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# BMJ Open Efficacy of a web-based self-help tool to reduce problem gambling in Switzerland: study protocol of a two-armed randomised controlled trial

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## ABSTRACT

**Introduction** The past-year prevalence of problem gambling worldwide averages 2.3%. Switzerland exhibits a slightly lower past-year prevalence rate, of 1.1%, among adults. Only a minority of these adults attend outpatient treatment. Surveyed problem gamblers have explained that they wanted to handle the problem on their own. The option of a web-based self-help programme could potentially reach those users who hesitate to approach treatment centres and help them to reduce or stop their problem gambling. The effectiveness of such web-based interventions has been shown in other countries.

**Methods and analysis** This two-armed randomised controlled trial (RCT) will examine the efficacy of a web-based self-help intervention, relative to an active control condition with a self-help manual, at reducing problem gambling. The active intervention programme, spanning 8 weeks, consists of nine modules developed to reduce gambling and attenuate psychopathological comorbidity, including depression, anxiety and stress-related disorder symptoms, relying on motivational interviewing and cognitive behavioural therapy. With a target sample size of 352, questionnaire data will be collected at baseline, and at 8 and 24 weeks after baseline. Primary outcomes will be the number of days one has gambled in the last 30 days. Secondary outcomes will include money and time spent on gambling activities, changes in gambling-related problems (Problem Gambling Severity Index, Gambling Symptom Assessment Scale), use of alcohol and cigarettes, and psychopathological comorbidity. All data analysis will comply with the intention-to-treat principle.

**Ethics and dissemination** The RCT will be conducted in accordance with the Declaration of Helsinki; the consort eHealth Guidelines for studies on medical devices; the European Directive on medical devices 93/42/EEC, Swiss Law and Swiss Regulatory Authority requirements. The study was approved by the ethics committee of the Canton of Zurich. Results will be published in a scientific peer-reviewed journal. Participants will be informed via e-mail about study results via a lay-person-friendly summary of trial findings.

**Trial registration number** Current Controlled Trials registry (ISRCTN16339434).

## Strengths and limitations of this study

- This will be the first study in Switzerland on the effectiveness of a web-based self-help intervention (*Win Back Control*) to reduce problem gambling.
- This study applies a bolder approach to compare the intervention with an already empirically supported manual as an active control condition and, at the same time, be more ethically sound for people in need compared with using a waitlist control group.
- The developed intervention could bridge the treatment gap and help problem gamblers who otherwise might not seek out traditional mental healthcare.
- One limitation of the current study is the exclusion of gamblers who are currently receiving other treatments to reduce their gambling.
- Another is that, all measurements will be self-reported from the participants and cannot be externally validated.

## INTRODUCTION

Switzerland has a wide array of gambling facilities. There are 21 casinos and about 9000 lottery-vending points, which together raise around SFr1.5 billion yearly.<sup>1</sup> This makes Switzerland one of the densest countries in the world, in terms of gambling opportunities.<sup>2</sup> Nevertheless, problem gambling prevalence is comparable or even lower than in other European countries. Recent data indicate a past-year gambling rate of 46.6%, and a problem-gambling prevalence rate of 1.1% in Switzerland.<sup>3</sup> In a world-wide report<sup>4</sup> that assessed problem gambling, depending on the specific country and survey year, the standardised past-year rate of problem gambling was estimated to range from 0.5% to 7.6%, with an average rate across all countries of 2.3%. There seem to be geographical and cultural differences within Switzerland. Gambling is more pervasive in the French and

Italian-speaking regions of Switzerland than in German-speaking regions.<sup>5</sup> The inclusion of gambling disorder in the Diagnostic and Statistical Manual of Mental Disorders 5th Edition (DSM-V)<sup>6</sup> and the forthcoming International Classification of Diseases Mental and Behavioural Disorders 11th Revision (ICD-11),<sup>7</sup> as the first behavioural addiction, serves as acknowledgment of gambling as the most distinguishable behavioural addiction. Moreover, this change highlights the need for further treatment options for people who suffer from gambling disorder. Nevertheless, treatments offered in Switzerland<sup>8</sup> and worldwide remain scarce.

Besides the problems that are inherent to problem gambling (eg, preoccupation with gambling, monetary loss), there is a high rate of psychopathological comorbidity. Seventy-eight per cent of problem gamblers and 95.5% of pathological gamblers have an additional Diagnostic and Statistical Manual of Mental Disorders 4th Edition (DSM-IV) diagnosis.<sup>9</sup> Pathological gambling is statistically correlated with an increased risk of developing substance dependencies (OR, 3.9–5.9).<sup>10</sup> Affective disorders and anxiety disorders are present in 32.7%–48.8% of problematic/pathological gamblers, but only in 6.5%–12.3% of the general population.<sup>11</sup> Evidence suggests that fewer than 10% of pathological gamblers are in treatment,<sup>12 13</sup> with the majority seeking treatment only after a significant life crisis.<sup>14</sup> This, combined with relatively high treatment attrition rates, ranging between 17% and 76%,<sup>15 16</sup> suggests that most problem gamblers remain untreated.

Similar international studies have discovered that problem gambling rates among adolescents (age 12–17 years) are typically two to three times those found in adults.<sup>17 18</sup> Young adults age 18–24 years also show gambling-related problems to a greater extent than any other adult group.<sup>19 20</sup> Likewise, in Switzerland, in a study<sup>21</sup> conducted in the French part of the country on a sample of military conscripts (age 18–24 years), the prevalence of problem gambling was 1.4%. In another study conducted in the French part of Switzerland, the prevalence of at-risk gambling was 5.5% in a sample of adolescents age 14–17 years.<sup>22</sup> Young people rarely acknowledge problems or look for treatment, despite high rates of problem gambling.<sup>23</sup> Online tools have the potential to reach and support young adults attempting to deal with gambling-related problems, given their familiarity with and preference for the internet, and the anonymity of such tools.<sup>24</sup> In a similar vein, surveyed adult problem gamblers state that they wanted to ‘solve the problem on their own’.<sup>25</sup> This personal decision should be supported to enhance self-determination capabilities.<sup>26</sup> Another observation that supports the self-help narrative is that the gambling bans from casinos in Switzerland total 46 468 people,<sup>1</sup> and >70% stem from self-exclusion.<sup>27</sup> Internet interventions operate in a private and anonymous way that respects the gambler’s need for autonomy. There is evidence that the internet enables people to be more open and honest, and to offer more accurate self-evaluations regarding their

actual problems.<sup>28</sup> The use of internet-based self-help programmes can even increase professional help-seeking behaviour in gamblers.<sup>29</sup>

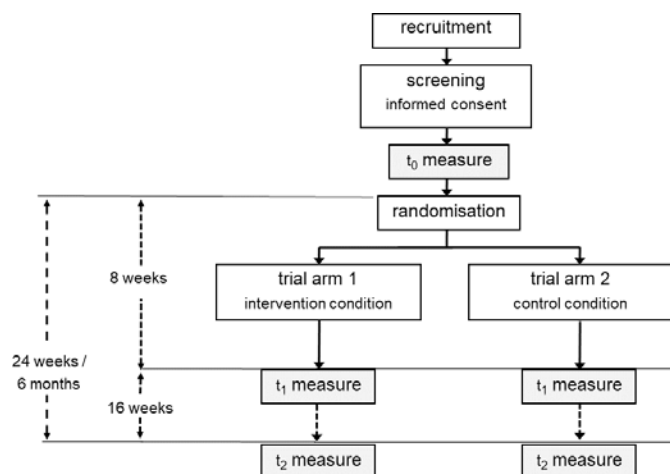
Besides these advantages of internet interventions, the cost-effectiveness of these interventions compares favourably to face-to-face interventions.<sup>30 31</sup> Most internet interventions employ a variety of different cognitive behavioural therapy (CBT)<sup>32</sup> and motivational interviewing<sup>33</sup> techniques. In one Cochrane report,<sup>34</sup> CBT was found to be effective at reducing gambling behaviour and other symptoms of pathological and problem gambling immediately following therapy. Cowlishaw and colleagues<sup>34</sup> also agree that there is evidence of some benefit from motivational interviewing therapy, in terms of reduced gambling behaviour, though not necessarily the other symptoms of pathological and problem gambling; but they also acknowledge the small numbers of studies in this area. Several internet interventions for problem gambling have implemented these techniques and shown their effectiveness in various countries.<sup>35–38</sup> These studies document significantly reduced gambling-related problems—including anxiety and depression—even up to 36 months after the intervention ends.<sup>36</sup>

Taken together, currently available data provide evidence that the majority of problem gamblers are not in treatment, even though many of them suffer tremendously from gambling-related problems. A diverse range of treatment options, provided in the least restrictive setting possible, appears most favourable for problematic and pathological gamblers. 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. Online interventions aim not to replace face-to-face counselling services; nonetheless, they offer an alternative for those who prefer to help themselves and can be used additionally to provide other forms of treatment. The study presented in this protocol seeks to investigate the effectiveness of a web-based self-help intervention at reducing problem gambling, while also considering the most frequent psychopathological comorbidity. This is the first study on the efficacy of a web-based tool to reduce problem gambling in Switzerland.

## METHODS AND ANALYSIS

### Study design

The web-based self-help programme *Win Back Control* will be evaluated with a two-arm randomised controlled trial (RCT), comparing the effectiveness of (1) a web-based self-help intervention and (2) a self-help manual aimed at reducing problem gambling. Blinding is not possible with the applied design. Participants will be unaware of the study hypotheses, but will know if they have been assigned to either the internet intervention or the self-help manual, the latter sent by email or downloadable as a PDF file. Any blinding of study personnel is unwarranted, as we will not be directly involved in either the intervention or the assessment. After completing the baseline



**Figure 1** Flowchart of the study based on CONSORT criteria. CONSORT, Consolidated Standards of Reporting Trials.

assessment ( $t_0$ ), participants will be randomly allocated to one of the two study arms. Further assessments will take place, both 8 weeks ( $t_1$ ) and 24 weeks ( $t_2$ ) after baseline (figure 1). The trial has been registered with the ISRCTN registry.

## Recruitment of study participants

Recruitment will take place from March 2019 either until September 2020 or until the target number of 352 participants is reached. Participants will be recruited through the *Win Back Control* website ([winbackcontrol.ch](http://winbackcontrol.ch)), which is already established and is linked to various

internet health portals. Additionally, advertisements will be placed in relevant internet forums and newspapers (or online versions thereof). Depending on the recruitment process, additional ads on Facebook or Google will be placed. The study will mainly recruit people from Switzerland; however, participants from other countries will not be excluded.

All participants who complete the 24-week follow-up assessment will receive either an online voucher of SFr30 or be able to donate that amount to charity.

## Registration and consent procedure

Participants can register online by providing only minimal personal data, including their email address, phone number (for follow-up questionnaires) and basic demographic information (age, gender, level of education, household income).

Informed consent will be accepted once participants have checked several boxes reiterating important study information and submitting their consent by clicking a submission button.

Participants will be assigned to be randomised if deemed eligible, according to the inclusion and exclusion criteria (see [table 1](#)).

## Randomisation and trial flow

After completing their online baseline assessment, participants will be randomised by the server in a 1:1 ratio into one of two groups.

Participants in the intervention group 1 will receive automated email reminders to login and record their

**Table 1** Inclusion and exclusion criteria and underlying rationale

Inclusion criteria	Rationale
(1) Informed consent via the web form	To ensure knowledge of procedures and the declaration of consent
(2) Minimal age of 18 years	To ensure a minimum age of participation
(3) Gambling activity at least once weekly over the 30 days prior to study entry	To ensure that the programme reaches the intended population; increase validity
(4) A PGSI score $\geq 3$	To ensure that the programme reaches the intended population; increase validity
(5) At least once weekly internet access and a valid email address	To ensure at least some access to the intervention
(6) Proficiency in German or French	To ensure that participants will be able to understand the information provided
Exclusion criteria	Rationale
(1) Self-reported engagement in other outside psychosocial treatments for problem gambling	To avoid confounding treatment effects
(2) Last 90-day psychosis or mania	To avoid having individuals with these problems enter the study
(3) Presence of a severe substance use disorder (DAST score $>5$ or AUDIT score $>20$ )	Individuals with a severe substance use disorder need more intensive treatment than provided
(4) Elevated suicidality (scoring greater than 'minimal risk' on a screener)	To increase safety, participants with elevated suicidality will be referred for face-to-face treatment

AUDIT, Alcohol Use Disorders Identification Test; DAST, Drug Abuse Screening Test; PGSI, Problem Gambling Severity Index.



gambling activity, money won or lost, and mood in their gambling diary every week.

The two interventions will each last 8 weeks. Follow-up assessments will be 8 and 24 weeks after the start of the programme. As such, there will be a baseline (pretreatment) assessment, an 8-week assessment immediately following the treatment programme, and a final assessment 16 weeks post-treatment (24 weeks postbaseline).

Since subjects will have access to any other online and offline counselling services that are available, they will be asked about their possible use of other treatment services over the course of observation at their final follow-up assessment.

Follow-up assessments will be completed online after a reminder is sent by email to all participants, in which they also will be reminded about the compensation of SFr30. If the final assessment is not completed within 2 days, a reminder will be sent out and another one after 5 days. If these reminders still go unanswered, participants will be contacted by phone roughly 1 week after the third email has been sent and offered a phone interview with study collaborators to complete the follow-up. Should participants still refuse, they will be asked to answer questions about the primary outcomes only or—should they still refuse—to provide a reason for refusing, which will then be documented.

Figure 1 is a flowchart depicting the flow of subjects through the study.

## Hypotheses

We formulated the following detailed study hypotheses with respect to the main outcome: reduction in the number of days of gambling over the last 30 days,

comparing the baseline, 8-week and 24-week follow-up assessments:

1. The web-based self-help programme (study arm 1) will be more effective than the self-help manual (study arm 2) at reducing gambling.

Furthermore, we have the following expectations for the secondary outcomes between the baseline, 8-week follow-up and 24-week follow-up assessments:

2. The web-based self-help programme (study arm 1) will be more effective than the self-help manual (study arm 2) at reducing the severity of gambling and gambling-related problems, as measured after the 8 weeks of intervention and at 24-week follow-up.
3. The web-based self-help programme (study arm 1) will be more effective than the self-help manual (study arm 2) at reducing symptoms of psychopathological comorbidity, as measured after the 8 weeks of intervention and at 24-week follow-up.
4. The web-based self-help programme (study arm 1) will be more effective than the self-help manual (study arm 2) at reducing alcohol and cigarette use, as measured after the 8 weeks of intervention and at 24-week follow-up.
5. Participants in study arm 1 will be more satisfied overall with the intervention received than those in study arm 2 after their 8-week intervention.

## Intervention

*Win Back Control* is an automated web-based self-help tool developed by the Swiss Research Institute for Public Health and Addiction (ISGF, [www.isgf.ch](http://www.isgf.ch)) to reduce or stop gambling in problem gamblers. The web-based self-help intervention is comprised of a dashboard, a

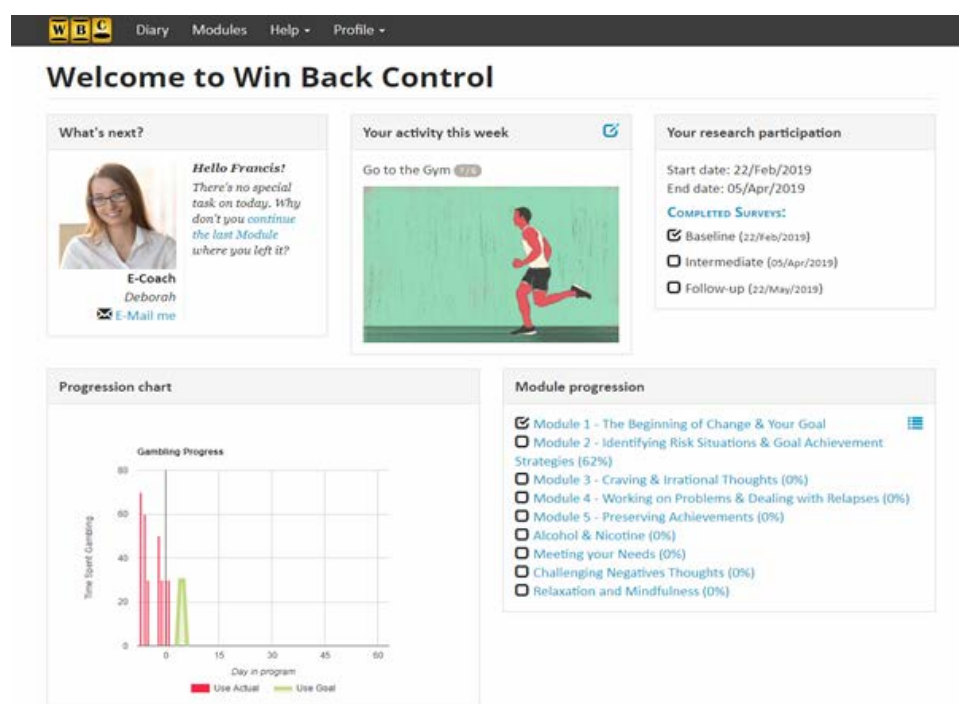


Figure 2 Dashboard in intervention group 1, gives quick overview over the programme progress.

gambling diary and nine modules that were designed to reduce gambling, relying on the principles of motivational interviewing,<sup>33</sup> self-control practices and cognitive behavioural therapy.<sup>32</sup> The modules stem from previously developed web-based interventions for cannabis and alcohol use<sup>39 40</sup> developed by the ISGF, and on the self-help manual 'Becoming a Winner', which was written by Hodgins and Makarchuk.<sup>41</sup> The core modules (1–5) must be completed in their intended sequence, meaning that finishing each core module unlocks access to the next one. The complimentary modules are designed to address common comorbidity (substance use, anxiety disorders and depression) that are present in some problem gamblers but not all. Complimentary modules will be shown and recommended based on the baseline evaluation, which should reduce the intervention's complexity. Participants will be encouraged to repeat any modules they feel they need or that they perceive as helpful. Since *Win Back Control* is considered a medical device, according to EU guidelines 93/42/EWG and 2007/47/EWG, its conformity has been assessed and potential risks have been evaluated. It is now fully Conformité Européenne (CE) certified. The CE certification includes technical documentation (software release, test protocols, software requirements), clinical evaluation and a risk management plan. The following elements of *Win Back Control* will be used in study arm 1.

### Dashboard

The central hub is the dashboard, designed to provide useful information at a quick glance. The dashboard displays the dates of the two follow-up assessments and indicates when they have been completed. The same

holds for the individual intervention modules, which, when the corresponding icons are clicked on, will lead participants to the page in the module where they left off, the last time they worked on it. There also is a way for participants to enter gambling data directly from the last 2 weeks, so that a progress graph is displayed. Another feature is an activity planner that lets participants plan an activity for the current week, upload a picture and rate the level of enjoyment they anticipate having prior to the activity, and the level of enjoyment they actually experienced, as rated once they have finished it.

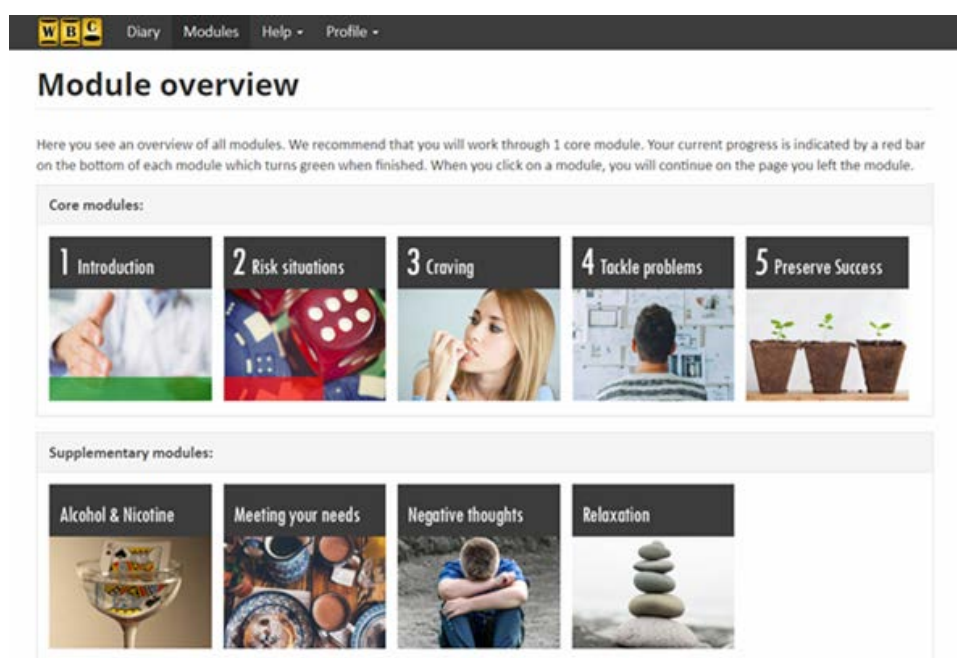
Figure 2 shows the dashboard implemented in the intervention group 1.

### Self-help intervention modules

There are a total of nine self-help intervention modules, which are depicted on the intervention website's module overview page (see figure 3), as well as on the dashboard. A short summary of module content is provided in table 2. Participants are encouraged to complete one of the core modules (1–5) each week. As stated earlier, the core modules must be completed in their intended sequence, though users are encouraged to repeat any modules they choose. A red bar in the module-overview indicates any progress they have made within each module; that bar turns green once a user has completed the entire module. The user will be encouraged to complete as many modules as possible.

### Gambling diary

Participants will be encouraged to completely fill out their gambling diary on no less than a weekly basis. There, they will be asked to record their goal about how much they



**Figure 3** Module overview in intervention group 1, separated in core and supplementary modules.

**Table 2** Modules

Module	Content
Module 1: the beginning of change and your goal	<ul style="list-style-type: none"> <li>▶ General overview.</li> <li>▶ Introduction to fictional companions.</li> <li>▶ Reflections on personal gambling.</li> <li>▶ Setting a personal reduction goal.</li> </ul>
Module 2 : identifying risk situations and goal-achievement strategies	<ul style="list-style-type: none"> <li>▶ Identifying personal high-risk situations.</li> <li>▶ Recognising seemingly irrelevant, but triggering decisions.</li> <li>▶ Strategies to change gambling habits.</li> <li>▶ Resisting gambling in specific situations (eg, situations involving negative emotions).</li> <li>▶ Developing personal strategies to reduce/abstain from gambling.</li> </ul>
Module 3: craving and irrational thoughts	<ul style="list-style-type: none"> <li>▶ Concept of craving.</li> <li>▶ Ways to deal with feelings of craving.</li> <li>▶ Learning about irrational thoughts that lead to more frequent and longer gambling, and how to defuse these irrational thoughts.</li> </ul>
Module 4: working on problems and dealing with relapses	<ul style="list-style-type: none"> <li>▶ Relationships between gambling, problems and depressive symptoms.</li> <li>▶ Skills to deal with solvable and unsolvable problems.</li> <li>▶ Relapse prevention.</li> <li>▶ Dealing with relapses.</li> </ul>
Module 5: preserving achievements	<ul style="list-style-type: none"> <li>▶ Review of programme.</li> <li>▶ List of five personalised points to help secure achievements after the programme is complete.</li> </ul>
Module E1: alcohol and nicotine	<ul style="list-style-type: none"> <li>▶ Discuss connection between gambling and alcohol and nicotine.</li> <li>▶ Tips and strategies to drink and smoke less.</li> </ul>
Module E2: meeting your needs	<ul style="list-style-type: none"> <li>▶ Strengthening social contacts.</li> <li>▶ Decreasing excessive ruminations.</li> <li>▶ Developing healthier sleeping habits.</li> </ul>
Module E3: challenging negative thoughts	<ul style="list-style-type: none"> <li>▶ Discuss the link between thoughts, feelings, behaviours and bodily sensations.</li> <li>▶ Review common thinking errors (or cognitive distortions).</li> <li>▶ Introduce balanced thinking.</li> </ul>
Module E4: relaxation and mindfulness	<ul style="list-style-type: none"> <li>▶ Simple introduction to the concept of mindfulness.</li> <li>▶ Progressive muscle relaxation.</li> <li>▶ Imagination exercises.</li> </ul>

want to gamble over upcoming days and how much they actually gambled in past days (in minutes). Additionally, they can enter how much money they won or lost and their mood on each specific day. A graph is generated live with these data inputs, providing the user with visual feedback. The ability to anonymously set daily gambling goals could strengthen the self-efficacy of users. The potential to track their own wins and losses will counteract the selective memory, often exhibited by gamblers, which recalls large wins but has difficulty recalling losses.<sup>42</sup> Mood tracking will encourage introspection and will help each user see the connection between their emotions and their gambling. **Figure 4** shows a 2-week sample diary.

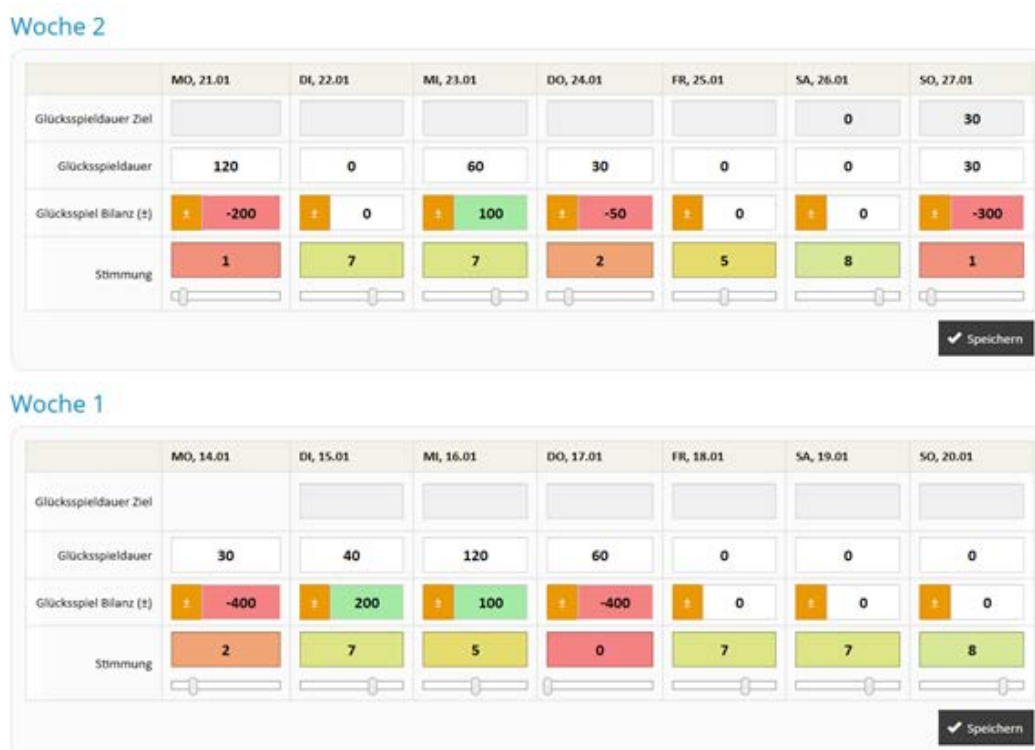
#### Normative feedback

After each finished assessment, users will be shown a page that gives them feedback, based on how they scored

on specific questionnaires. This feedback should give them a better understanding of their current situation and increase the usefulness of the assessment to them, thereby ideally enhancing follow-up rates. It also gives the user specific recommendations about which modules could be particularly helpful to them. **Figure 5** presents one example of the normative feedback presented after completing the baseline assessment.

#### Control condition

We will use an active control condition, as there has been concern of overestimating treatment effects when employing a waiting list control design,<sup>43</sup> as well as it being more ethical to provide actual immediate help to addicts. Those in the active control group will receive a copy of the self-help manual 'Becoming a Winner: Defeating Problem Gambling', written by Hodgins and



**Figure 4** A 2-week sample of the gambling diary used in intervention group 1.

Makarchuk,<sup>41</sup> via the website and by email. The manual was translated into German and French and adapted to fit the gambling opportunities in Switzerland. The efficacy of this manual has been documented in several studies.<sup>44 45</sup> At the last follow-up assessment, participants will be asked if, over the course of their 24 weeks in the study, they used other treatments and what they were; these data will then be analysed.

### Measurements

Sociodemographic data will include sex, age and level of education. Table 3 provides an overview of and schedule for the assessment tools that will be employed.

### Primary outcome

The primary outcome of interest will be the number of days of gambling over the last 30 days.

### Secondary outcomes

*Money lost* over the last 30 days and *time gambling* in the last 7 days will be rated via the Timeline Follow-Back (TLFB) method.<sup>46</sup>

The *Problem Gambling Severity Index* (PGSI) contains nine-items that assess a broad array of problems experienced by individuals who engage in problem gambling (eg, feelings of guilt, financial problems and so on).<sup>47</sup> The PGSI is the most widely used self-report measure of gambling harms in the literature. The total PGSI score will be used in this study to capture changes in gambling harms following intervention.

The *Gambling Symptom Assessment Scale* (G-SAS) is a 12-item self-report questionnaire that was designed

specifically to capture changes in gambling symptoms following treatment.<sup>48</sup> The main advantage of using the G-SAS as a secondary measure of gambling symptom change is that it includes several questions about gambling urges.

*Alcohol and cigarette use* will be assessed using the TLFB method.<sup>46</sup>

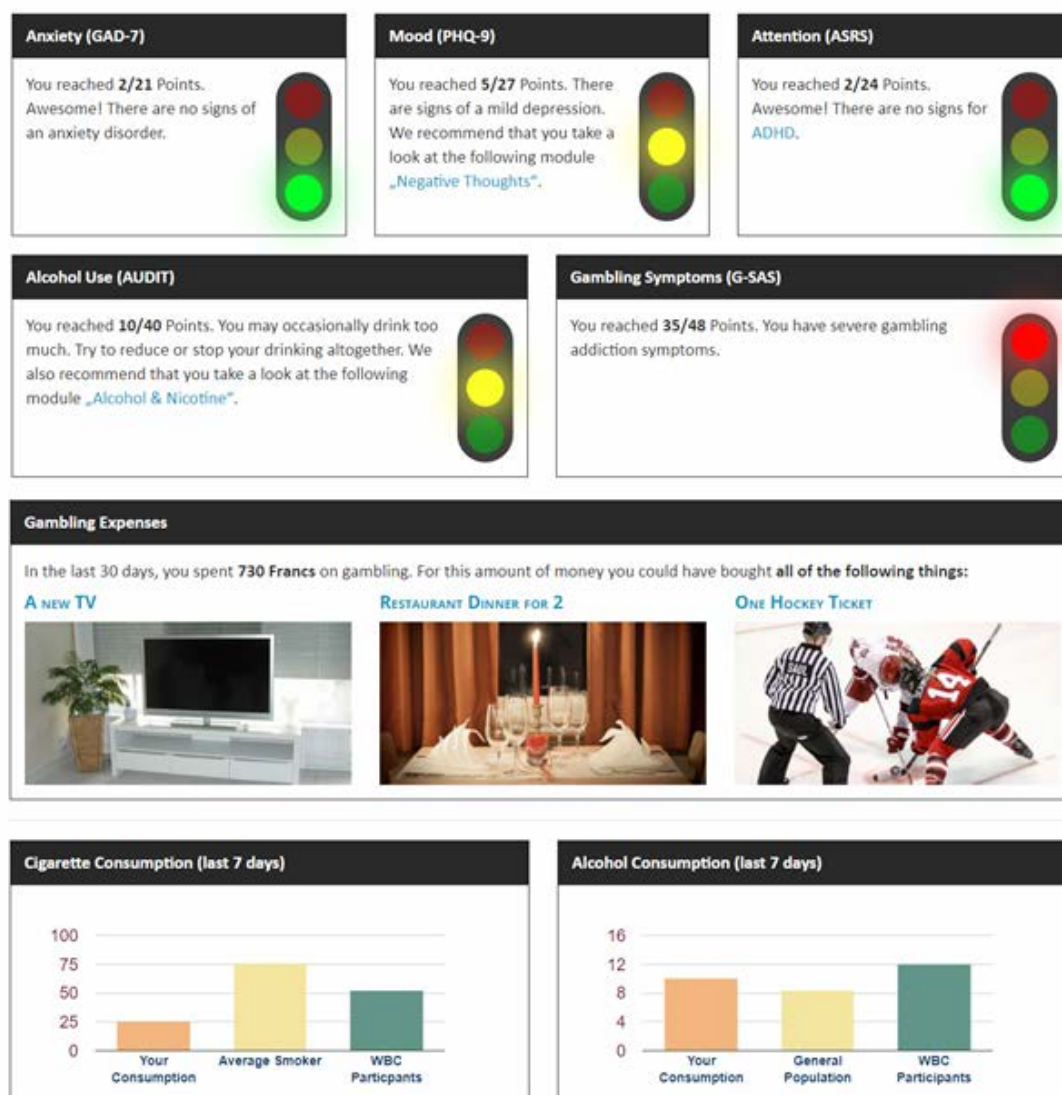
The *Patient Health Questionnaire-9* is a reliable and validated, 9-question tool developed to assess an individual's degree of depression.<sup>49</sup> With a total score of 27, a score of 10 or higher is a considered a good indication of a major depressive disorder.<sup>50</sup>

The *Generalised Anxiety Disorder 7* (GAD-7) is a 7-item, self-report questionnaire to screen for and estimate the severity of generalised anxiety disorder, and has good reliability as well as factorial and concurrent validity.<sup>51</sup> Its items ask about nervousness, inability to stop worrying, excessive worry, restlessness, difficulty relaxing, easy irritation and the fear of something awful happening. Total scores range from 0 to 21, with a recommended threshold at which GAD is considered likely of 10.

The six-item short version of the *ADHD Self-Report Scale-VI.1* can be self-administered easily and quickly.<sup>52</sup> With a total possible score of 24 and a cut-off score of 14, this six-item version has been shown to have strong concordance with clinician diagnoses, while being significantly shorter than the full 18-item version.

The *short screening scale for DSM-IV posttraumatic stress disorder* (PTSD-7) is designed to assess for a lifetime history of PTSD.<sup>53</sup> A score of 4 or more on the seven-symptom screening scale suggests PTSD. The National





**Figure 5** A personalised normative feedback based on the user's questionnaires data and norms.

Comorbidity Study Replication<sup>10</sup> showed that 14.8% of lifetime problem gambler also met the criteria for lifetime PTSD.

The *Monetary Choice Questionnaire* (MCQ) will be used to assess delay discounting,<sup>54</sup> which has consistently been linked to addictive disorder treatment response.<sup>55</sup> The MCQ is a widely used and extensively validated measure of discounting. Individuals make 27 choices between smaller, immediate rewards and larger delayed rewards, which are preconfigured at various levels of hyperbolic discounting.

The *Alcohol Use Disorders Identification Test* (AUDIT)<sup>56</sup> and the *Drug Abuse Screening Test* (DAST-10)<sup>57</sup> are both widely used questionnaires. They will be used to screen for the exclusion criterion of a severe substance use disorder.

The use of drugs besides alcohol and cigarettes will be assessed using the *National Institute on Drug Abuse Screening tool* (NIDA ASSIST).<sup>58</sup> Some examples of these additional substances include cannabis, cocaine, prescription medication, methamphetamines and opioids.

The *P4-Screener*<sup>59</sup> is a brief 4-item measure to assess potential suicide risk. If an elevated risk of suicide (scoring greater than 'minimal risk') is recognised at any of the three assessments, the study participant will be advised to call an emergency number and/or visit any local facility listed in a prepared list.

The *Client Satisfaction Questionnaire*, adapted to internet-based interventions (CSQ-I), has been shown to be a suitable measure, from the user's perspective, for evaluating web-based health interventions. It is scored easily by summing up the individual item scores to produce a score ranging from 8 to 32, with higher scores indicating greater satisfaction.<sup>60</sup>

Furthermore, the occurrence of any negative effects will be identified, as in Rozental *et al*, at the 24-week follow-up assessment.<sup>61</sup>

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.

**Table 3** Schedule for the assessment instruments

Assessment instruments	Baseline (t <sub>0</sub> )	8 weeks (t <sub>1</sub> )	24 weeks (t <sub>2</sub> )
1. Sociodemographics	X		
2. Timeline Follow back for Gambling, Smoking and Alcohol	X	X	X
3. Patient Health Questionnaire for Depression (PHQ-9)	X		X
4. Generalised Anxiety Disorder Screener (GAD-7)	X		X
5. Adult ADHD Self-Report Scale (ASRS-V1.1)	X		X
6. PTSD-Screening according to the DSM-IV (PTSD-7)	X		X
7. Problem Gambling Severity Index (PGSI)	X	X	X
8. Gambling Symptom Assessment Scale (G-SAS)	X	X	X
9. Monetary Choice Questionnaire (MCQ)	X	X	X
10. Alcohol Use Disorders Identification Test (AUDIT)	X		X
11. National Institute on Drug Abuse Screening (NIDA ASSIST)	X		X
12. Drug Abuse Screening Test (DAST-10)	X		X
13. Suicidality Screener (P4-SCR)	X	X	X
14. Client Satisfaction Questionnaire for Interventions (CSQ-I)		X	
15. Negative effects according to Rozental			X

Lastly, we will ask all participants if they have used any treatment other than *Win Back Control* or *Becoming a Winner* during the 24 weeks and, if so, to select from a predefined list of services.

As an indicator of treatment adherence, data will be collected on how many modules have been completed by each participant. Treatment retention will be measured as the number of weeks during which the gambling diary was filled out and the last login over the 8-week period.

### Sample size calculation

Anticipating that a Cohen's *d* of 0.30, based on our previous study experience,<sup>39</sup> will be realistic for the effect-size differences between the defined main outcome of the web-based tool and the manual, a sample size of *n*=176 in each study group would have 80% power, based on

calculations performed with G\*Power software, with an alpha error of 5% and two-tailed testing. Thus, we aim to recruit a total of 352 participants. Adjusting for drop-outs is not deemed necessary, as missing data will be imputed.

### Data analyses

Data will be analysed according to the intention-to-treat (ITT) principle. To address missing data for the ITT analyses, we will apply multiple imputation procedures with the package MICE<sup>61</sup> in R (R Foundation for Statistical Computing, Vienna). MICE involves specifying a multi-variate distribution for the missing data, and drawing imputations from their conditional distributions by Markov chain Monte Carlo techniques. We plan to use 20 imputed data sets, as deemed sufficient by Buuren and Groothuis-Oudshoorn.<sup>62</sup>

The imputation model will include all primary and secondary outcome variables. Adjunct variables, like demographic data, may be included if they improve convergence of the imputation model.

We will test for differences in primary and secondary continuous outcome variables between the two study arms at baseline and the follow-up points using linear mixed models (LMMs). The LMMs will be specified to model clusters and repeated measures by defining random effects for study condition and time (repeated measures). Appropriate distributions for non-normal continuous outcomes will be specified (eg, negative binomial, zero-inflated).

### Data security

The *intervention* was programmed and developed with the Content Management System Drupal 7 which uses a MySQL-Database. The intervention will be maintained by the computer programmers at the ISGF. All connections are encrypted and password-protected through a SSL protocol. Each user will have only see his/her own information. The final data will be exported from the database. For the data analysis, the data will be stored on local computers at the PI's institution.

Email address and phone number will be deleted after the study is completed.

### Patient and public involvement

The current intervention was evaluated by former problem gamblers and gambling experts. They made key inputs regarding content, presentation and wording of the programme. There was no patient and public involvement in the study design, hypotheses, outcome measures or recruitment. Participants will be informed via email about study results via a lay-person-friendly summary of trial findings, if they have requested so at the time of registration.

### ETHICS AND DISSEMINATION

The study will be conducted in accordance with the ethics board-approved protocol and the principles stated in the

current version of the Declaration of Helsinki; the consort eHealth Guidelines<sup>63</sup> for studies on medical devices; the European Directive on medical devices 93/42/EEC; and the ISO Norm 14155 and ISO 14971, Swiss Law and Swiss Regulatory Authority requirements. The CEC and regulatory authorities will receive annual safety and interim reports and be informed about study termination, in agreement with local requirements.

Results will be published in a scientific peer-reviewed journal.

## DISCUSSION

Several published studies have documented the effectiveness of internet-delivered interventions for problem gambling.<sup>35–38</sup> Only one of the programmes<sup>38</sup> was a stand-alone intervention; however, the others were accompanied by weekly (although short) telephone support. Two of the programmes did not apply a control condition<sup>36,37</sup>; one compared the effects of the intervention with a waiting list<sup>35</sup>; and one compared the programme to brief normative feedback.<sup>38</sup> The currently proposed study applies a bolder approach to compare the intervention with an already empirically supported manual<sup>45</sup> as an active control condition. The current design will provide insights into how and if the presentation of information influences the recovery process of gamblers; yet, at the same time, be more ethically sound for people in need. The results of this RCT will show if a web-based self-help tool could help problem gamblers in Switzerland. After this evaluation, if found to be effective, the programme will be rendered freely available for public health, and translated into Italian.

## Limitations

The following study limitations must be considered:

First, gamblers who are currently receiving other treatments to reduce their gambling will be excluded. However, *Win Back Control* was designed to reach gamblers who—for personal or practical reasons—would not attend traditional addiction counselling. Second, all measurements will be self-reported. Third, as found with our previous web-based intervention,<sup>38</sup> we expect relatively high rates of dropout from both treatment arms. Lastly, another possible limitation of web-based studies is the potential for reduced adherence rates, due to the distant nature of the intervention.

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**Contributors** MPS set up the initial idea and plan for this study. CB did the first draft of the paper and prepared the final manuscript. CB, MPS and SS developed the intervention of study arm 1. Study arm 2 was developed by DH and adapted to Switzerland by CB, YK and SA. AW and CB programmed and implemented the study websites of Win Back Control. EB, YK, SA, SH, MK and DH helped throughout the development of the interventions and gave valuable feedback to the present study protocol. All authors approved the final version of the manuscript submitted for publication. CB is the guarantor.

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