



**Transdiagnostic, affect-focused, psychodynamic, guided self-help for depression and anxiety through the Internet: study protocol for a randomized controlled trial**

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# Transdiagnostic, affect-focused, psychodynamic, guided self-help for depression and anxiety through the Internet: study protocol for a randomized controlled trial

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For peer review only

## Abstract

### Introduction

Cognitive behavior therapy delivered in the format of guided self-help via the Internet has been found to be effective for a range of conditions, including depression and anxiety disorders. Recent results indicate that guided self-help via the Internet is a promising treatment format also for psychodynamic therapy. However, to date and to our knowledge, no study has evaluated Internet-delivered psychodynamic therapy as a transdiagnostic treatment. The affect-phobia model of psychopathology by McCullough et al. provides a psychodynamic conceptualization of a range of psychiatric disorders. The aim of this study will be to test the effects of a transdiagnostic guided self-help treatment based on the affect-phobia model in a sample of clients with depression and anxiety.

### Methods and analysis

This study will be a randomized controlled trial with a total sample size of 100 participants. The treatment group receives a 10-week, psychodynamic, guided self-help treatment based on the transdiagnostic affect-phobia model of psychopathology. The treatment consists of eight text-based treatment modules and includes therapist contact in a secure online environment. Participants in the control group receive similar online therapist support without any treatment modules. Outcome measures are the 9-item Patient Health Questionnaire Depression Scale (PHQ-9) and the 7-item Generalized Anxiety Disorder Scale (GAD-7). Process measures that concerns emotional processing and mindfulness are included. All outcome and process measures will be administered weekly via the Internet and at six-month follow-up.

## Discussion

This trial will add to the body of knowledge on Internet-delivered psychological treatments in general and to psychodynamic treatments in particular. We also hope to provide new insights in the effectiveness and working mechanisms of psychodynamic therapy based on the affect-phobia model.

## Ethics and dissemination

The protocol was approved by the regional ethics board of Linköping, Sweden.

Written informed consent will be obtained from all participants.

## Trial Registration

ClinicalTrials.gov: NCT01532219

## Article summary

### Article focus

- Depression and anxiety disorders are major health problems, which lower the quality of life for the individual and generate large costs for society.
- Internet-delivered CBT in the form of guided self-help are effective in the treatment of depression and anxiety disorders.
- Psychodynamic therapy via the Internet seem effective for specific disorders, but has not been evaluated as a transdiagnostic Internet-delivered treatment
- A transdiagnostic, affect-focused, psychodynamic, Internet-delivered guided self-help will be tested in a sample of participants with depression and anxiety disorders.

### Key messages

- Treatments based on the affect-phobia model of psychopathology has not previously been evaluated as guided self-help delivered via the Internet.
- Potential processes of change will be measured during treatment and mechanisms of the treatment will be investigated. This will contribute both to

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3 the field of psychodynamic treatments and to that of Internet-delivered  
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5 psychological treatments in general.  
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### 8 **Strengths and limitations of this study**

- 9 • This randomized controlled trial will compare the effectiveness of an affect-  
10 focused, psychodynamic intervention to an active control condition.  
11
- 12 • A sample of 100 participants will be used to ensure sufficient power.  
13
- 14 • Mechanisms of change will be investigated using state-of the art methods for  
15 evaluating longitudinal mediation.  
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### 20 **Introduction**

21  
22 Depression and anxiety disorders are major health problems, which lower the quality  
23 of life for the individual and generate large costs for society [1, 2]. Lifetime  
24 prevalence for mood disorders and anxiety disorders have been estimated to be 20.8%  
25 and 28.8%, respectively [3]. Treatment alternatives include various psychotherapies,  
26 among which cognitive behavior therapy (CBT) has an established strong empirical  
27 base [4, 5]. However, psychodynamic therapy has also shown promising results for  
28 the treatment of depression [6], panic disorder [7] and generalized anxiety disorder  
29 (GAD) [8]. During the last decade, there has been significant progress in research  
30 concerning psychological guided self-help treatments and Internet-delivered  
31 psychotherapies [9, 10]. Recent meta-analyses have shown that Internet-delivered  
32 CBT (ICBT), given as guided self-help, and face-to-face psychotherapy, is equally  
33 effective in the treatment of depression and anxiety disorders [11].  
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52 Almost all published studies in the field of Internet-delivered psychological  
53 treatments have endorsed a CBT approach. However, results from two recent  
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3 randomized trials concerning depression and GAD indicate that psychodynamic  
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5 therapy can also be delivered via the Internet [12, 13].  
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### 8 **Transdiagnostic and unified treatments**

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10 A large portion of evidence-based psychological treatments target specific conditions,  
11  
12 e.g. depression and social anxiety disorder. There are also transdiagnostic and unified  
13  
14 protocols where the treatment material has been arranged to fit a broader range of  
15  
16 patients [14]. Typically, the interventions in these protocols are based on  
17  
18 psychological treatment components that target common behavioral patterns in  
19  
20 various disorders, such as avoidance behaviors and maladaptive thought patterns,  
21  
22 using e.g., exposure, cognitive restructuring, and emotion regulation techniques [14].  
23  
24 Transdiagnostic Internet-delivered CBT protocols have been developed and tested  
25  
26 with promising results among clients with anxiety disorders and depression [15, 16].  
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### 29 **Affect-phobia treatment and affect-focused psychodynamic treatment**

30  
31 McCullough et al [17] described a treatment model which is an example of a unified  
32  
33 treatment grounded in psychodynamic theory. The model, called *affect-phobia*  
34  
35 *treatment* (APT), follows the fundamental structure of psychodynamic psychotherapy  
36  
37 as outlined by Malan's triangle of conflict (i.e., defenses and anxieties block the  
38  
39 expression of feelings) and triangle of person (i.e., work with conflicts in relation to  
40  
41 the therapist and current and past persons) [18]. In a psychodynamic therapy based on  
42  
43 the APT model, the therapist typically clarifies defenses, helps the client to observe  
44  
45 and experience the underlying affects, and helps the client to regulate associated  
46  
47 anxiety [17]. Formally, the treatment includes three main treatment objectives:  
48  
49 defense restructuring (recognizing and relinquishing maladaptive defenses), affect  
50  
51 restructuring (desensitization of affects through exposure to conflicted feeling), and  
52  
53 self/other restructuring (improvement in sense of self and relationship with others). In  
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summary, the main goal of psychodynamic psychotherapy based on the APT model is to help clients experience and to adaptively express feelings, that have been previously avoided [17].

Two randomized trials have investigated the efficacy of APT for personality disorders [19, 20]. These trials showed that affect-phobia treatment can be effective in reducing general psychiatric symptoms. However, except for case-series and some small uncontrolled studies (e.g. [21]), to date no trial has investigated the efficacy of APT for patients with a primary Axis I disorder.

### **Processes of change**

To develop more effective psychotherapeutic treatments, it is crucial to understand the mechanisms of change that contribute to improvement in therapy. However, the mechanisms that cause therapeutic change are still largely unknown. In the experiential and psychodynamic traditions, including APT, experiencing and processing of the affective experience is considered central to therapeutic change [22, 23]. Typically, the therapist in APT helps the client recognize maladaptive defenses, regulate anxiety, and to gradually experience feelings through systematic desensitization to the conflicted emotions [17]. Thus, emotional processing seems to be a relevant concept for understanding psychological treatments based on the APT model.

## **Methods and analysis**

### **Design of the study and ethics statement**

The current study will be a randomized controlled trial with a sample size of 100 participants. The study protocol was approved by the regional Ethics Review Board in



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2  
3 Linköping, Sweden. Written informed consent will be obtained from all participants  
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5 using an online screening environment.  
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### 8 **Study population**

9 Patients will be recruited from the community via advertisements in newspapers and  
10 on the Internet. To be included in the study, the participant must be at least 18 years  
11 of age and fulfill a primary DSM-IV diagnosis of either depression, social anxiety  
12 disorder, panic disorder, or generalized anxiety disorder. The Mini-International  
13 Neuropsychiatric Interview (M.I.N.I.; [24]) will be used to diagnose DSM-IV  
14 disorders. In addition, the participant must score at least 10 on either the 9-item  
15 Patient Health Questionnaire Depression Scale (PHQ-9 [25]) or the 7-item  
16 Generalized Anxiety Disorder Scale (GAD-7 [26]). Participants with a primary  
17 diagnoses of post-traumatic stress disorder and obsessive-compulsive disorder will be  
18 excluded. This restriction is due to the fact that the APT model does not conceptualize  
19 these disorders as phobias of affect, and hence, the treatment material used is not  
20 assumed to be applicable in these cases [17]. Additional exclusion criteria include  
21 suffering from a severe psychiatric conditions such as bipolar disorder or psychosis;  
22 alcohol abuse; and ongoing participation in any psychotherapy. Moreover, if the  
23 participant is receiving psychotropic medication, the dosage must have been stable for  
24 at least three months prior to the start of the treatment.  
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### 46 **Sample size**

47 A power calculation [27] using a linear mixed-effects model (10 time points with an  
48 autoregressive error structure with a random intercept and slope) showed that  
49 approximately 46 (46.3) participants in each condition would be sufficient to detect a  
50 moderate between-group effect size of Cohen's  $d = 0.50$  ( $\alpha$  level = 0.05) with 80%  
51 power. Assuming a total attrition rate of 10% (at equal rate across time and  
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3 condition), a similar power calculation estimated sample size to be approximately 51  
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5 (51.3) participants per condition. Given these results, we aim to include 100  
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7 participants in the study.  
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### 10 **Interventions**

11 The treatment will be given as guided self-help with minimal text-based guidance  
12  
13 provided on a weekly basis. This treatment format is an established way of delivering  
14  
15 psychological treatments for depression and anxiety disorders [9, 11]. The text  
16  
17 material used in the treatment modules will be based on the book “Living Like You  
18  
19 Mean It” by Ronald J. Frederick [28], which is theoretically grounded in  
20  
21 psychodynamic theory and affective science and follows a similar structure as the  
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23 original APT manual. There are eight modules in total, which all contain homework  
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25 exercises that a client needs to complete before proceeding on to the next module.  
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31 This treatment emphasizes the practice of mindfulness more than in traditional  
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33 psychodynamic therapy. Throughout treatment, the client is taught how to apply  
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35 mindfulness in the process of identifying, attending to, and being present with  
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37 emotional experience. In the context of the APT model, practicing “emotional  
38  
39 mindfulness” can be one way of learning how to be aware of, experience, and tolerate  
40  
41 emotions. The treatment teaches the client to gradually develop mindful presence as a  
42  
43 response to the physical manifestation of emotions which, within the APT model, can  
44  
45 be considered as exposure to one's feelings. All interventions are grounded in the  
46  
47 affect-phobia model illustrated by the conflict triangle: Maladaptive defenses are  
48  
49 identified and relinquished, anxiety is regulated, and warded off feelings are  
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51 approached and experienced. After experiencing one's core feelings, the client is  
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53 encouraged, when appropriate, to express these feelings in interpersonal contexts.  
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3 Expressing feelings to others is seen as essential to shifting both the sense of self and  
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5 others. Detailed steps of the treatment are described in Figure 1.  
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10 The online therapists will have contact with clients using a secure online environment  
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12 resembling e-mail, but with enhanced security. This mode of communication follows  
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14 a standard procedure used in a range of studies investigating ICBT [9]. The primary  
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16 role of the therapists will be to give feedback on the clients' exercises and  
17  
18 experiences, and to administer gradual access to the treatment modules. Therapists  
19  
20 will also be available on one day per week to answer additional questions. All  
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22 therapists will be supervised biweekly by Ronald J. Frederick, the author of the book  
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24 on which the treatment is based.  
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29 Participants in the active control group will not receive any text-based treatment  
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31 modules. They will, however, receive online therapist contact, where the therapists  
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33 will provide support but will not use any specific psychological techniques other than  
34  
35 basic therapeutic skills such as empathic listening and asking for clarifications. A  
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37 similar active control condition has been used in previous treatment studies [12].  
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#### 40 41 **Randomization and procedure**

42 After applying to the study, the participant will be directed to an online screening  
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44 consisting of demographic questions and of online versions of the clinical outcome  
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46 measures and the process measures (see below). These results will later be used as a  
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48 pre-treatment assessment. A participant will be contacted for a telephone-based  
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50 diagnostic interview if he or she has completed the screening and meets the initial  
51  
52 inclusion criteria (a score of at least 10 on either the PHQ-9 or the GAD-7). The  
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54 interview consists of diagnostic interview questions about depression and anxiety  
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3 disorders in addition to questions about use of medications and psychological  
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5 treatments. Primary diagnosis assessed during the interview will be recorded.  
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8 Psychiatric diagnoses are confirmed using the M.I.N.I. [24].  
9

### 10 **Assessments**

11 Clinical outcome will be measured both by self-report questionnaires and a clinical  
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13 interview. Mechanisms of change will be measured by two self-report measures.  
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15 Clinical and process self-report measures will be administered weekly during the  
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17 treatment phase. At the six-month follow-up, a clinical interview will be conducted in  
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19 addition to self-report measures.  
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### 24 **Clinical outcome measures**

25 Measures of depression and anxiety will be the 9-item Patient Health Questionnaire  
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27 Depression Scale (PHQ-9 [25]) and the 7-item Generalized Anxiety Disorder Scale  
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29 (GAD-7 [26]). The PHQ-9 is an established measure of depression which contains  
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31 nine items, each scored 0–3 and with a total score in the range of 0 to 27. It has been  
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33 shown to have good psychometric properties (Cronbach's  $\alpha$  in the range 0.86 – 0.89)  
34  
35 [29]. The GAD-7 was originally developed to diagnose generalized anxiety disorder,  
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37 but has also proved useful in detecting and assessing severity of panic, social anxiety,  
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39 and post-traumatic stress disorder [26]. Psychometric properties have been proved to  
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41 be good also for the GAD-7 (Cronbach's  $\alpha = 0.92$ ) [29].  
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48 The combination of PHQ-9 and GAD-7 for measuring depression and anxiety have  
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50 been used in several treatment trials, e.g. in the implementation of psychological  
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52 therapies for anxiety and depression in British routine practice, which includes data  
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54 from 7859 patients [30].  
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3 In addition to the self-report measures, clinical outcome will be measured in a clinical  
4 interview. Psychiatric diagnoses will be assessed at post-treatment and at follow-up  
5 using the M.I.N.I. The interview also aims to give an estimate of global improvement,  
6 measured by the 7-point version of the Clinical Global Impression - Improvement  
7 (CGI-I) scale [31]. Assessors of outcome in the clinical interview will be blind to  
8 treatment condition.  
9  
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### 11 **Process measures**

12 In affect-phobia therapy, emotional processing is assumed to be related to symptom  
13 change. To explore this further in the current study, the Emotional Processing Scale  
14 (EPS-25) [32] will be used to assess emotional processing deficits and the process of  
15 emotional change during treatment. The measure contains five sub-scales, three of  
16 these relate to emotional control or dysregulation (emotional avoidance, suppression,  
17 unregulated emotion, one sub-scale (impoverished emotional experience) shares some  
18 properties with the alexithymia construct [32], and the last sub-scale (signs of  
19 unprocessed emotion) refers to persistent and intrusive emotional phenomena. The  
20 total score of the EPS-25 reflects the overall level of emotional processing deficit  
21 [32]. Psychometric properties for the EPS-25 has been found to be strong (Cronbach's  
22  $\alpha = 0.92$ ) [32].  
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45 As described above, the treatment has a strong mindfulness component. Thus, the  
46 amount of mindfulness skills that the client acquires during treatment may be related  
47 to outcome. To assess the influence of mindfulness, the Five Facets of Mindfulness  
48 Questionnaire (FFMQ; [33]) is included to measure general mindfulness skills. The  
49 original FFMQ by Baer et al. [33] contains 39 items, while the Swedish version that  
50 will be used in this study consists of 29 items [34]. The correlation between the  
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3 Swedish FFMQ and the original FFMQ is  $r = .98$  [34]. The FFMQ was constructed as  
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5 a multi-faceted assessment of mindfulness, measuring a general tendency to be  
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7 mindful in daily life, which is defined by five factors: observing, describing, acting  
8  
9 with awareness, non-judging of inner experience, and non-reactivity to inner  
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11 experience [33]. Psychometric properties have been proved to be good for the  
12  
13 Swedish 29-item FFMQ (Cronbach's  $\alpha = 0.81$ ) [34].  
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### 16 17 **Statistical analyses**

18 Differences in efficacy between the treatment and the active control group will  
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20 primarily be investigated by modeling interaction effects of group and time. In order  
21  
22 to adhere to the intention-to-treat principle, the outcome variables will be analyzed  
23  
24 using mixed effects models, given their ability to handle missing data [35]. To  
25  
26 examine processes of change in full detail using week-to-week measurements of both  
27  
28 processes (i.e., emotional processing and mindfulness) and outcomes, state-of the art  
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30 methods for evaluating longitudinal mediation will be employed [36]. All analyses  
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32 will use full information maximum likelihood estimation, which provides unbiased  
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34 estimates and correct standard errors in the presence of missing data, assuming data  
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36 loss is missing for non-ignorable reasons [37].  
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### 41 42 **Main research questions and hypotheses**

- 43 - Is a transdiagnostic, affect-focused, psychodynamic, Internet-delivered, guided self-  
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45 help approach effective in reducing symptoms of depression and anxiety, when  
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47 compared to an active control condition?  
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49 - Do the degrees of emotional processing and mindfulness change more in the  
50  
51 treatment condition than in the active control condition?  
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53 - Do the degrees of emotional processing and mindfulness mediate symptom change  
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55 on depression and anxiety measures?  
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## Discussion

This study will test the efficacy of a transdiagnostic, psychodynamically oriented, 10-week, guided self-help treatment, based on an affect-phobia model of psychopathology. In addition, the study will explore working mechanisms of the treatment.

An important aim of the treatment tested is to stay close to the APT model. The conceptualization of psychological problems are the same as in the original manual and the treatment is structured similarly. While the treatment does differ in some aspects (e.g., by not making use of transference relations) it is still reasonable to assume that the essence of affect-phobia treatment is preserved. To our knowledge, no studies have investigated the efficacy of a similar treatment protocol via the Internet.

Hence, this study will contribute to the empirical base of Internet-delivered psychological treatments in general and to that of psychodynamic approaches in particular. Moreover, no previous treatment study exists that evaluates the efficacy of face-to-face affect-phobia therapy for Axis I-disorders using a randomized controlled trial. Therefore, this study also adds to the empirical base of psychodynamic therapies in general.

Investigating the mediating effects of emotional processing and mindfulness provides an opportunity to explore the mechanisms of change in affect-focused, psychodynamic therapy. The processes that contribute to therapeutic change are largely unknown. This study aims to explore how emotional processing is related to treatment outcome and thus tests the assumption that emotional processing is a crucial process in psychodynamic treatments based on the APT model. In addition, the role of mindfulness is similarly explored.

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5 Moreover, there is a lack of psychodynamic therapy in other treatment formats than  
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7 individual and group. Using the Internet format of delivery makes it possible to reach  
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9 individuals who lack access to therapists nearby, or who simply do not want to meet  
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11 face-to-face [9].  
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16 In addition, there are also benefits of using one transdiagnostic protocol compared to  
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18 having several specific programs. Clients with different disorders and comorbidities  
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20 can be treated using the same protocol. This approach could potentially increase a  
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22 scope of a treatment implementation in, for example, a psychiatric clinic or in primary  
23  
24 care. By developing transdiagnostic protocols, the amount of therapist training could  
25  
26 also potentially be reduced, as clinicians may need to learn fewer programs.  
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### 30 **Competing interests**

31  
32 RJF is the author of the book used as a basis for the treatment manual.  
33  
34

### 35 **Authors' contributions**

36  
37 RJ in collaboration with HH and GA designed the study. RJ and HH drafted the  
38  
39 manuscript. BL, RJF and GA reviewed and revised the manuscript. All authors have  
40  
41 read and approved the final manuscript to be published.  
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47  
48 and Linköping University (Professor contract).  
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## Figures

### Figure 1 - Description of the modules in the treatment.

Description of the modules in the treatment.

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**Module 1.** Introduction and problem formulation using the affect-phobia model.

**Module 2.** Historical understanding and explanation of the problem described.

**Module 3.** Mindfulness practice to start approaching emotional experience.

**Module 4.** Defense restructuring.

**Module 5.** Anxiety regulation techniques.

**Module 6.** Affect experiencing techniques.

**Module 7.** Affect expression and self/other restructuring.

**Module 8.** A summary of the previous material and advice for continued work.



**Transdiagnostic, affect-focused, psychodynamic, guided self-help for depression and anxiety through the Internet: study protocol for a randomized controlled trial**

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4 **Transdiagnostic, affect-focused, psychodynamic,**  
5 **guided self-help for depression and anxiety**  
6 **through the Internet: study protocol for a**  
7 **randomized controlled trial**  
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## Abstract

### Introduction

Cognitive behavior therapy delivered in the format of guided self-help via the Internet has been found to be effective for a range of conditions, including depression and anxiety disorders. Recent results indicate that guided self-help via the Internet is a promising treatment format also for psychodynamic therapy. However, to date and to our knowledge, no study has evaluated Internet-delivered psychodynamic therapy as a transdiagnostic treatment. The affect-phobia model of psychopathology by McCullough et al. provides a psychodynamic conceptualization of a range of psychiatric disorders. The aim of this study will be to test the effects of a transdiagnostic guided self-help treatment based on the affect-phobia model in a sample of clients with depression and anxiety.

### Methods and analysis

This study will be a randomized controlled trial with a total sample size of 100 participants. The treatment group receives a 10-week, psychodynamic, guided self-help treatment based on the transdiagnostic affect-phobia model of psychopathology. The treatment consists of eight text-based treatment modules and includes therapist contact in a secure online environment. Participants in the control group receive similar online therapist support without any treatment modules. Outcome measures are the 9-item Patient Health Questionnaire Depression Scale (PHQ-9) and the 7-item Generalized Anxiety Disorder Scale (GAD-7). Process measures that concerns emotional processing and mindfulness are included. All outcome and process measures will be administered weekly via the Internet and at six-month follow-up.

## Discussion

This trial will add to the body of knowledge on Internet-delivered psychological treatments in general and to psychodynamic treatments in particular. We also hope to provide new insights in the effectiveness and working mechanisms of psychodynamic therapy based on the affect-phobia model.

## Ethics and dissemination

The protocol was approved by the regional ethics board of Linköping, Sweden.

Written informed consent will be obtained from all participants.

## Trial Registration

ClinicalTrials.gov: NCT01532219

## Article summary

### Article focus

- Depression and anxiety disorders are major health problems, which lower the quality of life for the individual and generate large costs for society.
- Internet-delivered CBT in the form of guided self-help are effective in the treatment of depression and anxiety disorders.
- Psychodynamic therapy via the Internet seem effective for specific disorders, but has not been evaluated as a transdiagnostic Internet-delivered treatment
- A transdiagnostic, affect-focused, psychodynamic, Internet-delivered guided self-help will be tested in a sample of participants with depression and anxiety disorders.

### Key messages

- Treatments based on the affect-phobia model of psychopathology has not previously been evaluated as guided self-help delivered via the Internet.
- Potential processes of change will be measured during treatment and mechanisms of the treatment will be investigated. This will contribute both to

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3 the field of psychodynamic treatments and to that of Internet-delivered  
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5 psychological treatments in general.  
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### 8 **Strengths and limitations of this study**

- 9 • This randomized controlled trial will compare the effectiveness of an affect-  
10 focused, psychodynamic intervention to an active control condition.  
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- 12 • A sample of 100 participants will be used to ensure sufficient power.  
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- 14 • Mechanisms of change will be investigated using state-of the art methods for  
15 evaluating longitudinal mediation.  
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### 20 **Introduction**

21  
22 Depression and anxiety disorders are major health problems, which lower the quality  
23 of life for the individual and generate large costs for society [1, 2]. Lifetime  
24 prevalence for mood disorders and anxiety disorders have been estimated to be 20.8%  
25 and 28.8%, respectively [3]. Treatment alternatives include various psychotherapies,  
26 among which cognitive behavior therapy (CBT) has an established strong empirical  
27 base [4, 5]. However, psychodynamic therapy has also shown promising results for  
28 the treatment of depression [6], panic disorder [7] and generalized anxiety disorder  
29 (GAD) [8]. During the last decade, there has been significant progress in research  
30 concerning psychological guided self-help treatments and Internet-delivered  
31 psychotherapies [9, 10]. Recent meta-analyses have shown that Internet-delivered  
32 CBT (ICBT), given as guided self-help, and face-to-face psychotherapy, is equally  
33 effective in the treatment of depression and anxiety disorders [11].  
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52 Almost all published studies in the field of Internet-delivered psychological  
53 treatments have endorsed a CBT approach. However, results from two recent  
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3 randomized trials concerning depression and GAD indicate that psychodynamic  
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5 therapy can also be delivered via the Internet [12, 13].  
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### 8 **Transdiagnostic and unified treatments**

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10 A large portion of evidence-based psychological treatments target specific conditions,  
11  
12 e.g. depression and social anxiety disorder. There are also transdiagnostic and unified  
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14 protocols where the treatment material has been arranged to fit a broader range of  
15  
16 patients [14]. Typically, the interventions in these protocols are based on  
17  
18 psychological treatment components that target common behavioral patterns in  
19  
20 various disorders, such as avoidance behaviors and maladaptive thought patterns,  
21  
22 using e.g., exposure, cognitive restructuring, and emotion regulation techniques [14].  
23  
24 Transdiagnostic Internet-delivered CBT protocols have been developed and tested  
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26 with promising results among clients with anxiety disorders and depression [15, 16].  
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### 29 **Affect-phobia treatment and affect-focused psychodynamic treatment**

30  
31 McCullough et al [17] described a treatment model which is an example of a unified  
32  
33 treatment grounded in psychodynamic theory. The model, called *affect-phobia*  
34  
35 *treatment* (APT), follows the fundamental structure of psychodynamic psychotherapy  
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37 as outlined by Malan's triangle of conflict (i.e., defenses and anxieties block the  
38  
39 expression of feelings) and triangle of person (i.e., work with conflicts in relation to  
40  
41 the therapist and current and past persons) [18]. In a psychodynamic therapy based on  
42  
43 the APT model, the therapist typically clarifies defenses, helps the client to observe  
44  
45 and experience the underlying affects, and helps the client to regulate associated  
46  
47 anxiety [17]. Formally, the treatment includes three main treatment objectives:  
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49 defense restructuring (recognizing and relinquishing maladaptive defenses), affect  
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51 restructuring (desensitization of affects through exposure to conflicted feeling), and  
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53 self/other restructuring (improvement in sense of self and relationship with others). In  
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3 summary, the main goal of psychodynamic psychotherapy based on the APT model is  
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5 to help clients experience and to adaptively express feelings, that have been  
6  
7 previously avoided [17].  
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11 Two randomized trials have investigated the efficacy of APT for personality disorders  
12 [19, 20]. These trials showed that affect-phobia treatment can be effective in reducing  
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14 general psychiatric symptoms. However, except for case-series and some small  
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16 uncontrolled studies (e.g. [21]), to date no trial has investigated the efficacy of APT  
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18 for patients with a primary Axis I disorder.  
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### 22 23 24 **Processes of change**

25 To develop more effective psychotherapeutic treatments, it is crucial to understand the  
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27 mechanisms of change that contribute to improvement in therapy. However, the  
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29 mechanisms that cause therapeutic change are still largely unknown. In the  
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31 experiential and psychodynamic traditions, including APT, experiencing and  
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33 processing of the affective experience is considered central to therapeutic change [22,  
34  
35 23]. Typically, the therapist in APT helps the client recognize maladaptive defenses,  
36  
37 regulate anxiety, and to gradually experience feelings through systematic  
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39 desensitization to the conflicted emotions [17]. Thus, emotional processing seems to  
40  
41 be a relevant concept for understanding psychological treatments based on the APT  
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43 model.  
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### 48 49 **Main research questions and hypotheses**

50 - Is a transdiagnostic, affect-focused, psychodynamic, Internet-delivered, guided self-  
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52 help approach effective in reducing symptoms of depression and anxiety, when  
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54 compared to an active control condition?  
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3 - Do the degrees of emotional processing and mindfulness change more in the  
4 treatment condition than in the active control condition?  
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7 - Do the degrees of emotional processing and mindfulness mediate symptom change  
8 on depression and anxiety measures?  
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## 11 **Methods and analysis**

### 12 **Design of the study and ethics statement**

13 The current study will be a randomized controlled trial with a sample size of 100  
14 participants. The study protocol was approved by the regional Ethics Review Board in  
15 Linköping, Sweden. Written informed consent will be obtained from all participants  
16 using an online screening environment.  
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### 26 **Study population**

27 Patients will be recruited from the community via advertisements in newspapers and  
28 on the Internet. To be included in the study, the participant must be at least 18 years  
29 of age and fulfill a principal DSM-IV diagnosis of either depression, social anxiety  
30 disorder, panic disorder, or generalized anxiety disorder. The Mini-International  
31 Neuropsychiatric Interview (M.I.N.I.; [24]) will be used to diagnose DSM-IV  
32 disorders. Last-semester MSc students from a five-year clinical psychology program,  
33 who have been trained in the diagnostic procedure, will conduct the interviews by  
34 telephone. In addition, the participant must score at least 10 on either the 9-item  
35 Patient Health Questionnaire Depression Scale (PHQ-9 [25]) or the 7-item  
36 Generalized Anxiety Disorder Scale (GAD-7 [26]). Participants with a principal  
37 diagnoses of post-traumatic stress disorder or obsessive-compulsive disorder will be  
38 excluded. This restriction is due to the fact that the APT model does not conceptualize  
39 these disorders as phobias of affect, and hence, the treatment material used is not  
40 assumed to be applicable in these cases [17]. Additional exclusion criteria include  
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3 suffering from a severe psychiatric conditions such as bipolar disorder or psychosis;  
4 risk of suicide, assessed by the M.I.N.I. [24]; alcohol or drug abuse; and ongoing  
5 participation in any psychotherapy. Moreover, if the participant is receiving  
6 psychotropic medication, the dosage must have been stable for at least three months  
7 prior to the start of the treatment.  
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### 14 **Sample size**

15 A power calculation [27] using a linear mixed-effects model (10 time points with an  
16 autoregressive error structure with a random intercept and slope) showed that  
17 approximately 46 (46.3) participants in each condition would be sufficient to detect a  
18 moderate between-group effect size of Cohen's  $d = 0.50$  ( $\alpha$  level = 0.05) with 80%  
19 power. Assuming a total attrition rate of 10% (at equal rate across time and  
20 condition), a similar power calculation estimated sample size to be approximately 51  
21 (51.3) participants per condition. Given these results, we aim to include 100  
22 participants in the study.  
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### 35 **Interventions**

36 The treatment will be given as guided self-help with minimal text-based guidance  
37 provided on a weekly basis. This treatment format is an established way of delivering  
38 psychological treatments for depression and anxiety disorders [9, 11]. The text  
39 material used in the treatment modules will be based on the book “Living Like You  
40 Mean It” by Ronald J. Frederick [28], which is theoretically grounded in  
41 psychodynamic theory and affective science and follows a similar structure as the  
42 original APT manual. There are eight modules in total, which all contain homework  
43 exercises that a client needs to complete before proceeding on to the next module.  
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3 This treatment emphasizes the practice of mindfulness more than in traditional  
4 psychodynamic therapy. Throughout treatment, the client is taught how to apply  
5 mindfulness in the process of identifying, attending to, and being present with  
6 emotional experience. In the context of the APT model, practicing “emotional  
7 mindfulness” can be one way of learning how to be aware of, experience, and tolerate  
8 emotions. The treatment teaches the client to gradually develop mindful presence as a  
9 response to the physical manifestation of emotions which, within the APT model, can  
10 be considered as exposure to one's feelings. All interventions are grounded in the  
11 affect-phobia model illustrated by the conflict triangle: Maladaptive defenses are  
12 identified and relinquished, anxiety is regulated, and warded off feelings are  
13 approached and experienced. After experiencing one's core feelings, the client is  
14 encouraged, when appropriate, to express these feelings in interpersonal contexts.  
15 Expressing feelings to others is seen as essential to shifting both the sense of self and  
16 others. Detailed steps of the treatment are described in Figure 1.  
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36 The online therapists will have contact with clients using a secure online environment  
37 resembling e-mail, but with enhanced security. This mode of communication follows  
38 a standard procedure used in a range of studies investigating ICBT [9]. The primary  
39 role of the therapists will be to give feedback on the clients' exercises and  
40 experiences, and to administer gradual access to the treatment modules. In addition,  
41 the therapists will provide support, clarifications of the material and other forms of  
42 help that will enable the clients to complete the material on time. The therapists will  
43 answer questions once every day, during weekdays. All therapists will be supervised  
44 biweekly by Ronald J. Frederick, the author of the book on which the treatment is  
45 based.  
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5 The therapists will be three last-semester MSc students from a five-year clinical  
6 psychologist program. All therapists will have a clinical training in affect-focused  
7 psychodynamic psychotherapy and treatment experience using this method.  
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14 Participants in the active control group will not receive any text-based treatment  
15 modules. They will, however, receive online therapist contact, where the therapists  
16 will provide support but will not use any specific psychological techniques other than  
17 basic therapeutic skills such as empathic listening and asking for clarifications. A  
18 similar active control condition has been used in previous treatment studies [12].  
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### 23 24 25 26 **Randomization and procedure**

27 After applying to the study, the participant will be directed to an online screening  
28 consisting of demographic questions and of online versions of the clinical outcome  
29 measures and the process measures (see below). These results will later be used as a  
30 pre-treatment assessment. A participant will be contacted for a telephone-based  
31 diagnostic interview if he or she has completed the screening and meets the initial  
32 inclusion criteria (a score of at least 10 on either the PHQ-9 or the GAD-7). The  
33 interview consists of diagnostic interview questions about depression and anxiety  
34 disorders in addition to questions about use of medications and psychological  
35 treatments. The principal diagnosis assessed during the interview will be recorded.  
36  
37 Psychiatric diagnoses are confirmed using the M.I.N.I. [24]. The participants will be  
38 allocated to one of the two groups in a 1:1 ratio using block randomization. An  
39 independent person, separate from the staff conducting the study, will handle the  
40 randomization using an online randomization tool.  
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### Assessments

Clinical outcome will be measured both by self-report questionnaires and a clinical interview. Mechanisms of change will be measured by two self-report measures. Clinical and process self-report measures will be administered weekly during the treatment phase. At the six-month follow-up, a clinical interview will be conducted in addition to self-report measures.

### Clinical outcome measures

Measures of depression and anxiety will be the 9-item Patient Health Questionnaire Depression Scale (PHQ-9 [25]) and the 7-item Generalized Anxiety Disorder Scale (GAD-7 [26]). The PHQ-9 is an established measure of depression which contains nine items, each scored 0–3 and with a total score in the range of 0 to 27. It has been shown to have good psychometric properties (Cronbach's  $\alpha$  in the range 0.86 – 0.89) [29]. The GAD-7 was originally developed to diagnose generalized anxiety disorder, but has also proved useful in detecting and assessing severity of panic, social anxiety, and post-traumatic stress disorder [26]. Psychometric properties have been proved to be good also for the GAD-7 (Cronbach's  $\alpha = 0.92$ ) [29]. The choice to administer outcome and process measures weekly, prevented the inclusion of further measures of anxiety.

The combination of PHQ-9 and GAD-7 for measuring depression and anxiety have been used in several treatment trials, e.g. in the implementation of psychological therapies for anxiety and depression in British routine practice, which includes data from 7859 patients [30]. Both the PHQ-9 and the GAD-7 are considered primary outcome measures in the study.

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3 In addition to the self-report measures, clinical outcome will be measured in a clinical  
4 interview via telephone. Psychiatric diagnoses will be assessed at post-treatment and  
5 at follow-up using the M.I.N.I. The interview also aims to give an estimate of global  
6 improvement, measured by the 7-point version of the Clinical Global Impression -  
7 Improvement (CGI-I) scale [31]. Assessors of outcome in the clinical interview will  
8 be blind to treatment condition.  
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### 16 17 **Process measures**

18 In affect-phobia therapy, emotional processing is assumed to be related to symptom  
19 change. To explore this further in the current study, the Emotional Processing Scale  
20 (EPS-25) [32] will be used to assess emotional processing deficits and the process of  
21 emotional change during treatment. The measure contains five sub-scales, three of  
22 these relate to emotional control or dysregulation (emotional avoidance, suppression,  
23 unregulated emotion, one sub-scale (impoverished emotional experience) shares some  
24 properties with the alexithymia construct [32], and the last sub-scale (signs of  
25 unprocessed emotion) refers to persistent and intrusive emotional phenomena. The  
26 total score of the EPS-25 reflects the overall level of emotional processing deficit  
27 [32]. Psychometric properties for the EPS-25 has been found to be strong (Cronbach's  
28  $\alpha = 0.92$ ) [32]. While the EPS-25 is primarily included to measure a specific change  
29 process, it is also considered a secondary outcome measure in this trial.  
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48 As described above, the treatment has a strong mindfulness component. Thus, the  
49 amount of mindfulness skills that the client acquires during treatment may be related  
50 to outcome. To assess the influence of mindfulness, the Five Facets of Mindfulness  
51 Questionnaire (FFMQ; [33]) is included to measure general mindfulness skills. The  
52 original FFMQ by Baer et al. [33] contains 39 items, while the Swedish version that  
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3 will be used in this study consists of 29 items [34]. The correlation between the  
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5 Swedish FFMQ and the original FFMQ is  $r = .98$  [34]. The FFMQ was constructed as  
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7 a multi-faceted assessment of mindfulness, measuring a general tendency to be  
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9 mindful in daily life, which is defined by five factors: observing, describing, acting  
10  
11 with awareness, non-judging of inner experience, and non-reactivity to inner  
12  
13 experience [33]. Psychometric properties have been proved to be good for the  
14  
15 Swedish 29-item FFMQ (Cronbach's  $\alpha = 0.81$ ) [34]. The FFMQ is considered a  
16  
17 secondary outcome measure, besides being a process measure.  
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### 20 21 22 **Statistical analyses**

23 Differences in efficacy between the treatment and the active control group will  
24  
25 primarily be investigated by modeling interaction effects of group and time. In order  
26  
27 to adhere to the intention-to-treat principle, the outcome variables will be analyzed  
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29 using mixed effects models, given their ability to handle missing data [35]. To  
30  
31 examine processes of change in full detail using week-to-week measurements of both  
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33 processes (i.e., emotional processing and mindfulness) and outcomes, state-of the art  
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35 methods for evaluating longitudinal mediation will be employed [36]. Multiple  
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37 analyses will be conducted in an exploratory fashion. This includes the testing of  
38  
39 hypotheses that a change in a process variable at a specific time-point causes a change  
40  
41 in an outcome variable at a later time-point. An exploratory approach will allow  
42  
43 several hypotheses to be tested that will open up for further research in the field of  
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45 mechanisms of change in affect-focused psychotherapy. All analyses will use full  
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47 information maximum likelihood estimation, which provides unbiased estimates and  
48  
49 correct standard errors in the presence of missing data, assuming data loss is missing  
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51 for non-ignorable reasons [37].  
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## Discussion

This study will test the efficacy of a transdiagnostic, psychodynamically oriented, 10-week, guided self-help treatment, based on an affect-phobia model of psychopathology. In addition, the study will explore working mechanisms of the treatment.

An important aim of the treatment tested is to stay close to the APT model. The conceptualization of psychological problems are the same as in the original manual and the treatment is structured similarly. We assume that the essence of affect-phobia therapy is preserved in the guided self-help treatment. However, the treatment do differ in some aspects, e.g by not explicitly making use of transference relations. While we do not rule out that transference phenomena can occur, no interventions are included that address this. To our knowledge, no studies have investigated the efficacy of a similar treatment protocol via the Internet. Hence, this study will contribute to the empirical base of Internet-delivered psychological treatments in general and to that of psychodynamic approaches in particular. Moreover, no previous treatment study exists that evaluates the efficacy of face-to-face affect-phobia therapy for Axis I-disorders using a randomized controlled trial. Therefore, this study also adds to the empirical base of psychodynamic therapies in general.

Investigating the mediating effects of emotional processing and mindfulness provides an opportunity to explore the mechanisms of change in affect-focused, psychodynamic therapy. The processes that contribute to therapeutic change are largely unknown. This study aims to explore how emotional processing is related to treatment outcome and thus tests the assumption that emotional processing is a crucial

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3 process in psychodynamic treatments based on the APT model. In addition, the role of  
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5 mindfulness is similarly explored.  
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10 Moreover, there is a lack of psychodynamic therapy in other treatment formats than  
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12 individual and group. Using the Internet format of delivery makes it possible to reach  
13  
14 individuals who lack access to therapists nearby, or who simply do not want to meet  
15  
16 face-to-face [9].  
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20 In addition, there are also benefits of using one transdiagnostic protocol compared to  
21  
22 having several specific programs. Clients with different disorders and comorbidities  
23  
24 can be treated using the same protocol. This approach could potentially increase a  
25  
26 scope of a treatment implementation in, for example, a psychiatric clinic or in primary  
27  
28 care. By developing transdiagnostic protocols, the amount of therapist training could  
29  
30 also potentially be reduced, as clinicians may need to learn fewer programs.  
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### 34 35 **Competing interests**

36  
37 RJF is the author of the book used as a basis for the treatment manual.  
38

### 39 40 **Authors' contributions**

41  
42 RJ in collaboration with HH and GA designed the study. RJ and HH drafted the  
43  
44 manuscript. BL, RJF and GA reviewed and revised the manuscript. All authors have  
45  
46 read and approved the final manuscript to be published.  
47

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52  
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54

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## 43 **Figures**

### 44 **Figure 1 - Description of the modules in the treatment.**

45 Description of the modules in the treatment.  
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# Transdiagnostic, affect-focused, psychodynamic, guided self-help for depression and anxiety through the Internet: study protocol for a randomized controlled trial

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Word count: 2797

Keywords: Depression, anxiety, Internet-administered psychological treatments,  
psychodynamic therapy, affect-phobia treatment

For peer review only

## Abstract

### Introduction

Cognitive behavior therapy delivered in the format of guided self-help via the Internet has been found to be effective for a range of conditions, including depression and anxiety disorders. Recent results indicate that guided self-help via the Internet is a promising treatment format also for psychodynamic therapy. However, to date and to our knowledge, no study has evaluated Internet-delivered psychodynamic therapy as a transdiagnostic treatment. The affect-phobia model of psychopathology by McCullough et al. provides a psychodynamic conceptualization of a range of psychiatric disorders. The aim of this study will be to test the effects of a transdiagnostic guided self-help treatment based on the affect-phobia model in a sample of clients with depression and anxiety.

### Methods and analysis

This study will be a randomized controlled trial with a total sample size of 100 participants. The treatment group receives a 10-week, psychodynamic, guided self-help treatment based on the transdiagnostic affect-phobia model of psychopathology. The treatment consists of eight text-based treatment modules and includes therapist contact in a secure online environment. Participants in the control group receive similar online therapist support without any treatment modules. Outcome measures are the 9-item Patient Health Questionnaire Depression Scale (PHQ-9) and the 7-item Generalized Anxiety Disorder Scale (GAD-7). Process measures that concerns emotional processing and mindfulness are included. All outcome and process measures will be administered weekly via the Internet and at six-month follow-up.



## Discussion

This trial will add to the body of knowledge on Internet-delivered psychological treatments in general and to psychodynamic treatments in particular. We also hope to provide new insights in the effectiveness and working mechanisms of psychodynamic therapy based on the affect-phobia model.

## Ethics and dissemination

The protocol was approved by the regional ethics board of Linköping, Sweden.

Written informed consent will be obtained from all participants.

## Trial Registration

ClinicalTrials.gov: NCT01532219

## Article summary

### Article focus

- Depression and anxiety disorders are major health problems, which lower the quality of life for the individual and generate large costs for society.
- Internet-delivered CBT in the form of guided self-help are effective in the treatment of depression and anxiety disorders.
- Psychodynamic therapy via the Internet seem effective for specific disorders, but has not been evaluated as a transdiagnostic Internet-delivered treatment
- A transdiagnostic, affect-focused, psychodynamic, Internet-delivered guided self-help will be tested in a sample of participants with depression and anxiety disorders.

### Key messages

- Treatments based on the affect-phobia model of psychopathology has not previously been evaluated as guided self-help delivered via the Internet.
- Potential processes of change will be measured during treatment and mechanisms of the treatment will be investigated. This will contribute both to

1  
2  
3 the field of psychodynamic treatments and to that of Internet-delivered  
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5 psychological treatments in general.  
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### 8 **Strengths and limitations of this study**

- 9 • This randomized controlled trial will compare the effectiveness of an affect-  
10 focused, psychodynamic intervention to an active control condition.  
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- 12 • A sample of 100 participants will be used to ensure sufficient power.  
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- 14 • Mechanisms of change will be investigated using state-of the art methods for  
15 evaluating longitudinal mediation.  
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### 20 **Introduction**

21  
22 Depression and anxiety disorders are major health problems, which lower the quality  
23 of life for the individual and generate large costs for society [1, 2]. Lifetime  
24 prevalence for mood disorders and anxiety disorders have been estimated to be 20.8%  
25 and 28.8%, respectively [3]. Treatment alternatives include various psychotherapies,  
26 among which cognitive behavior therapy (CBT) has an established strong empirical  
27 base [4, 5]. However, psychodynamic therapy has also shown promising results for  
28 the treatment of depression [6], panic disorder [7] and generalized anxiety disorder  
29 (GAD) [8]. During the last decade, there has been significant progress in research  
30 concerning psychological guided self-help treatments and Internet-delivered  
31 psychotherapies [9, 10]. Recent meta-analyses have shown that Internet-delivered  
32 CBT (ICBT), given as guided self-help, and face-to-face psychotherapy, is equally  
33 effective in the treatment of depression and anxiety disorders [11].  
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52 Almost all published studies in the field of Internet-delivered psychological  
53 treatments have endorsed a CBT approach. However, results from two recent  
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3 randomized trials concerning depression and GAD indicate that psychodynamic  
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5 therapy can also be delivered via the Internet [12, 13].  
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### 8 **Transdiagnostic and unified treatments**

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10 A large portion of evidence-based psychological treatments target specific conditions,  
11  
12 e.g. depression and social anxiety disorder. There are also transdiagnostic and unified  
13  
14 protocols where the treatment material has been arranged to fit a broader range of  
15  
16 patients [14]. Typically, the interventions in these protocols are based on  
17  
18 psychological treatment components that target common behavioral patterns in  
19  
20 various disorders, such as avoidance behaviors and maladaptive thought patterns,  
21  
22 using e.g., exposure, cognitive restructuring, and emotion regulation techniques [14].  
23  
24 Transdiagnostic Internet-delivered CBT protocols have been developed and tested  
25  
26 with promising results among clients with anxiety disorders and depression [15, 16].  
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### 29 **Affect-phobia treatment and affect-focused psychodynamic treatment**

30  
31 McCullough et al [17] described a treatment model which is an example of a unified  
32  
33 treatment grounded in psychodynamic theory. The model, called *affect-phobia*  
34  
35 *treatment* (APT), follows the fundamental structure of psychodynamic psychotherapy  
36  
37 as outlined by Malan's triangle of conflict (i.e., defenses and anxieties block the  
38  
39 expression of feelings) and triangle of person (i.e., work with conflicts in relation to  
40  
41 the therapist and current and past persons) [18]. In a psychodynamic therapy based on  
42  
43 the APT model, the therapist typically clarifies defenses, helps the client to observe  
44  
45 and experience the underlying affects, and helps the client to regulate associated  
46  
47 anxiety [17]. Formally, the treatment includes three main treatment objectives:  
48  
49 defense restructuring (recognizing and relinquishing maladaptive defenses), affect  
50  
51 restructuring (desensitization of affects through exposure to conflicted feeling), and  
52  
53 self/other restructuring (improvement in sense of self and relationship with others). In  
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3 summary, the main goal of psychodynamic psychotherapy based on the APT model is  
4  
5 to help clients experience and to adaptively express feelings, that have been  
6  
7 previously avoided [17].  
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11 Two randomized trials have investigated the efficacy of APT for personality disorders  
12 [19, 20]. These trials showed that affect-phobia treatment can be effective in reducing  
13  
14 general psychiatric symptoms. However, except for case-series and some small  
15  
16 uncontrolled studies (e.g. [21]), to date no trial has investigated the efficacy of APT  
17  
18 for patients with a primary Axis I disorder.  
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### 22 23 24 **Processes of change**

25 To develop more effective psychotherapeutic treatments, it is crucial to understand the  
26  
27 mechanisms of change that contribute to improvement in therapy. However, the  
28  
29 mechanisms that cause therapeutic change are still largely unknown. In the  
30  
31 experiential and psychodynamic traditions, including APT, experiencing and  
32  
33 processing of the affective experience is considered central to therapeutic change [22,  
34  
35 23]. Typically, the therapist in APT helps the client recognize maladaptive defenses,  
36  
37 regulate anxiety, and to gradually experience feelings through systematic  
38  
39 desensitization to the conflicted emotions [17]. Thus, emotional processing seems to  
40  
41 be a relevant concept for understanding psychological treatments based on the APT  
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43 model.  
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### 48 49 **Main research questions and hypotheses**

50 - Is a transdiagnostic, affect-focused, psychodynamic, Internet-delivered, guided self-  
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52 help approach effective in reducing symptoms of depression and anxiety, when  
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54 compared to an active control condition?  
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3 - Do the degrees of emotional processing and mindfulness change more in the  
4 treatment condition than in the active control condition?  
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7 - Do the degrees of emotional processing and mindfulness mediate symptom change  
8 on depression and anxiety measures?  
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## 11 **Methods and analysis**

### 12 **Design of the study and ethics statement**

13 The current study will be a randomized controlled trial with a sample size of 100  
14 participants. The study protocol was approved by the regional Ethics Review Board in  
15 Linköping, Sweden. Written informed consent will be obtained from all participants  
16 using an online screening environment.  
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### 26 **Study population**

27 Patients will be recruited from the community via advertisements in newspapers and  
28 on the Internet. To be included in the study, the participant must be at least 18 years  
29 of age and fulfill a principal DSM-IV diagnosis of either depression, social anxiety  
30 disorder, panic disorder, or generalized anxiety disorder. The Mini-International  
31 Neuropsychiatric Interview (M.I.N.I.; [24]) will be used to diagnose DSM-IV  
32 disorders. Last-semester MSc students from a five-year clinical psychology program,  
33 who have been trained in the diagnostic procedure, will conduct the interviews by  
34 telephone. In addition, the participant must score at least 10 on either the 9-item  
35 Patient Health Questionnaire Depression Scale (PHQ-9 [25]) or the 7-item  
36 Generalized Anxiety Disorder Scale (GAD-7 [26]). Participants with a principal  
37 diagnoses of post-traumatic stress disorder or obsessive-compulsive disorder will be  
38 excluded. This restriction is due to the fact that the APT model does not conceptualize  
39 these disorders as phobias of affect, and hence, the treatment material used is not  
40 assumed to be applicable in these cases [17]. Additional exclusion criteria include  
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3 suffering from a severe psychiatric conditions such as bipolar disorder or psychosis;  
4 risk of suicide, assessed by the M.I.N.I. [24]; alcohol or drug abuse; and ongoing  
5 participation in any psychotherapy. Moreover, if the participant is receiving  
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10 psychotropic ~~meditation~~medication, the dosage must have been stable for at least three  
11  
12 months prior to the start of the treatment.

### 13 14 15 **Sample size**

16 A power calculation [27] using a linear mixed-effects model (10 time points with an  
17  
18 autoregressive error structure with a random intercept and slope) showed that  
19  
20 approximately 46 (46.3) participants in each condition would be sufficient to detect a  
21  
22 moderate between-group effect size of Cohen's  $d = 0.50$  ( $\alpha$  level = 0.05) with 80%  
23  
24 power. Assuming a total attrition rate of 10% (at equal rate across time and  
25  
26 condition), a similar power calculation estimated sample size to be approximately 51  
27  
28 (51.3) participants per condition. Given these results, we aim to include 100  
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31 participants in the study.  
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### 34 35 **Interventions**

36 The treatment will be given as guided self-help with minimal text-based guidance  
37  
38 provided on a weekly basis. This treatment format is an established way of delivering  
39  
40 psychological treatments for depression and anxiety disorders [9, 11]. The text  
41  
42 material used in the treatment modules will be based on the book “Living Like You  
43  
44 Mean It” by Ronald J. Frederick [28], which is theoretically grounded in  
45  
46 psychodynamic theory and affective science and follows a similar structure as the  
47  
48 original APT manual. There are eight modules in total, which all contain homework  
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50 exercises that a client needs to complete before proceeding on to the next module.  
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3 This treatment emphasizes the practice of mindfulness more than in traditional  
4 psychodynamic therapy. Throughout treatment, the client is taught how to apply  
5 mindfulness in the process of identifying, attending to, and being present with  
6 emotional experience. In the context of the APT model, practicing “emotional  
7 mindfulness” can be one way of learning how to be aware of, experience, and tolerate  
8 emotions. The treatment teaches the client to gradually develop mindful presence as a  
9 response to the physical manifestation of emotions which, within the APT model, can  
10 be considered as exposure to one's feelings. All interventions are grounded in the  
11 affect-phobia model illustrated by the conflict triangle: Maladaptive defenses are  
12 identified and relinquished, anxiety is regulated, and warded off feelings are  
13 approached and experienced. After experiencing one's core feelings, the client is  
14 encouraged, when appropriate, to express these feelings in interpersonal contexts.  
15 Expressing feelings to others is seen as essential to shifting both the sense of self and  
16 others. Detailed steps of the treatment are described in Figure 1.  
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36 The online therapists will have contact with clients using a secure online environment  
37 resembling e-mail, but with enhanced security. This mode of communication follows  
38 a standard procedure used in a range of studies investigating ICBT [9]. The primary  
39 role of the therapists will be to give feedback on the clients' exercises and  
40 experiences, and to administer gradual access to the treatment modules. In addition,  
41 the therapists will provide support, clarifications of the material and other forms of  
42 help that will enable the clients to complete the material on time. The therapists will  
43 answer questions once every day, during weekdays. All therapists will be supervised  
44 biweekly by Ronald J. Frederick, the author of the book on which the treatment is  
45 based.  
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5 The therapists will be three last-semester MSc students from a five-year clinical  
6 psychologist program. All therapists will have a clinical training in affect-focused  
7 psychodynamic psychotherapy and treatment experience using this method.  
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14 Participants in the active control group will not receive any text-based treatment  
15 modules. They will, however, receive online therapist contact, where the therapists  
16 will provide support but will not use any specific psychological techniques other than  
17 basic therapeutic skills such as empathic listening and asking for clarifications. A  
18 similar active control condition has been used in previous treatment studies [12].  
19  
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#### 21 **Randomization and procedure**

22 After applying to the study, the participant will be directed to an online screening  
23 consisting of demographic questions and of online versions of the clinical outcome  
24 measures and the process measures (see below). These results will later be used as a  
25 pre-treatment assessment. A participant will be contacted for a telephone-based  
26 diagnostic interview if he or she has completed the screening and meets the initial  
27 inclusion criteria (a score of at least 10 on either the PHQ-9 or the GAD-7). The  
28 interview consists of diagnostic interview questions about depression and anxiety  
29 disorders in addition to questions about use of medications and psychological  
30 treatments. The principal diagnosis assessed during the interview will be recorded.  
31  
32 Psychiatric diagnoses are confirmed using the M.I.N.I. [24]. The participants will be  
33 allocated to one of the two groups in a 1:1 ratio using block randomization. An  
34 independent person, separate from the staff conducting the study, will handle the  
35 randomization using an online randomization tool.  
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### Assessments

Clinical outcome will be measured both by self-report questionnaires and a clinical interview. Mechanisms of change will be measured by two self-report measures. Clinical and process self-report measures will be administered weekly during the treatment phase. At the six-month follow-up, a clinical interview will be conducted in addition to self-report measures.

### Clinical outcome measures

Measures of depression and anxiety will be the 9-item Patient Health Questionnaire Depression Scale (PHQ-9 [25]) and the 7-item Generalized Anxiety Disorder Scale (GAD-7 [26]). The PHQ-9 is an established measure of depression which contains nine items, each scored 0–3 and with a total score in the range of 0 to 27. It has been shown to have good psychometric properties (Cronbach's  $\alpha$  in the range 0.86 – 0.89) [29]. The GAD-7 was originally developed to diagnose generalized anxiety disorder, but has also proved useful in detecting and assessing severity of panic, social anxiety, and post-traumatic stress disorder [26]. Psychometric properties have been proved to be good also for the GAD-7 (Cronbach's  $\alpha = 0.92$ ) [29]. The choice to administer outcome and process measures weekly, prevented the inclusion of further measures of anxiety.

The combination of PHQ-9 and GAD-7 for measuring depression and anxiety have been used in several treatment trials, e.g. in the implementation of psychological therapies for anxiety and depression in British routine practice, which includes data from 7859 patients [30]. Both the PHQ-9 and the GAD-7 are considered primary outcome measures in the study.

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3 In addition to the self-report measures, clinical outcome will be measured in a clinical  
4 interview via telephone. Psychiatric diagnoses will be assessed at post-treatment and  
5 at follow-up using the M.I.N.I. The interview also aims to give an estimate of global  
6 improvement, measured by the 7-point version of the Clinical Global Impression -  
7 Improvement (CGI-I) scale [31]. Assessors of outcome in the clinical interview will  
8 be blind to treatment condition.  
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### 16 17 **Process measures**

18 In affect-phobia therapy, emotional processing is assumed to be related to symptom  
19 change. To explore this further in the current study, the Emotional Processing Scale  
20 (EPS-25) [32] will be used to assess emotional processing deficits and the process of  
21 emotional change during treatment. The measure contains five sub-scales, three of  
22 these relate to emotional control or dysregulation (emotional avoidance, suppression,  
23 unregulated emotion, one sub-scale (impoverished emotional experience) shares some  
24 properties with the alexithymia construct [32], and the last sub-scale (signs of  
25 unprocessed emotion) refers to persistent and intrusive emotional phenomena. The  
26 total score of the EPS-25 reflects the overall level of emotional processing deficit  
27 [32]. Psychometric properties for the EPS-25 has been found to be strong (Cronbach's  
28  $\alpha = 0.92$ ) [32]. While the EPS-25 is primarily included to measure a specific change  
29 process, it is also considered a secondary outcome measure in this trial.  
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48 As described above, the treatment has a strong mindfulness component. Thus, the  
49 amount of mindfulness skills that the client acquires during treatment may be related  
50 to outcome. To assess the influence of mindfulness, the Five Facets of Mindfulness  
51 Questionnaire (FFMQ; [33]) is included to measure general mindfulness skills. The  
52 original FFMQ by Baer et al. [33] contains 39 items, while the Swedish version that  
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3 will be used in this study consists of 29 items [34]. The correlation between the  
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5 Swedish FFMQ and the original FFMQ is  $r = .98$  [34]. The FFMQ was constructed as  
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7 a multi-faceted assessment of mindfulness, measuring a general tendency to be  
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9 mindful in daily life, which is defined by five factors: observing, describing, acting  
10  
11 with awareness, non-judging of inner experience, and non-reactivity to inner  
12  
13 experience [33]. Psychometric properties have been proved to be good for the  
14  
15 Swedish 29-item FFMQ (Cronbach's  $\alpha = 0.81$ ) [34]. The FFMQ is considered a  
16  
17 secondary outcome measure, besides being a process measure.  
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### 20 21 22 **Statistical analyses**

23 Differences in efficacy between the treatment and the active control group will  
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25 primarily be investigated by modeling interaction effects of group and time. In order  
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27 to adhere to the intention-to-treat principle, the outcome variables will be analyzed  
28  
29 using mixed effects models, given their ability to handle missing data [35]. To  
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31 examine processes of change in full detail using week-to-week measurements of both  
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33 processes (i.e., emotional processing and mindfulness) and outcomes, state-of the art  
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35 methods for evaluating longitudinal mediation will be employed [36]. Multiple  
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37 analyses will be conducted in an exploratory fashion. This includes the testing of  
38  
39 hypotheses that a change in a process variable at a specific time-point causes a change  
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41 in an outcome variable at a later time-point. An exploratory approach will allow  
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43 several hypotheses to be tested that will open up for further research in the field of  
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45 mechanisms of change in affect-focused psychotherapy. All analyses will use full  
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47 information maximum likelihood estimation, which provides unbiased estimates and  
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49 correct standard errors in the presence of missing data, assuming data loss is missing  
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51 for non-ignorable reasons [37].  
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## Discussion

This study will test the efficacy of a transdiagnostic, psychodynamically oriented, 10-week, guided self-help treatment, based on an affect-phobia model of psychopathology. In addition, the study will explore working mechanisms of the treatment.

An important aim of the treatment tested is to stay close to the APT model. The conceptualization of psychological problems are the same as in the original manual and the treatment is structured similarly. We assume that the essence of affect-phobia therapy is preserved in the guided self-help treatment. However, the treatment do differ in some aspects, e.g by not explicitly making use of transference relations.

While we do not rule out that transference phenomena can occur, no interventions are included that address this. To our knowledge, no studies have investigated the efficacy of a similar treatment protocol via the Internet. Hence, this study will contribute to the empirical base of Internet-delivered psychological treatments in general and to that of psychodynamic approaches in particular. Moreover, no previous treatment study exists that evaluates the efficacy of face-to-face affect-phobia therapy for Axis I-disorders using a randomized controlled trial. Therefore, this study also adds to the empirical base of psychodynamic therapies in general.

Investigating the mediating effects of emotional processing and mindfulness provides an opportunity to explore the mechanisms of change in affect-focused, psychodynamic therapy. The processes that contribute to therapeutic change are largely unknown. This study aims to explore how emotional processing is related to treatment outcome and thus tests the assumption that emotional processing is a crucial

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3 process in psychodynamic treatments based on the APT model. In addition, the role of  
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5 mindfulness is similarly explored.  
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10 Moreover, there is a lack of psychodynamic therapy in other treatment formats than  
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12 individual and group. Using the Internet format of delivery makes it possible to reach  
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14 individuals who lack access to therapists nearby, or who simply do not want to meet  
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16 face-to-face [9].  
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20 In addition, there are also benefits of using one transdiagnostic protocol compared to  
21  
22 having several specific programs. Clients with different disorders and comorbidities  
23  
24 can be treated using the same protocol. This approach could potentially increase a  
25  
26 scope of a treatment implementation in, for example, a psychiatric clinic or in primary  
27  
28 care. By developing transdiagnostic protocols, the amount of therapist training could  
29  
30 also potentially be reduced, as clinicians may need to learn fewer programs.  
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### 34 35 **Competing interests**

36  
37 RJF is the author of the book used as a basis for the treatment manual.  
38

### 39 40 **Authors' contributions**

41  
42 RJ in collaboration with HH and GA designed the study. RJ and HH drafted the  
43  
44 manuscript. BL, RJF and GA reviewed and revised the manuscript. All authors have  
45  
46 read and approved the final manuscript to be published.  
47

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50  
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52  
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54

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## Figures

### Figure 1 - Description of the modules in the treatment.

Description of the modules in the treatment.

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**Module 1.** Introduction and problem formulation using the affect-phobia model.

**Module 2.** Historical understanding and explanation of the problem described.

**Module 3.** Mindfulness practice to start approaching emotional experience.

**Module 4.** Defense restructuring.

**Module 5.** Anxiety regulation techniques.

**Module 6.** Affect experiencing techniques.

**Module 7.** Affect expression and self/other restructuring.

**Module 8.** A summary of the previous material and advice for continued work.

Description of the modules in the treatment.  
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