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.

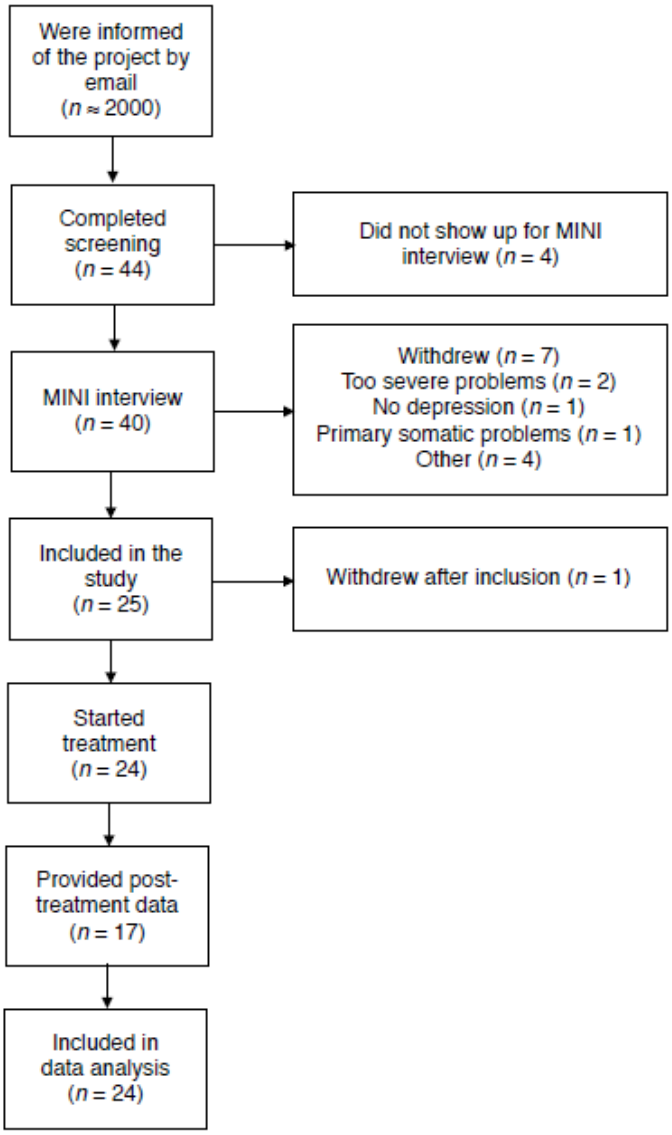

Figure 1. Flow of participants

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%)
	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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