Author’s response to reviews

Title: A self-guided internet-based intervention for individuals with gambling problems: study protocol for a randomized controlled trial

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Author’s response to reviews:

Dear Dr. Buntrock, dear reviewers,

Thank you for providing us with the opportunity to revise our manuscript TRLS-D-18-00845 (title: A self-guided internet-based intervention for individuals with gambling problems: study protocol for a randomized controlled trial) for publication in Trials. We greatly appreciate the constructive feedback and helpful suggestions from Dr. Volpato and Dr. Zaninotto who acted as reviewers in the open peer-review system operated by Trials. We are indebted to the positive comments particularly from Dr. Volpato (e.g., “The introduction represents the research in an appropriate and concise context; the hypotheses are clear […]”). At the same time, both reviewers raised a number of areas for improvement.

We read the reviews carefully and have revised the manuscript accordingly. In this response letter, we discuss how we addressed each recommendation. Line numbers listed in our response refer to locations in the revised manuscript (version with tracked changes). Revisions in the manuscript are marked as track changes. We believe the manuscript was considerably strengthened with these revisions.
As you will see, we have tried to comply with each single point and hope that the manuscript is now suitable for publication.

Response to Dr. Volpato (Reviewer #1 - open peer-review system):

“Title: The paper's title is informative and reflects the content of the article.”

Thank you for this comment, Dr. Volpato.

“Key Words: They are appropriate and complete.”

Thank you for this positive remark.

“Abstract: The abstract is written in a sufficiently clear way. I suggest you to provide a more specific indication about the possible implications of key findings of your study.”

Thank you for this helpful advice. We agree and added information about the possible benefits (e.g., narrow the treatment gap, saving scarce and expensive resources as therapists) as well as possible clinical implications of the results (e.g., broader use and promotion of such interventions in the future) in the abstract.

“Trial Registration: Please, provide the URL”

Thank you for this advice. We added the URL of the trial registration on page 3 line 55 (https://clinicaltrials.gov/ct2/show/NCT03372226).

“Introduction: The introduction presents the research in an appropriate and concise context.

The related references are adequate and pertinent to the present study. The hypotheses are clear.”

Thank you for the positive remarks.

“Methods: Please, specify how you measure both primary and secondary outcomes in the paragraph "Measures".”
Please find the paragraph measures, where the primary and secondary outcome measures are described, in lines 272-315. The primary outcome is the reduction of gambling severity (measured with the Pathological Gambling Adaptation of Yale-Brown Obsessive Compulsive Scale; PG-YBOCS). Secondary outcomes include the reduction of depressive symptoms (measured with the Patient Health Questionnaire - 9 depression module; PHQ-9) and gambling specific dysfunctional thoughts (measured with the Gambling Attitudes and Beliefs Survey; GABS).

“Discussion: They are reported in a clear way. Tables and figures are well organized.”

Thank you for the positive feedback.

Response to Dr. Zaninotto (Reviewer #2 - open peer-review system):

“The authors wrote a manuscript describing a protocol in which they want to use an internet-based intervention to improve gambling and depressive symptoms.

There are major methodological issues in this paper that keeps hard to understand how the authors are planning to manage.“

Thank you very much for the thorough review of our manuscript, Dr. Zaninotto. We appreciate your critical feedback and are confident that we can resolve most of the issues. We think that your constructive comments and the resulting adjustments have helped to improve the quality of the manuscript.

“The hypotheses are not clear. In the abstract, there is a mix of gambling measurement (I have no idea what they are trying to measure here) and depressive symptoms. What is the primary outcome???”

We regret this apparent misunderstanding and are not sure how this confusion arose as both primary and secondary outcomes can be found in the abstract. Here it is stated that the primary outcome will be the change in pathological gambling measured with the PG-YBOCS from pre to post. The change in depressive symptoms and gambling related dysfunctional thoughts (assessed with the PHQ-9 and GABS) represent secondary outcomes. In order to avoid misunderstandings, in the revised version, we now write out the measurements. Thus, the measure of the primary outcome is the Pathological Gambling Adaptation of Yale-Brown Obsessive Compulsive Scale (PG-YBOCS). Secondary outcomes include the reduction of depressive symptoms (measured
with the Patient Health Questionnaire - 9 depression module; PHQ-9) and gambling specific dysfunctional thoughts (measured with the Gambling Attitudes and Beliefs Survey; GABS).

“In the introduction, the authors again did not specify what they are trying to measure.”

According to the SPIRIT guidelines, in the introduction authors should describe the background and rationale, the objectives and the trial design. We fulfil these requirements. In the last section of the introduction, we clearly describe the goal of the study as well as our hypotheses and expectations (see lines 161-168). According to the SPIRIT guidelines, the measurements should be described in the methods section and we adhered to this criterion here (see lines 272-315). However, to also address another comment, we have now included the outcome measures at the end of the introduction (see lines 164-167).

“The most important peace: how do the authors trust the data? How do they know if someone can self-enroll many times to receive 20 Euros card? Or if the participants are faking the symptoms or their age to participate in the study?”

We agree with you that this is an important issue of (most kind of) internet-interventions, which has been dealt with extensively in the literature, which is now cited. The characteristics of internet-interventions, as self-referral recruitment of study participants via the internet and online self-rating questionnaires have several pros and cons. Advantages of online administration of questionnaires are, for example, that the risk of missing values can be reduced, and exclusion criteria can be easily queried, such that subjects can be automatically excluded once they reach critical values. There are several studies (Andersson & Titov, 2014; Hedman, Ljótsson, Rück, et al., 2010; Carlbring, Brunt, Bohman, et al., 2007) asserting that data from online questionnaires can be collected without compromising psychometric characteristics. However, this kind of assessment has indeed several limitations, such as the difficulty of checking accuracy of responses (however, we have performed plausibility checks with regard to test-retest reliability) and of obtaining additional information. We assume that those limitations of internet-interventions and assessments are commonly known to our readers. In the discussion, we name several other limitations of our study, such that we do not have third-party ratings to assure diagnoses by means of structured interviews, since we wanted to offer study participation completely anonymous. Structured interviews via telephone would have also raised the threshold for participation (see lines 357-359). Regarding your second question: In the logfiles of the data we can see, from what device the participant logged into the online-assessment so that we could have noticed if the same person had logged in repeatedly to receive the 20 Euros voucher.
Addressing your last doubt, we would like to emphasize that, even in a face-to-face conversation, symptoms can be faked, and wrong answers can be given.

“The introduction is badly linked with the main proposal of the study. The authors report things like cognitive restructuring, internet-based self-report, telephone support, in which I couldn't see the relationship with the proposal. The authors reported 2 types of gambles and I didn't get why this information is relevant. Also, the authors cited a meta-analysis but did not discuss the main results.”

Please excuse us for only partially agreeing to this. We think (and so does Reviewer 1) that the introduction (background) is generally well-structured and relates to the main aim of the study. However, we agree that the structure can be improved and therefore we have inserted paragraphs to make the topics clearer. We have also deleted a section in the upper part of the background section (diagnostic classification and changes in DSM-5) as this has no direct relevance to the objective of the study. Furthermore, we have revised the paragraph on the effectiveness of internet-based interventions since we agree that we weren’t very clear here. We also added some information on the differentiation between guided and self-guided internet-based interventions (see lines 104-127). In the revised version, the outcomes of all meta-analyses mentioned are discussed.

“Moreover, the authors report the attrition rates of two studies as 83% and 97% and they are estimating their study lost as 50%. There is an incongruence here!”

Thank you for this helpful comment. The two rates that you name are the attrition rates of the same study (attrition rates at post and follow-up), so the 97% is a rate for a later follow-up and has therefore no direct relevance for our estimation. However, we agree that this might be confusing for the reader and added studies on adherence in internet-interventions as well as on adherence among pathological gamblers, on the basis of which we have made our estimate (see lines 192-193).

“Also, they report that guidance has adverse effects in internet-based intervention - 1st, I don't know why this information is relevant; 2nd, I didn't understand how they can be affirmative on that.”
We cite a study that found adverse effects of guidance in a sample of online poker gamblers. As described (lines 137-145), the study found higher attrition rates for the group that received guidance. This is a relevant finding for further studies in this field and supports the use of our program as it is self-guided.

“The penultimate paragraph is badly written and could be addressed in the methods section.”

We feel this criticism is too harsh and would like to emphasize that the entire manuscript was corrected by a professional copy editor. If you mean by “penultimate paragraph” the subsection “Ethical aspects and data safety”, it already can be found in the methods section. Below, there is just one other section "Discussion" (one long paragraph). Unfortunately, we cannot see that this section is “badly written”. Maybe you could specify it a little and give details with reference to the lines, so that we can directly see which sections you are referring to.

“The aim of the study is not clear and the hypothesis very weak.”

Thank you for the comment. The aim of our study is clearly described at the end of the background section. Here we write “The aim of the study is to evaluate the efficacy and acceptance of the internet-based intervention “Restart” that is aimed at treating gambling-related and emotional problems.” In order to formulate the hypotheses more clearly, we added the outcome measures as follows. “We expect that the internet-based intervention leads to a significant reduction of pathological gambling (primary treatment target) as measures with the Pathological Gambling Adaptation of Yale-Brown Obsessive Compulsive Scale, gambling-specific cognitive distortions (measured with the Gambling Attitudes and Beliefs Survey) as well as depressive symptoms (measured with the Patient Health Questionnaire - 9 depression module) when compared with a control group that receives no treatment” (see lines 162-168). Such formulation of aims and expectations in studies on the efficacy of treatment programs are common and verifiable (c.f., Beevers et al., 2017; Bücker, Bierbrodt, Hand, Wittekind, & Moritz, 2018; Meyer et al., 2015).

“The study design should be re-written. The conditions are not clear and neither the endpoints.”

Please excuse our disagreement here. We think (and so does Reviewer 1) that the subsection “study design” is clearly written. The two arms of the RCT (the intervention group receives access to self-guided internet-intervention “Restart”; the wait-list control group receives full access to the program following the post-assessment) are described as well as the assessment times (pre and post) and intervention period (8 weeks). The primary and secondary endpoints are named in the abstract, at the end of the introduction and in the subsection “measures”.
“The sample size reports an estimated dropout of 50% based on previous studies???. Which papers???(see above).”

We hope that this comment has been sufficiently addressed before. We added studies on adherence in internet-interventions as well as on adherence among pathological gamblers, on the basis of which we have made our estimate (see lines 192-193).

“I didn't understand the recruitment strategy.”

Thank you for bringing this to our attention. We have added some information. As described in the “Recruitment” subsection, we recruited participants via a Google adwords campaign (Google advertisement). This is a common method most companies or suppliers use to direct customers to their website and increasingly adopted by researchers. Depending on the terms a person enters into the Google search engine, certain pages are suggested to them - most people look at the top results of the Google search. Here it is possible to place an advertisement for a fee per click, which is then displayed directly at the top. In our study, we created such an advertisement which directs to a website with information about the study and a further link to the online baseline assessment. By entering relevant keywords such as “problematic + gambling + help”, the ad for our study is displayed. We added this more detailed information in the corresponding section (see lines 195-201). Again, this strategy is increasingly used by researchers.

“There are many points in the randomization that needs to be clarified, such: self-selected? Participants are allocated to the conditions according to the randomization plan and based on the date and timeline of the baseline assessment????? Please explain.”

Thank you for this comment. The allocation of participants in our study is different from the standard procedure, in which study members actively approach participants and where there is a previous contact between the researcher (or person, who is allocating) and the participants (which is the reason for the need of concealed allocation). In our study, participants click on the Google advertisement themselves and, if they are interested in participating, start with the baseline online-assessment (that's why called it “self-selected”). After completion of the baseline assessment, the researcher receives an e-mail, with the information that a new participant has completed the baseline assessment. He then takes a look into the randomization plan and sends the respective allocation (either intervention group or wait-list control group) to the participant. This is performed chronologically, that is, based on the time and date of completion of the baseline assessment, to prevent any arbitrary allocation of participants. We added this information to the manuscript (see lines 227-238).
“The intervention is badly described: what is CBT 3rd wave??? What are they considering mindfulness-based and metacognitive technique based on their Figure 1???”

Thank you for the comment. We assume that you are referring to Table 1 and not Figure 1. We can assure that the term third wave of cognitive behavioral therapy is common for people interested in this topic. The term has been established in the late 1990s and is consensual among both researchers and clinicians. As you can see in Table 1, the module “mindfulness” addresses mindfulness-based techniques (e.g., relaxation and breathing exercises, body scan, yoga-elements). Furthermore, the module “modifying thoughts” includes metacognitive elements and addresses depressive and gambling-specific cognitive distortions (e.g., negative filter, gambler’s fallacy, illusion of control). We added this more detailed information in Table 1.

“Please explain about the audio files and videos.”

Thank you for this advice. We added information on the content of the audio files and videos (see line 254-255), where it is now saying that there are audio files (e.g., mindfulness-based relaxation and breathing exercises) and videos with psychoeducational content (e.g., about a model of the development of sleep disturbances) included in the program.

“How are they controlling the participant participation?”

We are not fully sure what is meant by “participant participation”. In case you mean the actual usage of the internet-intervention: The duration that the individual participants were logged in, can be checked by us via the logfiles of the program. We added this information (see lines 337-338) and thank you for bringing this to our attention.

“The primary and secondary outcome measures don't make a strong link with the background.”

The primary outcome measure is the Pathological Gambling Adaptation of Yale-Brown Obsessive Compulsive Scale (PG-YBOCS) that is regarded as a reliable and valid measure of pathological gambling severity, and is an established diagnostic tool for both clinicians and researchers in the diagnostic and treatment of pathological gamblers (Pallanti, DeCaria, Grant, Urpe, & Hollander, 2005). Secondary outcomes include the reduction of depressive symptoms measured with the Patient Health Questionnaire - 9 depression module (PHQ-9), which has very good psychometric characteristics (Kroenke & Spitzer, 2001) and is recommended by the DSM-5 Working Group of the American Psychiatric Association as an instrument for measuring the severity of major depression according to the new DSM-5 criteria. Lastly, as we are interested in
gambling specific dysfunctional thoughts (see background section), we are measuring those with the Gambling Attitudes and Beliefs Survey (GABS). All outcomes obviously relate to the background.

“Are they using baseline scores as covariates???”

As you can read in the methods section (subsection statistical analyses), we will conduct ANCOVA analyses with pre-to-post time as within group factor, condition as between group factor and (of course) baseline scores as covariate (see line 317-319).

“Many basic assumptions for a good protocol are missing. The authors should follow the CONSORT Statement.”

Thank you for this thoughtful advice. However, we are sure that for study protocols SPRIRT guidelines are more suitable (see author guidelines of Trials). We followed those guidelines within this manuscript. The SPRIRT checklist was uploaded to the editorial manager.

We thank the two reviewers for their valuable comments, which have helped to further raise the quality of the study protocol. We hope that the manuscript is now suitable for publication. If concerns remain, we would be grateful to be granted another opportunity for revision.

Yours sincerely,

Lara Bücker and Steffen Moritz (on behalf of all co-authors)