ICT4Depression

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

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Deliverable 5.3 / 5.4:

Feasibility and usability of the ICT4Depression system

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Contributing partners (this deliverable only)	All partners involved in the project.
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Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services).	
RE	Restricted to a group specified by the consortium (including the Commission Services).	X
CO	Confidential, only for members of the consortium (including the Commission Services).	

Contents

General Introduction

The general objective of WP5 is to test MoodBuster with actual users. This is done in two phases: first, a short pilot study was conducted to test the technical setup and tune the system towards the human users. See deliverable 5.1 for the results of this pilot. Second, we conducted a study in which the feasibility of the ICT4Depression self-management system – in terms of process and clinical effectiveness – was examined,. A pre-test- post-test design was applied. According to the original project proposal 100 participants would be recruited among primary care patients of general practitioners both in the Netherlands (50) and Sweden (50). As advised by the EU review experts during the evaluation of the project (April 2012), the sample size was reduced to 50 participants (25 for the Netherlands and 25 for Sweden).

Specific objectives for WP5 are the following:

Task 5.1: Pilot study to test technical setup and tune parameters (objective OV.1; result in D5.1)
Task 5.2: Design of multi-site pre-test – post-test study protocol (result in D5.2)
Task 5.3: Recruitment and instruction of GP's and study patients (result in D5.3 and D5.4)
Task 5.4: Conducting the open study (objective OV.II; result in D5.3 and D5.4)
Task 5.5: Analysis of results, including patients' experiences and rating of treatment satisfaction (result in D5.3 and D5.4)
Task 5.6: Proposal for a randomized controlled trial, in which the effects of the ICT4Depression system will be compared to care-as-usual in primary care (result in D5.5).

Deliverables

D5.1: Report of findings during pilot study (Month 24)
D5.2: Approved study protocol (Month 24)
D5.3: Analysis in report format on the feasibility of the CAU-plus system, including suggestions for improvement of the CAU-plus system on the basis of study results. (Month 40)
D5.4 Two articles on the open study with the system ready for submission in international peer reviewed academic journals (Month 40).
D5.5 Proposal for the evaluation of the efficacy and cost-effectiveness of the ICT4Depression system in terms of a randomized controlled trial. (Month 36)

Task 5.1, 5.2 and 5.6 resulting in respectively D5.1, D5.2 and D5.5 are already accomplished and these deliverables were submitted in December 2011 (D5.1 and D5.2) and December 2012 (D5.5). Task 5.3, 5.4 and 5.5 all end up in deliverable D5.3

and D5.4. The current deliverable (D5.3) reports the results on the feasibility of the MoodBuster (Care As Usual – plus = CAU-plus) system, including suggestions for improvement of the system on the basis of study results. **This is a revised version, including the analysis based on all Dutch patients that participated in the trial (not just the 7 ones that were finished by April 30, but all 22).** An evaluation of the technical aspects, including the working of the biomedical devices, the reasoning system, and the medication adherence system is already reported in D4.7 in December 2012. **An update to this deliverable, including the full analysis of the Dutch trial is submitted in parallel with this revised Deliverable.** Thus, this D5.3 deliverable focuses on the feasibility and the usability of the system according to patients and primary care takers. The last mentioned deliverable, D5.4, entails the drafts of two scientific papers. Those are formed by the two main sections of this deliverable and therefore part of this Deliverable.

Sweden and the Netherlands applied the same intervention (but in different languages). A brief description of this intervention is provided here:

Moodbuster is an unguided automated self-help treatment that incorporates the following 3 integrated functionalities: 1. Self-help treatment modules, 2. A monitoring system and 3. A reasoning system.

1. *Self-help treatment modules.*

Seven self-management modules are available through the Internet as well as through the mobile phone. The majority of the modules are based on mainly CBT psychological treatments that have been shown to be effective in face-to-face and internet-based treatments.

a) Psycho education. As many people with depression have little knowledge about depression they all start with the psycho education module. This module aims to provide information about depression, its causes and what can be done about it. It also contains a strong motivational component in order to avoid drop out of participants.

b) Exercise therapy. This type of therapy seems be effective in the treatment of depression (Mead et al. 2008). Exercise is a low-threshold, non-stigmatizing treatment of depression. This module contains information about (different types of) exercise and assignments to get more active.

c) Behavioral activation. Behavioral activation therapy is an effective treatment for depressive disorders as shown in a considerable number of studies and a meta-analysis (Cuijpers and colleagues 2008). In this module one learns to find a balance

between the amount of pleasant activities and necessary activities.

d) Problem-solving. Problem-solving therapies have been found to be effective in the treatment of depression, both in face-to-face therapies (Cuijpers et al. 2008), as well as in internet-based therapies (Van Straten et al. 2008, Warmerdam et al. 2008; 2010). In this module people learn strategies to cope with different kind of problems.

e) Cognitive restructuring. This module also builds on existing evidence-based internet-based interventions for depression (Andersson et al. 2005; 2006). In this module the participant learns to recognize negative automatic thougths and to replace them by more positive realistic thoughts.

f) Relapse prevention. Relapse rates after successful treatment of depression are high (Bockting et al., 2005). However, research shows that relapse prevention is possible through the use of longer-term psychological treatments, and treatments specifically aimed at relapse prevention (Vittengl et al., 2007). The relapse prevention module focuses on recognizing signs of a relapse, making plans to cope with these signs and anticipating on future events that could trigger a relapse.

g) Medication adherence module. This module informs the participant about the importance of medication adherence. Exercises are included that try to uncover possible barriers for taking medication. Participants can also see their own medication adherence in a graph.

2. Monitoring system.

Monitoring behavior and emotions is an important component within the treatment of depression. This information is also used to give the participants adequate and personal feedback from the reasoning system. In Moodbuster information is gathered via ecological momentary assessments (EMA; Ebner-Priemer & Trull, 2009). EMA is a valid method to gather real-time data about context, behavior and emotions (Wenze & Miller, 2010). In Moodbuster the mobile phone will be used to prompt the patient for a self-assessment of his mood and feelings, using an intuitive (graphical) interface. Participants will receive daily at random a request to rate their mood on their mobile phone. The minimum amount of required mood ratings is five. In addition, participants are asked to rate their sleep quality and anxiety once a day.

A second aspect of behavior that is monitored concerns biomedical information. Wearable biosensors are developed that measure several reactions of the body to emotional changes, such as electro-dermal activity, respiration, electrocardiography changes.

Medicine intake is the third aspect that is being monitored. Participants who take medication for their depression use an electronic medicine monitoring system.

This device is able to detect medicine intake for different types of medication packaging relevant for depression (e.g. blisters, dose organizers, etc.).

3. Reasoning system.

The data obtained from the monitoring system will be interpreted by reasoning modules that can translate sensor information and information provided by patient into therapy information, that can reason about the progress of therapy and that can deduce/advice what therapy is most likely to be successful given the current state of the patient.

The reasoning system is able to provide feedback to both the depressed patient (providing information on progress of the therapy, appropriate therapy models given the state of the patient, motivations and warnings, e.g. concerning compliance with drug descriptions) and to the GP (providing decision support for treatment planning). Patients will receive this personalized automated feedback weekly on the basis of their answers to the prompt questions, home work made and bio-sensors. This is partly done via the cell phone, and partly via a personal website. Simple reminders and motivational messages are best suited for communication via the mobile phone, while a website is more appropriate for detailed progress feedback. In addition, the caregiver will get information about the progress of the patient on a weekly basis.

1. Pilot in Sweden

1.1 Background

The Linköping pilot trial on the Moodbuster treatment was planned and conducted by the research group in Linköping, Sweden, under the lead of Prof. Andersson. As previously mentioned in this report, Moodbuster was developed within the ICT4Depression project and the treatment components were partly derived from previous evidence based treatment protocols in Swedish (Andersson, Bergström, Holländare, Lenndin, & Vernmark, 2007) and in Dutch (Warmerdam, van Straten, Twisk, Riper, & Cuijpers, 2008). Moodbuster is aimed to be delivered as a self-help depression treatment via Internet and as a mobile-based treatment as well. Moodbuster uses ecological momentary assessment and intervention techniques including the assessment of physiological symptoms in an integrated manner (Warmerdam, et al., 2012). This represents a novel aspects of cognitive behavioural self-help.

The research group in Linköping has substantial experience in the conduct of developing Internet interventions and clinical trials on guided internet-based self-help treatment for depression, with the treatment being tested against a moderated online discussion forum (Andersson, et al., 2005) and also against e-mail based therapy (Vernmark, et al., 2010) and waitlist control groups. Long-term effects up to 3.5 years after treatment completion have been found (Andersson et al. 2013), and in a different version the treatment has been found to work as well for partially remitted depressed patients (Holländare, et al., 2011). In addition, treatments based on a different treatment approaches have been tested including acceptance and commitment therapy (Carlbring, et al., In press) and psychodynamic therapy (Johansson, Ekbladh, et al., 2012). A tailored version of cognitive behaviour therapy has been developed and tested (Johansson, Sjöberg, et al., 2012), but in contrast to the Moodbuster treatment developed in this project the treatment algorithm for tailored treatment is only based on self-report and not data collected in real time or biological data.

In contrast to the Dutch pilot trial the Swedish trial was conducted with a depressed student population. Students were deliberately targeted before a population of primary care patients as it is known that technology-based treatments have been found to work for this population (Tillfors, et al., 2008). A student sample was also regarded as being more likely to be able to handle smartphones, sensors and possible technical problems during the pilot phase of the project. We also had previous experiences from another project on smart phone delivered treatment (Ly, Dahl, Carlbring, & Andersson, 2012) and also have an ongoing trial on smartphone treatment of depression (Ly, Carlbring, & Andersson, 2012).

1.2 Research questions

The aim of the study was to test the feasibility of the Moodbuster program in a sample of university students. We expected decreased symptoms of depression and general anxiety. We were also interested in the subjective experiences of using the Moodbuster.

2. Methods

2.1 Ethics statement

The pilot-study was approved by the Regional Ethics Board of Linköping, Sweden (Registration number 2012/109-32). All participants provided signed informed consent as part of the interview process. Written informed consent was obtained from all participants during a diagnostic interview.

2.2 Participants and recruitment

Participants were recruited from a student population at Linköping University in Sweden. Linköping University is a multi-faculty university with 27 000 students and 3900 employees (www.liu.se). Recruitment was conducted by sending information about the treatment study to sub-groups of the student population, using various e-mail lists. Inclusion criteria for the study were a) being at least 18 years old, b) having a total score of 5 or more on the 9-item Patient Health Questionnaire Depression Scale (PHQ-9; (Kroenke, Spitzer, & Williams, 2001)), c) no assessed risk of suicidality, d) no concurrent psychological treatment, e) a diagnosis of major or minor depression according to the DSM-IV (American Psychiatric Association, 2000).

Applicants to the study were instructed to complete an online screening containing demographical questions and the outcome measures described below. A participant was scheduled for a diagnostic interview if he or she had completed the screening and met the initial inclusion criteria. In the interview, diagnostic questions about mood disorders were asked in addition to questions about use of medications and psychological treatments. Additionally, an assessment of suicidal ideation was conducted. The diagnostic interview was based on the MINI diagnostic interview (Sheehan, et al., 1998). Four M.Sc. clinical psychology students who had been trained in the diagnostic procedures conducted the interviews. The senior researcher discussed all interview protocols with the interviewers and made the final decision to include or exclude a participant.

Approximately 2000 students were reached by the information e-mails. Out of these, 44 completed the online screening. While all these participants were scheduled for the diagnostic interview, it was completed by 40 of the 44 individuals.

Based on the interview protocols, a decision of inclusion was made for 25 individuals. One participant chose to drop out before the treatment started. The final set of participants therefore included 24 participants. See Figure 1 for an overview of the flow.

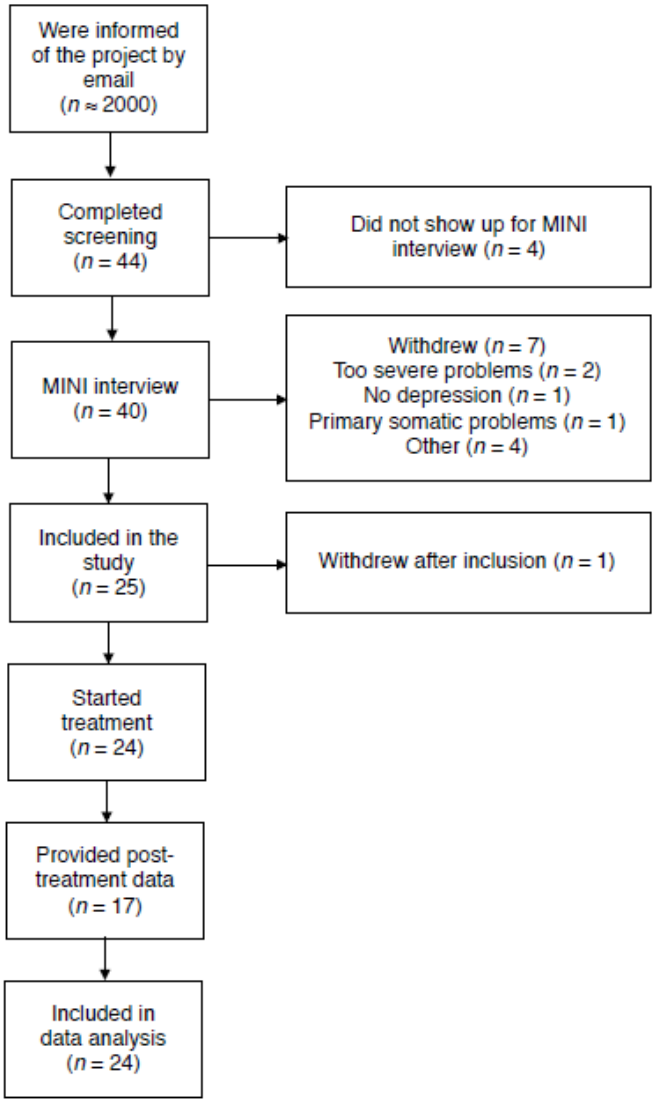

Figure 1. Flow of participants

The included set of participants consisted of 11 (46%) women and 13 (54%) men. All had a diagnosis of major or minor depression. The average age was 24 years (with a range from 20 to 33 years). Nine (37%) were in a relationship. Self-rated general knowledge of computers was high (4.7 out of 5 on average), and

similarly knowledge of smartphones was high (4.1 out of 5 on average). Ten (42%) had previous experience of psychological treatments. Only two (8.3%) had previous experience from antidepressants and out of these only one (4.2%) were on medication during the trial. See Table 1 below for more details.

Table 1: Demographic description of the participants

		Participants
Gender	Female	11 (45.8%)
	Male	13 (54.2%)
Age	Mean (SD)	24.0 (3.3)
	Min-Max	20-33
Marital status	In a relationship	9 (37.5%)
	Single	15 (62.5%)
Educational level	College or university, completed	0 (0%)
	College or university, ongoing	24 (100.0%)
	Other	0 (0%)
Employment status	Student	24 (100.0%)
	Other	0 (0%)
Medication	No experience	21 (87.5%)
	Prior experience	2 (8.3%)

		Participants
	Present	1 (4.2%)
Psychological treatment	No experience	14 (58.3%)
	Prior experience	10 (41.7%)
	Present	0 (0%)

2.3 Outcome measures

The 9-item Patient Health Questionnaire Depression Scale - PHQ-9(Kroenke, et al., 2001) and the 7-item Patient Health Questionnaire Generalized Anxiety Disorder Scale (GAD-7; (Spitzer, Kroenke, Williams, & Lowe, 2006)) were used as measures of depression and anxiety severity. Both measures were administered at pre-treatment, weekly during treatment, and at post-treatment. The measures were administered via the Internet, which has been shown to be a valid format for questionnaires regarding depression and anxiety (Carlbring, et al., 2007; Holländare, Andersson, & Engström, 2010).

2.4 Treatment and weekly telephone calls

The Moodbuster treatment is an integration of unguided self-help treatment modules delivered via a smartphone application (see page XX), an intelligent reasoning system and data from wearable biomedical sensor devices. In addition, participants who received the treatment were also contacted weekly by telephone for clinical monitoring and support of the system. These telephone calls were conducted by the same M.Sc. clinical psychology students who conducted the clinical interviews. In all, the treatment lasted for six weeks. The self-help treatment modules included were psychoeducation, behavioral activation, problem solving therapy, cognitive restructuring, exercise therapy, medication adherence, and relapse prevention. A more detailed description of all treatment material and the entire system tested is available elsewhere (Warmerdam, et al., 2012).

2.5 Statistical analyses

The study had an open design in that no control group was used. To investigate treatment effects on symptoms of depression and anxiety, dependent *t*-tests were used. For participants who did not complete the post-treatment assessment, data from the last available weekly measure was used. Using this procedure, data from all participants was included in the final analyses and therefore the intention-to-treat principle was adhered to.

Recovery from depression was investigated using the established limits on the PHQ-9 and defined as having a post-treatment score of < 10. In addition, complete recovery from depression was also investigated using the definition of a post-treatment score of < 5. Analyses of recovery were conducted using data from all 24 participants.

Within-group effect sizes (Cohen's *d*) were calculated by dividing the differences in means by the pooled standard deviations, as described in Borenstein et al. (2009).

3. Results

3.1 Attrition

Seven (29%) of the 24 participants did not provide post-treatment data. As described above, the last available data from the weekly assessments was carried forward to the post-assessment.

3.2 Outcome measures

There were significant effects of time, both on symptoms of depression and anxiety (both *t*'s > 5.50 and both *p*'s < .001). Within-group effects were in the moderate to high range. The complete results are available in Table 2.

Table 2. Means, SDs and effect sizes (Cohen's *d*) for measures of depression and anxiety for all (*N* = 24) participants

	Pre-treatment, Mean (SD)	**Post-treatment, Mean (SD)**	***t*(23)**	**Within-group effect-size, *d* (95% CI)**
PHQ-9	13.04 (4.1)	7.67 (5.6)	5.58***	1.07 (0.60 – 1.54)
GAD-7	9.29 (6.0)	6.08 (5.9)	5.50***	0.54 (0.33 – 0.74)

Note. *** = *p* < .001. PHQ-9 = 9-item Patient Health Questionnaire Depression Scale; GAD-7 = 7-item Patient Health Questionnaire Generalized Anxiety Disorder Scale.

3.3 Recovery from depression

The number of participants who recovered from their depression (post-treatment PHQ-9 score of < 10) after treatment was 18 out of 24 (75%). Complete recovery (post-treatment PHQ-9 score of < 5) was reached by 10 (42%) participants. Details on recovery rates are given in Table 3.

Table 3. Recovery rates before and after completion of the treatment program, all (*N* = 24) participants.

	Pre-treatment, *n* (%)	**Post-treatment, *n* (%)**
Recovery (PHQ-9 < 10)	7 (29%)	18 (75%)
Complete recovery (PHQ-9 < 5)	0 (0%)	10 (42%)

Note. PHQ-9 = 9-item Patient Health Questionnaire Depression Scale.

3.2 Feasibility

For our target population of students with mild to moderate depression it was relatively easy to recruit participants. The use of sensors can be regarded as a negative aspect but did not have any major implications for the recruitment and completion of the pilot trial.

3.3 Usability

We asked questions regarding usability of the system which were rated on a five point Likert type scale (1 = very bad; 2 = bad; 3 = neither good nor bad; 4 = good; 5 = very good).

For the first question “What is your opinion on the mobile application?” we obtained a mean score of 2.75. Comments from participants included a good structure and easy to work with, and that the information and treatment was always close at hand. The mood ratings helped identify good moods. The texts had a good length and the films were appreciated. Some participant would have liked to be able to do more of the exercises in the app, but some participants preferred the web page. Problems reported included problems with the calendar, that the system crashed sometimes and that the data were not saved on one occasion. Some of the participants found it difficult to navigate the system and would like it to be more like other android apps. Some participants wished to have a page were they could see completed pages, exercises and chapters.

The second question was ”What is your opinion on the sensors?” This obtained a mean rating of 2.21. The wrist sensor had a good fit and functioned well for most participants. The chest sensor was often regarded as too large and that it lost contact with the system. Another comment was that it would be helpful to have

an easy way to see if everything was working or not. Some participants found it difficult to see how the sensors would make them feel better, and the purpose was a bit unclear to them.

The third question was ”What is your opinion on the web site?” This obtained a mean rating of 3.30. Comments included that the web site was user friendly and easy to understand, and that the correlation between the app and the web page was good (except for the number of stars). The mood graph was appreciated. Among the problems were problems saving data from exercises, problems with log in (for a few) and software was not compatible with all web browsers.

We also asked a question regarding satisfaction with the therapists. This was highly appreciated with a mean score of 4.29. Comments included that contact once each week was good enough and that the contactgave participants a deadline and increased motivation. It felt good to talk to someone and the technical support was necessary. A few participants requested more personal support and thought a monthly meeting would have been helpful.

We asked a question regarding ”What is your general opinion of the treatment?”. This received a mean rating of 3.21. Comments in relation to this question included interesting reading, that the treatment had given reason to reflect on things and created a willingness to change aspects of life. It was viewed as an easy way to help your self and work continually with problems in life. However, it was also confusing with so many aspects to keep track on, and more help with planning the treatment would have been useful. The treatment is a good idea but the technical aspects needs more work.

Finally we asked a question derived from the treatment credibility scale by Borkovec and Nau (Borkovec & Nau, 1972): ”Would you recommend this treatment to a friend?” This obtained an average rating of 3.50 (1 = no, I really would not - 5 = yes, I really would).

Our own experiences included that is was hard to motivate participants to do what they should when there are so many things to keep in mind. It would have been helpful with feedback from the system to keep track of participants progress. All the technical preparations helped us get to know the system and it was very helpful for us when participants had questions. Our participants were very technologically skilled (e.g., students) and could solve many difficulties on their own and explain their problems over the phone. Since weekly telephone calls were part of the protocol problems could be handled immediately.

4. Discussion

In this pilot study, we aimed to test the feasibility of Moodbuster as a depression treatment. We included a small pilot sample consisting of university students. Data collected before and after treatment showed clear reductions of depressive and anxiety symptoms with a large effect for depressive symptoms and a moderate

effect for anxiety symptoms. Overall there were both positive and negative comments from participants and clinicians.

Several aspects of the trial can be discussed. First, we believe that the Moodbuster treatment appears to work as well as guided internet treatment with large effects on depressive symptoms (Andersson & Cuijpers, 2009). It needs to be underscored however that the way we tested Moodbuster was in a guided format as weekly telephone calls were included. Hence we cannot know if the treatment would work as an unguided treatment supported by reasoning system components. Second, the administration format including the use of sensors and smart phone did not appear to influence the outcomes in a negative manner, even if there were some complaints regarding usability. At this stage we cannot say how much the intelligent reasoning system and data from wearable biomedical sensor devices influenced the outcome, but at least we believe that the treatment as administered in this pilot trial was safe. We could not take advantage of the medication adherence module as there were not patients on medication. This might be due to the student sample we recruited. In spite of the fact that we recruited students, we did include proper diagnostic assessments (in a live interview) and all included had a diagnosis of minor or major depression.

There are limitations with the trial. First, as we did not include a control group or randomization there is not way to secure that it is the treatment that is responsible for the improvements found. Second, there were indeed some problems with the equipment and hence the support provided and the study population was motivated in retrospect as clinical patients in a regular primary care setting would be more likely to give up when facing technical problems. Indeed, even in this sample there were dropouts who did not complete the full trial. It is likely that an updated system will have fewer technical problems.

4.1 Conclusions

This exploratory study indicates that Moodbuster can be used as a treatment for mild to moderate depression.

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1. 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).

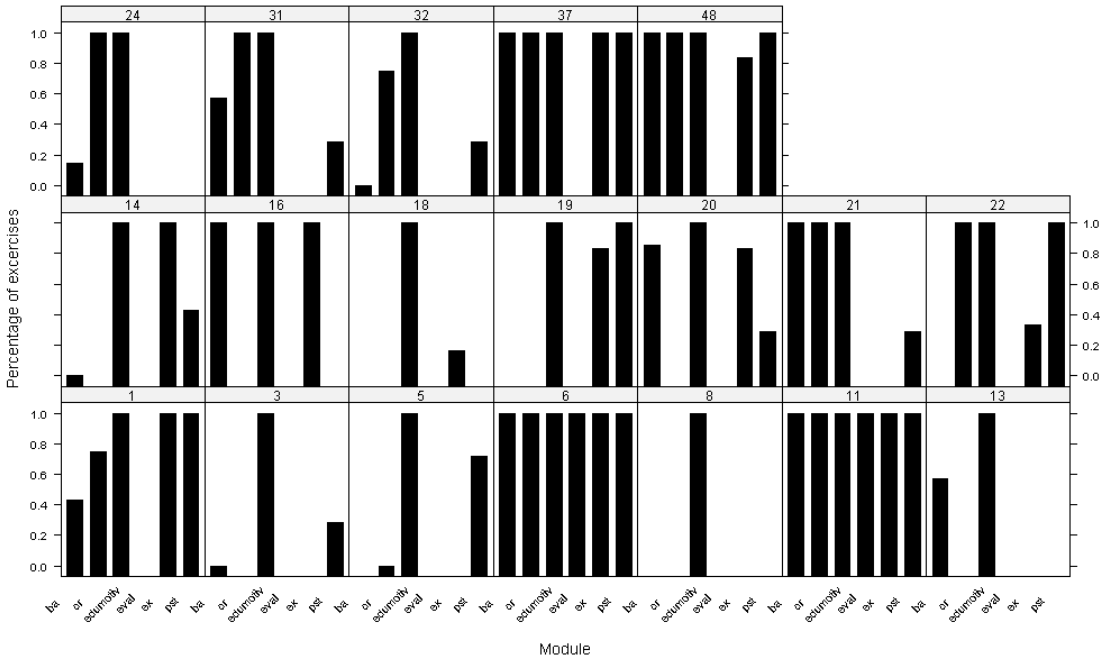

Figure 3: Moodbuster treatment module usage of the participants of the moodbuster pilot trial. Module completion is depicted as a percentage of the total number of exercises in each module (ba: behavioral activation; cr: cognitive restructuring; edumotiv: psycho-education; pst: problem solving therapy;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

* $p < .0001$

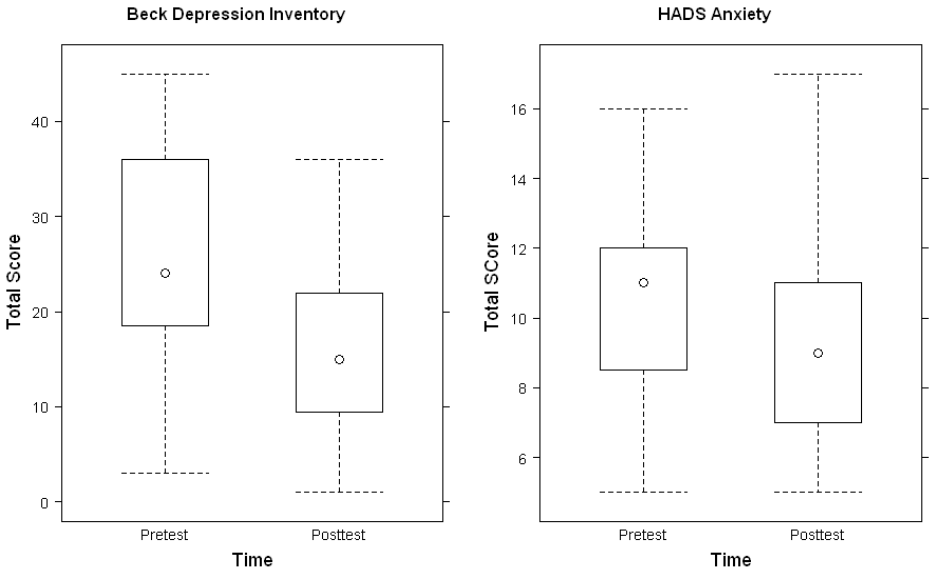

Figure 4: Changes in depression and anxiety symptoms from pre- to posttest.

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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General conclusion and discussion

The purpose of the two pilots was to test the feasibility and the usability of Moodbuster and to obtain a first indication of the possible clinical effects of the treatment program. Participants in the Swedish pilot consisted of young, highly educated students with a technical background. In the Dutch trial, participants were middle aged, mainly highly educated and recruited via the general population. Outcomes in both groups were comparable. The moodbuster system was deployable, safe and used by the participants. Encouragingly, clinical outcome measures indicated probable positive effects on depressive symptoms and anxiety symptoms. Participants reported fair clientsatisfaction 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.

In both pilots, the usability of the website was rated highest and the usability of the medical sensors devices received the lowest ratings. Patients were quite satisfied with the help they received from Moodbuster. Clinical progress was visible in the Swedish pilot, which added some form of guidance to Moodbuster, as well as in the Dutch pilot.

Recruitment of students in Sweden seemed feasible, while recruitment of patients in Dutch primary care was problematic. We believe that a more integrated extensive recruitment strategy could have overcome the problems encountered in the Netherlands. According to primary care takers various factors could play a role here. Factors that were mentioned included 'not thinking of informing patients about the study', 'patients problems are not suitable for this kind of unguided treatment', 'not willing to wear sensor devices' and 'abundance of information in the waiting room of the general practice'. However, recruitment from the general population went quite well.

An overall conclusion, based on the results from the two pilot trials, is that the Moodbuster platform provides a possibly valuable addition to current treatment options for depression, although we recommend further improvements in the usability of the system. In addition, future controlled trials should be conducted to confirm the clinical effects of the program.