

Randomized Controlled Trial of Two Transdiagnostic Web-Based Interventions - REMOTION (compensation-oriented) and Res-Up! (capitalization-oriented) - in Routine Outpatient Psychotherapy: Therapy Online Plus (TOP)

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Abstract

Background: Internet-based interventions can improve treatment accessibility, prevent chronicity and reduce waiting times. Transdiagnostic approaches to such interventions may adopt one of two orientations: a compensation (COMP) focus, aimed at addressing deficits, or a capitalization (CAP) focus, which seeks harnessing individuals' existing strengths. Despite their potential, the effectiveness of transdiagnostic internet-based interventions for individuals on waiting lists and their integration into routine care remains insufficiently evaluated.

Objective: Aim of this study was to examine two transdiagnostic web-based interventions focusing on improving emotion regulation (COMP) and improving resilience (CAP) compared to a control group in individuals waiting for routine outpatient psychotherapy.

Methods: At four outpatient centers in Germany, adult participants were recruited and randomized into one of two intervention groups: "REMOTION" [COMP] and "Res-Up!" [CAP], or the control group without access to the interventions. Assessments occurred at baseline, 6-weeks post and 12-weeks follow-up. Primary outcome was symptom severity. Secondary outcomes focused on emotion regulation and resilience. Other outcomes included depressive symptoms, self-compassion and self-esteem.

Results: No significant differences were found between the intervention groups and the control group for the primary outcome symptom severity (BSI-18), while all groups significantly improved over time. Secondary outcomes for emotion regulation improvement found significant between-groups differences only in comparing REMOTION [COMP] to CG in acceptance of negative emotions (FrAGE NE). For resilience and all other outcomes, most groups improved significantly over time, but treatment groups did not differ from CG.

Conclusions: Though we were able to find significant improvements across time for the treatment groups, participants in the control group improved significantly as well. Findings for between-groups interactions show small additional benefits for participation in REMOTION [COMP] for emotion regulation compared to the CG only. The study provides information for future research concerning the effectiveness of transdiagnostic internet-based interventions during waiting times and beyond. Clinical Trial: ClinicalTrials.gov NCT04352010, International Registered Report Identifier (IRRID)

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Original Manuscript

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The trial is registered with clinicaltrials.gov (NCT04352010).

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Abstract

Background: Internet-based interventions can improve treatment accessibility, prevent chronicity and reduce waiting times. Transdiagnostic approaches to such interventions may adopt one of two orientations: a compensation (COMP) focus, aimed at addressing deficits, or a capitalization (CAP) focus, which seeks harnessing individuals' existing strengths. Despite their potential, the effectiveness of transdiagnostic internet-based interventions for individuals on waiting lists and their integration into routine care remains insufficiently evaluated.

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between-groups differences only in comparing REMOTION [COMP] to CG in acceptance of negative emotions (FrAGE NE). For resilience and all other outcomes, most groups improved significantly over time, but treatment groups did not differ from CG.

Conclusions: Though we were able to find significant improvements across time for the treatment groups, participants in the control group improved significantly as well. Findings for between-groups interactions show small additional benefits for participation in REMOTION [COMP] for emotion regulation compared to the CG only. The study provides information for future research concerning the effectiveness of transdiagnostic internet-based interventions during waiting times and beyond.

Trial Registration: ClinicalTrials.gov NCT04352010, International Registered Report Identifier (IRRID)

Keywords: rct, internet-based therapy, transdiagnostic, resilience, emotion regulation

Introduction

Approximately 1 in 6 people (17.6%) worldwide met the criteria for a mental disorder and nearly one third (29.2%) had experienced a mental disorder at some point in their life [1]. Mental health concerns and disorders have a profound negative impact on individuals affected by symptoms and, therefore, on society as a whole. Still, only 11-40% of patients receive treatment in Germany [2, 3]. The most common reasons for this are long waiting times for psychotherapy [e.g. 20.1 weeks in 2019; 4], fear of stigmatization, or barriers inherent to the type of disorder, e.g., social anxiety and suicidality [5] or depression [6]. When looking at respective psychotherapy interventions in general, a differentiation has been made between compensation-(COMP) versus capitalization-oriented (CAP) *interventions*. COMPs identify dysfunctional maintenance factors of psychopathology and teach, respectively train, the person to use new strategies or build new behavior against relative deficits, whereas CAPs aim to draw on the person's already existing strengths [7-11]. In a wide sense this includes: action repertoire, resilience strategies, and external and internal resources. While the differentiation between a COMP-and CAP-focus has implications for therapeutic interventions, research comparing COMP-and CAP-interventions is sparse and there is no agreement on which of these two strategies should mainly be pursued in psychotherapy [7, 10, 12-15].

Interventions provided via app or web are an innovative way of delivering much needed treatments [16-18]. With limited access to psychotherapy, online interventions are an economical, flexible and practical addition to conventional treatment [17]. Particularly when face-to-face psychotherapy is not available due to limited resources (like insufficient availability of therapists or fear of facing stigmatization), internet-based interventions may help to avoid long waiting times for treatment and thus mitigate the chronification of mental health problems [16]. Research on internet-based self-help interventions in psychotherapy shows effectiveness of different intervention programs for a variety of mental disorders [17, 19, 20]. Different types of internet-based interventions can function as stand-alone online programs or be conceptualized as blended treatments – the combination of face-to-face psychotherapy with online interventions [21].

Concerning internet-based interventions during waiting times for psychotherapy, a recent review of Huang, Wang [22] found only five RCTs and three uncontrolled studies focusing on depression and anxiety. While these studies showed no additional benefit for internet-based interventions compared to waiting-lists, the authors conclude that more high-quality RCTs with larger sample sizes are warranted. Especially transdiagnostic internet-based interventions might be a promising approach as they are suitable for patients with a wide spectrum of mental health problems and comorbid disorders can be addressed [23, 24]. To our knowledge, studies comparing COMP-with CAP-oriented interventions in an internet-based format do not exist. Moreover, COMP vs. CAP-oriented internet-based interventions have not been examined during wait times for psychotherapy. On the one hand, one could presume that, COMP-oriented interventions are needed during wait times to counter dysfunctional maintenance factors of psychopathology. On the other hand, one could argue that especially during waiting periods, when therapeutic support is limited, it is particularly important to activate and support a person's strengths and thus follow a CAP-oriented approach.

Thus, this randomized controlled trial explores, for the first time, the effect of two transdiagnostic web-based, provided via internet browser, interventions compared to a care-as-usual-only control group (CG). Emotion regulation (with a COMP-focus) and resilience (with a CAP-focus) were focused as transdiagnostic trainings, as both have been shown to be effective methods in psychotherapy [25].

Emotion Regulation as the Compensation-oriented Approach

The concept of emotion regulation is relevant to the treatment of a wide range of mental

health disorders [26-30]. Different definitions of emotion regulation exist in literature. According to Gross [31] emotion regulation is the process by which individuals influence which emotions they have, when they have them, and how they experience and express them. Several web-and mobile-based mental health interventions have been developed to target this construct [32, 33]. Using the extended process model of emotion regulation that differentiates between the identification, selection and implementation phases of emotion regulation as a framework [34] the web-based REMOTION intervention was developed [35]. The internet-based program used in this trial aims to improve patients' emotion regulation and thus reduce their symptom severity. The program has been tested in an outpatient psychotherapy setting in a pilot randomized controlled trial [36] and also as an add-on to acute inpatient psychiatric care in a pilot randomized controlled trial [37, 38].

Resilience as the Capitalization-oriented Approach

Resilience and resources/strengths are often discussed in the field of positive psychology [39], focusing on factors increasing health rather than decreasing symptoms. Most research on resilience aims on building new strengths [40]. However, the evidence-based Personal Model of Resilience (PMR), developed by Padesky and Mooney from a cognitive perspective [41], takes a clear capitalization-approach: The PMR emphasizes individuals' pre-existing strengths and resilient strategies, aiming to enhance awareness and utilization of these strengths. Its basic premise is that everyone possesses resilience strategies that are already part of their behavioral repertoire and can be employed in challenging situations. The PMR is grounded in evidence-based standards for cognitive behavioral therapy [42] and has proven to be helpful in several studies [43-45]. In this study, Res-Up! is implemented in the web-based version of the program as the treatment for fostering resilience in participants. The internet-based version of the PMR "Res-Up!" (Resilience program of the University of Witten/Herdecke) showed medium effect sizes in improving resilience ($d=.51-.55$) and emotional competence ($d=.51$), greater effect sizes for self-compassion ($d=.70$), and small effect sizes for self-esteem ($d=.41$) [46].

Aims

Many controlled studies have shown the efficacy of internet-based interventions. There is still limited evidence about the effectiveness of transdiagnostic approaches for internet-based interventions in routine psychotherapeutic practice and specifically their usefulness in bridging the gap between no support and the beginning of psychotherapy, especially during waiting times for therapy [22]. In this study, the *goal* was to assess the effectiveness of a compensation-oriented (REMOTION [COMP]) and a capitalization-oriented (Res-Up! [CAP]) web-based intervention in an outpatient psychotherapeutic routine setting in comparison to a control group (CG). In accordance with previous research [47], we hypothesized that both interventions were more efficacious than no additional treatment. The primary outcome targets overall symptom severity. Secondary outcomes assess improvement of resilience and emotion regulation as the specific target areas of the individual interventions, while other outcomes target depressive symptoms, self-esteem and self-compassion.

Methods

Study Design

Two web-based interventions ("REMOTION" [COMP] & "Res-Up!" [CAP]) were compared to a control group (CG) in a multi-center 3-arm randomized controlled trial. All three groups took part in the usual recruitment procedure at the outpatient centers, including a consultation session after which they were added to the waiting lists. The two treatment groups additionally received the respective web-based intervention. Participants in the intervention groups received access to the respective program immediately, whereas participants in the CG were given access to one or both

interventions of their own choice after 12 weeks, i.e. completion of the last assessment. Three assessments were conducted: baseline, after 6 weeks (post) and after 12 weeks (follow-up) for all participants. Participating centers of the trial were the outpatient clinics of the Training Center for Psychological Psychotherapy OWL (Bielefeld, Germany), the Centers for Psychotherapy Dortmund and Muenster (all training centers of the German Association for Behavior Therapy-Deutsche Gesellschaft für Verhaltenstherapie, DGVT) and the Center for Mental Health and Psychotherapy (Department of Psychology and Psychotherapy, University Witten/Herdecke, Germany).

Sample Size Calculation

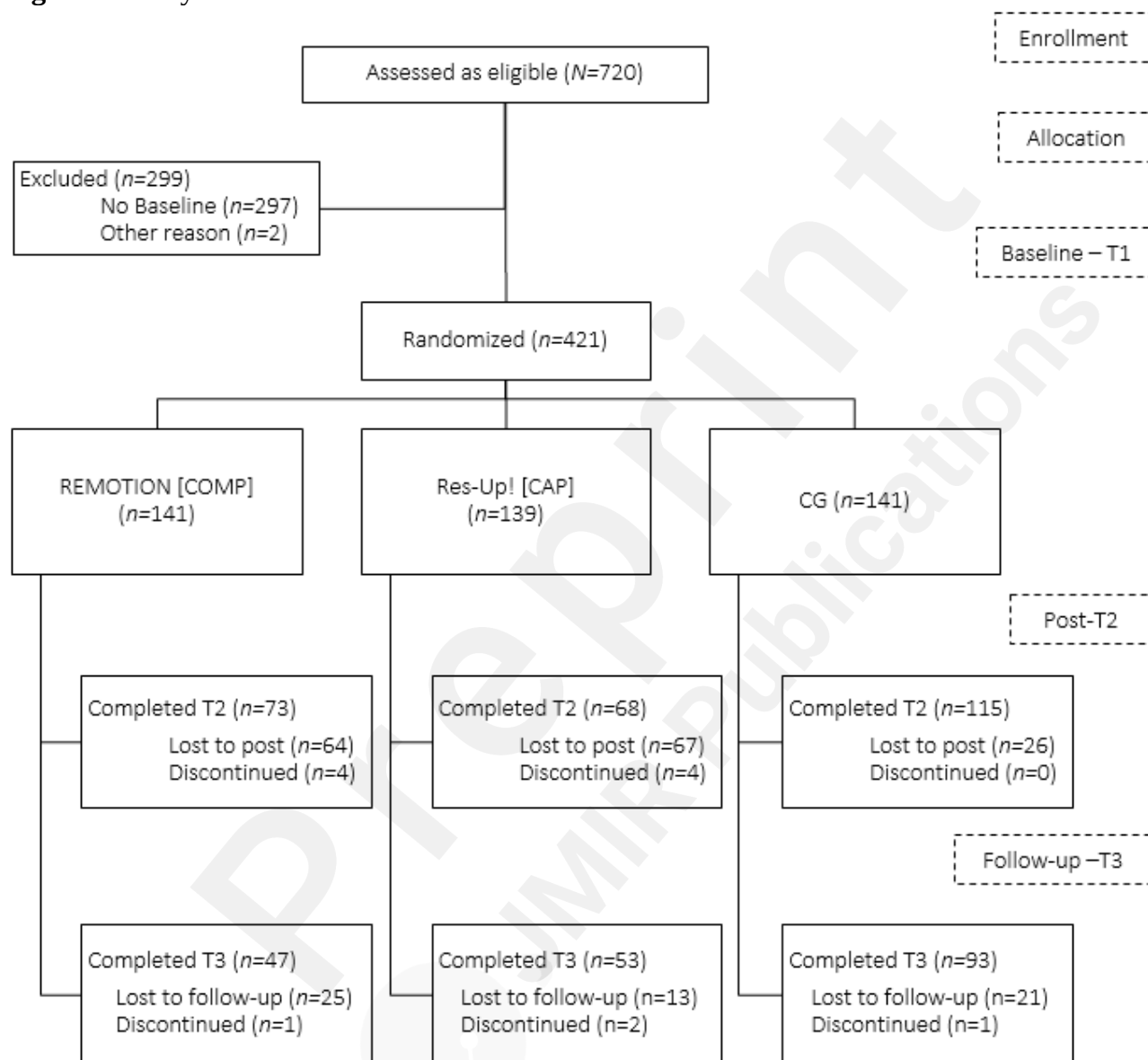
G* Power [48] was used to calculate sample size. We planned to detect small effect sizes of Cohen's $d=0.20$ (resp. Cohen's $f=0.1$) regarding the Time x Group interaction for the two active conditions compared to CG at a Bonferroni-corrected α error level of .006. According to the power analysis, a sample size of 103 participants in each of the active study arms is required to detect a statistically significant difference with a power ($1-\beta$) of .80. Results differ from the study protocol due to the previously uncorrected α level. Due to the high drop-out rate (54.3% instead of the estimated 25%), experienced already early in the study during Corona-lockdowns, sample size was increased, to allow additional per protocol analyses. Drop-out rates from online assessments are a frequently reported problem of internet-based interventions [47, 49]. We tried to accommodate for this initially, by choosing an at least minimally guided format, thus giving participants the possibility to contact the study team via text messages throughout the whole study, which should have increased adherence to the internet-based programs [50].

Recruitment, Randomization and Trial Organization

Participant recruitment and data collection started in April 2020 and ended in July 2022 (thus mostly during Corona-lockdowns in Germany). Participants were recruited during registration to regular psychotherapy in the described outpatient centers in Germany. Recruiting outpatient centers received information about the study from a member of the study team (see Trimpop et al., 2023). Information on the study and the interventions (REMOTION [COMP] and Res-Up! [CAP]) was given to interested individuals coming to the institution for a face-to-face consultation session with additional written information by trained psychotherapists at all centers. Given the long waiting times for psychotherapy in Germany (ranging from 3 months to 1.5 years), the consultation generally does not mark the beginning of psychotherapy but is scheduled to evaluate whether the person suffers from a clinically relevant psychiatric disorder, and clients are added to waiting lists for psychotherapy afterwards. All participants were required to give their informed written consent before enrollment in the study, which was solicited by the respective practitioner and handed to one specified member of the study team, including necessary information (name, birthdate, diagnoses, date of recruitment and email). After proving study eligibility, participants were sent an email from the study team with an individualized code to the baseline measure via Qualtrics [51]. Answering individual questionnaires took approximately 30 minutes at every assessment point. After baseline completion, participants were randomly assigned by a randomized computer generator [in Qualtrics; 51] to one of the three treatment arms. As completion of the interventions took approximately six weeks, post treatment measures were provided six weeks after baseline. Follow-up measures were provided to participants 12 weeks after baseline; follow-up was set this close to the post measure in order to reach participants with minimal overlap with face-to-face psychotherapy. Participants in the CG were informed that access to the programs would be granted after completing follow-up. In the experimental conditions participants received an email with their online access to either (1) REMOTION [COMP] (focusing on emotion regulation), or (2) Res-Up! [CAP] (focusing on resilience) according to their randomly assigned group. Participants were given the option to contact a member of the study team via text messages during the intervention ["guidance on demand";

"minimal human guidance"; 52], but were not actively contacted by the team (excluding: reminders to complete the interventions or questionnaires and a welcome message). Ultimately, 421 participants were randomized into 3 arms with a 1:1:1 allocation ratio (CG, REMOTION [COMP] & Res-Up! [CAP]; 141, 141, 139). Participants in the sample showed a variety of different mental disorders with varying symptom severity, which matches the transdiagnostic approach of the interventions. Figure 1 displays the flow of patients through the study.

Figure 1. Study Flow Chart



Eligibility Criteria

Inclusion criteria were (1) current diagnosis of a mental disorder according to ICD-10, (2) recruitment at one of the participating outpatient clinics listed above, (3) interest to receive psychotherapy at one of the centers, but not currently enrolled, (4) at least 18 years of age, (5) reliable internet access. Exclusion criteria were: (1) current severe episode of major depression, (2) current psychotic disorder, (3) acute suicidal tendency, (4) other severe mental disorder, e.g. current alcohol or substance abuse, current bipolar disorder, (5) insufficient German language skills. Diagnostic criteria was assessed via clinical assessment or structured clinical interview. Access to face-to-face psychotherapy after enrollment was not restricted while participants were working with the programs, mirroring naturalistic conditions.

Ethical Approval

The study was conducted according to local regulations and the Declaration of Helsinki. The study was approved by the ethics committee of the University Witten/Herdecke (no. 221/2019). Written informed consent regarding the gathered data and following analyses as well as scientific publications in an anonymous form was obtained from all patients by the recruiting therapists in outpatient centers. The trial is registered with clinicaltrials.gov (NCT04352010). Data was only analyzed in an anonymous form and de-identified by a member of the research team.

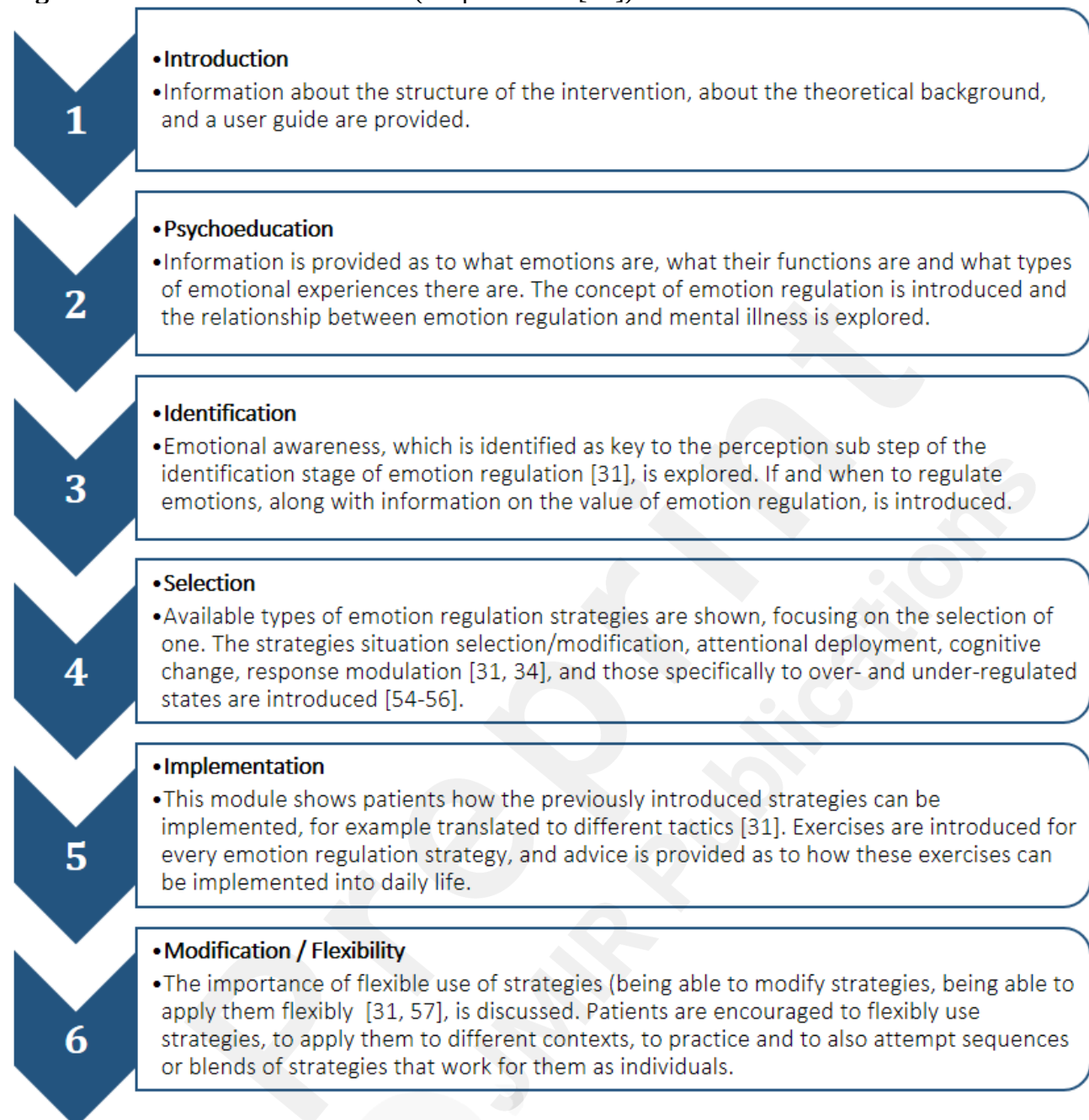
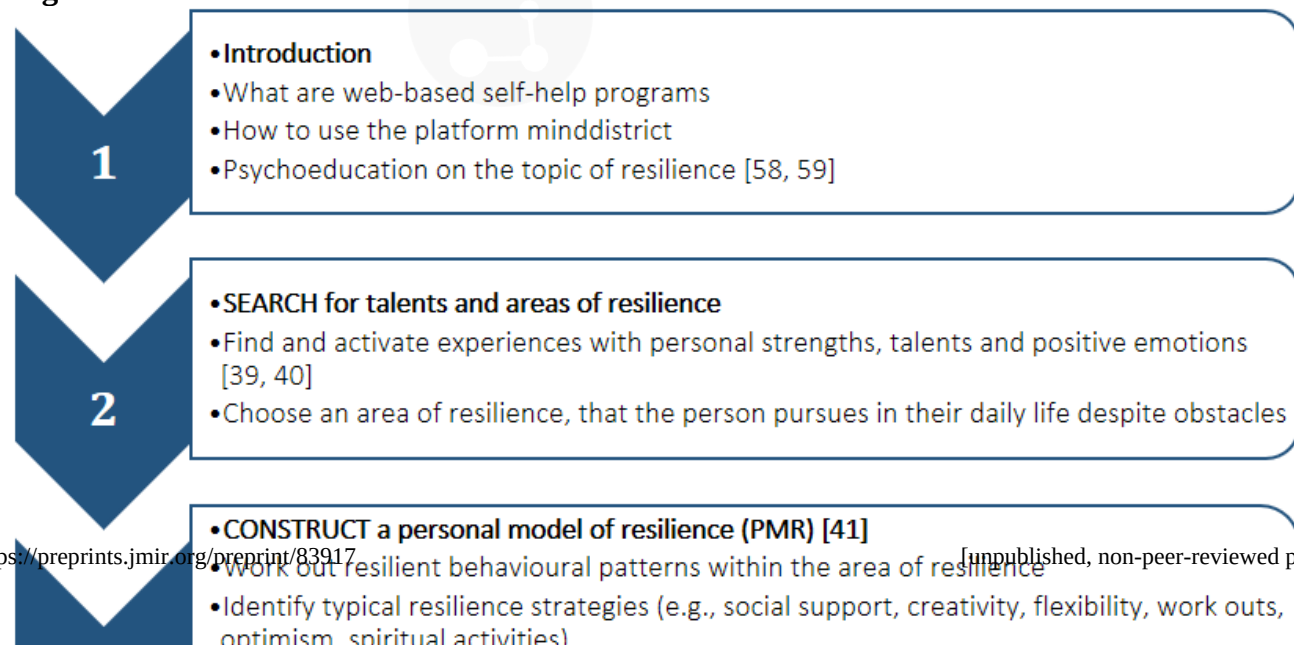
Interventions

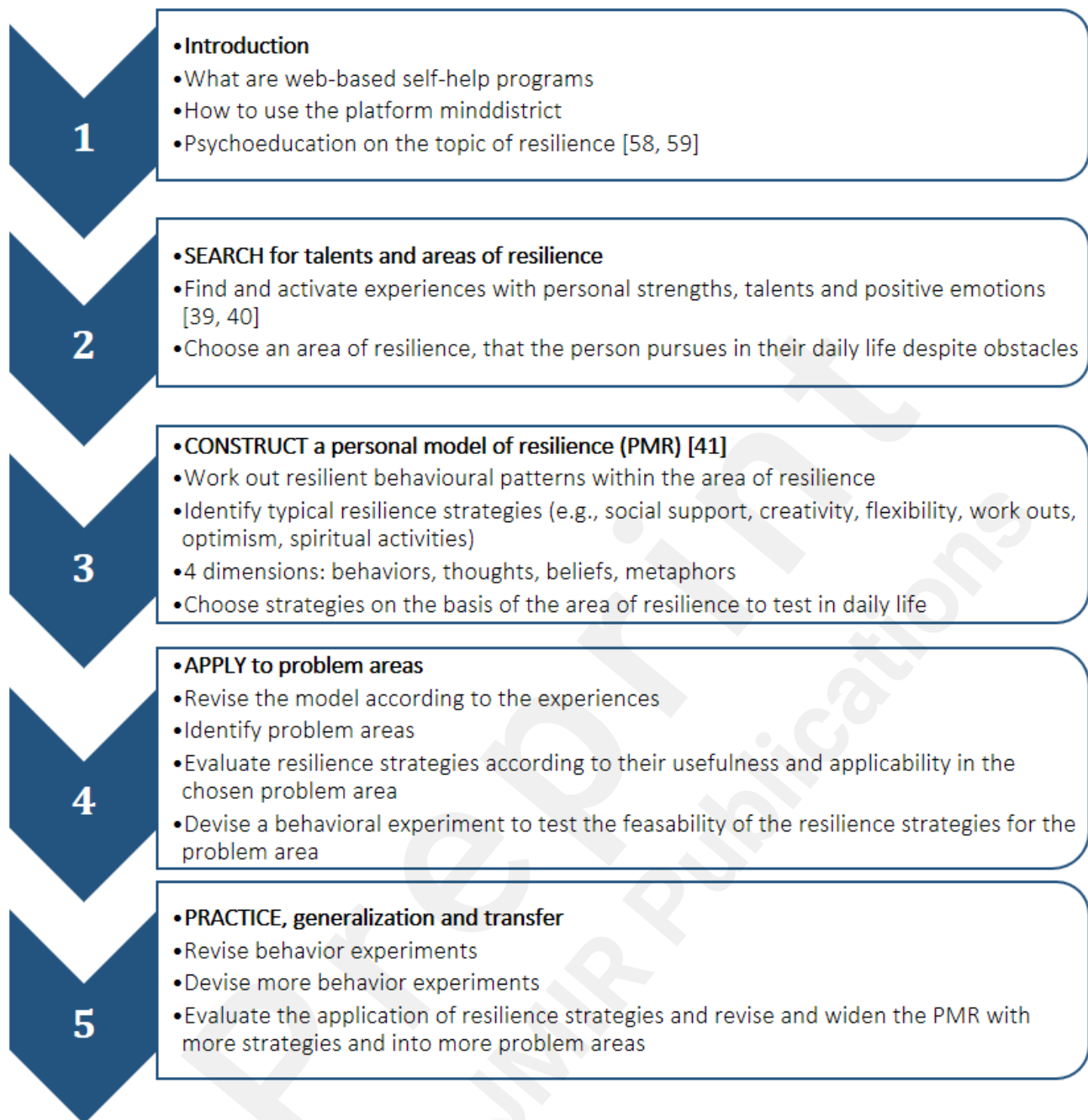
Participants of both interventions were asked to complete one module per week. A variety of psychotherapy elements (Cognitive Behavioral Therapy, Positive Therapy etc.) are integrated in the program, including video, text, and audio along with different types of exercises. Participants were reminded to continue working if they had not used the intervention for an entire week, but received no other active guidance component (like weekly emails). However, participants were able to contact the study team via text messages, if any questions occurred (guidance on demand). To increase adherence, reminder messages to complete the modules in time were sent. Completion of both programs was intended to take around 6 weeks.

REMOTION as compensation-oriented intervention. REMOTION [COMP] is a web-based intervention, password protected access is provided by the University of Bern. A detailed theoretical background for the intervention can be found in Bielinski, Krieger [35]. The goal of the intervention is to improve emotion regulation and reduce patient symptom severity. Figure 2 shows the modules and content of the intervention.

Res-Up! as capitalization-oriented intervention. Res-Up! [CAP] is a web-based intervention focusing on patients' strengths and positive experiences developed and managed at the University Witten/Herdecke (Germany) and provided via Minddistrict (www.minddistrict.de). It is based on the Personal Model of Resilience [PMR; 41], which is a positive cognitive intervention that utilizes patients' existing strengths to overcome problems. Participants work on one of five consecutive modules (see Figure 3) per week; completing a module takes about 1-2 hours. A detailed description of Res-Up! can be found in Trimpop, Bielinski [53].

Control Group (CG). Participants in the CG answered the questionnaires before randomization as well as 6, and 12 weeks later. Access to the web-based intervention of their choice was given after completing the 12-week follow-up assessment. During the waiting time, participants were allowed to stay on the wait list or start psychotherapy as they would usually.

Figure 2. Contents of REMOTION (adapted from [35])**Figure 3.** Contents of Res-Up!



Measures

Demographic information of participants was recorded at baseline and at the second and third time point (for a detailed overview see Appendix, Table A). Information concerning additional psychotherapy of participants during the course of the study was gathered at baseline, 6 weeks and 12 weeks. Participants were asked if they were currently attending psychotherapy sessions ('yes' or 'no'). Patient's diagnostic status was obtained during the initial interview by conducting a Structured Clinical Interview I (German version) for Diagnostic [60, 61] or by a clinical assessment by an experienced psychotherapist. Outcomes were gathered online via link to online self-report questionnaires based on Qualtrics software [51]. Data collection was supported by e-mail reminders. Irrespective of whether the participant started parallel face-to-face treatment or the state of completion of the program, assessments occurred at the given time points. Participants received weekly reminders via email up to a maximum of three, if they did not fill out questionnaires.

Primary Outcome Measure

General symptom severity measured with the Brief Symptom Inventory – short form [BSI-18; German version; 62, 2011] of the SCL-90-Revised [SCL-90R; 63] was the primary outcome measure. The BSI-18 consists of 18 items and is a frequently used questionnaire to measure general symptom severity, with three subscales: somatization, depression and anxiety (Cronbach's α =.85-.89) with good psychometric properties [64], comparable to those of the SCL-90R [63]. In our sample, Cronbach's α ranged from .88 to .91.

Secondary Outcome measures

Emotion regulation was assessed via the following two instruments: (1) Self-assessment of Emotion Regulation Skills [SEK-27; Fragebogen zur standardisierten Selbsteinschätzung emotionaler Kompetenzen; 65], a German 27-item self-report measure of emotion regulation skills with high reliability and validity (Cronbach's α =.90; in our sample=.93-.95). (2) Questionnaire Assessing the Acceptance of Unpleasant and Pleasant Emotions [FrAGe; Fragebogen zur Akzeptanz von Gefühlen; 66], a German 32-item self-report measure of acceptance and suppression of pleasant and unpleasant emotions with good reliability and validity. In our sample, Cronbach's α was .93-.95.

Resilience was assessed via the following two instruments: (1) Witten Strengths and Resource Form [WIRF; 67], a German 37-item self-report of personal and external strengths with high reliability (Cronbach's α =.84-.88; in our sample=.91-.94). (2) the Connor-Davidson Resilience Scale [CD-RISC-10; 68] an internationally used 10-item self-report of individual resilience with high reliability (Cronbach's α =.81-.90; in our sample=.84-.88).

Severity of depression was assessed with the German version of the Patient Health Questionnaire-9 [PHQ-9; 69]. The PHQ-9 is an internationally used 9-item self-report for screening, diagnosing, monitoring and measuring the severity of depression with a high retest reliability and validity (Cronbach's α >.86; in our sample=.81-.86).

Self-esteem was assessed with the Rosenberg-Self-Esteem Scale [RSES; 70], an internationally used 10-item self-report of general self-esteem with high reliability and validity (Cronbach's α =.72-.85; in our sample=.91-.92).

Self-compassion was assessed with the Self-Compassion Scale [SCS-D; 71], an internationally used 26-item self-report of self-compassion with high reliability and validity (Cronbach's α >.90; in our sample=.90-.93).

The *therapeutic alliance* between participants and the web-based intervention / study team was measured with an adapted version of the Working Alliance Inventory for guided internet interventions [WAI-I; 72] at the end of the intervention (6 weeks) and in the follow-up (12 weeks). The WAI-I is a 12-item self-report scale. For the purpose of this study, the term "psychologist" was substituted with the term "study team" in the questionnaire. The WAI-I has good internal consistency at total and subscale level (Cronbach's α between .92-.94; in our sample=.92-.94).

Sample characteristics

Groups did not differ concerning demographics and diagnosis, comorbidity and medication at baseline (s. Table 1). Participants showed a wide variety of mental disorders und comorbidity, with depression being the most common diagnosis (48.46%).

Table 1. Demographics of all randomized participants

Characteristics, n (%)	Entire Sample	REMOTION [COMP]	Res-Up! [CAP]	CG
Total, N/n	421	141	139	141

Age, <i>M (SD)</i>	36.50 (13.01)	35.36 (13.30)	37.55 (12.81)	36.57 (12.91)
Sex				
Female	270 (64.1)	95 (67.4)	86 (61.9)	89 (63.1)
Male	148 (35.2)	45 (31.9)	52 (37.4)	51 (36.2)
Other	3 (0.7)	1 (0.7)	1 (0.7)	1 (0.7)
	$\chi^2(4)=0.87, p=.93, \phi=0.05$			
Nationality				
German	402 (95.5)	138 (97.9)	128 (92.1)	136 (96.5)
Other	19 (4.2)	3 (2.1)	11 (7.7)	5 (3.5)
	$\chi^2(2)=4.62, p=.10, \phi=0.11$			
Relationship Status				
Single	181 (43.0)	64 (45.4)	59 (42.4)	58 (41.1)
In a relationship	198 (47.0)	64 (45.4)	65 (46.8)	69 (49.0)
Separated	42 (10.0)	13 (9.2)	15 (10.8)	14 (9.9)
	$\chi^2(4)=0.44, p=.98, \phi=0.03$			
Employment				
Employed	240 (56.9)	80 (56.7)	83 (59.7)	75 (53.2)
Unemployed	43 (10.2)	11 (7.8)	16 (11.5)	16 (11.3)
Student/In Training	106 (25.1)	34 (24.1)	30 (21.6)	43 (30.5)
No Answer	32 (7.6)	16 (11.4)	10 (7.2)	7 (5.0)
	$\chi^2(8)=10.47, p=.23, \phi=.16$			
Education				
University	156 (37.1)	58 (41.1)	45 (32.4)	53 (37.6)
Apprenticeship	128 (30.4)	40 (28.4)	47 (33.8)	41 (29.1)
Secondary school	105 (24.9)	33 (23.4)	31 (22.3)	41 (29.1)
Obligatory Education	32 (7.6)	10 (7.1)	16 (11.5)	6 (4.3)
	$\chi^2(6)=9.75, p=.19, \phi=.14$			
Medication				
Yes	127 (30.2)	83 (58.9)	89 (64.0)	77 (55.3)
No	294 (69.8)	58 (41.1)	50 (36.0)	64 (44.7)
	$\chi^2(2)=2.01, p=.37, \phi=.07$			
Comorbidity				
Yes	127 (40.9)	44 (31.2)	46 (33.1)	37 (26.2)
No	294 (59.1)	97 (68.8)	93 (66.9)	104 (73.8)
	$\chi^2(2)=1.19, p=.55, \phi=.05$			
Diagnosis				
Depressive disorder (F32, F33)	204 (48.5)	71 (50.4)	66 (47.5)	67 (48.2)
Anxiety disorder (F40, F41)	66 (15.7)	22 (15.6)	18 (12.9)	26 (18.4)
Reaction to severe	83 (19.7)	25 (17.7)	28 (20.1)	30 (20.6)

stress and adjustment
disorder (F43)

Other (e.g.>10x: F42, 68 (16.1) 23 (16.3) 27 (19.4) 17 (12.8)
F45, F50, F60)

$$\chi^2(6)=4.23, p=.65, \phi=.10$$

Note. M: Mean, SD: Standard Deviation; CG: control group; for the diagnosis, ICD-10 codes are provided

Statistical Analyses

Data was analyzed using an intention-to-treat (ITT) approach, including all randomized patients in the outcome analyses (see Figure 3). For categorical data, amount or percentage were reported. Effect sizes of all between-and within-groups for pre to follow-up changes were computed as Cohen's *d* [73], using an ITT approach unless stated otherwise. In addition, reliable change indices (RCI; Jacobson & Truax, 1991) of changes were analyzed by subtracting T1 means from T3 means of every participant, divided by the standard error of differences between the two scores of the respective (sub-)scales [74]. Scores of under 1.96 were considered as relevant decreases, above 1.96 were considered as relevant increases. Depending on the questionnaire, this will indicate improvements or reductions in the respective factors.

Effects of the intervention and control groups on the primary and secondary outcome measures across time were analyzed with multilevel models (MLMs). MLMs are recommended for ITT analyses with missing data, because of the possibility to accommodate for larger amounts of missing data without having to exclude or impute data, not depending on limited assumptions about the variance-covariance matrix. Previous research showed that the power of MLM is comparable to (or even higher than) power of ANOVA designs [75-77].

MLMs were used to observe changes in symptom severity (primary), emotion regulation and resilience (secondary), and depressive symptoms, self-esteem and self-compassion (other outcomes). Three-level models were used, considering the repeated assessments (Level 1) as nested within patients (Level 2), nested within locations (Level 3). The base Model 0 was calculated using random intercepts with fixed slopes on the patient level and no predictors were included. *Pseudo R*² was used as a measure of effect size for Level 1 [78], which represents the amount of explained Level 1 variance, i.e. amount of within-patient fluctuations in the respective main predictor, accounted for by the respective model. The intraclass correlation coefficient (ICC) was used as a measure of proportion of variance for the random effect within Level 2 and can be interpreted as the expected correlation between two randomly drawn Level 1 units within a given randomly drawn Level 2 unit [79]. The magnitude of this measure can be interpreted similar to a correlation coefficient, thus representing an effect size index [79, 80]. Model fit of competing models was compared by means of likelihood ratio tests for nested models and the Akaike Information Criterion (AIC), with smaller values indicating a better fit. Time was coded 0, 6, 12 assuming a linear trend with realistic intervals according to the measurement points at baseline, 6 weeks and 12 weeks, and included as main predictor in Model 1. Between group effects were added in Model 2 for the three arms (REMOTION [COMP], Res-Up! [CAP] and CG) to control for variance between the groups before treatment. In the final Model 3, we added the interaction time x group as main predictor, to observe possible differences in the change of the respective outcomes between the groups across time. Simple slope analyses were conducted to examine within-group changes over time for each outcome. A Bonferroni-corrected alpha level of $\alpha=.006$ was applied to adjust for multiple (nine) comparisons. Results were reported in accordance with CONSORT [s. Figure 1; Consolidated Standards of Reporting Trials; 81] and CONSORT-EHEALTH checklists [82].

Results

Descriptive statistics for all measures are displayed in Table 2. Effect sizes in Table 2 were calculated for participants with pre-and follow-up-data.

Table 2. ITT means and standard deviations across all instruments and treatment arms

	Entire Sample	REMOTION	Res-Up!	CG
BSI-18				
T1	1.29 (0.67)	1.32 (0.66)	1.28 (0.67)	1.27 (0.69)
T2	1.16 (0.70)	1.11 (0.71)	1.21 (0.70)	1.16 (0.70)
T3	1.07 (0.65)	0.95 (0.62)	1.18 (0.77)	1.07 (0.59)
Within-group ES	0.27	0.34	0.32	0.21
BSI somatization				
T1	0.87 (0.73)	0.87 (0.77)	0.91 (0.72)	0.82 (0.71)
T2	0.84 (0.73)	0.77 (0.67)	0.89 (0.76)	0.85 (0.76)
T3	0.78 (0.64)	0.67 (0.59)	0.92 (0.75)	0.76 (0.59)
Within-group ES	0.16	0.27	0.20	0.07
BSI anxiety				
T1	1.37 (0.81)	1.40 (0.80)	1.34 (0.77)	1.36 (0.87)
T2	1.23 (0.83)	1.16 (0.85)	1.28 (0.81)	1.24 (0.83)
T3	1.13 (0.75)	0.99 (0.70)	1.26 (0.87)	1.13 (0.68)
Within-group ES	0.25	0.28	0.31	0.20
BSI depression				
T1	1.63 (0.92)	1.68 (0.90)	1.58 (0.91)	1.61 (0.96)
T2	1.42 (0.92)	1.40 (0.95)	1.47 (0.87)	1.41 (0.93)
T3	1.30 (0.90)	1.20 (0.88)	1.36 (0.97)	1.31 (0.86)
Within-group ES	0.25	0.28	0.27	0.22
SEK-27-Σ (SD)				
T1	50.98 (18.27)	50.09 (17.18)	51.32 (19.85)	51.53 (17.79)
T2	53.86 (17.75)	56.93 (16.21)	51.85 (17.63)	53.21 (18.59)
T3	57.61 (20.04)	59.49 (17.84)	60.71 (21.08)	55.06 (20.34)
Within-group ES	-0.27	-0.41	-0.38	-0.15
FrAGe NE				
T1	3.07 (0.88)	2.92 (0.86)	3.14 (0.90)	3.16 (0.86)
T2	3.21 (0.79)	3.18 (0.72)	3.21 (0.91)	3.22 (0.76)
T3	3.31 (0.92)	3.36 (0.74)	3.40 (1.05)	3.24 (0.92)
Within-group ES	-0.25	-0.48	-0.39	-0.06
FrAGe PE				
T1	4.45 (1.01)	4.38 (0.99)	4.44 (1.03)	4.52 (1.00)
T2	4.41 (1.03)	4.54 (0.94)	4.34 (1.14)	4.38 (1.01)
T3	4.46 (1.05)	4.54 (1.08)	4.34 (1.13)	4.48 (0.99)
Within-group ES	-0.02	-0.11	-0.01	0.02
CD-RISC-10				
T1	1.68 (0.72)	1.65 (0.69)	1.64 (0.76)	1.75 (0.70)
T2	1.71 (0.74)	1.68 (0.79)	1.66 (0.76)	1.76 (0.69)
T3	1.86 (0.75)	1.87 (0.88)	1.84 (0.75)	1.86 (0.70)
Within-group ES	-0.21	-0.25	-0.31	-0.14
WIRF				

T1	2.78 (0.71)	2.73 (0.69)	2.74 (0.74)	2.86 (0.68)
T2	2.86 (0.72)	2.89 (0.70)	2.72 (0.80)	2.92 (0.68)
T3	2.90 (0.79)	2.84 (0.85)	2.89 (0.87)	2.95 (0.71)
Within-group ES	-0.19	-0.19	-0.29	-0.13
PHQ-9-Σ (SD)				
T1	12.67 (5.23)	12.91 (5.23)	12.69 (5.28)	12.40 (5.37)
T2	11.42 (5.50)	10.78 (5.43)	11.84 (5.08)	11.58 (5.77)
T3	10.74 (5.66)	9.76 (5.43)	11.41 (5.86)	10.82 (5.64)
Within-group ES	0.28	0.43	0.26	0.22
RSES-Σ (SD)				
T1	14.28 (7.34)	13.37 (6.87)	14.18 (7.92)	15.28 (7.14)
T2	14.66 (7.06)	14.64 (7.38)	13.91 (6.89)	15.12 (6.98)
T3	15.77 (7.20)	16.69 (6.96)	15.36 (7.74)	15.56 (7.03)
Within-group ES	0.08	0.23	0.20	-0.06
SCS-D				
T1	2.41 (0.59)	2.33 (0.59)	2.43 (0.63)	2.47 (0.55)
T2	2.44 (0.58)	2.48 (0.57)	2.41 (0.60)	2.43 (0.58)
T3	2.62 (0.66)	2.64 (0.69)	2.68 (0.69)	2.57 (0.64)
Within-group ES	0.34	0.37	0.47	0.25

Note. BSI-18: Brief Symptom Inventory-18 [62]; SEK-27: Self-assessment of Emotion Regulation Skills [65]; FrAGE: Questionnaire Assessing Acceptance of Unpleasant and Pleasant Emotions [66], PE: pleasant/positive emotions, NE: unpleasant/negative emotions; CD-RISC-10: Connor-Davidson Resilience Scale [68]; WIRF: Witten Strengths and Resource Form [67]; PHQ-9: Patient Health Questionnaire-9 [69]; RSES: Rosenberg-Self-Esteem Scale [70]; SCS-D Self-compassion Scale - German [71]; ES: effect size for the pre-post difference (Cohen's *d*); CG: control group; entire sample: $176 \geq n \leq 421$; REMOTION sample: $42 \geq n \leq 141$; Res-Up! sample: $47 \geq n \leq 139$; CG sample: $87 \geq n \leq 141$

Primary Outcome

In the first set of analyses, we examined whether the three groups differed in total scores of the primary outcome measure BSI-18 and respectively on the three subscales somatization, anxiety, and depression, within the groups and across time (s. Table 3). Simple slope analyses for time effects of symptom severity showed significant decrease over time in all three groups (all $p < .006$), except for BSI-18 somatization, which did not reach significance in any group (all $p > .006$).

Results of the MLMs showed that the largest proportion of variation in symptom severity (72.0%) could be attributed to differences between patients, while only 2% could be attributed to differences between locations. In Model 1 time was added as a predictor. Symptom severity decreased significantly across the three measurements, $b = -0.02$, $p < .001$. The model fit improved significantly, $\chi^2(1) = 36.14$, $p < .001$, resulting in a just slightly improved *pseudo-R*² of 0.01 (fixed effects) and 0.75 (total effects). For the subscales: somatization $\chi^2(1) = 7.26$, $p < .01$, n.s.; anxiety $\chi^2(2) = 29.29$, $p < .001$; depression $\chi^2(2) = 32.58$, $p < .001$. In Model 2 we added the three arms (CG, REMOTION [COMP], Res-Up! [CAP]) to analyze differences between groups. Model fit did not improve, $\chi^2(2) = 0.59$, $p = .74$, (subscales: somatization $\chi^2(2) = 0.71$, $p = .70$; anxiety $\chi^2(2) = 0.48$, $p = .79$, depression $\chi^2(2) = 1.22$, $p = .54$) suggesting that symptom severity at baseline did not differ between the three conditions. In the final model (Model 3), we examined the time x group interaction to examine whether the change in symptom severity differed between the three arms over the course of the study. Model fit did not improve significantly for the GSI ($\chi^2(2) = 1.31$, $p = .52$) or the subscales (all $p > .05$), suggesting that the change in symptom severity did not differ between the three

conditions over time. Consequently, our assumption that there is a stronger symptom reduction in the experimental conditions compared to CG was not supported by these results.

Table 3. Results of MLM analyses: Fixed and random effects of symptom severity (BSI-18)

	Model 0	Model 1	Model 2	Model 3
	<i>b</i> (SE)	<i>b</i> (SE)	<i>b</i> (SE)	<i>b</i> (SE)
Criterion: BSI-18				
Intercept	1.22*** (0.05)	1.28*** (0.06)	1.26*** (0.07)	1.24*** (0.07)
Time	/	-0.02*** (0.00)	-0.02*** (0.00)	-0.01*** (0.00)
Group				
CG	/	/	Reference	Reference
REMOTION [COMP]	/	/	0.05 (0.07)	0.08 (0.08)
Res-Up! [CAP]	/	/	0.01 (0.08)	0.02 (0.08)
TimeXGroup				
CG	/	/	/	Reference
REMOTION [COMP]	/	/	/	-0.01 (0.01)
Res-Up! [CAP]	/	/	/	-0.00 (0.01)
Pseudo-R² (fixed/total)	0.00 / 0.73	0.01 / 0.75	0.01 / 0.75	0.02 / 0.75
ICC				
Patient	0.72	0.73	0.73	0.73
Location	0.02	0.02	0.02	0.02
AIC	1411.55	1377.41***	1380.82	1383.72
Criterion: BSI-18 Somatization				
Intercept	0.84*** (0.05)	0.86*** (0.05)	0.83*** (0.07)	0.82*** (0.07)
Time	/	-0.01 (0.00)	-0.01 (0.00)	-0.00 (0.00)
Group				
CG	/	/	Reference	Reference
REMOTION [COMP]	/	/	0.03 (0.08)	0.06 (0.08)
Res-Up! [CAP]	/	/	0.07 (0.08)	0.09 (0.08)
TimeXGroup				
CG	/	/	/	Reference
REMOTION [COMP]	/	/	/	-0.01 (0.01)
Res-Up! [CAP]	/	/	/	-0.00 (0.01)
Pseudo-R² (fixed/total)	0.00 / 0.70	0.00 / 0.70	0.00 / 0.70	0.01 / 0.71
ICC				
Patient	0.69	0.69	0.69	0.69
Location	0.01	0.01	0.01	0.01
AIC	1551.66	1549.70	1549.85	1552.05
Criterion: BSI-18 Anxiety				
Intercept	1.29*** (0.06)	1.36*** (0.07)	1.35*** (0.09)	1.34*** (0.09)
Time	/	-0.02*** (0.00)	-0.02*** (0.00)	-0.02*** (0.00)
Group				
CG	/	/	Reference	Reference
REMOTION [COMP]	/	/	0.04 (0.09)	0.06 (0.09)
Res-Up! [CAP]	/	/	-0.02 (0.09)	-0.01 (0.09)
TimeXGroup				
CG	/	/	/	Reference
REMOTION [COMP]	/	/	/	-0.01 (0.01)
Res-Up! [CAP]	/	/	/	-0.00 (0.01)
Pseudo-R² (fixed/total)	0.00 / 0.70	0.01 / 0.72	0.01 / 0.72	0.01 / 0.72
ICC				
Patient	0.69	0.69	0.69	0.69
Location	0.02	0.02	0.02	0.02
AIC	1759.29	1732.00***	1735.52	1738.83
Criterion: BSI-18 Depression				
Intercept	1.53*** (0.05)	1.61*** (0.06)	1.59*** (0.08)	1.58*** (0.09)
Time	/	-0.02*** (0.00)	-0.02*** (0.00)	-0.02*** (0.01)

Group				
CG	/	/	Reference	Reference
REMOTION [COMP]	/	/	0.08 (0.10)	0.10 (0.11)
Res-Up! [CAP]	/	/	-0.03 (0.10)	-0.02 (0.11)
TimeXGroup				
CG	/	/	/	Reference
REMOTION [COMP]	/	/	/	-0.01 (0.01)
Res-Up! [CAP]	/	/	/	-0.00 (0.01)
Pseudo-R ² (fixed/total)	0.00 / 0.70	0.01 / 0.72	0.02 / 0.72	0.02 / 0.72
ICC				
Patient	0.70	0.71	0.71	0.71
Location	0.01	0.01	0.01	0.01
AIC	2002.33	1971.75***	1974.53	1978.17

Note. Fixed effects are displayed. Significance values of AIC indicate results from a likelihood ratio test comparing the current model to the previous model. BSI-18: Brief Symptom Inventory-18 [62], CG: control group; *b*: estimate of predictor of the multilevel regression analysis, SE: Standard Error, ICC: Intraclass Correlation Coefficient, AIC: Akaike Information Criterion. * $p < .006$, *** $p < .001$

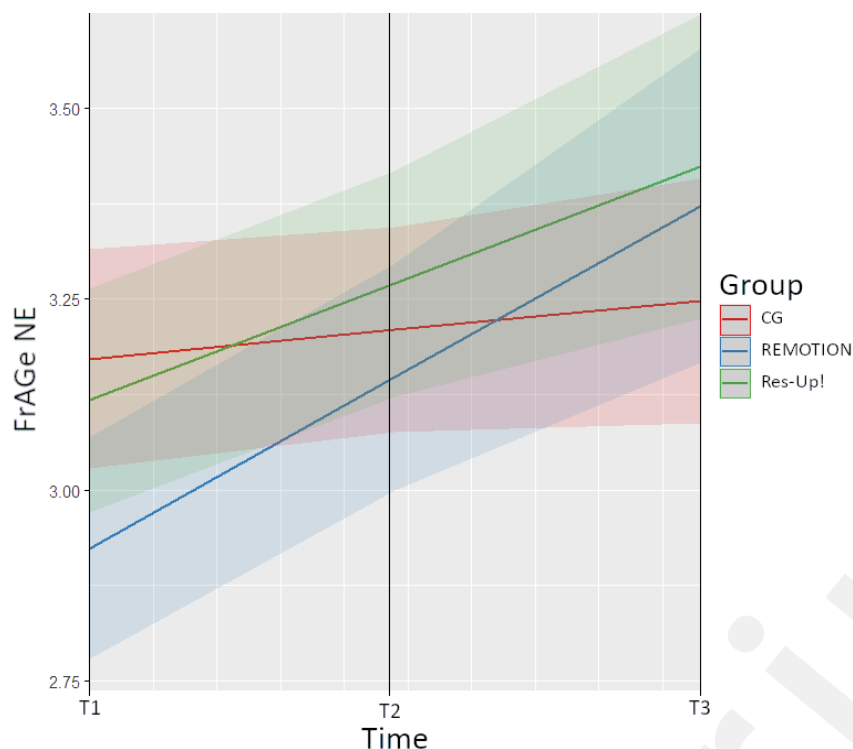
Secondary Outcomes

Emotion Regulation

For the secondary outcome analysis in emotion regulation, we examined whether the three groups differed in the SEK-27 and respectively the FrAGE scores, with the two subscales Acceptance of Negative Emotions (NE) and Acceptance of Positive Emotions (PE), within the intervention groups and across time. Simple slope analyses for time effects showed the following results: SEK-27 improved significantly over time in REMOTION ($p = .0001$) and Res-Up! ($p = .0002$), but not in the CG ($p = .05$). FrAGE NE showed significant increases in REMOTION ($p < .0001$) and Res-Up! ($p = .002$), while changes in the CG were not significant ($p = .30$). FrAGE PE did not show significant change in any group (all $p > .006$).

Results of the MLMs showed that the largest proportion of change in emotion regulation (SEK-27: 69%; FrAGE NE: 63%; PE: 79%) could be attributed to differences between patients, while no (SEK-27: 0%; FrAGE NE: 0%; FrAGE PE: 0%) variation in emotion regulation skills could be attributed to differences between locations. In Model 1 emotion regulation increased significantly for the SEK-27: $b = 0.44$, $p < .001$, and the FrAGE NE: $b = 0.02$, $p < .001$, but not for the FrAGE PE: $b = -0.01$, $p = .91$. Model fit improved significantly for the SEK-27 ($\chi^2(1) = 28.58$, $p < .001$), and the FrAGE NE ($\chi^2(1) = 21.76$, $p < .001$), but not for the FrAGE PE ($\chi^2(2) = 0.01$, $p = .91$). When adding the three conditions in Model 2 to find differences between groups, model fit did not improve for the SEK-27 ($\chi^2(2) = 0.11$, $p = .95$), the FrAGE NE ($\chi^2(2) = 3.29$, $p = .19$), or FrAGE PE ($\chi^2(2) = 0.53$, $p = .77$) suggesting that emotion regulation at baseline did not differ between the three conditions. In the final Model 3, model fit showed no significant improvement for SEK-27 ($\chi^2(2) = 5.04$, $p = .08$). There were no significant group interaction effects for (1) time x REMOTION [COMP], $b = 0.37$, $p = .06$, and (2) time x Res-Up! [CAP], $b = 0.36$, $p = .07$ when compared to time x CG. Regarding FrAGE, model fit did not improve significantly for the subscale FrAGE NE ($\chi^2(2) = 9.71$, $p = .008$), taking into account the adjusted alpha level (.006). For the FrAGE NE subscale, compared with time x CG, we found highly significant differences between time x REMOTION [COMP], $b = 0.03$, $p < .001$, but not for time x Res-Up! [CAP], $b = 0.02$, $p = .06$ groups. Model fit did not improve significantly for FrAGE PE ($\chi^2(2) = 3.22$, $p = .20$). Results for group interactions for the FrAGE PE showed no effect between time x REMOTION [COMP] ($p = .09$) or time x Res-Up! [CAP] ($p = .81$) with time x CG. Plots are depicted in Figure 4. Consequently, our assumption that there is a stronger increase in the experimental conditions is supported for emotion regulation in REMOTION [COMP] compared to CG with respect to FrAGE NE only.

Figure 4. Plot for FrAGE NE across all groups



Resilience

For the secondary outcome analysis concerning resilience, we examined whether the three groups differed in the CD-RISC-10 and the WIRF scores within the intervention groups and across time. Simple slope analyses for time effects showed the following results: CD-RISC-10 improved significantly only in the Res-Up! group ($p=.0008$). Changes in REMOTION ($p=.04$) and the control group ($p=.06$) were not statistically significant at the corrected level. WIRF improved over time in Res-Up! ($p=.02$), but this effect did not reach the corrected alpha threshold. No significant changes were found in REMOTION ($p=.05$) or the control group ($p=.12$).

Results of the MLMs showed that the largest proportion of variation in resilience (CD-RISC-10: 75%; WIRF: 68%) could be attributed to differences between patients, while the lesser to none (CD-RISC-10: 0%; WIRF: 3%) to differences between locations. In Model 1 resilience increased significantly for both CD-RISC-10: $b=0.01$, $p<.001$, and WIRF: $b=0.01$, $p<.001$. The model fit improved significantly for the CD-RISC-10 ($\chi^2(1)=17.65$, $p<.001$) and WIRF ($\chi^2(1)=11.94$, $p<.001$). In the Models 2 and 3 no significant changes or interactions could be observed for the CD-RISC-10 (Model 2: $p=.44$; Model 3: $p=.33$, interactions compared to time x CG: time x REMOTION [COMP], $b=0.00$, $p=.57$ and time x Res-Up! [CAP], $b=0.01$, $p=.13$). Model fit did not improve either for the WIRF (Model 2: $p=.20$; Model 3: $p=.60$, interactions compared to time x CG: time x REMOTION [COMP], $b=0.00$, $p=.52$ and time x Res-Up! [CAP], $b=0.01$, $p=.34$).

Other Outcomes

Depressive Symptoms, Self-Esteem, Self-Compassion

For further outcome analyses, we examined whether the three groups differed in the change of scores of the measures PHQ-9, RSES and SCS within the intervention groups and across time. Simple slope analyses for time effects showed the following results: PHQ-9 significantly decreased over time in all groups: REMOTION ($p<.0001$), Res-Up! ($p=.004$), and the control group ($p=.0008$), with all values meeting the Bonferroni-corrected significance threshold. RSES results did not meet the corrected significance threshold for REMOTION ($p=.007$) and Res-Up! ($p=.01$) and no significant change was observed in the control group ($p=.46$). SCS significantly increased across all three groups (all $p<.006$).

Results of the MLMs showed that the largest proportion of variance (PHQ-9: 70%; RSES: 81%; SCS: 77%) could be attributed to differences between patients, while less to no variation (PHQ-9: 1%; RSES: 0%; SCS: 0%) could be attributed to differences between locations. There was an overall time effect for PHQ-9 (Model 1: $\chi^2(1)=39.27$, $p<.001$), but no other effects across all models (Model 2: $p=.86$; Model 3: $p=.16$, interactions compared to time x CG: time x REMOTION [COMP], $b=-0.10$, $p=.06$ and time x Res-Up! [CAP], $b=-0.01$, $p=.84$). No effects were found, taking into account the adjusted alpha level (.006), for RSES (Model 1: $\chi^2(1)=5.32$, $p=.02$; Model 2: $p=.21$; Model 3: $\chi^2(2)=9.47$, $p=.009$, interactions compared to time x CG: time x REMOTION [COMP], $b=0.02$, $p=.009$ and time x Res-Up! [CAP], $b=0.01$, $p=.01$). Overall time effects were found for SCS ($\chi^2(1)=39.74$, $p<.001$), but no further effects or interactions (Model 2: $p=.28$; Model 3: $p=.10$, interactions: all $ps>.05$) could be found.

Face-to-face psychotherapy during the study

Both REMOTION [COMP] and CG had a higher rate of parallel regular face-to-face psychotherapy at one (intermittent) or all (two or three) of the assessments (s. Table 4). Answers were categorized as follows: "Never" – No concomitant psychotherapy during the whole study, "Intermittent" – Concomitant psychotherapy at one or two of three time points, "Continuous" – Concomitant psychotherapy at all three time points.

Table 4. Additional psychotherapy during the course of the study

Therapy, M (SD)	Entire Sample	REMOTION [COMP]	Res-Up! [CAP]	CG
Never	271 (64.3)	89 (63.2)	99 (71.2)	83 (58.8)
Intermittent	91 (21.9)	25 (17.7)	25 (18.0)	41 (29.1)
Continuous	59 (14.0)	27 (19.1)	15 (10.8)	17 (12.1)
Total, N/n	421	141	139	141
$\chi^2(4)=11.51$, $p=.02^*$, $\phi=.17$				

Note. CG: control group

Adherence to the web-based interventions

REMOTION [COMP]. Of all patients randomized to the REMOTION group, 18.4% ($n=26$; Table 5) never started the intervention despite getting access. On average, participants who logged in to REMOTION at least once, completed half of the program by the follow-up (completed modules: $M=3.04$, $SD=1.95$). A module was considered complete if all pages of the module were visited at least once.

Res-Up! [CAP]. Of all patients randomized to the Res-Up! group, 2.9% ($n=4$; Table 5) never started the intervention, despite getting access. On average, participants completed less than half of the program ($M=2.39$, $SD=1.80$). Parallel to completing post and follow-up measures, 60.4% ($n=84$) of the participants of Res-Up! dropped out after completing Module 2. Most participants, who continued after Module 2, completed the program (23.7%), rather than drop out in Module 3 (8.6%) or 4 (4.3%).

Table 5. Number of REMOTION and Res-Up! modules completed at follow-up

completed modules	n		%		cumulative %	
	REMOTION	Res-Up!	REMOTION	Res-Up!	REMOTION	Res-Up!
0	9	27	6.4	19.4	6.4	19.4
1	27	16	19.1	11.5	25.5	30.9

2	12	41	8.5	29.5	34.0	60.4
3	19	12	13.5	8.6	47.5	69.1
4	16	6	11.3	4.3	58.9	73.4
5	14	33	9.9	23.7	68.8	97.1
6	18	-	12.8	-	81.6	-
Never started	26	4	18.4	2.9	100	100.0

Note. n=141 (REMOTION), 139 (Res-Up!)

Patients' Working Alliance

Overall, patients' rating of the working alliance stayed the same for REMOTION [COMP] from T2 to T3 and improved slightly for Res-Up! [CAP] (see Appendix, Table B). No significant differences between the working alliance ratings in the REMOTION [COMP] and Res-Up! [CAP] groups were found in paired t-tests (all $ps > .05$).

Reliable Change Index (RCI)

To assess clinically significant individual-level changes, Reliable Change Index (RCI) percentages were calculated for each outcome, with thresholds set at ± 1.96 . Scores were calculated for participants with pre-and follow-up-data. For measures where improvement is indicated by symptom reduction (BSI-18 and subscales, PHQ-9), a higher proportion of participants in the CG exhibited reliable improvement compared to the intervention groups. Specifically, 8.5% of CG participants showed reliable improvement on the PHQ-9, compared to 5.7% for REMOTION [COMP] and 5.8% for Res-Up! [CAP]. Across all BSI subscales and in all groups, deterioration rates remained low, with REMOTION [COMP] generally showing the lowest rates of reliable worsening.

For outcomes expected to increase with psychological improvement (emotion regulation, resilience, self-esteem, self-compassion), Res-Up! [CAP] showed the highest proportion of reliable improvement in resilience (CD-RISC-10; 7.2%) and emotion regulation (SEK-27; 8.6%). The control group exhibited the strongest positive changes in resource use (WIRF; 14.2%), self-compassion (SCS; 12.1%), and self-esteem (RSES; 12.1%). Reliable change was negligible across groups for the FrAGE-PE and FrAGE-NE subscales, indicating limited effects on the acceptance of positive and negative emotions. Overall, the CG displayed unexpectedly strong rates of reliable improvement on both symptom and strength-based measures.

Discussion

This study compared two transdiagnostic web-based self-help intervention programs, focusing on either emotion regulation as a compensation-oriented intervention, REMOTION [COMP], or resilience as a capitalization-oriented intervention, Res-Up! [CAP], to a control group (CG). Patients were recruited in routine psychotherapeutic outpatient practice during waiting times. All groups improved significantly over time on symptom severity (BSI-18) as primary outcome as well as on most secondary outcomes: emotion regulation (SEK-27 and FrAGE) and resilience (CD-RISC-10, WIRF), as well as on depressive symptoms (PHQ-9) and self-compassion (SCS), but not self-esteem (RSES). Contrary to our hypotheses, we could not find additional improvements of symptom severity, resilience, depressive symptoms, self-esteem or self-compassion in the intervention groups compared to CG. Solely concerning one emotion regulation measure, the FrAGE NE, a significant increase of the acceptance of negative emotions was found for REMOTION [COMP] compared to the CG.

Primary Outcome Measures

Concerning the primary outcome measure of symptom severity (BSI-18), our sample showed significant improvements of symptom severity over time across all conditions, except for the BSI-18 subscale for somatization. Nevertheless, contrary to expectation, the CG improved significantly over time as well. Therefore, no significant differences between the improvements of intervention groups compared to CG could be found, concluding that our assumption of significantly greater reduction of symptom severity in the experimental conditions compared to the CG, was not supported. Other studies showed similar findings for patients on waitlists [83]. Visual inspections of trajectories suggests, that a later follow-up measurement time point might have led to significant differences between groups.

Secondary and Other Outcome Measures

The secondary outcome measures similarly showed significant improvements of emotion regulation (SEK-27; FrAGe) and resilience (WIRF; CD-RISC-10) across all conditions and time. For the *emotion regulation* measures a significant difference between REMOTION [COMP] and the CG was detected for the subscale of acceptance of negative emotions (FrAGe NE) of the FrAGe, but not on the acceptance of positive emotion (FrAGe PE) scale. The greater improvement concerning acceptance of negative emotions in the REMOTION [COMP] group compared to the control group aligns with findings from a pilot trial, where a sensitivity analysis showed the potential beneficial effects of REMOTION [COMP] on emotion regulation [36]. However, it should be noted that REMOTION [COMP] was provided as an add-on to psychotherapy in the above study. Comparing Res-Up! [CAP] to CG, no significant additional improvement could be shown. For the SEK-27, no significant additional improvement for both treatment arms compared to the CG could be found, suggesting no additional beneficial effects for both programs REMOTION [COMP] and Res-Up! [CAP] compared to CG. For *improvement of resilience*, we could not find significant differences in the changes of treatment groups compared to CG. Thus, the hypothesis, that the intervention arms would improve resilience more than the CG, must be rejected.

Other Outcomes. Further analyses of *depressive symptom* reduction (PHQ9) and *self-compassion* (SCS) showed similar significant improvements in all conditions over time, but not *self-esteem* (RSES). Observed trajectories suggest as well, that significant between-group effects had been likely, if a later follow-up measurement would have been conducted.

Implications

The main result of our study is that the active web-based treatments in our study, REMOTION [COMP] and Res-Up! [CAP], overall did not outperform the control group in most outcomes. According to recent literature, focusing on internet-based interventions during waiting time for psychotherapy, that include waiting list control groups, this result pattern of equivalent outcomes in designs with comparisons to a control group, seems to prevail [22, 83, 84]. Only with respect to REMOTION [COMP] and the acceptance of negative emotions, our findings suggest that there might be a benefit in participating in web-based interventions for emotion regulation while waiting for psychotherapy.

First, our findings might be explained by the heterogeneity within the groups with respect to parallel face-to-face psychotherapy. Access to psychotherapy was not limited at any time during the study, as we did not expect participants to receive therapy so fast after their first visit to the outpatient centers. Since there was no a-priori control of this factor, the percentage of participants receiving therapy varied greatly across conditions: While only 28.6% of patients in Res-Up! [CAP] received additional regular psychotherapy at some point or throughout the course of the study participation, 37.1% in REMOTION [COMP] and 41.4% in the CG did (s. Table 4). Face to Face therapy parallel to internet-based treatments can greatly influence the process and incremental

effects of internet-based treatments may therefore, have not been detected. This is especially relevant, because the percentages highly differed between groups. Second, participants in the CG were informed, that they would get access to one or both programs of their choice after completing all three assessments. A meta-analysis on the effects of waiting for face to face treatment found changes with small effect sizes in the waiting list control groups of over 29 RCTs, indicating positive influence of being on the waiting list for a treatment compared to not [85]. As the information of being on a waiting list alone can influence the reduction of symptoms or improvement of protective factors [86, 87], the significant improvement of the CG across all measures and time points might be due to said factors. Third, since outcome trajectories indicated larger improvements for a later time point, it may also be possible, that we missed occurring longer-term improvements because of the relatively short follow-up period. Though it might also have led to an even higher drop-out rate. Additional follow-up measurement points further away from the end of treatment should be included in future studies to discover potential long-term effects.

Concerning the question whether a compensation-focused (REMOTION) or a capitalization-focused (Res-up!) approach might be more appropriate in an online setting, our findings do not allow an answer, as there were no significant outcome differences between the two interventions. To determine whether web-based interventions during waiting times could be effective, more studies are needed, and parallel psychotherapy should be analyzed more closely and in randomized trials.

Limitations

Several limitations first in study design and second in intervention design have to be considered. The possibility to generalize our findings to the general population of outpatient psychotherapy patients in Germany is limited, since we applied exclusion and inclusion criteria and recruited a selected sample. The trial showed high drop-out rates for measurements of 54.3% overall and especially for the treatment groups 64.3% (REMOTION [COMP]: 67.1%, Res-Up! [CAP]: 61.4%, CG: 34.3%), which we tried to accommodate for by pursuing an intention-to-treat-analysis via MLMs and a higher number of participants recruited. Moreover, only 12.8% in REMOTION [COMP] and 23.7% in Res-Up! [CAP] completed all modules of the respective intervention, but intervention drop-outs were not excluded due to the ITT approach. While high drop-out rates are a frequently reported problem of internet-based interventions [22, 47, 49], they are likely to be one of the main explanations for our results, for measurements drop-outs and especially for the intervention drop-outs. Additionally, unguided internet-based self-help interventions without any contact between patient and provider are less effective than therapist-supported internet interventions [50]. Since we offered only minimal support and participants had to come forward on their own to receive it, this structure of the internet-based interventions may have impacted the outcomes [52, 88].

Future directions

Results from this study highlight difficulties for implementation and limits of internet-based effectiveness of such interventions during waiting-times for psychotherapy. In particular, the study created new knowledge on web-based interventions focusing on resilience and emotion regulation, aligned with capitalization and compensation approaches to psychotherapy. Further analyses may want to examine the interaction of the intervention foci with patient variables: If patients with a particularly high level of adaptive emotion regulation strategies especially benefit from an intervention focusing on the improvement of emotion regulation strategies, it would imply a capitalization change process. If patients with a particularly low level of adaptive emotion regulation strategies profit particularly from an intervention focusing on the improvement of emotion regulation strategies, this points to a compensation change process. Respective interaction effects between patients' resilience and a resilience focused intervention can be hypothesized. Thus, in further analyses differential effects of patients' initial levels of resilience and emotion regulation

competencies on the outcome of a resilience and emotion regulation intervention will also be explored. Potential limits of internet-based interventions during waiting times, are especially present when waiting times are shorter and there is an overlap of intervention and face-to-face psychotherapy. Therefore, better ways to implement internet-based interventions in the routine setting are direly needed. The results of our study implicate that a focus on more integrated ways of combining such interventions with face-to-face psychotherapy is needed rather than implementing them as stand-alone during patient wait times.

Conclusion

Therapy Online Plus is a multi-center randomized controlled trial, comparing a care as usual only control group (CG) with two care as usual plus one of two transdiagnostic web-based interventions. One intervention directed at compensating emotion regulation problems – REMOTION – and the other directed at capitalizing on patients' strengths – Res-Up! – in a clinical sample. Results showed significant improvements across time, but no additional benefits of the intervention groups on general symptom severity compared to the control group. Slight benefits of REMOTION on emotion regulation in the form of a higher acceptance of negative emotions compared to CG could be found. Contrary to our expectation, a high percentage of patients in all groups got access to face-to-face therapy during the waiting time, which is likely to have substantial impact on the outcome trajectories. The study extends knowledge on potentials and challenges of implementing transdiagnostic internet-based interventions in routine outpatient psychotherapy settings during waiting times and beyond.

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

Data Availability

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' Contributions

LFT was responsible for overall recruitment of patients at the outpatient clinics and provided guidance and technical support for Res-Up!, LLB was responsible for data collection via Qualtrics and provided guidance and technical support for REMOTION. LFT conducted data analysis and wrote the initial version of the manuscript. JSV and SA supported LFT in the data analysis. All authors contributed to further drafts of the manuscript. UW and TB are the principal investigators of the study. No AI tools were used in the creation of this article.

Study Protocol

Available under <https://www.researchprotocols.org/2023/1/e41413/>

Abbreviations

AIC: Akaike Information Criterion

BSI-18: Brief Symptom Inventory-short form

CD-RISC-10: Connor-Davidson Resilience Scale

CG: control group *

* In retrospect, we concluded, that CAU as a name for the control group was misleading, as all groups received care as usual. The intervention groups received internet-based treatment additionally. Therefore, we decided to rename the control group from CAU to CG, different from the study protocol.

FrAGe: Questionnaire Assessing the Acceptance of Unpleasant and Pleasant Emotions

FrAGe NE: ", Subscale for Unpleasant Emotions

FrAGe PE: ", Subscale for Pleasant Emotions

ICC: Intraclass correlation coefficient

PMR: Personal Model of Resilience

Res-Up!: Resilienz – unkompliziert und persönlich!

PHQ-9: Patient Health Questionnaire-9

RSES: Rosenberg-Self-Esteem Scale

SCS-D / SCS: Self compassion Scale – German Version

SEK-27: Self-assessment of Emotion Regulation Skills

WAI-I: Working Alliance Inventory I (adapted for online interventions)

WIRF: Witten Resource Questionnaire

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Appendix

Table A. Assessments listed by Time Points

Variable	Instrument	Time Point		
		Baseline	6 Weeks	12 Weeks
Demographics		x	x	x
Structured clinical interview / clinical assessment		x		
Primary Outcome				
Symptom severity	BSI-18	x	x	x
Secondary Outcomes				
Emotion regulation	SEK-27; FrAGe	x	x	x
Resilience	WIRF; CD-RISC-10	x	x	x
Depressive symptoms	PHQ-9	x	x	x
Self-esteem	RSES	x	x	x
Self-compassion	SCS-D	x	x	x
Working Alliance	WAI-I		x	x

Note. BSI-18: Brief Symptom Inventory-18 [62]; SEK-27: Self-assessment of Emotion Regulation Skills [65]; FrAGe: Questionnaire Assessing Acceptance of Unpleasant and Pleasant Emotions [66]; CD-RISC-10: Connor-Davidson Resilience Scale [68]; WIRF: Witten Strengths and Resource Form [67]; PHQ-9: Patient Health Questionnaire-9 [69]; RSES: Rosenberg-Self-Esteem Scale [70]; SCS-D: Self-compassion Scale – German [71]; WAI-I: Working Alliance Inventory Internet interventions [72]

Table B. ITT intervention sample working alliance (WAI-I)

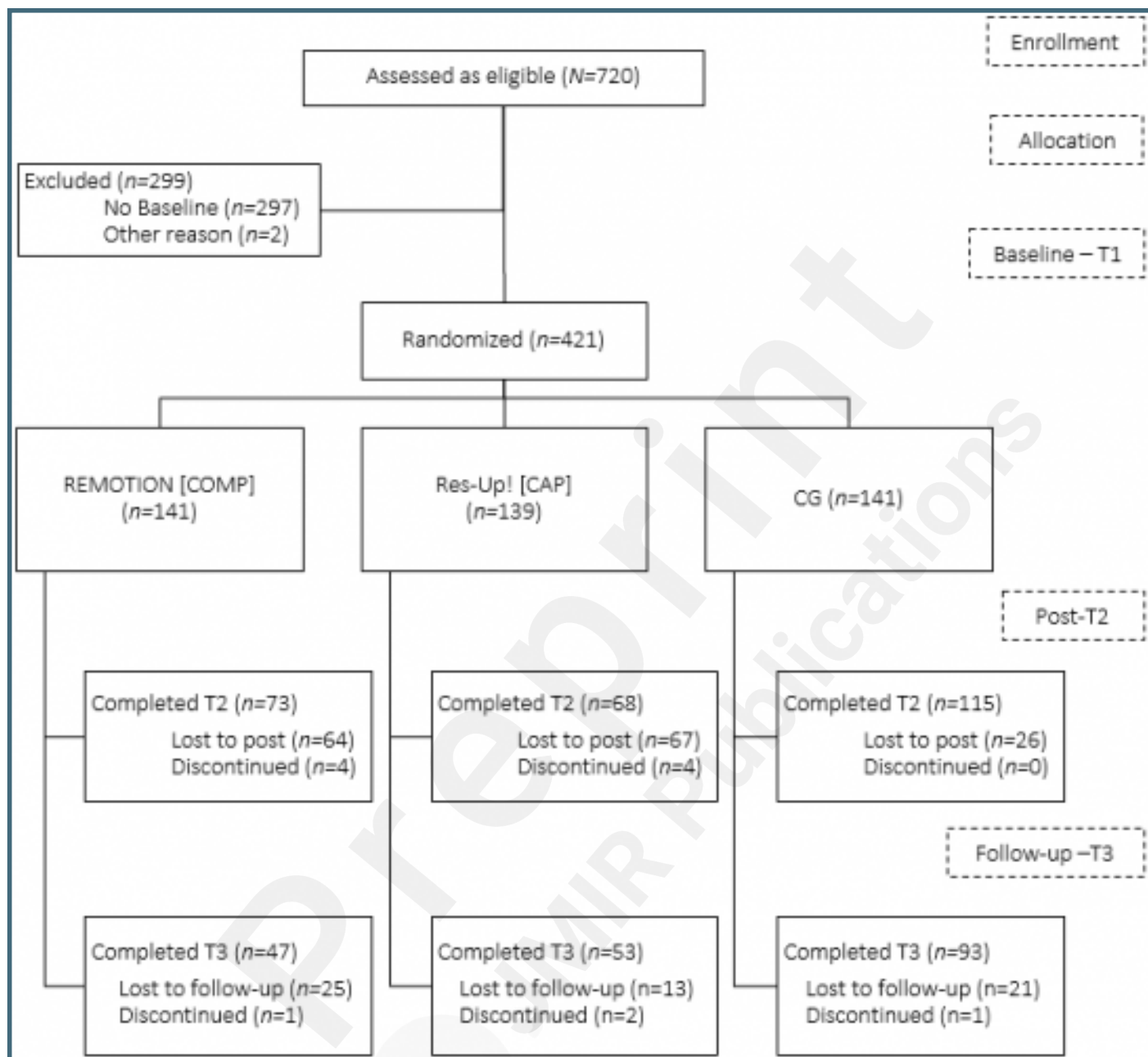
	Total	REMOTION [COMP]	Res-Up! [CAP]
<i>n</i>	83	42	41
T2, M (SD)	2.67 (0.76)	2.74 (0.83)	2.60 (0.68)
T3, M (SD)	2.77 (0.94)	2.77 (0.96)	2.77 (0.93)
<i>p</i>	.23	.69	.25
ES	-0.13	-0.06	-0.18

Note. WAI-I: Working Alliance Inventory Internet version; ES: effect size for the pre-post difference (Cohen's *d*); Total: sample of REMOTION plus Res-Up! without CG

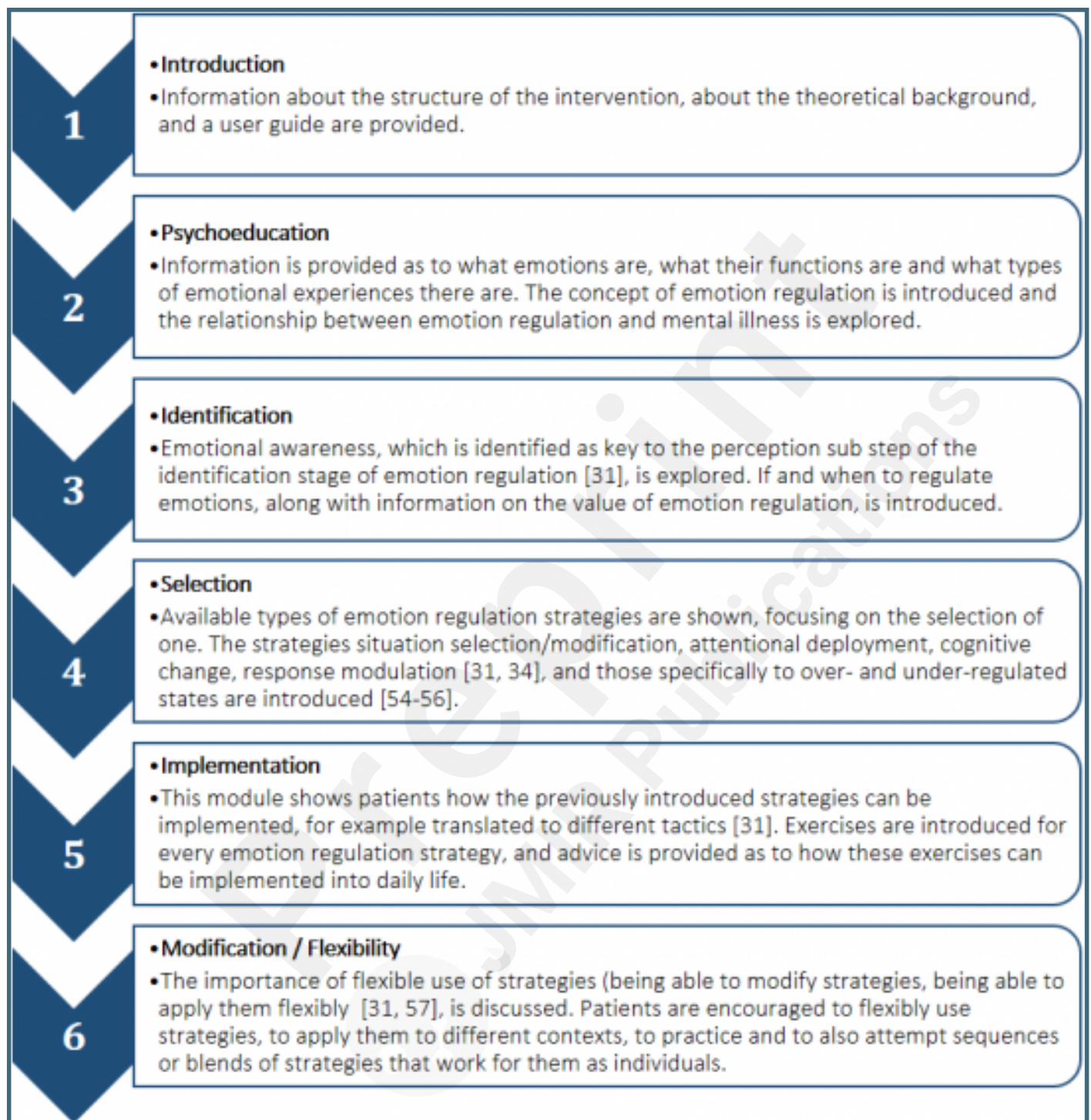
Supplementary Files

Figures

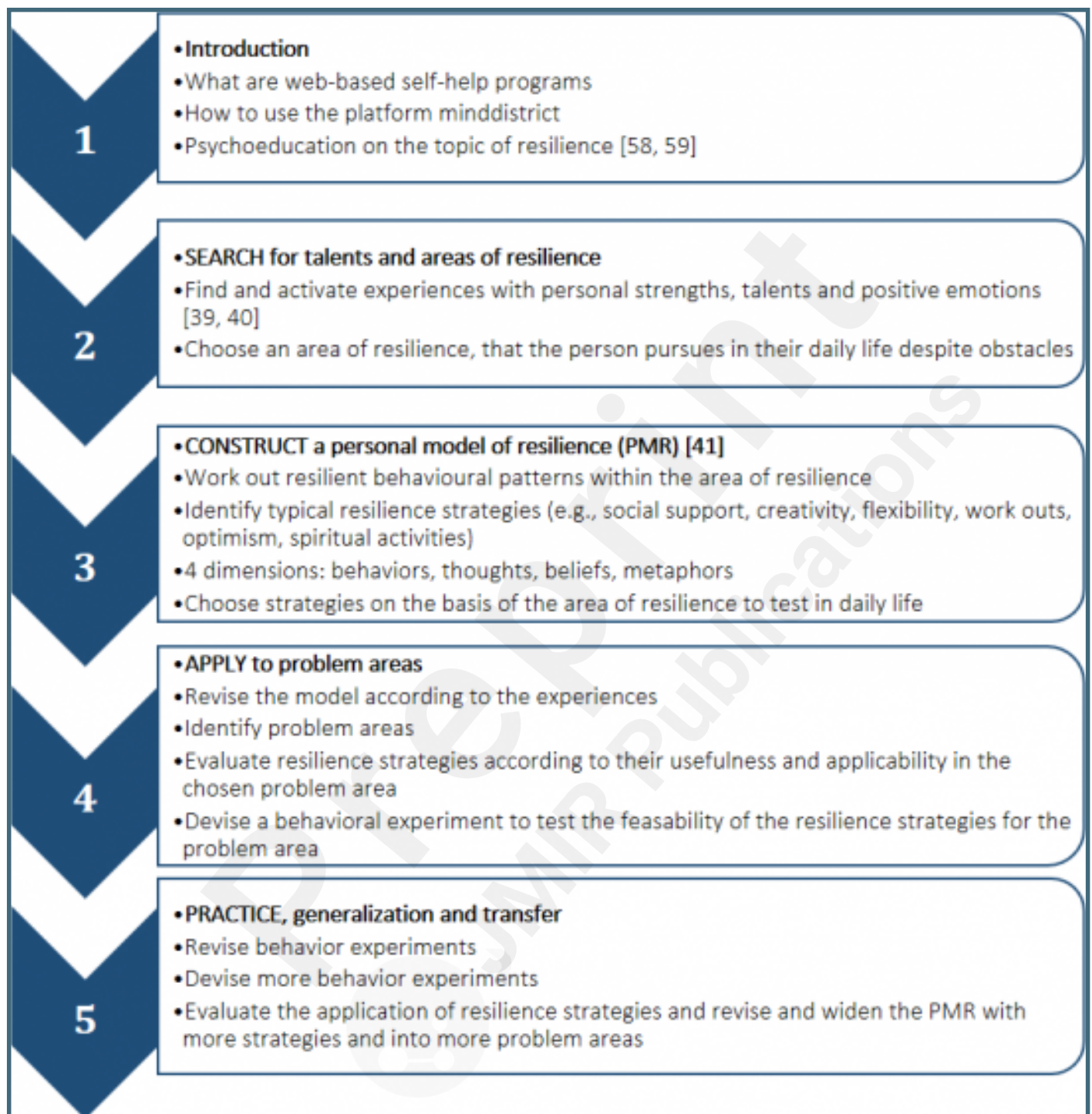
Study flow chart.



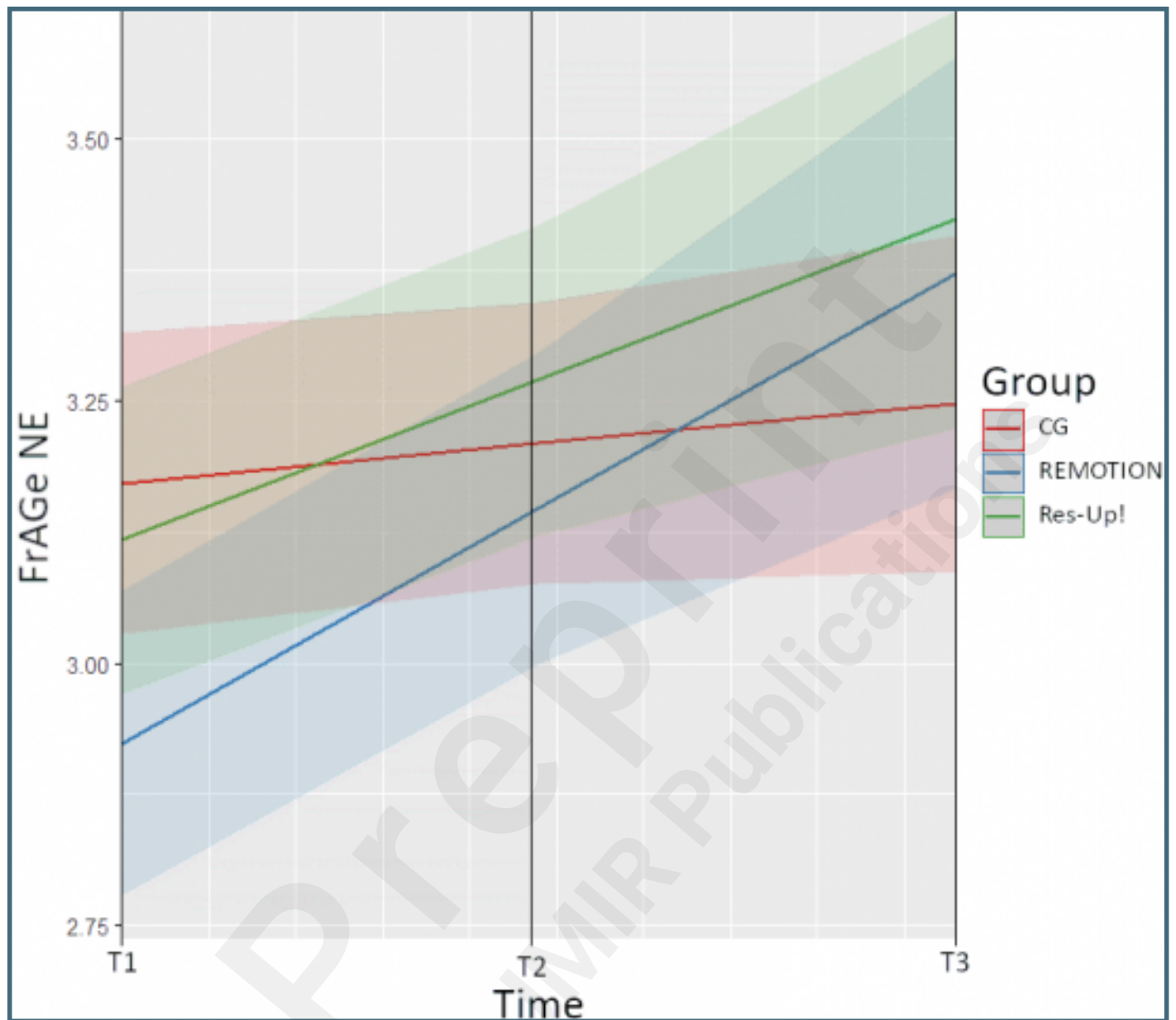
Contents of REMOTION adapted from [35].



Contents of Res-Up!.



Plot for FrAGe NE across all groups.



CONSORT (or other) checklists

CONSORT.

URL: <http://asset.jmir.pub/assets/31987b7d3078982ff615ebf26f5a4172.pdf>

