A single-blinded, randomized clinical trial of how to implement an evidence-based treatment for generalized anxiety disorder [IMPLEMENT] - effects of three different strategies of implementation

Flückiger, Christoph ; Forrer, Lena ; Schnider, Barbara ; Bättig, Isabelle ; Bodenmann, Guy ; Zinbarg, Richard E

Abstract: BACKGROUND: Despite long-standing calls to disseminate evidence-based treatments for generalized anxiety (GAD), modest progress has been made in the study of how such treatments should be implemented. The primary objective of this study was to test three competing strategies on how to implement a cognitive behavioral treatment (CBT) for out-patients with GAD (i.e., comparison of one compensation vs. two capitalization models). METHODS: For our three-arm, single-blinded, randomized controlled trial (implementation of CBT for GAD [IMPLEMENT]), we recruited adults with GAD using advertisements in high-circulation newspapers to participate in a 14-session cognitive behavioral treatment (Mastery of your Anxiety and Worry, MAW-packet). We randomly assigned eligible patients using a full randomization procedure (1:1:1) to three different conditions of implementation: adherence priming (compensation model), which had a systematized focus on patients' individual GAD symptoms and how to compensate for these symptoms within the MAW-packet, and resource priming and supportive resource priming (capitalization model), which had systematized focuses on patients' strengths and abilities and how these strengths can be capitalized within the same packet. In the intention-to-treat population an outcome composite of primary and secondary symptoms-related self-report questionnaires was analyzed based on a hierarchical linear growth model from intake to 6-month follow-up assessment. This trial is registered at ClinicalTrials.gov (identifier: NCT02039193) and is closed to new participants. FINDINGS: From June 2012 to Nov. 2014, from 411 participants that were screened, 57 eligible participants were recruited and randomly assigned to three conditions. Forty-nine patients (86%) provided outcome data at post-assessment (14% dropout rate). All three conditions showed a highly significant reduction of symptoms over time. However, compared with the adherence priming condition, both resource priming conditions indicated faster symptom reduction. The observer ratings of a sub-sample of recorded videos (n = 100) showed that the therapists in the resource priming conditions conducted more strength-oriented interventions in comparison with the adherence priming condition. No patients died or attempted suicide. INTERPRETATION: To our knowledge, this is the first trial that focuses on capitalization and compensation models during the implementation of one prescriptive treatment packet for GAD. We have shown that GAD related symptoms were significantly faster reduced by the resource priming conditions, although the limitations of our study included a well-educated population. If replicated, our results suggest that therapists who implement a mental health treatment for GAD might profit from a systematized focus on capitalization models. FUNDING: Swiss Science National Foundation (SNSF-Nr. PZ00P1_136937/1) awarded to CF.

Research Paper

A Single-blinded, Randomized Clinical Trial of How to Implement an Evidence-based Treatment for Generalized Anxiety Disorder [IMPLEMENT] — Effects of Three Different Strategies of Implementation

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ABSTRACT

Background: Despite long-standing calls to disseminate evidence-based treatments for generalized anxiety (GAD), modest progress has been made in the study of how such treatments should be implemented. The primary objective of this study was to test three competing strategies on how to implement a cognitive behavioral treatment (CBT) for out-patients with GAD (i.e., comparison of one compensation vs. two capitalization models).
Methods: For our three-arm, single-blinded, randomized controlled trial (implementation of CBT for GAD [IMPLE-MENT]), we recruited adults with GAD using advertisements in high-circulation newspapers to participate in a 14-session cognitive behavioral treatment (Mastery of your Anxiety and Worry, MAW-packet). We randomly assigned eligible patients using a full randomization procedure (1:1:1) to three different conditions of implementation: *adherence priming* (compensation model), which had a systematized focus on patients' individual GAD symptoms and how to compensate for these symptoms within the MAW-packet, and *resource priming* and *supportive resource priming* (capitalization model), which had systematized focuses on patients' strengths and abilities and how these strengths can be capitalized within the same packet. In the intention-to-treat population an outcome composite of primary and secondary symptoms-related self-report questionnaires was analyzed based on a hierarchical linear growth model from intake to 6-month follow-up assessment. This trial is registered at ClinicalTrials.gov (identifier: NCT02039193) and is closed to new participants.
Findings: From June 2012 to Nov. 2014, from 411 participants that were screened, 57 eligible participants were recruited and randomly assigned to three conditions. Forty-nine patients (86%) provided outcome data at post-assessment (14% dropout rate). All three conditions showed a highly significant reduction of symptoms over time. However, compared with the adherence priming condition, both resource priming conditions indicated faster symptom reduction. The observer ratings of a sub-sample of recorded videos (n = 100) showed that the therapists in the resource priming conditions conducted more strength-oriented interventions in comparison with the adherence priming condition. No patients died or attempted suicide.
Interpretation: To our knowledge, this is the first trial that focuses on capitalization and compensation models during the implementation of one prescriptive treatment packet for GAD. We have shown that GAD related symptoms were significantly faster reduced by the resource priming conditions, although the limitations of our study included a well-educated population. If replicated, our results suggest that therapists who implement a mental health treatment for GAD might profit from a systematized focus on capitalization models.
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1. Introduction

In European countries, the lifetime prevalence of generalized anxiety disorder (GAD) varies from 5 to 10% (Lieb et al., 2005). Uncontrollable worrying as a primary symptom of GAD leads to a maladaptive cognitive strategy to avoid experiencing anxiety (Borkovec et al., 2004) and emotional states in general (Roemer et al., 2005). Individuals with GAD show deficits in detecting and regulating emotional states, which may accelerate a positive feedback circuit between general stress symptoms and pathological worrying (Mennin et al., 2009). Finally, experiential avoidance may lead to a restriction in proactive behaviors as

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individuals become focused on avoiding events and situations rather than pursuing activities that are consistent with their personal values (Michelson et al., 2011).

Psychological treatment that intends to be fully therapeutic conducted by trained professionals (bona fide psychotherapy) is an effective treatment for GAD compared to no treatment and treatment as usual (Hanrahan et al., 2013; Cuijers et al., 2014) but also is more generally an effective treatment for individuals who suffer from any type of anxiety and/or depression (Flückiger et al., 2014). There are a number of treatment protocols for cognitive behavioral therapy (CBT) that include interventions such as psycho education, relaxation techniques, cognitive restructuring of (meta-) cognitions, (imagery-) exposure, and in vivo confrontation that primarily reference standard techniques to correct and compensate for GAD symptoms (Barlow et al., 1992; Zinbarg et al., 2006). In spite of the empirical evidence of the overall efficacy of the protocols, there is a systematic lack of knowledge regarding how therapists should implement these overall protocols and how they can create productive levels of competent adherence to treatment protocols (Webb et al., 2010; Owen & Hilsenroth, 2014). From a broader perspective, psychotherapy dialogues could be observed as highly interactive and responsive treatments through which therapists and patients work together to achieve well-specified treatment goals that consider the patient's entire living environment (Norcross, 2011; Wampold & Imel, 2014). Patients are likely not uniformly skilled, and therapists might respond to these skills differentially. Pre-existing and/or immediately activated strengths and deficits in targeted domains could be used in individualizing treatment either by building new behaviors against relative deficits (i.e., compensation model) or by building upon relative strengths in the target areas (i.e., capitalization model). According to the compensation model, treatments will be more successful in so far as the therapists target the patient's disorder-relevant individual deficits and vulnerabilities. In contrast, the capitalization model would lead one to expect treatments to be more successful insofar as the therapist targets the patient's relative strengths and resources (Cheavens et al., 2012; Flückiger & Grosse, 2008). Even the separation into compensation and capitalization models is probably a false dichotomy, as therapists often simultaneously respond to the participants' targeted weaknesses as well as strengths. Indeed, there is a broad tradition in balancing capitalization as well as compensation strategies in many psychotherapeutic orientations (Scheel et al., 2013). However, during the sessions, therapists performing such treatments might have a particular pull into one or the other model in general (Gassmann & Grawe, 2006) and also more specifically in GAD (Flückiger et al., 2013). According to Rosenhan's lasting posit helpers might have to actively construct their clinical realities not only on insane but also on sane perspectives independently of the underlying treatment orientation (Rosenhan, 1984).

Rather than creating increasing numbers of new overall treatment packets, an additional approach to investigating clinical research designs may be to increase the understanding of already effective psychotherapies. The present study experimentally examined three ways of conducting a CBT protocol and their relation to treatment efficacy and therapist competence.

1.1. Aims of the Trial

This trial investigates three different ways of how to implement a bona fide psychotherapy based on a cognitive behavioral therapy protocol using peer dyad supervision (primings). The participants are randomly assigned to three priming conditions: (a) adherence priming (compensation model), (b) resource priming (capitalization model) or (c) supportive resource priming (capitalization model). The main research questions are as follows: Are the different priming conditions related to differences in the efficacy of GAD outcomes, general outcomes and dropout rates? More specifically, we expect that resource priming in particular fosters therapist skills and flexibility in in-session strengths-orientation that might lead to better treatment outcomes.

2. Methods

2.1. Study Design

This study is a randomized controlled trial with three active treatment arms. This trial was conducted at the psychotherapy outpatient clinic in the Department of Psychology at the University of Zürich, Switzerland. Fig. 1 depicts three treatment conditions (adherence priming, resource priming, and supportive resource priming) at four assessments (times: intake, intermediate, post, follow-up). This study protocol was approved by the Ethical Committee of Canton Zurich (KEK 2011-0475) and overseen by the Ethical Committee of the Philosophical Faculty of the University of Zurich (PhiF-EK_20.1.2012). The trial was registered at ClinicalTrials.gov (identifier: NCT02039193) (Flückiger, 2014).

2.2. Participants

2.2.1. Patient Inclusion/Exclusion Criteria

Participants were included in the study if they (a) fulfilled the diagnostic criteria for GAD based on the structured interview for DSM, (b) were 18 years of age or older, (c) had sufficient knowledge of German and (d) agreed to the informed consent. Participants were excluded for the following reasons: (a) they had a score of 2 or higher on the suicide item of the Beck Depression Inventory and/or were found to have active suicidal plans during the diagnostic screening interview, (b) they were currently taking a psychotic or bipolar disorder medication, or (c) they were currently receiving treatment from a professional psychotherapist. Prescribed medications for anxiety or depressive disorders did not exclude participants from the study, if the dosage had remained constant for at least one month. The presence of a comorbidity did not result in exclusion from the study if GAD was in the foreground according to the severity rating of the Diagnostic Interview for DSM diagnoses.

2.2.2. Recruitment

Participants were recruited by means of advertisements in high-circulation newspapers delivered for free through the Swiss public transport system. Individuals interested in participating in the study contacted the study office via SMS, e-mail or phone. Positively screened patients were invited for an intake assessment that used a standardized interview to determine whether they would be included or excluded. Participants who were not screened positively were informed of more appropriate treatments via a phone call or, if requested, face-to-face contact.

2.2.3. Randomization and Treatment Allocation

After meeting the inclusion criteria, patients were randomly assigned to one of the three conditions (adherence priming, resource priming, or supportive resource priming). Treatment allocation was performed using an online application for full randomization. The allocation concealment was conducted by an independent research assistant. Because all patients were treated using the same CBT protocol, patients were blinded to their treatment allocation and were not informed about the randomization procedure.

2.2.4. Therapists

Thirteen graduated psychologists with at least 2 years post-graduate training were recruited from local psychotherapy-training centers that provided up to 600 h of weekend workshops, including practice introductions of general therapist skills, cognitive behavioral interventions, process experiential approaches, and interpersonal approaches in single, couple, and group settings. The therapist recruitment was focused on learning how to conduct the "original" MAW-packet (Zinbarg et al., 2006; Craske & Barlow, 2006) attracted by an initial 16-hour workshop presented by the (co-)developer of this cognitive behavioral treatment
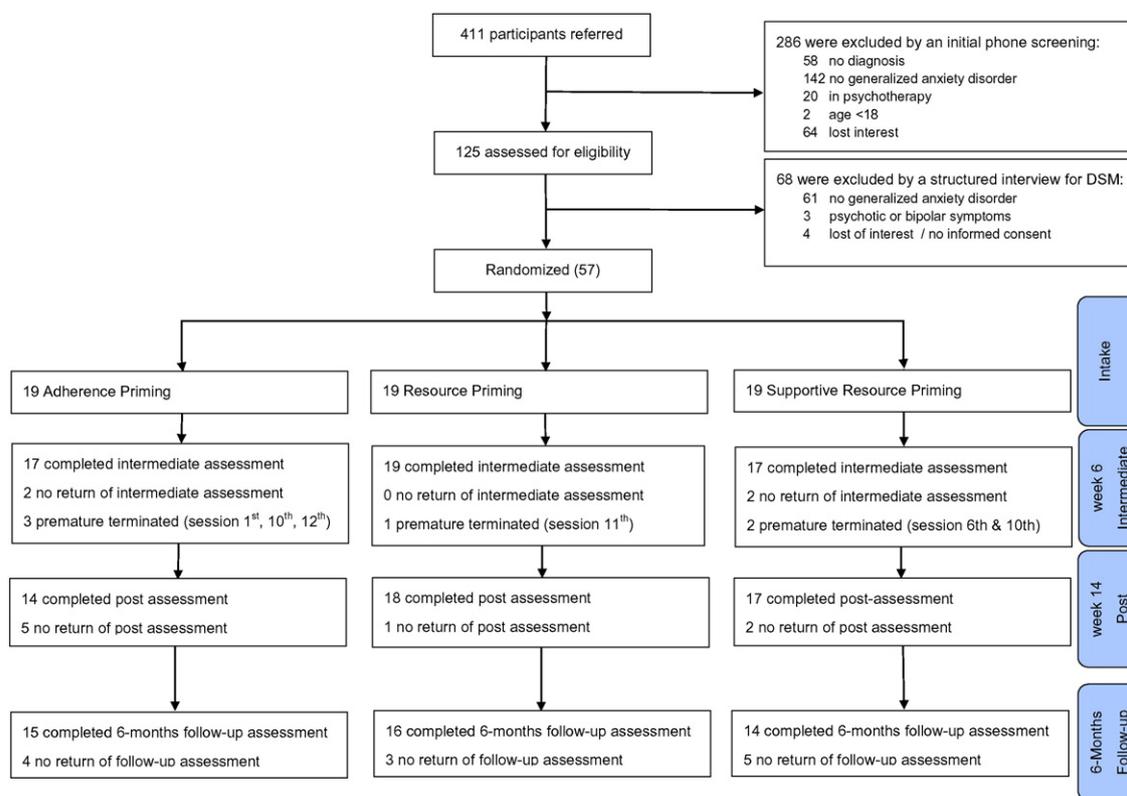
Fig. 1. Trial profile.

manual (RZ). The majority of the therapists had considerable experience as study therapists in a prior randomized controlled trial (ClinicalTrials.gov identifier: NCT01012856). To clarify formal study questions, the therapists had 1-hour study meetings in small groups on a monthly basis. These study meetings were conducted for all three priming conditions together. To emphasize the external validity of the implementation study, CBT-supervisors were self-selected by each therapist. All therapists had individualized CBT-supervisions on a 14-day basis, which is included in their regular postgraduate training protocol (within the 200 hour requirement to obtain a psychotherapy license in Switzerland). This supervision was based on a list of approximately 30 accredited CBT-supervisors for postgraduate CBT-trainings.

The assignment of a priming condition to a therapist was conducted by a joint face-to-face meeting at the very beginning of the study. To respect and coordinate the therapists' preferences (i.e., preferences in terms of working days and time schedules), the therapists first selected their priming partners and second, they selected a priming condition. Six groups were made (five groups with two therapists, one group with three therapists) and each group had to choose a priming condition (two groups per condition). Five groups had a preference to a specific condition. Only one group had none and was assigned to the adherence priming condition. In an anonymous retrospective evaluation, all therapists answered the following dichotomous question with no: "In retrospect, I would prefer to have selected another priming condition."

2.3. GAD Treatment Protocol

2.3.1. Mastery of Your Anxiety and Worry Guidelines (MAW-Packet)
The MAW-packet encompasses CBT interventions introduced by Craske and Barlow (Zinbarg et al., 2006; Craske & Barlow, 2006). This internationally well-known standard CBT packet for GAD typically consists of psycho-education on generalized anxiety disorder, relaxation training (RT), cognitive restructuring (CR) and in vivo situational exposure for patients with overt behavioral avoidance. Furthermore, imagery exposure as

a GAD-specific form of in sensu exposure was applied to reduce subtle experiential avoidance behaviors. The manualized therapy followed a treatment format of 14 50-minute sessions and a booster session after 6 months (15 sessions in total) based on the MAW-workbook that was delivered for every patient. The MAW-workshop was focused on how to appropriately adapt the duration and timing of the various standard CBT interventions to the patients' individual behaviors. At the start of every therapy, the interviewer who runs the structured interview for DSM summarized the results of the intake assessments in a two-page case vignette to facilitate the exchange of information between the intake assessment and the therapists that conducted the MAW-packet.

2.3.2. Peer Dyadic Supervision (Priming)
To systematically investigate various strategies of how to implement a standard CBT protocol, all therapists were tutored in peer dyads. On days of sessions 1 to 5, the therapists were required to contact their peer partner face-to-face or on the phone to discuss the upcoming session in a 5- to 10-minute brief conversation based on a standardized style-sheet (primings; for a comparable procedure, see Flückiger and Grosse Holtforth (2008). The primings operationalize different models on how to involve the patient into the treatment. There were three priming conditions:

(1) Adherence priming (compensation model): Immediately before sessions 1 to 5, a therapist conducted a 5-minute conversation with the tutoring partner about how to implement the disorder-specific interventions that were described in the treatment protocol. These communications were focused on patient individual GAD symptoms and any related comorbidities and how those individual sufferings could be adequately compensated for in the prescriptive treatment protocol based on a standardized style-sheet (see online Appendix). These style-sheets were filled out by the therapist prior to the first therapy session using all of the intake assessment data, including the video recordings of the structured interview for DSM. Based on the patients' individual sufferings,

adherence priming intended to operationalize a common straight-forward strategy of how therapists can involve patients in the treatment protocol (Whisman, 2008).

(2) Resource priming (capitalization model): Immediately before sessions 1 to 5, a therapist conducted a 5-minute conversation about the potential strengths and abilities of the patient and how these immediately activated strengths could be capitalized to conduct the treatment protocol based on a standardized style-sheet (see Appendix) (Flückiger et al., 2010). These style-sheets were filled out by the therapist prior to the first therapy session using all of the intake assessment data, including the video-recordings of the structured interview for DSM. Resource priming intended to operationalize an explicit matching strategy of how therapists respond to patients' strengths and weaknesses to involve patients in the treatment protocol. According to the therapist-guide of the MAW-manual, every therapy session should include basic capitalization strategies such as an emphasis on positive changes during the past week or reinforcement of progress during the sessions (Zinbarg et al., 2006).

(3) Supportive resource priming (capitalization model): The supportive resource priming condition used the very same style-sheet and form of peer dyads as the resource priming condition. The only difference in this condition was a slightly higher flexibility in the treatment protocol. More specifically, the therapists in consultation with their patients were allowed to invite a helpful significant person from the patient's entourage (such as a partner or best friend) to participate to sessions 1 (introduction of the GAD-rationale) and 7 (after intermediate assessment). In addition the therapists tried to find ways; this helpful person could support the patient in their treatment plan (capitalization of supportive others) (Zinbarg et al., 2007). In case the patient or the supportive other person did not consent to direct therapy participation (in 4 cases), therapists were encouraged to find indirect ways for patients to involve the significant other to support the patient in their treatment plan.

2.4. Measures

2.4.1. Structured Clinical Interview for DSM

At intake, the GAD diagnosis and its core symptomatology were identified by trained interviewers according to the structured interview section for GAD [DIPS] (Margraf et al., 1991). Further mental disorders were assessed using the face-to-face diagnostic interview for DSM-IV [SKID-I] (Wittchen et al., 1997) by trained and supervised interns with at least a Bachelor degree in Clinical Psychology. These interns were not enrolled as therapists. Patients were only included in the study if three evaluations (self-evaluation, phone screening, structured interview) came to a common agreement for a GAD diagnosis. Reliabilities were not assessed for the present study.

2.4.2. Outcomes

All outcome measures are taken at intake, between weeks 6 and 7 (intermediate assessment), at week 14 (post-assessment), and at the 6-month follow-up (± 2 weeks) based on self-report Likert-scales. Disorder-specific (primary) outcomes: The Beck Anxiety Inventory [BAI] (Beck et al., 1988) is a 21-item measure for general anxiety symptoms ($\alpha = 0.92$ in the present sample). The Penn State Worry Questionnaire [PSWQ] (Meyer et al., 1990) is a 16-item measure of the frequency and intensity of worry. It has considerable internal consistency ($\alpha = 0.86$ in the present sample). Secondary outcomes: The Beck Depression Inventory II [BDI-II] (Beck et al., 1996) is a 21-item measure for depressive symptoms ($\alpha = 0.92$ in the present sample). The 9-item short version of the Symptom Check List [SCL-9] (Klaghofer & Brähler, 2001) is an index for general severity ($\alpha = 0.86$ in the present sample). The short

version of the Resource Self-Report Questionnaire [RES] (Troesken & Grawe, 2004) measures various domains of individual and interpersonal strengths ($\alpha = 0.92$ in the present sample). All the primary and secondary outcome measures were highly intercorrelated ($0.74 > r > 0.47$, $p < 0.001$ see Appendix II) and a principal component factor analysis extracted one factor that explained 67.5% of the total variance. For the purposes of the present study report, we therefore included a standardized composite measure ("outcome composite") that takes all the 5 primary and secondary symptom-related self-report measures into account ($\alpha = 0.73$ in the present sample).

2.4.3. Cognitive Therapy Scale (CTS-G)

The adapted German version of the cognitive therapy scale is a Likert scale observer-rating that assesses therapist competencies for cognitive behavioral therapy (Weck et al., 2010). The CTS-G is composed of 14 items covering a *session-structuring* scale (e.g., agenda setting, focus on key cognitions or behaviors) and a *general therapeutic competence* scale (e.g., interpersonal effectiveness, use of feedback) applied at 10-minute intervals during the sessions and aggregated to an overall session mean. The CTS-G had considerable reliability (Kruskal $\gamma > 0.78$ for single items; $\alpha = 0.88$ and 0.80, respectively, for the two scales in the present sample based on a subsample of 15 randomly selected independently evaluated sessions). For the purposes of the study, we analyzed the item that operationalizes strengths-orientation (i.e., "resource activation") as well as the two scales. Observers were two master's students in clinical psychology who participated in the initial MAW workshop. For the observer-based measure, a sub-sample of the first 25 completed therapies was video-analyzed in sessions 2, 5, 8 and 11 and randomly assigned to one of the two reviewers (a total of 100 sessions; 32 sessions in the adherence priming condition, 32 sessions in the resource priming condition and 36 sessions in the supportive priming condition). Raters were blinded to the priming conditions.

2.5. Statistical Analyses

Our target sample size was 57 patients, split equally between the three conditions. Within the pretest–posttest-control group design, the reported effect sizes (ES Δ) are based on the mean pre-post change in the treatment group minus the mean pre-post change in the control group, divided by the pooled pretest standard deviations that can be interpreted as a Cohens d (Morris, 2008). Based on the grant preconditions, we intended to conduct maximally 60 therapies (20 participants in each condition) between June 2012 and November 2014. As in prior psychotherapy trials, we expected a dropout rate of approximately 20% at post-assessment. Assuming an Alpha-error of 5%, a power of 80% and a correlation coefficient for the repeated assessments of r = .50, such a sample size is able to detect moderate efficacy differences. However, because such data were not previously generated within comparable designs in GAD, there was no rigorous means of estimating required sample size. Now that these data have been collected sample size approximations are possible for future studies.

Based on the intent-to-treat sample, efficacy differences were analyzed using hierarchical linear models consisting of repeated assessments at Level 1 and patients at Level 2 (and therapists at Level 3). Because the intercept-only models indicated marginal therapist variance at Level 3, we conducted 2-level growth models that included Level 1 and Level 2. Restricted maximum likelihood models were fit ($yIJ = \beta_{00} + \beta_{01}$ AdPr $+ \beta_{02}$ RePr $+ \beta_{10} *$ Time $+ \beta_{11} *$ Time $*$ AdPr $+ \beta_{12} *$ Time $*$ AdPr $+ \beta_{20} *$ Time$^2 + \beta_{21} *$ Time$^2 *$ AdPr $+ \beta_{12} *$ Time $*$ AdPr $+ r_{0j} + r_{1j} + e$tj). Whereas, Time and Time^2 indicate the linear growth (β_{10}) and quadratic growth (β_{20}) of symptom reduction over the 4 assessment times (intake, intermediate, post, 6-month follow-up). AdPr and RePr represent dummy codings for adherence priming (AdPr) and resource priming (RePr) at intake (β_{01}, β_{02}), for linear growth (β_{11}, β_{12}) as well as for quadratic growth (β_{21}, β_{22}). Furthermore r_{0j} and r_{1j} are the error-terms for intercept and linear slope at

Level 2 and $e t j$ is the error term at Level 1. The CTS-G observer-ratings of the above-mentioned 100 sessions were analyzed within a traditional repeated MANOVA design (3 conditions [adherence priming, resource priming, supportive resource priming] by 4 repeated sessions [sessions 2, 5, 8, 11] by 3 CTS-G scales [resource activation, session-structuring competence, general therapeutic competence]).

3. Results

Between June 2012 and November 2014, with the last assessments completed in May 2015, 411 self-selected interested people were screened via phone call and 125 participants were interviewed, of whom 57 were eligible. The 57 eligible participants gave informed consent and were randomly assigned to one of the three conditions (19 participants in each condition, Fig. 1). The number of attended sessions per subject was 13.4 (SD = 2.2). Fifty-one (89.5%) participants attended the full allocated intervention of 14 sessions, and 49 (86.0%) participants completed post-assessments (2 participants who had attended the 14 sessions decided not to participate to the post-assessment). From the 57 subjects that started the treatment, the adherence priming group had a higher rate of missing post-assessments (5 patients, 26.3%) in comparison with the other two conditions (1 patient, 5.3%/2 patients, 10.5%; $X^2[2] = 3.8$, p = 0.08). However, this trend disappeared at the follow-up assessment with 45 participants (with overall 12 participants [21.5%] who missed follow-up assessments).

Comparable to other psychotherapy studies with GAD patients, all three groups showed a high number of comorbidities and the mean age was approximately 40 years (see Table 1). In comparison with the general Swiss population, there was a slight tendency toward a higher percentage of graduate occupations and bilingual people from an international background; this might be due to a research-oriented population of out-patients that indicated interest in participating in a university-based clinical trial. The majority of participants were female,

Table 1
Baseline characteristics of patients and therapists.

	All enrolled subjects	Adherence priming	Resource priming	Supportive resource priming
Patients				
n	57	19	19	19
Age (SD)	43.9 (12.1)	42.9 (10.5)	42.5 (13.1)	46.3 (12.9)
Female/male (%)	43/14 (25)	12/7 (37)	18/1 (5)	13/6 (32)
Comorbidities				
At least one further diagnosis (%)	30 (53)	7 (37)	12 (63)	11 (58)
Anxiety disorder (%)	20 (35)	6 (32)	7 (37)	7 (37)
Depression (%)	10 (18)	1 (5)	6 (32)	3 (16)
Further treatments				
On psychotropic medication (%)	15 (26)	4 (21)	7 (37)	4 (21)
Past psychotherapy (%)	24 (42)	7 (37)	6 (32)	11 (58)
Socio cultural aspects				
Graduate occupation (%)	19 (33)	8 (42)	5 (26)	6 (32)
Swiss-German as first language (%)	34 (60)	11 (58)	13 (68)	10 (53)
On persistent close partnership (%)	34 (60)	11 (58)	12 (63)	11 (58)
Therapists				
n	13	4	4	5
Age (SD)	30.2 (3.7)	31.8 (3.9)	29.0 (2.2)	29.8 (5.1)
female/male	13/0	4/0	4/0	5/0
PhD degree (%)	8 (62)	3 (75)	3 (75)	2 (40)
Prior experience in an RCT (%)	9 (69)	3 (75)	3 (75)	3 (60)
Recent appointment in an in-patient clinic (%)	5 (38)	2 (50)	2 (50)	1 (20)
Sessions of supervision per therapy (SD)	6.4 (4.5)	6.5 (4.7)	6.3 (4.3)	6.5 (4.7)

and full randomization produced a higher percentage of women in the resource priming condition. However, there was no indication that this randomly produced unequal distribution was outcome-relevant (p > 0.11 for all outcomes). Therapists were approximately 30 years old on average and were all Swiss-German-speaking female psychologists with considerable knowledge and practice on conducting psychotherapies under RCT conditions (see Table 1).

Therapists reported that the preparation of the style-sheets at the beginning of the therapies took 29 min on average (SD = 20.9). The single primings were conducted by face-to-face or phone contact and took 10.2 min on average (SD = 6.25). A total of 84.4% of the primings were conducted in the peer-format, and 16.5% were conducted by the therapists themselves (because of a conflicting schedule of the peer-partner). The means of the outcomes measures at pre-, intermediate, post-assessment and follow-up assessments and the pre-post effect sizes are presented at Table 2.

3.1. Treatment Efficacy From Intake to Follow-up Assessment

The results of the hierarchical linear model from the outcome composite are presented at Table 3 (for the results of the single outcome measures see Appendix II). Full randomization selected slightly less burdened patients for the adherence priming condition at intake (β_{00}); however, these differences were not statistical significant. The model indicated a significant linear and quadratic growth (β_{10}/β_{20}) representing a U-shaped curve of symptom reduction over time for all three conditions. However, there were medium linear (β_{11}) and quadratic (β_{21}) differences in symptom reductions in favor of both resource priming conditions in comparison with the adherence priming condition, indicating faster symptom reduction within the two resource priming conditions (see Fig. 2). During the course of the study, no serious adverse event (SAE) such as death or attempted suicide was registered.

3.2. Observer Ratings (CTS-G)

The means of the observer ratings of the 100 video-analyzed sessions are presented in Table 4. On a scale from "0" to "6", the mean competences over the conditions were evaluated at about a "4" (therapist applies a sufficient range of methods with skill and flexibility, enabling the patient to develop new perspectives), with a range from "2" (therapist applies either insufficient or inappropriate methods, and/or with limited skill and flexibility) to "6" (excellent range and application, or successful application in the face of difficulties). The multivariate analyses indicated differences between the three priming conditions (Pillai's Trace: F [6/42] = 21.0, p = 0.001, $\eta_p^2 = 0.76$). As expected, both resource priming conditions revealed higher scores in the resource activation item in comparison with the adherence priming condition (F[2/22] = 10.8; p = 0.001; $\eta_p^2 = 0.50$). Furthermore, the resource priming condition indicated higher session-structuring (F[2/22] = 5.5; p = 0.01, $\eta_p^2 = 0.33$) and general therapeutic competence (F[2/22] = 7.6; p = 0.003, $\eta_p^2 = 0.41$) in comparison with the supportive resource and the adherence priming conditions. Zero-order correlations between the observer ratings and the outcome composite at post-assessment revealed the following: Resource activation: r = 0.11; session-structuring competence: r = 0.04; general therapeutic competence: r = 0.00 (for all p = n.s.).

4. Discussion

The results of the planed analysis corroborate the hypothesis that implementation strategies may impact the treatment efficacy of evidence-based treatment in GAD. The present implementation study indicated that both resource priming conditions lead to a faster reduction of symptom-related outcomes in comparison with the adherence priming condition apparent at the post-assessments. Based on the in-

Table 2

Descriptives of the outcome measures.

Measures	Adherence priming		Resource priming		Supportive resource priming		Pre–post ESΔ_1		
	n	M (SD)	n	M (SD)	n	M (SD)	1.–2.	1.–3.	2.–3.
Disorder specific outcomes									
BAI									
Intake	19	23.4 (11.6)	19	24.4 (12.3)	19	22.7 (9.4)			
Intermed	17	17.1 (10.5)	19	13.8 (9.1)	17	11.3 (5.6)			
Post	14	14.8 (9.6)	18	11.8 (9.1)	17	9.9 (5.8)	−0.43	−0.53	−0.03
Follow-up	15	13.0 (10.4)	16	9.4 (8.4)	14	13.7 (10.1)			
PSWQ									
Intake	19	63.2 (7.2)	19	65.4 (7.8)	19	63.7 (7.0)			
Intermed	17	59.8 (5.8)	19	58.3 (8.8)	17	55.8 (8.7)			
Post	14	55.0 (8.2)	18	53.0 (11.4)	17	51.2 (7.8)	−0.42	−0.54	−0.01
Follow-up	15	52.6 (8.1)	16	50.9 (12.5)	14	50.4 (7.0)			
Secondary outcomes									
BDI-II									
Intake	19	16.9 (8.0)	19	22.7 (10.1)	19	21.4 (10.3)			
Intermed	17	14.4 (10.5)	19	13.7 (8.2)	17	15.6 (8.3)			
Post	14	10.6 (8.8)	18	11.7 (10.5)	17	10.2 (5.5)	−0.49	−0.67	−0.02
Follow-up SCL-9	15	8.7 (5.4)	16	7.5 (7.5)	14	10.8 (6.8)			
Intake	19	14.3 (7.5)	19	16.4 (6.7)	19	17.9 (6.7)			
Intermed	17	13.5 (6.5)	19	11.2 (5.5)	17	11.3 (5.1)			
Post	14	10.1 (6.7)	18	8.8 (6.6)	17	8.9 (5.1)	−0.51	−0.81	−0.24
Follow-up	15	7.0 (4.9)	16	8.0 (7.3)	14	8.5 (4.9)			
RES$_2$									
Intake	19	116.5 (22.0)	19	107.7 (31.8)	19	112.0 (33.0)			
Intermed	17	123.3 (24.6)	19	129.9 (32.9)	17	126.3 (29.6)			
Post	14	140.0 (20.6)	18	144.5 (39.7)	17	144.5 (29.5)	−0.42	−0.35	0.12
Follow-up	15	125.7 (31.6)	16	144.7 (34.2)	14	130.4 (27.5)			
Outcome composite$_3$									
Intake	19	55.2 (8.2)	19	58.3 (10.3)	19	57.7 (9.1)			
Intermed	17	51.9 (8.3)	19	49.6 (8.8)	17	48.9 (7.9)			
Post	14	47.8 (8.9)	18	45.5 (11.4)	17	45.1 (6.0)	−0.53	−0.69	−0.02
Follow-up	15	45.3 (7.2)	16	43.9 (10.7)	14	45.8 (8.8)			

Legend. BAI = Beck Anxiety Inventory, PSWQ = Penn State Worry Questionnaire, BDI = Beck Depression Inventory II, SCL = Symptom Check List 9, RES = Resource Self-report Questionnaire. Intake = intake assessment, Intermed = intermediate assessment at week 6, post = post-assessment at week 14, Follow-up = 6-month follow-up.

1. = adherence priming, 2. = resource priming, 3. = supportive resource priming.

$_1$ = Relative effect sizes (ESΔ) from intake to post-assessment; adherence priming is reference group; ES of RES is reversed.

$_2$ = higher scores represent more resources.

$_3$ = Standardized composite of symptom reduction of all 5 self-report questionnaires.

session observer ratings, both resource priming conditions indicated higher strengths-orientation ("resource activation") in comparison with the adherence priming condition. The implementation of an evidence-based treatment is largely principle-based, allowing considerable therapeutic flexibility in the determination and timing of different treatment aspects (Norcross, 2011; Cheavens et al., 2012; Castonguay & Beutler, 2006). Therefore, therapists using these treatments must make decisions about these different treatment aspects.

There are several theoretical considerations that might or might not explain these efficacy differences alone or in combination with each other. As a final common pathway, individuals who suffer from GAD might show restrictions in proactive behaviors as they become focused on avoiding events rather than approaching activities with personal values. The capitalization model might sensitize the therapists for productive proactive patient behaviors in generalized anxiety (Roemer et al., 2005; Flückiger et al., 2013) and also in humans more generally (Bohart & Tallman, 1999; Padesky & Mooney, 2012); and vice versa, the adherence priming condition might tend to make therapists maintain the restricted focus on avoiding negative events (e.g., get out of GAD) and rigid information processing (Newman & Llera, 2011).

Interestingly, the resource priming condition indicated higher in-session and general therapeutic competences in comparison with the supportive priming condition and the adherence priming condition. Although meta-analytic findings and our study results do not support that the general a priori defined (cognitive behavioral) therapist competences are generally correlated with treatment outcomes (Webb et al., 2010), our results indicate a somewhat paradoxical picture that therapists who were straightforwardly focused on a common strategy to

get competent adherence to the treatment protocol did not achieve higher competence scores than those therapists who did not have such an explicit focus. Nonetheless, these findings are in line with the

Table 3

Growth model from intake to 6-month follow-up assessment.

	Outcome composite	
	Coeff (SE)	t-Ratio
Fixed part		
For intake		
Base (β_{00})	57.6 (2.0)	
Adherence priming (β_{01})	−2.3 (2.7)	0.9
Resource priming (β_{02})	0.4 (3.0)	0.1
For linear growth		
Base (β_{10})	−33.4 (6.9)	4.9***
Adherence priming (β_{11})	19.9 (8.9)	2.2*
Resource priming (β_{12})	5.1 (10.2)	0.5
For quadratic growth		
Base (β_{20})	21.4 (6.7)	3.2**
Adherence priming (β_{21})	−17.0 (8.6)	2.2*
Resource priming (β_{22})	−6.4 (9.0)	0.7
Random part		
Level 2 intercept (r_{0j})	45.5	
Level 2 linear growth (r_{1j})	18.9	
Level 1 (e_{tj})	28.5	

dfs for t-ratio = 54; 194.

Outcome composite of symptom reduction based on BAI, PSWQ, BDI-II, SCL-9, and RES.

  * p < 0.05.
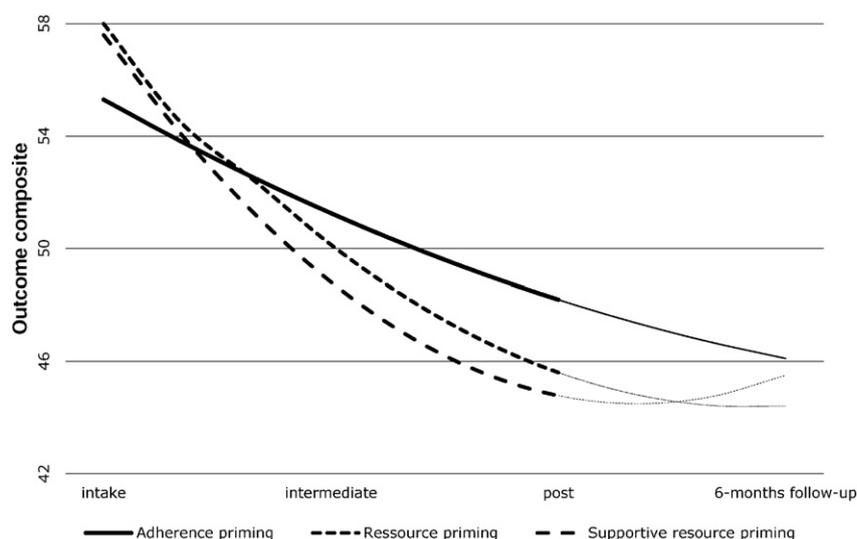
  ** p < 0.01.

  *** p < 0.001.

Fig. 2. Growth models of symptom reduction from intake to follow-up assessment. Legend: M = 50, SD = 10; standardized outcome composite of 5 self-report questionnaires BAI, PSWQ, BDI-II, SCL-9, and RES.

results that therapists' adherence flexibility (Owen & Hilsenroth, 2014) and further aspects of therapists' flexibility in general might impact therapist-patient in-session interactions as well as treatment outcomes (Wampold & Imel, 2014; Ackerman & Hilsenroth, 2003; Grawe, 2006).

In designing the present study, we considered possible alternative explanations for potential efficacy differences: *First, patient preferences.* In human treatments where patients and treatment providers closely work together, patients might have preferences for a certain treatment protocol (such as e.g. a psychodynamic or a cognitive behavioral therapy) and therefore might explicitly contact a specialized provider. Patients are usually informed about the specific treatment approach or modality and are therefore able to detect the specified randomized condition of their treatment (e.g., group vs. single setting; treatment tradition). Because this trial did not contrast distinctive overall treatment protocols, patients were not informed about any randomization procedure at any stage of the study implementation. However, the patients were informed about the overall treatment protocol (MAW-packet), and within this packet, the patient's preferences for specific interventions and procedures might well be a careful advisement in all three priming conditions. *Second, therapists' preferences.* Therapists were recruited to learn a specific treatment protocol of a neglected disorder in the mental health system (GAD). At the recruitment, they were not informed about the major research interest in the three randomized priming conditions. However, as in many randomized clinical intervention studies, therapists were not randomized for the conditions, and the therapists' preferences for committing to a priming partner, a priming condition and the supervisors were taken into account. In the adherence of priming condition there was a peer dyad that had no preference to a specific priming condition, which resulted in concerns from the research team that these therapists might tend to be slightly more flexible or alternatively less allegiant to this condition. However, therapists'

preferences for emphasizing a specific intervention component such as in vivo situational exposure or cognitive restructuring within the MAW-packet might be well considered in all three conditions. *Third, researcher allegiance.* Researcher's interests might impact the performance of therapists and the study conduction more generally, for example, the therapists might have believed that the supportive resource priming condition was preferred by the research team (e.g. GB as CBT-couple therapist and head of the department where this trial was conducted) and therefore had extraordinary engagement in this condition. However, when arranging the research team, the three senior researchers had three different theoretical backgrounds and were themselves divided in their predictions, with each having contrary expectations about the relative efficacy of the three conditions. Furthermore, the design of three treatment arms was selected to enable study replication for potential effects in favor of capitalization models. Nonetheless, researcher allegiance may have impacted the present study results even though the authors intended to minimize such effects (Wampold & Imel, 2014).

There are several substantial limitations that merit consideration. First, the careful selection process of individuals who suffer from GAD limited the sample size, as is a common phenomenon in all randomized clinical trials on GAD. The meta-analysis of Hanrahan, for example, indicated a mean intent-to-treat sample size of 48 participants for each study. Second, the study enrolment might have tended to select well-educated individuals who suffer from GAD. Although the comorbidity rates and the prior psychotherapies indicate lasting distress and suffering in these individuals, this study population might also tend to be well skilled in other functional areas. It might be true that the individuals in this population were especially encouraged and attracted by the capitalization model. Third, the (on average) 30-year-old female therapists with considerable experience in participating in randomized controlled

Table 4
In-session competence ratings.

CTS-G	Adherence priming	Resource priming	Supportive resource priming	Posthoc[1]
	M (SD)	M (SD)	M (SD)	
Resource activation	4.0 (0.09)	4.6 (0.09)	4.4 (0.08)	1. < 2. = 3.
Session-structuring comp.	3.9 (0.09)	4.3 (0.09)	3.9 (0.08)	1. = 3. < 2.
General therapeutic comp.	4.0 (0.07)	4.3 (0.07)	4.1 (0.06)	1. = 3. < 2.

1. = adherence priming, 2. = resource priming, 3. = supportive resource priming, CTS-G = Cognitive Therapy Scale − German version.
[1] = Tukey.
n = 100 sessions.

trials were highly intrinsically motivated to learn the present treatment protocol initiated, e.g., by the initial workshop. This might limit the generalizability of the present implementation study to settings with less dedicated therapists. Forth, because the individuals that suffer from GAD probably are the most direct source of information to evaluate their worrying, the outcomes were assessed by self-report measures. However, other sources of information e.g. rated by observer might provide a broader picture of treatment outcomes. Fifth, the observer-ratings were focused on competence ratings of selected sessions. More comprehensive analyses of all sessions may provide a much more precise picture of competence and adherence ratings over the whole therapy.

Clearly, before further replications, the present promising but preliminary data should be interpreted cautiously.

Beyond replication, future research with larger samples of patients as well as therapists might examine more precise pathways along common processes through which the capitalization model may outperform the compensation model. For example, therapists' dedicated engagement in a therapy and/or a patient might represent a shared aspect of capitalization models and therapist/researcher allegiance concepts (Wampold & Imel, 2014). Furthermore, future trials should not only be designed to investigate priming effects between conditions, but should also be designed to investigate potential priming effects within therapists using crossed-therapist designs (Baldwin & Imel, 2013). In respect to patient populations, capitalization and compensation models should be tested in other populations to examine if and how the patients might benefit from or be harmed by capitalization models (Wingate et al., 2005). The present trial shows the promise of theoretically driven systematic strategies of how to implement an overall treatment packet. It highlights the empirically slightly disregarded practical issue of "how to implement" rather than "what to implement" under rigorous randomized controlled study conditions.

Contributors

CF, RZ and GB designed the trial. CF was funded by the Swiss National Science Foundation (SNSF) and had the main lead in the trial. RZ provided the CBT training for the trial therapists and research workers. IB, LF, and BS conducted the data collection. CF, LF, and BS conducted the analyses of the trial outcomes and observer ratings. CF took responsibility for drafting the study report. All authors contributed to reading and correcting the study report and approved the final report. We thank all of the participants and therapists for their engagement in the trial.

Declaration of Interests

We declare no competing interests.

Role of the Funding Source

Appendix. Supplementary Data

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ebiom.2015.11.049.

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