

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Efficacy of a web-based self-help tool to reduce problem gambling in Switzerland: study protocol of a two-armed randomized controlled trial
AUTHORS	Baumgartner, Christian; Bilevicius, Elena; Khazaal, Yasser; Achab, Sophia; Schaaf, Susanne; Wenger, Andreas; Haug, Severin; Keough, Matthew; Hodgins, David; Schaub, Michael P.

VERSION 1 – REVIEW

REVIEWER	Clara Hellner Karolinska Institutet, Stockholm, Sweden
REVIEW RETURNED	23-Jul-2019

GENERAL COMMENTS	<p>Comment on manuscript bmjopen-2019-032110 "Efficacy of a web-based self-help tool to reduce problem gambling in Switzerland: study protocol of a two-armed randomized controlled trial"</p> <p>Thank you for inviting me to review this paper.</p> <p>The manuscript is a study protocol that aims to compare a self-help program for problem gamblers (nine modules provided via the internet) with a self-help manual (available as pdf). Overall, the manuscript is well written and easy to follow. International standards for intervention research are applied, including ethical review.</p> <p>Comments:</p> <ul style="list-style-type: none"> In the introduction, it is stated that the prevalence rate of problem gambling is lower in Switzerland while, at the same time, gambling opportunities are highly accessible. Also, it is mentioned that there are geographical/cultural differences in gambling prevalence. This does not affect the necessity of developing interventions for problem gamblers (of course) but do the authors have any possible explanation to why prevalence rates are lower? In particular, would they expect that those who enrol for this study in any way may differ from gamblers in other countries (i.e. do these circumstances in any way influence how readers in other countries should interpret the results?)
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	<ul style="list-style-type: none"> • Minor issue: The authors focus partly on adolescents and young adults in the introduction, but the intervention is aimed at those >18. Did the authors have any specific target group in mind when they developed the intervention? • P. 6, line 26-32: I am not convinced that self-exclusion from casinos could be interpreted as a sign of “the self-help narrative”, since pressure from family members could have played a part. Also, without access to professional support, any action the gambler takes will appear as “self-help”. • P. 7, line 17, “<i>Web-based self-help offers a promising and cost-effective alternative for problem gamblers who are not yet in treatment or are hesitant to seek face-to-face treatment</i>”: This is just a reflection, but although I fully agree with the idea of providing online help to those who prefer this format, lack of access to other alternative treatment formats will affect who turns to internet (it could be perceived as “better than nothing”) that in turn may affect adherence and outcome. • Registration and consent: <ul style="list-style-type: none"> ○ Even though the participants provide “minimal personal data” (p. 9, line 7) they will not be anonymous (as is stated on p. 14, line 38). • Inclusion and exclusion criteria: <ul style="list-style-type: none"> ○ No specific comment. • Randomization and trial flow: <ul style="list-style-type: none"> ○ Weekly log in (P. 10, line 28-29): Will the control group be subject to weakly measures as well? Here it is stated that only the intervention group will be required to log in and record their gambling activity. Will the groups only be compared on the three measure points (baseline, 8 weeks, 24 weeks?). It is stated on ○ P 10, line 48: I assume “follow-up visit” does not mean a personal visit? • Hypotheses: <ul style="list-style-type: none"> ○ One hypotheses refers to alcohol and cigarette use. Is it possible to provide a rationale for why one would expect these to be affected as well? There is of course the possibility that merely looking after oneself better may affect life style overall (or that life style overall may affect gambling), but on the other hand one could expect smoking to be associated with craving. ○ If one want to test the hypothesis that participants in study arm 1 will be more satisfied with the intervention than those in study arm 2, one has to make sure that both groups adhere to the intervention. How will adherence to the self-help manual (study arm 2) be assessed? • Intervention: <ul style="list-style-type: none"> ○ Will all participants in study group 1 be expected to complete all nine modules? This was not fully clear, since it is stated that five modules are core modules and four are “complimentary”. As I understand the text, participants will complete
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	<p>various number of modules. If so, how will this affect the evaluation?</p> <ul style="list-style-type: none"> ○ Could the authors describe (briefly) what the certification according to CE implies? That might be of interest. ○ It is stated that one has the possibility to self-report gambling data and get feedback on the dash board (p. 12, line 52, and p. 14, line 34 and onwards). It was not entirely clear to me what data is to be reported for research purposes (i.e. following the development of the gambler) and when self-report is seen as an intervention in itself. Could this be expressed more clearly? It may be that the only assessments that will be used for evaluation of the two arms are the measures reported at baseline, 8w and 24w, but this was not clear. <ul style="list-style-type: none"> • Control condition: <ul style="list-style-type: none"> ○ Please describe how you will assess to what extent participants in the control condition adhered to the self-help manual. If not, the control condition may be equal to “no intervention” but the authors will not know. ○ It is stated that one exclusion criterion is that you take part in some other intervention for problem gambling. Thus, the comment on p. 15. line 36-38 was a bit confusing. • Measures: <ul style="list-style-type: none"> ○ Apart from assessing common comorbidities such as substance use, anxiety and depression, measures on ADHD and PTSD are included. I can understand ADHD, but what is the rationale for PTSD? ○ It is positive that the authors include measures such as G-SAS, since measuring only gambling as an outcome may result in a lot of zeros. • Sample size calculation <ul style="list-style-type: none"> ○ This paragraph refers to a study of an internet intervention for cannabis use. This is a potential weakness; on the other hand research on gambling is scarce. • Data analyses, data security, PPI and ethics: Satisfactory. • Discussion: <ul style="list-style-type: none"> ○ As described, there are only a few studies on internet-delivered interventions for problem gambling. My main concern with this design is how the authors will assess how much “active treatment” the control group will get (no reminders, no weekly assessment)?
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REVIEWER	malcolm battersby flinders university, Australia
REVIEW RETURNED	23-Sep-2019
GENERAL COMMENTS	please justify not including rationale for calculation of drop outs or non completers as at least 50% possibly 80% as part of sample size calculation, more than 'imputation'

Reviewer 1:

R1_Q1: In the introduction, it is stated that the prevalence rate of problem gambling is lower in Switzerland while, at the same time, gambling opportunities are highly accessible. Also, it is mentioned that there are geographical/cultural differences in gambling prevalence. This does not affect the necessity of developing interventions for problem gamblers (of course) but do the authors have any possible explanation to why prevalence rates are lower? In particular, would they expect that those who enrol for this study in any way may differ from gamblers in other countries (i.e. do these circumstances in any way influence how readers in other countries should interpret the results?)

R1_A1: Good question. The lower rates of gambling may stem from the fact there are different types of measurements and cut-offs used in previous Swiss surveys compared to other countries. A new survey (Dey & Haug, 2019) shows the prevalence of problem gambling in 2017 was between 0.9% - 2-8% depending on the measurement, which is comparable to other European countries. The differences between the French-speaking and German-speaking parts was hypothesized to be cultural but other factors like political decisions or rural vs urban may be influential as well. Potential results always have to be considered with such an understanding and effects may vary between different countries.

R1_Q2: Minor issue: The authors focus partly on adolescents and young adults in the introduction, but the intervention is aimed at those >18. Did the authors have any specific target group in mind when they developed the intervention?

R1_A2: The reason why minors are not included is that gambling below the age of 18 is illegal and there were legal concerns if they would be allowed to participate in such a study without the consent of their parents. The motive for highlighting the prevalence in young adults is their affinity for technology and tools like ours may initially be more attractive to them than traditional care.

R1_Q3: P. 6, line 26-32: I am not convinced that self-exclusion from casinos could be interpreted as a sign of “the self-help narrative”, since pressure from family members could have played a part. Also, without access to professional support, any action the gambler takes will appear as “self-help”.

R1_A3: Of course there may be some influence by the family but based on the questionnaire data from self-excluders (Litscher, 2016) only a small group excluded themselves “At the request of family and friends”. I don’t understand the second sentence. I agree that any action that aims to alleviate problems without the guidance of a professional could be described as “self-help”.

R1_Q4: P. 7, line 17, “*Web-based self-help offers a promising and cost-effective alternative for problem gamblers who are not yet in treatment or are hesitant to seek face-to face treatment*”: This is just a reflection, but although I fully agree with the idea of providing online help to those who prefer this format. Lack of access to other alternative treatment formats will affect who turns to internet (it could be perceived as “better than nothing”) that in turn may affect adherence and outcome.

R1_A4: Lack of access to other alternative treatment may not be the biggest issue in Switzerland: “Since the implementation of a gambling policy, specialized prevention and treatment centres have been created in most Swiss cantons” (Billieux et al., 2016)
Nonetheless, we are aware that the population we are targeting is probably going to be different from the population that seeks help in person and the nature of online-intervention will affect the outcomes (Low threshold to enter – low threshold to leave)

R1_Q5: Registration and consent:
Even though the participants provide “minimal personal data” (p. 9, line 7) they will not be anonymous (as is stated on p. 14, line 38).

R1_A5: We used the word anonymous in the sense of “non-identifiable”.

R1_Q6: Randomization and trial flow:

Weekly log in (P. 10, line 28-29): Will the control group be subject to weakly measures as well? Here it is stated that only the intervention group will be required to log in and record their gambling activity. Will the groups only be compared on the three measure points (baseline, 8 weeks, 24 weeks?). It is stated on P 10, line 48: I assume “follow-up visit” does not mean a personal visit?

R1_A6: The weekly diary entries are not intended as measurement per se but as part of the intervention program to support self-efficacy and goal setting. The groups will be compared based on the three measuring points.

I changed the word “visit” to “assessment” to avoid confusion: ...over the course of observation at their final follow-up assessment.

R1_Q7: Hypotheses:

One hypotheses refers to alcohol and cigarette use. Is it possible to provide a rationale for why one would expect these to be affected as well? There is of course the possibility that merely looking after oneself better may affect life style overall (or that life style overall may affect gambling), but on the other hand one could expect smoking to be associated with craving.

R1_A7: The program does not solely address gambling but also alcohol and cigarette use, therefore we expect those to be affected, too. Two elements are targeting alcohol and cigarette use. One is the personalized normative feedback and the second is a module that is dedicated to this issue (Module E1: Alcohol & Nicotine). Other elements may contribute as well in the way it was mentioned in question (changing one’s own life style) .

R1_Q8: If one want to test the hypothesis that participants in study arm 1 will be more satisfied with the intervention than those in study arm 2, one has to make sure that both groups adhere to the intervention. How will adherence to the self-help manual (study arm 2) be assessed?

R1_A8: Adherence to the manual is indeed complicated. We measure if the manual was downloaded (based on server information) and later we asked the participants if they have used the manual and to which extent. I added the information to the protocol:

Participants in the control group will be asked if they have used the provided manual and to which extent, at the 24-week follow-up assessment.

R1_Q9: Will all participants in study group 1 be expected to complete all nine modules? This was not fully clear, since it is stated that five modules are core modules and four are “complimentary”. As I understand the text, participants will complete various number of modules. If so, how will this affect the evaluation?

R1_A9: No. They will be encouraged to complete as many modules as possible. The number of modules will be measured and will be used for further analysis. The main evaluation will be not affected, as we work under an ITT design.

R1_Q10: Could the authors describe (briefly) what the certification according to CE implies? That might be of interest.

R1_A10: I added following parts: The CE certification includes technical documentation (software release, test protocols, software requirements), clinical evaluation and a risk management plan.

R1_Q11: It is stated that one has the possibility to self-report gambling data and get feedback on the dash board (p. 12, line 52, and p. 14, line 34 and onwards). It was not entirely clear to me what data is to be reported for research purposes (i.e. following the development of the gambler) and when selfreport is seen as an intervention in itself. Could this be expressed more clearly? It may be that the

only assessments that will be used for evaluation of the two arms are the measures reported at baseline, 8w and 24w, but this was not clear.

R1_A11: As mentioned in **R1_A6**, this data will be only be prompted for to increase self-efficacy and goal setting.

R1_Q12: Control condition:

Please describe how you will assess to what extent participants in the control condition adhered to the self-help manual. If not, the control condition may be equal to “no intervention” but the authors will not know.

R1_A12: See R1_A8

R1_Q13: It is stated that one exclusion criterion is that you take part in some other intervention for problem gambling. Thus, the comment on p. 15. line 36-38 was a bit confusing.

R1_A13: I made the wording more specific to avoid confusion:

1) Self-reported engagement in other outside psychosocial treatments for problem gambling

and

any treatment other than *Win Back Control* or *Becoming a Winner* during the 24 weeks

R1_Q14: Measures: Apart from assessing common comorbidities such as substance use, anxiety and depression, measures on ADHD and PTSD are included. I can understand ADHD, but what is the rationale for PTSD?

R1_A14: A link between PTSD and problem gambling has mostly been shown in army veterans but the dissociation effect that gambling can offer could still be sought out by other people suffering PTSD.

R1_Q15: Sample size calculation

This paragraph refers to a study of an internet intervention for cannabis use. This is a potential weakness; on the other hand research on gambling is scarce.

R1_A15: Based on the available research we decided that the current program/design is more akin to this research than other gambling studies.

R1_Q16: As described, there are only a few studies on internet-delivered interventions for problem gambling. My main concern with this design is how the authors will assess how much “active treatment” the control group will get (no reminders, no weekly assessment)?

R1_A16: See R1_A8

Reviewer 2:

R2_Q1: Please justify not including rationale for calculation of drop outs or non completers as at least 50% possibly 80% as part of sample size calculation, more than 'imputation'

R2_A1: Oversampling as a way to deal with drop-outs is usually used to maintain the necessary power sought out in the power analysis. But we assume that our missing data is not missing at random (people performing worse dropping out) and using multiple imputation based on available data and an ITT-design should minimize the bias that would occur if only complete data (with or without oversampling) would be analysed while maintaining the necessary power to detect the main effect size. Oversampling would only be necessary if the drop-out rate would be so high that we could not make a sound imputation model but this is not expected. Another reason is that the power calculation is based on effect sizes achieved in previous research using similar designs and expecting similar dropout rates. Possible precision losses through the use of imputation is already factored in by this base assumptions. There is very little research in this kind of gambling research, so we rely more on research in online interventions (e.g. Kählke et al., 2019; Weisel et al., 2018) to make educated guesses.

Literature

Billieux, J., Achab, S., Savary, J. F., Simon, O., Richter, F., Zullino, D., & Khazaal, Y. (2016). Gambling and problem gambling in Switzerland. *Addiction*, 111(9), 1677-1683.

Dey, Michelle; Haug, Severin (2019) Glücksspielverhalten und Problematik in der Schweiz im Jahr 2017. Zürich: ISGF.

Kählke, F., Berger, T., Schulz, A., Baumeister, H., Berking, M., Cuijpers, P., ... & Ebert, D. D. (2019). Efficacy and cost-effectiveness of an unguided, internet-based self-help intervention for social anxiety disorder in university students: protocol of a randomized controlled trial. *BMC psychiatry*, 19(1), 197.

Lischer, S. (2016). Gambling-related problems of self-excluders in Swiss casinos.

Weisel, K. K., Zarski, A. C., Berger, T., Schaub, M. P., Krieger, T., Moser, C. T., ... & Ebert, D. D. (2018). Transdiagnostic tailored internet-and mobile-based guided treatment for major depressive disorder and comorbid anxiety: Study protocol of a randomized controlled trial. *Frontiers in psychiatry*, 9, 274.

VERSION 2 – REVIEW

REVIEWER	Clara Hellner Karolinska Institutet, Stockholm, Sweden
REVIEW RETURNED	10-Nov-2019

GENERAL COMMENTS	The authors have answered most of my questions. I was a bit surprised that they did not make more changes to the ms but answered my questions in the response letter only (e.g. the issue of "anonymity" in treatment is complicated). However, this is a study protocol and their will be opportunities to clarify things in the future.
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REVIEWER	Prof Malcolm Battersby Flinders University Australia
REVIEW RETURNED	11-Nov-2019

GENERAL COMMENTS	all aspects have been addressed
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VERSION 2 – AUTHOR RESPONSE

Reviewer 1:

R1_Q1: The authors have answered most of my questions. I was a bit surprised that they did not make more changes to the ms but answered my questions in the response letter only (e.g. the issue

of "anonymity" in treatment is complicated). However, this is a study protocol and there will be opportunities to clarify things in the future.

R1_A1: I added more changes on the request of the editor and I share that sentiment that some concerns should be addressed more clearly in the completed study with updated references. As well in future study designs as the current study is already ongoing and some changes cannot be made.