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# Development and initial evaluation of blended cognitive behavioural treatment for major depression in routine specialized mental health care



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#### ABSTRACT

Background: Blended care combines face-to-face treatment with web-based components in mental health care settings. Blended treatment could potentially improve active patient participation, by letting patients work though part of the protocol autonomously. Further, blended treatment might lower the costs of mental health care, by reducing treatment duration and/or therapist contact. However, knowledge on blended care for depression is still limited. Objectives: To develop a blended cognitive behavioural treatment (bCBT) for depressed patients in an outpatient specialized mental health care centre and to conduct a preliminary evaluation of this bCBT protocol.

Method: A bCBT protocol was developed, taking recommendations into account from depressed patients (n=3) and therapists and experts in the field of e-health (n=18). Next, an initial evaluation of integrated high-intensive bCBT was conducted with depressed patients (n=9) in specialized mental health care. Patients' clinical profiles were established based on pre-treatment diagnostic information and patient self-reports on clinical measures. Patient treatment adherence rates were explored, together with patient ratings of credibility and expectancy (CEQ) before treatment, and system usability (SUS) and treatment satisfaction after treatment (CSQ-8). During and after treatment, the blended treatment protocol was evaluated in supervision sessions with the participating therapists (n=7).

Results: Seven out of nine patients started bCBT, of whom five completed  $\geq$  90% of treatment. System usability was evaluated as being above average (range 63 to 85), and patients were mostly to very satisfied with bCBT (range 16 to 32). Patients reported improvements in depression, health-related quality of life and anxiety. We observed that therapists evaluated the highly structured blended treatment as a helpful tool in providing evidence-based treatment to this complex patient group.

Discussion: Although no conclusions can be drawn based on the current study, our observations suggest that a blended CBT approach might shorten treatment duration and has the potential to be a valuable treatment option for patients with severe depression in specialized mental health care settings. Further exploration of the effectiveness of our bCBT protocol by means of a randomized controlled trial is warranted.

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#### 1. Introduction

Cognitive behavioural treatment (CBT) for depression has been studied extensively and has proved to be a clinically effective

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psychotherapy (Butler et al., 2006; Cuijpers et al., 2013a, b). More recently, studies have shown that CBT for depression can be effectively administered in web-based settings (Andersson and Cuijpers, 2009; Andrews et al., 2010; Kelders et al., 2015; Richards and Richardson, 2012). Furthermore, web-based treatment appears to be acceptable to both patients and therapists (Andrews and Williams, 2014; Becker and Jensen-Doss, 2013).

Although most studies focussed on patients with mild to moderate symptoms (Richards and Richardson, 2012), recent studies also show

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promising treatment effects and acceptability for patients with more severe symptoms (Andrews and Williams, 2014; Hedman et al., 2014; Ruwaard et al., 2012; Williams and Andrews, 2013). Furthermore, internet interventions guided by a professional have been shown to have similar treatment effects to face-to-face treatment (Andersson et al., 2014), although the number of studies that examined the relative efficacy of face-to-face versus online psychotherapy is limited.

An important potential benefit of web-based treatment is that it can facilitate the delivery of evidence-based treatment protocols, such as CBT (Andrews and Williams, 2014). Research suggests that only a limited amount of patients in routine practise actually receives evidence-based treatment (Gyani et al., 2014; Harvey and Gumport, 2015). This is caused both by under-treatment of mental disorders such as depression (Demyttenaere et al., 2004; Harvey and Gumport, 2015) and therapist drift from evidence-based treatment protocols (Waller, 2009). By providing CBT in a web-based format, therapist adherence to evidence-based treatment protocols can potentially be improved (Andersson, 2010; Månsson et al., 2013), because the online treatment environment provides all core treatment constructs (Andrews and Williams, 2014). In addition, online treatment is believed to improve the accessibility and affordability of evidencebased mental health care. Studies suggest that online treatments may reduce therapist time per patient, because patients are encouraged to work through the treatment protocol more autonomously, and therapists can provide feedback online instead of during face-to-face sessions at the clinic (Hedman et al., 2014; Kenter et al., 2015). This, in turn, may lower treatment costs and allow therapists to take on more

Within the Dutch health care system these potential benefits are highly relevant to specialized mental health care, because mental health services in this setting focus on more complex, chronic and severe patients. Therefore, treatment costs tend to be higher compared to primary care (Spijker et al., 2013) in combination with long waiting lists due to treatment duration and limited financial resources (Bower and Gilbody, 2005; Lovell and Richards, 2000).

Despite the potential benefits of online treatment, only a small number of patients are reached with online therapies in routine practise, particularly in specialized mental health care (Bremmer and van Es, 2013; Kenter et al., 2015). A possible reason for the relatively low uptake in routine practise could be that end-users, such as patients and therapists, lack knowledge about the potential costs and benefits of online treatment (Bremmer and van Es, 2013). Further, therapists are sceptical about whether online treatment could benefit treatment outcomes compared to face-to-face treatment (Becker and Jensen-Doss, 2013).

The integration of online treatment into routine mental health care could potentially be stimulated by offering treatment in a blended format (Cuijpers and Riper, 2014). This form of treatment integrates face-to-face treatment sessions and online sessions into one treatment protocol (Riper et al., 2013). Blended treatment aims to preserve personal contact and the therapeutic relationship that is associated with stand-alone face-to-face psychotherapy, while utilizing webbased treatment to stimulate active patient participation and improve the accessibility and affordability of treatment (Kenter et al., 2015).

Another possible benefit of blended treatment is that it can facilitate increased treatment intensity, for example by adding one online session per week alongside a face-to-face session. A recent metaregression analysis (Cuijpers et al., 2013b) indicated that intensifying treatment augments the effectiveness of face-to-face psychotherapy, with a treatment intensity of two sessions per week increasing the effect size with g=0.45 compared to one session per week.

Although high intensity blended treatment has not yet been studied, preliminary evidence that a blended treatment format can offer CBT effectively was provided by the uncontrolled study of Mansson and

colleagues (Månsson et al., 2013), focussing on a community-based sample of patients with moderate anxiety or depression (n=15). Further, a recent Delphi study suggested that blended treatment is positively perceived by patients and therapists (Van der Vaart et al., 2014).

Other available studies focussed on combined cognitive behavioural face-to-face and online treatment for depression. The results suggest that this combination treatment can achieve promising clinical results (Hickie et al., 2010; Høifødt et al., 2013; Kenter et al., 2013; Robertson et al., 2006). However, combining the two treatment formats rather than blending them into one treatment protocol can also lead to increased treatment dosage and higher costs (Kenter et al., 2015).

The current study expands on the aforementioned studies by developing a highly structured and integrated blended CBT (bCBT) protocol for depressed patients in specialized mental health care. This paper describes the development of the protocol and initial experiences with blended treatment.

#### 2. Methods

#### 2.1. Development of blended cognitive behavioural treatment (bCBT)

Our primary objective was to develop a bCBT protocol for depression in specialized mental health care, because, to the best of our knowledge, such a protocol was not yet available.

## 2.1.1. Therapist and expert recommendations

In order to acquire input on how online and face-to-face treatment sessions could be integrated, we consulted CBT therapists working at a specialized mental health care centre in Amsterdam, the Netherlands, and Dutch experts in the field of web-based treatment (n=18) in four two-hour group discussions. During these meetings, we discussed possible benefits and limitations of online and face-to-face sessions, and participants could express specific recommendations for the blended CBT protocol. Sessions were recorded and transcribed,  $^1$  and minutes were taken during the sessions by the first author (LK).

Next, authors one (LK), two (JR), three (JW), four (PvO) and seven (HR) discussed the findings. Based on group consensus, the following therapist recommendations were incorporated into the treatment protocol:

- Treatment starts with a face-to-face session, in order to establish
  a therapeutic relationship, motivate patients for treatment and
  explain working with the online treatment environment to
  patients.
- Face-to-face sessions and online sessions are provided in equal measure (50%/50% ratio). Therapists expected that the proposed ratio would enable them to provide adequate therapist support to patients, thus promoting treatment motivation and preventing patients from dropping out of treatment.
- Face-to-face sessions focus on adapting the treatment content to individual patient needs, for example by practising skills in role plays and helping patients to identify their core problems. Online sessions are used to offer background information, record mood ratings and provide homework excercises.
- The treatment is structured as a fixed sequence of treatment modules, instead of tailoring online content to individual patients by allowing therapists and patients to choose from treatment modules and/or adjust the order of modules. This was done primarily to ensure delivery of the full CBT protocol. Therapists also noted that a flexible rather than fixed approach would

<sup>&</sup>lt;sup>1</sup> Due to technical problems, the audio recordings of one therapist group-session and one expert group session were not usable.

require them to have extensive knowledge on the content of the protocol and experience with working with the web-based treatment environment. This led them to prefer working with a fixed treatment protocol during the initial evaluation phase.

- Online sessions include an optional, open-ended session evaluation question, to allow patients 1) to comment on the online sessions, and 2) to promote reflective thinking on the meaning and impact of the homework excersises.
- Email reminders are sent in order to encourage patients to access the online platform and engage in treatment.
- Online therapist feedback is provided after each online session, in order to monitor and motivate patients between the face-to-face and online sessions.

#### 2.1.2. Patient recommendations

In order to incorporate the patient perspective, we showed the prototypes of the bCBT protocol (MS Word document) and web-based treatment delivery system (Minddistrict; www.minddistrict.com), to a convenience sample of patients (n=3) during a 90-min group meeting. The patients (two males, one female) were in the final phase of face-to-face CBT treatment for depression at an outpatient clinic of a specialized mental health care centre in Amsterdam, the Netherlands. The meeting took place at the mental health care centre and was led by the third author (JW). Minutes were taken during the meeting by the first author (LK). Next, authors one (LK), two (JR), three (JW), four (PvO) and seven (HR) discussed the patient recommendations. Based on group consensus, the following elements were incorporated into the treatment protocol:

- The patients raised concerns about the amount of homework. Based on this, online exercises are split into 'mandatory' and optional exercises, to ensure that completion of exercises is feasible on 'bad days', preventing unnecessary negative effects of treatment workload.
- No changes were made to the web-based treatment delivery system.
- The patients have access to one new session at a time in the webbased treatment system, instead of all sessions at once.
- At the beginning of each face-to-face session, 15 min are reserved for
  patients to discuss personal issues that arose over the past week.
  This can be related to the online homework, but can also incorporate
  discussions of other challenges that patients faced.
- Face-to-face sessions are provided on a weekly basis, because the patients thought it was important to see their therapist regularly at the specialized mental health care clinic. This matched the therapist recommendations.

#### 2.2. Initial evaluation of blended cognitive behavioural treatment (bCBT)

The prototype of the bCBT protocol was offered to a small group of patients, in order to explore the reach and acceptability of the bCBT protocol. Measurements were taken at baseline (pre-treatment) and post-treatment (10 weeks). The Medical Ethics Review Committee of the VU University Medical Centre in Amsterdam, the Netherlands approved the study (REF 2013/381). The study was carried out between January 2014 and May 2014.

# 2.2.1. Participants

Patients (n=9) were recruited at an outpatient clinic of a specialized mental health care centre in Amsterdam, the Netherlands. To participate, patients had to be 18 years or older and be diagnosed with a current depressive episode, based on the criteria from the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR, APA, 2000). Additionally,

patients needed to have adequate proficiency in the Dutch language, and access to the Internet at home via a (tablet) computer. Patients were excluded from the study if individual and/or outpatient CBT for depression was not indicated, or if they were already receiving psychotherapy. Concurrent pharmacotherapy was not an exclusion criterion. Inclusion and exclusion criteria were assessed at the outpatient clinic during the routine face-to-face intake assessment.

#### 2.2.2. Procedures

The third author (JW) approached patients after their intake assessment at the outpatient clinic and informed them about the study and bCBT. Potential participants received an information brochure via email. After providing written informed consent, patients filled in the online baseline self-report questionnaires. Before the start of blended treatment, the use of the online treatment platform was demonstrated to the included patients during an individual 30-min face-to-face session at the outpatient clinic. Face-to-face treatment sessions (45 min) took place at the clinic and patients completed the online sessions at home. After blended treatment, patients were asked to fill in the online post-treatment assessments.

Once every two weeks a supervision meeting was held with the participating therapists. At the end of the study, when all patients had completed the blended protocol, a final evaluation meeting was held in order to provide therapists with the opportunity to evaluate the bCBT protocol. Minutes were taken during all supervision sessions. The final evaluation meeting was audio-recorded and transcribed.

#### 2.2.3. Measures

In order to gain insight into the feasibility (Leon et al., 2011) of bCBT, we first examined the reach of the intervention in terms of the proportion of patients enrolled at the mental health care centre that was eligible for bCBT. Next, the clinical profiles and treatment outcomes of patients that were enrolled in bCBT were explored based on patients' electronic patient records and clinical self-report measures. Finally, patients' treatment adherence to bCBT, and patient self-reports on treatment acceptability, usage and satisfaction were assessed. All self-report measures used in our study are considered to have good psychometric properties and were administered via the Internet.

2.2.3.1. Clinical profiles. Information on baseline functioning was extracted from the electronic patient files. This information included current DSM-IV-TR diagnosis (APA, 2000), use of anti-depressant medication and current Global Assessment of Functioning (GAF) index score (APA, 2000). Socio-demographic information such as gender, age, nationality, level of education and employment status were collected with a self-report questionnaire at baseline as part of the current study. In addition, clinical self-report measures were used to gain insight into the clinical patient profiles before and immediately after treatment. We used questionnaires that were proposed by the mental health care centre for routine outcome measurement (ROM) before and immediately after treatment.

The 30-item self-report version of the Inventory of Depressive Symptoms (IDS-SR<sub>30</sub>) was used to assess the *severity of depressive symptoms* in the past week (Rush et al., 2000). Total scores range from 0 to 84, with higher scores indicating greater severity of depressive symptoms (Trivedi et al., 2004). The severity index ranges from 0 to 4 and is built up as follows; IDS-SR<sub>30</sub> scores 0 to 13 = 0 (None), scores 14 to 25 = 1 (Mild), scores 26 to 38 = 2 (Moderate), scores 39 to 48 = 3 (Severe), and scores 49 to 84 = 4 (Very severe).

The Beck Anxiety Inventory (BAI) (Beck and Steer, 1993) was used to measure *anxiety*. Total scores range from 0 to 63, with higher scores indicating a higher level of anxiety (Trivedi et al., 2004). The severity index ranges from 0 to 3 and is built up as follows; BAI scores 0 to

9 = 0 (Normal or no anxiety), scores 10 to 18 = 1 (Mild to moderate), scores 19 to 29 = 2 (Moderate to severe), and scores 30 to 63 = 3 (Severe anxiety) (Aaron T Beck et al., 1988).

Furthermore, health-related quality of life was measured with the EuroQol questionnaire (EQ-5D-3 L) (EuroQol Group, 1990; Lamers et al., 2006). The questionnaire is composed of a visual analogue scale (VAS) ranging from 0 to 100, and five items with 3 response categories each. The combination of responses on the five items is converted into health states based on utility weights (Lamers et al., 2006). Health state scores range from 0 to 1, with 1 representing the best possible state of health (Brooks, 1996).

2.2.3.2. Patient evaluation of bCBT. Treatment expectancy and credibility were measured before the start of bCBT with the 6-item credibility/expectancy questionnaire (CEQ)(Devilly and Borkovec, 2000). Total scores on the credibility and expectancy scales range between 3 and 27. Total scores for the overall scale range between 6 and 54. Higher scores indicate higher credibility and more positive treatment expectations (Devilly and Borkovec, 2000).

After bCBT, patients rated system usability of the online treatment platform on the 10-item System Usability Scale (SUS) (Bangor et al., 2008; Brooke, 1996). Total SUS scores are converted to a 0 to 100 scale, with higher scores being indicative of greater system usability. A SUS score above 68 is considered above average (Sauro, 2011), indicating acceptable experienced system usability.

Post-treatment satisfaction with bCBT was measured with the Client Satisfaction Questionnaire-8 (CSQ-8) (Larsen et al., 1979). The CSQ-8 consists of 8 items. The total scores range between 8 and 32, with higher scores indicating better treatment satisfaction (De Brey, 1983).

Information on treatment adherence (number of completed face-to-face sessions) was extracted from the electronic patient files. Information on the use of the number of completed online sessions was extracted from the web-based treatment platform (Minddistrict; www.minddistrict.com).

## 2.2.4. Analyses

Data on treatment adherence, credibility, usage and satisfaction and clinical measures are presented on an individual patient level. Simple summary statistics (M, SD) are presented to provide a clinical description of the included group of participants.

#### 3. Results

#### 3.1. Blended cognitive behavioural treatment (bCBT)

Based on the information gathered in the development phase, an integrated bCBT protocol was developed by authors one (LK), two (JR), three (JW), four (PvO) and seven (HR). Fig. 1 provides an overview of the treatment content and sequence.

The content of the blended protocol is based on a Dutch protocol for face-to-face CBT in specialized mental health care (Bockting and Huibers, 2011) which recommends providing 16 to 20 weekly sessions. This face-to-face CBT protocol is based on the protocol by Beck (Beck et al., 1979). The blended treatment is intensified compared to standard CBT, delivering one face-to-face session and one online session per week for ten weeks, instead of one face-to-face per week for 20 weeks. Both face-to-face and online sessions are highly structured, and are comprised of psycho-education, behavioural activation, cognitive therapy and relapse prevention (Spijker et al., 2013) with the same order and dosage for all patients.

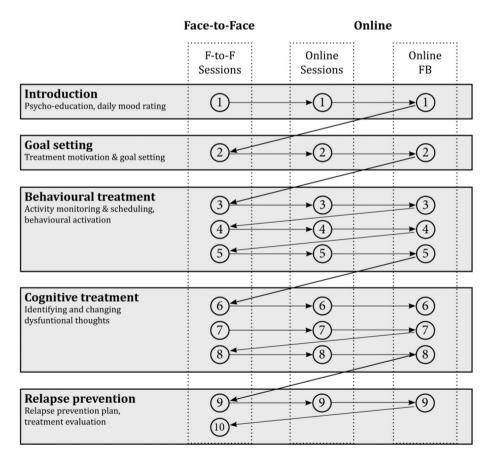


Fig. 1. Overview of the blended treatment protocol Note: F-to-F sessions: face-to-face sessions; Online FB: online feedback.

#### 3.1.1. Face-to-face sessions

Treatment starts with a face-to-face session in which 1) the therapist and patient become acquainted with each other, 2) the general aspects of bCBT are explained, and 3) the online treatment platform is introduced. Each further face-to-face session begins with a short open reflection on the patient's mood, experiences and homework in the past week, before addressing that week's topic dictated by the protocol. If patients do not complete a scheduled online session prior to their visit to the clinic, therapists guide patients through the online session during the face-to-face session.

#### 3.1.2. Online sessions

The online element of bCBT consists of two parts: 1) a session that patients work through by themselves, and 2) personalized therapist feedback on the completed homework assignments. Nine online sessions elaborate on the themes of the face-to-face sessions, and consist of psycho-education (written information, and a short video in which the information is explained in lay terms), and homework exercises, which are illustrated by vignettes of two fictional patients. In order to facilitate the use of the online platform, an additional online session that provides specific information on how to work with the platform is available at the start of treatment.

Patients are encouraged to access the online platform on a daily basis, in order to keep a mood diary and complete homework exercises, such as daily activity monitoring. The online sessions are delivered through a web-based treatment platform (Minddistrict; www.minddistrict.com), which patients and therapists access securely with a personal login account. The "back office" of the platform enables professional users such as therapists and supervisors to monitor patients and/or therapists. A messaging system enables therapists to communicate with each other and with their patients on the platform. When patients do not complete a scheduled online session on time, therapists use the messaging system to motivate patients to complete the online session before the upcoming face-to-face session.

#### 3.2. Initial evaluation of bCBT

#### 3.2.1. Recruitment and allocation of patients

Fig. 2 describes the flow of patients in the study. During the two-month recruitment period, fifty-two patients with depressive symptoms were referred to the mental health care centre. The intake staff at the mental health care centre indicated treatments other than individual CBT for twenty-seven patients (52%). Most often this concerned an indication for 1) other types of psychotherapy (n = 12) such as interpersonal therapy (IPT), psychoanalytic treatment or cognitive behavioural analysis system of psychotherapy (CBASP) or 2) inpatient or day-treatment (n = 11).

Twenty-five patients (48%) were indicated for cognitive behavioural treatment (CBT). Out of these patients, ten were excluded because the primary diagnosis was not depression, and one patient had

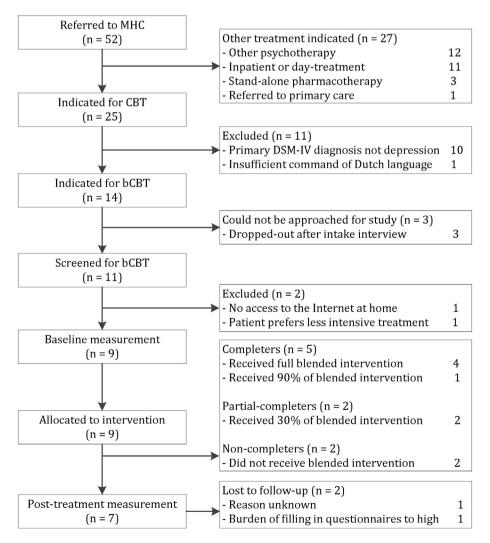


Fig. 2. Patient Flow Diagram.

**Table 1**Patient characteristics pre-intervention and post-treatment at individual patient level and group level.

|                             | Time | Pt 1   | Pt 2   | Pt 3   | Pt 4   | Pt 5   | Pt 6   | Pt 7   | Pt 8  | Pt 9   | Mean (SD)     |
|-----------------------------|------|--------|--------|--------|--------|--------|--------|--------|-------|--------|---------------|
| Demographic characteristics |      |        |        |        |        |        |        |        |       |        |               |
| Sex                         | T0   | M      | M      | F      | M      | F      | F      | F      | M     | F      | -             |
| Age                         | T0   | 45     | 43     | 27     | 30     | 39     | 29     | 50     | 45    | 33     | 37.98 (8.36)  |
| Education                   | TO   | High   | Mod.   | High   | Low    | High   | High   | Low    | Mod.  | High   | -             |
| Employed                    | TO   | Y      | Y      | Y      | Y      | Y      | Y      | Y      | N     | N      | -             |
| Current GAF                 | T0   | 50     | 45     | 50     | -      | 55     | 45     | 50     | 65    | 50     | 51.25 (6.41)  |
| Anti-depressant use         | T0   | Y      | N      | Y      | N      | Y      | Y      | N      | N     | N      | -             |
| Co-morbid disorder          | T0   | N      | Y      | Y      | Y      | Y      | Y      | N      | Y     | Y      |               |
| Treatment characteristics   |      |        |        |        |        |        |        |        |       |        |               |
| # Face-to-face sessions     | T1   | 3      | 10     | 11     | 6      | 9      | 10     | 1      | 10    | 4      | 7.11 (3.69)   |
| # Online sessions           | T1   | 3      | 9      | 9      | 0      | 9      | 9      | 0      | 7     | 2      | 5.33 (4.03)   |
| Treatment duration (weeks)  | T1   | 3      | 10     | 13     | 7      | 13     | 10     | 1      | 12    | 3      | 7.92 (4.57)   |
| Evaluation of bCBT          |      |        |        |        |        |        |        |        |       |        |               |
| CEQ total                   | T0   | 31     | 37     | 42     | 32     | 33     | 34     | 33     | 33    | 31     | 33.88 (3.61)  |
| CEQ credibility             | T0   | 19     | 18     | 21     | 17     | 17     | 22     | 18     | 17    | 18     | 18.56 (1.81)  |
| CEQ expectancy              | T0   | 12     | 19     | 21     | 15     | 16     | 12     | 15     | 16    | 13     | 15.33 (3.23)  |
| SUS                         | T1   | 78     | 68     | 70     | -      | 85     | 75     | -      | 63    | 77     | 73.21 (7.32)  |
| CSQ-8                       | T1   | 22     | 21     | 23     | -      | 32     | 21     | -      | 16    | 24     | 22.71 (4.82)  |
| Clinical measures           |      |        |        |        |        |        |        |        |       |        |               |
| IDC CD (indow)              | T0   | 21 (1) | 48 (3) | 28 (2) | 58 (4) | 53 (4) | 42 (3) | 48 (3) | 40(3) | 26(2)  | 40.44 (12.87) |
| IDS-SR (index)              | T1   | 5 (0)  | 24(1)  | 11(0)  | -      | 26(2)  | 23 (1) | 50 (4) | 36(2) | 11(0)  | 23.25 (14.73) |
| BAI (index)                 | T0   | 10(1)  | 29(3)  | 10(1)  | 38 (3) | 43 (3) | 21(2)  | 22 (2) | 10(1) | 15 (1) | , , ,         |
| BAI (IIIdex)                | T1   | 2(0)   | 22(2)  | 10(1)  | -      | 19(2)  | 18 (1) | -      | 9 (0) | 10(1)  | 12.86 (7.03)  |
| EQ-VAS                      | T0   | 44     | 50     | 50     | 19     | 46     | 40     | 50     | 33    | 70     | 44.67 (13.9)  |
| EQ-VA3                      | T1   | 90     | 75     | 75     | _      | 76     | 59     | _      | 66    | 82     | 74.71 (10.09) |
| EQ-5D                       | T0   | 0.810  | 0.377  | 0.604  | 0.190  | 0.686  | 0.427  | 0.251  | 0.337 | 0.686  | 0.481 (0.221) |
| FG-2D                       | T1   | 1      | 0.686  | 0.774  | -      | 0.686  | 0.209  | -      | 0.772 | 0.896  | 0.718 (0.251) |

#: Number of; BAI: Beck Anxiety Inventory; CEQ: Credibility/Expectancy Questionnaire; CSQ-8: Client Satisfaction Questionnaire-8; IDS-SR: Inventory of Depressive Symptomatology, Self-Report. Index: IDS-SR Severity index; Education level: Lower: primary school education; Mod. (Moderate): High school or vocational education; Higher: college degree or upwards; EQ-VAS: EuroQol-5D-3 L VAS scale; EQ-5D: EuroQol-5D-3 L; GAF index: Global Assessment of Functioning, Mastery: Mastery Scale; Mod.: Moderate; Pt: Patient number; SD: standard deviation; SUS: system usability scale. Note: given sample limitations, means and standard deviations in the last column should be interpreted as a descriptive summary of the clinical profile of the group of participants only.

insufficient command of the Dutch language. Fourteen patients (27%) thus met inclusion criteria, of whom three decided not to receive treatment at the specialized mental health care centre. Therefore, eleven patients could be approached for study participation, of whom nine agreed to participate in the study and filled in the baseline questionnaires.

#### 3.2.2. Study and treatment adherence

Complete follow-up data is available from seven out of nine patients (see Table 1). The two patients who did not complete the follow-up measures also did not start bCBT (patients 4 and 7). Patient 4 chose to receive face-to-face CBT instead of bCBT, because of a malfunctioning computer at home. Patient 7 could no longer travel to the outpatient clinic for the face-to-face sessions, due to financial problems.

Out of the seven patients who started bCBT, five completed 90% or more of the blended treatment protocol, receiving the full face-to-face protocol and completing seven (n=1) or all nine (n=4) online sessions. In this group the bCBT protocol was delivered in 10 to 13 weeks (mean =12, SD =1.3). Reasons for the two other patients to discontinue bCBT after the start of treatment were a full remission of the depressive disorder due to the use of anti-depressant medication (patient 1) and a shift in the main focus of treatment from depression to attention deficit disorder (patient 9).

# 3.2.3. Patient characteristics and clinical profiles

Characteristics of the nine participants (five females, four males) are displayed in Table 1. Six patients reported severe to very severe depressive symptoms on the IDS-SR<sub>30</sub> and seven were diagnosed

with a co-morbid disorder such as anxiety, post-traumatic stress disorder or an autism spectrum disorder. Four patients reported that the current depressive episode was their first episode. For two patients the current episode was their second episode, and the remaining three patients reported having two or more prior episodes.

At follow-up a decrease in depression severity was reported by seven out of eight patients. Severity of depressive symptoms in this group ranged from no severity (n = 3), to mild severity (n = 2) to moderate severity (n = 3). Patient 7 reported an increase of two points on de IDS-SR<sub>30</sub> compared to baseline, indicating very severe depressive symptoms. Anxiety scores at follow-up decreased in six out of seven patients. Severity of anxiety symptoms in this group ranged from normal or no anxiety at follow-up (n = 2), to mild to moderate symptoms (n = 2), to moderate to severe anxiety symptoms (n = 2). Patient 3 reported having the same mild to moderate anxiety level before and after treatment.

Health-related quality of life increased in four patients. Patient 5 reported the same level of health-related quality of life at follow-up and patient 6 reported a decrease in health-related quality of life after treatment, due to an increase in physical pain.

## 3.2.4. Patient evaluation of bCBT

3.2.4.1. Treatment credibility and expectancy. Table 1 displays pretreatment credibility and expectancy (CEQ) scores for all nine patients. Total scores ranged from 31 to 42 (mean = 33.9, SD = 3.6), with six out of nine patients reporting a neutral attitude concerning overall treatment credibility and expectancy and three patients having a somewhat to moderately positive attitude.

When treatment credibility and expectancy are explored separately, the range of patients' treatment credibility scores was 17 to 22 (mean = 18.6, SD = 1.8,), with all patients rating bCBT as somewhat (n = 7) to moderately credible (n = 2). Treatment expectancy ranged from 12 to 21 (mean = 15.3, SD = 3.2), ranging from slightly negative (n = 3), to neutral (n = 4), to moderately positive (n = 2). Patients' rational expectations appeared to be higher than their emotional expectations (range 40 to 84, mean = 57.7, SD = 17.3 for *thinking* versus range 10 to 70, mean 46.4, SD = 19.8, for *feeling*).

#### 3.2.5. System usability

At follow-up, seven patients completed the system usability scale (SUS), evaluating system usability of the web-based treatment platform. Table 1 displays individual patient scores. Six out of seven patients scored 68 or higher, which is indicative of an above average score (Sauro, 2011). Total scores ranged from 63 to 85 (mean = 73.2, SD = 7.3), which can be translated into system evaluation adjectives ranging from 'OK' to 'good' (n = 2) to 'good' to 'excellent' (n = 5) (Bangor et al., 2009).

# 3.2.6. Treatment satisfaction

At follow-up, seven patients completed the Client Satisfaction Questionnaire-8 (CSQ-8), evaluating blended treatment satisfaction. Table 1 displays individual patient scores. The range in treatment satisfaction scores was 16 to 32 (mean = 22.7, SD = 4.8). One participant (patient 8) was somewhat dissatisfied with the content of CBT treatment, suggesting that another type of psychotherapy (such as CBASP) might have been a better fit. The other six participants were mostly (n = 5) to very satisfied (n = 1) with bCBT.

#### 3.2.7. Exploration of written patient evaluations

As discussed in the Methods section, patients could provide a written evaluation at the end of each online session. The openended question, phrased "what was your experience with this lesson", was added to enable patients to 1) to comment on (evaluate) the online sessions, and/or 2) to promote reflective thinking on the meaning and impact of the homework excersises. Relative to the number of completed online sessions per patient, patients provided 33% to 100% of possible responses (mean = 68.14, SD = 21.43).

An explorative evaluation was performed, comparing the content of responses to the intended categories 1) session evaluation and 2) reflection. A summary of all responses (n=35) can be found in Appendix A. The majority of responses appeared to be of a reflective nature (n=25), with patients elaborating on the emotional reaction they had to the session and/or evaluating their progress. Examples of such responses are: "I found it hard to write everything down. I recognize a lot of myself in the text. I want to get started in order to regain control" and "Because I ruminate a lot, things have not been going well for me. I want to do things right, but I at the same time I do realize that just doing things is more important. I became aware of the fact that I need structure".

Patients provided information on how they evaluated the session on six occasions. For example, two patients commented on the way cognitive dysfunctions were illustrated. This was done by presenting reactions of two fictional patients to various scenarios, such as losing your job, with one patient providing negative interpretations and thoughts and the other patient providing more positive alternative views. An example of an evaluative response was: "I did not like the way the dysfunctions were presented. It reminded me of high school. Nevertheless I answered all questions".

We also noticed that patients used the open-ended question to provide information on context (n=11), such as circumstances under which the online session was completed: "I feel stressed because the weekend has started and I forgot to work on this session. Yoga was not as relaxing as I hoped and at the moment I am having two of my friends over", or past-week experiences: "I went to see colleagues. It felt good, but now it is hard to unwind again. That still is an important theme for me".

In addition to the responses on the open-ended question, two patients provided their therapist with an evaluation of bCBT in general. Patient 5 stated that: "the online part of treatment really helped me a lot because you can always access it and by doing so you can put everything into practise more easily". Patient 6 had a different experience, and stated that she felt like "after e-health the 'real treatment' could start", explaining further that the treatment protocol felt restricting because it did not address the full spectrum of her problems.

#### 4. Discussion

The aim of this study was to develop an integrated high-intensive bCBT for depression in outpatient specialized mental health care and to conduct an initial evaluation of the treatment protocol. Our results indicate that bCBT has the potential to be a suitable intervention for depression in specialized mental health care.

## 4.1. Reach of bCBT

There was a high willingness to receive blended treatment. Out of the eleven patients that could be approached for study participation during the two-month recruitment period, nine agreed to receive bCBT. The difference between the total number of referred patients and the number of patients screened for bCBT is largely explained by the fact that only a limited proportion of patients was indicated for CBT for depression (15 out of 52; 29%). This was mainly due to the fact that patients were often indicated for other treatments than CBT by the intake staff, such as IPT, CBASP or intensive group treatment (day treatment). In order to accommodate more patients within specialized mental health care, it could therefore be valuable to explore the option of blending online and face-to-face sessions for these kinds of treatment as well.

Despite making up a relatively small proportion of referred patients, our patient group did appear to be representative for the patient population that is expected in outpatient specialized mental health care, which includes patients presenting with co-morbid disorders, moderate to (very) severe depressive symptoms and serious impairments in general functioning (Piek et al., 2011).

# 4.2. Adherence

In the current study, four out of nine patients received the full bCBT protocol and one patient completed 90% the protocol (i.e. all 10 face-to-face sessions and 7 out of 9 online sessions). We observed slight differences in the number of face-to-face sessions needed to ensure delivery of the full content of the bCBT protocol, with one patient receiving nine face-to-face sessions, three patients receiving all ten sessions and one patient receiving eleven sessions. Treatment duration among completers ranged from 10 to 13 weeks, indicating that bCBT indeed has the potential to shorten treatment duration compared to the minimum of 16 to 20 weeks needed in face-to-face CBT.

Reasons for discontinuing bCBT once treatment had started appeared to be unrelated to the blended nature of treatment. Perhaps unsurprisingly, we found that having Internet access and a functional computer at home are key elements for patients in order to be able

to receive bCBT. Therapists also noted this during supervision sessions, adding that having access to up-to-date hard- and software at the mental health care centre is needed in order to make sure the online treatment environment can be accessed during the face-to-face session.

Although the sample size is too small to draw conclusions, we consider the adherence rates to be promising. Future research needs to establish to what extent these rates are representative for the patient group in general and how they compare to standard face-to-face CBT. For example, a recent meta-analysis found that overall, patients completed 84% of sessions in face-to-face CBT and 80% of sessions in guided online CBT (Van Ballegooijen et al., 2014).

#### 4.3. Patient evaluation of bCBT

A notable finding is that while patients' pre-treatment expectations were mainly neutral, most patients appeared to have positive attitudes towards bCBT after they received treatment. Patients' responses to the open-ended question at the end the first online session appear to mirror this somewhat sceptical baseline attitude, with three patients mentioning that it was hard to start with this online session (see Appendix A).

In future research it would be interesting to further investigate patients' attitudes towards bCBT and to study the consequences for treatment adherence. For example, the study by Wilhelmsen and colleagues (Wilhelmsen et al., 2013) found that a sense of relatedness in terms of feeling connected to the therapist and being able to identify with the online CBT modules appears to be an important element for patients (n=14) to persist with bCBT in primary care.

#### 4.4. Study observations

During the supervision sessions, we observed that therapists evaluated the highly structured protocol as easy to use and to implement in their daily practise. When compared to standard face-to-face therapy, therapists expressed it was convenient and timesaving to have all homework forms and diaries available online, instead of using paper-and-pencil versions. In addition, we observed that the bCBT protocol appeared to help therapists to adhere to an evidence-based treatment manual, since patients have insight in the content of treatment. Based on this, we believe that bCBT can potentially reduce therapist drift from the treatment protocol.

However, due to the complex and co-morbid nature of this particular patient group, a highly structured protocol that predominantly focuses on depression will not always provide enough treatment for some patients to reach remission, and continuation of CBT or a referral to another treatment will be necessary. This can also be seen in the current study. Nevertheless, looking at their clinical profiles after treatment, most patients did appear to benefit from bCBT. By treating depression first with an evidence-based treatment such as CBT, we believe better decisions can be made concerning the next steps in treatment.

# 4.5. Study limitations

This study should be seen as a first step in the development and evaluation of intensive bCBT for depressed patients in specialized mental health care and our observations provide some insight in the potential use of bCBT. However no conclusions can be drawn based on the current sample and our findings cannot be generalized beyond the included group of patients.

Further, although the system usability measure (SUS) gives a general indication of how patients evaluated the web-based treatment platform, we advise future studies to examine treatment satisfaction and system usability more closely, for example by assessing actual use of all web-based treatment elements via logfiles (Van Gemert-Pijnen et al., 2014), or by observing patients as they work through one or more of the online sessions.

Finally, extensive collection and evaluation of qualitative data was beyond the scope of the current paper. Therefore, no formal methods were used to quantify the needs and recommendations of end-users. We would advise future studies to examine qualitative evaluations more thoroughly by using formal methods. Examples of such evaluations can be found in the studies by Wilhelmsen et al. (2013)), Van der Vaart et al. (2014)) and Ly et al. (2015).

#### 5. Conclusion

Our observations suggest that blending face-to-face and online CBT sessions has the potential to be a valuable treatment option for patients with severe depression at specialized mental health care settings. This finding needs to be interpreted with caution, as more extensive research is required to establish whether our initial observations can be generalized beyond the current study.

By combining a personalized approach with the standardized structure of evidence-based treatment protocols, it seems possible to retain and combine the benefits associated with stand-alone online and face-to-face treatments. Further, bCBT can potentially reduce the number of face-to-face sessions and overall length of therapy. This could benefit accessibility of care and might lower the costs of mental health care.

Exploration of the effectiveness of blended depression treatment by means of a randomized controlled trial is warranted to confirm this. Therefore, such a study is currently conducted by our group (Kooistra et al., 2014). In addition to CBT, it might be valuable to explore blended formats for other psychotherapies, such as IPT and CBASP, in order to extent the reach of blended treatment.

# Authors' information

The authors declare that they do not have competing interests.

## **Authors' contributions**

HR (PI) and JvGP obtained funding for this study. All authors contributed to the design of the study and LK, JE, JW, HR and PvO contributed to development of the intervention. LK and JW coordinated the recruitment of patients and the data collection. JW was responsible for the supervision of therapists during the study. LK wrote the manuscript. All authors read, contributed and approved the final manuscript.

### **Conflict of interest**

The authors declare that they do not have any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within three years of beginning the submitted work that could inappropriately influence, or be perceived to influence, their work.

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# Appendix A. Patients' written responses to the online sessions.

| Patient                | Session   | Labe     |
|------------------------|---|----------|
| Online session         | 1: psycho-education   |          |
| Patient 1              | It was good to look back at what happened in the fall. How can it be that you are down one moment and you feel so much better in the next? I now recognize negativity in others and see how that blocks you. As soon as I start thinking too much about myself, I try to meditate. This really works for me.                                  | R        |
| Patient 2              | I found it hard to write everything down. I recognize a lot of myself in the text. I want to get started in order to regain control.  | R        |
| Patient 3              | This lesson did not provide me with a lot of new information. I am not quite sure how I feel about our example patients. I get that the content of their depression is not really important within this context, but my experience is very different from theirs.   | Е        |
| Patient 5              | Difficult. I would rather not think about it.   | R        |
| Patient 8              | It was difficult to start with this session. I either postponed it, or let myself be distracted by other things. To be honest I would rather not think about it.  | R        |
| Patient 9              | It was really good to think about everything. The story of the female example patient made me really emotional. I recognize feeling overwhelmed by all the things that need to be done. The lesson took me to complete than I anticipated, but this does not surprise me: -)  | R        |
| Online session         | 2: motivation and goal-setting  |          |
| Patient 1              | Reading everything I wrote, I know who I am but I also see that I play several characters in my life. I would like to make this less confusing and more homogenous. I know that meditation is a great way to achieve this.  | R        |
| Patient 3              | I feel stressed because the weekend has started and I forgot to work on this session. Yoga was not as relaxing as I hoped and at the moment I am having two of my friends over.   | С        |
| Patient 5              | I think this was a difficult session. It took me a few days to complete it. I know how I want things to be, but even now I am not sure whether this will ever happen.   | R        |
| Patient 8              | I had great difficulty with completing this session and I postponed working on it for a long time. At first glance I could not think of any goal or possible change. Then I understood that setting (positive and feasible) goals is the first step towards improvement, and that it is therefore important.                                  | R        |
| Online session         | 3: activity monitoring  |          |
| Patient 1              | s. activity monitoring It made me aware of the amount of activities that I engage in during the day. I realize now that I haven't been living in a structured way. I do have to pay attention not to engage in everything that crosses my path [] I can see that I have a social life again and that feels good.                              | R        |
| Patient 2              | I found it hard to keep track of my activities and to grade how they made me feel. Yesterday I felt really insecure [shares personal information about  | C/R      |
| Patient 3              | his home life] It was an emotional, but also a good experience to talk to different people.  I did not have a good week; my life sort of fell apart. Now I just want to lie on my couch.  | С        |
| Patient 5              | This was not a good week, hy he sort of left apart. Now I just want to le on my couch.  This was not a good week [shares personal details about her home life] It is difficult to read everything that I wrote. I would have liked to experience  | C/R      |
| i aticiit 3            | this week in a more positive way.   | C/K      |
| Online session         | 4: positive activities  |          |
| Patient 2              | I quickly came to the conclusion that I need to change. I almost immediately started working on this.   | R        |
| Patient 5              | It was a helpful session. I should pay more attention to the things I like doing and just schedule them. If I start planning things, this will provide structure. Knowing what my day will look like in the morning might prevent me from panicking when I think about all the things that I need to do during the day.                       | R        |
| Patient 6<br>Patient 8 | I went to see colleagues. It felt good, but now it is hard to unwind again. That still is an important theme for me.  I copied the list with things that can make you feel better. Maybe it is a good idea to print this and hang it on the wall. I think I will do the same with my list of goals, so that I will continue to remember them. | C/R<br>C |
| 0.11                   |   |          |
| Patient 2              | 5: structure and planning  Difficult Pagages I ruminate a let, things have not been going well for me. I want to do things right, but I at the same time I do realize that just doing.  | R        |
| Patient 2              | Difficult. Because I ruminate a lot, things have not been going well for me. I want to do things right, but I at the same time I do realize that just doing things is more important. I became aware of the fact that I need structure.   | K        |
| Patient 3              | The to-do lists are going well. I do find it difficult to fit them in a specific time schedule.   | R        |
| Patient 5              | I have noticed that it is very helpful for me to plan ahead. This Wednesday I planned to take a walk. When the moment to go out came, I really did not  | C/R      |
|                        | feel like going. I went anyway, because that was how I planned it. Afterwards I felt a lot better and regretted not doing this sooner. If I would not have planned the walk, I would have stayed in and aid on the couch.   |          |
| Patient 8              | I find it difficult to write down all the things that I do during the day, let alone grade how these activities made me feel. This is why I stopped doing it.   | E        |
| Online session         | 6: cognitive dysfunctions   |          |
| Patient 2              | I recognized a lot of myself in the text. Negative thinking just creeps up on you and it is hard to keep fighting this.   | R        |
| Patient 3              | The way the different dysfunctions are presented with the two fictional women was too simplified for my taste. I thought this was insulting.  | E        |
| Patient 5              | I started writing down several thoughts. While doing this, I realized that these thoughts all stem from the same cognitive dysfunction. It was difficult to think about this, because normally I would just avoid thinking about it.  | R        |
| Patient 6              | I did not like the way the dysfunctions were presented. It reminded me of high school. Nevertheless I answered all questions.   | E        |
| Patient 8              | I am a bit at a loss. It is 8 o'clock at night and I do not feel like doing anything. I might just go to bed.   | С        |
|                        | 7: recognizing dysfunctional thoughts   | E/D      |
| Patient 2<br>Patient 3 | I think this is hard to do. I did not have a good week.   | E/R<br>C |
| Patient 6              | I believe I try to suppress certain fears and thoughts, but then certain events still remind me of them. So for me I think events remind me of my   | C/R      |
| ratient 0              | thoughts, rather than causing them to occur. [Provides an example of a past week experience during which this process occurred].  | C/K      |
| Online session         | 8: changing dysfunctional thoughts  |          |
| Patient 2              | It all seems easy to do, but in practise it is harder to accomplish.  | E/R      |
| Patient 5              | This was a good session for me, because I quickly became aware of what I was doing wrong.   | R        |
| Patient 6              | [Provides personal information on past week experiences with negative thinking]   | С        |
|                        | 9: relapse prevention   | P        |
| Patient 2              | I know this works in private situations, but I am not sure what will happen at work.  This was not easy for me, but it fall good to think about it. I do not feel quite stable yet. Two weeks are I fall on ton of the world and then last week I.  | R        |
| Patient 5              | This was not easy for me, but it felt good to think about it. I do not feel quite stable yet. Two weeks ago I felt on top of the world and then last week I felt less happy again. Nevertheless, I could come out of this again! This gives me hope for the future.   | R        |
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E: Evaluation of online session; C: Context; R: Reflection.

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