Patterns of Use and Withdrawal Syndrome in Dual Cannabis and Tobacco Users: Mixed-Methods Study Protocol (DuCATA_GAM-CAT)

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Abstract

Background: Approximately one in six cannabis users develops a cannabis use disorder (CUD) and the odds increasing to one in two among daily users.

Objective: The DuCATA_GAM-CaT project aims to identify cannabis-tobacco withdrawal symptoms among individuals with CUD who are attending substance abuse programs (SAP).

Methods: The project employs a mixed-methods approach consisting of three studies. First, a participatory qualitative study involves focus groups comprised of individuals with CUD, clinicians, project researchers, and an expert gamification company to co-design a gamified web application. Second, a longitudinal prospective study follows individuals with CUD attending SAP for six weeks. Participants report their cannabis-tobacco usage patterns, type and frequency of tobacco use, nicotine dependence, withdrawal symptoms, psychoemotional factors, and motivation to quit both substances. Predictive analysis techniques are employed to analyze clinical, demographic, psychological, and environmental data to predict the probability of achieving abstinence. Third, homogeneous focus groups are conducted to explore participants' experiences during their CUD treatment.

Results: As of April 2024, the project has completed the first study, defining eligible cannabis user profiles, developed the initial webapp prototype, and initiated recruitment across 10 centers, with 60 participants enrolled, aiming for 150 participants soon.

Conclusions: All participants provide informed consent, and their information is kept confidential and anonymized in accordance with confidentiality rules. The research team is committed to disseminating the results obtained to professional and patient groups, as well as informing public health agents, in order to positively influence political and social decision-makers and design programmers. Additionally, we aim to prioritize publication of the results in high-impact journals specializing in drug abuse, public health, and health care services research. Clinical Trial: The DuCATA project has been registered at Clinicaltrials.gov under the identifier [NCT05512091].

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ABSTRACT

Background. Approximately one in six cannabis users develops a cannabis use disorder (CUD) and the odds increase to one in two for daily users.

Objective. The DuCATA_GAM-CaT project (Dual use of Cannabis and Tobacco Monitored though a Gamified Webapp) aims to identify cannabis-tobacco patterns of use and withdrawal symptoms among individuals with CUD who are attending substance abuse programs (SAP).

Methods. The project employs a mixed-methods approach consisting of three studies. First, a participatory qualitative study involves focus groups comparising individuals with CUD, clinicians, project researchers, and an expert gamification company to co-design a gamified web application. Second, a longitudinal prospective study to follow individuals with CUD attending SAP over six weeks. Participants report their cannabis-tobacco usage patterns, type and frequency of tobacco use, nicotine dependence, withdrawal symptoms, psychoemotional factors, and motivation to quit both substances. Predictive analysis techniques are employed to analyze clinical, demographic, psychological, and environmental data to predict the probability of achieving abstinence. Third, homogeneous focus groups to explore participants' experiences during their CUD treatment.

Results. By June 2024, the project had completed the first study, defining eligible cannabis user profiles, developed the initial webapp prototype, and initiated recruitment across 10 centers, with 74 participants enrolled, aiming to reach 150 participants soon.

Conclusions. All participants provide informed consent, and their information is kept confidential and anonymized following confidentiality rules. The research team is committed to disseminating the results obtained to professional and patient groups, as well as informing public health agents, to positively influence political and social decision-makers and design programmers. Additionally, we aim to prioritize the publication of the results in high-impact journals specializing in drug abuse, public health, and health care services research.

Trial registration number. The DuCATA project has been registered at Clinicaltrials.gov under the identifier [NCT05512091].

Keywords. cannabis, tobacco, substance abuse, withdrawal symptoms

INTRODUCTION

Cannabis and tobacco use

Cannabis has emerged as the most widely used illegal drug globally [1]. In Spain, it also holds the status of the most commonly used illegal drug. According to the latest survey conducted in Spain in 2019, 37.5% of adults aged 15-64 have experimented with cannabis at some point in their lives, with 10.5% reporting usage in the last month (men: 11.4%; women: 4.7%) [2]. Furthermore, approximately one in six cannabis users develop a cannabis use disorder (CUD) and the odds are increasing to one in two among daily users [2].

In Western countries, cannabis use is commonly intertwined with tobacco**,** resulting in a significant prevalence of combined usage that continues to rise [3]. For instance, in the United States, the daily use of both substances remained stable over the years from 2005 to 2014, with a usage percentage of 6%. This proportion is higher than that of individuals who consume only cannabis without tobacco, which is around 2% [4]. However, it's important to note that dual cannabis and tobacco use, or co-use, can manifest in various patterns: (i) concurrent use, where both substances are consumed simultaneously in the form of joints, which is the most prevalent form of cannabis use in Europe [3, 5, 6]; sequential concurrent use, involving the use of cannabis followed by tobacco or vice versa; (iii) asynchronous concurrent use, characterized by cannabis and tobacco usage within the past month but not necessarily during the same instance of consumption; and (iv) exclusive cannabis use, where tobacco is not involved [4].

Moreover, dual cannabis-tobacco use entails a nuanced description of dependence diagnosis for both substances collectively and individually, alongside the emergence of withdrawal symptoms, particularly when cannabis consumption is reduced or halted [7–9]. Cannabis withdrawal symptoms typically manifest within two to four days after a reduction or cessation of consumption, peak during the first week, and may persist for up to four weeks [10]. The cannabis withdrawal syndrome is recognized and included in the Diagnostic and Statistical Manual of Mental Disorders, DSM-5 [11]. It is characterized by symptoms such as irritability, anger or aggression, nervousness or anxiety, sleep difficulties (e.g., insomnia, disturbing dreams), decreased appetite or weight loss, restlessness, depressed mood, and at least one of the following physical symptoms causing significant discomfort: abdominal pain, shakiness/tremors, sweating, fever, chills, or headache. The symptoms can be assessed using the "Cannabis Withdrawal Checklist" scale. While this scale has been validated [12] and utilized primarily in English-speaking populations [13–16] its applicability elsewhere warrants consideration.

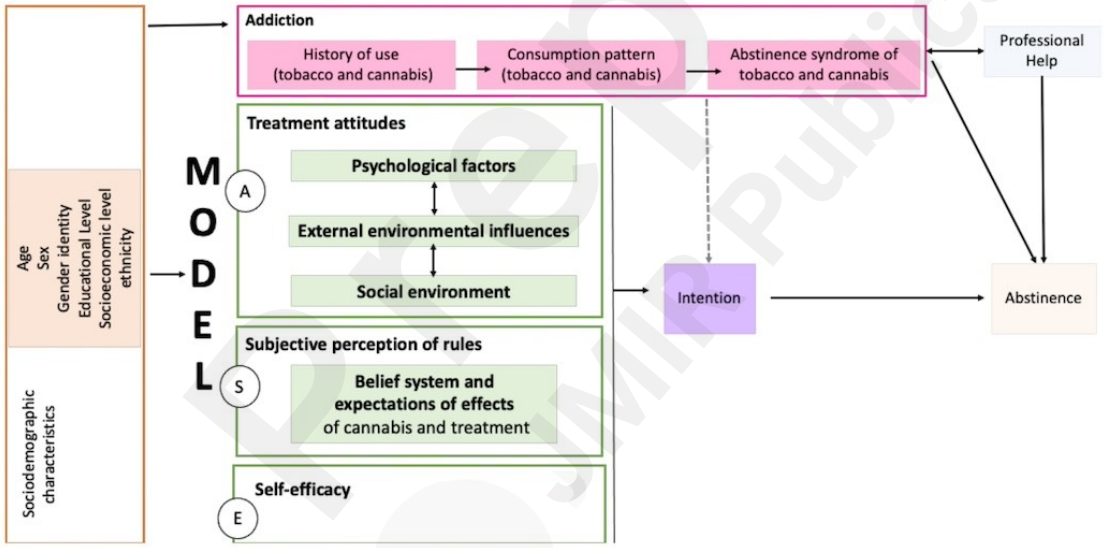
A meta-analysis has estimated that 47% of cannabis users experience withdrawal syndrome upon cessation, with its occurrence often linked to tobacco use [9]. Additionally, the severity of the cannabis withdrawal syndrome inversely affects the likelihood of successful cessation, with more severe symptoms correlating with lower rates of quitting [9]. Given that cannabis withdrawal syndrome frequently contributes to relapse [17], resulting in modest rates of abstinence maintenance, it's noteworthy that only 30% of individuals who undergo treatment manage to sustain abstinence during the initial month [18]. Various factors contribute to relapse, including the use of other psychoactive substances [19], psychological variables (emotions, social pressure, etc.), perceptions

of social norms, self-efficacy [20], and sociodemographic variables (sex, age, ethnicity, etc.) [16].

Cannabis and tobacco dependence withdrawal syndromes

The limited number of studies conducted on individuals undergoing treatment for cannabis use disorder (CUD) who also use tobacco fail to provide sufficient insight into the interaction between the consumption patterns of both substances. Consequently, there exists a potential misclassification of withdrawal syndromes between cannabis and tobacco [10, 21]. As a result, the influence of cannabis and tobacco dependence, along with their respective withdrawal syndromes, on cannabis use remains unclear, particularly in conjunction with other cognitive and environmental factors previously associated with substance use and cessation. Drawing from the social science literature and conceptual models that aid in understanding individual behaviors, we propose utilizing the Attitudes, Social Influences, and Efficacy (ASE) Model [20] to decipher the factors affecting cessation and maintenance processes. Therefore, we integrate this model [20] with individual attributes (such as sex, age, socioeconomic status, etc.) and addiction characteristics (smoking pattern, dependence, etc.) to unravel this intricate phenomenon (see Figure 1).

Figure 1. Logic Model of the study (De Vries, 1988).



ASE model applied to understand the cannabis-tobacco dual use and withdrawal.

The lack of a detailed characterization of the influence of tobacco and cannabis use is partly due to the absence of techniques enabling real-time assessment, such as Ecological Momentary Assessment (EMA) [22]. While these powerful tools have been employed to characterize and predict patterns among individuals with alcohol use disorder [23, 24], they have yet to be utilized among cannabis users. Consequently, the combination of these tools could facilitate the characterization of the prevalence and patterns of dual cannabis-tobacco consumption, including a detailed description of the severity and types of symptoms experienced by users during cannabis withdrawal syndrome.

Consequently, due to limited knowledge regarding (1) how tobacco impacts cannabis withdrawal

syndrome and (2) the effect of dual consumption on dropout probabilities during CUD treatment, we propose the DuCATA study. This mixed-methods project encompasses three studies (qualitative, quantitative, and mixed-methods) with a clinical and epidemiological focus, enabling the characterization and monitoring of consumption and withdrawal syndromes of cannabis and/or tobacco among individuals initiating treatment for CUD. The monitoring of dual cannabis-tobacco use and withdrawal symptoms will be conducted via a prospective follow-up of participants utilizing a gamified web application [25] based on the EMA Model [22, 26] facilitating real-time collection of participants' consumption and symptoms based on their daily experiences. Gamification, through the incorporation of gaming elements, encourages active user participation in data reporting, thereby enhancing adherence to the registry and improving data quality [25] .

This knowledge bears significant implications for clinical practice and public health, as it will provide precise insights into the characteristics of dual cannabis-tobacco users, a profile increasingly prevalent in programs. Moreover, it will enable us to utilize and validate an instrument developed in April 2023 for monitoring cannabis withdrawal symptoms among the Spanish population and investigating nicotine dependence. Ultimately, we are confident that comprehending and describing the dual use of cannabis-tobacco will equip future studies with a tool to accurately assess this complex phenomenon and facilitate the design of tailored interventions.

Study objectives

The research aims of the "Characterization of the pattern of consumption and withdrawal syndrome of dual use of cannabis and/or tobacco in people with CUD who start cessation treatment: DuCATA study" can be described as follows, indicating the studies in which each objective falls:

Objective 1 (First Study): Determinate the treatment preferences of individuals with CUD, based on age (18-34, >=35 years) and sex, for the design of a gamified webapp.

Objective 2 (Second Study): Examine the consumption patterns of cannabis and tobacco products among individuals seeking help to reduce and/or quit their cannabis use. This includes considering structural determinants of inequality (age, sex, social class/educational level, territory) and clinical history (use of other substances, psychiatric comorbidity, etc.), and identifying different typologies of cannabis-tobacco users, such as concurrent use, sequential use, asynchronous use, and exclusive cannabis use.

Objective 3 (Second Study): Analyze changes in tobacco use during the cannabis treatment process based on the identified typologies of cannabis-tobacco users and the level of clinical care they receive (with or without assistance for quitting tobacco).

Objective 4 (Second Study): Validate the "Cannabis Withdrawal Checklist" scale in the Spanish population and explore the relationship between the intensity and duration of craving and abstinence.

Objective 5 (Second Study): Describe and predict the likelihood of cannabis and tobacco abstinence based on consumption patterns (e.g., type of consumption), psychological factors (trait and state),

and contextual factors (e.g., environment, social influences, activities) while considering structural determinants of inequality.

Objective 6 (Third Study): Investigate the clinical experiences of individuals undergoing treatment for CUD, taking into account their typologies, age, and sex.

In conclusion, the "DuCATA study" aims to achieve six objectives across different studies. These objectives involve understanding treatment preferences for CUD through a gamified webapp, examining the patterns of cannabis and tobacco use among individuals seeking help, validating assessment scales, and exploring clinical experiences.

METHODS

Project design

The project adopts a sequential mixed-methods research design encompassing three studies. The first study, a qualitative participatory action study aimed at addressing Objective 1 by exploring key elements pertinent to the co-design of the gamified webapp. The second study is a prospective longitudinal (cohort) study targeting objectives 2 to 5 to quantitatively examine implementation and effectiveness outcomes. The third is a qualitative phenomenological study addressing objective 6 to delve into participants' experiences within the project. This integrated approach enables a comprehensive investigation into the patterns of consumption and withdrawal syndrome associated with dual cannabis and/or tobacco use among individuals undergoing cessation treatment for CUD, synthesizing qualitative insights with quantitative findings to provide a holistic understanding of the research objectives.

Ethics approval and consent to participate:

Human subject ethics review approvals or exemptions: The study protocol has been reviewed and approved by the Hospital Universitari de Bellvitge Ethics Committee (Ref. PR328/19) and registered on www.clinicaltrials.gov [NCT05512091] [27]. The research complies with institutional guidelines and adheres to Law 3/2018 of Personal Data Protection and the General Data Protection Regulation 2016/679 of the European Union.

Informed consent: All participants have provided or will provide informed consent before participating in the study. They have been or will be informed of their right to drop out at any time without any negative consequences. For any secondary analyses utilizing existing data, the original consent includes permission for secondary analysis without the need for additional consent.

Privacy and confidentiality: The confidentiality of all information has been or will be ensured, and the research team has adhered or will adhere strictly to confidentiality rules. Data will be anonymized to protect participant privacy. If data cannot be anonymized, protective measures will be in place to safeguard participant information.

Compensation details: Participants do not receive monetary compensation for their participation. Instead, they are thanked and acknowledged for their valuable contribution to the research.

First study: Development of a Gamified Webapp.

Objective*:* To develop a gamified webapp co-designed by the research team and potential users.

Method*:* This study employs a participatory action approach, utilizing focus groups to explore the perspective of potential users and ensure high usability and adherence. Subjects include ten cannabis-tobacco users or former users selected from three substance abuse programs (SAP) in Barcelona province, based on purposive sampling and inclusion criteria of age ≥18, undergoing treatment for cannabis use, and owning a smartphone. The focus groups consist of 5 participants, homogeneously grouped by sex and age profiles, with sessions lasting 60 to 90 minutes. Both focus groups and participatory activities are conducted, engaging participants in discussions and interactive exercises while recording conversations for analysis. Each group is led and coordinated by three individuals, including an expert in qualitative research, a webapp developer, and a project investigator member.

Recruitment: Purposive sampling is employed to recruit participants meeting the inclusion criteria. The eligibility criteria are determined by yhe clinicians of the SAP centers that collaborate in the study.

Data collection technique*:* Focus groups and participatory activities, were employed, consisting of two pilot sessions (where a homemade board game was used to explore participants' gaming preferences), and three participatory sessions (including two exploratory sessions with clinicians and former cannabis users to profile this population, and a third session of in-depth interviews to explore into participants' personal experiences overcoming cannabis use). These sessions were conducted to gather pertinent information for webapp design. Each session involved discussions among participants to explore various themes, such as users' experiences with gamified webapps, expectations and preferences regarding app features, preferred game types, and personal experiences related to cannabis use.

Data analysis: Transcriptions of focus group discussions and participatory activities serve as primary data for analysis, involving familiarization, coding, theme development, data interpretation, and validation. The thematic categorical content analysis will be conducted using Atlas-ti. Based on these findings, a webapp prototype is developed.

Design of the webapp: With input from participating groups, an external company experienced in gamified webapp design, along with patients and researchers, designs the webapp prototype. The prototype incorporates variables of interest in an engaging manner. The same participants involved in co-design will pilot the webapp.

Second Study: Monitoring Patterns of Cannabis and Tobacco Use among a Cohort of Cannabis Users searching for treatment

Objective*:* To monitor patterns of use of cannabis and tobacco, withdrawal symptoms, abstinence, and other indicators among cannabis users.

Method: This study employs a prospective longitudinal follow-up approach. The inception cohort consists of cannabis users attending Substance Abuse Program (SAP) centers in the province of Barcelona during 2023 to initiate treatment for their disorder.

Eligibility for centers and clinicians*:* All SAP coordinators in the province of Barcelona (48 centers) are contacted. We plan to recruit 10 to 14 centers, each recruiting 8 to 12 participants on average.

Recruitment*:* Clinicians recruit individuals who have commenced reducing or quitting cannabis use attending in SAP. Participants are invited to self-manage and self-report their cannabis-tobacco use and symptomatology through a gamified webapp and an external software that sends questionnaires regularly (every 6 days) to monitor other behavioral and contextual aspects. Before launching the study, the recruitment protocol is piloted in three SAP centers to make necessary adjustments for ease of recruitment by clinicians and increased acceptability among eligible participants.

Cohort members*:* Cannabis users beginning treatment for CUD at SAP centers in Catalonia.

Inclusion criteria: Participants must be over 18 years old, daily cannabis users regardless of tobacco consumption pattern or type, in treatment for cannabis use or another substance in a SAP, followed by collaborating clinicians, own a smartphone or computer with internet connection, commit to daily participation in the webapp for 6 weeks, have and use WhatsApp and email, and provide informed consent.

Exclusion criteria: Individuals unable to guarantee 6 weeks of follow-up, those without access to a device for 6 weeks, inability to read and understand Spanish, and moderate/severe cognitive limitations and/or severe psychopathology, which will be assessed by clinicians during consultation at the time of participant invitation.

Sample size: According to recent meta-analysis, the probability of cannabis cessation in this patient population treated using diverse therapeutic approaches is RR=1.48 (28). Given its heterogeneity, we will use a more conservative estimate (RR=1.20). Thus, with an alpha risk of 0.05, beta risk of 0.20 in a bilateral contrast, and accounting for 20% losses to follow-up, 282 subjects will be required. Approximately 2,000 people start treatment for cannabis use each year in Catalonia [28], making it feasible to recruit 282 subjects within a one-year period.

Instruments*:*

1) Gamified Webapp: developed in the first study to prospectively follow up participants and monitor cannabis and tobacco use, as well as identify withdrawal symptoms (see Table 1). The game of the gamified webapp was named DuCATA: Your heroic journey deserves to be told (the original name is: 'DuCATA: Tu viaje heroico merece ser contado').

Table 1. Variables included in the webapp to monitor tobacco and cannabis use

	Frequency	Variable	Description
1	Every 72 hours	Tobacco use in the last 48 hours	Have you used tobacco in the last 48 hours, with or without cannabis?
2	Every 72 hours	Cannabis use in the last 48 hours	Have you used cannabis in the last 48 hours?
3	Every 72 hours	Number of joints	How many joints have you consumed in the last 48 hours?
4	Every 72 hours	Cannabis reduction	Compared to 2 days ago, have you reduced your cannabis use?
5	Every 72 hours	Cannabis withdrawal checklist	Have you suffered any of these symptoms in the last 48? Shakiness/tremulousness Depressed mood Decreased appetite Nausea Irritability Sleep difficulty Sweating Craving to smoke marijuana Restlessness Nervousness/anxiety Increased aggression Headaches Stomach pains Strange dreams Increased anger

2) Monitoring Software: designed to record participants' recruitment, obtain their baseline information, and periodically send additional questionnaires to assess participant behavior, contextual factor, etc. (see Table 2). This software was created to carry out the study, and we have named it DuCATA software.

Table 2. Baseline and follow-up variables regarding sociodemographic characteristics, tobacco, cannabis use, attitudes, social norms, and motivation to quit of the participants (variables included in the monitoring software)

Variables	**Temporality**				
	Baseline before acceptance	Baseline after acceptance	6 days Software	18 days Software	Final Software
DEPENDENT VARIABLES					
Cannabis addiction	x	x	x		x
Cannabis use pattern	x	x	x		
Dependency severity		x	x		
Cannabis type and way of use		x		x	
Cannabis withdrawal symptoms		x	x		
Addiction to tobacco	x	x			x
Tobacco use pattern		x	x		
Nicotine dependence		x	x		
Alcohol addiction		x	x		

Attitudes		x			
Psychoemotional factors		x		x	
Social environment		x		x	
Subjective perception of norms		x		x	
Beliefs and expectations of consumption and treatment					x
Self-efficacy		x	x		
Level of approach in smoking/cannabis received		x			x
Motivation cannabis drop out		x	x		
Motivation tobacco drop out		x	x		
INDEPENDENT VARIABLES					
Recruiting center	x				
Sociodemographic variables		x			
Basic mental and physical health measures		x		x	
Family environment/Place of residence		x			

Primary quantitative effectiveness outcomes of the webapp in monitoring behavioral changes:

Endpoints: [A] variables reported every 3 days during 6 weeks within the webapp [B] variables collected in the external software at baseline and every 6 days.

Cannabis use: [A] Consumption of cannabis in the last 48 hours (yes/no), reduction of cannabis in the last 48 hours (yes/no), and cannabis abstinence or reduction requiring a cannabis withdrawal test. [B] Cannabis product used (hashish, marijuana, etc.), mode of administration (smoked, snorted, ingested, etc.), frequency of cannabis use in the last month and week, type of use (alone, accompanied, both), and reasons for use (addiction, recreational, social, sleeping, etc.).

Tobacco use: [A] tobacco consumption in the last 48 hours (yes/no) [B] Pattern of tobacco use: type of tobacco product/s (manufactured cigarettes, roll-your-own, electronic cigarettes, heated tobacco, or similar) frequency of use (daily and occasional), number of units (cigarettes, etc.), and nicotine dependence measured using the Heavy Smoking Index (0 to 6), classified as low [0-2], moderate [3-4], and high [5-6])[29, 30].

Abstinence from cannabis, tobacco, and both: [A] (yes/no) If abstinent of both substances we will ask for a CO measurement test (performed by their clinician and introduced in the software).

Cannabis-tobacco users will be classified as: concurrent use, sequential concurrent use, asynchronous concurrent use, and exclusive cannabis use.

ASE Model variables (Attitudes, Subjective Norm, and Self-efficacy) [B].

Attitudes: Motivation to quit measured on a Likert scale, psychological factors (states of change or

readiness to quit cannabis and tobacco, psychological distress) [31]. *Psychological distress* by using the General Health Questionnaire (GHQ-12) [32].

Self-perceived health status: will be assessed based on "How would you say your general health is?" (Excellent, very good, good, fair, fair, poor).

Self-Efficacy: defined as the individual's confidence to quit cannabis and/or tobacco [33] This will be assessed by asking participants, “To what extent do you feel capable of quitting cannabis consumption?” using a Likert scale ranging from 0 to 10 (0= very low to 10= very high).

Independent variables: Socio-demographic variables: [Baseline] Sex, age, education level, employment status, and occupation. Mental and physical health measures: Mental illness presence and comorbidities. Centers where care is received. Family environment: cohabitation, socioeconomic level, etc.

Implementation outcomes*:* To test the acceptability, appropriateness, and feasibility besides using the qualitative methodology explained above, we will quantitatively measure these dimensions amongst all the participants enrolled in the cohort. We will employ the scale developed by Weiner et. al. [34] that consists of 12 items scored from 1 (completely disagree) to 5 (completely agree). This evaluation will be conducted at the end of the follow-up period (6 weeks), and we will collect this information using a customized questionnaire administered via phone call or text message. Additionally, we will assess other implementation outcomes at the end of study 2 by gathering data on the following: Acceptability: The number of individuals who accept or decline to participate in the study. Fidelity/Adherence: The duration of participants' usage of the webapp, time devoted to playing, number of completed sessions, etc. Satisfaction: Participants' opinions about the proposed webapp. These variables will be measured using the metadata of the webapp (encrypted).

Recruitment Procedure*:* Clinicians verify participant eligibility using a checklist of inclusion and exclusion criteria. They provide oral and written information to potential participants through a leaflet containing study details and information about the study sponsors. Potential participants are informed about the study objectives, procedures, potential risks, benefits, confidentiality measures, and their right to withdraw at any time. This process ensures that only eligible participants who meet the criteria are enrolled in the study.

Additionally, clinicians show a short video explaining the purpose of the research and soliciting participants' collaboration (available at: https://youtu.be/K8-MdCRVzhU [35]). If participants agree to participate, they sign the informed consent and then complete a questionnaire with brief personal information (telephone number, email, name, and National Identity Document). Subsequently, participants register on the webapp and engage with the game daily.

Statistical methods: For independent variables, a descriptive analysis will be conducted, including frequencies, percentages, and their 95% confidence intervals**.** To assess effectiveness measures such as changes in cannabis-tobacco use, withdrawal syndrome, and treatment adherence, frequencies and percentages will be described for baseline and main assessment endpoints according to the four patterns of cannabis use: (i) concurrent, (ii) sequential concurrent, (iii) asynchronous concurrent, (iv)

exclusive cannabis. Incidence rates of abstinence and symptomatology will be calculated for the same assessment endpoints across the four patterns. Relative risks (RR) of quitting or reducing cannabis and tobacco, as well as quit attempts for both substances (95% CI), adjusted for independent variables and initial consumption pattern, will be calculated using Cox or Poisson robust regression models. Predictive analysis techniques including logistic regression and random forest will be utilized to model the probability of events occurring based on other factors. Time series analysis will be employed to observe consumption trends during follow-up, and survival analysis of recurring events will be conducted to observe abstinence or reduction processes among participants.

For all analyses, SPSS for Windows version 21, Python 3, R version 4.0.3 and Scikit-learn will be used. The level of significance will be set at 5% ($p<0.05$).

Third study: Assessment of the acceptability of the webapp.

Objective. To evaluate the acceptability of the webapp and investigate participant and clinician experiences during Study II, focusing on implementation outcomes.

Method*:* Qualitative phenomenology study employing participatory groups.

Sample*:* Participants will be selected from Study II cohort members based on their webapp usage experience. Four groups comprising 5-7 participants each are anticipated.

Recruitment*:* Purposive sampling will be utilized, targeting individuals meeting the inclusion criteria and having engaged with the webapp. Homogeneity criteria will be applied to ensure diversity across fidelity levels and gender: Group 1: High fidelity male users; Group 2: Low fidelity male users; Group 3: High fidelity female users; Group 4: Low fidelity female users.

Main themes*:* Exploration of barriers and opportunities encountered during webapp usage; Assessment of the utility of webapp monitoring for cannabis/tobacco use and mood; Identification of preferred and disliked features of the webapp.

Data collection technique*:* Focus groups, with an expected duration of 60 to 90 minutes. Conversations will be recorded to facilitate transcription and analysis while ensuring confidentiality. Each group will be facilitated by two individuals, including an expert in qualitative research and a project investigator.

Data analysis*:* Transcribed data will undergo analysis involving familiarization, coding, theme development, interpretation, and validation; the thematic categorical content analysis will be conducted using Atlas-ti. Insights garnered will inform the refinement of a webapp prototype.

RESULTS

By June 2024, significant progress had been achieved in the DuCATA_GAM-CaT project.

First study: Development of a Gamified Webapp.

Study 1, focusing on qualitative investigation through participatory focus groups, was completed, providing valuable insights into the profile of cannabis users eligible for the project.

Additionally, an initial prototype of the gamified web application has been developed, representing a critical advancement in addressing cannabis-tobacco withdrawal symptoms among individuals with Cannabis Use Disorder (CUD) attending Substance Abuse Programs (SAP).

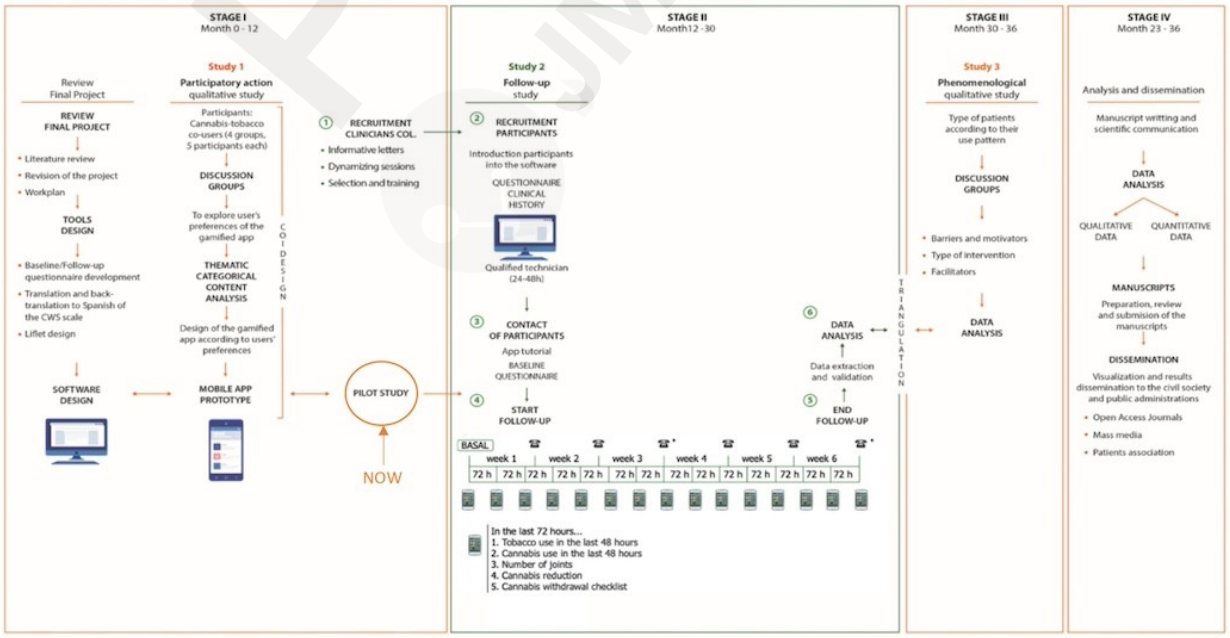
Second Study: Monitoring Patterns of Cannabis and Tobacco Use among a Cohort of Cannabis Users searching for treatment

Recruitment efforts have commenced across 10 centers, with 74 participants enrolled to date. We anticipate reaching our target enrollment of 150 participants shortly (see Figure 2). This longitudinal prospective study will track participants' cannabis-tobacco usage patterns, types and frequencies of tobacco use, nicotine dependence levels, withdrawal symptoms, psychoemotional factors, and motivation to quit both substances over a six-week period.

Third study: Assessment of the acceptability of the webapp.

Once Study 2 is finished, we will start this qualitative study, which is scheduled for January 2025.

Figure 2. Study timeline



DISCUSSION

To address the objective of the study, we aimed to characterize the patterns of cannabis and tobacco use among individuals initiating cannabis treatment at SAP centers, while also monitoring cannabis withdrawal syndrome in both tobacco users and non-users. Our primary objectives include acquiring knowledge and establishing the groundwork for a clinical intervention program theory.

Main Findings: Our study will provide insights into the diverse patterns of cannabis and tobacco use among participants entering treatment at SAP centers. We will identify their symptomatology if cannabis withdrawal syndrome appears, whether in combination with tobacco use or alone, which will help us determine the overlap of the symptoms.

Additionally, the mixed-method design of our study will allow for the triangulation of results from various perspectives, facilitating a comprehensive understanding of the phenomena under investigation.

Comparison to prior work: We will compare our results with the scarce literature on the topic. We will be able not only to understand the complexity of use and withdrawal symptoms but also to explore the use of a gamified app for monitoring several variables of interest.

Strengths and Limitations: A key strength of our study lies in its methodological rigor, combining qualitative exploration with quantitative measurement. However, the study is limited by its observational nature and the potential for self-report biases in substance use reporting.

Future Directions: Moving forward, these findings can inform the development of targeted intervention strategies aimed at cannabis cessation, whether used exclusively or in combination with tobacco. Future studies could further explore specific intervention protocols and assess their efficacy in diverse clinical settings.

Conclusion: In conclusion, our study contributes valuable insights into the complex interplay between cannabis and tobacco use behaviors and withdrawal symptoms. These findings lay a foundation for future research and intervention efforts aimed at addressing cannabis use disorder within substance abuse treatment programs.

List of abbreviation

DuCATA: Dual users of Cannabis and Tobacco
GAM-CaT: Gamification Cannabis and Tobacco
CUD: Cannabis Use Disorder
DSM-V: Diagnostic and Statistical Manual of Mental Disorders
ASE model: Attitudes, Social, Influences and Efficacy Model
EMA: Ecological Momentary Assessment

SAP: Substance Abuse Program
RR: Relative Risks

DECLARATIONS

Consent for publication

Not applicable

Availability of data and materials

Data is available upon request. Informants have been anonymized to protect their personal data.

Competing interests

None declared.

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Authors' Contributions

JS: conceptualization, methodology, investigation, formal analysis, writing-original draft, supervision, AF: conceptualization, methodology, investigation, ME: investigation, project administration, writing-review & editing, MF: investigation, writing-review & editing, MB: investigation, writing-review & editing, YC: formal analysis, writing-review & editing, MP: investigation, writing-review & editing, NR: investigation, writing-review & editing, PR: investigation, writing-review & editing, EM: investigation, writing-review & editing, CC:

conceptualization, methodology, investigation, writing-review & editing, supervision, JC: investigation, writing-review & editing, supervision, JMS: investigation, writing-review & editing, SM: investigation, writing-review & editing. PB: investigation, writing-review & editing. MA: investigation, writing-review & editing. AR: investigation, writing-review & editing. JB: investigation, writing-review & editing, JV: software, investigation, writing-review & editing, XR: investigation, writing-review & editing, JG: investigation, writing-review & editing, EF: conceptualization, methodology, investigation, CM: conceptualization, methodology, investigation, data curation, writing-original draft, supervision, funding acquisition.

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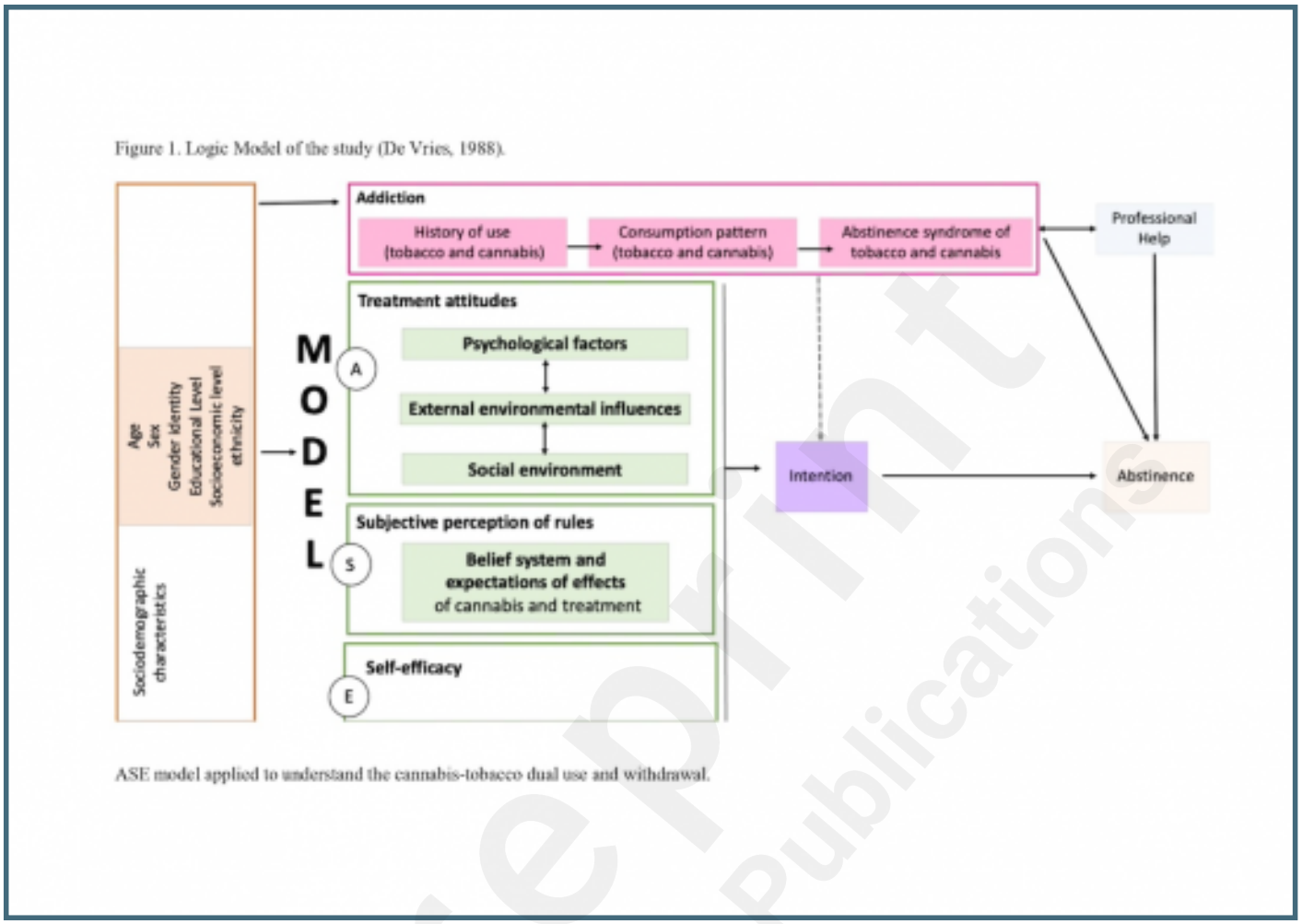
Supplementary Files

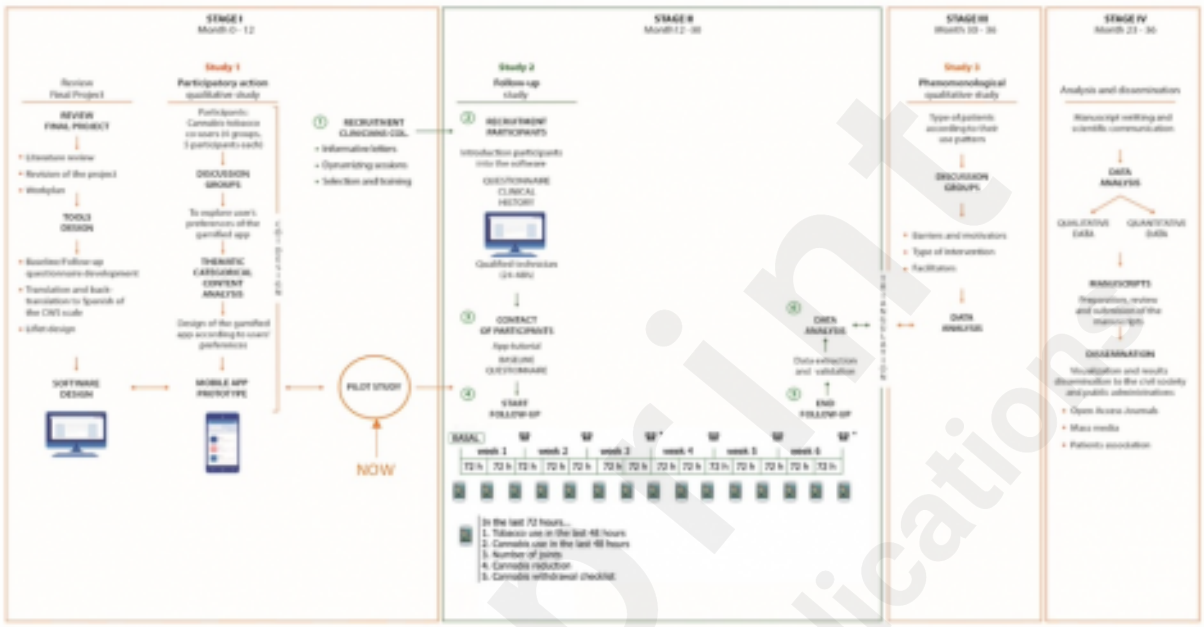
Figures

Logic Model of the study (De Vries, 1988).



Study timeline.

Figure 2. Study timeline



Related publication(s) - for reviewers eyes onlies

Funding surces (PhD candidate).
URL: http://asset.jmir.pub/assets/3e28e907e1b8ec2817a664975c56e51d.pdf