Research article

Long-term effects of bouldering psychotherapy on depression: benefits can be maintained across a 12-month follow-up

Laura Schwarz [a,*], Lisa Dorscht [a], Stephanie Book [a], Eva-Maria Stelzer [a], Johannes Kornhuber [b], Katharina Luttenberger [a]

[a] Department of Medical Psychology and Medical Sociology, Friedrich-Alexander-University Erlangen-Nürnberg (FAU), University Clinic for Psychiatry and Psychotherapy, Erlangen, Germany
[b] Department of Psychiatry and Psychotherapy, University Hospital Erlangen, Friedrich-Alexander-University Erlangen-Nürnberg (FAU), Germany

ABSTRACT

Background: Previous studies have identified positive effects of Bouldering Psychotherapy (BPT) on symptoms of depression. The aim of the present study was to investigate the short- and long-term effects of BPT on 97 participants with depression.
Methods: BPT took place once a week over a period of 8 weeks. In a waitlist control group design, participants were assessed at baseline and after 8 weeks (end of BPT for the intervention group; start of BPT for the waitlist group), 16 weeks, and 12 months. The main outcome was severity of depression measured with the Beck Depression Inventory II (BDI-II).
Results: Depression scores dropped by 7.21 on the BDI-II during the first intervention period with a Cohen's *d* of 0.59. A regression analysis at t1 showed that group allocation ($p < .001$) was the only significant predictor besides the baseline depression score ($p < .001$). A 12-month (after t0) follow-up measurement showed that the decrease in depression severity remained stable during that time, with values of $d = 0.37$ for the intervention group and $d = 0.43$ for the waitlist group.
Limitations: Limitations of the study are the assessment of symptoms via only self-report, the lack of a control group during follow-up, and different durations of the follow-up period in the two groups.
Conclusion: Our results augment the findings of previous studies regarding the short-term effects of BPT and provide initial evidence that the positive effects of BPT on depression severity can be maintained across a period of 12 months.

1. Introduction

With a lifetime prevalence of 8–12% in most countries (Andrade et al., 2003), depression is one of the most common psychiatric disorders as well as a leading cause of disability (World Health Organization, 2008). Estimations by the World Health Organization (WHO) predict that depression will be the second leading cause of health impairments in 2020 and the most frequent impairment in industrialized nations by 2030 (World Health Organization, 2001, 2008, 2012), posing a substantial burden on both the individual suffering from depression and public health.

There are a variety of treatment options for depression, usually involving antidepressants, psychological therapies, or a combination of the two (APA, 2010). Today, two thirds of all depressed patients are treated pharmacologically to reduce their depression symptoms (Olfson and Marcus, 2010). Whereas prescribed antidepressants are often efficacious in managing severe symptoms of depression, they are also associated with side effects (APA, 2010), poor adherence, a negative stigma (Martinez et al., 2018), and a time lag between the initiation of the medication and the first improvements in mood (Machado-Vieira et al., 2010).

By contrast, psychotherapy focuses on the problems that underlie the depression rather than on the symptoms, and the side effects tend to be less extreme. However, there is a large gap between supply and demand. In many countries, very few people with mental disorders consult a physician for treatment (Andrews, 2000). In the UK, for example, only 10% of people suffering from anxiety or depression receive psychological treatment (McManus et al., 2009). This problem is twofold: The

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treatment rate is so low, on the one hand, because treatment is not sought, but on the other hand, because treatments are not even offered due to a lack of therapeutic resources (Andrews, 2000).

Given this urgency to provide depressed patients with effective and long-lasting treatment strategies, new therapies are needed to complement traditional approaches. Physical activity, which can be recommended to most people and does not carry a negative social stigma (Dunn et al., 2005), has become increasingly popular as a treatment option. With reported effect sizes (Cohen's *d* and Hedges' *g*) between 0.62 and 0.77 (moderate to strong effects, respectively) (Cooney et al., 2013; Josefsson et al., 2014), physical activity has been added to the German guidelines for the treatment of depression as a supplementary therapeutic method (DGPPN et al., 2017). It has also been added to the clinical guidelines presented by the National Institute for Health and Care Excellence (NICE) for the treatment of mild to moderate depression (National Institute for Health and Care Excellence, 2009).

One mode of exercise only recently found effective in the treatment of depression involves bouldering (Luttenberger et al., 2015; Stelzer et al., 2018). Bouldering is a style of climbing in which the climber tries to master short but tricky climbing routes that are usually less than four to five meters high. Unlike rock climbing, bouldering is performed without a rope and harness, making climbing shoes the only equipment needed. Safety mats are placed on the ground in order to protect climbers from serious injuries. Climbing gyms provide climbing routes with different levels of difficulty (coded with different colors in most gyms), enabling individuals with various levels of physical fitness to boulder together without feeling over- or unchallenged and also giving beginners the opportunity to experience a sense of achievement.

Research has uncovered evidence of a therapeutic effect of climbing and bouldering on various health problems, such as chronic pain (Engbert and Weber, 2011; Kim and Seo, 2015), multiple sclerosis (Steimer and Weissert, 2017; Velikonja et al., 2010), cerebral palsy (Schram Christensen et al., 2017), and severe haemophilia (Stemberger et al., 2014). Benefits of climbing and bouldering have also been reported for psychological problems such as attention-deficit/hyperactivity disorder (ADHD) (Lee and Song, 2015; Veser et al., 2009; Wallner, 2010), anxiety disorders (Wallner, 2010), and eating disorders (Wallner, 2010; Wermuth, 2007).

Regarding the treatment of depression, case reports and observational studies have shown positive effects of climbing and bouldering on depressive symptoms (Mehl and Wolf, 2008; Mollenhauer et al., 2011; Schnitzler, 2009; Wallner, 2010). A recent controlled – but not randomized – trial involving 40 in-patients suffering from major depressive disorder suggested benefits of rock climbing for acute emotion regulation strategies (Kleinstaeuber et al., 2017). However, these studies have demonstrated a variety of methodological weaknesses such as low case numbers, unvalidated questionnaires, or a lack of randomization or control groups, and their results should therefore be interpreted with caution (Buechter and Fechtelpeter, 2011; Rimer et al., 2012).

To overcome these methodological challenges, our work group conducted a randomized controlled pilot study with four waves (each wave with one intervention group and one waitlist group) to investigate the effect of a bouldering intervention on depressive symptoms. The four waves were previously comprised of two samples (sample 1: waves 1 and 2 (Luttenberger et al., 2015); sample 2: waves 3 and 4 (Stelzer et al., 2018)) and were analyzed with respect to different research questions. In fact, both samples showed that bouldering psychotherapy (BPT) was effective in reducing symptoms of depression in comparison with a waitlist control group. To increase the validity of these separate papers, our workgroup combined the two samples and evaluated the effect of BPT with a larger sample size.

Besides the question of whether bouldering is an effective therapy for depression or not, it is still unclear how long these benefits extend beyond the period of active intervention. In an attempt to fill this research gap with the present study, we additionally aimed to investigate the long-term effects of BPT with a 12-month follow-up measurement.

1.1. Research questions

1 Does the severity of depression measured by the BDI-II differ between the intervention and waitlist groups immediately following the intervention?
2 Does the severity of depression remain stable across the follow-up period 12 months later?

2. Method

2.1. Study design and procedure

The study was conducted from August 2013 to February 2015 at the Psychiatric University Hospital Erlangen and was designed as a prospective, waitlist controlled pilot study. Depending on their date of registration, the participants were subdivided into four waves, each with one intervention group and one waitlist group. The individual participants were randomly assigned to either the intervention or the waitlist control group. The two groups completed the bouldering treatment consecutively, starting with the intervention group during the first 8-week interval followed by the waitlist group during the second 8-week interval. Over the course of the study, the individual treatment of each participant was not influenced or changed during the intervention or at any other point (see Figure 1 for the study design).

The effects of the study were evaluated at four measurement points using the instruments described below: one baseline measure (t0), followed by measurements taken after 8 weeks (t1) and 16 weeks (t2). The long-term effects of the treatment were assessed at a follow-up measurement point after 12 months (tF). For the intervention group, this was on average 10 months (Mean: 10.1, Median: 8.5) after the intervention had ended, and for the waitlist group, it was about 8 months (Mean: 7.7, Median: 7.0) after the intervention had ended. The 8-week difference in the duration of the follow-up periods was due to the study design. The groups were given BPT consecutively (i.e., 8 weeks apart), but the follow-up measurements were given at the same time, which caused a difference in the duration of the follow-up periods (see Figure 1).

Participants voluntarily participated in the study and were able to leave the study at any point without suffering from any disadvantages. All procedures were approved by the Friedrich-Alexander-Universität Erlangen-Nürnberg Ethics Committee (Re.-No.99_13 B).

2.2. Data collection

At each measurement point, participants completed a packet of self-report measures that included three validated questionnaires commonly used to assess dimensions of depression and related constructs as well as a case progression questionnaire. Data collection was performed by two master students in clinical psychology who were not involved in the therapy.

2.3. Bouldering intervention

The bouldering intervention took place once a week for 8 weeks. Up to twelve people attended the group therapy at a time. Each session lasted 3 h, from 10 a.m. to 1 p.m., supervised by at least two therapists (psychologists or registered nurses with a specific psychiatric qualification). Every therapist had received specific training at the Austrian "Institute for Therapeutic rock climbing." One of the therapists in each group was additionally qualified as a climbing instructor by the German Alpine Association.

Each of the eight sessions focused on a specific subject (e.g., self-efficacy or anxiety and trust). Each session was further split into five parts. It began with a short meditation or mindfulness exercise (part one), followed by a brief psychoeducational part on the session's topic (part two) and a subject-related active part (part three). After a short break, every participant was able to boulder in small groups or on their own
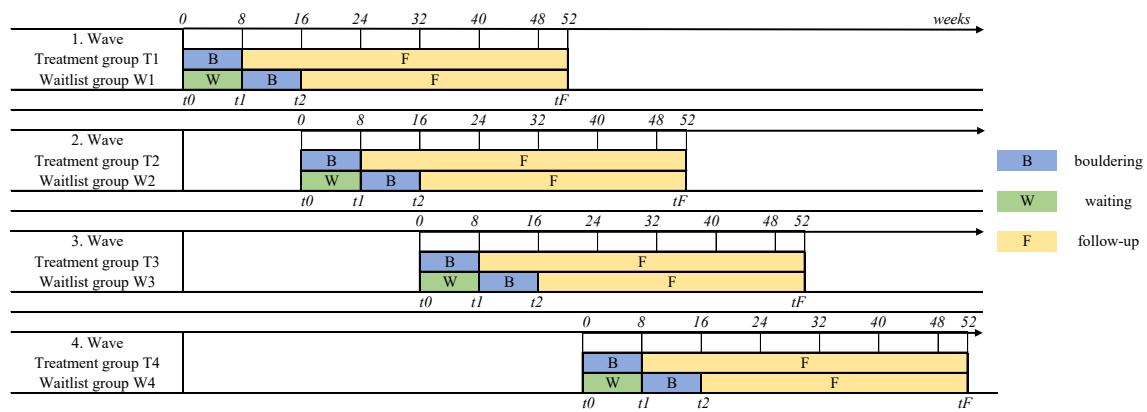
Figure 1. Study design.

(part four) in order to work on their personal projects while supported by the therapists. Each session ended with another mindfulness exercise (part five) that summed up the acquired capabilities and how they could be useful for daily life. For a more detailed description of the treatment and the different sessions, see Luttenberger et al. (2015).

2.4. Recruitment and randomization

The study participants were recruited in different ways. Informational material with contact details was laid out at the two psychiatric hospitals in Erlangen and at local psychotherapists' offices or places that offered other specific services that provided support for people with depression (e.g., self-help groups). In addition, nonbinding informational events, announced via the Internet or newspapers, were held for interested people. A face-to-face meeting with one of the therapists to obtain more specific information including written consent was mandatory for all participants.

For each wave, we created a computer-generated randomization list. All participants in one wave were randomly assigned to either the intervention group or the waitlist group. In a few cases, randomization was not possible (e.g., when the maximum number of participants had been reached in one group). If participants were unable to attend more than five of the eight sessions during one of the intervention periods, he or she was assigned to another wave.

2.5. Inclusion and exclusion criteria

The inclusion criteria consisted of a score of less than 13 points on the WHO depression scale (Bech, 2004). Participants were also required to provide informed consent and to be available on Thursday mornings to take part in the bouldering therapy.

Exclusion criteria consisted of current endangerment to oneself and others, involvement in inpatient treatment, current substance abuse, and/or the inability to do physical exercise due to health issues or a Body Mass Index (BMI) less than 18.

2.6. Instruments

During the screening, participants had to complete a short screening tool for depression called the WHO questionnaire on well-being so that their current level of depression could be determined (Bech, 2004). Additional participant information included age, gender, educational level, employment status, current medication, current psychotherapy, BMI, and whether they had experience with rock climbing or bouldering

or not. Several questionnaires were used to evaluate the participants, but we focused on only one outcome measure in this study.

2.7. The Beck Depression Inventory II (BDI-II)

The Beck Depression Inventory (Beck et al., 1996; Hautzinger et al., 2006) is the most common self-assessment tool for evaluating the intensity of symptoms of depression during the past two weeks. Each of the 21 items is rated on a four-point scale arranged by increasing severity. Sum scores range from zero to 63. A score of 13 or less represents minimal depression symptoms, scores between 14 and 19 indicate mild depression, scores between 20 and 28 indicate moderate depression, and scores of 29 or above indicate severe depression.

2.8. Statistical procedure

The four intervention groups and the four waitlist groups were combined prior to data analysis. We used descriptive methods (frequencies, percentage, means, and standard deviations) to examine the baseline characteristics. Differences between the participants who dropped out and those who completed the study as well as differences between the two groups were evaluated via χ^2 tests and independent t-tests. We checked all questionnaire items for outliers and missing values by computing frequency analyses. If less than 20% of a scale's items were missing, the values were replaced with the mean item score from the respective scale at that time point.

In order to increase the power of subsequent statistical procedures, for participants who dropped out between t1 and tF, missing data were imputed by applying the expectation maximization (EM) algorithm. All analyses were performed with the imputed data from 97 participants.

In order to evaluate research question 1 (difference between the groups in severity of depression at t1), we computed difference scores using the BDI-II sum scores from t0 and t1, demonstrating the change over the intervention period for the intervention group versus the waiting period for the waitlist group. These difference scores were compared with an independent t-test. In addition, for research question 1, a regression analysis was computed with sex, age, medication (antidepressants yes or no), psychotherapy (yes or no), group (intervention versus waitlist), and severity of depression at baseline (t0). Cohen's d was calculated as a measure of effect size.

To evaluate research question 2 (long-term changes in severity of depression over the course of the study), two repeated-measures ANOVAs were calculated for all four measurement points (t0, t1, t2, and tF), one for the intervention group and one for the waitlist group. The

Greenhouse-Geisser adjustment was used to correct for violations of sphericity. SPSS 21.0 was used to carry out all statistical analyses.

3. Results

3.1. Description of study participants

A total of 108 participants fulfilled the inclusion criteria and were assigned to either the intervention or the waitlist group. In the first 8-week interval, 11 participants dropped out, five in the intervention group and six in the waitlist group. In the second 8-week interval, another nine people dropped out for various reasons. During the follow-up period, 19 participants could not be contacted by the research team (see Figure 2 for more detailed information).

Of the remaining 97 participants who had completed the first 8 weeks, 48 participants had been randomly assigned to the intervention group and 49 to the waitlist group. 56 (57.7%) participants were female, and 41 (42.3%) were male. Participants had an average age of 45 years ($SD = 12.2$) and an average WHO well-being score of 7.95 ($SD = 4.89$). In addition to the BPT intervention, about 70% of the participants were currently undergoing psychotherapeutic treatment or were currently taking antidepressant medication (see Table 1).

The intervention and waitlist groups showed no statistically significant differences in any key characteristics, such as age, gender, or WHO screening sum. Even though the intervention group had a slightly lower BDI-II sum score at t0 than the waitlist group ($n = 97$, BDI difference at t0 = 3.7 points), the difference was not statistically significant ($p = .101$; see Table 1).

Participants who dropped out during the first 8 weeks were not included in our analysis ($n = 11$; 8 female, 3 male). Dropouts did not differ from the rest of the sample in age (dropouts, mean age = 40.23; continuers, mean age = 44.90) or baseline WHO screening depression score (dropouts, mean screening sum = 5.27; continuers, mean screening sum = 7.98; *t*-test $p = .081$).

3.2. Research question 1

After the first 8-week interval, the intervention and waitlist groups differed significantly in the extent to which they improved in depression severity (*t*-test: $p = .005$). The intervention group improved by 7.21 points, whereas the waitlist group improved by only 2.14 points. The effect size was moderate with a Cohen's *d* of 0.59. A regression analysis showed that group allocation ($p < .001$) was the only significant predictor besides the baseline depression score ($p < .001$) (see Table 2). Participants in the intervention group had a significantly lower BDI-II sum score at t1 than the waitlist group. Receiving additional psychotherapy showed a trend toward significance ($p = .075$) such that the participants who received additional psychotherapy had a higher BDI-II sum score at t1.

3.3. Research question 2

A repeated-measures ANOVA with a Greenhouse-Geisser correction demonstrated that for both groups, the mean performance levels differed significantly between measurements; intervention group: $F(2.29, 107.35) = 11.89$, $p < .001$, partial $\eta^2 = .20$, and waitlist group: $F(2.58, 123.69) = 13.78$, $p < .001$, partial $\eta^2 = .22$. A Bonferroni-adjusted post hoc analysis revealed that both groups improved significantly (intervention group $p = .013$ and waitlist group $p = .003$) from the beginning of the intervention to the follow-up measurement (see Table 3). During the course of the study, the intervention group's BDI-II depression score dropped by 4.44 points (from t0 to tF), and the waitlist group's score dropped by 4.76 points (from t1 to tF). The changes in depression severity measured by the BDI-II sum score across all four measurement points are illustrated in Figure 3.

Both groups improved significantly during the intervention period (first 8-week interval for the intervention group and second 8-week interval for the waitlist group) (intervention group $p < .001$ and waitlist group $p = .001$) but not during the waiting period (first 8-week interval for the waitlist group) or during the follow-up period (see Table 3). From the beginning of the intervention (t0 for the intervention group and t1 for the waitlist group) until the follow-up measurement (tF), the effect size was 0.43 for the waitlist group (duration: 10 months) and 0.37 for the intervention group (duration: 12 months).

4. Discussion

The results of this study indicate positive short- and long-term effects of BPT on severity of depression. Regarding the short-term effects, the results support the previous findings on the same data with the separate samples (Luttenberger et al., 2015; Stelzer et al., 2018). The larger sample size used in the present study increased the validity compared with previous results. During the 8-week BPT intervention period, depression scores dropped by 7.21 points on the BDI-II. The effect size was moderate with a Cohen's *d* of 0.59, which is comparable to the effect sizes found in meta-analyses on the effect of exercise on depression (Josefsson et al., 2014; Krogh et al., 2011; Rimer et al., 2012; Silveira et al., 2013). During the bouldering intervention, both groups dropped from a moderate to a mild depression score in the clinical range, which was maintained over the follow-up period.

To our knowledge, this study is the first to show the long-term effectiveness of BPT for people with depression. Even though existing studies have pointed to the importance of long-lasting treatments for depression (Andrews, 2001), there is still a lack of profound research evaluating the long-term effects of different treatment options for depression (Uher and Pavlova, 2016). The current findings provide initial evidence for the long-term effectiveness of a bouldering intervention. Thus, the promise that this specific form of climbing has shown for alleviating symptoms of depression in the short term was verified in the long term. Both groups maintained a mild depression score and did not show significant increases in depression severity. The effect size was moderate with a Cohen's *d* of 0.37 for the intervention group and a Cohen's *d* of 0.43 for the waitlist group. The lower effect size in the intervention group can be explained by the longer follow-up period in comparison with the waitlist group. The 8-week difference in the duration of the follow-up periods was due to the study design. The groups received BPT consecutively, but they were assessed for the follow-up measurement at the same time, which resulted in a difference in the duration of the follow-up periods (see Figure 1). An effect size of 0.53 was shown for cognitive behavioral therapy as an adjunct to pharmacotherapy in a six-month follow-up measurement (Wiles et al., 2013), which is comparable to our findings.

In clinical case reports and intervention studies, various mechanisms have been suggested to underlie the antidepressant effect of climbing in a psychiatric setting, such as a regaining of self-confidence and self-efficacy (Lukowski et al., 2013; Veser et al., 2009; Wallner, 2010), increases in cognitive functioning (Schnitzler, 2009; Veser et al., 2009; Wallner, 2010) or social competences (Lukowski et al., 2013; Veser et al., 2009; Wallner, 2010), as well as a sense of achievement and motivation (Mehl and Wolf, 2008; Veser et al., 2009). These psychological mechanisms as well as a variety of skills the participants learned in an interactive way during the intervention might persist after the intervention and help participants overcome illness-related problems in the long-term.

About 70% of the participants were simultaneously receiving pharmacotherapy or psychotherapy in addition to our study intervention. Other studies have supported the use of exercise as an adjunct therapy to traditional treatments for depression (Krogh et al., 2011), suggesting that the antidepressant effects may occur more quickly and may be larger via the combination of exercise with pharmacotherapy and/or psychotherapy. We were not able to verify this effect in our study. This might be traced back to the way we recruited our study participants: Participants
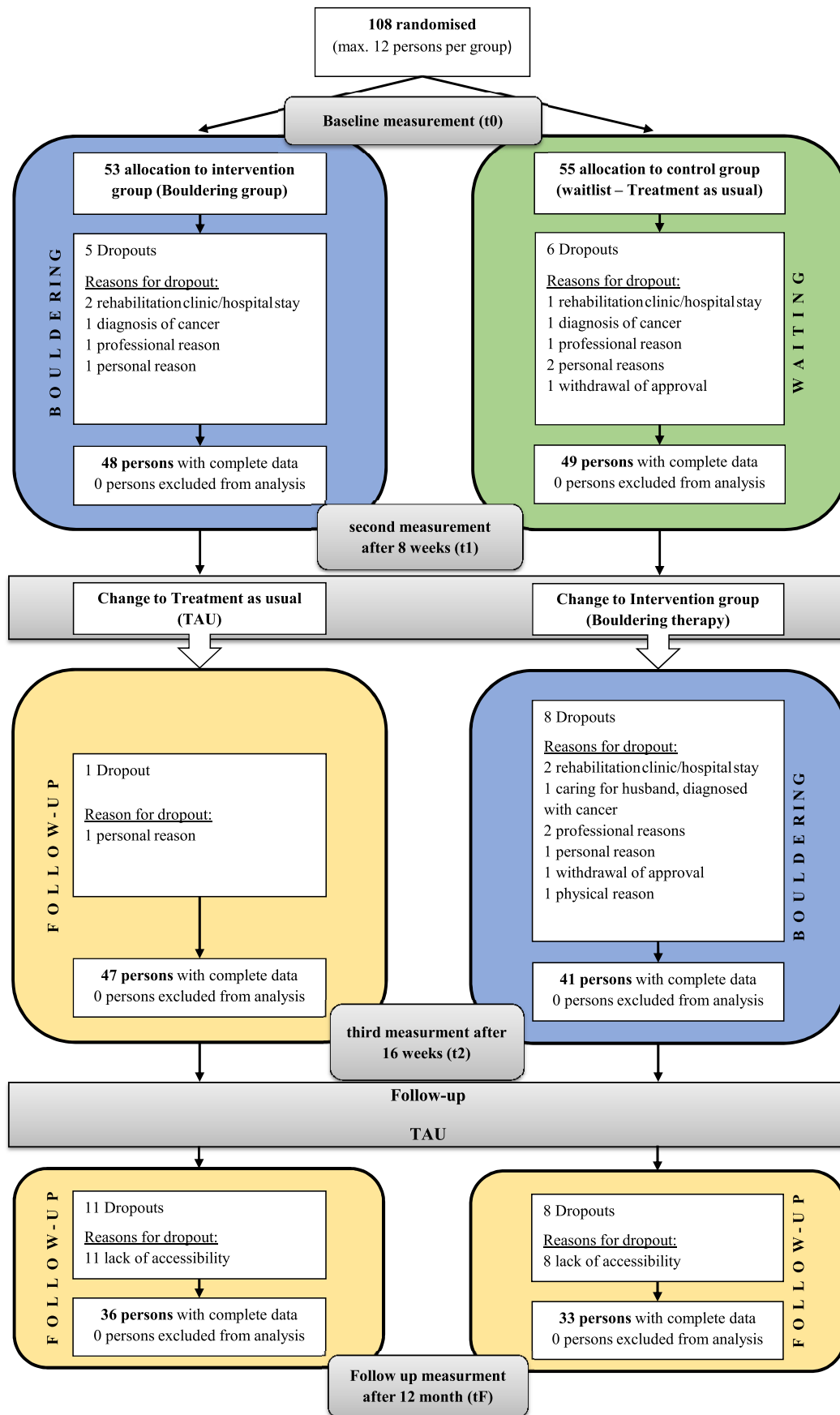
Figure 2. Consort flow chart.

Table 1. Sample characteristics ($n = 97$).

Variable	Intervention group (n = 48)		Waitlist group (n = 49)		Total (n = 97)		Test of group differences x^2	T	p
Age, M (SD)	44.37	(13.2)	45.43	(11.3)	44.91	(12.2)		0.424	.67
Sex, n (%)							0.495		.48
Women	26	(54.2)	30	(61.2)	56	(57.7)			
Men	22	(45.8)	19	(38.8)	41	(42.3)			
School education, n (%)							1.764		.78
8 years	1	(2.1)	3	(6.1)	4	(4.1)			
10 years	8	(16.7)	11	(22.4)	19	(19.6)			
13 years	8	(16.7)	8	(16.3)	16	(16.5)			
Vocational training	12	(25.0)	11	(22.4)	23	(23.7)			
University	19	(39.6)	16	(32.7)	35	(36.1)			
BMI, M (SD)	25.71	(5.12)	25.64	(4.97)	25.68	(5.02)		0.74	.94
Additional psychotherapy, n (%)							0.083		.77
Yes	33	(68.8)	35	(71.4)	68	(70.1)			
No	15	(31.3)	14	(28.6)	29	(29.9)			
Antidepressants, n (%)							1.921		.17
Yes	30	(62.5)	37	(75.5)	67	(69.1)			
No	18	(37.5)	12	(24.5)	30	(30.9)			
Experience with bouldering or rock climbing, n (%)							1.430		.23
Yes	16	(33.3)	11	(22.4)	27	(27.8)			
No	32	(66.7)	38	(77.6)	70	(72.2)			
WHO well-being scale, M (SD)	8.21	(5.08)	7.76	(4.75)	7.98	(4.89)		0.454	.65
BDI-II at t0, M (SD)	21.10	(11.06)	24.78	(10.78)				1.656	.101

Table 2. Regression analysis with BDI-II at t1 as the dependent variable.

independent variables	Unstand. b	Stand. b	p	95% Cl Lower	Upper limit
Sex (female)	0.65	0.03	.708	-2.78	4.08
Age	0.03	0.03	.709	-0.11	0.16
Group allocation (intervention)	-6.11	-0.26	**<.001***	-9.44	-2.78
BDI-II baseline	0.71	0.66	**<.001***	0.55	0.86
Antidepressive medication	-1	-0.04	.588	-4.66	2.66
Additional psychotherapy	3.26	0.13	*.075*	-0.33	6.85

Significant p-values ($<.05$) are in bold and marked with *. p-values below .1 are italicized.

were mostly recruited through the clinical outpatient center, with the result that participants with a longer and more severe history of depression were more likely to be receiving additional psychotherapy than participants with milder forms.

Table 3. BDI-II sum scores and ANOVAs for all four measurement points for the intervention and waitlist groups.

BDI-II, M (SD)				ANOVA mean difference	p
Intervention group (n = 48)					
t0	21.1	(11.06)	t0 → tF	- 4.44	.013*
t1	13.9	(11.01)	t0 → t1	- 7.21	<.001*
t2	14.48	(11.65)	t1 → t2	0.58	.580
tF	16.67	(12.61)	t2 → tF	2.19	.164
Waitlist group (n = 49)					
t0	24.78	(10.78)	t1 → tF	- 4.76	.003*
t1	22.64	(11.01)	t0 → t1	-2.14	.124
t2	17.35	(12.20)	t1 → t2	- 5.29	.001*
tF	17.88	(11.21)	t2 → tF	0.53	.614

5. Strengths and limitations

5.1. Strengths

The strengths of the study are the controlled and randomized design for the short-term effects and the rather large sample size. Furthermore, we imputed missing values via the EM algorithm, which is considered a valid and powerful tool. Compared with simpler techniques, such as overall mean imputation, it does not produce biased estimates and does not complicate subsequent analyses (Donders et al., 2006). Another strength is the long follow-up period of 12 months for the intervention group and 10 months for the waitlist group, which enabled us to assess the long-term effects of our intervention after the treatment.

5.2. Limitations

A limitation of our study is that we evaluated symptoms exclusively through self-reports, a method that is known to be prone to systematic and unsystematic biases (Bortz and Döring, 2006). However, all questionnaires included in our study are commonly used in the clinical literature, and we additionally focused on multivariate measures rather than single-scale instruments.

There are also limitations concerning the design of the follow-up measurement. Because the waitlist group also received the bouldering intervention during the course of the study, there was no control group for the follow-up period. In addition, the follow-up period for the intervention group was 8 weeks longer than the follow-up period for the waitlist group.

6. Future research perspectives

Future research should compare the bouldering intervention with psychotherapy alone or other forms of physical activity that have been found to be effective in the past. In addition, future studies should be conducted to determine whether the positive impact will hold for different patient groups (e.g., outpatients and inpatients) as well as for
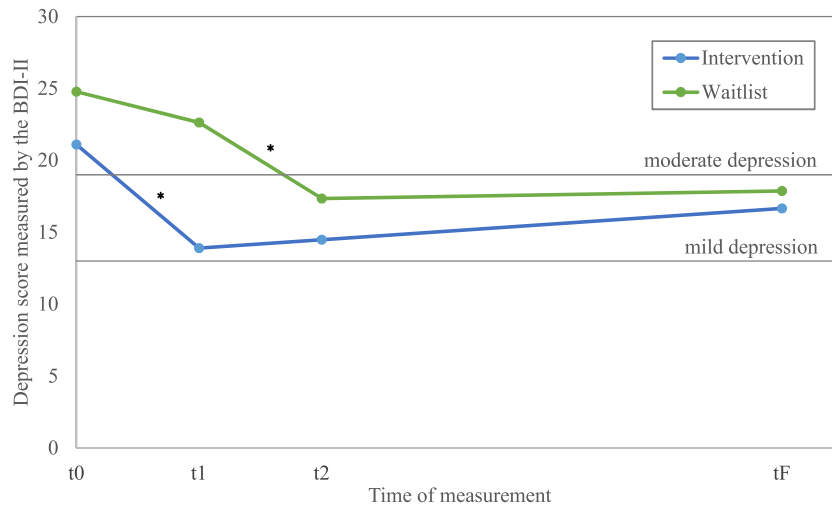
Figure 3. Changes in severity of depression operationalized by the BDI-II over all 4 measurement points for the intervention (n = 48) and waitlist (n = 49) groups.

other mental health disorders. We would like to point out that the bouldering psychotherapy we described in this study is very different from a regular bouldering lesson, and the bouldering psychotherapy instructors are required to have a profound psychotherapeutic background in addition to climbing skills (Luttenberger et al., 2015). Long-term effects of the bouldering intervention should be examined in comparison with a control group and in comparison with the long-term effects of other therapy options, such as psychotherapy alone. A more profound knowledge of the potential modes of action of therapeutic climbing or bouldering would further advance the field.

7. Conclusion

The results of this study provide additional evidence that bouldering psychotherapy can be effective in the treatment of depression. This is the first study to examine the long-term effects of the bouldering intervention on symptoms of depression, showing that positive benefits could be maintained over a period of up to 12 months. Further research is required.

Declarations

Author contribution statement

L. Schwarz: Analyzed and interpreted the data; Wrote the paper.

L. Dorscht: Analyzed and interpreted the data.

S. Book: Performed the experiments; Wrote the paper.

E. Stelzer: Performed the experiments.

J. Kornhuber: Conceived and designed the experiments.

K. Luttenberger: Conceived and designed the experiments; Analyzed and interpreted the data; Wrote the paper.

Competing interest statement

The authors declare no conflict of interest.

Additional information

The clinical trial described in this paper was registered at Current controlled trials under the registration number ISRCTN17623318.

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