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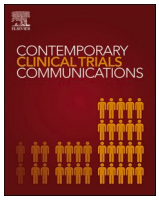

Evaluating the effectiveness of mobile app-based self-guided psychological intervention to reduce craving and lapse risk in problematic substance use and behaviors: Protocol for a randomized control trial in the general population

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ABSTRACT

Background: The prevalence of substance and behavioral addiction is estimated between 10 and 15% of the global population and remains a severe public health concern. Moreover, addiction treatment has several barriers, such as a lack of access to professional treatment or stigmatization. Mobile health interventions emerge as a promising solution.

Methods: This two-armed randomized controlled trial (RCT) aims to assess the efficacy of a mobile app-based self-guided psychological intervention delivered via a smartphone app (Nałogometr) in reducing craving and lapse risk in problematic behaviors and substance use compared to a control condition. Participant recruitment and data collection will start in June 2022 and end in September 2022. Due to the nature of the study, i.e., a nationwide study of problematic substance use and behaviors, we will aim to recruit all individuals willing to participate. The four-week intervention condition includes short-term and long-term modules based mainly on mindfulness and cognitive behavioral therapy. Longitudinal data on several variables related to craving and lapse risk are collected daily using ecological momentary assessment (EMA). The primary outcomes of interest will be the self-reported number of lapses and craving level in daily EMA. Moreover, a questionnaire battery assessment is administered at baseline in the first week following onboarding, after five weeks, and after six months. The secondary outcome measures will include the severity of problematic substance use or behaviors, anxiety and depression, and life satisfaction.

Results: Results will be submitted for publication in peer-reviewed journals.

Clinical trial registration: [https://clinicaltrials.gov/], identifier [NCT054 34,429].

Author contributions

MG, MS, KL, AB, and PM devised the initial plan for this study. AB, PM, KL, KO, and KSz did the first draft of the paper and prepared the final manuscript. KS, KSz, KO, MB, BW, and MN helped throughout the development of the intervention and gave valuable feedback to the present study protocol. All authors approved the final version of the manuscript submitted for publication.

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1. Introduction

Addictions can be chronic conditions with a high potential for relapse [1]. Substance and behavioral addiction are crucial public health problems concerning about 10–15% of the global population [2]. In Poland, alcohol and tobacco addictions are the most common, concerning respectively 2% and 21% of the general population [3]. The prevalence of drug addiction rate is more difficult to estimate in Poland; however, the percentage of entrants into treatment for particular illicit substances can give some insight, where the most common is amphetamine (33%) and cannabis (32.8%), followed by opioids (15%) and cocaine (3.1%) [4]. Even though substance use disorders (SUD) are still the most common addictions, there is an increasing trend in the prevalence of non-substance behavioral addictions (e.g., gambling disorder, internet addiction, compulsive buying, and pornography viewership) in the Polish population [3]. Moreover, these symptom clusters are increasingly recognized in the formal diagnostic classifications as independent disorders [5,6].

While treatments for substance and non-substance addictions exist, most patients do not enter treatment. There are several reasons, but one of the more important is related to the low-level availability of trained healthcare providers for addictive disorders—it is estimated that about 80% of people are in such situations, which is true across countries [7,8]. Moreover, many people suffering from addiction do not decide to seek help viewing one's problem as not severe or stigmatized [9,10] or because of a preference for self-reliance or beliefs that treatment is ineffective [10–12].

Mobile health (mHealth) interventions emerge as a promising solution to fill the gap between those needing and receiving addiction treatment. They can be easily accessible to hard-to-reach populations and help circumvent stigma. Moreover, due to a high potential for relapse in addiction [1], mHealth interventions may be a valuable tool for enhancing the post-therapeutic effects after treatment [13].

In general, mobile health refers to mobile technologies supporting health, including mental health, and constitutes a rapidly evolving area [14]. The delivery of mHealth interventions through smartphone apps is of particular interest because of their popularity and accessibility [15]. However, the critical evidence of their effectiveness still needs to be addressed [16]. With over 300 0000 health applications available [17], a small number have been clinically tested before entering the market [18]. With those already being studied, results show that they can positively influence health behaviors [19]. Previous research suggests mobile applications can effectively reduce substance use, craving management, and behavior change in addictive disorders [20,21]. To offer mHealth apps as effective tools in addictive disorders, they should be developed regarding scientific evidence or theory, and their effectiveness should be evaluated in randomized controlled trials (RTC).

1.1. Mobile interventions for addictive disorders and the nałogometr mobile app

Nałogometr mobile app will be used to deliver mobile interventions in the planned RC. It is a theory- and science-driven mobile application that aims to reduce lapse risk and craving levels in people with problematic behaviors or substance use and those who have already developed an addiction. Patients from Poland's addiction treatment and rehabilitation center helped in the process of creating the application's content. Researchers conducted workshop meetings during which the effects of work on the application and its appearance were shown so far, and patients shared their impressions and ideas, which were then taken into account in further corrections. In addition, the researchers conducted short interviews about what patients found most helpful and attractive, what they found least, and what they felt might be missing from the application. *Nałogometr* consists of self-guided psychological intervention modules created mainly based on cognitive-behavioral therapy (CBT) and mindfulness, which has been shown as an effective treatment approach for various addictions [22–26].

The CBT-based interventions aim to identify and modify dysfunctional thoughts (cognition) and actions (behavior). They focus on addressing triggers, identifying and modifying outcome expectancies, developing more effective coping strategies, emotional regulation, improving motivation, impulse control, and relapse prevention [24].

Mindfulness-based interventions (MBI) refer to maintaining a moment-by-moment awareness of one's feelings, thoughts, body sensations, and environment. They have successfully reduced dependence, craving, and other addiction-related symptoms but also improved mood state, distress tolerance, and emotion dysregulation in both substance and behavioral addictions [27].

Mindfulness and CBT are two researched therapeutic approaches within the context of addiction treatment. Integrating mindfulness and CBT in addiction treatment facilitates the heightened awareness concerning thoughts, emotions, and physical sensations associated with addiction, in addition to fostering the development of healthier coping strategies, identification of triggers, and relapse prevention [28,29]. A study by Bowen [30] reported significantly lower rates of substance use among adults who received mindfulness-based relapse prevention (MBRP) than those in the treatment-*as*-usual (TAU) condition throughout a 4-month post-intervention period. Notably, MBRP participants exhibited more substantial reductions in cravings and increases in acceptance and acting with awareness compared to individuals in the TAU condition. Furthermore, another study [29] found that acceptance, awareness, and nonjudgment significantly mediated the relationship between receiving MBRP and self-reported craving levels immediately following treatment.

In addition to those mentioned above, self-guided psychological interventions, the *Nałogometr* app, was also developed to facilitate self-monitoring and self-management in its users—all of which are considered effective techniques for behavior change in addictive disorders [31,32]. The app allows users to self-report behaviors and psychophysiological states in real-time using ecological momentary assessment (EMA) and deliver personalized feedback based on one's answers. EMA is a method that involves gathering frequent and real-time information about individuals' behaviors and experiences in their natural environments. Unlike traditional surveys, which provide one-time measurements, EMA captures the dynamic nature of behavioral changes over time. By utilizing EMA and self-monitoring techniques, individuals can promote behavior change and self-management by fostering awareness of addictive behaviors and triggers, tracking progress toward goals, implementing self-rewards, setting reminders, receiving reinforcement, and obtaining personalized feedback [33].

Currently, there are no evidence-based mobile apps in Poland that could effectively reduce craving and lapse risk in problematic behaviors and substance use or addiction. Therefore, the present study aims to test the effectiveness of mobile app-based self-guided psychological intervention delivered via a smartphone app (*Nałogometr*) in reducing craving and lapse risk in problematic behaviors (compulsive sex, pornography, overeating, gaming, gambling) and substance use (cannabis, nicotine, heroin, benzodiazepines, analgesics, sedatives) in a two-armed randomized controlled trial (RCT) among the general population of adults in Poland. If effective, the app could be widely recommended among people with a wide range of addictions. The primary outcome will be the change in the craving and lapses level between baseline and follow-up assessments and after single engagement interventions, depending on the intervention module. The secondary outcome measures will include beneficial changes in the intervention groups' levels of problematic substance use or behaviors severity, anxiety and depression, and life satisfaction over time compared to the control group.

2. Materials and methods

2.1. Study design

This is a two-arm participant-blinded (single-blinded) RCT, which compares a (1) intervention condition with the (2) waitlist control condition (see Fig. 1 for participants flow chart). Participants in the intervention condition will have access to self-guided psychological intervention modules five days after randomization and will receive weekly EMA reports. Those in the waitlist control group will only have access to the weekly ecological momentary assessment (EMA) reports and will be granted access to all intervention materials after five weeks following study enrollment. Study conditions will be balanced based on multiple variables provided during the onboarding process: (1) main addiction type; (2) participation in addiction-related therapy; (3) gender; (4) age; (5) addiction severity; (6) abstinence duration.

Questionnaire battery (Table 1) assessments will take place: (1) at baseline in the first week following onboarding in; (2) after five weeks (end of the 4-weeks intervention testing period); (3) post-measurement after six months. In addition, longitudinal data on several variables (see supplementary materials Table 4S) related to craving and lapse risk will be collected daily using EMA.

The study has been preregistered in the Open Science Framework (OSF) repository (https://osf.io/cfh9n?view_only=ccbbcb08c5c146cab37b0d2df23b585b) and registered at https://clinicaltrials.gov/platform (Trial Registration: NCT05434429, Date of registration: June 28, 2022).

2.2. Sample size

In order to determine the required sample size, we carried out a simulation-based power analysis. In this simulation, we assumed a linear mixed-effects model with pre-treatment and post-treatment measurements in the control and intervention group. Based on the results of previous substance use reduction mobile intervention studies [for a review, see Staiger et al. (20)], a small effect size (Cohen d = 0.2) was also assumed. The results of this analysis indicated that approximately 200 participants will be required to achieve at least 80% power of detecting an effect of the treatment.

In addition, due to the nature of the study, i.e., a nationwide study of problematic substance use and behaviors, we will aim to recruit all individuals willing to participate. Our sampling strategy has been designed to maximize the demographic diversity of the resulting sample, particularly with respect to demographic characteristics (e.g., gender, age, geographic and socioeconomic setting) within each addiction profile.

Table 1
Overview of the questionnaire assessment.

Assessment instrument	Baseline (week 1)	Follow-up (week 5)	Follow-up (6 months)
Sociodemographic questions	*x*		
Substances use-related measure			
Cannabis (SDS)	*x*	*x*	*x*
Cannabis (CUDIT-R)	*x*	*x*	*x*
Nicotine (FTND)	*x*	*x*	*x*
Heroin, Benzodiazepines, Analgesics, Sedatives (DUDIT)	*x*	*x*	*x*
Behavioral addiction measures			
Overeating (BEDS-7)	*x*	*x*	*x*
Pornography (BPS-PL))	*x*	*x*	*x*
Gambling (SOGS)	*x*	*x*	*x*
Compulsive Sex (CSBD-19)	*x*	*x*	*x*
Gaming (IGDS9-SF)	*x*	*x*	*x*
Psychopathological symptoms measures			
Depression and anxiety (HADS)	*x*	*x*	*x*
Psychological functioning measures			
Sensation seeking (BSSS)	*x*	*x*	*x*
Emotion regulation (DERS)	*x*	*x*	*x*
Impulsivity (UPPS–P)	*x*	*x*	*x*
Coping with Stress (Mini-COPE)	*x*	*x*	*x*
Life satisfaction (SWLS)	*x*	*x*	*x*

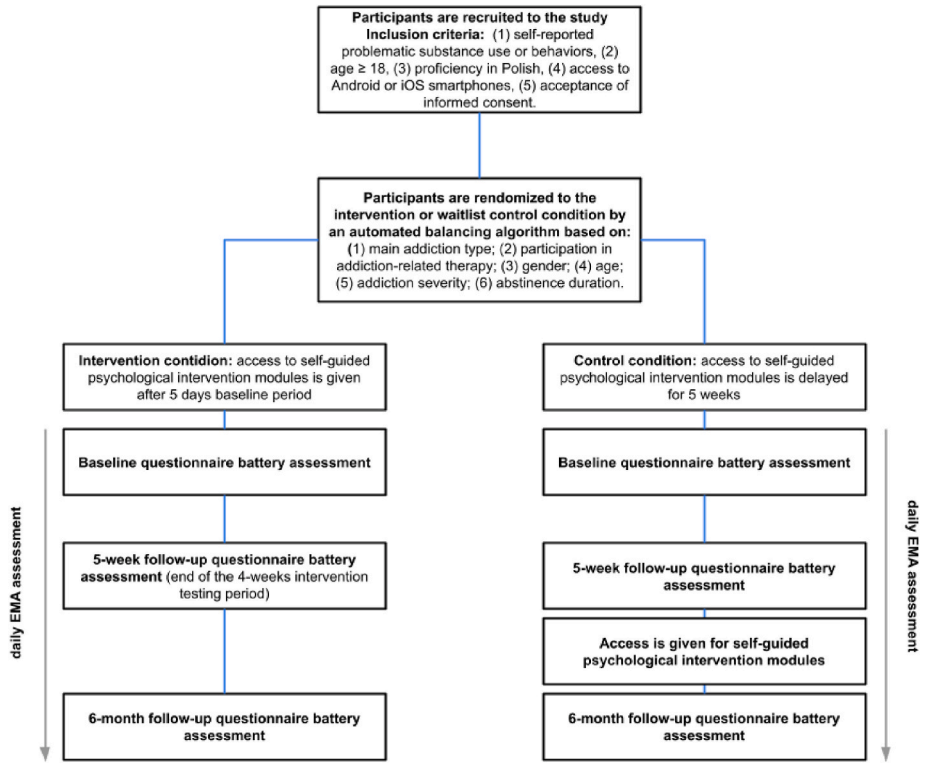

Fig. 1. Participant flow chart.

2.3. Recruitment of study participants

The study will take place from June 2022 until September 2022; during this period, participants will be recruited constantly. We will recruit participants from the general population in Poland using social media, advertisements, and newsletters. The study will be conducted via the mobile application *Nałogometr*. Participants will be included in the study if they will meet the following criteria: (1) self-reported problematic substance use or behaviors, (2) minimum age of 18, (3) proficiency in Polish, (4) access to Android or iOS smartphones, and (5) acceptance of informed consent.

2.4. Randomization

Randomization will be applied using an automated balancing algorithm. The algorithm will aim to partition participants into the intervention group or the control based on the initial onboarding assessment to make the resulting groups as balanced as possible with regard to the characteristics outlined in the study design section, i.e., (1) main addiction type; (2) participation in addiction-related therapy; (3) gender; (4) age; (5) addiction severity; (6) abstinence duration.

2.5. Hypotheses

Concerning the primary outcome, we hypothesize that participating in the intervention condition (study arm 1)— compared to the control condition (study arm 2) — will result in lower levels of craving and lapses comparing the baseline and the follow-up assessments after five weeks of implementation through a mobile app. This effect will be maintained at a 6-month follow-up. Moreover, we hypothesize that a significant reduction will follow single engagement in short-term and self-guided psychological interventions in craving and lapse risk. Regarding the secondary outcomes, we hypothesize that participating in the intervention condition—compared to the control condition—will result in lower levels of substance or behavioral addiction measured by dedicated questionnaires (Table 1), lower levels of anxiety and depression, and higher levels of life satisfaction.

2.6. Procedure

The trial is conducted via the Nałogometr mobile app (available from the Google Play or App Store) without any need for the research team's involvement, including collecting informed consent and data collection. The data collection points are shown in Fig. 1.

The download and onboarding process in *Nałogometr* will be used as the onset of the baseline in our study. Upon first use, the app will automatically navigate the participant through necessary permissions and consents about the collection of different types of data. After logging in, participants will be asked to complete a baseline onboarding questionnaire that collects demographic information and their substance use or behavioral habits. The participant indicates the main addiction he wants to work on while using the application. In addition, each participant can enter other addictive behaviors that he/she observes. However, the whole intervention will be focused on the main addiction, and on that basis, participants will be classified into further analyses. Furthermore, standardized questionnaires will be collected at three time points across the study period. Participants will have one week to complete the assigned questionnaires. The entire battery of questionnaires is available to each participant at three time points. However, if participant indicates that they have not used such substances, e.g., nicotine, they will not have to complete such a questionnaire. The additional and supplementary questionnaires are intended for all participants at each of the three time points. The questionnaire schedule across the study period for each participant is presented in Table 1.

The overview of the data collection schedule is presented in Fig. 1.

2.7. Mobile application

Nałogometr (https://nalogometr.pl/) is an app available for iOS and Android devices and is designed to support a user interested in reducing their problematic substance use or behaviors. The main app dashboard was developed to be simple and easy to use. It allows for quick access to EMA, self-guided psychological interventions, and weekly feedback reports; the module's availability depends on the study's condition.

Weekly feedback reports. The mobile app automatically processes and analyzes EMA data entered by the user and generates personalized feedback for the past seven days. Reports contain information about sober and non-sober days, changes in craving and lapse risk relative to the previous week, and finally, the relationships between craving and the three most important EMA items and protective factors.

Self-guided psychological intervention modules. Two main self-guided intervention modules are available. The short-term self-guided intervention module includes mainly audio-guided sessions on gratitude, thoughts management, auto-empathy, and relaxation (Fig. 2). Moreover, they are based on breath relaxation exercises, craving management, and motivation to change. These interventions are akin to other well-tested and scientifically backed interventions based on self-guided audio listening exercises [e.g. Refs. [27]. The long-term self--guided intervention module includes mainly CBT-based interventions concentrated on thought management techniques and audio-guided meditation and mindfulness sessions focused on raising the awareness of emotions, effectively reading body signals, and coping with stress. The app also provides journaling techniques focused on enhancing self-efficacy, self-confidence, and positive attitude and improving understanding of the relationship between situations, thoughts, mood, and sobriety. All interventions mentioned above will be delivered five days following study enrollment in the intervention condition. Participants will have the option to engage in any intervention after this period at any chosen time. However, they will not be obligated to do so, nor will a strict intervention delivery schedule be followed.

2.8. Measures

Sociodemographic data will include gender, age, and place of residence. Substance use-related questions will include frequency of use, lifetime use, treatment-seeking, and abstinence period (see supplementary section: Table 1S, 2S, and 3S). EMA assessments will measure (three times a day): addiction-related craving and lapse occurrences, as well as current mood, arousal, pressure, anxiety, procrastination, loneliness, tiredness, anger, hunger, and uncertainty (see supplementary section: Table 4S).

2.9. Primary outcome

The primary outcomes of interest will be the self-reported in daily EMA: a number of lapses (an item asking whether or not the lapse occurred since the last survey [yes/no]) and craving level (an item asking how strong is one's urge to use [substance] at the moment on a scale of 0–6 [none - incalculable]).

2.10. Secondary outcomes

2.10.1. Problematic substance use

Cannabis. The Severity of Dependence Scale (SDS) [34] will provide a self-reported measure of the psychological aspects of cannabis dependence. A five-item, one-dimensional tool has a uniform scale for questions 1–4 from 0 ('never or almost never') to 3 ('always'). Question 5 has the same scale with different signatures where 0 means 'not difficult at all' and 3 means 'impossible'. The general score ranges from 0 to 15 - where the cut-off score depends on the user's drug type - with the higher values reflecting higher dependence. Cannabis Use Disorder will be accessed with The Cannabis Use Disorders Identification

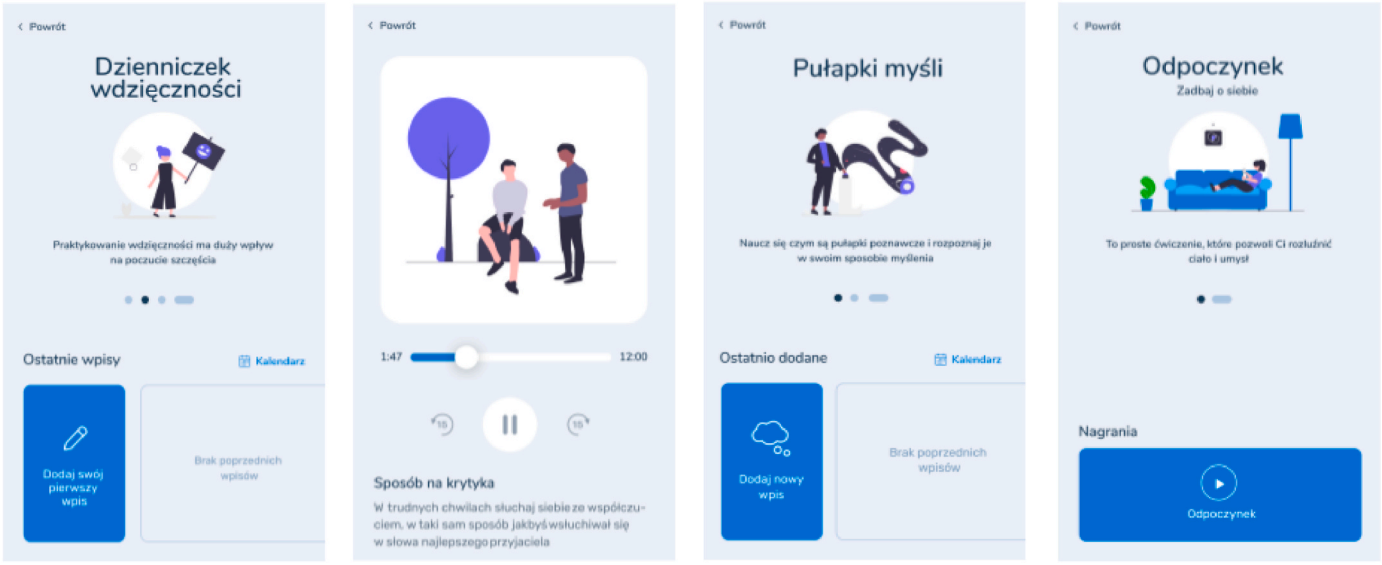

Fig. 2. Screenshot examples of the self-guided intervention modules in Nałogometr.

Test-Revised (CUDIT-R) [35], an eight items one-dimensional scale. Questions 1–7 are scored on a 0 ('never') to 4 ('daily or almost daily') scale, and question 8 is scored as 0 ('never'), 2 ('Yes, but not in the past six months') or 4 ('Yes, during the past 6 months'). A score between 8 and 11 indicates hazardous cannabis use, and scores above 12 points indicate possible cannabis use disorder.

Nicotine. Nicotine dependence was assessed by The Fagerstrom Test for Nicotine Dependence (FTND) [36]. The questionnaire comprises six questions, with varying choices in each. Each option is accompanied by a number indicating its score for the questionnaire scoring system. The total score is categorized as follows: 0–2 indicates a very low dependence, 3–4 indicates a low dependence, 5–7 indicates a moderate-to-high dependence, and lastly, 8+ indicates a very high dependence.

Heroin, Benzodiazepines, Analgesics, Sedatives. The Drug Use Disorders Identification Test (DUDIT) will be used to measure self-report problematic drug use. The DUDIT is an 11-item screening instrument, the first nine items are scored on a 5-point scale (0–4), and the last two are scored on a 3-point scale (0, 2, and 4, respectively). The overall score is a sum of scores on all items, with a maximum of 44. A cut-off of >24 has been used for indexing dependence for both sexes.

2.10.2. *Problematic behaviors*

Gaming. Gaming disorder was assessed using Internet Gaming Disorder Scale–Short-Form (IGDS9-SF), a 9-items one-dimensional tool reflecting nine criteria for Internet Gaming Disorder in DSM-5 [37]. Items are rated on a 5-point scale (1 = 'never', 2 = 'rarely', 3 = 'sometimes', 4 = 'often', 5 = 'very often'), and results can range from a minimum of 9 to a maximum of 45 points, with higher scores indicating a higher degree of IGD and a cut-off of 32 [37].

Overeating. The BEDS-7 screener consists of 7 questions to detect the possibility of the patient having a binge eating disorder (BED) [38]. First, a filter question is asked if the participant experienced at least one episode of excessive overeating during the last three months. If answered yes, the next question is about feeling distressed from episodes of excessive eating (with possible answers: 'Yes', 'No'), followed by five questions using a Likert-like rating scale ('Never or Rarely', 'Sometimes', 'Often', 'Always'). An answer of 'Yes' to both first two questions with a response of 'Often', 'Always', or 'Sometimes' to questions 3–6, and an answer of 'Never or Rarely' or 'Sometimes' to question 7 will yield a result of showing symptoms of BED.

Gambling. Gambling disorder will be measured with South Oaks Gambling Screen (SOGS) [39] with 16 items of the one-dimensional tool. The participant is asked to indicate the type of gambling practices at least once in one's life. The first three questions are qualitative: participants indicated how much money they put at risk at maximum in their life, who from their surroundings tend to gamble, and how they come back the next day to get back. The rest of the items are answered yes/no, and each 'yes' answer is rated 1 point. The score is calculated as a sum (without questions 1,2,3,12, and 16) with 0 meaning no problem with gambling, 1–4 indicating minor issues with gambling, and scores higher than 4 indicating the risk of pathological gambling.

Compulsive sex. Compulsive sexual behavior disorder will be accessed with a short version of the Compulsive Sexual Behavior Disorder Scale (CSBDS-19) [40], including 19 items with possible answers from 1 – strongly disagree to 4 – strongly agree. The tool has five scales: control, salience, relapse, dissatisfaction, and negative consequences. The minimum score is 19, and the maximum is 76, with a cut-off of 50 points indicating possible compulsive sexual behavior disorder.

Pornography use. Pornography use will be measured with Brief Pornography Screener (BPS) [41], a 5-item, one-dimensional scale. All questions regarding pornography use in the last six months are scored from 0 ('never') to 2 ('very often'). The minimum score is 0, and the maximum is 10. A total score of 4 and over indicates problematic pornography use.

2.10.3. *Additional measures*

Depression and anxiety. Depression and anxiety will be measured with a 14-items Hospital Anxiety and Depression Scale (HADS) [42]. Each of the two subscales consists of 7 items, scoring from 0 to 3. For both subscales, scores of 8–10 indicate mild depression/anxiety, and scores between 11 and 21 indicate depression/anxiety disorder.

Life satisfaction. The Satisfaction With Life Scale (SWLS) will be used to assess participants' satisfaction with their life [43]. SWLS consists of five statements about life satisfaction, where participants indicate their agreement with each statement on a 7-point Likert scale. Higher scores indicate a higher level of life satisfaction, with a maximum of 35.

2.11. *Supplementary measures*

Sensation-seeking. The Brief Sensation Seeking Scale (BSSS) will measure the sensation-seeking trait [44]. BSSS is an 8-item tool with four factors: (1) disinhibition, (2) boredom susceptibility, (3) thrill and

adventure seeking, and (4) experience seeking. Each subscale has two items rated on a scale from 1 ('strongly disagree') to 5 ('strongly agree'). Results for the general score range from 8 to 40 (and each subscale score from 2 to 10), with higher scores indicating a higher sensation-seeking trait.

Impulsivity. The Short UPPS-P Impulsive Behavior Scale (SUPPS–P) will measure impulsivity [45]. The UPPS-P is a 20-item 5-dimensional tool: (1) negative urgency, (2) lack of perseverance, (3) lack of premeditation, (4) sensation seeking, and (5) positive urgency. Each item is scored from 1 ('strongly disagree') to 4 ('strongly agree'). The minimum score on each subscale is 4, and the maximum is 16.

Stress coping. Participants' coping with stress disposition will be accessed with the Mini-COPE Stress Management Inventory [46] which originally consists of 28 statements included in 14 strategies (2 statements in each strategy). In addition, strategies can be divided into three subscales: (1) focusing on the task, (2) focusing on emotions, and (3) focusing on avoidance. Participants can answer on a 4-point scale from 1 ('I hardly ever do this') to 3 ('I almost always do this'). The mean from both statements must be calculated to receive the result for each strategy.

Emotion regulation. A brief version of the Difficulties in Emotion Regulation Scale (DERS) will be used to measure emotion dysregulation [47]. The tool consists of 18 items with six subscales: (1) non-acceptance of emotional responses, (2) difficulty engaging in goal-directed behavior, (3) impulse control difficulties, (4) lack of emotional awareness, (5) limited access to emotion regulation strategies and (6) lack of emotional clarity. The scale has a 5-point Likert scale from 1 ('Almost never') to 5 ('Almost always'). Total scores range from 18 to 90 and 3 to 15 for each subscale. The higher result is related to more significant difficulties in emotion regulation.

2.12. Data analysis

We will use factorial design mixed-effects models to compare questionnaire battery scores between experimental groups and the control across measurements. These models allow for robust comparisons of intervention and control groups at multiple time points. In addition to the focal explanatory variables, demographic covariates will be included in the model, such as gender, age, level of education, and place of residence, as well as the individual addiction profile. To further enhance the results of the study, we will perform an interrupted time series analysis, which provides an in-depth evaluation of our intervention over time. This analysis will be applied to the data collected throughout the study via EMA in order to determine how the introduction of different types of interventions affects the longitudinal trends in our primary and secondary outcome measures. For the primary outcomes—craving and lapse rates—we will assess the immediate and longer-term changes in these variables post-intervention. For the secondary outcomes—levels of substance or behavioral addiction, anxiety and depression, and life satisfaction—we will likewise examine how the trends in these variables are influenced by the introduction of our intervention.

We will include participants who complete at least 21 EMA assessments spread across the intervention testing period of 5 weeks. Furthermore, for the six-month follow-up intervention effects retention analysis, we will include participants who complete at least three EMA assessments within the follow-up period. Moreover, in the intervention group, we will retain participants who log onto the app and use the long-term and short-term self-guided intervention modules at least four times and once, respectively (defined as minimal therapeutic exposure). Finally, for the secondary outcome analysis, we will include participants who complete the baseline and at least one follow-up assessment.

For missing data, we will first perform a Missing Completely at Random (MCAR) test [48] to determine if the missing data occurred independently of the observed and unobserved data. Second, if necessary, we will proceed with data imputation methods to replace the missing values, improving the statistical power of our study. As for participant attrition, our aim was to create an engaging study protocol that encourages volunteers' continuous participation without the need for special incentives. This approach, although it does not include specific incentives, can reduce potential bias that might arise from incentivized participation.

2.13. Data management

As described above, all data will be collected continuously throughout the duration of the study via the *Nałogometr* mobile app, available on App Store and Google Play, and stored on a secured server. Key project personnel, i.e., Principal Investigators (PIs) and Co-Investigators (CIs) will be the data stewards and will be responsible for documenting and managing the data during the collection, analysis, and publication phases. Additional project personnel, i.e., project coordinators, data analysts, and data scientists, will receive the data as per instructions from the PIs and CIs in an anonymized format. Following publication processes, the data will be archived and stored on a similarly secured server.

Data documentation will include codebooks that document the following: data collection protocols, methodology, and sample; description of specific data sources, e.g., types of measures that correspond to each raw data unit.

As per the needs of the particular project phase and according to current research questions, data will be queried and exported as ASCII files and made available to the additional project staff. Such datasets will include an individual (anonymized) participant identifier code, demographic information, relevant variable labels, and values. According to the current research questions, additional project staff will perform any data transformations necessary for the final and published analyses. Any publications that result from the data collected will be prepared only with the use of anonymized (de-identified) datasets and will pertain only to aggregate-level results. Due to the expected absence of (high) risks for participants of this study, establishing a data monitoring committee is not necessary. Each additional staff member will produce documentation about what and how data was used for the research task. This responsibility will include documentation pertaining to the decisions related to any data transformations and coding performed (including variable lists and definitions of the raw data used and how the derived variables were produced), as well as the analytical methods and techniques performed for any particular research task.

Please contact the corresponding author for any additional data management procedure details.

3. Discussion

This study protocol describes the design of a randomized controlled trial to determine the effectiveness of self-guided psychological intervention modules delivered within a smartphone app (Nałogometr) at reducing craving and lapse levels in problematic substance use and behaviors. The embedded trial and analysis will evaluate the effectiveness of intervention modules for different problematic behaviors and substance use. Moreover, in exploratory analyses, we plan to investigate whether user engagement moderates or changes in psychological functioning measures (e.g., sensation seeking, impulsivity, stress coping, emotion regulation) mediate the effectiveness of the interventions, which allow us to extend insights into designing effective mobile interventions for problematic substance use and behaviors mentioned before. If these interventions are effective, they can significantly contribute to treatment and addiction prevention in the future. The substantial advantage of developed interventions is their wide availability or accessibility for users as they can be delivered by smartphone. Mobile app interventions may reduce treatment barriers with many advantages for users, such as staying anonymous and avoiding stigma, and may be especially useful in places where professional help is unavailable [7–10]. The RCT has ecological validity as it is planned to be

conducted in the general population, for which mobile interventions could be available if their effectiveness is shown. We plan a six months follow-up to conduct a longer-term evaluation and check the sustainability of the potential change in the user's behavior - it is a crucial factor for relapse prevention through the management of craving. A limitation of the present study should be mentioned: the dropout level is expected to be high based on the previous studies [49,50].

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Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of the Institute of Psychology Polish Academy of Science Ethics Committee (14/VIII/2021).

Informed consent statement

Informed consent was obtained from all subjects involved in the study.

Data availability statement

Not applicable.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

Acknowledgments

Not applicable.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2023.101180.

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