Therapy Online Plus (TOP) - Evaluation of Two Online Interventions ("Res-Up!" & "REMOTION") in Routine Outpatient Psychotherapy: Protocol of a Randomized Controlled Trial

Leonie Franziska Trimpop, Laura Luisa Bielinski, Thomas Berger, Ulrike Willutzki

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Abstract

Background: Only 11-40% of those affected by a mental disorder in Germany receive treatment. New approaches to improve the German health care system are needed in order to counter chronification. Online-interventions have been shown to be effective as stand-alone as well as add-ons to routine practice. Interventions designed for a wide range of mental disorders such as transdiagnostic interventions are needed to make treatment for mental disorders more accessible and thus shorten waiting times. In general, interventions can be differentiated as having either a capitalization focus - thus drawing on already existing strengths (CAP) - or a compensation focus - trying to compensate for deficits (COMP). Up to now, the effectiveness of transdiagnostic online-interventions with either a CAP- or a COMP-focus has not yet been evaluated.

Objective: This study is the first to examine the effectiveness of two online-interventions focusing on (1) the activation of resilience and drawing on existing strengths (CAP: Res-Up!) and (2) the improvement of emotion regulation (COMP: REMOTION), compared to care as usual in routine outpatient psychotherapy.

Methods: Adults with at least one mental health disorder will be recruited at four outpatient centers in Germany. Assessments will be made at baseline (T0), at 6-weeks-posttreatment (T1) and at 12-weeks follow-up (T2). Primary outcome will be symptom severity (BSI-18). Secondary outcomes will focus on emotion regulation and resilience.

Results: Participant recruitment and data collection started in April 2020 and are ongoing as of July 2022. Results of the study are expected in 2023.

Conclusions: This randomized controlled trial will compare care as usual with the transdiagnostic internet-interventions Res-Up! and REMOTION and will thus inform future studies concerning the effectiveness of transdiagnostic online interventions in routine outpatient psychotherapy. Clinical Trial: ClinicalTrials.gov NCT04352010, International Registered Report Identifier (IRRID)

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Protocol

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

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Keywords: rct, online therapy, transdiagnostic, resilience, emotion regulation, capitalization, compensation

Introduction

Approximately 1 in 6 people worldwide meet the criteria for a mental disorder in the last 12 months (17.6%), 29.2% are identified as having experienced a mental disorder at some time of their life.[1] Mental health problems and disorders have a profound impact on individuals affected by symptoms and society as a whole. Still, in Germany only 11-40% of patients receive treatment,[2] often due to the long waiting times for psychotherapy (20.1 weeks in 2019).[3] Therefore, the German mental health care system needs innovative intervention concepts, using approaches beyond standard face-to-face therapy and serving a wide range of mental disorders. Transdiagnostic interventions provided via internet can provide such an approach.[4-6]

Internet-based Interventions

Recent global developments have fast-forwarded digitalization and thus the use of internet-based tools to support mental health care has rapidly increased all over the world. Research on internet-based interventions in psychotherapy supports the effectiveness of different intervention programs for a variety of mental.[5,7,8] With limited access to psychotherapy, online interventions are an economical, flexible and practical alternative or addition to conventional treatment.[5] Particularly when face-to-face psychotherapy is not available due to limited resources (like insufficient availability of therapists) internet-based interventions can help to avoid long waiting times for treatment and thus mitigate the chronification of mental health problems.[4]

Among internet-based interventions, stand-alone online programs can be differentiated from blended treatment (BT) – the combination of face-to-face psychotherapy and an online intervention.[9] While BT can take on many different forms,[10] a differentiation can be made between integrated blends (for example conceptual coordination between online intervention elements and face-to-face psychotherapy sessions via a specified protocol) and add-on blends (for example, an online intervention provided in parallel, prior to and/or after face-to-face psychotherapy without conceptual coordination or integration between the two). BT, where an online intervention was provided as an add-on to face-to-face psychotherapy, has been shown to be more effective than psychotherapy alone.[11] A transdiagnostic approach might be particularly relevant for add-on conceptualisations as coordination with a potential face-to-face therapy focusing on a specific disorder is less relevant.

While even unguided internet-based interventions (without any contact between patient and provider of the intervention) seem to be effective, therapist-supported internet interventions are most likely more effective than self-guided treatments.[5,12,13] While the exact mechanism behind the benefit of guidance remains unclear, this may be due to higher adherence and lower drop-out rates resulting from the positive effect of the accompanying support on motivation and on engagement with the intervention.[5,11]

Capitalization or Compensation: Basic orientations in psychotherapy

Overall, a differentiation has been made in psychotherapy research between capitalization-oriented (CAP) versus compensation-oriented *interventions* (COMP). CAPs aim to draw on the person's already existing strengths, (in a wide sense: action-repertoire, resilience strategies, external and internal resources), COMPs identify dysfunctional maintenance factors of psychopathology and teach, respectively train the person to use new strategies or build new behavior against relative deficits.[14-18] In an early study,[18] Wingate and colleagues compared the outcomes of compensation versus capitalization in the treatment of suicidality in young adults, finding results favouring COMPs, while other studies find results favouring CAPs.[14,17] According to the current sparse research, there is no agreement on which of these two strategies should be pursued in psychotherapy.[14,17,19-22]

Certain interventions in psychotherapy are inherently more focused on capitalization (for example

focusing on action-repertoire, resilience strategies, external and internal resources) or on compensation (for example focusing on the building of new strategies for deficit compensation). While outcome differences between CAPs and COMPs in face-to-face psychotherapy seem to be small,[14] there are no studies comparing the two approaches for online therapy. Online therapy involves less therapeutic guidance and thus relies more strongly on the person's self-management capacities. Thus, possible effects of therapists' support in face-to-face therapy compensating deficits in both CAP and COMP cease in an online setting. Thus, this randomized controlled trial explores, for the first time, the effect of two transdiagnostic online interventions inherently capitalization or compensation-oriented: Activation of resilience (CAP) respectively improvement of emotion regulation (COMP) compared to a care-as-usual group (CAU).

As discussed above, capitalization and compensation can be conceptualized as features of interventions. Another possible conceptualization is via the interaction of intervention focus with patient variables. If particularly patients with a high level of adaptive emotion regulation strategies profit from an intervention focusing on the improvement of emotion regulation strategies this would point towards a capitalization change process. If patients with a 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. Thus in this trial, differential effects of patients' initial resilience respectively emotion regulation competencies on the outcome of a resilience as well as emotion regulation intervention will also be explored.

Resilience

Resilience as psychological resistance to adversity was originally conceptualized in the context of developmental psychology.[23,24] Today, resilience and resources are often discussed in the field of positive psychology,[25] which focuses on factors that make and keep people healthy rather than ill. While most research on resilience and resources has a compensation focus, aiming to create new resources and building up new strengths,[26] the Personal Model of Resilience (PMR) is a CAP intervention that was developed by Padesky and Mooney from a cognitive perspective.[27]

The PMR focuses on individuals' pre-existing resources and resilient strategies to increase awareness and implementation of these strengths. Basic assumptions of the PMR are: Every person is resilient and has resilience strategies that are already part of their action repertoire and have the potential to also be used in challenging situations. The model is based on evidence-based standards for cognitive behavioural therapy.[28]

The model was evaluated in a pilot study with students,[29] a randomized study with a waiting control group,[30] and in an online version with active plus waiting control groups (Online intervention program vs. Face-to-Face vs. ABC-model vs. WCG (waiting control group)).[31] Medium effect sizes for the face-to-face model and small effect sizes for the online version were observed. Based on the feedback of participants, the online version was redesigned and is being re-evaluated.[32] The redesigned version of the program (Res-Up!; Resilience program of the University of Witten/Herdecke) showed medium effect sizes in preliminary results for 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).[32]

Emotion Regulation

Emotion regulation refers to the way individuals attempt to influence emotions and includes the up and the down regulation of positive and negative emotions in accordance with regulatory goals.[33] Emotion regulation and specifically the fostering of flexible use of different emotion regulation strategies are important topics in the treatment of mental health disorders and more specifically also in psychotherapy research. This is made evident by the large number of publications that focus on the topic of emotion regulation.[34-37] Interestingly, emotion regulation has been discussed as a

transdiagnostic factor related to psychopathology and the treatment of mental health disorders.[34,38-40] More recently, several mental health interventions that address and/or target emotion regulation have been developed as internet or mobile-based programs. For example, Böhme and Berking describe the application of an emotion regulation APP based on Affect Regulation Training (ART).[41]

By using the extended process model of emotion regulation as a theoretical framework to structure an emotion regulation intervention,[42] Bielinski and colleagues developed REMOTION.[43] The internet-based program aims to reduce the symptom severity of patients with a range of different diagnoses while improving their emotion.[43] REMOTION is currently being examined as a blended intervention in an outpatient psychotherapy setting in a pilot randomized controlled trial.[43] It is also currently being examined as an add-on to acute inpatient psychiatric care in another pilot randomized controlled trial (Clinicaltrials.gov identifier: NCT04990674). Results for both trials are expected in 2023.

Aims

Internet-based interventions have been efficient and helpful considering different mental disorders and in self-selected samples in many controlled studies.[7] Nevertheless, little is known about the efficacy of internet interventions in routine psychotherapeutic practice and their usefulness as Add-On to conventional psychotherapy (blended treatment).

The *first goal* of this study is to assess the effectiveness of two internet-based interventions (Res-Up! & REMOTION) in an outpatient psychotherapeutic routine setting in comparison to care as usual

The *second goal* of this study is to explore in an online-therapy context the implementation of interventions with either a capitalization (CAP) or compensation (COMP) focus by using two transdiagnostic internet-based intervention programs, centered either on activating resilience (CAP; "Res-Up!") or on emotion regulation (COMP; "REMOTION").

In addition, differential effects of initial resilience and emotion-regulation competencies on the effectiveness of Res-Up! and REMOTION will be explored.

Methods

Study Design

The study is a multi-center 3-arm randomized controlled trial in which a care-as-usual (CAU) approach will be compared to two different online intervention programs (CAP: Res-Up! and COMP: REMOTION), that will be administered as add-on to care-as-usual.

Participants in the intervention groups will be given access to Res-Up! and REMOTION immediately whereas participants in the CAU will receive access to one of the interventions after 12 weeks (participants in the CAU can choose which intervention they want to access). Assessments will occur at baseline, 6 weeks (post) and 12 weeks (follow-up) for all participants. Assessments at 6 and 12 weeks will occur irrespective of whether the participant is in face-to-face treatment.

The multi-center trial will take place at the outpatient clinics of the Training Center for Psychological Psychotherapy OWL (Bielefeld, Germany), the Centers for Psychotherapy Dortmund and Muenster (all German Association of Behavioral Therapy (DGVT)) and the Center for Mental Health and Psychotherapy (Department of Psychology and Psychotherapy, University Witten/Herdecke, Germany).

Primary and secondary outcomes will be gathered online via link to online self-report questionnaires based on Qualtrics software[44] at baseline, 6 weeks, and 12 weeks after baseline.

All participants will be required to give their informed consent before enrollment in the study. The written consent will be obtained by trained psychotherapists at the outpatient centers. Furthermore, all participants are given the option to contact a study member during the intervention ("guidance on demand") either via e-mail (REMOTION) or Chat (Res-Up!), but are not actively contacted by the team (except for reminders to complete the interventions or questionnaires and a welcome message).

Figure 1 displays the flow of patients through the study.

Figure 1. Flow of participants.
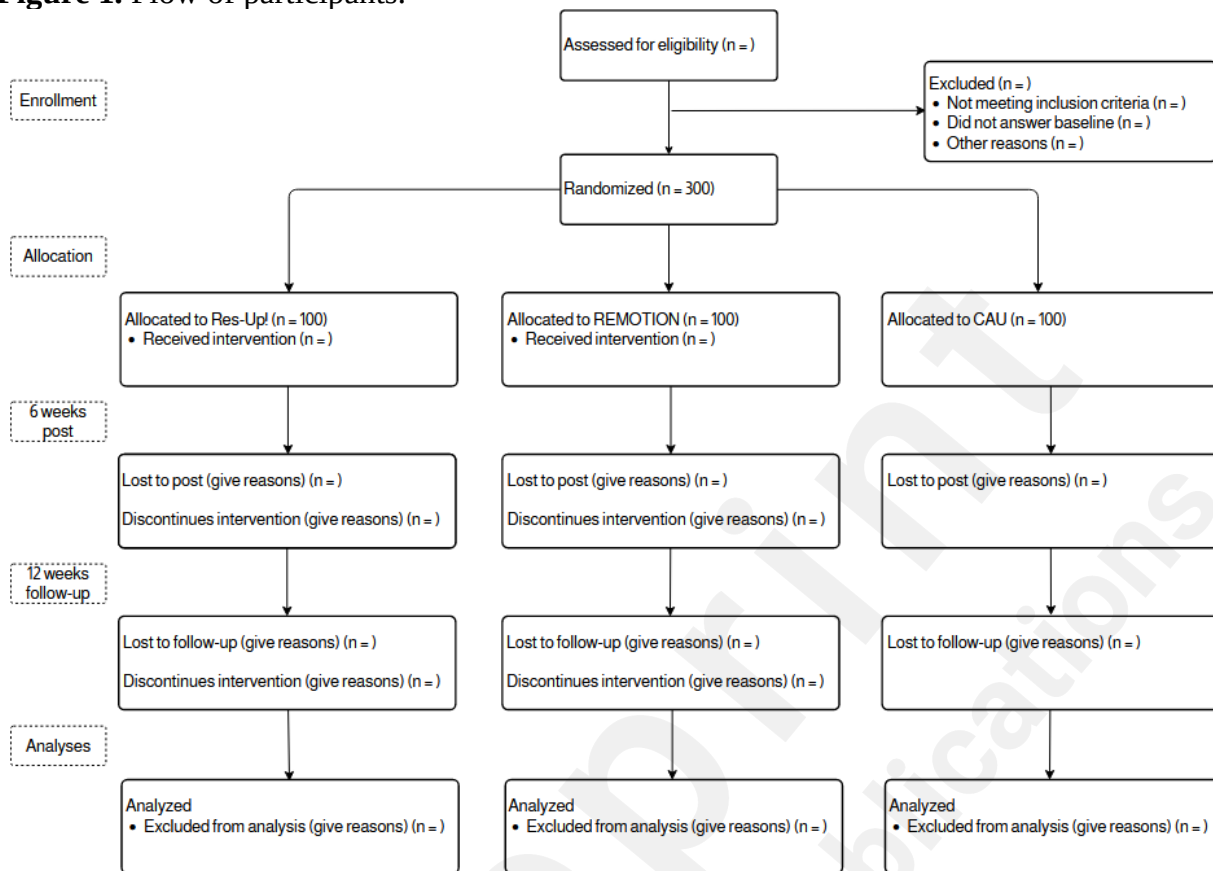
Sample Size Calculation

Sample size was calculated with the software G* Power.[45] We aim to detect small effect sizes of Cohen's d = .20 regarding the Time x Group interaction for the two active conditions at an alpha error level of .05. A power analysis revealed that a sample size of 80 participants in each of the active study arms is required to detect a statistically significant difference with a power (1-beta) of .80. Sample size was further estimated based on a drop-out rate of approximately 25%. We finally decided to randomize 100 participants to each of the conditions (3 arms, 100 per arm; CAU, Res-Up! and REMOTION). The second goal of the study is exploratory and thus no assumptions about differential effects can be made.

Eligibility Criteria

Inclusion criteria are (1) current diagnosis of a mental disorder according to DSM-5 / 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: (1) current severe episode of major depression, (2) current psychotic disorder, (3) acute suicidal tendency, (4) other severe mental disorder, e.g., bipolar disorder, (5) insufficient German language skills. Access to face-to-face psychotherapy after enrollment is not restricted while participants are working with the online-programs in order to approximate naturalistic conditions.

Recruitment and Randomization

Recruiting training centers for psychological psychotherapists in Germany are located in Bielefeld, Dortmund, Muenster (training centers of the German Association for Behavior Therapy - Deutsche Gesellschaft für Verhaltenstherapie, DGVT) and in Witten, Germany (Center of Mental Health and Psychotherapy, Witten/Herdecke University). Trained psychotherapists at all centers will inform interested individuals coming to the institution for a face-to-face consultation session. As waiting lists for psychotherapy are quite long in Germany 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 with a structured clinical interview. Interviewers gather written consent to participate in the study which is forwarded to the study team members. After study eligibility is proven, participants receive an email with a personalised code to the baseline questionnaires. Once participants have filled out the baseline questionnaires, they are randomized via Qualtrics software[44].

Ethical Approval

The study will be 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 will be obtained from all patients. The trial is registered with clinicaltrials.go (NCT04352010).

Interventions

RES-UP!

Res-Up! is an internet-based intervention focusing on patients' strengths and positive experiences developed at the University Witten/Herdecke (Germany). The intervention is based on the Personal Model of Resilience (PMR),[27] which is a positive cognitive intervention that utilizes patients' strengths to overcome problems. The PMR activates resilient emotions, thoughts, metaphors, images and behaviors in four steps structured into five modules. A variety of psychotherapy elements (Cognitive Behavioral Therapy, Emotion Focused Therapy, Positive Therapy etc.) are integrated in the program. Participants are asked to work on one of five consecutive modules per week; completing a module takes about one to two hours. Res-Up! is conducted on the online-platform Minddistrict[46] which has been approved by the privacy policy office of Witten/Herdecke University prior to the start of the study. The intervention can be administered as a stand-alone or add-on treatment to psychotherapy. Basic assumption of the PMR is that every individual has a repertoire of resilience strategies which can be used in everyday life or in situations of crisis. Res-Up! aims to identify these strategies and improve, support, and implement them in problematic situations where they were not used before.

In the first module participants are educated on the concept of resilience. In the second session individual resilience areas of the participant are elaborated. The goal of the third module is to construct the individual's current Personal Model of Resilience. The PMR is further developed in the fourth module in which resilient strategies from the model are used and adapted for still problematic areas. At the end of this module a behavioral experiment is planned. The experiment is evaluated in the last module. To further increase participants' motivation to use their model and resilience strategies the individual's experiences with the PMR are summarized.

Training and intervention elements are presented as informational texts as well as interactive modules, individualized questions, videos, and audio files. Throughout the whole intervention participants can ask for guidance (via chat or email) by a member of the study team who is trained in the program and has at least a master's degree in psychology. To increase adherence reminder messages to complete the modules in time are sent via chat. With continuous participation, participants should complete the intervention within 6 weeks.

REMOTION

The internet intervention REMOTION is aimed at reducing symptom severity and improving emotion regulation of individuals with different mental health disorders.[43] The theoretical background and exact structure of REMOTION has been described in detail elsewhere.[43] REMOTION includes an introduction and five further modules and individuals are asked to work on one module per week, ideally for around 1-2 hours per week. Intervention elements are presented in different formats including video, text and audio along with different types of exercises throughout the program. The intervention is accessed via a platform provided by the University of Berne and the access is password protected. Table 1 shows the content of the intervention.

For the current study described in this protocol, and in order to allow comparability with the Res-Up! Intervention, REMOTION is administered as a stand-alone or an add-on treatment to psychotherapy. If individuals do not work with the program for an entire week, they are then reminded to work with the program, but no other active guidance component (like weekly emails) are added. Individuals are however able to contact the study team via e-mail if they have any questions. Like Res-Up!, completion of the REMOTION program should take around 6 weeks.

Table 1. The Content of REMOTION shown in detail.

Module	Content
Introduction	Information about the structure of the intervention, about the theoretical background, and an user guide are provided in this module.
Psychoeducation	Information is provided as to what emotions are, what their functions are and what types of emotional experiences there are. The concept of emotion regulation is introduced and the relationship between emotion regulation and mental illness is explored.
Identification	Emotional awareness, which is identified as key to the perception substep of the identification stage of emotion regulation,[42] is explored in this module. If and when to regulate emotions, along with information on the value of emotion regulation, is introduced in this module.
Selection	This module shows patients what types of emotion regulation strategies are available. The focus is on the selection of an emotion regulation strategy.[42] The strategies situation selection /modification, attentional deployment, cognitive change and response modulation are introduced in this module.[47] Furthermore, strategies specific to over- and underregulated states are also introduced.[48-50]
Implementation	This module shows patients how the previously introduced strategies can be implemented, for example translated to different tactics.[42] Exercises are introduced for every emotion regulation strategy, and advice is provided as to how these exercises can be implemented into daily life.
Modification / Flexibility	The importance of flexible use of strategies (being able to modify strategies, being able to apply them flexibly,[42,51] is discussed in this module. Patients are

	encouraged to flexibly use strategies, to apply them to different contexts, to practice and to also attempt sequences or blends of strategies that work for them as individuals.
Note.[43], CC BY 4.0	

Care-As-Usual Group (CAU)

Participants in the CAU will not get access to the online-interventions for 12 weeks after baseline. They will answer the questionnaires before randomization as well as 6 respectively 12 weeks later. They get access to the online-interventions of their choice after completing the follow-up assessment. During the waiting time, participants are allowed to stay on the wait list or start psychotherapy as they would usually.

Trial organization

Participants are being recruited during their registration to regular psychotherapy in the outpatient centers in Germany mentioned above. Recruiting outpatient centers received information about the study from a member of the study team via a short instruction manual, an instruction video and a personal introduction for psychotherapists in associated centers. Information on the study and the interventions (Res-Up! and REMOTION) is given to interested patients face-to-face with additional written information by trained psychotherapists. Written consent to participate is solicited by the respective practitioner. Written consent and necessary information (name, birthdate, diagnoses, date of recruitment and email) is given to a member of the study team. Participants then receive an email from the study team with an individualized code to the baseline measure via Qualtrics[44]. Answering individual questionnaires will take approximately 30 minutes at every assessment point. After completing the baseline, participants are randomly assigned by a randomized computer generator (in Qualtrics[44]) to one of the three treatment arms. Six weeks after baseline the post treatment measures and 12 weeks after baseline the follow-up measures are provided.

Participants in the CAU are informed, that they will have to complete the two following assessments and will get access to the program of their choice after completing the follow-up. In the experimental conditions participants receive an email with their online access to either (1) Res-Up! (focusing on resilience), or (2) REMOTION (focusing on emotion regulation).

Measures

Overview

Items recording demographic information of patients will be presented at baseline, and a reduced battery at 6 weeks and at 12 weeks. Patient diagnostic status will be obtained during the initial interview by conducting a Structured Clinical Interview I (German version) for Diagnostic and Statistical Manual of Mental Disorders respectively a clinical assessment by an experienced psychotherapist.[52,53] A full description of all outcomes in the study is provided in Table 2. All measures will be provided online. Data collection will be supported by e-mail reminders.

Table 2. Assessments listed by time points.

Variable	Instrument	Time Point		
		Baseline	**6 weeks**	**12 weeks**
Demographics		x	x	x

Structured clinical interview or clinical assessment		x		
Primary Outcome				
Symptom severity	BSI-18	x	x	x
Secondary Outcomes				
Resilience	WIRF; CD-RISC-10	x	x	x
Emotion regulation	SEK-27; FrAGe	x	x	x
Other Outcomes				
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 - short form,[54,55] PHQ-9 Patient Health Questionnaire-9,[56] WIRF Witten Resource Questionnaire,[57] CD-RISC-10 Connor-Davidson Resilience Scale,[58] SEK-27 Self-assessment of Emotion Regulation Skills,[59] FrAGe Questionnaire Assessing the Acceptance of Unpleasant and Pleasant Emotions,[60] RSES Rosenberg-Self-Esteem Scale,[61] SCS-D Self-Compassion Scale – German,[62] WAI-I Working Alliance Inventory I (adapted for online interventions)[63]

Primary Outcome Measure

The primary outcome measure in this study is general symptom severity measured with the Brief Symptom Inventory – a short form (BSI-18; German version)[54] of the SCL-90-Revised (SCL-90R).[64] The BSI-18 has 18 items and is a frequently used questionnaire to measure general symptom severity (Cronbach's α = .85 - .89) with good psychometric properties,[55] comparable to those of the SCL-90R.[64]

Secondary Outcome measures

Resilience will be assessed by two instruments: (1) the Witten Resource Questionnaire (WIRF),[57] a 37-item self-report of personal and external resources with high reliability (Cronbach's α = .72 - .85), and (2) the Connor-Davidson Resilience Scale (CD-RISC-10),[58] an internationally used 10-item self-report of individual resilience with high reliability (Cronbach's α = .81 - .90).

Emotion regulation will be assessed via the following two instruments: (1) Self-assessment of Emotion Regulation Skills (SEK-27; Selbsteinschätzung emotionaler Kompetenzen),[59] a 27-item self-report measure of emotion regulation skills with high reliability and validity (Cronbach's α = .90), and (2) the Questionnaire Assessing the Acceptance of Unpleasant and Pleasant Emotions (FrAGe; Fragebogen zur Akzeptanz von Gefühlen),[60] a 32-item self-report of the acceptance and suppression of pleasant and unpleasant emotions with good reliability and validity.

Other Outcome measures

Severity of depression will be assessed with the German version of the Patient Health Questionnaire-9 (PHQ-9).[56] 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).

Self-esteem will be assessed with the Rosenberg-Self-Esteem Scale (RSES),[61] an internationally used 10-item self-report of general self-esteem with high reliability and validity (Cronbach's α = .72 - .85).

Self compassion will be assessed with the Self-Compassion Scale (SCS-D),[62] an internationally used

26-item self-report of self-compassion with high reliability and validity (Cronbach's α > .90).

In addition, the *therapeutic alliance* between participants and the online-intervention / study team will be measured with an adapted version of the Working Alliance Inventory for guided Internet Interventions (WAI-I).[63] The WAI-I showed good internal consistency at total and subscale level (Cronbach's α between .92–.94). For the purpose of this study, the term psychologist was substituted with the term study team in the questionnaire.

Information about whether patients started psychotherapy while working with the online interventions will be gathered at 6 weeks and 12 weeks. An overview of the assessments and the measures is provided in Table 1. Participants receive weekly reminders via email up to a maximum of three if they do not answer the questionnaires in time.

Planned analysis

Data will be analyzed using an intention-to-treat (ITT) approach, including all randomized patients in the outcome analyses and handling missing data accordingly. The primary outcome measure, general symptom severity, will initially be analyzed descriptively. The effects of the interventions on the primary and secondary outcome measures will be analyzed with linear mixed-effect models (LMMs). LMMs are recommended for ITT analyses with missing data, because of the possibility to accommodate for missing data without having to exclude or impute data and do not depend on limited assumptions about the variance-covariance matrix . Sensitivity analysis will be conducted to analyze the impact of drop-outs, psychotherapy and medication on results. Effect sizes of all within-groups for pre to follow-up changes will be computed as Cohen's *d*.

For categorical data, amount or percentage will be reported. Significance testing of dichotomous data will be conducted with chi-square tests. Results will be reported in accordance with CONSORT (Consolidated Standards of Reporting Trials)[65] and CONSORT-EHEALTH checklists.[66]

Expected Results

Participant recruitment and data collection started in April 2020, and as of July 2022, are ongoing. Results for the study are expected in 2023.

Discussion

This study aims to compare a CAU control to two transdiagnostic online intervention programs, focusing either on resilience (as an example of capitalization strategies) or on emotion regulation (as an example of compensation strategies).

In accordance with previous research,[11] we hypothesize that both interventions will be more efficacious than no additional treatment (CAU). According to Fuhr and colleagues online interventions, that focus on individual parts of psychotherapy – preferably in a blended approach, might be more effective than all elements of a disorder-specific therapy, when implemented in a routine setting.[12] Due to the dearth of studies comparing Capitalization vs. Compensation interventions directly, no directed hypothesis can be formulated in this context. While the primary outcome targets symptom severity, secondary outcomes assess resilience and emotion regulation as the specific target areas of the individual interventions.

The study will be conducted in Germany in four outpatient centers in a clinical sample of approximately 300 participants, 100 per each of the three study arms. Matching the transdiagnostic approach of the interventions, participants in the sample will have a variety of different mental disorders and varying symptom severity. Results from this study will be valuable for practitioners, patients, and mental health services in all fields, due to the transdiagnostic approach. Furthermore, it will contribute to the knowledge and efficacy of evidence-based online intervention programs and possibilities of implementation in outpatient routine care. In particular, it will create new knowledge for online interventions focusing on resilience and emotion regulation and thus shine light on

possible differences of capitalization- and compensation-oriented interventions in online settings.

Limitations

There could be several *limitations* that can be considered. First, our results might not be generalizable to the general population of outpatient psychotherapy patients, since we will apply exclusion and inclusion criteria and recruit a self-selected sample. Clinical practitioners in outpatient clinics recruit participants and inform in advance, to ensure a clinical sample. Second, drop-out rates from online assessments due to non-adherence to the interventions are a frequently known problem of internet-based interventions.[11] Furthermore, participants have the possibility to contact the study team via email or chat throughout the whole intervention which should increase adherence to the online programs and support motivation.[13]

Conclusions

TOP+ is a multi-center randomized controlled trial, comparing for the first time in a clinical sample a care as usual group with two transdiagnostic interventions, one capitalization-oriented (Res-Up!) and the other compensation-oriented (REMOTION). To explore the comparison of the two transdiagnostic online intervention programs, it will assess the transdiagnostic effectiveness of the above interventions, considering different mental disorders. Furthermore, results will extend existing knowledge about the possibilities of implementing online-interventions in routine psychotherapy settings.

Recruitment Status

Start date: April 13, 2020
Recruitment completion: July, 2022
End date: End of 2022 / Start of 2023

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Conflicts of Interest

The authors have no conflicts of interest to disclose.

Abbreviations

TOP: Therapy Online Plus
CAP: capitalization
COMP: compensation
BT: blended treatment

RCT: randomized controlled trial
CAU: care-as-usual
PMR: Personal Model of Resilience
BSI-18: Brief Symptom Inventory - short form
PHQ-9: Patient Health Questionnaire-9
WIRF: Witten Resource Questionnaire
CD-RISC-10: Connor-Davidson Resilience Scale
SEK-27: Self-assessment of Emotion Regulation Skills
FrAGe: Questionnaire Assessing the Acceptance of Unpleasant and Pleasant Emotions
RSES: Rosenberg-Self-Esteem Scale
SCS-D: Self-Compassion Scale – German
WAI-I: Working Alliance Inventory I (adapted for online interventions)

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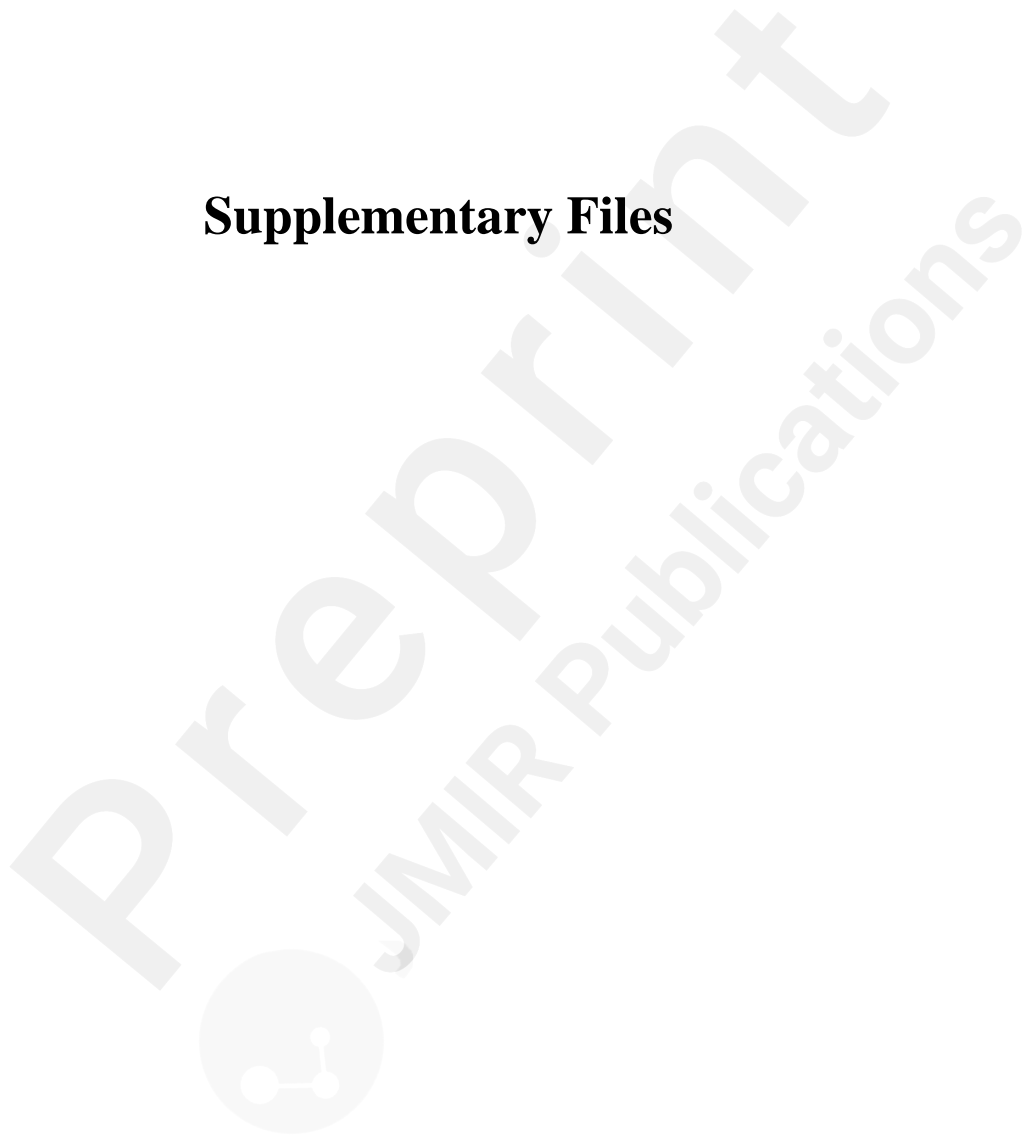
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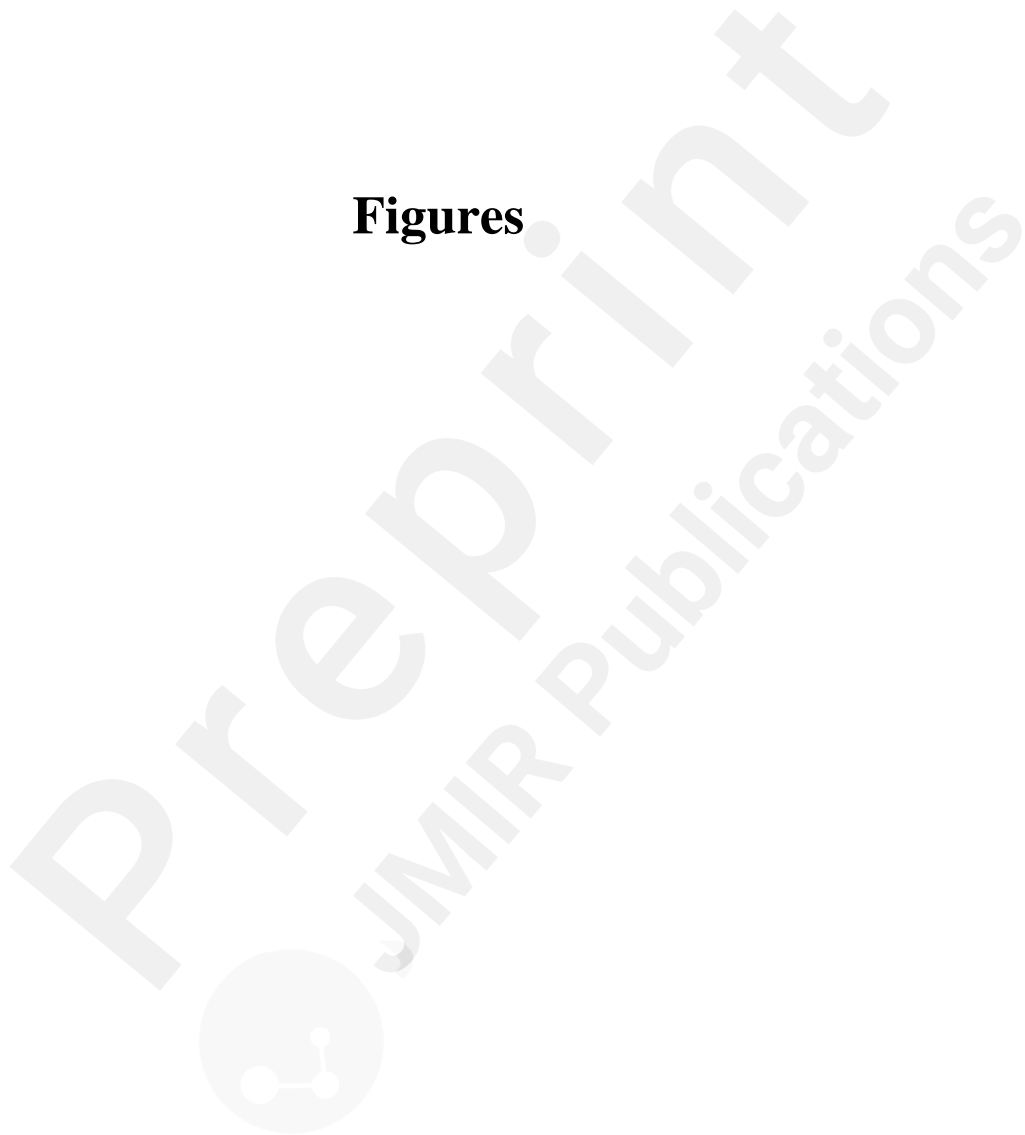66. Eysenbach G, Group C-E. CONSORT-EHEALTH: improving and standardizing evaluation reports

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Supplementary Files

Figures

Flow of participants.