowest with respect to 'service' (item 2), 'met needs' (item 3) and 'would use again' (item 10), and rated highest with respect 'general satisfaction' (item 7).

Table 7. Mean item scores on the Client Satisfaction Questionnaire (N=19)

	Mean
1. How would you rate the quality of service you have received from Moodbuster?	2.7
2. Did you get the kind of service you wanted?	2.5
3. To what extent has Moodbuster met your needs?	2.4
4. If a friend were in need of similar help, would you recommend Moodbuster to him or her?	2.6
5. How satisfied are you with the amount of messages you have received from Moodbuster?	2.7
6. Did Moodbuster help you to deal more effectively with your problems?	2.8
7. In an overall, general sense, how satisfied are you with the help you have received from Moodbuster?	3.0
8. If you were to seek help again, would you use Moodbuster again?	2.5

3.4 Feasibility and usability according to primary care takers

To explore the feasibility and usability of Moodbuster in primary care in more detail we conducted a number of semi-structured interviews with specialized nurses. With regard to the recruitment of patients via these nurses, four scenarios have happened; a. none of the information brochures were given to patients, b. a part of the information brochures were given to patients, c. all information brochures were given to patients and d. information brochures were put in the waiting room of the general practice. For each of these scenarios, one nurse was interviewed.

a. *None of the information brochures were given to patients. Will be* added in final report.
b. *A part of the information brochures were given to patients*. One nurse, who informed two of her patients about the study, mentioned some reasons why it is difficult to recruit in this way. She stated that it's difficult to think about informing patients about research in general while doing your daily work. Another reason was that most patients have many co-morbid problems (depression was not at the forefront), which made them in her eyes not suitable for this study. She was, however, positive about Moodbuster and about e-health in general. Noteworthy to mention is that the two patients who received information did not sign in for the study either because of not willing to use a 'second' smarthphone on top of their own smartphone or because of not willing to wear sensor devices.
c. *All information brochures were given to patients*. Will be added in final report.
d. *Information brochures were put in the waiting room of the general practice.* One care taker put all brochures in the waiting room. Half of the brochures was taken by patients of which none subscribed themselves. According to the care taker the patients are overwhelmed by the available information about various treatments and studies which are accessible through the general practice.

3.5 Clinical progress

Results obtained with the clinical outcome measures are displayed in Table 5. Figure 2 provides a graphical view on changes in symptom levels. At baseline, participants reported moderate levels of depression and anxiety. After treatment, participants reported less symptoms of depression and anxiety: mean scores decreased to 16.4 (BDI) and 9.3 (HADS), with large to small-to-moderate effect sizes (BDI: d = .88; HADS: d = .33). Improvement were significant only with regard to depressive symptoms ($p < .001$).

Table 8. Means, SDs and effect sizes (Cohen's *d*) for measures of depression, anxiety and quality of life for all patients (*N* = 22)

	Pre-treatment, Mean (SD) N=22	Post-treatment, Mean (SD) N=19	*t*(df = 18)	Within-group effect-size, *d* (95% CI)
BDI	27.0 (11.6)	16.4 (9.5)	4.5*	.83 (.44 – 1.22)
HADS	10.5 (3.0)	9.3 (3.2)	1.6	.33 (-.09 - .76)

* $p < .0001$

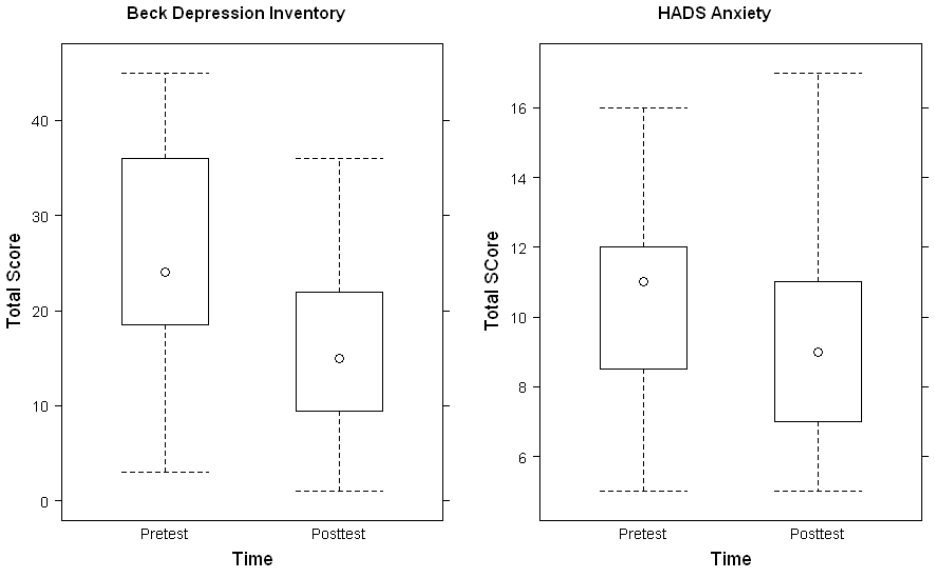

Figure 4: Changes in depression and anxiety symptoms from pre- to posttest.

4. Discussion

In this pilot study, we aimed to test the feasibility and usability of Moodbuster as a depression treatment. As in the Swedish pilot study, we found that moodbuster system was deployable, safe and used by the participants. Encouragingly, clinical outcome measures indicated probable positive effects on depressive symptoms. Finally, participants seemed quite satisfied with Moodbuster, although usability ratings clearly showed that the system

needs to be improved in terms of ease-of-use, especially with regard to the sensors. With proper modifications, the Moodbuster platform should be ready for more controlled clinical trials.

Some limitations of this pilot study demand attention. First, it seems not feasible to recruit patients in primary care through specialized nurses in the way we did. Nothwithstanding the fact that we have engaged both GPs and specialized nurses at the start of our project. The main problem as we have experienced it, lied in time constraints and the fact that GP practices were engaged in many pilot-studies. The purpose was to include patients in primary care, however this turned out not to be feasible in the brief period available. Therefore we included self-referred depressed patients from the general population. For the purpose of assessing the feasibility from a patient perspective, we assumed that this is not so different compared to a GP population. Moreover, the sample consisted of adult patients with moderate-to-severe depressive symptoms. The majority had a diagnosis of major depression. However, more pilot studies in GP settings are necessary to confirm this feasibility hypothesis. Primary care takers encountered diverse problems in general practice during the recruitment such as "not believing in Internet-treatment", "no suitable patients for this study" or "no willingness to participate among the patients who received information". From other trials, we have good experience with recruiting patients from the general population although we expected more willingness.

Second, we encountered some problems regarding the usability of the biomedical devices resulting in patients not wearing them after a short period of trying. We believe that at this moment the biomedical sensor devices are more suitable to use in a controlled lab setting and not in people's daily life. Evaluation of the medication adherence system is difficult as there were just three patients on medication who were eligible to use them.

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