



## Efficacy of an internet-based psychological intervention for problem gambling and gambling disorder: Study protocol for a randomized controlled trial

Laura Diaz-Sanahuja<sup>a,\*</sup>, Daniel Campos<sup>b,e</sup>, Adriana Mira<sup>c</sup>, Diana Castilla<sup>c,d</sup>,  
Azucena García-Palacios<sup>a,d</sup>, Juana María Bretón-López<sup>a,d</sup>

<sup>a</sup> Universitat Jaume I, Castellón, Spain

<sup>b</sup> Universidad de Zaragoza, Huesca, Spain

<sup>c</sup> Universidad de Valencia, Valencia, Spain

<sup>d</sup> CIBER Fisiopatología Obesidad y Nutrición (CIBEROBn), Instituto Salud Carlos III, Madrid, Spain

<sup>e</sup> Instituto de Investigación Sanitaria Aragón (IISAragon), Zaragoza, Spain

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### ABSTRACT

Gambling Disorder is a prevalent non-substance use disorder, which contrasts with the low number of people requesting treatment. Information and Communication Technologies (ICT) could help to enhance the dissemination of evidence-based treatments and considerably reduce the costs. The current study seeks to assess the efficacy of an online psychological intervention for people suffering from gambling problems in Spain. The proposed study will be a two-arm, parallel-group, randomized controlled trial. A total of 134 participants (problem and pathological gamblers) will be randomly allocated to a waiting list control group ( $N = 67$ ) or an intervention group ( $N = 67$ ). The intervention program includes 8 modules, and it is based on motivational interviewing, cognitive-behavioral therapy (CBT), and extensions and innovations of CBT. It includes several complementary tools that are present throughout the entire intervention. Therapeutic support will be provided once a week through a phone call with a maximum length of 10 min. The primary outcome measure will be gambling severity and gambling-related cognitions, and secondary outcome measures will be readiness to change, and gambling self-efficacy. Other variables that will be considered are depression and anxiety symptoms, positive and negative affect, difficulties in emotion regulation strategies, impulsivity, and quality of life. Individuals will be assessed at baseline, post-treatment, and 3-, 6-, and 12-month follow-ups. During the treatment, participants will also respond to a daily Ecological Momentary Intervention (EMI) in order to evaluate urges to gamble, self-efficacy to cope with gambling urges, gambling urge frequency, and whether gambling behaviour occurs. The EMI includes immediate automatic feedback depending on the participant's responses. Treatment

**Abbreviations:** A, Action; CBT, Cognitive Behavioral Therapy; CONSORT-EHEALTH, Consolidated Standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth; C, Contemplation; CIDI, Composite International Diagnostic Interview; DERS, Difficulties in Emotion Regulation Scale; DGOJ, Directorate General for the Regulation of Gambling; DSM-III-R, Diagnostic and Statistical Manual of Mental Disorders, 3rd Edition Revised; DSM-IV, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition; DSM-5, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition; EDBs, Emotion Driven Behaviours; EMA, Ecological Momentary Assessment; EMI, Ecological Momentary Intervention; GD, Gambling Disorder; GE, Gambling Expectancies; GI, Gambling history interview and current gambling situation and related variables assessment; GRCS-S, Gambling-Related Cognitions Scale; G-SAS, The Gambling Symptom Assessment Scale; GSEQ, Gambling Self-Efficacy Questionnaire; HADS, Hospital Anxiety Depression Scale; IB, Interpretative Bias; IC, Illusion of Control; ICD-10, International Statistical Classification of Diseases and Related Health Problems 10th Revision; ISG, Perceived Inability to Stop Gambling; M, Maintenance; MI, Motivational Interviewing; MFS, Monitoring, Feedback and Support; MINI, Mini International Neuropsychiatric Interview; NA, Negative Affect; NODS, NORC DSM-IV Screen for Gambling Problems; OASIS, The Overall Anxiety Severity and Impairment Scale; ODSIS, The Overall Depression Severity and Impairment Scale; PA, Positive Affect; PANAS, The Positive and Negative Affect Schedule; P, Precontemplation; PC, Predictive Control; PFIs, Personal Feedback Interventions; QLI, Quality Life Index; RCT, Randomized Controlled Trial; SCID-P, The Structured Clinical Interview; SPIRIT, Standard Protocol Items Recommendations for Interventional Trials; SUS, System Usability Scale; UPPS-P, The Short UPPS-P Impulsivity Scale; URICA, The University of Rhode Island Change Assessment Scale; WL, Waiting List.

\* Corresponding author at: Department of Basic Psychology, Clinical and Psychobiology, Universitat Jaume I, Avenida de Vicent Sos Baynat, s/n, 12071 Castellón, (Spain).

E-mail addresses: [lsanahuj@uji.es](mailto:lsanahuj@uji.es) (L. Diaz-Sanahuja), [miraa@uji.es](mailto:miraa@uji.es) (A. Mira), [diana.castilla@uv.es](mailto:diana.castilla@uv.es) (D. Castilla), [azucena@uji.es](mailto:azucena@uji.es) (A. García-Palacios), [breton@uji.es](mailto:breton@uji.es) (J.M. Bretón-López).

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acceptance and satisfaction will also be assessed. The data will be analysed both per protocol and by Intention-to-treat. As far as we know, this is the first randomized controlled trial of an online psychological intervention for gambling disorder in Spain. It will expand our knowledge about treatments delivered via the Internet and contribute to improving treatment dissemination, reaching people suffering from this problem who otherwise would not receive help.

Trial registration: [Clinicaltrials.gov](https://clinicaltrials.gov) as NCT04074681. Registered 22 July 2019.

## 1. Introduction

Gambling behaviour is a common and acceptable social leisure activity for adults, and it is readily available and promoted (O'Loughlin and Blaszczynski, 2018; Russell et al., 2018a). Gambling behaviour occurs on a continuum, ranging from non-gambling or recreational gambling to gambling disorder (Volberg, 2015). Gambling Disorder (GD) is a non-substance-related disorder defined as persistent and recurrent problematic gambling behaviour leading to clinically significant impairment or distress (American Psychiatric Association [APA], 2013). Individuals with GD usually need to bet increasing amounts of money in order to achieve the desired excitement, and they show an irritable emotional state when they try to cut down or stop gambling. Although they have repeatedly attempted to control, cut back, or stop gambling, they have been unsuccessful. Feelings of distress are common triggers of gambling behaviour, and when gamblers have lost money, they usually gamble again for "chasing" purposes. Individuals with GD are often worried about gambling (e.g., thinking about past experiences, planning their next wagers, or thinking about different ways to get money for betting) and lie about the extent of their involvement. For this reason, different important life areas, such as the occupation, educational opportunities, and significant relationships, can be affected. The complexity of GD characteristics is associated with high comorbidity with other psychological disorders. The most frequent are substance use disorders (nicotine dependence; alcohol abuse and dependence), major depressive disorder, and anxiety disorders (Lorains et al., 2011; Håkansson et al., 2018).

The most prevalent way to gamble is offline (Dirección General de Ordenación del Juego [DGOJ], 2015), but since online gambling was legalized in Spain in 2012, the number of active gamblers and the amount of money spent on gambling activities have increased in our country. The Gross Gaming Revenue (GGR) in the third quarter of 2020 was 197.17 million €, which represents a 2.83% increase compared to the same quarter in 2019. Moreover, there are 881,755 active gamblers and 330,262 other gamblers, representing a growth of 1.40% and 29.88%, respectively (DGOJ, 2020). Currently, casinos and other gambling venues are closed because of the COVID-19 pandemic, and customers' sports betting activity has stopped. According to Lindner (2020), total gambling activity decreased by 13.29% during the first phase of the pandemic. Although total betting decreased, there was a slight increase in online casino gambling (Columb et al., 2020; Lindner, 2020; Marsden et al., 2020). This slight increase in total online gambling is not indicative of an increase in problematic gambling, but due to the high accessibility and anonymity of this gambling format, it could pose a risk of a rise in problem gambling that requires further research. GD is a public health problem with a prevalence rate ranging from 2% to 5% in North America, 0.5% to 5.8% in Asia, 0.4% to 0.7% in Oceania, and 0.1% to 3.4% in Europe (Calado and Griffiths, 2016).

A recent review shows that Cognitive Behavioral Therapy (CBT) is the most frequent type of therapy for the treatment of GD, but other therapies used are Motivational Interviews (MI), monitoring feedback and support, and exposure therapy (van der Maas, 2019). Goslar et al. (2017) indicate that the efficacy of face-to-face and high intensity structured Internet-based programs with MI and CBT components is equivalent, but these results have to be interpreted with caution because of the low number of studies. Another meta-analysis reports that online multi-session treatments have larger effect sizes than brief interventions

(e.g., single-session Personal Feedback Interventions, PFIs) on reducing the amount of time and money spent on gambling. Nevertheless, PFIs are more efficacious when combined with psychoeducation and MI, and they can be used as a harm-reduction strategy (Peter et al., 2019). Several RCTs support the efficacy of Internet-based interventions for GD. Furthermore, a two-arm RCT was conducted in Germany (Online intervention "Deprexis"; and no intervention control group). Deprexis consists of 10 modules based on CBT principles and third-wave therapy for treating GD and comorbid depressive symptoms. The intervention lasted eight weeks, and the main therapeutic components included were behavioral activation, cognitive restructuring, interpersonal and problem-solving skills, relaxation, acceptance, mindfulness, and positive psychology. Significant reductions were found in depressive and gambling symptoms, with moderate to large effects (Bücker et al., 2018). In Canada, Cunningham et al. (2019) conducted a two-arm RCT (online CBT gambling intervention; online CBT gambling intervention and online mental health distress program) that also supported the efficacy of CBT for the treatment of GD. Therefore, CBT is considered the treatment of choice for GD, and the efficacy of CBT Internet-based psychological interventions has been shown in many countries. Interventions delivered through the Internet are appropriate for targeting populations with gambling problems that might not have access to treatment in other ways. Currently, they could be an adequate option for addressing difficulties in receiving face-to-face treatment due to the COVID-19 pandemic (De Witte et al., 2021).

However, it is important to consider the problematic attrition rates in RCTs of online interventions for gambling disorders, which vary from 6% to 65% in the first follow-up assessment (between 6 and 12 weeks) (Bücker et al., 2018; Carlbring and Smith, 2008; Casey et al., 2017; Cunningham et al., 2009; Hodgins et al., 2019; Magnusson et al., 2019). In this regard, it is relevant to introduce new tools to increase engagement and retention in these types of interventions. Ecological Momentary Assessment/Intervention (EMA/EMI) could be an option for dealing with the dropout rate problem. EMA/EMI have shown good results in other psychological disorders, such as substance use disorders (e.g., smoking cessation), anxiety disorders (e.g., social anxiety disorder, generalized anxiety disorder), and major depressive disorders (LaFreniere and Newman, 2016; Colombo et al., 2019; Linardon et al., 2019; Miralles et al., 2020). Literature related to EMA for GD is scarce and focuses on studying the influence of some contextual factors (e.g., gambling advertisement exposure) on the intention to gamble and gambling behaviour (Browne et al., 2019; Russell et al., 2018b). To the authors' knowledge, only one study, conducted by Hawker et al. (2021a), recently developed an EMI (GamblingLess: Curb Your Urge) that demonstrated its acceptability, feasibility, and preliminary effectiveness in preventing gambling episodes by reducing craving intensity in people with gambling problems. They measure gambling episodes, gambling cravings, and gambling self-efficacy, and they include automatic recommendations to use strategies for managing gambling urges (e.g., psychoeducation, mindfulness, and relaxation-based activities). They report 71% and 72% reductions in the average number of gambling episodes and craving occurrences, respectively. Thus, EMI features can be useful for managing craving occurrences and avoiding relapses, what could increase patients' treatment adherence.

As far as we know, this study is the first Internet-based program combined with an EMI that also includes several complementary tools for improving adherence and treatment quality for GD in Spain or other

Spanish-speaking countries.

For this reason, the main aim of the study proposed is to assess the efficacy of an online psychological intervention combined with an EMI for the treatment of GD in Spain, by comparing the improvement between the baseline and post-intervention assessments in the CBT and waiting list control groups. Secondary objectives are:

- a) to explore whether the pretest-posttest changes in the CBT group are maintained at the 3-, 6-, and 12-month follow-ups.
- b) to identify variables statistically associated with the pretest-posttest change in the CBT group, taking into account the level of GD severity.
- c) to investigate the progression of gambling behaviour (money wagered and amount of time) in the intervention group for 90 days.
- d) to explore relationships between gambling urges (frequency and intensity) and self-efficacy to cope with gambling urges in t0 with gambling behaviour (money wagered and amount of time) in t0 and t1.

The study hypotheses are: 1) Participants in the experimental condition will display significantly higher improvements in gambling outcomes at post-intervention; 2) Anxiety and depressive symptoms, negative affect, and impulsivity will be significantly reduced after the intervention in the experimental group; 3) A significant increase in positive affect, emotion regulation, and quality of life will be found after the treatment; 4) A significant reduction in gambling urges and gambling behaviour and a significant increase in self-efficacy to cope with gambling urges; 5) Gambling urges (frequency and intensity) and self-efficacy to cope with gambling urges will be positively and negatively associated with gambling behaviour, respectively. Gambling severity, readiness to change, anxiety and depressive symptoms, and comorbidity with mild alcohol and/or substance use disorders could exacerbate these relationships.

The study will contribute to the gambling field by providing more flexible and cost-effective alternatives and overcoming barriers to treatment seeking. Furthermore, we will explore innovative ways to develop more personalized interventions, such as the use of the EMI and complementary tools that could improve the quality of current psychological programs and adherence to them.

## 2. Methods

### 2.1. Study design

The proposed study is a randomized, parallel-group, two-arm, superiority trial. Online informed consent will be obtained before the screening assessment on Qualtrics, and eligible participants will be randomly allocated to an online CBT-based intervention group or a waiting list control group. There will be five measurement points in the experimental condition (e.g., baseline, post-treatment, and 3-, 6-, and 12-month follow-ups). As in previous studies (Díaz-García et al., 2021; Quiñonez-Freire et al., 2021; Mira et al., 2019a), the post-treatment assessment of the intervention group will be performed individually depending on the completion speed, but the WL control group will be assessed at week twelve because it is the maximum time the experimental group has to finish the intervention. For ethical reasons, the individuals in the control group will be able to receive full access to the Internet-based psychological intervention after being on the waiting list for 12 weeks and filling out the post-treatment assessment. Nevertheless, an undesired event would not only imply the participant's departure from the trial, but s/he would also be offered the possibility of receiving psychological care at the Emotional Disorder Clinic at Universitat Jaume I, or of being referred if his/her medical condition required it. This trial was registered on the [ClinicalTrials.gov](https://www.clinicaltrials.gov) database (NCT04074681) and will be carried out taking into account the CONSORT 2010 (Consolidated Standards for Reporting Trials; [www.consort-statement.org](http://www.consort-statement.org))

(Moher et al., 2010) and the CONSORT-EHEALTH guidelines (Consolidated Standards for Reporting Trials of Electronic and Mobile Health Applications and Online TeleHealth) (Eysenbach and CONSORT-EHEALTH Group, 2011). Furthermore, the protocol manuscript is written in accordance with the SPIRIT 2013 statement (Standard Protocol Items: Recommendations for Interventional Trials) (Chan et al., 2013). Fig. 1 shows the flow diagram of the study design.

### 2.2. Sample size and power calculations

The a priori determination of the sample size in this investigation was carried out focusing on the differential pre-treatment-posttreatment change in the treatment and control groups as the main question. This question was assessed with the  $F$  statistic for the interaction between the group (treatment vs. control) and the measurement time (pre-treatment vs. post-treatment). Assuming an effect size of moderate magnitude ( $f = 0.25$ ), (Cohen, 1988) a significance level of 5%, a statistical power of 95%, and a correlation between pre-treatment and post-treatment measures of 0.5, a total of 54 participants are needed. The reason for assuming an effect size of moderate magnitude was that there is no clear evidence about the expected effect of online CBT when compared with an inactive control group. Therefore, following Cohen's (1988) guidelines, a moderate effect was assumed. A correlation coefficient of 0.5 between the pretest-posttest change scores was assumed, based on Rosenthal (1991). Taking into account that a large amount of attrition was expected, and based on Merkouris et al. (2017) recommendation to adopt a conservative dropout rate of 50%, we increased it to 60%. Thus, the total sample size was set at 134 participants, 67 in each group. These calculations were carried out with the program G\*Power 3.1.9.2 (Buchner et al., 2014).

### 2.3. Ethics

The study procedures were approved by the Innovation Office and TI audit and the Ethics Committee of Universitat Jaume I (Castellón, Spain) on May 2, 2019 (CD/026/2019). The study will be conducted following The Declaration of Helsinki and good clinical practice. Participation will be completely voluntary, and individuals will not receive any incentives. The study will be explained to them, and they will have to provide written informed consent through Qualtrics. They must declare that they freely and voluntarily agree to participate in this study and fill out the questionnaires required. Nevertheless, participants will be informed that they can leave the study at any time. Current EU and Spanish legislation on privacy and data protection will be followed in carrying out the proposed study. Data will be encrypted and stored securely in accordance with the Advanced Encryption Standard. In order to protect participants' privacy, personal details will be saved separately from clinical information through an Active Directory and codified numerically for use in subsequent analyses. Access to the participants' personal data will be restricted to the therapist responsible for carrying out the study, who will use a specific password stored in an encrypted manner that meets all the requirements of the Organic Law of Personal Data Protection. The personal data will be preserved for 5 years, and after this time, considering the psychologists' clinical criteria, they will proceed with their destruction. Nevertheless, participants will be able to request their deletion before the period mentioned above. Relevant parties (e.g., investigators, trial participants, trial registries, journals, and the ethical committee) will be informed of any significant modifications in the protocol presented.

### 2.4. Eligibility criteria

Inclusion criteria include: being 18 years or older; willingness to participate in the study and sign the informed consent; having and handling a computer, Internet, and an email address; ability to understand, read, and write Spanish; being a problem gambler (3-4 items) or a

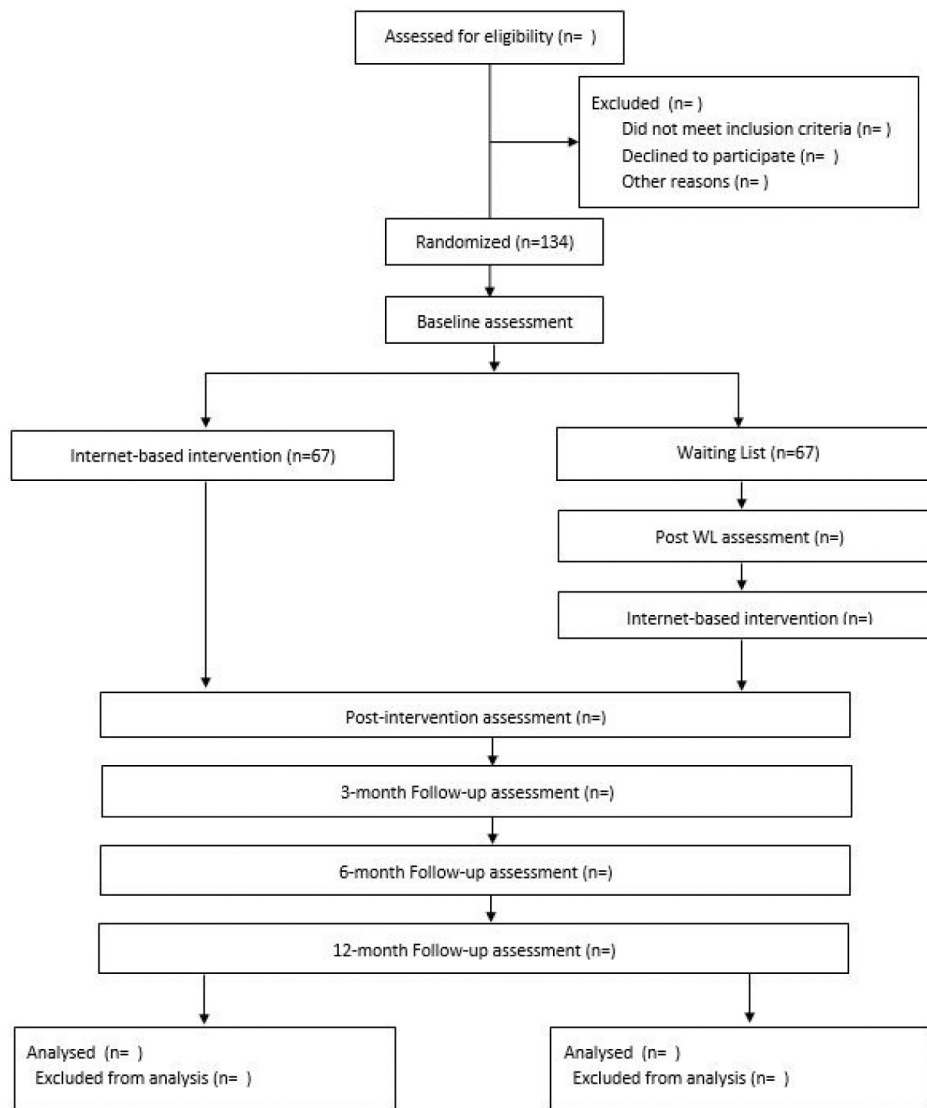


Fig. 1. Flow diagram.

pathological gambler (5 or more items), according to the cut-off points established by the Norc diagnostic screening for gambling disorders (NODS) (Becoña, 2004); and willingness to provide follow-up data on gambling. Individuals will be excluded if they have any serious mental disorders (e.g., bipolar and related disorders and schizophrenia spectrum and other psychotic disorders), moderate or severe alcohol and/or substance use disorder (assessed by the Mini International Neuropsychiatric Interview, MINI) (Sheehan et al., 1997, 1998), or any medical illness that keeps them from carrying out the program. In addition, participants will not be included if their gambling behaviour occurs in the context of a manic episode or due to the intake of dopaminergic medication (e.g., Parkinson's disease), if high suicidal risk is present (assessed by the MINI), and/or if they are receiving another psychological treatment while the study is still ongoing. Receiving pharmacological treatment is not an exclusion criterion during the study period, but participants with an increase and/or change in the medication two months prior to enrolment will not be considered for the trial. An increase and/or change in the medication during the study period in the experimental group will imply the participants' exclusion from subsequent analyses, but a decrease in pharmacological treatment is accepted.

## 2.5. Recruitment, randomization, and blinding

The sample will be obtained from the community and recruited through advertisements in the written and online press, as well as through dissemination in professional (LinkedIn) and non-professional (e.g., Facebook, Twitter, and Instagram) social networks. Moreover, people who come to the Psychological Assistance Service of Universitat Jaume I will be offered the chance to participate in the study. Informative pamphlets about the study will also be posted with a contact telephone number in foundations and associations related to this problem, as well as in health services and universities. In addition, there will be an email prepared where interested individuals can leave their contact data to participate in the project. Although there are different recruitment sources, the sample will be homogeneous because the NODS will be used to confirm that they meet problem gambling or GD criteria. After providing informed consent, they will complete the NORC DSM-IV Screen for Gambling Problems (NODS) (Becoña, 2004) by Qualtrics. If they meet the criteria for problem gambling or GD, the screening interview will be conducted by telephone, and it will consist of the Mini International Neuropsychiatric Interview (MINI) (Sheehan et al., 1997, 1998) and the Gambling history interview and current gambling situation and related variables assessment (GI). Participants who meet the inclusion criteria will be selected and allocated to either the control or

the experimental condition, with a 1:1 allocation ratio, and stratified by problem gambling severity (problem/gambling disorder) to ensure proportion equivalence between the two groups. Allocation will be performed according to a random number sequence generated by Randomizer software (<https://www.randomizer.org/>). To prevent selection bias, the allocation sequence will be concealed from the researchers and clinicians involved in assigning the participants to the intervention groups until the moment of assignment. On both the pre-test and the post-test, the raters will be masked to whether the participant is in the treatment or control group. Due to the nature of the intervention, it will not be possible to mask the participants or the clinicians who will apply the intervention. Participants who meet the inclusion criteria will be asked to provide the name and contact information of a co-therapist, so that we can explain his/her function throughout the treatment and receive qualitative information about the participant's situation or stability.

## 2.6. Intervention

### 2.6.1. Online intervention description

This intervention consists of an online self-applied interactive program ([www.psicologiaytecnologia.es](http://www.psicologiaytecnologia.es)) for problem and pathological gamblers, designed to teach adaptive ways to cope with this problem via the Internet. It is based on CBT and extensions and innovations of CBT (e.g., psychoeducation about emotions, emotional avoidance and emotion driven behaviours, mindfulness, emotion regulation strategies). It contains eight sequential therapeutic modules: 1) motivation for change, 2) psychoeducation, 3) stimulus control (e.g., self-prohibition and blocking of usual gambling websites with therapist confirmation) and responsible debt payment, 4) cognitive restructuring, 5) urge surfing and emotion regulation, 6) planning of significant activities, 7) coping skills and exposure with response prevention, and 8) relapse prevention (for details see Table 1). The modules are presented in this order because at the beginning the therapeutic aim is to: increase their awareness of the problem and motivation to change their gambling behaviour; protect them from gambling-related stimuli; and help them to begin to tolerate the abstinence syndrome. After that, we explain different strategies to better prepare participants for the exposure with response prevention, established in functional concepts that can be better understood by considering the terms included in the different psychological strategies mentioned. Regarding the program's length, it should be carried out in eight weeks, one module per week, but participants will be able to advance at their own pace for a maximum period of 12 weeks. All of these modules have a similar structure: a section with questions about the previous module; the therapeutic content presented through text, images, vignettes, and videos; exercises and activities; a self-assessment questionnaire to determine whether participants have understood the concepts adequately; tasks to perform before going on to the next modules; and a brief summary of the module. All the modules can be reviewed by participants online at any time, but PDF files can also be downloaded and examined offline.

The intervention includes a weekly 10-minute phone call to clarify doubts about the program's functioning and encourage participants to continue with the treatment, but additional clinical content will not be provided. This support phone call will be made by trained PhD students.

Participants will be assessed after Module 6, "What alternative activities can I plan?"; during the pertinent weekly phone call in order to decide whether they are prepared to proceed to Module 7, "How can I cope with gambling urges in my daily life?"; which refers to the exposure with response prevention therapeutic component. If they are not prepared to go on to the following module, we will recommend that they continue to apply stimulus control and the strategies they have learnt so far. Due to the relevance of the stimulus control and exposure with response prevention components and the essential role of a co-therapist during their application, these modules include two documents that explain the most important aspects the co-therapist should take into

**Table 1**  
Program contents.

Module	Objectives	Contents
M0. Welcome module.	Providing information about the program's functioning.	-Program functioning and structure description. -Recommendations to optimize skills training and learning. -Therapist support explanation and ways of contacting. -Explanation of the assessment times, delivery modes, and emphasis on the importance of records, exercises, and activities. -Check list of the necessary conditions to carry out the program.
M1. Motivation for change.	Giving information about the specific program and increasing motivation for change.	-Brief description of the content of each module. -Change stages in addictions. -Decisional balance. -Resources currently dedicated to the different areas of life (e.g., gambling activities, job, studies, family, interpersonal relationships, leisure) vs. what patients would like areas of life to be according to their values. Reflection on discrepancies/similitudes between the current situation pie chart and what patients would like it to be, and whether this distribution is currently in accordance with their objectives and values. -Differentiation between lapse and relapse. -Establishment of general and specific objectives, and steps required to achieve these aims based on personal values.
M2. Psychoeducation.	Understanding gambling.	-Chance game characteristics. -Reasons for gambling. -Gambling stages. -Types of gamblers. -Factors influencing the onset and maintenance of GD and its features.
M3. Stimulus control and responsible return of debts.	Gambling cessation and commitment to returning debts responsibly.	-Justification for this therapeutic component, and the relevance of a co-therapist. -Limiting accessibility to money, gambling venues, and gambling friends. -Commitment to accomplishing stimulus control through a behavioral contract. -List of debts and returns planning.
M4. Cognitive restructuring	Identification and correction of thoughts that contribute to GD onset and maintenance.	-Explanation of the importance of thoughts and how they influence emotions, behaviours, and physiological responses through the ABC model. -Definition of dysfunctional thoughts or thinking traps related to gambling. -Identification and correction

(continued on next page)

Table 1 (continued)

Module	Objectives	Contents
M5. Urge surfing and emotion regulation	Identifying emotions and understanding their function and how to tolerate and change emotional responses.	of one's dysfunctional thoughts. -Understanding emotions. -Emotional avoidance and Emotion Driven Behaviours (EDBs). -Emotion regulation strategies (e.g., Problem-solving, opposite action technique, and emotional distancing technique).
M6. Planning significant activities	Lifestyle balance and reconnecting with significant others through these alternative activities.	-Planning different positive activities according to their values (e.g., activities that participants used to or already enjoy, and new activities they would like to be involved in). -Involving significant others in alternative activities. -Training mindfulness in these alternative significant activities.
M7. Coping skills and exposure with response prevention	Habituation to the gambling conditioned stimulus without gambling.	-Explanation of the exposure with response prevention foundations. -Establishment of the exposure hierarchy. -Gradual exposure to different gambling-related situations according to the established hierarchy. -Assertive communication techniques to decline invitations to wager (e.g., compliment sandwich and the broken record technique).
M8. Relapse prevention	Avoid relapses and maintain changes gained through the intervention.	-Evaluation of the patient's progress and achievements. - Identification of high-risk situations and anticipation of possible breakdowns. -Review of the techniques learned to deal with these situations. -Recommendations to prevent and/or manage a lapse/relapse.

account. In addition, the therapist will telephone the co-therapists at both points in time to resolve possible doubts after reading these files. Phone calls to the co-therapists will last a maximum of 10 min.

Moreover, the online intervention is combined with an EMI, and several complementary tools will be presented throughout the intervention process (for details see Table 2). If high suicide risk is detected, an alert will automatically be sent to the clinical group. The therapist will contact the patients and offer alternative options to protect them.

### 2.6.2. EMI description

During the treatment (12 weeks), participants should respond daily to four questions through Qualtrics in order to assess urges to gamble (on a scale from 0 "Not at all" to 10 "maximum"), gambling urge frequency (on a 5-point Likert scale from "Never" to "Almost always"), self-efficacy to cope with gambling urges (on a scale from 0 "Not at all" to 10 "Completely"), and whether they have wagered that day or not (see Fig. 2). They will receive one notification per day to respond to the EMI questions at 8 PM. These questions are relevant because if participants perceive that they have low self-efficacy to cope with gambling urges, the EMI sends feedback to motivate them to remain abstinent and

Table 2

Complementary tools on the web platform.

"Home"	It is located on the main menu of the website and corresponds to the starting point of the intervention. Through this tool, participants can access the other sections of the treatment platform.
"Calendar"	This element shows where individuals are in the program, the days they entered, and pending and completed activities.
"Plan for Returning debts"	Participants report the percentage of money they have been able to return at baseline, post-treatment, and 3-, 6-, and 12-month follow-ups (0% "No returns"; 1-25%; 26-50%; 51-75%; 76-99%; 100% "There are no debts/Returning debts completed"). They will receive a personalized feedback message by email depending on the value they indicate. If they have not begun yet, the message will remind them of the importance of this component. If they have started the process, the message will reward them for their progress and encourage them to continue with their plans to return debts, emphasizing that they are getting closer to achieving their objective.
"My progress"	This section makes it possible to monitor the individual's progress. It includes graphics of the progress on different variables, such as gambling urges, perceived self-efficacy to control gambling in high-risk situations, percentage of debts returned, and percentage of time thinking about or being involved in gambling related activities (e.g., searching for videos or information about gambling activities; thinking about how to get money for betting; thinking about past gambling events or planning future possible bets; betting).
"What have I learned?"	In this part, participants can access the full completed modules to review them as often as they like.

recommend strategies that they have already learned. If they indicate that they have wagered, the EMI also sends feedback to encourage them to fill in a gambling self-register (date; type of game; time spent, money spent) (Echeburúa and Báez, 1994) and carry out a functional analysis of the relapse ("Why did I gamble?"). The main objective is to make them aware of the circumstances that facilitate the gambling behaviour and the short- and long-term consequences, as well as to plan strategies they can use in the future in similar circumstances, in order to avoid a lapse/relapse. Participants can download the PDF with this feedback and the functional analysis they filled out in Qualtrics. In addition, if they report high self-efficacy to cope with gambling urges, the EMI sends feedback that consists of reinforcing their continued abstinence and reminding them to pay attention to future gambling risk situations where they can apply the appropriate strategies they have learned (see Appendix A).

Some of these complementary tools have been used in previous studies, such as feedback about their gambling behaviour and a section for carrying out a functional analysis if they gamble (Casey et al., 2017; Magnusson et al., 2019). However, our proposal also includes specific feedback based on the responses (e.g., if they gamble or if they report low or high self-efficacy to cope with gambling urges), as well as reminders and a calendar. In addition, there is another section for monitoring their progress on several clinical variables, as well as a debt payment plan progress section and feedback by email. These complementary tools and the EMI will provide a more personalized intervention, and they could help to reduce dropouts and increase treatment adherence.

### 2.7. Assessment measures

The primary outcome is the change in gambling severity and gambling-related cognitions from baseline to post-treatment in both the CBT and control groups, and post-module outcomes are gambling urges, self-efficacy to control gambling, and anxiety and depressive symptoms. In addition, follow-ups at 3, 6, and 12 months are also assessed. Assessment points and instruments are shown in Table 3.

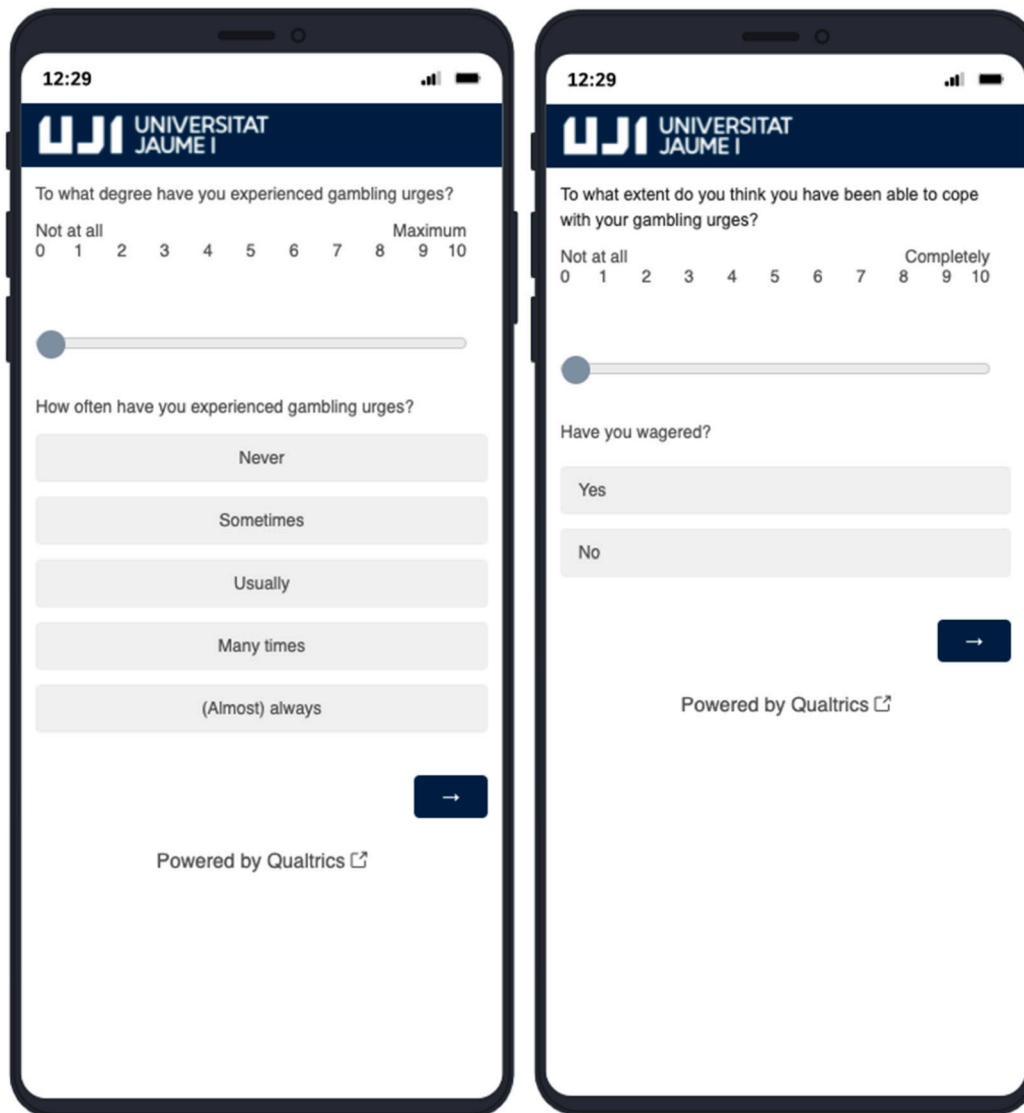


Fig. 2. EMI features.

### 2.7.1. Diagnostic interview

**2.7.1.1. Mini international neuropsychiatric interview (the M.I.N.I. 7.0.2, 8/8/16 version) (Sheehan et al., 1997, 1998).** The MINI is a brief, structured diagnostic interview designed to assess the most common psychiatric disorders in the ICD-10 and DSM-5 (major depressive episode; obsessive-compulsive disorder; posttraumatic stress disorder; alcohol use disorder; substance use disorder; any psychotic disorder; anorexia nervosa; bulimia nervosa; generalized anxiety disorder; medical, organic, drug cause ruled out; and antisocial personality disorder). Questions are rated dichotomously (yes/no), and clinical judgment should be used in coding the responses, asking for examples if necessary. Validity and reliability are supported, and similar properties to the SCID-P for the DSM-III-R and the CIDI are shown, but it can be administered in a much shorter time. A copyright licence for use of the standard M.I.N.I. 7.0.2 in Spanish, based on DSM-5 criteria, will be requested from the authors.

**2.7.1.2. NORC DSM-IV screen for gambling problems (NODS) (Gerstein et al., 1999; Becoña, 2004).** The NODS is a hierarchically structured, 17-item screening tool designed to assess at-risk, problem, and pathological gambling. It refers to the experience with gambling throughout their

lives and in the past year, and the response options are dichotomous (Yes/No). The total score ranges from 0 to 10 (1-2 affirmative items correspond to at-risk gambling; 3-4 items correspond to problem gambling; and 6 or more items correspond to pathological gambling). The data obtained for specificity and sensitivity are good. Test-retest reliability is 0.98, and validity is excellent, considering that it corresponds strictly to the DSM-IV criteria. We will use the 12-month version at pre-test to establish the diagnosis based on the DSM-IV-TR, and the 3-month version of the NODS to assess the progress made in gambling severity throughout the intervention and in follow-up assessments.

**2.7.1.3. Gambling history interview and current gambling situation and related variables assessment (GI).** This interview is based on the Structured Interview of the Gambling History and on the Gambling dependent variables questionnaire (Echeburúa and Báez, 1994). In addition to selecting five items from the first interview to assess the patient's gambling habits and the onset and aggravation of the patient's gambling behaviour (including ups and downs and periods of abstinence), five other interesting items related to the current gambling situation are added. They refer to economic debts, the people or entities they owe money to and the specific amount, whether they have access to money and the ways they can get it, what they have done so far to solve the

**Table 3**  
Overview of measures and time-points.

Measures	Screening	Baseline	DM	Post-M	Post-T	3 MFU	6 MFU	12 MFU
Diagnostic interview								
MINI	X							
NODS (12-month version)	X							
NODS (3-month version)					X	X	X	X
GI	X							
Primary outcome measures								
G-SAS		X		X	X	X	X	X
GRCS-S		X			X	X	X	X
Secondary outcome measures								
URICA		X			X	X	X	X
GSEQ		X		X	X	X	X	X
<sup>a</sup> EMI outcome measures								
Gambling urges								
Frequency								
Intensity								
Self-efficacy								
Gambling behaviour								
Money wagered								
Amount of time								
Additional measures								
Socio-demographics								
HADS		X			X	X	X	X
ODSIS				X				
OASIS				X				
DERS		X			X	X	X	X
PANAS		X			X	X	X	X
UPPS-P		X			X	X	X	X
QLI		X			X	X	X	X
SUS				X <sup>b</sup>	X			
Treatment expectations questionnaire		X						
Opinion/Satisfaction questionnaire					X			
<sup>a</sup> Negative Effects Questionnaire					X			

DERS: Difficulties in Emotion Regulation Scale; DM: Daily Measure; GI: Gambling history interview and current gambling situation and related variables assessment; GRCS-S: Gambling-Related Cognitions Scale; G-SAS: The Gambling Symptom Assessment Scale; GSEQ: Gambling Self-Efficacy Questionnaire; HADS: Hospital Anxiety and Depression Scale; MFU: Months Follow-up; MINI: Mini International Neuropsychiatric Interview; NODS: NORC DSM-IV Screen for Gambling Problems; OASIS: The Overall Anxiety Severity and Impairment Scale; ODSIS: The Overall Depression Severity and Impairment Scale; PANAS: The Positive and Negative Affect Schedule; Post-M: Post-Module; Post-T: Post-Treatment; QLI: Quality of Life Index; SUS: System Usability Scale; UPPS-P: The Short UPPS-P Impulsivity Scale; URICA: The University of Rhode Island Change Assessment Scale.

<sup>a</sup> These measures will be filled out only by the intervention group.

<sup>b</sup> After the first use.

problem, how long it has been since their last bet, and the specific risky places. It was developed ad hoc due to the relevance of considering this information.

### 2.7.2. Primary outcome measures

**2.7.2.1. The gambling symptom assessment scale (G-SAS) (Kim et al., 2009).** The G-SAS is a 12-item self-report instrument that assesses gambling symptom severity, but it is not a screening or diagnostic instrument. It can detect changes in gambling symptom severity during treatment, and it provides data about the pattern of change in each subgroup of symptoms in order to analyse the variation in the response pattern to each treatment. All the items refer to an average number of symptoms in the past seven days. The statements included correspond to gambling urges; average frequency, duration, and control of thoughts associated with gambling; time spent on gambling or gambling-related behaviour; anticipatory tension and/or excitement caused by an imminent gambling act; excitement and pleasure associated with winning; emotional distress; and personal trouble. All items are rated on a 4-point scale, and the total score ranges from 0 to 48. The higher the score, the higher the gambling symptom severity (mild = 8-20; moderate = 21-30; severe = 31-40; extreme = 41-48). This scale shows high internal consistency ( $\alpha = 0.87$ ) and good convergent validity with other measures associated with gambling symptom severity in a sample of pathological gamblers. Because this instrument does not have a Spanish version,

standardized procedures (translation/back-translation) were followed to adapt the G-SAS to the Spanish language. The validation process is currently taking place, and Cronbach's alpha will be calculated with the data at hand.

**2.7.2.2. Gambling-related cognitions scale (GRCS-S) (Raylu and Oei, 2004; Del Prete et al., 2017).** The GRCS-S is a self-report instrument designed to assess five domains of gambling-related cognitions (interpretative bias, IB; the illusion of control, IC; predictive control, PC; gambling expectancies, GE; and perceived inability to stop gambling, ISG). It contains 23 items that are rated on a 7-point Likert-type scale (1 = I strongly disagree; 7 = I strongly agree). The total score consists of adding the scores on all the items. The score for each subscale is obtained by adding the scores on the set of items in each subscale. The higher the total score, the higher the number of gambling-related cognitions presented. The GRCS-S shows adequate psychometric properties in a sample composed of treatment-seeking gamblers and non-treatment-seeking gamblers: concurrent and criterion-related validity are verified, the full-scale reliability is 0.95, and reliability for the subscales ranges from 0.68 to 0.91 (GE = 0.77; IC = 0.68; PC = 0.84; ISG = 0.91; IB = 0.89).



### 2.7.3. Secondary outcome measures

**2.7.3.1. The University of Rhode Island Change Assessment Scale (URICA)** (McConaughy et al., 1983; Gómez-Peña et al., 2011). The URICA is a 28-item self-report instrument that includes four subscales and assesses four of the five stages of change proposed by Prochaska & DiClemente (precontemplation, P; contemplation, C; action, A; and maintenance, M) on a 5-point Likert-type scale (1 = strongly disagree; 5 = strongly agree). Scores for each subscale range from 8 to 40, and they are obtained by adding the scores on the five items included in each subscale. A second-order score is obtained for the degree of 'Readiness to change' (C + A + M-P). The URICA shows good psychometric proprieties in a sample of pathological gamblers. The internal consistency values are adequate for the stages of change assessed, as well as for the total score corresponding to 'Readiness to change'. Specifically, the Cronbach's alpha coefficients range from 0.74 to 0.84, taking into account the different stages (Precontemplation = 0.74; Contemplation = 0.80; Action = 0.84; and Maintenance = 0.74), and Cronbach's alpha for the total score is 0.84.

**2.7.3.2. Gambling self-efficacy questionnaire (GSEQ)** (May et al., 2003; Winfree et al., 2013). The GSEQ is a self-report instrument that assesses perceived self-efficacy to control gambling in high-risk situations through 16 six-point Likert scale items. Participants are asked to indicate how confident they feel on a scale that ranges from 0% (Not at all confident) to 100% (Very confident) in increments of 20%. Specifically, it includes intrapersonal (e.g., unpleasant emotions, physical discomfort, pleasant emotions, testing personal control, and urges and temptations) and interpersonal (conflict with others, social pressure, and pleasant times with others) factors, based on Marlatt's (1985) model of relapse situations for addictive behaviours. The overall score is calculated considering the mean response on all the items, and it can range from 0 to 100. The higher the overall scores, the higher the overall confidence about controlling their gambling behaviour. There is evidence of convergent and discriminant validity, and the internal consistency is high ( $\alpha = 0.99$ ) in a community sample.

**2.7.3.3. EMI measures.** Gambling urge intensity and frequency, self-efficacy to cope with gambling urges, gambling behaviour (yes/no), money wagered (euros), and amount of time gambling (minutes) are also assessed for 90 days in the experimental group.

### 2.7.4. Additional measures

**2.7.4.1. Sociodemographic information.** In order to explore the characteristics of the sample, information is collected, such as age, gender, sex, marital status, type of coexistence, educational level, profession, occupational situation, income, native and residence country, spiritual beliefs, and whether they have previously received psychological treatment for gambling problems or for other reasons.

**2.7.4.2. Hospital anxiety depression scale (HADS)** (Zigmond and Snaith, 1983; Castresana et al., 1995). The HADS is a self-report instrument that consists of 14 items and has two subscales: seven items measure depressive symptoms and the other seven items measure anxiety symptoms. Respondents are asked to indicate which option fits them the most, taking the past week into account. Each item is rated on a four-point scale ranging from 0 to 3. The scores for both subscales are obtained by adding the scores on all the items, and both subscales range from 0 to 21. Scores up to 8 indicate an absence of significant morbidity, scores from 8 to 10 correspond to a borderline case, and scores higher than 10 indicate morbidity. The internal consistency ranges from 0.42 to 0.71 ( $p < 0.01$ ) for the depression subscale, and from 0.36 to 0.64 for the anxiety subscale.

**2.7.4.3. The overall depression severity and impairment scale (ODSIS)** (Bentley et al., 2014; Mira et al., 2019b). The ODSIS is a 5-item self-report instrument that evaluates a unidimensional factor referring to the severity and functional impairment associated with depression during the past week. There are five response options for each item, and they are coded from 0 to 4. The total score is obtained by adding the scores on all the items, and it ranges from 0 to 20. Scores of 5 or more indicate depressive symptoms. This scale is validated online considering a sample of patients with depressive or anxiety disorders. It shows excellent internal consistency ( $\alpha = 0.92$ ), and construct, convergent, and discriminant validity are supported.

**2.7.4.4. The overall anxiety severity and impairment scale (OASIS)** (Campbell-Sills et al., 2009; González-Robles et al., 2018). The OASIS is a 5-item self-report instrument that assesses a unidimensional factor referring to the severity and frequency of anxiety symptoms, as well as the behavioral avoidance and functional impairment related to these symptoms in the previous week. There are five response options for each item, and they are coded from 0 to 4. The total score is obtained by adding the scores on all the items, and it ranges from 0 to 20. Scores above 8 show the presence of anxiety symptoms. This scale is validated online in a sample of patients with depression and anxiety. It shows good internal consistency ( $\alpha = 0.86$ ) and adequate convergent and discriminant validity, as well as sensitivity to change.

**2.7.4.5. Difficulties in emotion regulation scale (DERS)** (Gratz and Roemer, 2004; Hervás and Jódar, 2008). The DERS is a self-report measure that includes 28 items and assesses five factors related to difficulties in emotion regulation processes: emotional lack of control, life interference, lack of emotional attention, emotional confusion, and emotional rejection. Participants have to report how often the items apply to them on a 5-point Likert-type scale ranging from 1 (almost never; 0-10%) to 5 (almost always; 91-100%). A score for each subscale is obtained by adding the scores on the items on each subscale and taking reversed items into account. A final score is obtained by adding the scores on all the items. The higher the scores, the greater the difficulties in emotion regulation processes. DERS has good psychometric properties in the general population. Internal consistency is 0.93, test-retest reliability is adequate, and convergent and incremental validity are shown.

**2.7.4.6. The positive and negative affect schedule (PANAS)** (Watson et al., 1988; Díaz-García et al., 2020). The PANAS consists of 20 items that assess two independent dimensions, positive affect (PA) and negative affect (NA). PANAS is used to measure trait and state affectivity. Each dimension consists of 10 items rated on a 5-point Likert-type scale (1 = very slightly or not at all; 2 = a little; 3 = moderately; 4; quite a bit; 5 = very much). Participants have to indicate to what extent they have experienced each emotion generally and during the past week. Total scores are calculated by adding the scores on the items in each dimension, and it ranges from 10 to 50. The scale has adequate convergent and discriminant validity, good internal consistency, and sensitivity to change. Cronbach's alpha is 0.91 for the PANAS-PA and 0.87 for the PANAS-NA.

**2.7.4.7. The short UPPS-P impulsivity scale (UPPS-P)** (Lynam et al., 2006; Cándido et al., 2012). The UPPS-P assesses five impulsivity traits (negative urgency, lack of premeditation, lack of perseverance, sensation seeking, and positive urgency) through 20 items rated on a four-point Likert scale (1 = strongly agree; 4 = strongly disagree). Scores for each of the five factors and a global score for the UPPS-P are obtained considering direct and inverse items. It is calculated by adding the scores on the four items in each factor. The higher the score, the higher the impulsivity. The UPPS-P presents good psychometric properties in a sample of university students. Internal consistency is acceptable ( $\alpha$

ranges from 0.61 to 0.81), and external validity is supported.

**2.7.4.8. Quality of life index (QLI)** (Mezzich et al., 1999; Mezzich et al., 2000). The QLI is a 10-item self-report instrument that assesses the concept of quality of life, taking into account 10 dimensions rated on a 10-point Likert-type scale (1 = poor; 10 = excellent): physical well-being, psychological/emotional well-being, self-care and independent functioning, occupational functioning, interpersonal functioning, social-emotional support, community and services support, personal fulfillment, spiritual fulfillment, and overall perception of quality of life. The total score corresponds to the average score of the set of items and ranges from 1 to 10 (1-4,5 = perception of the quality of life below the average; 4,6-8,1 = perception of the quality of life on the average; 8,2-10 = perception of the quality of life above the average). Internal consistency ( $\alpha = 0.89$ ) and test-retest reliability (0.89) are high, and discriminant validity is shown in a sample of psychiatric patients.

**2.7.4.9. System usability scale (SUS)** (Brooke, 1996). The SUS is one of the most widely used tools for evaluating the usability of ICT applications. Usability is a construct that refers to the ease with which users can use a technology to achieve a particular goal in a given context. This questionnaire consists of 10 items with which the user must show his/her degree of agreement on a 5-point Likert scale (1 = Strongly disagree, 5 = Strongly agree). The correction formula allows a total score to be calculated, expressed as a percentage (0–100), where a higher score indicates greater perceived ease and product quality (Bangor et al., 2008). The validation process for the Spanish version is being carried out, and our group has used this questionnaire in several research studies (Botella et al., 2016b; Campos et al., 2018).

**2.7.4.10. Treatment acceptance measures.** Treatment Expectations and The Opinion and Satisfaction questionnaires (Borkovec and Nau, 1972) assess the participants' expectations before the intervention and the satisfaction after receiving the program, respectively. Each of these instruments include 6 items that address the extent to which the treatment is logical, participants' degree of satisfaction, whether they would recommend it to others, its usefulness for their problem and for dealing with other problems, and to what extent it could be or was aversive, on a Likert scale ranging from 0 ("not at all") to 10 ("very much"). Psychometric properties are not available, but Cronbach's alpha will be calculated with the data at hand. This adaptation has been used in previous studies (Botella et al., 2009; Botella et al., 2016a; Botella et al., 2016b; Mira et al., 2019c; Tortella-Feliu et al., 2011).

**2.7.4.11. Negative effects questionnaire** (Rozental et al., 2018; Rozental et al., 2019). The NEQ is a 20-item self-report instrument that assesses the occurrence and characteristics of negative effects in psychological treatments and distinguishes five different factors: symptoms, quality, dependency, stigma, and hopelessness. It consists of three parts: respondents endorse specific items according to whether they occurred or not during treatment; they rate how negative the effect was on a four-point Likert-scale ranging from "Not at all" to "Extremely"; and they attribute the negative effect to the treatment they received or to other circumstances. The 20-item NEQ shows comparable validity to the original 32-item version. For the original version, the person-separation index was 0.89, and the item-separation index was 2.01, which increased to 1.08 and 2.61, respectively, in the present brief version. The instrument also contains one open-ended question in order to capture other negative effects that are not included in the items.

## 2.8. Statistical analysis

To confirm that there are no differences between the two groups in their sociodemographic and clinical variables at baseline, independent-sample *t*-tests for comparing two means will be carried out for

continuous variables, and Chi-square tests for categorical variables. Past research has shown that outcome variables that contain zeros (e.g., number of money spent on gambling) might show a non-normal distribution after a successful treatment due to a high skewedness as a result of the increase in the frequency of zeros. If this happens, mixed linear models can become biased. In our study, we will investigate whether scores are normally distributed both prior and after the intervention throughout Kolmogorov-Smirnov test. If normally distributed, we will implement a linear mixed model. On the contrary, if the treatment leads to a skewed distribution, we will implement the recommended analysis in past research called marginalized longitudinal two-part model, that offers a flexible and powerful way to model gambling outcomes (Magnusson et al., 2019).

If scores are normally distributed, to assess the main question, if there are no differences between the control and CBT groups on the pretest, a two-way ANOVA *F*-test of the interaction will be performed, with a between-groups factor (CBT vs. Control groups) and a within-group factor (pre-treatment vs. post-treatment assessments). However, if the groups are not equivalent in their sociodemographic variables, a two-way ANCOVA *F*-test of the interaction will be conducted, taking the non-equivalent variable/s as covariate/s. If these groups are not equal on the outcome variables at pre-treatment, a one-way ANCOVA *F*-test (between-groups factor) will be carried out, taking the pre-treatment scores on the outcome variable as a covariate. Regarding secondary objectives, different statistical tests will be used:

- (i) To assess whether the changes are maintained at 3-, 6-, and 12-month follow-ups, a one-way repeated-measures ANOVA *F*-test with five levels will be conducted on the CBT group alone. If there are significant differences among the repeated measures, post hoc tests will be carried out using the Dunn-Sidak method.
- (ii) To investigate potential differences in the pretest-posttest changes as a function of the level of the GD severity, only the CBT group will be considered in the analyses. A two-way ANOVA *F*-test of the interaction will be performed, with a between-group factor with two levels (problem gambling/GD) and a within-group factor that corresponds to the repeated-measures pre-treatment-posttreatment.
- (iii) In order to evaluate signs of the differential efficacy of the intervention at the follow-ups, only the CBT group will be considered in the analysis. A one-way repeated-measures ANOVA *F*-test with five levels and post hoc tests using the Dunn-Sidak method will be conducted for each severity level.
- (iv) In order to explore whether some factors could be statistically associated with the intervention's efficacy, only the group that receives the intervention will be considered, and a mediation/moderation analysis will be performed. The maximum number of variables to be included in the mediation/moderation model will be determined based on the sample size obtained in order to avoid capitalizing on chance. These analyses will be exploratory due to the small sample size. Based on these analyses, we will consider different sociodemographic and clinical outcomes (Mora-Salgueiro et al., 2021).
- (v) In addition to the statistical significance tests mentioned above, pertinent effect sizes will be calculated and reported. Statistical analyses will be carried out using IBM SPSS Statistics for Windows.

Efficacy analysis will be performed based on intention-to-treat (ITT). Drop-out rates will be calculated by reporting percentages and patterns of missing data. Sensitivity analyses will be performed to assess whether completers and dropouts exhibited relevant differences in sociodemographic and clinical variables, as well as in the dependent variables on the pretest. Missing data in the relevant variables will be imputed by applying multiple imputation (MI) methods (Graham, 2009). After imputing missing data, ANOVAs will be performed on the ITT data.

(vi) In order to examine gambling behaviour (amount of time and money wagered) progress throughout the intervention and the effect of gambling urges (frequency and intensity) and self-efficacy to cope with gambling urges on gambling behaviour, we will conduct marginalized longitudinal two-part model. If there are differences in the patterns, we will consider four pre-test outcomes to explore whether they could moderate the gambling behaviour results: 1) gambling severity (assessed by the NODS); 2) anxiety and depression symptoms (assessed by the HADS); 3) readiness to change (assessed by the URICA); and 4) comorbidity with mild alcohol and/or substance use disorder (assessed by the MINI). We consider no more than four outcome measures to avoid capitalizing on chance.

### 3. Discussion

The aim of this study is to describe the protocol for an RCT that will examine the efficacy of an online self-applied intervention for individuals with problem gambling and GD. A marked strength of this study is the innovative way of delivering psychological interventions in order to increase accessibility, especially considering the current difficulties in receiving treatment in other ways due to the COVID-19 pandemic. Internet-based interventions make it possible to overcome important treatment-seeking barriers, such as stigma, embarrassment, and accessibility (Cunningham, 2007; Gainsbury et al., 2013; Suurvali et al., 2008). They offer an anonymous way to receive the treatment, with greater flexibility and time and cost reductions (Gainsbury and Blaszczynski, 2011). Previous studies have supported the efficacy of online interventions based on CBT (DiNicola et al., 2020; Jonas et al., 2020), as well as the relevance of involving significant others in the treatment to enhance adherence (Nilsson et al., 2019).

With regard to evaluation, previous studies have used ecological momentary assessment to investigate experiences and behaviour in real-world settings, specifically in alcohol-dependent outpatients and young adults with heavy drinking episodes (Fridberg et al., 2019; Waters et al., 2020). In addition to random assessments, temptation assessments when there is a rise in the urge to use drugs provide relevant information to better understand the time course of these episodes. In the case of gambling disorder very few studies have been conducted for this purpose (Hawker et al., 2021b). Thus, daily assessment through an EMA app will provide immediate information that is not biased by retrospective completion and makes it possible to observe the progress of relevant variables over time, such as urges to gamble, self-efficacy to cope with gambling urges, and whether gambling behaviour occurs. Combining an EMI that incorporates this type of evaluation with the online intervention proposed in this study, which includes feedback, reminders, and alerts, will help to achieve more precise and personalized interventions.

The influence of therapist support on intervention efficacy is an issue that has not been sufficiently explored in GD. There are indicators of the advantages of therapist support for GD (Goslar et al., 2017), but due to the low number of studies that involve contact, the results should be interpreted with caution. The current study will extend the knowledge about the efficacy of psychological interventions for GD with automatic support applied by the EMI and email and human support provided by telephone. To our knowledge, this is the first Internet-based program combined with an EMI and this automatic and human support for GD in Spain, and it could also help to increase adherence to treatment and decrease the percentage of dropouts.

Because different psychiatric disorders are highly comorbid with GD, a relevant question that remains unanswered is how to better help these patients. Some studies have proposed adding an intervention to gambling treatment to address anxiety and depression (Cunningham et al., 2019) and co-occurring problem drinking (Cunningham et al., 2018). Cunningham et al. (2019) report similar reductions in gambling and depressive and anxiety symptomatology in the group with gambling treatment alone and the group that receives an additional distress

mental health treatment. However, there is no significant benefit of this additional intervention. Instead of focusing on treating specific disorders, another alternative would be to consider transdiagnostic components. Including transdiagnostic strategies in the treatment protocol could better target the broad heterogeneity of individuals suffering from gambling symptomatology and other associated psychopathologies (e.g., anxiety disorders and mood disorders). Emotional regulation difficulties have been shown to play an important role in the relationship between these pathologies (Jauregui et al., 2016; Rogier and Velotti, 2018; Marchica et al., 2019). B cker et al. (2018) designed an intervention based on CBT, acceptance, mindfulness, and positive psychology techniques, and they found significant reductions in depressive and gambling-related symptoms, with moderate to strong effect sizes. In addition, a recent systematic review supports the effectiveness of Mindfulness-Based interventions for substance and behavioral addictions (Toneatto et al., 2014; McIntosh et al., 2016; Sancho et al., 2018). For this reason, along the same lines as B cker et al. (2018), in addition to using CBT, elements from CBT extensions and innovations will be included (e.g., mindfulness and emotion regulation). They will contribute to acquiring adaptive strategies for coping with emotions, in order to tolerate intense emotions and physical sensations associated with withdrawal and cravings (Barlow et al., 2017).

Nevertheless, this study also has some limitations. One limitation is the small sample size for some of the study objectives. Although the treatment program is designed to target people suffering from problem gambling or GD, secondary results on the differential efficacy depending on the severity level across several time points should be interpreted with caution. They are exploratory results, and future research could address this research question with a larger sample. Second, the assessment instruments are self-reported measures, and so a response bias can influence data variability.

Third, it is possible to know whether the effects are maintained in the short to medium term, but not in the long term. Nonetheless, if sustained effects are observed at the 3-, 6, and 12-month follow-ups, future research could include assessments at 24 and 36 months, as in previous studies (Carlbring and Smith, 2008; Carlbring et al., 2012). Finally, WL control designs have been used in previous studies (Boudreault et al., 2018; Carlbring and Smith, 2008; Magnusson et al., 2019; Oei et al., 2018), and they are appropriate for estimating treatment effects compared to no-treatment. However, WL also has some limitations, such as the fact that we cannot control the unspecific effects of the intervention, as described by Cuijpers and Cristea (2016). Despite these deficiencies, the study has several strengths and could be beneficial for people suffering from mild to severe gambling symptomatology.

In sum, the results will contribute to extending the knowledge about Internet-based interventions for gambling problems, overcoming specific barriers that are present, especially in GD, and offering more cost-effective evidence-based psychological treatments to people who need them. In addition, they will point to future research that can clarify for which severity levels these treatments are more efficacious.

### 4. Conclusions

We expect the findings of the study to contribute to advancing the knowledge about Internet-based programs for the treatment of gambling problems. Moreover, they will contribute to improving the quality of Internet-based psychological programs and adherence to them by considering EMI and other complementary tools.

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## Ethics approval and consent to participate

The study was approved by the Innovation Office and TI audit, and the Ethics Committee of Universitat Jaume I (Castellón, Spain) on May 2, 2019 (CD/026/2019), and it will be conducted in accordance with The Declaration of Helsinki and good clinical practice. All participants will sign an informed consent form.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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## Appendix A. Daily assessment - EMI

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.invent.2021.100466>.

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