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ORIGINAL RESEARCH ARTICLE

The feasibility of brief behavioural activation treatment for depression in a PICU: a systematic replication

Martin Ø. Myhre^{1, 2, 3}, Børge Strømgren², Eimund F. Arnesen¹, Martin C. Veland¹

¹Clinic of Psychiatry, Lovisenberg Diakonale Hospital, Oslo, Norway; ²Institute of Behavioral Science, Oslo & Akershus University College of Applied Sciences, Oslo, Norway; ³Current address: National Centre for Suicide Research & Prevention, Institute of Clinical Medicine, University of Oslo, Norway Correspondence to: Martin Myhre, National Centre for Suicide Research & Prevention, University of Oslo, Sognsvannveien 21, Building 12, 0372 Oslo, Norway; m.o.myhre@medisin.uio.no

Behavioural treatments for depression have shown promising preliminary effects for depression in inpatient wards. However, more research is needed regarding their feasibility in psychiatric intensive care units (PICU). The aim of the current trial was to examine the feasibility of brief behavioural activation treatment for depression (BATD) in a PICU. 'BATD added to standard care' was compared to 'standard care' in a randomised controlled trial (RCT) with moderate to severely depressed inpatients. Between group differences on BDI-II (n = 19) was significant on post-test and gain-scores with strong effect sizes towards BATD, and response rates were significantly higher for participants who received BATD, with a strong effect size. Participants rated BATD as credible and acceptable in the setting. Treatment integrity was high and participant attrition was low for participants receiving BATD added to standard care. Preliminary support for BATD's clinical significance, credibility and acceptability was found among inpatients. The main limitation was the large number of ineligible participants due to the inclusion criteria. The current study provides further support for BATD's feasibility for treating depression among inpatients, including its administration by inpatient nursing staff.

Key words: Behavioral Activation, inpatients, depression, acute, randomised controlled trial, replication

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Declaration of interest: None.

Ethics: The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Introduction

Interest in behavioural treatments for depression reemerged after the development of Behavioral Activation (BA) (Martell et al. 2001) following the Jacobson et al. (1996) seminal component analysis of cognitive behavioural therapy for depression. Behavioural treatments for depression are now rated as having strong empirical support, (Cuijpers et al. 2007; Mazzucchelli et al. 2009) with the evidence mainly based on outpatient samples. Although fewer studies have examined inpatient psychological treatments of depression, a small but significant effect has been found in meta-analyses (Cuijpers et al. 2011). To integrate behavioural treatments into an inpatient setting, customisation of outpatient treatment procedures is necessary. The inpatient setting also provides implementation challenges such as patients with increased symptoms, severity and more comorbidity compared with outpatients within a hectic and time-limited treatment setting (Vuorilehto et al. 2007). Studies in primary care have shown that mental health professionals can administer behavioural treatments for depression while retaining treatment efficacy (Ekers et al. 2011a, b; Richards et al. 2016). The use of mental health workers to administer psychological interventions could improve the time-efficiency and patients' access to psychotherapy in wards.

Despite feasibility challenges, previous studies have shown that brief behavioural activation treatment for depression (BATD) (Lejuez et al. 2001, 2011) can be successfully implemented in inpatient psychiatric wards due to its time- and cost-efficient nature, manualised approach, and ideographic nature (Hopko et al. 2003; Curran et al. 2007). BATD has been modified for inpatient treatment by increasing the consultation rate to three sessions per week, each lasting approximately 20 minutes (Hopko et al. 2003). BATD-based protocols have been shown to be feasible for reducing depressive symptoms in drug abusers in residential care (Daughters et al. 2008; Magidson et al. 2011) and in a short-term inpatient setting with high severity participants (Webb et al. 2016).

Folke et al. (2014) also developed a protocol, based on BA (Kanter et al. 2009) adapted for a broad range of psychopathology, in which the treatment was divided into early, middle and late phases, with sessions twice a week. In a pilot trial, the protocol was found to successfully bridge the gap between inpatient and outpatient treatment (Folke et al. 2014). A later, multiple baseline trial also found support for the feasibility, effectiveness and clinical significance of BA (Folke et al. 2015). Gollan et al. (2014) developed and examined a milieu based group intervention based on BA (Behavioral Activation Communication), finding a greater change in positive affect compared to treatment as usual.

The first BATD study with inpatients was performed by

Hopko et al (2003) who, employing an RCT, compared BATD to supportive psychotherapy with depressed inpatients on an acute inpatient ward. They included 25 participants, and found significant differences with a strong effect size towards BATD. This study is to our knowledge currently the only one evaluating BATD with psychiatric inpatients employing an RCT.

The aim of the current study was to examine the feasibility of BATD with inpatients in Norway, extending the Hopko et al. (2003) study adding assessment of clinical significance (e.g. response and remission), acceptability and credibility. We predicted that participants receiving BATD added to standard care would improve significantly more on depression ratings and show response and remission, and rate BATD as a credible and acceptable treatment at a PICU.

Method

Participants

Participants were recruited through admission to the PICU, and 30 patients met the inclusion criteria. Five did not consent to participate, and one withdrew within a short time after inclusion and before treatment onset. Thus, 24 participants were randomly allocated. Unstructured clinical diagnosis based on ICD-10 criteria was used, and suicide ideation/attempt was scored if the participant was admitted due to current ideation or attempt.

Participants gave an informed, written consent. Participants could withdraw their consent at any time without consequences for further treatment. The Data Protection Official for Research evaluated and recommended the study. The study was submitted to the Regional Committees for Medical and Health Research Ethics, who decided that approval was not needed. However, permission to publish the study as research was granted.

Eligibility and inclusion criteria. The ward psychiatrists routinely assessed all admitted patients within 24 hours after admission. Eligibility to participate in the current study was included as a part of this assessment. Eligibility to participate was dependent upon: (1) a clinical diagnosis of depression; (2) no ongoing or history of psychosis; (3) no previous diagnosis of a chronic psychotic or bipolar disorder; and (4) that the ward psychiatrist approved participation. Following eligibility, the inclusion criteria were: (1) current moderate or severe symptoms, i.e. score of ≥ 19 on the Becks Depression Inventory-II (BDI-II; Beck et al. 1996); and (2) basic Norwegian or English speaking and writing skills.

Setting

The study was conducted at the PICU at a local hospital covering three of Oslo's urban districts, serving approxi-

mately 150 000 citizens with about 900 admissions a year. Admissions occurred 24/7 from a wide range of psychopathology, with admissions being both voluntary and involuntary. The PICU consists of three units: one acute admittance unit with six beds, and two treatment units with ten beds each.

Outcomes and measures

The main outcome was score on the Norwegian version of BDI-II (Beck et al. 1996), where scores range from 0 to 62, with higher scores indicating more severe depressive symptoms. The psychometric properties are similar to the English version, with good test–retest reliability (r = 0.77) and very good internal consistency ($\alpha = 0.91$) for normal populations (Beck et al. 1988; Aasen, 2001). Norm scores for BDI-II are: no depression, < 9; mild depression, 10–18; moderate depression, 19–29; and severe depression, > 29. The questionnaire was administered without supervision to the participants before and after treatment.

The Credibility and Expectancies Questionnaire (CEQ) (Borkovec & Nau 1972) assessed participants' perceived credibility of the therapy rationale and expectancies towards the treatment effect in the BATD group. Scores ranged from 0 to 57, where higher scores would indicate a greater degree of credibility and expectancy. The testretest reliability is good (r = 0.83), and internal consistency for credibility ($\alpha = 0.86$) and expectancies items ($\alpha = 0.90$) are good. The questionnaire was administered after the first session. The participants concealed their ratings, which were disclosed after discharge.

The Treatment Evaluation Inventory – Short Form (TEI-SF) (Kelley et al. 1989) was used to assess treatment acceptability in the BATD group. TEI-SF scores range from 0 to 36, where a high score indicates a high degree of acceptability. Internal consistency is good ($\alpha = 0.85$) (Kelley et al. 1989). TEI-SF was administered at discharge. Neither CEQ nor TEI-SF was administered to the standard care (SC) group, as there was no explicit treatment to evaluate.

Procedure

Participants were randomly assigned to either the BATD or the SC group by a predetermined 0-1-0-1 algorithm in a single blind, parallel group design. Allocation ratio was 1:1. The first author arranged the allocation sequence, allocation of participants, and assigned participants. The trail is registered at http://clinicaltrials.gov (ID: NCT02712918). The algorithm was broken once due to the ward psychiatrist not approving allocation to SC. This participant was excluded from the analysis while receiving BATD before the algorithm was retained. Data collection lasted from March until October 2015. The trial was terminated when the groups were equal in size, with more than 10 participants in each group. The procedure is outlined in Figure 1.

Interventions and integrity rating

Standard care. SC comprised no experimental manipulation, except the Bull's-Eye Values Survey (BEVS) (Lundgren et al. 2012) which is a value intervention from acceptance and commitment therapy (Hayes et al. 2012). A total of 7 participants completed the BEVS. SC contained mandatory components such as milieu therapy and regular sessions with a psychiatrist, doctor or psychologist. The frequency of the sessions was individualised, but typically occurred every other day. A psychiatrist evaluated all participants within 24 hours of admission. Suicide risk was assessed at admission and discharge. The Suicide Status Form (Jobes 2006) is a mandatory component for patients admitted due to suicidal ideation or attempts.

Elective individual treatments were pharmacological treatment, psychological treatment, psychosomatic physiotherapy, occupational therapy or sessions with a social worker. The ward had therapeutic, spiritual, occupational and psychoeducational groups which each lasted approximately 45 minutes, once per week.

BATD added to standard care. We used the revised BATD manual (Lejuez et al. 2011), which is a protocol driven approach to behavioural treatment of depression. BATD consists of self-monitoring, activity scheduling and assessment of goals and values. The intervention was administered individually in consultation rooms on the ward. BATD was added to the standard treatment described under SC. Integrity was rated by nursing staff who attended the session using the treatment integrity appendix of the BATD-R manual (Lejuez et al. 2011).

Minor adaptions from the original protocol were made to adapt the manual to brief admissions: (1) treatment was administered daily for sessions 1–3, and every other day from session 4; (2) activity scheduling started in session 2; (3) the BEVS supplemented the existing values intervention in session 2; and (4) the Contracts component was not introduced.

Therapist training and supervision

Three therapists administered BATD. The first author was the primary therapist and also trained and supervised the other two therapists. Training consisted of reading the protocol followed by two sessions of treatment integrity rating. Consecutive sessions were supervised. All of the therapists were learning disability nurses employed as milieu staff at the time of the study. Two of the therapists, including the first author, received masters level training in behaviour analysis.

Analysis plan

Between-group differences were tested with a Mann–Whitney U-test for continuous variables, and Pearson chi square or Fishers Exact test for categorical variables. See

MYHRE ET AL.

Table 1 for further information. For the purpose of analysis of between-group BDI-II score differences we used a mixed design with a between-group repeated measures factor (one-between-one-within subjects ANOVA) and independent samples t-tests to analyse between-group scores at pre-test and post-test. Each independent samples t-test was conducted at an alpha level of 0.025, so called Bonferroni Correction, to reduce a Type 1 error rate that may otherwise stem from multiple significance tests. A rule of thumb is to divide the alpha level of 0.05 by the number of tests conducted (Field 2013). The descriptive variables from Table 1 were used as predictor variables to control for interference from other variables using simple regression, with BDI-II gain-score as outcome variable.

Individual variability and clinical significance were analysed using percentage improvement (PI) (Hiller et al. 2012). The established criterion of 50% change from baseline was used as a responder criterion (Bandelow et al.

2006). Remission was defined as having responder status and a post-test score within the community sample (Hiller et al. 2012). The Seggar et al. (2002) cut-off criterion of 14.29 between clinical symptomatic and community samples was used. The Fisher's Exact test was used to test response and remission for independence between groups with phi as an effect size estimate.

Results

Participant characteristics and feasibility

As expected, a high degree of suicidal attempts or ideation, and comorbidity were found in eligible participants (Table 1). Demographic and clinical characteristics were not significantly different between the groups.

No participants dropped out of treatment in the BATD arm. The mean number of sessions administrated was 4.84

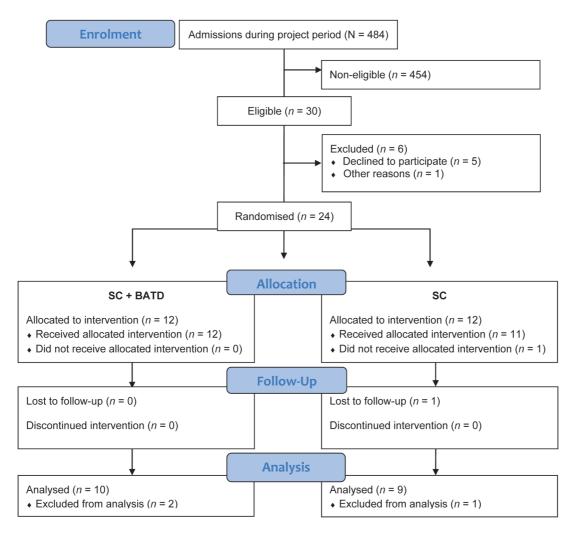


Fig. 1. CONSORT flow diagram over participant flow and distribution throughout the study.

Table 1. Participant characteristics

Variable	SC + BATD ^a	SC ^b	р
n	10	10	
Age M (SD)	30 (8.14)	30 (10.37)	0.853*
Gender	, ,	, ,	0.50**
Male <i>n</i>	4	3 7	
Female <i>n</i>	6	7	
Relationship status			0.51***
Single <i>n</i>	8	8	
Domestic partnership <i>n</i>	1	2	
Married n	1	0	
Education level			0.66***
≤ 10 years education <i>n</i>	5	3	
\leq 13 years education <i>n</i>	2	3	
> 13 years education <i>n</i>	3	4	
Distribution across the clinic			0.17***
Admission unit n	3	7	
Unit A n	4	1	
Unit B n	3	2	
Anxiety disorder <i>n</i>	6	6	0.67**
Suicidal ideation or attempts <i>n</i>	10	9	0.50**
Personality disorder <i>n</i>	2	4	0.31**
Substance or alcohol abuse <i>n</i>	3	2	0.50**
Pharmacological treatment with antidepressants <i>n</i>	3	6	0.37**
Admission length M (SD)	8.6 (5.89)	6.4 (3.63)	0.436*
Readmission n	`1 ´	0	0.53**
Dropout n	0	1	0.50**

Electro convulsive treatment was assessed, but is not reported in the table due to zero occurences in the sample. ^aBATD = brief behavioural activation treatment for depression; ^bSC = standard care; *Mann–Whitney U-Test; **Fishers Exact test; ***Pearson chi square.

(SD = 2.53, range = 8), and the mean length of admission in the BATD group was 8.6 days. Treatment integrity was rated in 19% of the sessions, with an integrity score of 100%.

Group results

Results from 19 participants were analysed: 10 from the BATD group, and 9 from the SC group. Three participants were excluded due to deviation from the randomisation algorithm. One participant dropped out.

A 2×2 one-between-one-within repeated measures ANOVA on BDI scores was conducted with groups (SC + BATD, SC) as the 'between subjects' factor and time (pretest, post-test) as the 'within subjects' factor. BDI-II results are displayed in Table 2. The results showed a significant main effect for groups (F(1, 17) = 4.72, p = 0.044, partial) $\eta^2 = 0.22$) and a significant main effect for time (F(1, 17) = 129.51, p < 0.000, partial $\eta^2 = 0.88$). There was also a significant group \times time interaction (F(1, 17) = 15.77, p = 0.001, partial η^2 = 0.48). An independent samples ttest was conducted to assess the difference between SC + BATD and SC groups at pre-test and post-test, with each test conducted at an alpha level of 0.025. At pre-test, the BDI-II scores did not differ significantly between the SC + BATD and SC groups (t(18) = 1,12, p = 0.28). BDI-II scores differed at post-test, where the SC + BATD group had significantly lower scores than SC (t(17) = 3.15, p = 0.006, d = 1.43). The BDI-II gain scores differed

Table 2. Beck's Depression Inventory-II scores

	n	М	SD	95% CI
SC + BATD				
Pre-test	10	39.2	8.84	[32.87-45.53]
Post-test	10	19.4	9.48	[12.62–26.18]
Gain score	10	-19.8	5.07	[-23.4316.17]
SC				
Pre-test	10	42.33	7.28	[36.74-47.93]
Post-test	9	32.78	9.05	[25.28–39.74]
Gain score	9	-9.56	6.17	[-14.34.82]

BATD, brief behavioural activation treatment for depression; SC, standard care.

significantly between SC + BATD and SC (t(20) = 2.87, p = 0.010, d = 1.44). Simple linear regression revealed no significant interaction with the analysed predictor variables.

Response and remission

Individual PI is illustrated in Figure 2. Of the 10 participants in the BATD condition, 6 met the 50% responder criterion while none of the participants in treatment-assusual (TAU) group met the criterion. Group differences on response were significant (χ^2 (1) = 7.892, p = 0.011) and the ES was strong (φ = 0.645, p = 0.005). No participant in the SC group was in remission at discharge, while 4 of 9 BATD group participants were in remission. Remission was non-significant between groups with a moderate ES (χ^2 = 4.560, p = 0.087; φ = 0.490, p = 0.033) for PI-50.

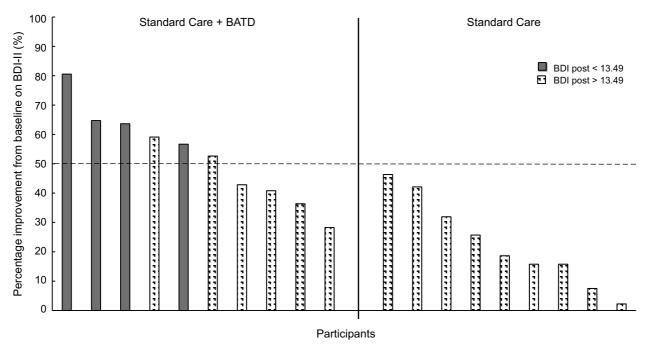


Fig. 2. Response and remission on BDI-II. Shows individual participants percentage improvement from baseline on Beck's Depression Inventory-II. The 50% response criterion is marked with the dashed horizontal line. Remission is defined as having responder status and post-test score < 13.49, marked filled bars. Scores are sorted from high to low. The groups are separated by a vertical line.

Credibility and acceptability

Seven BATD group participants rated the CEQ, yielding a mean score of 39.83 (SD = 13.93, 95% CI [25.21–54.46). The Credibility factor yielded a mean score of 22 (SD = 5.76, 95% CI [15.95–28.05]) and the Expectation factor a mean score of 19.33 (SD = 9.69, 95% CI [9.17–29.5]). Nine BATD group participants rated the TEI-SF, which gave a mean score of 39.17 (SD = 3.71, 95% CI [35.27–43.06]).

Discussion

The aim of the current study was to examine BATD's feasibility on a PICU in Norway, assessing credibility, acceptability and clinical significance. Significant group differences with a strong effect size were found between BATD and SC, and BATD also showed significantly higher response rates than SC when individual participants' percentage improvement was analysed. Remission rates were higher in participants receiving BATD, but not significantly so. Even though admissions were brief, a mean of five sessions was administered with high treatment integrity. BATD participants rated the treatment as credible and acceptable within the setting.

The results of the current study were similar to that of the RCT of Hopko et al. (2003). Pre-test scores were somewhat higher in the current study, possibly due to an earlier administration of pre-test assessment. It is noteworthy that Hopko et al. used a token economy already implemented in the unit, where tokens were achieved contingent upon BATD related goals and non-contingent in the TAU group (LePage 1999). Our study used no arranged reinforcement systems.

Treatment in a PICU is brief and focused on stabilising severe symptoms and regaining a basic level of functioning. Participants received further treatment in outpatient clinics after discharge. Given the brief admission time, remission is an ambitious but still clinically meaningful goal. Previous studies have also found evidence for clinically significant change using the Reliable Change Index (RCI), but across longer periods of time (Jacobson & Truax 1991; Ekers et al. 2011b; Folke et al. 2015). In high severity symptom samples (as in the current study) PI is a more conservative estimate than RCI and reduces regression bias (Jacobson & Truax 1991; Hiller et al. 2012). Consequently, response rates were lower than they would have been had RCI been applied, which could explain the lower response rates and no remission in the SC group.

Credibility and treatment expectancies ratings were rather high, with higher scores for credibility than for expectancies. High credibility could indicate successful presentation of rationale and treatment logic, and hence therapist training. The lower rating on expectancies (an affective rating) may reflect participants' initial degree of

depression (DeVilly & Borkovec 2000). Still, similar expectancies ratings to those of Webb et al. (2013) (who found pre-treatment expectancies to predict treatment outcome for depression) were found. The participants' high acceptability ratings may have been due to the ideographic and individualised nature of BATD. This could potentially indicate successful treatment administration. Both dimensions substantiate the feasibility of BATD in acute inpatient wards.

For use with a brief admission (< 7 days) we made minor changes to the treatment manual. BEVS was added since it was already implemented in the clinic. Treatment frequency (daily first 3 sessions, bi-daily from session 4) contributed to making the treatment feasible for the brief admissions, seemingly without influencing BATD's preliminary effectiveness. Unlike Folke et al. (2014), a protocol driven approach was applied, where each session had its defined content. The advantage of a protocol-driven approach is that it gives a clear structure that can facilitate therapist training. Mean admission time in the current study was brief and with relatively few sessions, indicating that BATD is feasible also for brief inpatient admissions while retaining the acceptability of the intervention.

A frequently stated advantage of BATD is that it requires less training and supervision than comparable psychotherapies (Lejuez et al. 2001). In the current study, previous results were replicated without expert training or supervision, and training was only based on the treatment manual (Lejuezetal. 2011). Studies have found that paraprofessional therapists can administer BATD effectively (Ekers et al. 2011b; Richards et al. 2016), which greatly reduces the cost of outpatient treatment. Our results provide support for the feasibility of the BATD manual, and that BATD can be administered effectively by paraprofessional therapists in the inpatient setting. Potential economic advantages could be higher remission rates, fewer re-admissions, and more treatment given within a brief admission. These factors all warrant future investigation.

Risk management is an essential part of treatment of acutely ill patients with severe symptoms. Treatment requires close co-operation between all staff at the PICU and monitoring of risk throughout the admission. Early phases of the treatment were primarily conducted within the PICU, where scheduled activities could be prompted by staff, before later focusing on activities alone, without prompts and also outside the unit. Activities that required leave were only possible for participants already granted leave by the unit psychiatrist. These activities were closely scheduled, monitored, and assessed by the therapist.

Limitations

Several methodological problems (such as a small sample size, a weak control condition, and use of psychometric measures validated for two weeks) limit our ability to draw inferences regarding effectiveness. A large trial addressing these limitations could help establish the effectiveness of BATD on acute inpatient wards. Such a trial should include BA specific measures, such as the Checklist of Unit Behaviors which is developed for inpatient wards (Hanson et al. 2013).

Regarding feasibility, the largest weakness is the eligibility criteria, which excluded a large proportion of patients from participation. This should however be taken as a methodological flaw and a practical challenge of the study's design, rather than evidence against the feasibility of BATD within the setting. As shown by the participant characteristics, the sample includes high severity and a high degree of comorbidity making discrete diagnosis challenging. Future studies should use eligibility criteria similar to those of Gollan et al. (2014) which would ease eligibility screening and improve representativeness.

Conclusion

BATD is a psychological treatment for depression that appears feasible within the context of a PICU. Even though the PICU provides challenges not common in outpatient settings, the setting does provide the opportunity to administer psychological treatments within the context of the ward, thus also reaching patients often not eligible for psychological treatment as outpatients. Having mental health professionals, such as nurses, administering a psychological treatment could improve availability and cost-effectiveness. BATD appears to be a feasible psychological treatment to implement on psychiatric inpatient wards, including its administration by inpatient nursing staff. The feasibility in the inpatient setting, along with its preliminary effectiveness, acceptability and credibility, all warrant further investigation of BATD with inpatients in a larger trial.

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