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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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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.

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 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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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 meta-analysis (Richards and Richardson, 2012), the authors of a recent meta-analysis 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

a phobia, of sorts, to one's feelings, the consequence of childhood experiences in which primary caregivers reacted negatively to the child's emotions. In the course of the years, anxiety and discomfort become associated with specific emotions and can intensify over time. Defense mechanisms, or coping strategies, develop to avoid the distress associated with particular feelings. The second concept is called emotional mindfulness and is based on the concept of mindfulness associated with Kabat-Zinn (1994). The idea is that patients need to develop awareness of their emotions to better address their associated distress by attending their bodily felt experience. Long-term, unconscious use of defense mechanisms prevents people from noticing their emotions and making adaptive use of their emotional experience. Therefore, participants are instructed to attend their bodily felt emotions. The intervention consists of eight units and is divided into four steps. In the first step, the awareness of one's emotions and related defenses is enhanced. The second step deals with the regulation of the anxiety that emerges when the feared emotion is approached. The third step helps to regulate and experience emotions through to completion. The last step contains supportive information on how to mindfully express the emotions to other people (Table 1).

The material was used to build an online platform programmed with HTML, CSS, PHP and MYSQL. The platform enables participants to log into their accounts, gain access to the units and tasks of the intervention as well as audio files, and send messages to the online therapist (only IG). Project members can manage participant's accounts, send messages to patients, plot charts of their health status after every unit, and view their writing in the various tasks (only IG).

The IG gets access to the above described intervention for ten weeks when they initially log in on the platform following discharge from inpatient/day hospital treatment. Participants will be informed that they should try to complete one unit a week and finish the intervention within ten weeks. Each unit is considered completed when participants have answered all questions in the unit's tasks and transmitted them to the online therapist. After transmission, participants will receive individual feedback on their replies within two weekdays. The online therapist is a trained psychologist, supervised by two experienced psychotherapists, who are familiar with the intervention.

2.3. Control condition

We use a wait-list control design. The WLC basically receives the same treatment as the IG. However, there are two essential differences. First, patients in the control group start with their intervention ten weeks after discharge from inpatient/day hospital treatment, which means that they start after the end of the intervention of the IG. Additionally, the control group is requested to write down their thoughts on the tasks in a notebook instead of typing them in text fields on the platform. Accordingly, they do not receive feedback from an online therapist on their writing.

Table 1
Content of the units of the intervention.

Introduction	
Unit 1	Introduction to and concepts of the intervention
Unit 2	Looking back on the emotional climate in the childhood
Step 1: Becoming Aware	
Unit 3	Becoming aware of emotions
Unit 4	Becoming aware of defense mechanisms
Step 2: Taming the Fear	
Unit 5	Learning how to regulate the anxiety that emerges with feared emotions
Step 3: Feeling it Through	
Unit 6	Learning how to regulate and experience emotions through to completion
Step 4: Opening Up	
Unit 7	Learning how to mindfully express emotions to other people
Summary	
Unit 8	Summary of the learned content in the intervention

2.4. Assessment

Assessments will be conducted at discharge from our clinic (T0), at the end of the intervention of the IG (T1), at two months follow-up (T2; only IG), and at the end of the intervention of the WLC (T3; only WLC). Time points are shown in Fig. 1.

All questionnaires are given online. Internet use is assessed on T0. Utilization of outpatient treatment, acceptance, satisfaction (ZUF-8; (Schmidt et al., 1989)), and use of the online self-help, as well as the therapeutic alliance (only IG; WAI-SR; (Wilmers et al., 2008)), are measured at T1 (IG) and T3 (WLC). The following instruments are used at every time point: the EUROHIS-QOL 8 (Brähler et al., 2007) is used to measure life satisfaction. The PHQ-9 (Löwe et al., 2002) and GAD-7 (Löwe et al., 2008) assess depression and anxiety. The SSS-8 (Gierk et al., 2014) is used to determine somatoform afflictions. Likewise, SEK-27 (emotional competence) (Berking and Znoj, 2008), RSE (self-esteem) (Roth et al., 2008), CDS-2 (depersonalization) (Michal et al., 2010) and SPE (subjective prognosis of work ability) (Mittag and Raspe, 2003) are administered on all four time points (Table 2).

In addition to these fixed time points, each participant receives 11 questions concerning the usefulness and utilization of the unit and the tasks as well as the PHQ-4 to monitor their distress after they complete the tasks of every unit.

2.5. Objectives and hypotheses

The primary objective of this trial is to examine the feasibility of our affect-focused transdiagnostic psychodynamic online self-help intervention by determining the satisfaction with the intervention. A secondary objective is to derive preliminary estimates of efficacy of the intervention concerning emotional competence, depression, anxiety and quality of life. We hypothesize that at least 75% of the patients in the IG will be “satisfied” or “very satisfied” with the intervention at T1. We further hypothesize that the patients in the IG will have higher emotional competence measured with the SEK-27 than the WLC at the end of the intervention of the IG (T1).

2.6. Outcomes

As the primary endpoint we defined satisfaction with the intervention in the IG measured with the ZUF-8 at T1.

Key secondary endpoint(s):

1) Emotional competence (SEK-27) at T1 and T2
2) Depression (PHQ-9) at T1 and T2
3) Quality of life (EUROHIS-QOL 8) at T1 and T2
4) Anxiety (GAD-7) at T1 and T2
5) Self-esteem (RSE) at T1 and T2
6) Somatoform afflictions (SSS-8) at T1 and T2
7) Subjective prognosis of work ability (SPE) at T1 and T2
8) Therapeutic alliance (WAI-SR) at T1
9) Depersonalization (CDS-2) at T1 and T2
10) Acceptance of the intervention at T1 (IG) and T3 (WLC)
11) Usage of the intervention at T1 (IG) and T3 (WLC).

2.7. Sample size calculation

As this is a feasibility study, no power analysis was conducted. We will invite consecutive inpatient and day hospital patients treated at the Department of Psychosomatic Medicine and Psychotherapy over a period of seven months to participate in the trial. Based on the treated patients per year in the clinic ($N = 392$), an anticipated participation rate of approx. 30% (Ebert et al., 2013b) and a recruiting phase of 29 weeks, we expect a sample size of $N = 66$ patients. Nevertheless, each patient in the planned period will be recruited, even if the sample size will be reached earlier.

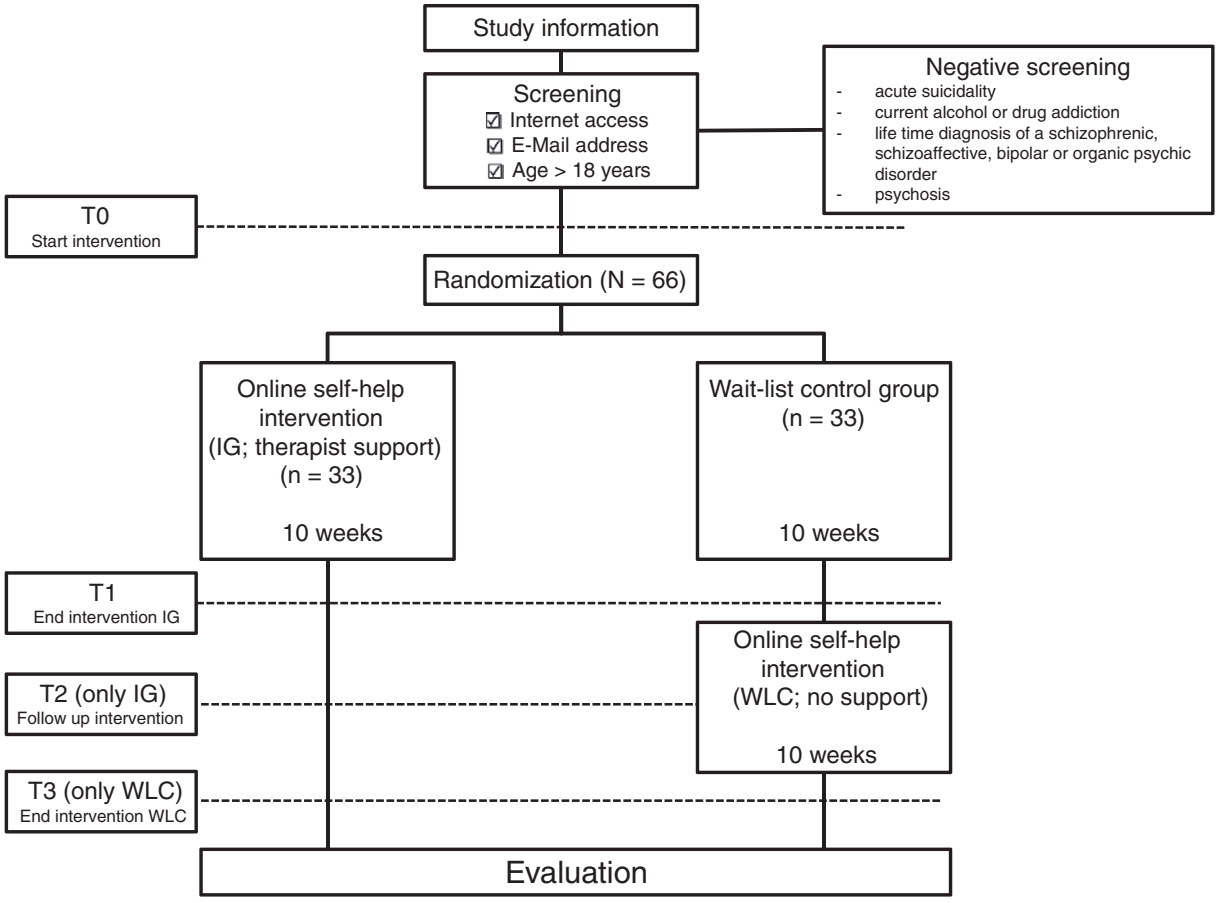

Fig. 1. Study design and temporal course of assessment; IG, intervention group; WLC, wait-list control group.

2.8. Randomization

The assignment of patients to the intervention and wait-list control group will be achieved by block-randomization at a ratio of 1:1. With the help of the computer software Research Randomizer (Urbaniak and Plous, 2015), randomization will be conducted centrally by the Study Center of Mental Disorders as an independent institution.

2.9. Statistical methods

The primary outcome and the secondary outcomes 1–9 will be evaluated with analysis of covariance (utilization of alternative aftercare as control variable) on the respective time points. Secondary outcomes 10 and 11 will be reported through descriptive statistics. With the participants' written consent, diagnoses will be taken from

Table 2
Schematic overview of frequency and scope of the study visits.

	Discharge	End of intervention IG[a]	Follow-up[b]	End of intervention WLC[c]
Study visits	T0	T1	T2	T3
Internet use	X			
WAI-SR		X		
ZUF-8		X		X
Acceptance of intervention		X		X
Intervention use		X		X
Utilization of outpatient treatment		X		X
SEK-27	X	X	X	X
PHQ-9	X	X	X	X
GAD-7	X	X	X	X
EUROHIS-QOL 8	X	X	X	X
RSE	X	X	X	X
SSS-8	X	X	X	X
SPE	X	X	X	X
CDS-2	X	X	X	X

[a] Questionnaires for both groups.
[b] Questionnaires only for IG.
[c] Questionnaires only for WLC.

the basic documentation used in the Department of Psychosomatic Medicine and Psychotherapy to conduct explorative analysis with the outcomes regarding different diagnosis. Furthermore, we will accomplish additional exploratory analyses with the primary and secondary (1–7 and 9–12) outcome measures by comparing the unsupported intervention of the WLC with the supported intervention of the IG. Effect sizes will be calculated to measure treatment effects. Missing data will be imputed using multiple imputation.

3. Discussion

Online self-help interventions for mental disorders have proven to be effective in treating different kinds of disorders and in a variety of health contexts. Research has shown that they can improve symptoms as single interventions and also as supplements (usually follow-ups) to other treatments. However, there is still little research on this topic in Germany. Bridging the gap to outpatient treatment after inpatient psychotherapy is an important field where self-help interventions may support the maintenance of treatment effects.

Given the lack of psychodynamic online treatments, we have chosen affect-focused psychodynamic psychotherapy which has shown to be effective for the treatment of anxiety and depression in a Swedish study (Johansson et al., 2013a). Concerning the mental disorders included in the mentioned study, the study was limited to depression and anxiety disorders. Based on their encouraging results and affect-phobia as the central theoretical concept, which provides a transdiagnostic approach, we want to examine the usefulness of the treatment for a broader range of disorders, like eating or somatoform disorder. Our approach is similar to the one of Farchione et al. (2012) who investigated a unified protocol for a transdiagnostic, emotion-focused CBT for emotional disorders. The unified protocol was developed because research has shown substantial overlap among anxiety and mood disorders (Moses and Barlow, 2006), that could be explained by a "general neurotic syndrome" (Tyrer, 1985), which might be an underlying factor across emotional disorders (Farchione et al., 2012).

Together with the broader inclusion criteria, we shifted the intended purpose from a single intervention to an aftercare following inpatient/day hospital psychotherapy. With these essential changes in mind, we want to investigate questions concerning the feasibility of our intervention in the first place. That includes the mere use of the intervention, the satisfaction with and the perceived usefulness of the intervention, as well as the effort spent for the participation on behalf of patients and the therapists. To measure these aspects, both questionnaires and tracking of the activity on the study platform will be used.

We assume, that our intervention proves to be accepted and useful by the participants, therefore the second step will be to evaluate efficacy of this newly developed intervention in a bigger RCT. Hence our second goal is to collect data for a future research project, especially preliminary estimates of efficacy. Therefore, we have planned our study in a randomized wait-list control design. Our primary goal regarding efficacy is to compare the intervention with therapist support to treatment as usual. This comparison will offer estimates concerning various outcomes, like emotional competence, depression, anxiety and quality of life. Obtained preliminary effect sizes will be used to calculate the necessary sample size for a larger randomized controlled trial. Furthermore, on the basis of the feasibility outcomes like satisfaction and acceptance, the design and content of the intervention will be optimized.

Since we have chosen a wait-list control design, we will conduct additional exploratory analyses to compare the therapist supported intervention with the unsupported intervention the WLC receives after waiting for ten weeks. This is of interest, because particularly trials investigating self-help interventions with no support at all are still rare.

Another important aspect of consideration, since studies have proven the effectiveness of online interventions, is the cost-benefit ratio. We still know little about the cost-effectiveness of online interventions although the first results were promising. Arnberg et al. (2014) identified two eligible studies in their meta-analysis with statements on cost-effectiveness. The online intervention in both of them proved to be cost-effective regarding the compared treatment (treatment as usual and group CBT). To compare our two treatment conditions regarding cost-effectiveness, we track the time the online therapist and his supervisor use for providing patient feedback in the condition with therapist support. This time, along with other economic variables, will be analyzed while considering the effectiveness of the treatment for every patient.

4. Conclusion

Taken all together, we want to provide further insight into the feasibility and preliminary efficacy of an affect-focused, transdiagnostic, psychodynamic online self-help intervention with different degrees of support. We want to determine whether such an intervention will (1) be used and accepted by patients leaving an inpatient/day hospital psychotherapeutic treatment, (2) help them maintain the therapy success achieved during their treatment and (3) support them to enhance their emotional competence and quality of life. Thus, the intervention could fill a significant gap in the German health care system, namely aftercare of patients following inpatient/day hospital psychotherapeutic treatment. Finally, the trial will contribute to the knowledge about psychodynamic online interventions which are still widely underrepresented.

Trial status

The first patients were enrolled in the study on 21 September 2015. Follow-up assessments for the remaining patients are expected to be completed by July 2016.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

JB, RZ and MEB designed the study in the first place. RJ, RJF and GA contributed significantly to the study design. JB wrote the first draft of the manuscript. MEB, RJ, RJF, GA, RZ and JB revised the manuscript and did the final draft. All authors read and approved the final manuscript.

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