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# Using a transdiagnostic, psychodynamic online self-help intervention to maintain inpatient psychosomatic treatment effects: Study protocol of a feasibility study



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### ARTICLE INFO

Article history: Received 17 June 2016 Received in revised form 19 July 2016 Accepted 19 July 2016 Available online 27 July 2016

Keywords: Psychodynamic treatment Inpatient psychotherapy Online self-help Feasibility Randomization Internet intervention

#### ABSTRACT

*Background:* Online self-help interventions have proven to be effective in treating various specific mental disorders, mainly depression and anxiety. Knowledge regarding their acceptance, efficacy, and usefulness in addition to inpatient or outpatient psychotherapy is limited. Therefore, we plan to evaluate an affect-focused, transdiagnostic, psychodynamic online self-help intervention following inpatient psychotherapy for mixed diagnoses in a feasibility study to determine acceptance, satisfaction, and preliminary estimates of efficacy.

*Methods*: The intervention is based on the book "Living Like You Mean It" by Ronald J. Frederick (2009) and the Swedish adaption by Johansson and colleagues (2013). The book was translated into German and thoroughly revised using parts of the Swedish adaption and additional tasks from their intervention. In a pilot phase, corrections concerning comprehensibility of the content and exercises were made based on patient's feedback. In the second step, we developed a website presenting the German adaption in eight units. In the third step, at least N = 66 patients from the Department of Psychosomatic Medicine and Psychotherapy will be recruited for a feasibility study. Patients are randomized into two groups. The intervention group (IG) will receive ten weeks of access to the online self-help intervention together with weekly therapeutic feedback on their progress. The wait-list control group (WLC) will receive access to the intervention for ten weeks as well, but without therapeutic feedback and with a ten-week delay. We will conduct assessments at the beginning of the intervention of the IG (T0), the end of the intervention of the IG (T1), two months later (only IG, T2), and at the end of the intervention of the WLC (T3). The primary outcome is satisfaction with the treatment as measured by the ZUF-8 at T1 and T3 respectively. Secondary outcome measures include emotional competence, depression, anxiety, and quality of life.

*Conclusion:* We expect insight into the usefulness and acceptance of an online self-help intervention used to maintain inpatient treatment effects. Furthermore, we await both groups to benefit from the participation in the intervention. Pre- post and between subject differences will be used as estimate effect sizes to calculate the necessary sample size for a larger efficacy trial.

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#### 1. Introduction

Mental disorders will be one of the greatest challenges to health care in this century (Wittchen et al., 2011). Wittchen et al. (2011) showed that 27% of the total adult population were affected by mental disorders

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every year, and only 26% of affected people made use of professional services. Furthermore, individuals with mental disorders reported three times the number of absence due to illness as compared to healthy people. After recovering from a mental disorder, they did not significantly differ from healthy peers regarding disability days (Jacobi et al., 2014). Despite a broad range of mental health care offers, a significant problem in the German health care system concerns gaps between different sectors of treatment (Schulz et al., 2011). A recent meta-analysis confirmed that inpatient psychotherapeutic treatment is effective (Liebherz and Rabung, 2013). However, provision of outpatient psychotherapy following discharge poses problems to many patients

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http://dx.doi.org/10.1016/j.invent.2016.07.003

who may need to wait up to six months for outpatient treatment and may relapse without timely support (Zepf et al., 2003). Preliminary studies have indicated that online aftercare may be helpful to maintain the benefits of inpatient psychotherapy (Bauer et al., 2011) respectively psychosomatic rehabilitation (Becker et al., 2014; Ebert et al., 2013a).

Online interventions have gained substantial impact in psychotherapy research over the last decade. Their versatility is a key factor for their application. They are location- and mostly time-independent. Therefore, they can be used in several settings, including preparation for (Becker et al., 2016) and supplementing (Zwerenz et al., 2015) treatment as well as stabilizing effects of treatment (Zwerenz et al., 2013). Furthermore, first meta-analyses have shown comparable effectiveness of these interventions and regular face-to-face psychotherapy (Andersson et al., 2014; Barak et al., 2008; Bee et al., 2008) especially for depression and anxiety (Andersson and Cuijpers, 2009; Andrews et al., 2010; Richards and Richardson, 2012). Most of these interventions were based on a self-help approach with varying degrees of therapeutic support. Although meta-analyses have shown the principal effectiveness of self-help interventions for depression and anxiety (Cuijpers et al., 2010) further research provided a more detailed view. Johansson and Andersson (2012) found a strong correlation between the outcome and the amount of therapeutic support. Although this finding is supported by another metaanalysis (Richards and Richardson, 2012), the authors of a recent metaanalysis stated that the effect of guidance might in fact be smaller as reported in previous analyses (Baumeister et al., 2014).

In the past, the majority of interventions followed a cognitive behavioral approach. In contrast, Johansson et al. (2013a) used a psychodynamic concept in their study. Their affect-focused psychodynamic intervention was based on an American self-help book (Frederick, 2009) which comprises the affect phobia therapy model as outlined by McCullough and Andrews (2001) as a key concept. In addition to this template with text-based units, weekly tasks were developed. In their trial, the authors recruited patients with anxiety disorders or depression and compared them to a control group who received online therapist support and clinical monitoring of symptoms, but no treatment modules. They achieved moderate (d = 0.48; anxiety) to large (d = 0.77; depression) effect sizes and significant higher remission rates in the intervention group. As facilitation of emotional experience is one of the core processes in successful psychodynamic psychotherapy (Johansson et al., 2013a), we broadened the scope of the study to a broad range of mental disorders and implemented it as aftercare following inpatient or day hospital treatment.

Satisfaction with online interventions is operationalized in different ways. Usually, constructs like usefulness or acceptance are used synonymous to assess satisfaction. However, in a systematic review, Andrews et al. (2010) divided acceptability in adherence and satisfaction. They found ten studies investigating the satisfaction with computer based therapy. The satisfaction in general was very high, with a median of 86% of the participants having been "satisfied" or "very satisfied" with the intervention.

In summary, online self-help interventions have proven to be effective in various mental disorders, mainly depression and anxiety. They have been mostly used as single interventions and are generally based on cognitive behavioral concepts. Knowledge regarding their acceptance, efficacy, and applicability in different settings is limited. In this trial we therefore assess the usefulness of an affect-focused, psychodynamic online self-help intervention as transdiagnostic aftercare.

We assume that our intervention will help patients with various mental illnesses maintain the improvements achieved during inpatient psychotherapy and consequently be regarded as satisfactory and used regularly. Therefore, we will examine satisfaction with and acceptance of the intervention as well as preliminary estimates on the efficacy concerning change in emotional competence and symptom reduction. In the long term, our goal is to help close the treatment gap after discharge from inpatient psychotherapy which is a major drawback in the German health care system.

# 2. Material and methods

# 2.1. Participants

Patients receiving inpatient and day hospital treatment at the Department of Psychosomatic Medicine and Psychotherapy at the University Medical Center of the Johannes Gutenberg-University Mainz will be informed about the study and its rationale in three weekly meetings providing information about the trial and the online platform. Eligible to participate are all patients of the Department of Psychosomatic Medicine and Psychotherapy, who have private access to the internet and an e-mail address, with a minimum age of 18 years. Exclusion criteria include acute suicidality, psychosis, current alcohol or drug addiction and a lifetime diagnosis of a schizophrenic, schizoaffective, bipolar or organic psychiatric disorder. With their written informed consent, eligible patients will be coded and randomized. Participants will receive their login to the study platform when they leave the inpatient, resp. day hospital treatment.

The Study Center of Mental Disorders (SPE) at the University Medical Center Mainz will be responsible for storing personal related data and randomizing participants. Administration of the internet platform, feedback for the patients in the IG and general management of the study will be done by psychologists of the Department of Psychosomatic Medicine and Psychotherapy.

Clinical protocol and written informed consent were approved by the Ethics Committee of the Federal State of Rhineland-Palatinate (Germany), which is responsible for the study center (Ref. No. 837.299.15 (10067)). All procedures described in the clinical trial protocol (ClinicalTrials.gov Identifier: NCT02671929) follow the ICH-GCP guidelines and the ethical principles described in the current revision of the Declaration of Helsinki. The trial will be carried out in keeping with local legal and regulatory requirements. A populated SPIRIT checklist is provided as an additional file.

The study platform is located on a firewall protected web server which uses an SSL-encrypted (secure sockets layer) access to the platform itself and the database containing the login information. All questionnaires will be administered via the online survey program SoSci Survey (https://www.soscisurvey.de) using SSL-coded internet connections. Furthermore, all patients use pseudonyms to log in on the study platform. As no personal data are stored on the web server, identification of the real identity of the user is not possible.

#### 2.2. Intervention

The intervention is based on the self-help book "Living Like You Mean It" by Frederick (Frederick, 2009) and the work by a Swedish work group around Johansson (Johansson et al., 2013b), who recently adapted the self-help book in one of their trials (Johansson et al., 2013a). First, we translated the original English manuscript into German. In the course of translation, we eliminated Anglicisms and adapted the content to fit the German culture. In the second step, we compared our version with the version of the Swedish work group and used some of the amendments they added to the units. In the next step, we translated and revised the tasks developed by the Swedish team. In the fourth step, we gave printouts of single units to day hospital patients to work through. With their feedback, we revised the units concerning misspelling, comprehensibility, and usability of the exercises. The last step included revising the diction and inconsistencies, as well as creating audio files of all exercises implemented in the intervention.

The intervention helps participants to experience and express their emotions. It is theoretically based on two concepts. The first concept is called affect phobia (McCullough and Andrews, 2001) which refers to Download English Version:

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