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A Blended Group Intervention for Depression: Results from an Uncontrolled Clinical Study on a Computer- and Multimedia Supported Resource-Oriented Group Intervention

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Abstract

Objective: This study investigated the acceptability and effectivity of a novel blended (face-to-face and computer-based) group intervention for the low-threshold treatment of depression and comorbid anxiety.

Design: Patient-centred uncontrolled clinical trial.

Setting: University outpatient setting in a general community sample. A multi-modal recruitment strategy (public health centres and public areas) was applied.

Participants: Based on independent interviews, 26 participants, diagnosed with major depressive disorder (81 % female; 23 % comorbidity > 1, 23 % comorbidity > 2), entered treatment. One patient dropped out before treatment had ended.

Intervention: Positive and resource-oriented psychology principles served as theoretical basement for the low-threshold intervention. The blended format included face-to-face therapy, complemented with multimedia presentations and a platform featuring videos, online work sheets, an unguided group-chat, as well as remote therapist-patient communication.

Main outcome measures: The Center for Epidemiological Studies-Depression scale (CES-D) and the twelve-item General Health Questionnaire (GHQ-12).

Results: Large to very large within-group effect sizes were found on self-reported depressiveness ($F_{(2, 24)}$ = 23.52, p < .001; d =1.58), general health ($F_{(2,24)}$= 10.61, p < .001; d =1.27), personal resources ($F_{(2,24)}$= 22.13, p < .001; d = 0.90) and mindfulness ($F_{(2,24)}$= 8.99, p < .001; d =0.90) at post-treatment. Results were stable over a period of three months. Satisfaction with treatment was very high and 72 % ranked in- and between-session media as an active working factor. Further, treatment intensification was described as important advantage.

Conclusion: The application of in- and between-session computer-support for the group treatment of depression seems highly feasible. The blended format might be an efficient strategy to improve current group therapy interventions and should be further tested in user-centred and comparative trials.

Trial registration: DRKS-ID: DRKS00010894

Strengths and limitations of this study

- This is the first clinical study on blended group therapy for depression. This innovative treatment combines two low intensity psychosocial interventions, recommended by the National Institute for Health and Care Excellence (NICE, 2009).
- Treatment satisfaction and system usability were assessed by standardised measures, resulting in good comparability with other blended studies. Corresponding results suggest a very high fit of the two intervention strategies.
- Participant selection was based on a multi-modal recruitment strategy and comorbidity was high. Data on treatment stability and adverse effects are provided.
- Small sample size and the uncontrolled design restrict the interpretation of our results. Randomised controlled studies should further investigate this promising treatment format.

DATA SHARING STATEMENT

We also assessed 5 short scales at pre-measurement. These short scales will be accumulated over different trials and serve as moderators of treatment success and online user behaviour. All data can be obtained by contacting the first or the last author of this study and will be readily shared.

CONTRIBUTOR SHIP STATEMENT

Raphael Schuster:	design, acquisition, analysis, drafting, revising
Verena Sparr:	acquisition, analysis
Isabelle Fichtenbauer:	acquisition, analysis
Thomas Berger:	drafting and revising
Anton-Rupert Laireiter:	design, drafting and revising

1. Introduction

Depression presents a relevant public health concern and imposes high costs on society as well as health systems (Vigo et al., 2016). Therefore, research priorities include health policy and systems research, in particular on how to deliver cost-effective interventions in a low-resource context (Tomlinson et al., 2009). Psychological online interventions have been found effective in reducing common mental health disorders, e.g. depression (Cuijpers et al., 2015) or anxiety (Păsărelu et al., 2017), in such low-resource contexts.

Online interventions offer many advantages. They can provide access to evidence-based treatments and patients can work through the intervention whenever they want (Andersson & Titov, 2014). Usually anonymity is preserved as patients participate at distance, resulting in low social barriers and low risk of stigmatization (Emmelkamp et al., 2014). From the health supplier perspective online interventions guarantee standardized treatments and show good scalability, which has led to the launch of first online clinics (Titov et al., 2015; Hedman et al., 2014). Internet-based interventions can also help with bridging waiting times (Kenter et al., 2013) or enhance treatment effects in aftercare (Ebert et al., 2013). At the same time, online interventions do not fit all patients' needs and personal therapy will remain the cornerstone of mental health care. Respectively, tools and methods developed in online therapy can be integrated into various forms of face-to-face psychotherapy (cf. Krieger et al., 2014).

Due to the variety of possible combinations between online interventions and psychotherapy it remains difficult to define blended interventions concisely. Van der Vaart and colleagues (2014) describe blended therapy as "[…] *a combination of online and face-to-face therapy, in which online sessions replace or substitute some (parts) of the sessions with a health professional* […]. According to Kooistra and colleagues (2014), the combination of both intervention strategies should merge into one integrated treatment format. In our study's context, modern media was also be used as a supportive in-session tool (e.g. multimedia presentations and videos). Thus, we define blended therapy as an integrated combination of face-to-face therapy with in- and between-session computer support, aiming at improving the delivery of evidence-based psychotherapy methods and resulting in possible acceleration or intensification of treatment. The online part of blended treatments often entails (video supported) psychoeducation, online exercises and remote therapist feedback on accomplished exercises, as well as mobile diaries and monitoring. These interventions are usually delivered via online platforms (cf. Månsson et al., 2013) or applications for mobile phones (Ly et al., 2014).

Blended therapy is at an early research stage - even though first studies reach back to the 1980s and 1990s (cf. Selmi et al., 1982; Selmi et al., 1990; Newman et al., 1996). Computer support has been found to be useful in the treatment of depression, anxiety or obsessive compulsive disorders (Newman et al., 1996). However, these studies do not adequately account for the rapid development modern technologies have undergone, and user-behaviour has changed dramatically ever since. When examining more recent literature, good acceptability and compatibility with standard treatments are found (Wright et al., 2002). Additionally, computer-assisted programs might shorten treatment duration while maintaining observed treatment effects (Wright et al., 2005). From a therapy process perspective, Månsson and colleagues (2013) suggest that blended interventions could foster adherence to evidence based treatment rationales. In Europe, research on blended therapy currently is on the rise as a multicentre study (E-Compared) commenced in eight countries (Kleiboer et al., 2016). The Netherlands seem to be Europe's most promotive nation when it comes to implementation of blended therapy (Ruwaard & Kok, 2015). According to the Netherlands' leading software provider (minddistrict) more than 17.000 professionals and 120.000 patients are currently using some of their blended services (Schuster, Berger & Laireiter, 2017).

With little exceptions, research on blended treatments has its primarily focus on individual therapy and little is known about its potential for group therapy. As it is a recommended treatment in health guidelines and national health policies (Riedel, 2015; Weber & Strauss, 2015), group therapy has various applications in in- and outpatient clinics (Yalom, 2005). The National Institute for Health and Care Excellence (NICE, 2009) recommends group cognitive behavioural therapy (GCBT) for people with mild to moderate depression who decline other low intensity psychosocial interventions, such as computerized cognitive behavioural therapy (cCBT) or physical activity programmes. Existing blended group therapy studies reveal good acceptability for the treatment of anxiety disorders and suggest possible savings of therapist time (Gruber, 2002; Przeworski & Newman, 2004; Newman et al., 2014). Additionally, this treatment format allows new ways of therapist-to-client and client-to-client interaction, such as online supervision of homework tasks or gamification (Miloff et al., 2015). Yet, literature on blended group treatments for depression remains very scarce, as there does not exist any literature prior to our first proof-of-concept study (Schuster et al., 2017). Here, good treatment effects were observed in an adult sample, exhibiting a variety of unspecified depressive symptoms. Participants perceived online and multimedia support to be of the same importance as group experience or specific CBT techniques, and in an open evaluation, 25 % freely described online and media support as an active working factor.

The present study aims to carry forward this work by applying the developed blended group rationale to a sample of clinically depressed adults and by evaluating its usefulness in a more struc-

tured and standardized way. Moreover, we were interested in the user behaviour over the course of time.

2. Methods

2.1 Procedure

The clinical one-arm trial was approved by the local ethics committee (Ethical Review Board, University of Vienna, Ref-Nr:00194) and registered at the German clinical trial register (DRKS-ID: DRKS00010894). Eligible persons were called and verbally informed consent was obtained by two independent interviewers. Subsequently, the complete Mini-International Neuropsychiatric Interview, MINI (Sheehan et al., 1998) was applied for study in- or exclusion. Ten days prior to treatment, eligible participants were required to complete an online battery of self-report measures. Sessions were held in a double trainer format by two trained and supervised psychologists (VS & IL), both in the final of their Master studies. At the beginning of the first group session, written informed consent was signed by all participants. One week after treatment ended, an online post-evaluation battery had to be completed. Follow-up data was obtained at 3-months.

2.2 Intervention

The treatment was an 7-week intensive psychoeducational group intervention in which personal group sessions (90 minutes) alternated with online exercises and remote therapist feedback (9 – 15 min. per patient and week). Psychological key techniques eclectically entailed cognitive behavioural therapy, positive psychology, mindfulness, acceptance and commitment therapy as well as a special emphasis on time- and self-management. Online modules were made accessible via a secure web-based environment. Accomplishing one online session took approximately 50 - 70 minutes (34 minutes of weekly videos included). Participants were able to logon the platform after treatment was completed. Group sessions were supported by multimedia, e.g. psychoeducational short clips and PowerPoint presentations. The basic treatment is described comprehensively in our preceding study (Schuster et al., 2017). Improvements concerned the psychoeducation section and the weekly diary as well as putting slightly more emphasis on cognitive restructuring techniques. Detailed information on the course modules is presented in *Table 1*.

2.3 Participant recruitment and selection

The study was advertised online (e.g. www.depression.at) and by handing out flyers in public health centres and frequented public areas, such as urban pedestrian areas in Vienna. All those interested

were invited to visit the study webpage and to fill out an online participation form. Recruitment ended after sufficient participants had been acquired.

Inclusion and exclusion criteria

Two independent psychologists with clinical experience conducted the clinical interviews. Participants aged between 18 – 65, familiar with the use of personal computers and suffering from mild to moderate depression and/or dysthymia and/or mild to moderate comorbid anxiety were eligible for the study. According to clinical judgement, participants were excluded if they suffered from severe depression, severe anxiety disorder, bipolar disorder, schizoaffective disorder, severe psychiatric and psychotic conditions, substance abuse, suicidal ideation, or if they exhibited low German-language and/or computer skills or if they were currently undergoing. Psychiatric medication was tolerated, but had to be kept constant for at least 3 month prior to trial onset. *Figure 1* presents the flowchart, demonstrating the recruitment and research procedure in detail.

2.4 Measures

2.4.1 Primary outcome

The primary outcome, reduction of depressed mood, was measured by the short form of the German translation of the CES-D, Center for Epidemiological Studies-Depression scale (Hautzinger & Bailer, 1993). This questionnaire assesses depression associated emotions, motor functions, and interactive, cognitive and somatic symptoms on a 16-item 4-step Likert-scale. Higher scores indicate higher levels of depression and the German version's cut-off value (CES-D > 17) has very high discriminative validity (Hautzinger & Bailer, 1993). The reliability of the CES-D has been shown to be excellent (Hautzinger et al., 2012). Cronbach's alpha in the present study was .84.

2.4.2 Secondary outcome measures

The General Health Questionnaire (GHQ-12; Goldberg & Williams, 1988) was selected to assess the degree of self-reported psychological distress. Items are rated on a 4-step bi-modal scale (0-0-1-1) with higher scores indicating higher levels of psychological distress. The GHQ-12 has shown satisfactory reliability (Goldberg et al., 1997) and good intercultural validity (Schrnitz, Kruse & Tress, 1999). A cut-off of > 1 served as a conservative measure with highest sensitivity and specificity in literature (Cano et al., 2001). Cronbach´s alpha was .83.

The German "Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten – Gesamtressourcen" (FERUS; Jack, 2007) (Questionnaire for the Assessment of Resources and Self-Management Abilities – common resources), consisting of the subscales "coping", "self-awareness", "self-efficacy", "self-verbalisation", and "hope" (44 items, 7-point Likert-scales), was applied for the

assessment of personal resources. Higher scores represent higher levels of self-rated personal resources. In the present study Cronbach's alpha of the total resources was .95.

The Mindful Attention Awareness Scale (MAAS; Brown & Ryan, 2003) assesses the frequency of mindful states, with higher levels indicating greater mindful awareness (15 items, 6-point Likert scale). We used a 6-item short version of the German MAAS (Michalak, Heidenreich, Ströhle & Nachtigall, 2008) and Cronbach´s alpha in the present study was .83.

2.4.3 Treatment satisfaction and system usability

Usability of online components was assessed by the System Usability Scale (SUS; Brooke, 1996). The SUS is a technology neutral and robust tool for assessing the quality of a given user interface. Empirically derived cut-off scores are graded from SUS > 85.5 (excellent usability) to SUS >71.4 (good usability) and SUS > 50.9 (acceptable usability) on a 10-item 5-point Likert scale (Bangor, Kortum & Miller, 2009). Cronbach's alpha for the current sample was .85.

Participants' satisfaction with the intervention was measured by the German version (ZUF-8; Schmidt et al., 1989) of the Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979). This widely used questionnaire addresses several aspects of service satisfaction and is based on an 8-item 4-point Likert scale. In this study Cronbach´s alpha was .88.

2.4.4 Appraisal of components, applicability and process aspects

Appraisal of components, applicability, and process aspects of the investigated treatment were assessed by a self-designed battery (55 items) at post-treatment. The battery comprised 9 items on seminar components, 6 items on specific functions (e.g. online platform), 6 items on satisfaction and perceived effectivity of the intervention, one ranking of perceived working factors (cf. Schuster et al., 2017), 16 items on optimal blend, intensity and duration (cf. van der Vaart, 2014), 9 items on mode of delivery (face-to-face or online) (cf. van der Vaart, 2014) and 8 items on perceived (dis-)advantages of blended therapy.

2.5 Statistical Analyses

Statistical analyses were carried out using SPSS 22 (IBM Inc., Armonk, NY, USA), and were based on the intention to treat principle (ITT). There were no study dropouts at post-treatment. Missing values at follow-up were imputed according to the last observation carried forward principle (LOCF). Significant changes were analysed by calculating a repeated measures ANOVA. Individual pre-post differences served as basis for the reliable change indexes (RCI; Jacobson & Truax, 1991) and we used internal consistency as a measure for RCI reliability (Lambert and Ogles, 2009), resulting in a reliable

change criterion of 7.22 scale points for the CES-D and 2.62 scale points for the GHQ-12. Additionally, participants were deemed to have undergone clinical significant improvement (CSI) when simultaneously exhibiting reliable change and scoring below CES-D or GHQ-12 post measurement cut-off (CES-D ≤ 17; GHQ-12 > 1). For the FERUS, individuals were deemed to have undergone reliable change, if pre and post scores differed more than 16.36 scale points. For the 6-item short version of the German MAAS, the reliable change criterion was 0.91 scale points. Within-group effect sizes were calculated with pooled standard deviation and reported in Cohen's d (Cohen, 1988). Power analysis was carried out using G*Power (Faul et al., 2007) and optimal sample size was N = 22 for a medium within-subjects effect size of d = 0.65 (alpha-error α = .05, power β = .90).

3. Results

3.1 Sample characteristics

There was no dropout during treatment, but three participants missed to fill out the follow-up evaluation and two had to be excluded due to changes in medication. One participant had to be excluded due to commencing psychotherapy. According to the CONSORT guidelines, detailed information on participants' flow can be gained from *Figure 1*. Women constituted the majority of the sample (81 %) and education was high (54 % tertiary education). Participants' age ranged from 23 to 51 (Mean = 33.9, SD = 7.5). A comprehensive overview of participant characteristics can be gained from *Table 2*.

3.2 Primary and secondary outcome measures

All outcome measures indicated significant changes and effect sizes were large to very large (see *Table 3*). For the primary outcome measure CES-D, a statistically significant reduction of self-reported depressive symptoms was found, F-value of $F_{(2,24)} = 23.52$, $p < .001$. Regarding secondary outcome measures, self-reported psychological distress, assessed by the GHQ-12, significantly decreased $F_{(2,24)} = 10.61$, $p < .001$. Furthermore, personal resources (FERUS) significantly increased, $F_{(2,24)} = 22.13$, $p < .001$, as well as the frequency of mindful states (MAAS), $F_{(2,24)} = 8.99$, $p < .001$. A proportion of 64 % of patients exhibited clinically significant improvement (CSI) for depressive symptoms and CSI for general health was observed in 62 %. Reliable change (RCI) was 72 % for depression and 62 % for general health. Only one participant deteriorated reliably (4 %). Results were stable over a 3-month follow-up period. Detailed information on observed means, standard deviations, effect sizes and reliable change is depicted in *Table 3*.

3.2 Treatment satisfaction and system usability

Usability of online components, assessed by the System Usability Scale (SUS; Brooke, 1996), unveiled an average usability of 85.3 (SD = 14.49) on a 100-point scale. Highest quality ratings (excellent usability, SUS > 85) were given by 56 % and another 24 % of participants rated the platform usability as "good" (SUS > 72). Only one participant (4 %) rated the usability as "low" (SUS < 51). Clients´ service satisfaction was measured by the Client Satisfaction Questionnaire (CSQ-8; Larsen et al., 1979), and average satisfaction was 27.4 (SD = 3.9) of 32 possible scale points, indicating good client satisfaction. On item-level (M= 3.43), an average rating of 3 indicates clients being "somewhat satisfied" and a rating of 4 scale points translates into "very satisfied". Here, 84 % of participants gave ratings ≥ 3 scale points.

3.3 Appraisal of components, applicability and process aspects

An additional self-designed battery was applied to explore the participants' retrospective perception of the seminar components used, applicability, and process aspects of the blended treatment.

3.3.1 Appraisal of components and usage data

The results in *Table 4* show that computer and modern media support were generally described as helpful (5.16 on 6-step Likert-type scale). Almost half of the participants described in-session media use, between-session communication with the therapist, weekly psychoeducational videos and the online platform as very helpful, whilst only a small proportion found them of little or no help. Interestingly, participants described group interaction as marginally less relevant compared to computer and modern media. However, the only clear deviation from the received appraisal was a lower rating for the unguided discussion forum. *Table 4* also contains statistics on logins and downloads, where a continuous decrease in activity can be identified over treatment.

3.3.2 Applicability of the blended treatment rationale

Table 5 depicts participants` appraisals of the blended format and the influence of computer support on therapeutic process aspects in general, as well as preferred duration of our group treatment. The vast majority (84 %) stated that they would not omit computer support and that this support has the potential to improve (80 %) and intensify group therapy (72 %). For our participants, blending fits best the needs of training-alike group treatments. Here 96 % agreed, that blended treatments could help improve and intensify (88 %) existing rationales. The applicability-rating of blended treatments for individual therapy was clearly less positive (48 %), while prior therapy experience (54%) did not predict this appraisal (r = 0.116, p = 0.580). With a median of 12-15 sessions, preferred treatment duration was 50 % - 100 % higher than actual treatment duration (7 weeks).

3.3.3 Treatment process aspects

Statements on treatment process entailed issues regarding perceived treatment flexibility, structure, information, and group interaction (*Table 5*). Only a small proportion of investigated participants perceived applied computer and media support as restricting or hindering (16 – 20 %). With a proportion of one quarter to one third, a relevant group of indecisive participants existed. 48 % of participants expressed a need for more group interaction and discussion time. In the ranking of subjectively perceived working factors 72 % of participants (rank 4 of 21) described in- and intersession media use as important treatment factor (*Table 6*).

4. Discussion

The aim of this study was to evaluate a recently developed resource-oriented blended group treatment in an uncontrolled sample of adults, meeting the diagnostic criteria of major depression or dysthymia. Corresponding outcome measures indicated high to very high treatment effects and a high response rate on self-reported depressive symptoms and general health. Results were maintained over a 3-month follow-up period. There was no dropout during treatment, and satisfaction with treatment and the blended format was high. Only one participant deteriorated reliably (4 %). Our results indicate that the investigated group treatment might be a suitable and short treatment option for mild to moderate depression. From the viewpoint of addressed patients, modern technology and communication techniques add value to the treatment.

General patient evaluation of the blended group treatment was positive. Most patients stated that they would not omit technology and that computer and multimedia support could help to improve existing treatments. These findings support prior literature (e.g. Månsson et al., 2013, Przeworski & Newman, 2004), and underpin the potential of technology in the group treatment of depression. Even though more than half of the patients had prior therapy experience, the appraisal was less positive for individual therapy. This finding can be explained by a possible sceptical preconception and lack of converse experience (cf. Kooistra et al., 2016). It also might reflect patients` perception of different preconditions of the two treatment settings. However, when compared to a concept study on blended individual psychotherapy (Kooistra et al., 2016), usability (SUS) and satisfaction scores (CSQ-8) of our group treatment were around one standard deviation above. As blended learning originates from educational groups (e.g. teaching or corporate trainings) (Zumbach, 2010), interventions with a more training-alike character might be particularly feasible for computer and media support. This assumption is supported by slightly more positive appraisals for psychological trainings compared to psychotherapy.

Our treatment entailed a variety of different computer and online components. The online discussion forum and remote patient-to-therapist communication have setting-specific relevancy as they open up additional pathways for client-to-client and client-to-therapist interaction in group therapy. While remote patient-to-therapist communication was easy to install and described as important, the unguided online discussion forum was of less relevance for our patients. According to positive findings in online chat group and gamification studies (e.g. Bauer, Wolf, Haug & Kordy, 2011; Miloff, Marklund & Carlbring, 2015), we conclude that online group interaction in blended treatments should either be guided by a therapist (Schulz et al., 2016), or include other incentives to increase usage and perceived relevancy. Consistently with prior results, participants related in- and intersession media use to therapy success (*Table 6*). In our first study (Schuster et al., 2017), 25 % of participants freely described computer support as an active treatment factor in an open text-based evaluation. The direct ranking presented in this study yielded a notably higher proportion of agreement. This can be seen as a conceptual replication and might best be understood as a catalytic potential of computer and media support in fostering other established treatment factors, such as imparting information (Yalom & Leszcz, 2005) or motivational clarification (Grawe, 2004).

Findings regarding process aspects of the blended group format revealed important patient preferences. Many currently conducted studies on blended therapy investigate possible savings of therapist time by reducing the number of sessions (Newman et al., 2014; Kleiboer et al., 2016). From an economical point of view, potential time savings are inherently appealing for some mental health care stakeholders (Ruwaard & Kok, 2015; Topooco et al., 2017). On the other hand, shortened treatments might entail certain risks, such as a weakened patient-to-therapist bonding (van der Vaart, 2014). eHealth experts therefore emphasise the need for participatory research and the importance of target audience`s perceptions when designing new treatments (e.g. Nicholas, Boydell & Christensen, 2016; Yardley et al., 2016). As for that matter, the majority of our sample retrospectively would have preferred more group sessions (12 – 15 sessions) and more time for group interaction during each session. Additionally, treatment intensification was described as an important advantage. Development of blended interventions therefore might benefit from assuring, that time-efficient short treatments actually meet expectations of addressed patients in the particular care setting.

Assessed objective usage data revealed a constant decrease of webpage logins and downloads. Whether this tendency indicates a relevant reduction of motivation to persist with blended therapy is unclear, as satisfaction with treatment was high and usage patterns in the first weeks can be described in terms of exaggerated activity. In this context, Yardely and collegues (2016) critically reflect on current approaches to validly conceptualize engagement by analysing log files of system

usage data. Further investigation on the significance of (dis-)continous usage data for the blended therapy process can be carried out by small trials of iterative participatory research.

Besides the promising results of the investigated treatment format, several limitations need to be considered when interpreting its findings. *First*, sample size was low and the one-arm study design lacks a control condition. Thus, findings of our study have to be interpreted with limited generalization and the true magnitude of observed treatment effects remains unclear. Also, the study design does not allow inferring the extent to which specific treatment elements (e.g. computer and multimedia elements) contributed to the observed effects. *Second*, participating therapists (IF and VS) lacked prior experience with blended therapy, but underwent preparatory training. Careful preparation and implementation as well as regular supervision seem to be critical success factors in blended therapy interventions (Kenter et al., 2015), and as some online therapy studies show, more experience with a given treatment can result in better outcomes over the course of time (El Alaoui et al., 2015). *Third*, even though clinical interviews were conducted to assess participants' psychopathological status, other properties of our sample might restrict generalisability. The majority of our sample was female and relatively well educated. While comparable sample properties can be found in many online studies and our recruitment was based on a multi-modal recruitment strategy (Linder et al., 2015), future research has to determine, if the investigated treatment proves also feasible for less educated or older patients. *Fourth*, half of our participants lacked alternative experience with other forms of (group) therapy. Those patients' appraisals should be interpreted as positive experience with the undergone treatment, in the absence of knowledge about possible alternatives. Additionally, the group format and the use of modern media might have discouraged certain patients from participating in our study.

5. Conclusions

The present study indicates that the blended treatment format is a feasible and valued option for the outpatient group treatment of depression. Due to their properties, psychoeducational groups might be particularly suitable for blending. Here, modern media can be used for in- and intersession support and from our patients perspective treatment intensification is described as an important advantage. Future research should investigate the blended group treatment in a randomized controlled trial.

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Conflict of interest

None of the authors has, or has had, any financial, personal or other relationship with people or organisations that would interfere with the interpretation and presentation of this study's findings.

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Table 1.

Psychoeducational lectures and computer-supported components of the intervention.

Week	Lectures & psychoeducation	Computer & multimedia components
	Pre-assessment	Worksheet 1 Video 1
C.1	Opening and information on course structure and online platform. Psychoeducation on depression. Introduction to the current concerns concept. Instruction for current concerns diary, and relaxation.	PPT-Presentation Worksheet 2 Video 2
C.2	Discussion of homework assignments. Psychoeducation on human perception and cognitive biases. Discussion on frequent cognitive distortions. Psychoeducation on acceptance and mindfulness core principles. Instruction for the thoughts and mindfulness diary task.	PPT-Presentation Video 3 Mobile phone diary*
P.3	Discussion of homework assignments. Psychoeducation on human memory and learning processes. Exercise on cognitive restructuring. Introduction to happiness diary and activity list.	PPT-Presentation Worksheet 3 Videos 4 & 5 Mobile phone diary*
P/A.4	Discussion of homework assignments. Psychoeducation on psychological motivation theories and goal setting, with emphasis on Vroom's VIE-theory (1964). Group exercise on "SMART" goal setting and instruction for Goal-Attainment-Scaling.	PPT-Presentation Online Goal Attainment-Scaling with feedback
	Break	
A.5	Revision of sessions 1-4. Psychoeducation on self-regulation and self-control. Group exercise on strengths and weaknesses profile. Discussion and refinement of individual goals. Instructions for weekly diary task.	PPT-Presentation Contract with myself- Worksheet 4 Mobile phone diary*
A.6	Discussion of homework assignments. Psychoeducation on time management, realistic time scheduling and the "small steps concept" by Kanfer. Group exercise on "time-thieves". Group discussion on practical aspects of time management and prioritisation. Introduction to specific time management methods. Group exercise "stress traffic light.	PPT-Presentation Worksheet 5 + Video 5 Mobile phone diary*
M.7	Revision of sessions 5-7. Psychoeducation on slow and problematic change patterns and handling of setbacks. Group discussion on problematic change and relapse prevention. Course conclusion.	PPT-Presentation
	Post-assessment	

Note: Letters C to M: Course stages (C = contemplation, P = preparation, A = action, M = maintenance); PPT-Presentation = in-session PowerPoint presentation; Mobile phone diary* = participants were free to choose between a mobile phone diary or a handwritten diary.

Table 2.

Demographic, behavioural and clinical characteristics of the study sample at pre-treatment (N=26).

Characteristic	Mean (SD) or n (%)
Age, mean (SD)	33.9 (7.5)
Gender, female, n (%)	21 (81)
Education, n (%)	
≥ 9 years (compulsory school)	2 (8)
≥ 12 years (A level)	9 (35)
≥ any tertiary education (e.g. university)	14 (54)
Employment, n (%)	
- full time	10 (38)
- part time	7 (27)
- currently none	8 (31)
Current psychopharmacological treatment, n (%)	3 (12)
Prior psychotherapeutic treatment, n (%)	14 (54)
Computer experience, n (%)	
- daily use	22 (85)
- few times a week	4 (15)
Diagnosis, n (%)	
Mild to moderate depression (F32.0 or F32.1)	26 (100)
+ Double depression (F32.0 or F32.1 + F34.1)	4 (15)
+ Generalized anxiety disorder (F41.1)	4 (15)
+ Social anxiety disorder (F40.1)	3 (12)
+ Panic disorder (F41.0)	2 (8)
+ Specific phobia (F40.2)	2 (8)
+ Hypochondriasis (F45.2)	1 (4)
Comorbidity (participants fulfilling two or more diagnostic criteria)	12 (46)
1 comorbidity	6 (23)
≥ 2 comorbidities	6 (23)

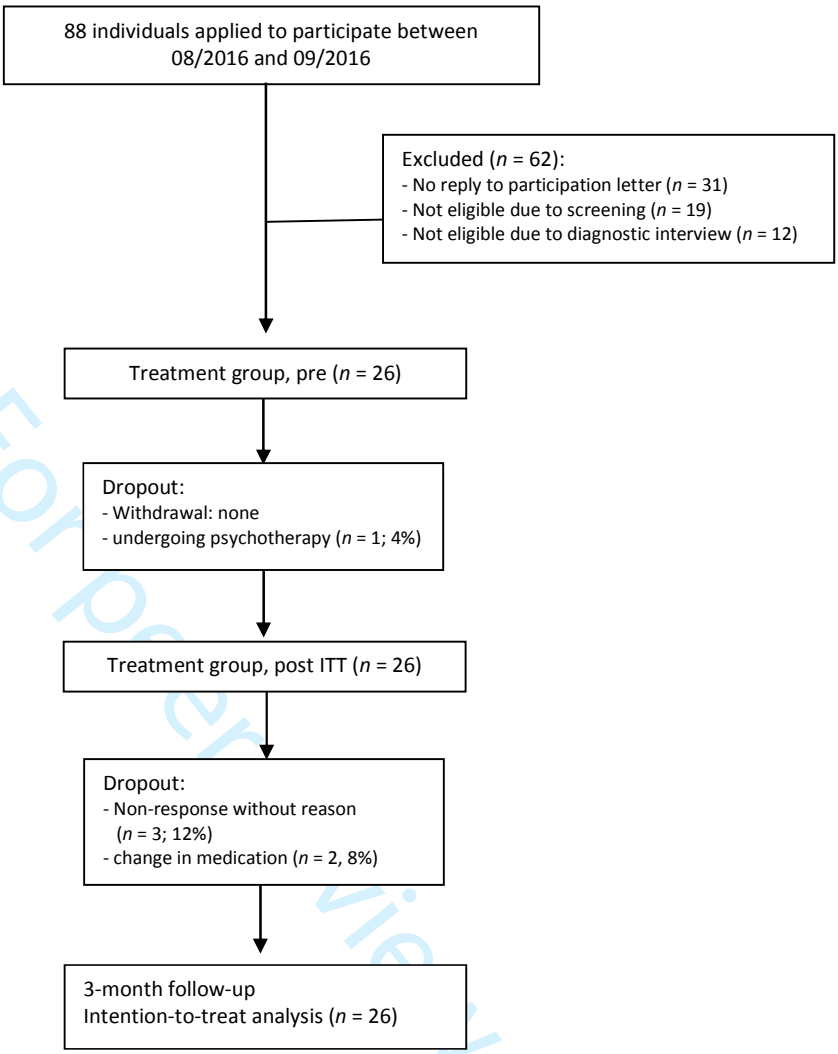

Figure 1. Study's flow chart

Table 3.

Means, standard deviations, effect sizes (Cohen's d) and reliable change for primary and secondary outcomes.

		Observed means (SD)			Effect sizes (observed means)	Reliable change	
	n	Pre	Post	Follow-up	Pre- to post effect size	Pre- to post RCI (CSI)	Pre- to follow-up RCI (CSI)
CES-D	25	24.8 (6.51)	14.1 (6.87)	14.6 (6.81)	1.58 [0.92 - 2.18]	72 (64)	60 (60)
GHQ-12	25	5.52 (2.29)	2.00 (3.18)	2.52 (3.27)	1.27 [0.64 – 1.86]	68 (62)	68 (44)
FERUS	25	134.8 (26.4)	157,7 (24.2)	154.4 (24.2)	0.90 [0.31 – 1.47]	56	48
MAAS	25	3.30 (0.80)	4.11 (0.99)	4.25 (0.94)	0.90 [0.30 – 1.47]	36	40

Note. Standard deviations are shown in round parentheses and 95 % confidence intervals are shown in square parentheses. CES-D: Center for Epidemiological Studies-Depression scale (cut-off > 17); GHQ-12: General Health Questionnaire (cut-off > 1); FERUS: Questionnaire for the Assessment of Resources and Strengths; MAAS: Mindful Attention Awareness Scale; RCI = reliable change index; CSI = clinically reliable improvement.

Table 4.

Appraisal of computer components and usage data.

Seminar components	Average	---	--	-	+	++	+++
Modern media in general	5.16	-	4	-	24	20	52
Weekly Lectures	5.40	-	-	-	16	28	56
In-session media	5.08	-	4	4	12	40	40
between-session communication with therapist	5.08	-	4	4	24	20	48
Weekly psychoeducational videos	4.88	4	-	8	20	28	40
Online platform	4.8	-	8	12	12	28	40
Group interaction	4.64 $^{+}$	-	-	4	28	36	32
Discussion forum	3.52***	-	4	48	40	8	-

Usage data	OS 1	OS 2	OS 3	OS 4	OS 5	OS 6	OS 7
Average logins per week (per module)	5.0	3.4	3.6	3.2	2.7	2.5	1.8
Average downloads of work sheet / week	1.9	1.3	1.5	1.1	1.0	0.9	-
Average downloads of in-session slides / week	1.3	1.0	1.2	0.9	0.8	0.6	0.4
Average logins during follow-up period	4.5						

Note. --- not at all helpful (%), -- not helpful (%), - of little help (%), + somewhat helpful (%), ++ helpful (%), +++ very helpful (%), $^{+}$= tendentially significant, ***= highly significant, OS = online session

Table 5.

Applicability of the blended treatment rationale and treatment process aspects.

Applicability of the blended treatment	Yes (%)	No (%)	*p* - Value
Would you prefer to omit computer and multimedia	16	84	
Do you think technology could help to improve group trainings	96	4	
… to improve group psychotherapy	80 *	20	$p = 0.043$
… to improve individual psychotherapy	48 ***	52	$p = 0.000$
Do you think technology could help to intensify group trainings	88	12	

… to intensify group psychotherapy		72 †	28	p = 0.103
Would you like to continue this treatment		88	12	
Optimal number of group sessions (Median)	12-15			

Treatment process aspects	Yes (%)	Neutral (%)	No (%)
Used contents resulted in too little flexibility	16	24	60
There was too much structure	20	24	56
There was too much information	16	32	52
I'd have preferred more time for talking and exchange	48	32	20

Note. † p < 0.1, * p < 0.05, *** p < 0.001.

Table 6.

Top 10 ranking of subjectively perceived working factors (n = 25).

Rank	Working factor	*n counts*	*% of all participants*
1.	Weekly lecutures	23	92
2.	Increase of positive thoughts	20	80
3.	Restructuring of negative thoughts	19	76
4.	In- and intersession media use	18	72
4.	Trainer (social and professional skills)	18	72
6.	Group (coherence and interpersonal learning)	17	68
6.	Positive activities	17	68
8.	Reflexion	16	64
9.	Mindfulness exercises	14	56
9.	Exercises on resources and strengths	14	56

Note: *n counts* = number of counts associated with a specific working factor; *% of all participants* = proportion of all participants

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	uncontrolled
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	yes, page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	yes, page 4
	2b	Specific objectives or hypotheses	yes, page 5&6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	no, one-armed
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	yes, page 6&7
	4b	Settings and locations where the data were collected	yes, page 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	yes, page 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	yes, page7&8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	yes, page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	none
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	none
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	none
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	none

		assessing outcomes) and how	none
	11b	If relevant, description of the similarity of interventions	none
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	yes, page 8&9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	none
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	yes, page 9&21
	13b	For each group, losses and exclusions after randomisation, together with reasons	yes, page 9&21
Recruitment	14a	Dates defining the periods of recruitment and follow-up	yes, page 9&21
	14b	Why the trial ended or was stopped	yes, page 6/7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	yes, page 9&22
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	yes, page 9&22
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	yes, page 9&22
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	none
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	none
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	yes, page 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	yes, page 13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	yes, page 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	yes, page 11-13
Other information			
Registration	23	Registration number and name of trial registry	yes, page 6
Protocol	24	Where the full trial protocol can be accessed, if available	yes, page 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	yes, page 13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Feasibility and efficacy of blended group therapy (bGT) for major depression: Uncontrolled interventional study in a university outpatient setting

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Feasibility and efficacy of blended group therapy (bGT) for major depression: Uncontrolled interventional study in a university outpatient setting

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Abstract

Objective: This study investigated the acceptability and efficacy of a novel blended (face-to-face and computer-based) group intervention for the low-threshold treatment of major depression and comorbid anxiety.

Design: Patient-centred uncontrolled interventional study.

Setting: University outpatient setting in a general community sample. A multi-modal recruitment strategy (public health centres and public areas) was applied.

Participants: Based on independent interviews, 26 participants, diagnosed with major depressive disorder (81 % female; 23 % comorbidity > 1, 23 % comorbidity > 2), entered treatment.

Intervention: Positive, acceptance-based and resource-oriented psychology principles served as the theoretical basis for the low-threshold intervention. The blended format included face-to-face therapy, complemented with multimedia presentations and a platform featuring videos, online work sheets, an unguided group-chat, as well as remote therapist-patient communication.

Main outcome measures: The Center for Epidemiological Studies-Depression scale (CES-D) and the twelve-item General Health Questionnaire (GHQ-12).

Results: Large to very large within group effect sizes were found on self-reported depressiveness ($F_{(2, 46.37)}$= 25.69, p < .001; d = 1.80), general health ($F_{(2,46.73)}$= 11.47, p < .001; d = 1.32), personal resources ($F_{(2,43.36)}$= 21.17, p < .001; d = 0.90) and mindfulness ($F_{(2,46.22)}$= 9.40, p < .001; d = 1.12) after a follow-up period of three months. Treatment satisfaction was very high and 69 % ranked computer and multimedia use as an active treatment factor. Furthermore, treatment intensification was described as important advantage. Almost half of patients would have preferred more time for personal exchange.

Conclusion: The application of in- and between-session computer support for the group treatment of major depression seems feasible. The development of blended interventions can benefit from assuring that highly structured treatments actually meet patients' expecations. As a next step, blended group therapy for depression should be tested in comparative trials in routine care.

Trial registration: DRKS-ID: DRKS00010894

Strengths and limitations of this study

- This is the first clinical study on blended group therapy (bGT) for major depression. This innovative treatment combines two low intensity psychosocial interventions, recommended by the National Institute for Health and Care Excellence.
- Participant selection was based on a multi-modal recruitment strategy and comorbidity was high. Data on treatment stability and adverse effects are provided.
- Results indicate a high fit between group therapy and supportive computer elements. The study entails a detailed view on applied treatment components, including possible improvements.
- Very high treatment effects were observed and blended elements were replicated as subjectively perceived active treatment factor.
- The uncontrolled study-design and the university outpatient-setting restrict the interpretability of results.

DATA SHARING STATEMENT

We also assessed 5 short scales at pre-measurement. These short scales will be accumulated over different studies and serve as moderators of treatment success and online user behaviour. All data can be obtained by contacting the first or the last author of this study and will be readily shared.

CONTRIBUTOR SHIP STATEMENT

Raphael Schuster:	design, acquisition, analysis, drafting, revising
Verena Sparr:	acquisition, analysis
Isabelle Fichtenbauer:	acquisition, analysis
Thomas Berger:	drafting and revising
Anton-Rupert Laireiter:	design, drafting and revising

1. Introduction

Depression presents a relevant public health concern and imposes high costs on society as well as on health systems [1]. Therefore, research priorities include health policy and system research, in particular, how to deliver cost-effective interventions in a low-resource context [2, 3]. Psychological online interventions have been found effective in reducing common mental health disorders, e.g. depression [4] and anxiety [5], in such low-resource contexts.

Online interventions offer many advantages; they can provide access to evidence-based treatments and patients can work through the intervention whenever they want [6]. Usually anonymity is preserved as patients participate at distance, resulting in low social barriers and low risk of stigmatization [7]. From a health suppliers perspective online interventions guarantee standardized treatments and show good scalability, which has led to the launch of the first online clinics [8, 9]. Internet-based interventions can also help with bridging waiting times [10] or enhance treatment effects during aftercare [11]. At the same time, online interventions do not fit all patients' needs (e.g. need for more personal contact or diverging preferences). Consequently, classical face-to-face therapy will remain an important basis of mental health care. That being said, tools and methods developed in online therapy can be integrated into various forms of face-to-face psychotherapy [12].

Due to the variety of possible combinations between online interventions and psychotherapy it remains difficult to define blended interventions concisely. Van der Vaart and colleagues [13] describe blended therapy as "[…] *a combination of online and face-to-face therapy, in which online sessions replace or substitute some (parts) of the sessions with a health professional* […]. According to Kooistra and colleagues [14], the combination of both intervention strategies should merge into one integrated treatment format. In our study's context, new media was also used as a supportive in-session tool (e.g. multimedia presentations and videos). Thus, we define blended therapy as an integrated combination of face-to-face therapy with computer or app support. It aims at improving the delivery of evidence-based psychotherapy methods and results in a possible acceleration or intensification of treatment. The online part of blended treatments often entails psychoeducation, online exercises and remote therapist feedback on accomplished exercises, as well as mobile diaries or monitoring [15]. Interventions are usually delivered via online platforms [16] or applications for mobile phones [17].

Blended therapy is at an early stage of research - even though first studies date back to the 1980s and 1990s [18-20]. At that time, computer support had been found to be useful in the treatment of depression, anxiety or obsessive compulsive disorders [20]. However, these early studies do not adequately account for the rapid development modern technologies have undergone, and user-

behaviour has changed dramatically since then. When examining more recent literature, good acceptability and compatibility with standard treatments are found [21]. Additionally, computer-assisted programs may well shorten treatment duration while maintaining observed treatment effects [22]. In Europe, research on blended therapy currently is on the rise, as a multicentre study (E-COMPARED) investigates possible time savings in routine care [23]. From a therapy process perspective, Månsson and colleagues [16] suggest that blended interventions could foster adherence to evidence based treatment rationales, because the structure provided by blended therapy might prevent therapists from so called therapist drift [24]. Regarding implementation of blended therapy, the Netherlands seem to be Europe's most promotive nation [25]. According to Netherlands' leading software provider (Minddistrict) more than 17.000 professionals and 120.000 patients are currently using some of their blended services [26].

With little exceptions, research on blended therapy has its primary focus on individual therapy and little is known about the potential for group therapy. As it is a recommended treatment in health guidelines and national health policies [27, 28], group therapy has various applications in in- and outpatient clinics [29]. For example, the National Institute for Health and Care Excellence [30] recommends group cognitive behavioural therapy (GCBT) for people with mild to moderate depression who decline other low intensity psychosocial interventions, such as computerized cognitive behavioural therapy (cCBT). Therefore, the integration of computer support and face-to-face group therapy might result in an optimized treatment, in which personal contact is preserved to a wide extend. Existing blended group therapy (bGT) studies reveal high acceptability for the treatment of anxiety disorders and suggest possible savings of therapist time [31, 32, 33]. Additionally, bGT allows new ways of therapist-to-client and client-to-client interaction, such as online supervision of homework tasks or gamification [34]. Yet, literature on bGT for depression remains very scarce, as there do not exist any published articles prior to our first proof-of-concept study [35]. Here, good treatment effects were observed in an adult sample, exhibiting a variety of unspecified depressive symptoms. Participants rated online and multimedia support as equally relevant as group experience or specific CBT techniques. In an open evaluation 25 % freely described online and multimedia support as an active treatment factor.

The present study aims to carry forward this work by applying the developed blended group intervention to a sample of clinically depressed adults, and evaluating its usefulness in a more structured and standardized way. Moreover, we were interested in analysing system usage and corresponding changes over the course of time.

2. Methods

2.1 Procedure

The clinical one-arm interventional study was approved by the local ethics committee (Ethical Review Board, University of Vienna, Ref-Nr:00194) and registered at the German clinical trial register (DRKS-ID: DRKS00010894). Eligible persons were called and informed consent was obtained verbally by two independent interviewers. Subsequently, the complete Mini-DIPS was applied for study in- or exclusion [36]. The Mini-DIPS is a 30-minute short version of the German DIPS (Diagnostic Interview for Psychological Disorders) [37], based on ICD-10 depression criteria. Ten days prior to treatment, eligible participants (N = 26) were required to complete an online questionnaire of self-report measures. Sessions were held in a double trainer format by two trained and supervised psychologists (VS & IL), both in the final year of their Master studies of clinical psychology. Both trainers had prior experience with conducting group therapy in clinical settings. Sessions took place in a specially equipped seminar room at the University of Vienna, Faculty of Psychology (Department of Applied Psychology: Health, Development and Promotion). At the beginning of the first group session, written informed consent was signed by all participants. One week after treatment ended, an online post-evaluation questionnaire was completed and follow-up data was obtained three months later.

2.2 Intervention

The treatment comprised a 7-week intensive psychoeducation, self-management group intervention, in which personal sessions (90 minutes) alternated with online exercises and remote therapist feedback. Psychological key techniques eclectically entailed cognitive behavioural therapy, positive psychology, mindfulness, acceptance and commitment therapy as well as a special emphasis on time- and self-management. The intervention focused on the reduction of depressive symptoms and aimed at increasing personal resources, but was not tailored to treat comorbid anxiety. Online modules were made accessible via a secure web-based non-profit environment, featuring videos, online work sheets, an unguided group-chat, as well as remote therapist-patient communication. Accomplishing one online session took approximately 50 - 70 minutes (34 minutes of weekly videos included). Group sessions were supported by multimedia, e.g. psychoeducational short clips and PowerPoint presentations. Participants were also able to logon the platform after the entire treatment had ended. The basic treatment is described comprehensively in our preceding study [35]. Improvements are in regards to the psychoeducation section and the weekly diary as well as putting slightly more emphasis on cognitive restructuring techniques. Detailed information on weekly modules is presented in *Table 1*.

2.3 Participant recruitment and selection

The study was advertised online (e.g. www.depression.at) and by handing out flyers in public health centres and populated public areas, such as urban pedestrian areas in Vienna. All those interested were invited to visit the study webpage and to fill out an online participation form. During the entire procedure, no special recruitment strategy was applied for comorbid anxiety. Recruitment ended after sufficient participants had been acquired.

Inclusion and exclusion criteria

Two independent psychologists with clinical experience conducted the diagnostic interviews. Participants aged between 18 – 65, familiar with the use of personal computers and suffering from mild to moderate levels of major depression and/or dysthymia and/or mild to moderate comorbid anxiety were eligible for the study. According to clinical judgement, participants were excluded if they suffered from severe depression (≥ 7 criteria, including main symptoms), severe anxiety disorder, bipolar disorder, schizoaffective disorder, severe psychiatric and psychotic conditions, substance abuse, suicidal ideation, or if they exhibited low German-language and/or computer skills. Participants were also excluded if they were currently undergoing psychotherapy. Psychiatric medication was tolerated, but had to be kept constant for at least three months prior to study onset. *Figure 1* presents the flowchart, demonstrating the recruitment and research procedure in detail.

2.4 Measures

2.4.1 Primary outcome

The primary outcome, reduction of depressed mood, was measured by the short form of the German translation of the CES-D, Center for Epidemiological Studies-Depression scale [38]. This questionnaire assesses depression associated emotions and motor functions, as well as interactive, cognitive and somatic symptoms on a 16-item 4-step Likert-scale. Higher scores indicate higher levels of depression and the German version's cut-off value (CES-D > 17) has high discriminative validity [38]. The reliability of the CES-D has been shown to be excellent [39]. Cronbach's alpha in the present study was .84.

2.4.2 Secondary outcome measures

The General Health Questionnaire (GHQ-12) [40] was selected to assess the degree of self-reported psychological distress. Items are rated on a 4-step bi-modal scale (0-0-1-1) with higher scores indicating higher levels of psychological distress. The GHQ-12 has shown satisfactory reliability [41] and good intercultural validity [42]. A cut-off of > 1 served as a conservative measure with highest sensitivity and specificity in literature [43]. Cronbach´s alpha was .83.

The German "Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten – Gesamtressourcen" (FERUS, Questionnaire for the Assessment of Resources and Self-Management

Abilities – common resources) [44], consisting of the subscales “coping”, “self-awareness”, “self-efficacy”, “self-verbalisation”, and “hope” (44 items, 7-point Likert-scales), was applied for the assessment of personal resources. Higher scores represent higher levels of self-rated personal resources. In the present study Cronbach’s alpha of the total resources was .95.

The Mindful Attention Awareness Scale (MAAS) [45] assesses the frequency of mindful states, with higher levels indicating greater mindful awareness (15 items, 6-point Likert scale). We used a 6-item short version of the German MAAS [46] and Cronbach´s alpha in the present study was .83.

2.4.3 Treatment satisfaction and system usability

Usability of online and multimedia elements was assessed by the System Usability Scale (SUS) [47]. The SUS is a technology-neutral robust tool for assessing the quality of a given user interface. Empirically derived cut-off scores are graded from SUS > 85.5 (excellent usability) to SUS >71.4 (good usability) and SUS > 50.9 (acceptable usability) on a 10-item 5-point Likert scale [48]. Cronbach’s alpha for the current sample was .85.

Participants' overall satisfaction with treatment was measured by the German version (ZUF-8) [49] of the Client Satisfaction Questionnaire (CSQ-8) [50]. This widely used questionnaire addresses several aspects of service satisfaction and is based on an 8-item 4-point Likert scale. In this study Cronbach´s alpha was .88.

2.4.4 Appraisal of new media elements, applicability and process aspects

Appraisal of new media elements, applicability, and process aspects of the investigated treatment were assessed by a self-designed questionnaire (55 items) at post-treatment. The questionnaire comprised 9 items on intervention elements, 6 items on specific functions (e.g. online platform), 6 items on satisfaction and perceived efficacy of the intervention, one ranking of perceived active treatment factors [35], 16 items on optimal blend, intensity and duration [13], 9 items on mode of delivery (face-to-face or online) [13], and 8 items on perceived (dis-)advantages of blended therapy.

2.5 Statistical Analyses

Statistical analyses were carried out using SPSS 24 [51]. Significant pre- to follow-up changes were analysed by linear mixed models (LMM), with restricted maximum likelihood estimation (REML) and compound symmetry as covariance type. Missing values on outcome measures were analysed in agreement with the intention to treat principle (ITT). Individual pre- to follow-up differences served as basis for the reliable change indexes (RCI) [52] and we used internal consistency as a measure for RCI reliability [53], resulting in a reliable change criterion of 7.22 scale points for the CES-D and 2.62

scale points for the GHQ-12. Additionally, participants were deemed to have undergone clinically significant improvement (CSI) when simultaneously exhibiting reliable change and scoring below CES-D or GHQ-12 post measurement cut-off (CES-D ≤ 17; GHQ-12 > 1). Within-group effect sizes were calculated with pooled standard deviation and reported in Cohen's *d* [54]. Power analysis was carried out using G*Power [55], resulting in an estimated sample size of $N = 22$, for a conservative medium within-subjects effect size of $d = 0.65$ (alpha-error $\alpha = .05$, power $\beta = .90$). Differences in appraisals of intervention elements (section 3.3.1) were calculated by t-tests (comparing against gran average), and for the analyses of treatment applicability and process aspects (section 3.3.2) paired t-tests were applied.

3. Results

3.1 Sample characteristics

There were no dropouts during treatment, but three participants did not fill out the follow-up evaluation. Two patients reported changes in medication and one patient commenced psychotherapy. According to ITT-principles, those patients remained in the analyses. According to the CONSORT guidelines, detailed information on participants' flow can be gained from *Figure 1*. Women constituted the majority of the sample (81 %) and education was high (54 % tertiary education). Participants' age ranged from 23 to 51 ($M = 33.9$, $SD = 7.5$). A comprehensive overview of participant characteristics can be gained from *Table 2*.

3.2.1 Primary and secondary outcome measures

All outcome measures indicated significant changes and effect sizes were large to very large (see *Table 3*). For the primary outcome measure CES-D, a statistically significant reduction of self-reported depressive symptoms was found, F-value of $F_{(2, 46.37)} = 25.69$, $p < .001$. Regarding secondary outcome measures, self-reported psychological distress, assessed by the GHQ-12, significantly decreased $F_{(2,46.73)} = 11.47$, $p < .001$. Furthermore, personal resources (FERUS) significantly increased, $F_{(2,43.36)} = 21.17$, $p < .001$, as well as the frequency of mindful states (MAAS), $F_{(2,46.22)} = 9.40$, $p < .001$. At follow-up, a proportion of 70 % of patients exhibited clinically significant improvement (CSI) for depressive symptoms and CSI for general health was observed in 75 %. One participant deteriorated reliably (4 %). Detailed information on observed means, standard deviations, effect sizes and reliable change is depicted in *Table 3*.

3.2.2 Treatment satisfaction and system usability

Usability of online and multimedia elements, assessed by the System Usability Scale (SUS) [47], unveiled an average usability of 85.3 ($SD = 14.49$) on a 100-point scale. Highest quality ratings (excellent

usability, SUS > 85) were given by 56 % and another 24 % of participants rated the platform usability as “good” (SUS > 72). One participant (4 %) rated the usability as “low” (SUS < 51). Clients´ service satisfaction was measured by the Client Satisfaction Questionnaire (CSQ-8) [50], and average satisfaction was 27.4 *(SD* = 3.9) of 32 possible scale points, indicating “good” client satisfaction. On item-level (*M* = 3.43), an average rating of 3 indicates clients being “somewhat satisfied” and a rating of 4 scale points translates into “very satisfied”. Here, 84 % of participants gave ratings ≥ 3 scale points.

3.3 Appraisal of new media elements, applicability and process aspects

To explore participants’ retrospective perception of new media elements, as well as applicability and process aspects of the blended treatment, an additional self-designed questionnaire was applied.

3.3.1 Appraisal of new media elements and usage data

The results in *Table 4* show that computer and multimedia support were generally described as helpful (*M* = 5.16 on 6-step Likert-type scale). Almost half of the participants described in-session multimedia use, between-session communication with the therapist, weekly psychoeducational videos and the online platform as very helpful, whilst a smaller proportion found them of little or no help. Interestingly, participants described group interaction as marginally less relevant compared to computer and multimedia. However, the only clear deviation from average was a lower rating for the unguided discussion forum. *Table 4* also provides descriptive statistics on logins and downloads, where a continuous decrease in activity can be identified over treatment.

3.3.2 Applicability of the blended treatment rationale

Table 5 depicts participants` appraisals of the blended format and the influence of computer support on therapeutic process aspects in general, as well as preferred duration of the applied group treatment. The majority (84 %) stated that they would not omit computer support and that this support has the potential to improve (80 %) and intensify group therapy (72 %). For our participants, blending best fitted the needs of training-alike group treatments. Here 96 % agreed, that blended treatments could help improve and intensify (88 %) existing rationales. The applicability-rating of blended treatments for individual therapy was clearly less positive (48 %), while prior therapy experience (54%) did not predict this appraisal (r = 0.116, p = 0.580). With a median of 12 - 15 sessions, preferred treatment duration was 50 % - 100 % higher than the actual treatment (7 weeks).

3.3.3 Treatment process aspects

Statements on treatment process entailed issues regarding perceived treatment flexibility, structure, information, and group interaction (*Table 5*). A small proportion of investigated participants per-

ceived applied computer and multimedia support as restricting or hindering (16 – 20 %). With a proportion of one quarter to one third, a group of indecisive participants existed. 48 % of participants expressed a desire for more group interaction and discussion time. In the ranking of subjectively perceived active treatment factors, 69 % of participants (rank 4 of 21) described in- and intersession computer and multimedia use as an important treatment factor (*Table 6*).

4. Discussion

The aim of this study was to evaluate a recently developed resource-oriented blended group treatment in an uncontrolled sample of adults, fulfilling the diagnostic criteria for major depression or dysthymia. Corresponding outcome measures indicated high to very high treatment effects and a high response rate on self-reported depressive symptoms and general health. Results were maintained over a 3-month follow-up period. There was no withdrawal from treatment, and satisfaction with treatment and the blended format was high. Only one participant deteriorated reliably (4 %). From the viewpoint of the addressed patients, modern technology and communication techniques add value to existing group treatments.

Regarding patients' general appraisals, the evaluation of the blended group treatment was positive. These findings support prior literature [16, 32], and underpin the potential of technology for the group treatment of depression. Most patients stated that they would not omit technology and that computer and multimedia support could help to improve existing treatments. Even though more than half of the patients had received prior therapy, the appraisal was less positive for individual therapy (cf. section 3.3.2). This finding can be explained by a possible sceptical preconception and lack of converse experience [14]. It might also reflect patients` perception of different preconditions of the two settings. However, when compared to a concept study on blended individual psychotherapy [14], usability (SUS) and satisfaction scores (CSQ-8) of our group treatment were around one standard deviation above. As blended learning originates from educational groups (e.g. teaching or corporate trainings) [56], interventions with more training-alike character may be particularly feasible for computer and multimedia support. This assumption is also reflected by slightly more positive appraisals for training-alike interventions, compared to classical group therapy (cf. section 3.3.2). Yet, presented results are preliminary and have to be interpreted with caution.

The investigated treatment entailed a variety of different computer and online elements. The online discussion forum and remote patient-to-therapist communication have setting-specific relevancy as they open up additional pathways for client-to-client and client-to-therapist interaction in group therapy. While remote patient-to-therapist communication was easy to install and described as

important, the unguided online discussion forum was of less relevance for our patients. According to positive findings in online chat group and gamification studies [34, 57], we conclude that online group interaction in blended treatments should either be guided by a therapist [58], or include other incentives to increase usage and perceived relevancy. During debriefing, some patients also explained, that their need for group interaction was satisfied by the weekly reunions.

Consistent with prior results, participants related in- and intersession computer and multimedia use to therapy success (*Table 6*). In our first study [35], 25 % of participants freely described computer support as an active treatment factor. The direct ranking presented in this study yielded a notably higher proportion of agreement. Additionally, treatment intensification was described as an important advantage. Results from a forthcomming qualitative article on patients' experiences with blended group therapy support the present findings (personal communication by Schuster, Raphael, September 2017). Regarding the interpretation, patients' appraisals might best be conceptualized as the description of a catalytic effect, which possibly fosters other established treatment factors, such as imparting information [29] or motivational clarification [59]. Even though first results from comparative studies are promising [60, 61], future research has to determine, if patients' positive appraisals translate into superior effects of blended therapy in routine care. Still, from a product development perspective, patients' connection of blended elements with therapy success can be seen as an important success criterion.

Findings regarding process aspects of the blended group format revealed important patient preferences. Many currently conducted studies on blended therapy investigate possible savings of therapist time by reducing the number of sessions (23, 33]. From an economical point of view, potential time savings are inherently appealing for some mental health care stakeholders [25, 62]. On the other hand, shortened treatments might entail certain risks, such as a weakened patient-to-therapist bonding [13]. eHealth experts therefore emphasise the need for participatory research and the importance of target audience's perceptions when designing new treatments [63, 64]. As for that matter, the majority of our sample retrospectively would have preferred more group sessions (12 – 15 sessions) and half of our sample requiered more time for group interaction during each session (cf. section 3.3.2). Development and future uptake of blended interventions may therefore benefit from assuring that highly structured or time-efficient treatments actually meet the expectations of addressed patients in a particular care setting.

Assessed objective usage data revealed a constant decrease of webpage logins and downloads (cf. section 3.3.1). Whether this tendency indicates a relevant reduction of motivation to persist with blended therapy is unclear, as satisfaction with treatment was high and usage patterns in the first weeks can be described in terms of exaggerated activity. In this context, Yardley and collegues [64]

critically reflect on current approaches to validly conceptualize engagement by analysing log files of system usage data. Further investigation on the significance of (dis-)continous usage data for the blended therapy process can be carried out by small studies of iterative participatory research.

Besides the promising results of the investigated treatment, several limitations need to be considered when interpreting its findings. *First*, sample size was low and the one-arm study design lacks a control condition. Thus, findings of our study have to be interpreted with limited generalization and the true magnitude of observed treatment effects remains unclear. Also, the study design does not allow inferring the actual extent to which specific treatment elements (e.g. computer and multimedia elements) effectively contributed to the observed effects. *Second*, participating therapists (IF and VS) lacked prior experience with blended therapy, but underwent preparatory training. Careful preparation and implementation as well as regular supervision seem to be critical success factors in blended therapy interventions [65], and as some online therapy studies show, more experience with a given treatment can result in better outcomes over the course of time [66]. *Third*, even though clinical interviews were conducted to assess participants' psychopathological status, other properties of our sample restrict generalisability. The majority of our sample was female and relatively well educated. While comparable sample properties can be found in many online studies and our recruitment was based on a multi-modal recruitment strategy [67], future research has to determine, if the investigated treatment proves also feasible for less educated or older patients. *Fourth*, compared to University of Salzburg (where the intervention was developed), the institute for applied psychology lacks a fully equipped routine outpatient clinic. As a consequence, further research in routine care is needed. *Fifth*, half of our participants lacked alternative experience with other forms of (group) therapy. Those patients' appraisals should be interpreted as positive experience with the undergone treatment, in the absence of experience with possible alternatives. Additionally, the group format and the use of new media might have discouraged certain patients from participating in our study.

5. Conclusions

The present study indicates that the blended format is feasible for the outpatient group treatment of major depression. Due to their properties, psychoeducational groups with elements of self-management or behavioural activation might be particularly suitable for blending. New media can be used for in- and intersession support and from patients' perspective, treatment intensification is described as an important advantage. Future research should investigate the feasibility and benefits of blended group therapy in routine care.

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Conflict of interest

None of the authors has, or has had, any financial, personal or other relationship with people or organisations that would interfere with the interpretation and presentation of this study's findings.

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Table 1.

Group sessions and computer and multimedia elements of the intervention.

Week	Group session	Computer & multimedia elements
	Pre-assessment	Worksheet 1 Video 1
C.1	Opening and information about intervention and online platform. Psychoeducation on depression. Introduction to the current concerns concept. Instruction for current concerns diary, and relaxation.	PPT-Presentation Worksheet 2 Video 2
C.2	Discussion of homework assignments. Psychoeducation on human perception and cognitive biases. Discussion on frequent cognitive distortions. Psychoeducation on acceptance and mindfulness principles. Instruction for the "Thoughts and mindfulness" diary task.	PPT-Presentation Video 3 Mobile phone diary*
P.3	Discussion of homework assignments. Psychoeducation on human memory and learning processes. Exercise on cognitive restructuring. Introduction to "Happiness" diary and activity list.	PPT-Presentation Worksheet 3 Videos 4 & 5 Mobile phone diary*
P/A.4	Discussion of homework assignments. Psychoeducation on psychological motivation theories and goal setting, with emphasis on Vroom's VIE-theory (1964). Group exercise on "SMART" goal setting and instruction for Goal-Attainment-Scaling.	PPT-Presentation Online Goal Attainment-Scaling with feedback
	Break	
A.5	Revision of sessions 1-4. Psychoeducation on self-regulation and self-control. Group exercise on strengths and weaknesses profile. Discussion and refinement of individual goals. Instructions for weekly diary task.	PPT-Presentation Contract with myself- Worksheet 4 Mobile phone diary*
A.6	Discussion of homework assignments. Psychoeducation on time management, realistic time scheduling. Group exercise "Time-thieves". Group discussion on practical aspects of time management and prioritisation. Introduction to specific time management methods. Group exercise "Stress traffic light".	PPT-Presentation Worksheet 5 + Video 5 Mobile phone diary*
M.7	Revision of sessions 5-7. Psychoeducation on slow and problematic change patterns and handling of setbacks. Group discussion on problematic change and relapse prevention.	PPT-Presentation
	Post-assessment	

Note: Letters C to M: Treatment stages (C = contemplation, P = preparation, A = action, M = maintenance); PPT-Presentation = in-session PowerPoint presentation; Mobile phone diary* = participants were free to choose between a mobile phone diary or a handwritten diary.

Table 2.

Demographic, behavioural and clinical characteristics of the study sample at pre-treatment (N = 26).

Characteristic	Mean (*SD*) or *n (%)*
Age, mean *(SD)*	33.9 (7.5)
Gender, female, *n (%)*	21 (81)
Education, *n (%)*	
≥ 9 years (compulsory school)	3 (12)
≥ 12 years (A level)	9 (34)
≥ any tertiary education (e.g. university)	14 (54)
Employment, *n (%)*	
- full time	11 (42)
- part time	7 (27)
- currently none	8 (31)
Current psychopharmacological treatment, *n (%)*	3 (12)
Prior psychotherapeutic treatment, *n (%)*	14 (54)
Computer experience, *n (%)*	
- daily use	22 (85)
- few times a week	4 (15)
Diagnosis, *n (%)*	
Major depression (F32.0 or F32.1)	26 (100)
+ Double depression (F32.0 or F32.1 + F34.1)	4 (15)
+ Generalized anxiety disorder (F41.1)	4 (15)
+ Social anxiety disorder (F40.1)	3 (12)
+ Panic disorder (F41.0)	2 (8)
+ Specific phobia (F40.2)	2 (8)
+ Hypochondriasis (F45.2)	1 (4)
Comorbidity (participants fulfilling two or more diagnostic criteria)	12 (46)
1 comorbidity	6 (23)
≥ 2 comorbidities	6 (23)

Table 3.

Means, standard deviations, effect sizes (Cohen's d) and reliable change for primary and secondary outcomes.

		Observed means (*SD*)			Effect sizes (observed means)	Reliable change	
	N	Pre	Post	Follow-up	Pre- to follow-up effect size	Pre- to post RCI (CSI)	Pre- to follow-up RCI (CSI)
CES-D	26	24.58 (6.51)	14.19 (6.73)	13.28 (6.06)	1.80 [1.13 - 2.41]	69 (65)	70 (70)
GHQ-12	26	5.50 (2.25)	2.00 (3.11)	2.05 (2.94)	1.32 [0.70 – 1.89]	65 (65)	75 (75)
FERUS	26	134.54 (25.94)	156.04 (25.22)	157.52 (25.31)	0.90 [0.31 – 1.45]	--	--
MAAS	26	3.29 (0.78)	4.05 (1.01)	4.25 (0.93)	1.12 [0.52 – 1.68]	--	--

Note. Standard deviations are shown in round parentheses and 95 % confidence intervals are shown in square parentheses. CES-D: Center for Epidemiological Studies-Depression scale (cut-off > 17); GHQ-12: General Health Questionnaire (cut-off > 1); FERUS: Questionnaire for the Assessment of Resources and Strengths; MAAS: Mindful Attention Awareness Scale; RCI = reliable change index; CSI = clinically reliable improvement.

Table 4.

Appraisal of intervention elements and usage data (N = 26).

Intervention elements	Average	---	--	-	+	++	+++
New media in general	5.16	-	4	-	24	20	52
Weekly group sessions	5.40	-	-	-	16	28	56
In-session multimedia	5.08	-	4	4	12	40	40
between-session communication with therapist	5.08	-	4	4	24	20	48
Weekly psychoeducational videos	4.88	4	-	8	20	28	40
Online platform	4.8	-	8	12	12	28	40
Group interaction	4.64 $^{+}$	-	-	4	28	36	32
Discussion forum	3.52***	-	4	48	40	8	-

Usage data	OS 1	OS 2	OS 3	OS 4	OS 5	OS 6	OS 7
Average logins per week (per module)	5.0	3.4	3.6	3.2	2.7	2.5	1.8
Average downloads of work sheet / week	1.9	1.3	1.5	1.1	1.0	0.9	-
Average downloads of in-session slides / week	1.3	1.0	1.2	0.9	0.8	0.6	0.4
Average logins during follow-up period	4.5						

Note. --- not at all helpful (%), -- not helpful (%), - of little help (%), + somewhat helpful (%), ++ helpful (%), +++ very helpful (%), $^{+}$= tentatively significant, ***= highly significant, OS = online session

Table 5.

Applicability of the blended treatment rationale and treatment process aspects (N = 26).

Applicability of the blended treatment	Yes (%)	No (%)	*p*-Value
Would you prefer to omit computer and multimedia elements?	16	84	
Do you think technology could help to improve group trainings?	96	4	
… to improve group psychotherapy?	80 *	20	$p = 0.043$
… to improve individual psychotherapy?	48 ***	52	$p = 0.000$
Do you think technology could help to intensify group trainings?	88	12	

… to intensify group psychotherapy?		72 †	28	p = 0.103
Would you like to continue this treatment?		88	12	
Optimal number of group sessions (*MD*)	12-15			

Treatment process aspects	Yes (%)	Neutral (%)	No (%)
Used contents resulted in too little flexibility	16	24	60
There was too much structure	20	24	56
There was too much information	16	32	52
I'd have preferred more time for talking and exchange	48	32	20

Note. † p ≤ 0.1, * p < 0.05, *** p < 0.001.

Table 6.

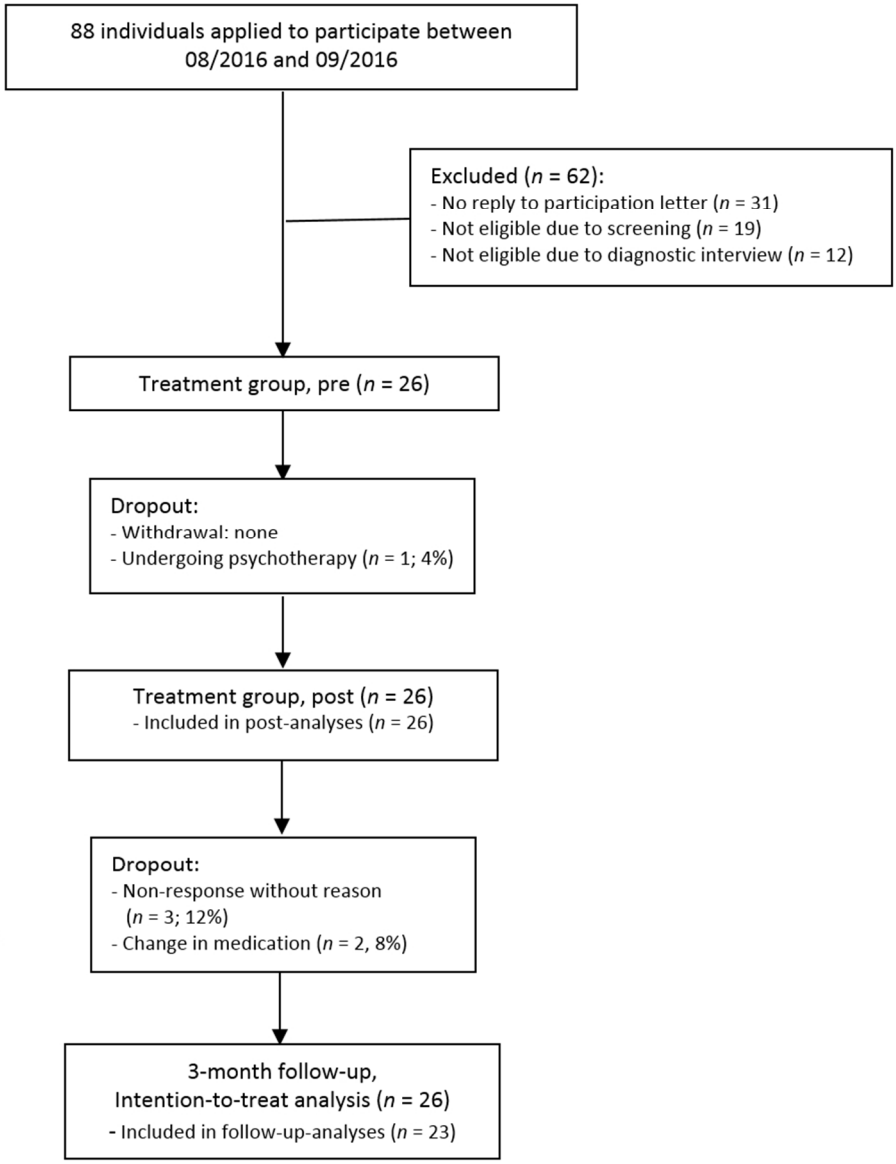
Top 10 ranking of subjectively perceived active treatment factors (N = 26).

Rank	Treatment factor	*n counts*	*% of all participants*
1.	Weekly lecutures	23	89
2.	Increase of positive thoughts	20	77
3.	Restructuring of negative thoughts	19	73
4.	Computer and multimedia use	18	69
4.	Trainer (social and professional skills)	18	69
6.	Group (coherence and interpersonal learning)	17	65
6.	Positive activities	17	65
8.	Reflexion	16	62
9.	Mindfulness exercises	14	54
9.	Exercises on resources and strengths	14	54

Note: *n counts* = number of counts associated with a specific treatment factor; *% of all participants* = proportion of all participants

Figure legend:

Figure 1. Study's flow chart


88 individuals applied to participate between 08/2016 and 09/2016
Excluded (n = 62):
- No reply to participation letter (n = 31)
- Not eligible due to screening (n = 19)
- Not eligible due to diagnostic interview (n = 12)
Treatment group, pre (n = 26)
Dropout:
- Withdrawal: none
- Undergoing psychotherapy (n = 1; 4%)
Treatment group, post (n = 26)
- Included in post-analyses (n = 26)
Dropout:
- Non-response without reason (n = 3; 12%)
- Change in medication (n = 2, 8%)
3-month follow-up, Intention-to-treat analysis (n = 26)
- Included in follow-up-analyses (n = 23)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	uncontrolled
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	yes, page 2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	yes, page 4
	2b	Specific objectives or hypotheses	yes, page 5&6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	no, one-armed
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	yes, page 6&7
	4b	Settings and locations where the data were collected	yes, page 6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	yes, page 6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	yes, page7&8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	yes, page 9
	7b	When applicable, explanation of any interim analyses and stopping guidelines	none
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	none
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	none
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	none
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	none

		assessing outcomes) and how	none
	11b	If relevant, description of the similarity of interventions	none
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	yes, page 8&9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	none
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	yes, page 9&21
	13b	For each group, losses and exclusions after randomisation, together with reasons	yes, page 9&21
Recruitment	14a	Dates defining the periods of recruitment and follow-up	yes, page 9&21
	14b	Why the trial ended or was stopped	yes, page 6/7
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	yes, page 9&22
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	yes, page 9&22
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	yes, page 9&22
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	none
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	none
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	yes, page 9
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	yes, page 13
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	yes, page 13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	yes, page 11-13
Other information			
Registration	23	Registration number and name of trial registry	yes, page 6
Protocol	24	Where the full trial protocol can be accessed, if available	yes, page 6
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	yes, page 13

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

BMJ Open

Feasibility of a blended group intervention (bGT) for major depression: Uncontrolled interventional study in a university setting

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Feasibility of a blended group intervention (bGT) for major depression: Uncontrolled interventional study in a university setting

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Abstract

Objective: This study investigated the feasibility of a novel blended (face-to-face and computer-based) group intervention for the reduction of depressive symptoms in major depression.

Design: Patient-centred uncontrolled interventional study.

Setting: University setting in a general community sample. A multi-modal recruitment strategy (public health centres and public areas) was applied.

Participants: Based on independent interviews, 26 participants, diagnosed with major depressive disorder (81 % female; 23 % comorbidity > 1, 23 % comorbidity > 2), entered treatment.

Intervention: Acceptance and mindfulness-based, as well as self-management and resource-oriented psychotherapy principles served as the theoretical basis for the low-threshold intervention. The blended format included face-to-face sessions, complemented with multimedia presentations and a platform featuring videos, online work sheets, an unguided group-chat, as well as remote therapist-patient communication.

Main outcome measures: The Center for Epidemiological Studies-Depression scale (CES-D) and the twelve-item General Health Questionnaire (GHQ-12).

Results: Large to very large within group effect sizes were found on self-reported depression ($F_{(2, 46.37)}$= 25.69, p < .001; d = 1.80), general health ($F_{(2,46.73)}$= 11.47, p < .001; d = 1.32), personal resources ($F_{(2,43.36)}$= 21.17, p < .001; d = 0.90) and mindfulness ($F_{(2,46.22)}$= 9.40, p < .001; d = 1.12) after a follow-up period of three months. Treatment satisfaction was high and 69 % ranked computer and multimedia use as a therapeutic factor. Furthermore, participants described treatment intensification as important advantage of the blended format. Half of patients (48 %) would have preferred more time for personal exchange.

Conclusion: The investigated blended group format seems feasible for the reduction of depressive symptoms in major depression. The development of blended interventions can benefit from assuring that highly structured treatments actually meet patients' needs. As a next step, the intervention should be tested in comparative trials in routine care.

Trial registration: DRKS-ID: DRKS00010894

Strengths and limitations of this study

- This is the first clinical study on blended group therapy (bGT) for major depression. This innovative intervention combines two low intensity psychosocial interventions, recommended by the National Institute for Health and Care Excellence.
- Participant selection was based on a multi-modal recruitment strategy and comorbidity was high. Data on adverse effects are provided.
- This is the first study to apply standardised measures of client satisfaction and system usability in bGT. Additionally, it provides a detailed view on participants' appraisals of the new format.
- The study entails a conceptual replication of previous findings on subjectively perceived therapeutic factors.
- The uncontrolled study-design and the university setting restrict the interpretability of results.

DATA SHARING STATEMENT

We also assessed 5 short scales at pre-measurement. These short scales will be accumulated over different studies and serve as moderators of treatment success and online user behaviour. All data can be obtained by contacting the first or the last author of this study and will be readily shared.

CONTRIBUTOR SHIP STATEMENT

Raphael Schuster:	design, acquisition, analysis, drafting, revising
Verena Sparr:	acquisition, analysis
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Anton-Rupert Laireiter:	design, drafting and revising

1. Introduction

Depression presents a relevant public health concern and imposes high costs on society as well as on health systems [1]. Therefore, research priorities include health policy and system research, in particular, how to deliver cost-effective interventions in a low-resource context [2, 3]. Psychological online interventions have been found effective in reducing common mental health disorders, e.g. depression [4] and anxiety [5], in such low-resource contexts.

Online interventions offer many advantages; they can provide access to evidence-based treatments and patients can work through the intervention whenever they want [6]. Usually anonymity is preserved as patients participate at distance, resulting in low social barriers and low risk of stigmatization [7]. From a health suppliers perspective online interventions guarantee standardized treatments and show good scalability, which has led to the launch of the first online clinics [8, 9]. Internet-based interventions can also help with bridging waiting times [10] or enhance treatment effects during aftercare [11]. At the same time, online interventions do not fit all patients' needs (e.g. need for more personal contact or diverging preferences). Consequently, classical face-to-face therapy will remain an important basis of mental health care. That being said, tools and methods developed in online therapy can be integrated into various forms of face-to-face therapy [12].

Due to the variety of possible combinations it remains difficult to define blended interventions concisely. Van der Vaart and colleagues [13] describe blended therapy as "[…] *a combination of online and face-to-face therapy, in which online sessions replace or substitute some (parts) of the sessions with a health professional* […]. According to Kooistra and colleagues [14], the combination of both intervention strategies should merge into one integrated treatment format. In our study's context, new media was also used as a supportive in-session tool (e.g. multimedia presentations and videos). Thus, we define blended therapy as an integrated combination of face-to-face sessions with computer or app support. It aims at improving the delivery of evidence-based therapy methods and results in a possible acceleration or intensification of treatment. The online part of blended interventions often entails psychoeducation, online exercises and remote therapist feedback on accomplished exercises, as well as mobile diaries or monitoring [15]. Interventions are usually delivered via online platforms [16] or applications for mobile phones [17].

Blended therapy is at an early stage of research - even though first studies date back to the 1980s and 1990s [18-20]. At that time, computer support had been found to be useful in the treatment of depression, anxiety or obsessive compulsive disorders [20]. However, these early studies do not adequately account for the rapid development modern technologies have undergone, and user-behaviour has changed dramatically since then. When examining more recent literature, good ac-

ceptability and compatibility with standard treatments are found [21]. Additionally, computer-assisted programs may well shorten treatment duration while maintaining observed treatment effects [22]. In Europe, research on blended therapy currently is on the rise, as a multicentre study (E-COMPARED) investigates possible time savings in routine care [23]. From a therapy process perspective, Månsson and colleagues [16] suggest that blended interventions could foster adherence to evidence based treatment rationales, because the structure provided by blended therapy might prevent therapists from so called therapist drift [24]. Regarding implementation of blended therapy, the Netherlands seem to be Europe's most promotive nation [25]. According to Netherlands' leading software provider (Minddistrict) more than 17.000 professionals and 120.000 patients are currently using some of their blended services [26].

With little exceptions, research on blended interventions has its primary focus on individual therapy and little is known about the potential for group treatments. As it is a recommended treatment in health guidelines and national health policies [27, 28], group therapy has various applications in in- and outpatient clinics [29]. For example, the National Institute for Health and Care Excellence [30] recommends group cognitive behavioural therapy (CBT) for people with mild to moderate depression who decline other low intensity psychosocial interventions, such as computerized cognitive behavioural therapy (cCBT). Therefore, the integration of computer support and face-to-face group sessions might result in an optimized treatment, in which personal contact is preserved. Existing blended group therapy (bGT) studies reveal high acceptability for the treatment of anxiety disorders and suggest possible savings of therapist time [31-33]. To achieve savings, typical standard treatments (12 – 14 session) are shortened by 33 - 57 % (6 – 8 sessions). Apart from potential savings, bGT allows new ways of therapist-to-client and client-to-client interaction, such as online supervision of homework tasks or gamification [34].

Literature on bGT for depression remains scarce, as there do not exist any published articles prior to our first proof-of-concept study [35]. Due to the demand for low-threshold treatments [36], we designed a CBT-based psychoeducational intervention entailing principles of resource-oriented psychotherapy and self-management therapy. Resource-oriented psychotherapy focuses on current concerns and tries to strengthen personal skills in order to achieve set goals [37]. Self-management therapy has a long tradition in the treatment of depression [38], and elements such as behavioural goal setting or activity monitoring are frequently applied in blended interventions [39, 40]. Finally, psychoeducational cognitive behavioural group therapy has recently been applied in a stepped care service model [41] within the *Improving Access to Psychological Therapies* (IAPT) programme. In our first study [35], high treatment effects were observed in an adult sample, exhibiting a variety of unspecified depressive symptoms. Further, participants rated online and multimedia elements as equally

relevant as group experience or specific CBT techniques. In an open evaluation, 25 % freely described online and multimedia support as a therapeutic factor. However, the absence of a systematic diagnostic procedure and the lack of standardised measures (e.g. client satisfaction and system usability) restrict the generalisability of findings.

The present study addresses these limitations by applying the developed blended group intervention to a sample of clinically depressed adults, and by evaluating its usefulness in a more structured and standardized way. Moreover, we analysed system usage and corresponding changes over the course of time. Lastly, the study provides a detailed view on participants' appraisals of the new format.

2. Methods

2.1 Procedure

The clinical one-arm interventional study was approved by the local ethics committee (Ethical Review Board, University of Vienna, Ref-Nr:00194) and registered at the German clinical trial register (DRKS-ID: DRKS00010894). Eligible persons were called and informed consent was obtained verbally by two independent interviewers. Subsequently, the complete Mini-DIPS was applied for study in- or exclusion [42]. The Mini-DIPS is a 30-minute short version of the German DIPS (Diagnostic Interview for Psychological Disorders) [43], based on ICD-10 depression criteria. Ten days before the intervention started, eligible participants (N = 26) were required to complete an online questionnaire of self-report measures. Sessions were held in a double trainer format by two trained and supervised psychologists (VS & IL), both in the final year of their Master studies of clinical psychology. Both trainers had prior experience with conducting group therapy in clinical settings. Sessions took place in a specially equipped seminar room at the University of Vienna, Faculty of Psychology (Department of Applied Psychology: Health, Development and Promotion). At the beginning of the first group session, written informed consent was signed by all participants. One week after the intervention ended, an online post-evaluation questionnaire was completed and follow-up data was obtained three months later.

2.2 Intervention

The treatment comprised a 7-week intensive CBT-based psychoeducation and self-management group intervention, in which personal sessions (90 minutes) alternated with online exercises and remote therapist feedback. CBT-based key techniques eclectically entailed mindfulness, acceptance and commitment therapy, cognitive strategies for negative thoughts, as well as a special emphasis on time- and self-management, and minor elements of positive psychology. The intervention focused on the reduction of depressive symptoms and aimed at increasing personal resources and self-management abilities. We carefully regarded best practice guidelines for empirically supported CBT

group treatments of depression (e.g. psychoeducation, behavioural goal setting, cognitive restructuring, relapse prevention, and double trainer setting) during the design of the intervention [44]. Online modules were made accessible via a secure web-based non-profit environment (Moodle with SSL-VPN access), featuring videos, online work sheets, an unguided group-chat, as well as remote therapist-patient communication. Accomplishing one online session took approximately 50 - 70 minutes (34 minutes of weekly videos included). The platform automatically tracked personal log data for each participant and week. Group sessions were supported by multimedia, e.g. psychoeducational short clips and PowerPoint presentations. Participants were also able to logon the platform after the group sessions had ended. The basic intervention is described comprehensively in our preceding study [35]. Improvements are in regards to the psychoeducation section and the weekly diary as well as putting more emphasis on cognitive restructuring techniques. Detailed information on weekly modules is presented in *Table 1*.

2.3 Participant recruitment and selection

The study was advertised online (e.g. www.depression.at) and by handing out flyers in public health centres and populated public areas, such as urban pedestrian areas in Vienna. All those interested were invited to visit the study webpage and to fill out an online participation form. Recruitment ended after sufficient participants had been acquired.

Inclusion and exclusion criteria

Two independent psychologists with clinical experience conducted the diagnostic interviews. Participants aged between 18 – 65, familiar with the use of personal computers and suffering from mild to moderate levels of major depression and/or dysthymia and/or mild to moderate comorbid anxiety were eligible for the study. According to clinical judgement, participants were excluded if they suffered from severe depression (≥ 7 criteria, including main symptoms), severe anxiety disorder, bipolar disorder, schizoaffective disorder, severe psychiatric and psychotic conditions, substance abuse, suicidal ideation, or if they exhibited low German-language and/or computer skills. Participants were also excluded if they were currently undergoing psychotherapy. Psychiatric medication was tolerated, but had to be kept constant for at least three months prior to study onset. *Figure 1* presents the flowchart, demonstrating the recruitment and research procedure in detail.

2.4 Measures

2.4.1 Primary outcome

The primary outcome, reduction of depressed mood, was measured by the short form of the German translation of the CES-D, Center for Epidemiological Studies-Depression scale [45]. This questionnaire

assesses depression associated emotions and motor functions, as well as interactive, cognitive and somatic symptoms on a 16-item 4-step Likert-scale. Higher scores indicate higher levels of depression and the German version's cut-off value (CES-D > 17) has high discriminative validity [45]. The reliability of the CES-D has been shown to be excellent [46]. Cronbach's alpha in the present study was .84.

2.4.2 Secondary outcome measures

The General Health Questionnaire (GHQ-12) [47] was selected to assess the degree of self-reported psychological distress. Items are rated on a 4-step bi-modal scale (0-0-1-1) with higher scores indicating higher levels of psychological distress. The GHQ-12 has shown satisfactory reliability [48] and good intercultural validity [49]. A cut-off of > 1 served as a conservative measure with highest sensitivity and specificity in literature [50]. Cronbach´s alpha was .83.

The German "Fragebogen zur Erfassung von Ressourcen und Selbstmanagementfähigkeiten – Gesamtressourcen" (FERUS, Questionnaire for the Assessment of Resources and Self-Management Abilities – common resources) [51], consisting of the subscales "coping", "self-awareness", "self-efficacy", "self-verbalisation", and "hope" (44 items, 7-point Likert-scales), was applied for the assessment of personal resources. Higher scores represent higher levels of self-rated personal resources. In the present study Cronbach's alpha of the total resources was .95.

The Mindful Attention Awareness Scale (MAAS) [52] assesses the frequency of mindful states, with higher levels indicating greater mindful awareness (15 items, 6-point Likert scale). We used a 6-item short version of the German MAAS [53] and Cronbach´s alpha in the present study was .83.

2.4.3 Client satisfaction and system usability

Usability of online and multimedia elements was assessed by the System Usability Scale (SUS) [54]. The SUS is a technology-neutral robust tool for assessing the quality of a given user interface. Empirically derived cut-off scores are graded from SUS > 85.5 (excellent usability) to SUS >71.4 (good usability) and SUS > 50.9 (acceptable usability) on a 10-item 5-point Likert scale [55]. Cronbach's alpha for the current sample was .85.

Participants' overall satisfaction with the treatment was measured by the German version (ZUF-8) [56] of the Client Satisfaction Questionnaire (CSQ-8) [57]. This widely used questionnaire addresses several aspects of service satisfaction and is based on an 8-item 4-point Likert scale. In this study Cronbach´s alpha was .88.

2.4.4 Appraisal of new media elements, applicability and process aspects

Appraisal of new media elements, applicability, and process aspects of the intervention were assessed by a self-designed questionnaire (55 items) at post-treatment. The questionnaire comprised 9 items on intervention elements, 6 items on specific functions (e.g. online platform), 6 items on satisfaction and perceived efficacy of the intervention, one ranking of perceived therapeutic factors [35], 16 items on optimal blend, intensity and duration [13], 9 items on mode of delivery (face-to-face or online) [13], and 8 items on perceived (dis-)advantages of blended therapy.

2.5 Statistical Analyses

Statistical analyses were carried out using SPSS 24 [58]. Significant pre- to follow-up changes were analysed by linear mixed models (LMM), with restricted maximum likelihood estimation (REML) and compound symmetry as covariance type. Missing values on outcome measures were analysed in agreement with the intention to treat principle (ITT). Individual pre- to follow-up differences served as basis for the reliable change indexes (RCI) [59] and we used internal consistency as a measure for RCI reliability [60], resulting in a reliable change criterion of 7.22 scale points for the CES-D and 2.62 scale points for the GHQ-12. Additionally, participants were deemed to have undergone clinically significant improvement (CSI) when simultaneously exhibiting reliable change and scoring below CES-D or GHQ-12 post measurement cut-off (CES-D ≤ 17; GHQ-12 > 1). Within-group effect sizes were calculated with pooled standard deviation and reported in Cohen's *d* [61]. Power analysis was carried out using G*Power [62], resulting in an estimated sample size of $N = 22$, for a conservative medium within-subjects effect size of $d = 0.65$ (alpha-error $\alpha = .05$, power $\beta = .90$). Differences in appraisals of intervention elements (section 3.3.1) were calculated by t-tests (comparing against grand average), and for intervention applicability (Questions 2 and 3 in section 3.3.2) and process aspects (section 3.3.3) paired t-tests were applied.

3. Results

3.1 Sample characteristics

There were no dropouts during the treatment period, but three participants did not fill out the follow-up evaluation. Two patients reported changes in medication and one patient commenced psychotherapy. According to ITT-principles, those patients remained in the analyses. According to the CONSORT guidelines, detailed information on participants' flow can be gained from *Figure 1*. Women constituted the majority of the sample (81 %) and education was high (54 % tertiary education). Participants' age ranged from 23 to 51 ($M = 33.9$, $SD = 7.5$). A comprehensive overview of participant characteristics can be gained from *Table 2*.

3.2.1 Primary and secondary outcome measures

All outcome measures indicated significant changes and effect sizes were large to very large (see *Table 3*). For the primary outcome measure CES-D, a statistically significant reduction of self-reported depressive symptoms was found, F-value of $F_{(2, 46.37)} = 25.69$, $p < .001$. Regarding secondary outcome measures, self-reported psychological distress, assessed by the GHQ-12, significantly decreased $F_{(2,46.73)} = 11.47$, $p < .001$. Furthermore, personal resources (FERUS) significantly increased, $F_{(2,43.36)} = 21.17$, $p < .001$, as well as the frequency of mindful states (MAAS), $F_{(2,46.22)} = 9.40$, $p < .001$. At follow-up, a proportion of 70 % of patients exhibited clinically significant improvement (CSI) for depressive symptoms and CSI for general health was observed in 75 %. One participant deteriorated reliably (4 %). Detailed information on observed means, standard deviations, effect sizes and reliable change is depicted in *Table 3*.

3.2.2 Client satisfaction and system usability

Usability of online and multimedia elements, assessed by the System Usability Scale (SUS) [54], unveiled an average usability of 85.3 (*SD* = 14.49) on a 100-point scale. Highest quality ratings (excellent usability, SUS > 85) were given by 56 % and another 24 % of participants rated the platform usability as "good" (SUS > 72). One participant (4 %) rated the usability as "low" (SUS < 51). Clients´ service satisfaction was measured by the Client Satisfaction Questionnaire (CSQ-8) [57], and average satisfaction was 27.4 *(SD* = 3.9) of 32 possible scale points, indicating "good" client satisfaction. On item-level (*M* = 3.43), an average rating of 3 indicates clients being "somewhat satisfied" and a rating of 4 scale points translates into "very satisfied". Here, 84 % of participants gave ratings ≥ 3 scale points.

3.3 Appraisal of new media elements, applicability and process aspects

To explore participants' retrospective perception of new media elements, as well as applicability and process aspects of the blended format, an additional self-designed questionnaire was applied.

3.3.1 Appraisal of new media elements and usage data

The results in *Table 4* show that computer and multimedia support were generally described as helpful (*M* = 5.16 on 6-step Likert-type scale). Almost half of the participants described in-session multimedia use, between-session communication with the therapist, weekly psychoeducational videos and the online platform as very helpful, whilst a smaller proportion found them of little or no help. Interestingly, participants described group interaction as marginally less relevant compared to computer and multimedia. However, the only clear deviation from average was a lower rating for the unguided discussion forum. *Table 4* also provides descriptive statistics on logins and downloads, where a continuous decrease in activity can be identified over the course of the treatment.

3.3.2 Applicability of the blended intervention

Table 5 depicts participants´ appraisals of the blended format and the influence of computer support on therapeutic process aspects in general, as well as preferred treatment duration. The majority (84 %) stated that they would not leave out computer support and that this support has the potential to improve (80 %) and intensify group therapy (72 %). For our participants, blending best fitted the needs of training-alike groups. Here 96 % agreed, that blended interventions could help improve and intensify (88 %) existing rationales. The applicability-rating of blended interventions for individual therapy was clearly less positive (48 %), while prior therapy experience (54%) did not predict this appraisal (r = 0.116, p = 0.580). With a median of 12 - 15 sessions, preferred treatment duration was 50 % - 100 % higher than the actual treatment duration (7 weeks).

3.3.3 Process aspects

Statements on process aspects of the intervention entailed issues regarding perceived flexibility, structure, information, and group interaction (*Table 5*). A small proportion of investigated participants perceived applied computer and multimedia support as restricting or hindering (16 – 20 %). With a proportion of one quarter to one third, a group of indecisive participants existed. 48 % of participants expressed a desire for more group interaction and discussion time. In the ranking of subjectively perceived therapeutic factors, 69 % of participants (rank 4 of 21) described in- and intersession computer and multimedia use as an important therapeutic factor (*Table 6*).

4. Discussion

This feasibility study presents a user-centred evaluation of a recently developed blended group intervention for the reduction of depressive symptoms in major depression. Results indicate a high fit between psychological groups and blended components in terms of client satisfaction, system usability, and the perceived relevancy of supportive computer and multimedia elements. Besides the standardised assessment of system usability and client satisfaction, the study entails a detailed view on blended elements, including possible improvements.

Corresponding primary outcome measures of the study indicate substantial effects on self-reported depressive symptoms and on general health. Compared to other psychoeducational group CBT interventions [41], observed reductions of self-reported depressiveness and rates of clinically significant improvement can be classified as high. According to resource-oriented psychotherapy principles [39, 51], participants also reported strengthened personal resources and self-management abilities (section 3.2.1). Results were maintained over a 3-month follow-up period. There was no withdrawal and

only one participant deteriorated reliably (4 %). These findings support prior literature on blended therapy [16, 32], and underpin the potential of technology for psychological group interventions.

Regarding client satisfaction and system usability, participants provided positive evaluations of the investigated blended group format. For example, most patients stated that they would not leave out technology and that computer and multimedia support could help to improve existing treatments. Even though more than half of the patients had received prior therapy, the appraisal was less positive for individual therapy (cf. section 3.3.2). This finding can be explained by a possible sceptical preconception and lack of opposite experience [14]. It might also reflect patients´ perception of different requirements of the two settings. However, when compared to a concept study on blended individual therapy [40], system usability (SUS) and client satisfaction scores (CSQ-8) of the investigated group intervention were around one standard deviation above. As blended learning originates from educational groups (e.g. teaching or corporate trainings) [63], interventions with more training-alike character may be particularly feasible for computer and multimedia support. This assumption is reflected by more positive appraisals for the improvement of training-alike interventions, compared to the improvement of classical group therapy (cf. section 3.3.2). However, the positive appraisal of treatment intensification between those forms of delivery did not differ significantly.

The investigated intervention entailed a variety of different computer and online elements. The online discussion forum and remote patient-to-therapist communication have setting-specific relevancy as they open up additional pathways for client-to-client and client-to-therapist interaction in group therapy. While remote patient-to-therapist communication was easy to install and described as important, the unguided online discussion forum was of less relevance for our patients. According to positive findings in online chat group and gamification studies [34, 64], we conclude that online group interaction in blended interventions should either be guided by a therapist [65], or include other incentives to increase usage and perceived relevancy. During debriefing, some patients also explained, that their need for group interaction was satisfied by the weekly reunions.

Consistent with prior results, participants related in- and intersession computer and multimedia use to the therapeutic success of the intervention (*Table 6*). In our first study [35], 25 % of participants freely described computer support as a therapeutic factor. The direct ranking presented in this study yielded a notably higher proportion of agreement and can be interpreted as a conceptual replication of previous results. Additionally, treatment intensification was described as an important advantage. Results from a forthcomming qualitative article on patients' experiences with the blended group format support present findings (personal communication by Schuster, Raphael, November 2017 [66]). Regarding the interpretation, patients' appraisals might best be conceptualized as the description of a catalytic effect, which possibly fosters other established therapeutic factors, such as

imparting information [29] or motivational clarification [37]. Even though first results from comparative studies are promising [67, 68], future research has to determine, if patients' positive appraisals translate into superior effects of blended therapy in routine care. Still, from a product development perspective, patients' connection of blended elements with treatment success can be seen as an important success criterion.

Findings regarding process aspects of the blended group format revealed important patient preferences. Many currently conducted studies on blended therapy investigate possible savings of therapist time by reducing the number of sessions (23, 31-33]. From an economical point of view, potential time savings are inherently appealing for some mental health care stakeholders [25, 69]. On the other hand, short interventions might entail certain risks, such as a weakened patient-to-therapist bonding [13]. eHealth experts therefore emphasise the need for participatory research and the importance of target audience's perceptions when designing new treatments [70, 71]. As for that matter, the majority of our sample retrospectively would have preferred more group sessions (12 – 15 sessions) and half of our sample requiered more time for group interaction during each session (cf. section 3.3.2). Development and future uptake of blended interventions may therefore benefit from assuring that highly structured or time-efficient treatment strategies actually meet the expectations of addressed patients in a particular care setting.

Assessed objective usage data revealed a constant decrease of webpage logins and downloads (cf. section 3.3.1). Whether this tendency indicates a relevant reduction of motivation to persist with the intervention is unclear, as satisfaction with the intervention was high and usage patterns in the first weeks can be described in terms of exaggerated activity. For example, we provided one work sheet per week for download, but the actual number of downloads was reasonably higher. In this context, Yardley and collegues [71] critically reflect on current approaches to validly conceptualize engagement by analysing log files of system usage data. Further investigation on the significance of (dis-)continous usage data can be carried out by small studies of iterative participatory research.

Besides the promising results of the investigated intervention, several limitations need to be considered when interpreting its findings. *First*, sample size was low and the one-arm study design lacks a control condition. Thus, findings of our study have to be interpreted with limited generalization and the true magnitude of observed effects remains unclear. Also, the study design does not allow inferring the actual extent to which specific intervention elements (e.g. computer and multimedia elements) effectively contributed to the observed effects. *Second*, participating therapists (IF and VS) lacked prior experience with the blended format, but underwent preparatory training. Careful preparation and implementation as well as regular supervision seem to be critical success factors for blended interventions [72], and as some studies on online interventions show, more experience with

a given treatment can result in better outcomes [73]. *Third*, even though clinical interviews were conducted to assess participants' psychopathological status, other properties of our sample restrict generalisability. The majority of our sample was female and relatively well educated. While comparable sample properties can be found in many online studies and our recruitment was based on a multi-modal recruitment strategy [74], future research has to determine, if the investigated intervention proves feasible for less educated or older patients. *Fourth*, compared to University of Salzburg (where the intervention was developed), the institute for applied psychology lacks a fully equipped routine outpatient clinic. As a consequence, further research in routine care is needed. *Fifth*, half of our participants lacked alternative experience with other forms of (group) therapy. Those patients' appraisals should be interpreted as positive experience with the undergone treatment, in the absence of experience with possible alternatives. Additionally, the group format and the use of new media might have discouraged certain patients from participating in our study.

5. Conclusions

The present study indicates that the blended group format is feasible for the reduction of depressive symptoms in major depression. Due to their properties, psychoeducational groups with elements of self-management or behavioural activation might be particularly suitable for blending. New media can be used for in- and intersession support and from patients' perspective, treatment intensification is described as an important advantage. Future research should investigate the feasibility and benefits of blended group interventions in routine care.

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Conflict of interest

None of the authors has, or has had, any financial, personal or other relationship with people or organisations that would interfere with the interpretation and presentation of this study's findings.

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Table 1.

Group sessions and computer and multimedia elements of the intervention.

Week	Group session	Computer & multimedia elements
	Pre-assessment	Worksheet 1 Video 1
C.1	Opening and information about intervention and online platform. Psychoeducation on depression. Introduction to the current concerns concept. Instruction for current concerns diary, and relaxation.	PPT-Presentation Worksheet 2 Video 2
C.2	Discussion of homework assignments. Psychoeducation on human perception and cognitive biases. Discussion on frequent cognitive distortions. Psychoeducation on acceptance and mindfulness principles. Instruction for the "Thoughts and mindfulness" diary task.	PPT-Presentation Video 3 Mobile phone diary*
P.3	Discussion of homework assignments. Psychoeducation on human memory and learning processes. Exercise on cognitive restructuring. Introduction to "Happiness" diary and activity list.	PPT-Presentation Worksheet 3 Videos 4 & 5 Mobile phone diary*
P/A.4	Discussion of homework assignments. Psychoeducation on psychological motivation theories and goal setting, with emphasis on Vroom's VIE-theory (1964). Group exercise on "SMART" goal setting and instruction for Goal-Attainment-Scaling.	PPT-Presentation Online Goal Attainment-Scaling with feedback
	Break	
A.5	Revision of sessions 1-4. Psychoeducation on self-regulation and self-control. Group exercise on strengths and weaknesses profile. Discussion and refinement of individual goals. Instructions for weekly diary task.	PPT-Presentation Contract with myself- Worksheet 4 Mobile phone diary*
A.6	Discussion of homework assignments. Psychoeducation on time management, realistic time scheduling. Group exercise "Time-thieves". Group discussion on practical aspects of time management and prioritisation. Introduction to specific time management methods. Group exercise "Stress traffic light".	PPT-Presentation Worksheet 5 + Video 5 Mobile phone diary*
M.7	Revision of sessions 5-7. Psychoeducation on slow and problematic change patterns and handling of setbacks. Group discussion on problematic change and relapse prevention.	PPT-Presentation
	Post-assessment	

Note: Letters C to M: Treatment stages (C = contemplation, P = preparation, A = action, M = maintenance); PPT-Presentation = in-session PowerPoint presentation; Mobile phone diary* = participants were free to choose between a mobile phone diary or a handwritten diary.

Table 2.

Demographic, behavioural and clinical characteristics of the study sample at pre-treatment (N = 26).

Characteristic	Mean (*SD*) or *n (%)*
Age, mean *(SD)*	33.9 (7.5)
Gender, female, *n (%)*	21 (81)
Education, *n (%)*	
≥ 9 years (compulsory school)	3 (12)
≥ 12 years (A level)	9 (34)
≥ any tertiary education (e.g. university)	14 (54)
Employment, *n (%)*	
- full time	11 (42)
- part time	7 (27)
- currently none	8 (31)
Current psychopharmacological treatment, *n (%)*	3 (12)
Prior psychotherapeutic treatment, *n (%)*	14 (54)
Computer experience, *n (%)*	
- daily use	22 (85)
- few times a week	4 (15)
Diagnosis, *n (%)*	
Major depression (F32.0 or F32.1)	26 (100)
+ Double depression (F32.0 or F32.1 + F34.1)	4 (15)
+ Generalized anxiety disorder (F41.1)	4 (15)
+ Social anxiety disorder (F40.1)	3 (12)
+ Panic disorder (F41.0)	2 (8)
+ Specific phobia (F40.2)	2 (8)
+ Hypochondriasis (F45.2)	1 (4)
Comorbidity (participants fulfilling two or more diagnostic criteria)	12 (46)
1 comorbidity	6 (23)
≥ 2 comorbidities	6 (23)

Table 3.

Means, standard deviations, effect sizes (Cohen's d) and reliable change for primary and secondary outcomes.

		Estimated means (*SD*)			Effect sizes (estimated means)	Reliable change	
	N	Pre	Post	Follow-up	Pre- to follow-up effect size	Pre- to post RCI (CSI)	Pre- to follow-up RCI (CSI)
CES-D	26	24.58 (6.51)	14.19 (6.73)	13.28 (6.06)	1.80 [1.13 - 2.41]	69 (65)	70 (70)
GHQ-12	26	5.50 (2.25)	2.00 (3.11)	2.05 (2.94)	1.32 [0.70 – 1.89]	65 (65)	75 (75)
FERUS	26	134.54 (25.94)	156.04 (25.22)	157.52 (25.31)	0.90 [0.31 – 1.45]	--	--
MAAS	26	3.29 (0.78)	4.05 (1.01)	4.25 (0.93)	1.12 [0.52 – 1.68]	--	--

Note. Standard deviations are shown in round parentheses and 95 % confidence intervals are shown in square parentheses. CES-D: Center for Epidemiological Studies-Depression scale (cut-off > 17); GHQ-12: General Health Questionnaire (cut-off > 1); FERUS: Questionnaire for the Assessment of Resources and Strengths; MAAS: Mindful Attention Awareness Scale; RCI = reliable change index; CSI = clinically reliable improvement.

Table 4.

Appraisal of intervention elements and usage data (N = 26).

Intervention elements	Average	---	--	-	+	++	+++
New media in general	5.16	-	4	-	24	20	52
Weekly group sessions	5.40	-	-	-	16	28	56
In-session multimedia	5.08	-	4	4	12	40	40
between-session communication with therapist	5.08	-	4	4	24	20	48
Weekly psychoeducational videos	4.88	4	-	8	20	28	40
Online platform	4.8	-	8	12	12	28	40
Group interaction	4.64 $^{+}$	-	-	4	28	36	32
Discussion forum	3.52***	-	4	48	40	8	-

Usage data	OS 1	OS 2	OS 3	OS 4	OS 5	OS 6	OS 7
Average logins per week (per module)	5.0	3.4	3.6	3.2	2.7	2.5	1.8
Average downloads of work sheet / week	1.9	1.3	1.5	1.1	1.0	0.9	-
Average downloads of in-session slides / week	1.3	1.0	1.2	0.9	0.8	0.6	0.4
Average logins during follow-up period	4.5						

Note. --- not at all helpful (%), -- not helpful (%), - of little help (%), + somewhat helpful (%), ++ helpful (%), +++ very helpful (%), $^{+}$= tentatively significant, ***= highly significant, OS = online session

Table 5.

Applicability of the blended intervention and treatment process aspects (N = 26).

Applicability of the blended intervention	Yes (%)	No (%)	*p*-Value
1) Would you prefer to leave out computer and multimedia elements?	16	84	
2) Do you think technology could help to improve group trainings?	96	4	
… to improve group psychotherapy?	80 *	20	$p = 0.043$
… to improve individual psychotherapy?	48 ***	52	$p = 0.000$

3) Do you think technology could help to intensify group trainings?	88	12	
… to intensify group psychotherapy?	72	28	$p = 0.103$
4) Would you like to continue this treatment?	88	12	
5) Optimal number of group sessions (*MD*)	12-15		

Treatment process aspects	Yes (%)	Neutral (%)	No (%)
Used contents resulted in too little flexibility	16	24	60
There was too much structure	20	24	56
There was too much information	16	32	52
I'd have preferred more time for talking and exchange	48	32	20

Note. * $p < 0.05$, *** $p < 0.001$.

Table 6.

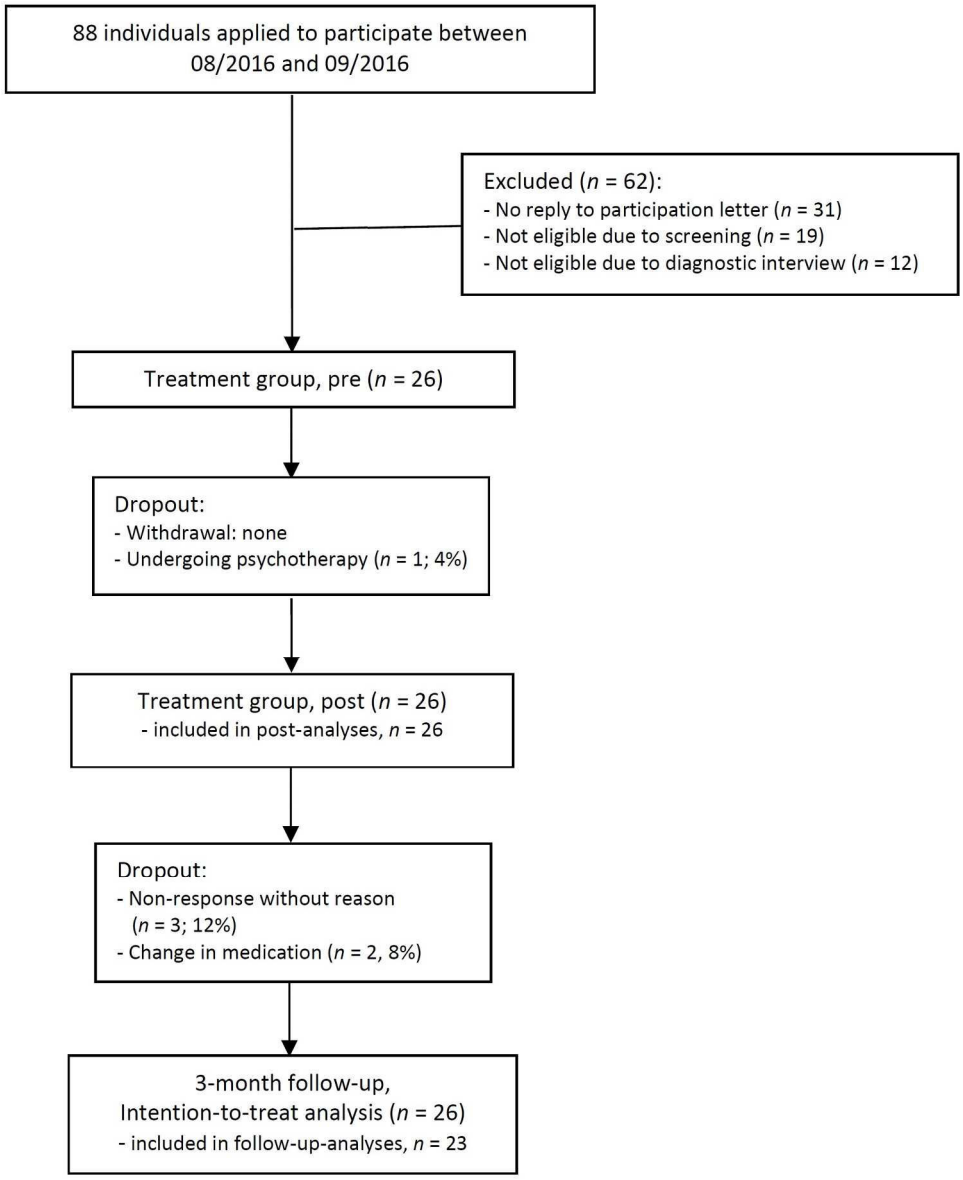
Top 10 ranking of subjectively perceived therapeutic factors (N = 26).

Rank	Therapeutic factor	*n counts*	*% of all participants*
1.	Weekly lecutures	23	89
2.	Increase of positive thoughts	20	77
3.	Restructuring of negative thoughts	19	73
4.	Computer and multimedia use	18	69
4.	Trainer (social and professional skills)	18	69
6.	Group (coherence and interpersonal learning)	17	65
6.	Positive activities	17	65
8.	Reflexion	16	62
9.	Mindfulness exercises	14	54
9.	Exercises on resources and strengths	14	54

Note: *n counts* = number of counts associated with a specific factor; *% of all participants* = proportion of all participants

Figure legend:

Figure 1. Study's flow chart



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STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-6
Objectives	3	State specific objectives, including any pre-specified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	6-7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	7 6 Not applicable
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	Not applicable
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-9
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*8-10*
Bias	9	Describe any efforts to address potential sources of bias	3, 6, 9
Study size	10	Explain how the study size was arrived at	9
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	9
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	9
		(*b*) Describe any methods used to examine subgroups and interactions	Not applicable
		(*c*) Explain how missing data were addressed	9
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	9

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	Not applicable
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	9, Fig 1
		(b) Give reasons for non-participation at each stage	9, Fig 1
		(c) Consider use of a flow diagram	Fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	21, Table 2
		(b) Indicate number of participants with missing data for each variable of interest	Not applicable
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	6, 10
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	#=4
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	-
		Cross-sectional study—Report numbers of outcome events or summary measures	-
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	22, Table 3
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not applicable
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable
Discussion			
Key results	18	Summarise key results with reference to study objectives	11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.