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A pilot randomized controlled trial of a digital cannabis harm reduction intervention for young adults with first-episode psychosis who use cannabis

Stephanie Coronado-Montoya [a,b], Amal Abdel-Baki [a,c], Paule Bodson-Clermont [b], David Boucher-Roy [b], José Côté [b,d], Candice E. Crocker [e], David Crockford [f,g], Jean-Gabriel Daneault [h], Simon Dubreucq [a,b], Maxime Dussault-Laurendeau [i], Benedikt Fischer [j,k,l,m,n], Pamela Lachance-Touchette [b], Tania Lecomte [o,p], Sophie L'Heureux [q,r], Clairélaine Ouellet-Plamondon [a,b,c], Marc-André Roy [r,s,t], Ovidiu Tatar [a,b], Philip G Tibbo [e], Marie Villeneuve [a], Anne Wittevrongel [b], Didier Jutras-Aswad [a,b,c,u,*]

[a] Department of Psychiatry and Addiction, Université de Montréal, Montréal, Canada
[b] Research Centre, Centre Hospitalier de l'Université de Montréal, Montréal, Canada
[c] Department of Psychiatry, Centre Hospitalier de l'Université de Montréal, Montréal, Canada
[d] Faculty of Nursing, Université de Montréal, Montreal, Canada
[e] Department of Psychiatry, Dalhousie University, Halifax, Canada
[f] Department of Psychiatry, University of Calgary, Calgary, Canada
[g] Hotchkiss Brain Institute, University of Calgary, Calgary, Canada
[h] Hôpital en santé mentale Albert-Prévost, Montréal, Canada
[i] Hôpital Charles Lemoyne, Greenfield Park, Canada
[j] Faculty of Health Sciences, Simon Fraser University, Vancouver, Canada
[k] Research & Graduate Studies Division, University of the Fraser Valley, Abbotsford, Canada
[l] Waypoint Research Institute, Waypoint Centre for Mental Health Care, Penetanguishene, Canada
[m] Department of Psychiatry, University of Toronto, Toronto, Canada
[n] Department of Psychiatry, Federal University of Sao Paulo, Sao Paulo, Brazil
[o] Department of Psychology, University of Montreal, Montreal, Canada
[p] Centre de Recherche de l'Institut Universitaire en Santé Mentale de Montréal, Montréal, Canada
[q] Clinique Notre-Dame des Victoires, Institut Universitaire en Santé Mentale, Centre Intégré Universitaire de Santé et Services Sociaux de la Capitale Nationale, Québec, Canada
[r] Department of Psychiatry and Neurosciences, Laval University, Québec, Canada
[s] Centre de Recherche de l'Institut Universitaire en Santé Mentale de Québec, Québec, Canada
[t] Centre de Recherche CERVO, Quebec, Canada
[u] University Institute on Addictions, Montreal, Canada

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ABSTRACT

Cannabis use is widespread and associated with worsened prognosis for young adults with first-episode psychosis (FEP). Few cannabis harm reduction interventions have been evaluated for this population, despite potential to improve outcomes in those not ready for cannabis abstinence/reduction-focused interventions. This study aimed to determine a) the acceptability of a digital harm reduction intervention, the Cannabis Harm-reducing App to Manage Practices Safely (CHAMPS) and b) the feasibility of conducting a trial comparing FEP-specialized early intervention services (EIS)+CHAMPS versus EIS-only with this population. We conducted a multi-site pilot randomized controlled trial comparing both arms in 101 young adults (18 - 35 years old) with FEP using

Abbreviations: App, application; CHAMPS, Cannabis Harm-reducing App to Manage Practices Safely; CSQ, Client Satisfaction Questionnaire; CUD, cannabis use disorder; EIS, early intervention services; FEP, first-episode psychosis; MPS, Marijuana Problems Scale; PANSS, Positive and Negative Syndrome Scale; PBSM, Protective Behavioral Strategies- Marijuana; RCQ, Readiness-to-Change Questionnaire; RCT, randomized controlled trial; REDCap, Research Electronic Data Capture; SD, standard deviation; SDS, Severity of Dependence Scale; TLFB, TimeLine FollowBack.

* Corresponding author at: CHUM Research Centre, 900 St-Denis, Viger Tower, room R05.746, Montréal, Québec, Canada H2X1P1.
E-mail address: didier.jutras-aswad@umontreal.ca (D. Jutras-Aswad).

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cannabis and attending EIS. Primary outcomes were trial retention rate (i.e., proportion of randomized participants retained at week 6; trial feasibility assessment) and CHAMPS completion rate (i.e., proportion of intervention participants completing four of six modules; CHAMPS acceptability assessment). Trial retention rate above 60 % indicated feasibility and completion rate above 50 % indicated acceptability. Additional outcomes included harm reduction strategy use, motivation to change cannabis behaviors, cannabis-related problems, cannabis use, psychotic symptoms and dependence severity, assessed at baseline, weeks 6, 12 and 18. Trial retention was 82.2 % and completion rate was 58.8 %, suggesting trial feasibility and CHAMPS acceptability. Signals of possible improvement in the intervention group were observed regarding harm reduction strategy use, motivation to change behaviors, cannabis-related problems and cannabis use frequency. This study supports conducting an efficacy trial assessing the potential of CHAMPS in improving outcomes for young adults with psychosis using cannabis.

1. Introduction

Young adults with first-episode psychosis (FEP) report widespread cannabis use and are particularly vulnerable to adverse outcomes related to cannabis use. These harms include longer hospitalizations, more frequent psychotic relapses, worse psychosocial functioning and worse treatment adherence (Bioque et al., 2022; Schoeler et al., 2016). Cannabis use disorder (CUD) is more common in young people with FEP (39 %−43 %) (Abdel-Baki et al., 2017b; Koskinen et al., 2009) than in the general population (2 %−7 %) (Choi et al., 2024; Compton et al., 2019). While the exact relationship between cannabis and psychosis remains unclear, with greater support for bi-directional or multiple factor models (Khokhar et al., 2018; Ksir and Hart, 2016), strong evidence highlights how cannabis use can impact the development and prognosis of psychosis (Bozzatello et al., 2019; Di Forti et al., 2015), rendering it a key modifiable risk factor and treatment target.

Interventions addressing cannabis use-related outcomes in people with FEP have primarily aimed for abstinence or use reduction (Coronado-Montoya et al., 2021; Hunt et al., 2019; Temmingh et al., 2018). These interventions have demonstrated relatively limited efficacy and reported suboptimal rates of engagement, ranging from 0 % - 59 % (Coronado-Montoya et al., 2021). There is no gold-standard treatment for CUD in people with FEP, and it is worth considering whether interventions exploring alternative outcomes (e.g., safer cannabis use) could also benefit this population.

Increasingly, clinicians, researchers and people with psychosis are advocating for the incorporation of cannabis harm reduction interventions into treatment strategies offered (Petros et al., 2023; Tatar et al., 2021). Harm reduction interventions have decreased use-related harms from other substances, such as alcohol use (Perrin et al., 2024). Cannabis harm reduction interventions can appeal to a broad spectrum of young adults with psychosis that are ready to modify their cannabis use-related behaviors to attain safer cannabis use, although not necessarily cease their cannabis use. The Lower-Risk Cannabis Use Guidelines is an example of a cannabis harm reduction tool (Fischer et al., 2022), also tailored for people with psychosis (Fischer et al., 2023). It provides evidence-based recommendations for safer cannabis use behaviors, including choosing products with lower delta-9-tetrahydrocannabinol or avoiding mixing cannabis with other substances. Of existing harm reduction tools, few have been translated into applicable, formal interventions for young adults with FEP (Coronado-Montoya et al., 2021).

Key barriers to implementing cannabis-focused interventions for young adults with FEP include lack of formal clinician training on cannabis interventions and heavy clinician workloads, with digital interventions suggested as potential solutions to these barriers (Tatar et al., 2021). Notably, young adults with FEP prefer cannabis harm reduction interventions to be delivered digitally rather than in-person (Coronado-Montoya et al., 2023b). Studies have suggested the acceptability and potential feasibility of digital interventions among young adults with FEP (Abdel-Baki et al., 2017a; Lal et al., 2015). Digital psychosocial interventions may provide certain benefits over in-person psychosocial treatments, such as timeliness, affordability and improved intervention accessibility (Pennou et al., 2019; Sugarman et al., 2017). Digital cannabis harm reduction interventions may be a promising avenue to explore for these individuals, especially since they align with patient preferences, which can improve intervention engagement (Pelletier et al., 2013; Tambuyzer and Van Audenhove, 2015).

1.1. Aims

To address the significant treatment gap for cannabis use among young adults with FEP, we developed the *Cannabis Harm-reducing App to Manage Practices Safely* (CHAMPS), a smartphone application (app)-based harm reduction intervention. Given its novelty in this population, we aimed to conduct a pilot randomized controlled trial (RCT) exploring CHAMPS as an adjunct intervention to early intervention services (EIS), the standard care for psychosis.

The primary objectives were to assess a) the feasibility of conducting a full-scale RCT comparing EIS+CHAMPS versus EIS-only in individuals with FEP using cannabis, measured by trial retention at week 6, and b) the acceptability of CHAMPS, measured by intervention completion. Secondary objectives explored changes in the use of cannabis harm reduction practices, motivation to change cannabis practices, cannabis-related problems, cannabis use, dependence severity and psychotic symptoms.

2. Methods

2.1. Design

A multi-site, parallel, two-arm, pilot RCT was conducted. This study was registered a priori on ClinicalTrials.gov (NCT04968275), and its protocol was published, which detailed the design of this trial and the CHAMPS intervention (e.g., allocation schedule, screening procedures, assessment descriptions) (Coronado-Montoya et al., 2023a). Results were reported in accordance with the extension of the Consolidated Standards of Reporting Trials statement for randomized pilot trials (Appendix A) (Eldridge et al., 2016). This study received ethical approval from the lead site, Centre Hospitalier de l'Université de Montréal (#20.433) and was conducted in accordance with best clinical practices and applicable regulatory requirements. Local ethical approval was obtained at each site.

2.2. Participants

Participants were recruited from six EIS sites in Nova Scotia and Quebec, Canada, from December 2021 to June 2023.

2.2.1. Inclusion/exclusion criteria

Eligible participants were 18 to 35 years old, had a psychotic disorder (e.g., schizophrenia spectrum disorder, mood disorder with psychotic features, substance-induced psychosis), attended EIS for minimum 3 months, used cannabis in the last 30 days, expressed interested in changing cannabis-related practices, provided informed consent, agreed to study procedures, and could read French or English.

Although young adulthood is often defined as under 25 or 30, we adopted the EIS age range (up to 35) to align with site practices and facilitate recruitment (Bertulies-Esposito et al., 2020). To allow for psychosis stabilization and some engagement in care, a minimum of 3 months in EIS care was required, with no maximum duration. Given the harm reduction focus, eligibility was based on self-reported cannabis use and desire to modify cannabis practices to reduce harms, rather than use frequency or CUD diagnosis. Psychotic disorder and CUD diagnoses were clinician-assessed using the Diagnostic and Statistical Manual of Mental Disorders, 5th edition (American Psychiatric Association, 2013). To determine interest in changing practices, clinical staff asked whether individuals were open to modifying their cannabis practices and provided examples (e.g., changing consumption methods, frequency, product types).

Individuals were ineligible if not meeting all aforementioned criteria, if participating in another cannabis-focused intervention, or if seeking CUD treatment to stop or decrease cannabis use. Those with CUD seeking CUD treatment were referred to a parallel treatment trial (Tatar et al., 2022).

2.2.2. *Randomization and blinding*

Participants were randomized in a 1:1 ratio to EIS+CHAMPS or EIS-only. Randomization was stratified by sex and CUD diagnosis (has CUD/no CUD) using permuted blocks of random size. The allocation sequence was generated by the lead site's Center for Integration and Analysis of Medical Data and randomization code access was controlled by the lead site's data management team. Research staff conducting the initial data analysis as per the statistical analysis plan were blinded to group assignment for all data except usage data and CHAMPS completion rate. Participants were not allowed to switch arm assignments. The control group was offered access to CHAMPS after trial completion (data not analyzed).

2.3. *Interventions*

Participants in the EIS-only arm (i.e., "Control") received standard EIS care at participating sites (see (Coronado-Montoya et al., 2023a)). Briefly, EIS are integrated services for people with FEP, which include psychosocial interventions (e.g., cognitive behavioral therapy, substance use interventions) and pharmacological interventions (e.g., antipsychotics). In Canada, EIS are guided by provincial and international guidelines for FEP (Early Psychosis Guidelines Writing Group and EPPIC National Support Program, 2016; Ministère de la Santé et des Services sociaux, 2022). While Canadian EIS guidelines emphasize addressing substance use, particularly through motivational interviewing and cognitive behavioral therapy, delivery varies: only 12 % of English-speaking and 57 % of French-speaking EIS programs offered cannabis-specific interventions (Aydin et al., 2016; Bertulies-Esposito et al., 2022). Most provided motivational interviewing, cognitive behavioral therapy and psychoeducation. Typically, people with FEP not wanting to stop or decrease their cannabis use receive cannabis use psychoeducation as standard of care. EIS delivery may have varied across sites.

EIS+CHAMPS arm (i.e., "Intervention") participants received the CHAMPS intervention and EIS usual care. CHAMPS, available in English and French, was a brief, self-guided digital psychosocial intervention for young adults with FEP, grounded in the Behavior Change Wheel framework (Coronado-Montoya, 2024; Michie et al., 2011). This framework integrates 19 behavior change frameworks, is useful for designing behavioral interventions, and has been applied in the context of people at risk of psychosis (Carney et al., 2016). CHAMPS incorporated motivational interviewing and harm reduction principles to encourage behavior change and promote safer cannabis use.

The app reflected user preferences for brief, digital cannabis interventions (Coronado-Montoya et al., 2023b) and focused on harm reduction strategies (e.g., avoiding polysubstance use, avoiding using to cope with negative emotions, limiting consumption per sitting). The CHAMPS intervention was co-designed with young adults having experienced psychosis and problematic cannabis use, clinicians and cannabis and psychosis experts.

CHAMPS consisted of six modules over six weeks, and a booster session four weeks later. The intervention guided participants through a reflection of their cannabis practices and impacts on their lives (modules 1 and 2), taught harm reduction strategies (module 3) and goal-setting skills (module 4), and assisted in setting personalized harm reduction-related goals (modules 4 - 6). The booster session was a single session that reinforced key intervention components and self-established goals. Additional content was available at discretion, including articles (e.g., "Managing craving") and testimonial videos co-produced with people with lived experience.

Accompanying EIS clinicians were instructed to encourage app use and offer support as needed, and not to influence participant responses in CHAMPS. Support could be technical (e.g., navigating app) or clinical (e.g., reviewing goal progress) in nature. With participant consent, clinicians could access the participant dashboard, which showed high-level app data (e.g., modules completed, select responses); no other participant data was shared.

2.4. *Measures*

Study measures will be briefly introduced below. Unless otherwise specified, measures were administered at four timepoints: baseline, week 6 (immediate post-intervention assessment), week 12 (follow-up assessment), and week 18 (follow-up assessment).

2.4.1. *Sociodemographic and clinical data*

A questionnaire administered at baseline collected the following demographic information: age, sex, gender, ethnicity, education, marital status, occupation status, annual income, living situation. Data on clinical variables such as psychotic disorder and CUD diagnoses were collected. Social support was assessed using the 10-item Social Provision Scale; higher scores indicated higher social support (range 10 - 40) (Caron, 2013).

2.4.2. *Primary outcomes*

To determine the feasibility of conducting a full-scale RCT to evaluate EIS+CHAMPS in this population, retention rate of all participants was calculated post-intervention (week 6); this was a primary outcome. This rate was determined by dividing the number of participants retained at week 6 by the total number of randomized participants. A participant was considered retained at week 6 if they completed at least one item on the first administered assessment, Readiness-to-Change Questionnaire (RCQ) and had a non-missing visit date at week 6. Based on trials of psychosocial digital interventions and in-person cannabis interventions for people with FEP (Alvarez-Jiménez et al., 2011; Anttila et al., 2012; Gottlieb et al., 2013; Granholm et al., 2011), we set an *a priori* 60 % retention rate as the threshold for clinical significance (see Coronado-Montoya et al., 2023).

To determine the acceptability of the CHAMPS intervention, completion rate in the intervention arm was assessed, representing another primary outcome. Completion rate was defined as the proportion of participants in the intervention arm who completed at least the first four modules of the CHAMPS app. The first four modules represented the core of the intervention and were hypothesized to expose participants to the main active ingredients that could influence participant behavior. A module having a valid module completion date was considered completed; this was automatically collected by the app. We set an *a priori* threshold of 50 % as the minimum level for clinical significance in CHAMPS completion, based on theoretical expertise of study investigators and clinicians and accounting for engagement difficulties in this population with similar interventions. As an example, a review of substance use treatments for young people found that the

average completion rate was 59 % across 88 studies (Wells et al., 2024).

2.4.3. Secondary outcomes

To examine the potential effects of EIS+CHAMPS on individuals' cannabis use practices, we descriptively assessed their use of harm reduction practices and motivation to change cannabis behaviors. Use of practices was assessed using the 17-item version of the Protective Behavioural Strategies Marijuana (PBSM) measure; higher scores indicated higher use of harm reduction practices (scaled score range 15 - 73) (Pedersen et al., 2017). Motivation to change cannabis practices was assessed using the RCQ, which has three subscales; the subscale with the highest score represents the participant's stage of change (Rollnick et al., 1992; Stephens et al., 2007). These stages, in order of increasing motivation, are: precontemplation, contemplation and action.

2.4.4. Exploratory outcomes

We collected data to describe potential changes in cannabis-related problems, cannabis use, psychotic symptoms and severity of dependence. Cannabis-related problems were measured using the Marijuana Problems Scale (MPS); higher scores indicated more serious cannabis-related problems (range 0 - 38) (Hodgins and Stea, 2018; Stephens, 1994). Number of participants using cannabis in past 14 days and cannabis use frequency (i.e., number of days using cannabis in past 14 days) were assessed using the TimeLine FollowBack (TLFB)(Robinson et al., 2014; Sobell et al., 1996); participants not using cannabis were coded as having 0 use days. Psychotic symptoms were measured using the six-item version of the Positive and Negative Syndrome Scale (PANSS-6); higher scores indicated higher psychotic symptom severity (range 7 - 42) (Østergaard et al., 2016, 2017). Cannabis dependence severity was measured using the Severity of Dependence Scale (SDS); higher scores indicated higher levels of dependence (range 0 - 15) (Gossop et al., 1997, 1995).

Other exploratory outcomes were assessed to complement our understanding of CHAMPS acceptability and RCT feasibility. Usage data, including module completion and time spent on each module was collected through the app dashboard for the intervention group. Trial parameter data were collected to estimate parameters required to design a full-scale RCT with this intervention. This included number of screened, consented and randomized participants, and the number of participants completing assessments at weeks 6, 12, and 18. Trial participation rates at each timepoint were determined by calculating the number of participants responding to at least one item on all self-reported assessments (i.e., RCQ, MPS, PBSM, SDS, TLFB, PANSS-6, Client Satisfaction Questionnaire (CSQ)) at that timepoint, divided by the number of participants randomized per arm. For the TLFB, participants had to answer at least one cannabis use-related question.

For the intervention group, intervention satisfaction was explored using the CSQ-I (Boß et al., 2016), a modified, comparable version of the CSQ-8 (i.e., rated and scored using same scale) (Larsen et al., 1979). For the control group, intervention satisfaction with the cannabis-focused component of EIS was assessed using the CSQ-8. Higher scores indicated higher intervention satisfaction (range 8 - 32).

2.5. Data collection

Trial participation lasted up to 22 weeks; this included baseline, weeks 6, 12 and 18 assessments. Assessments were conducted either in person, over the phone, or virtually. Research Electronic Data Capture (REDCap) (Harris et al., 2009) was used to collect participant data across study sites in a standardized, confidential, web-based format. Self-reported assessments were entered into REDCap by participants, and interview-based questionnaires (e.g., TLFB) were administered by research staff, then entered into REDCap. De-identified usage data of CHAMPS was automatically collected through the app dashboard and merged with REDCap data. Each participant had a unique study identifier number, and data were strictly confidential and password-protected on computerized databases. Only research staff could access records.

Data collection procedures and engagement strategies were detailed in a research manual of operations used to onboard site investigators, research coordinators and staff contributing to the trial. This manual also detailed strategies for engaging sites and participants (e.g., synchronizing study visits with EIS appointments, sending reminder texts/calls). The lead team held regular meetings with site investigators and with site coordinators to address recruitment and retention challenges and refine processes as needed.

2.6. Sample size

Convenience and precision estimates were used to inform our sample size calculations. Using a precision-based approach, we estimated that 100 participants were needed in this trial for the lower bound of the one-sided 95 % confidence interval of the true retention rate to be above 60 %, if at least 69 participants were retained at week 6. This target was considered possible based on our partnerships with Canadian EIS and prior experience recruiting relatively large samples from this population (e.g., (Coronado-Montoya et al., 2023b; Tatar et al., 2023)).

2.7. Statistical analysis

Baseline sociodemographic and clinical variables were computed for participants by study arm and total sample.

Primary outcomes were trial retention rate at week 6 and CHAMPS completion rate, with one-sided confidence intervals calculated using the Clopper-Pearson method (Clopper and Pearson, 1934).

Changes in harm reduction practices were reported using mean PBSM scores and standard deviations (SD) at baseline, weeks 6, 12, and 18, by study arm. Motivation to change cannabis practices was analyzed descriptively, reporting proportions of participants across readiness stages at all timepoints. The number and proportion of participants reporting cannabis use in past 14 days was calculated. Intervention satisfaction was summarized using mean CSQ-I/8 total scores. Exploratory outcomes—including MPS scores, cannabis use frequency (past 14 days), PANSS-6 scores, and SDS scores—were summarized using means and SDs at all timepoints. Within-groups post hoc exploratory analyses were conducted for scaled PBSM, MPS, and TLFB (use frequency) using paired *t*-tests to identify potentially significant differences from baseline to follow-ups; we reported effect sizes using Cohen's *d*. RCQ scores were also studied using a Stuart Maxwell test to evaluate changes in outcome distribution over time. P-values were not adjusted for multiple testing, and no other statistical tests were conducted for the exploratory analysis; analyses should accordingly be interpreted with caution. No formal between-groups analyses were performed.

Trial participation rates were reported by arm. For the intervention arm, time-based app usage data were reported using median and interquartile range. We calculated the number and percentage completing each module and the booster, median time spent per module, mean modules completed and median total time spent on the app.

All available data was presented for the above outcomes, with no imputation for missing data. Therefore, outcomes may have had different number of participants analyzed due to incomplete data for certain timepoints. The total score was calculated if at least 70 % of the items were answered and prorated (adjusted based on the number of items available); otherwise, it was considered missing. Focusing here on feasibility outcomes, we descriptively present potential efficacy outcomes for future studies, without formal hypothesis testing (Abbott, 2014).

Table 1
Screening and enrolment by study site.

Site	1	2	3	4[a]	5	6	Total
Screened	43	53	36	23	13	12	180
Eligible	25	53	18	22	13	12	143
Eligible and consented	25	19	18	19	12	10	103
Enrolled and randomized	25	19	17	18	12	10	101

[a] Only site in Nova Scotia, Canada (others in Quebec).

3. Results

3.1. Sample characteristics

Of 180 young adults with FEP screened in six EIS sites, 101 were enrolled into the study (Table 1); 51 participants were randomized to EIS+CHAMPS and 50 to EIS-only (Fig. 1). On average, participants were 25.2 years old, and the majority were men (72.3 %), were White (59.4 %), had at least a secondary school diploma for highest education (70.3 %) and had a maximum annual income of $20,000 CAD (60.4 %). Most participants had a CUD (87.1 %), and of those using cannabis in the past 14 days at baseline ($n = 98$), participants reported using cannabis 10.0 days (SD = 4.8) on average. For detailed baseline sociodemographic and clinical characteristics, see Tables 2 and 3.

3.2. Primary outcomes

The trial retention at week 6 was 82.2 % (83/101, one-sided 95 % confidence interval [74.7 %, 100 %]), surpassing the 60 % minimum threshold for trial retention. See Fig. 2 for trial participation patterns according to group.

The majority of the intervention group (30/51, 58.8 %, one-sided 95 % confidence interval [46.3 %, 100 %]) completed the core intervention components (i.e., first four modules), surpassing our 50 % minimum threshold for CHAMPS completion. One participant did not download the app, 4 never started any modules, and 5 started but never completed any modules, totaling 10 participants of the intervention group (19.6 %) who were considered as never using CHAMPS. Overall, 23 participants (45.1 %) finished the six modules and 12 participants (23.5 %) finished the six modules and booster session (Table 4).

3.3. Secondary outcomes

Participants in the intervention group reported mean PBSM scores changing from baseline (mean score 42.6, SD = 8.6) to week 6 (43.4, SD = 10.6), to week 12 (46.4, SD = 11.2), and to week 18 (45.9, SD = 10.2) (Fig. 3), with higher scores indicating increased use of protective strategies. Control group participants had mean PBSM scores changing from baseline (42.7, SD = 8.3) to week 6 (43.6, SD = 6.7), week 12 (44.6, SD = 6.9), and week 18 (44.0, SD = 8.2). Post hoc exploratory analyses revealed a significant increase within the intervention arm only at week 18 ($d = -0.45$, $p = 0.02$). In the control arm, there were significant pre-post increases in PBSM scores across all follow-up points, with small effects at week 6 ($d = -0.37$, $p = 0.02$), week 12 ($d = -0.50$, $p = 0.003$) and week 18 ($d = -0.35$, $p = 0.03$).

Regarding motivation to change, the intervention group saw the proportion of participants corresponding to the action stage increasing from baseline (62.7 %) to week 6 (70.5 %), to week 12 (71.9 %), and to week 18 (87.5 %) (Table 5). The control group had 58 % of participants in the action stage at baseline, which dropped to 53.8 % at week 6 and increased to 66.7 % at week 12 and 69 % at week 18. No post hoc significant within-group differences were found for RCQ.

3.4. Exploratory outcomes

Cannabis-related problems decreased over time in both groups (Fig. 4). In the intervention group, mean MPS scores declined from 10.3 (SD = 7.5) at baseline to 7.7 (SD = 6.2) at week 6, 4.6 (SD = 4.6) at week 12, and 5.8 (SD = 5.4) at week 18. Exploratory post-hoc analyses of within-group differences for EIS+CHAMPS showed significant reductions with small-to-medium effect sizes at week 6 ($d = 0.40$, $p = 0.01$), week 12 ($d = 0.66$, $p = 0.001$) and week 18 ($d = 0.47$, $p = 0.01$). Mean MPS scores in the control group also decreased, from 10.8 at baseline (SD = 8.2) to 9.0 at week 6 (SD = 7.4), 6.8 at week 12 (SD = 7.2) and 8.2 at week 18 (SD = 8.3). Post hoc exploratory analyses

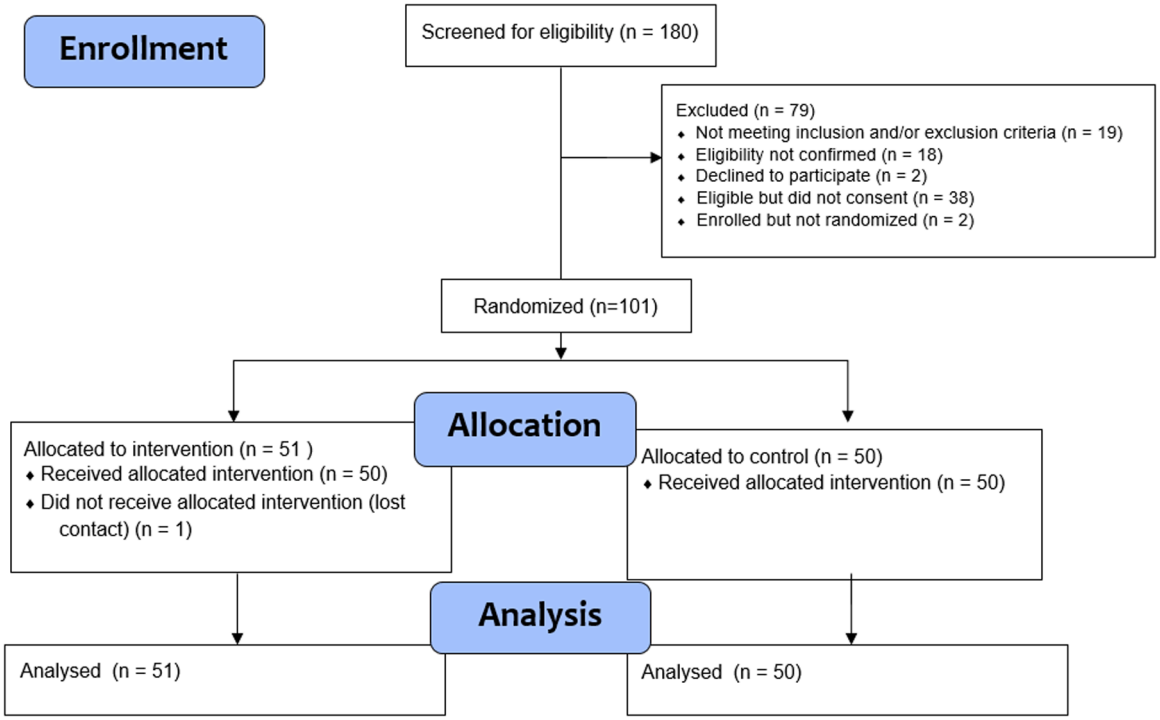

Fig. 1. CONSORT diagram for CHAMPS pilot trial.

Table 2
Sociodemographic characteristics.

Sociodemographic characteristics			
Variable	**Total Cohort (n = 101)**	**Intervention (n = 51)**	**Control (n = 50)**
Age, years (mean ± SD)	25.2 ± 3.9	25.5 ± 4.0	24.8 ± 3.8
Gender, n (%)			
Man	73 (72.3%)	37 (72.5%)	36 (72.0%)
Woman	19 (18.8%)	9 (17.6%)	10 (20.0%)
Other genders or non-binary	8 (7.9%)	4 (7.8%)	4 (8.0%)
Prefer not to answer	1 (1.0%)	1 (2.0%)	0 (0.0%)
Marital status, n (%)			
Single	76 (75.2%)	40 (78.4%)	36 (72.0%)
In a relationship	21 (20.8%)	10 (19.6%)	11 (22.0%)
Married or common-law	2 (2.0%)	0 (0%)	2 (4.0%)
Prefer not to answer/Other	2 (2.0%)	1 (2.0%)	1 (2.0%)
Highest level of education completed, n (%)			
Elementary school or lower	5 (5.0%)	4 (7.8%)	1 (2.0%)
Some secondary school partially completed	25 (24.8%)	14 (27.5%)	11 (22.0%)
Secondary school diploma	39 (38.6%)	17 (33.3%)	22 (44.0%)
Diploma or certificate from a trade school or vocational program	17 (16.8%)	8 (15.7%)	9 (18.0%)
University undergraduate degree (certificate, minor, major, bachelors)	10 (9.9%)	6 (11.8%)	4 (8.0%)
Other (e.g., CEGEP)	5 (5.0%)	2 (3.9%)	3 (6.0%)
Income, n (%)			
Less than 10,000$	26 (25.7%)	16 (31.4%)	10 (20.0%)
Between 10,000$ and 20,000$	35 (34.7%)	13 (25.5%)	22 (44.0%)
Between 20,000$ and 30,000$	16 (15.8%)	9 (17.6%)	7 (14.0%)
Between 30,000$ and 40,000$	4 (4.0%)	3 (5.9%)	1 (2.0%)
Above 40,000$	6 (5.9%)	3 (5.9%)	3 (6.0%)
Do not know/ Prefer not to answer	14 (27.5%)	7 (13.7%)	7 (14.0%)
Living situation, n (%)			
With partner/with children	9 (8.9%)	4 (7.8%)	5 (10.0%)
Alone	21 (20.8%)	10 (19.6%)	11 (22.0%)
With roommates	16 (15.8%)	8 (15.7%)	8 (16.0%)
With family: with parents, siblings	41 (40.6%)	23 (45.1%)	18 (36.0%)
Supervised housing or group home	6 (5.9%)	2 (3.9%)	4 (8.0%)
Rooming house or community housing resources	6 (5.9%)	3 (5.9%)	3 (6.0%)
In the hospital	1 (1.0%)	0 (0%)	1 (2.0%)
Experiencing homelessness	1 (1.0%)	1 (2.0%)	0 (0.0%)
Ethnicity[a], n (%)			
White	60 (59.4%)	35 (68.6%)	25 (50.0%)
Asian: South/Chinese/Other	6 (5.9%)	1 (2.0%)	5 (10.0%)
Hispanic	4 (4.0%)	2 (3.9%)	2 (4.0%)
North African / Middle Eastern	2 (2.0%)	0 (0%)	2 (4.0%)
Black: African	9 (8.9%)	3 (5.9%)	6 (12.0%)
Black: African American	6 (5.9%)	3 (5.9%)	3 (6.0%)
Black: Caribbean	14 (13.9%)	8 (15.7%)	6 (12.0%)
First Nation	2 (2.0%)	2 (3.9%)	0 (0.0%)
Metis	5 (5.0%)	1 (2.0%)	4 (8.0%)
Other	5 (5.0%)	2 (3.9%)	3 (6.0%)

Abbreviations: CEGEP, Collège d'enseignement general et professionnel; SD, standard deviation
Footnotes: a, The percentages for ethnicity do not add up to 100% because participants may identify with more than one ethnicity

revealed small-to-medium significant effects at weeks 12 ($d = 0.60$, $p = 0.001$) and 18 ($d = 0.39$, $p = 0.02$).

Table 6 shows the proportion of participants reporting 14-day cannabis use prevalence and use frequency, according to the TLFB. Among intervention participants, mean cannabis-using days remained at 9.2 days (SD = 5.2) through week 6, then changed to 8.0 days (SD = 5.3) at week 12 and 7.8 days (SD = 5.4) at week 18. The control group reported some variation over time, from 10.7 mean cannabis-using days (SD = 4.4) at baseline, to 9.6 days (SD = 5.4) at week 6, 9.5 days (SD = 5.0) at week 12, and 9.7 days (SD = 5.3) at week 18. No post hoc significant within-group differences were found for TLFB. Both groups reported little variation in psychotic symptoms and dependence severity across all timepoints, and similar intervention satisfaction at all follow-up points (Appendix B).

Table 3
Clinical characteristics and social support.

Variable	Total Cohort (n = 101)	Intervention (n = 51)	Control (n = 50)
Clinic, n (%)			
Attending clinic in Quebec	83 (82.2%)	42 (82.4%)	41 (82.0%)
Attending clinic in Nova Scotia	18 (17.8%)	9 (17.6%)	9 (18.0%)
Psychotic disorder, n (%)			
Schizophrenia	25 (24.8%)	10 (19.6%)	15 (30.0%)
Schizoaffective disorder	14 (13.9%)	8 (15.7%)	6 (12.0%)
Bipolar disorder with psychotic features	14 (13.9%)	6 (11.8%)	8 (16.0%)
Delusional disorder	1 (1.0%)	0 (0%)	1 (2.0%)
Psychotic disorder not otherwise specified	40 (39.6%)	23 (45.1%)	17 (34.0%)
Substance-induced psychotic disorder	7 (6.9%)	4 (7.8%)	3 (6.0%)
Cannabis use disorder, n (%)			
0-1: Does not meet criteria for cannabis use disorder	13 (12.9%)	8 (15.7%)	5 (10.0%)
2-3: Mild cannabis use disorder	40 (39.6%)	19 (37.3%)	21 (42.0%)
4-5: Moderate cannabis use disorder	36 (35.6%)	17 (33.3%)	19 (38.0%)
≥ 6: Severe cannabis use disorder	12 (11.9%)	7 (13.7%)	5 (10.0%)
Days of cannabis use in past 14 days at baseline, (n) mean ± SD	(98) 10.3 ± 4.6	(49) 9.6 ± 4.9	(49) 11.0 ± 4.2
Social support, SPS-10 Total Score, (n) mean ± SD	(101) 31.4 ± 6.7	(51) 32.1 ± 6.2	(50) 30.8 ± 7.2

Abbreviations: SD, standard deviation; SPS, Social Provisions Scale

On average, intervention arm participants completed 3.7 modules (SD = 2.5; excluding booster), with a median total app use time of 17.8 min (interquartile range = [9.7, 30.9]) over six weeks (Table 4).

4. Discussion

This multisite pilot RCT aimed to determine whether a digital harm reduction intervention, CHAMPS, was acceptable for young adults with FEP who continued to use cannabis, and whether conducting a full RCT evaluating EIS+CHAMPS in this population would be feasible. Findings suggested that 1) young adults with FEP using cannabis found CHAMPS acceptable and 2) that conducting an effectiveness trial of CHAMPS on harm reduction outcomes would be feasible.

In addition to in-person interventions, digital interventions for cannabis use are theoretically acceptable and preferable to in-person-only alternatives among young adults with FEP (Abdel-Baki et al., 2017a; Bonet et al., 2018; Coronado-Montoya et al., 2023b). However, trials report modest engagement rates at endpoint (26 % - 50 %) in this population (Schlosser et al., 2018; Steare et al., 2020). In our study, 58.5 % of participants completed core intervention components (one-sided 95 % confidence interval [46.3 %, 100 %]). While the lower bound fell below our 50 % threshold, the study was not powered for this outcome; this suggests acceptable engagement and favourably compares with previous findings of engagement (Schlosser et al., 2018; Steare et al., 2020).

Several factors may have facilitated CHAMPS acceptability. The app was co-designed with people with lived experience, a strategy associated with better uptake (Killikelly et al., 2017). Staff support (compared to no technical support) is linked to lower study attrition (Linardon and Fuller-Tyszkiewicz, 2020) and recommended for digital interventions for FEP (Lal et al., 2022). Accordingly, our study procedures required staff to assist participants with app download and starting the first

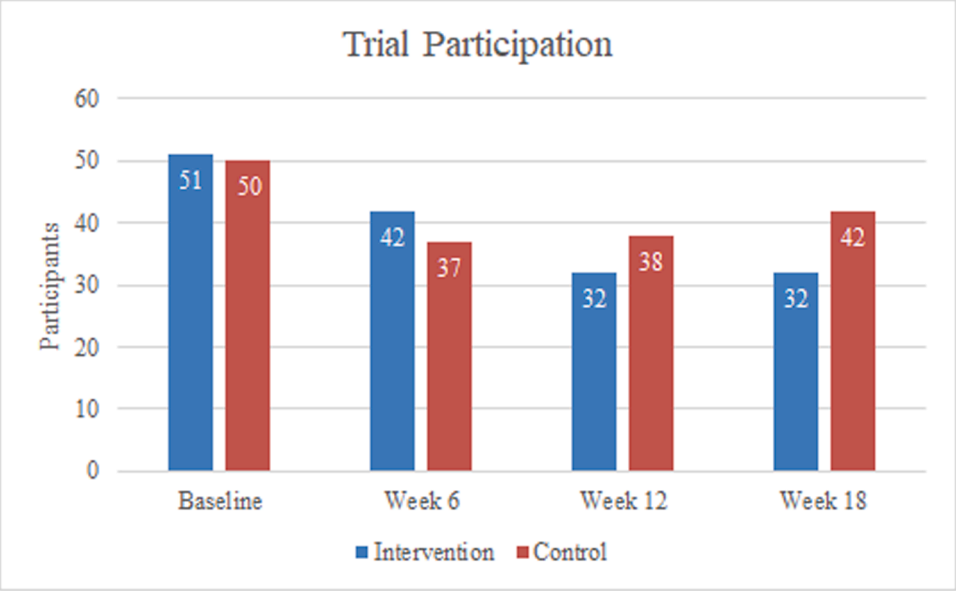

Fig. 2. Trial participation rates.

Table 4
CHAMPS app data usage.

CHAMPS app data usage			
Module number	Participants who completed module	% of participants randomized to intervention who completed module	Median time spent on module in minutes[a] [interquartile range]
1	41	80.4%	4.1 [2.9 ; 5.5]
2	37	72.5%	6.5 [5.2 ; 11.4]
3	32	62.7%	2.7 [1.7 ; 5.8]
4	30	58.8%	3.8 [2.2 ; 4.9]
5	26	51.0%	1.2 [0.8 ; 2.8]
6	25[b]	49.0%	3.2 [2.7 ; 4.6]
Booster	12	23.5%	1.3 [0.9 ; 4.7]

Footnotes:
[a] Time spent on module includes participants who started but never completed module
[b] While 25 participants completed Module 6, only 23 participants completed all six modules of CHAMPS. This nuance is explained by two participants who stopped using CHAMPS at Module 4 and 5, but who returned to complete the last module, Module 6.

module. Additionally, CHAMPS' harm reduction framework—recommended for this population (Tatar et al., 2021)—may have presented a low-barrier, appealing intervention and encouraged engagement.

CHAMPS was designed as a brief intervention (6 modules over 6 weeks, no more than 10–-20 minutes each), to align with patient preferences (Coronado-Montoya et al., 2023b); participants spent a median of 17.8 min on the app, with many completing the entire intervention. Ten participants (19.6 %) never accessed the app despite referral by their clinical team and follow-up by the research team. Half of them came from the same site, suggesting possible site-specific barriers. Brief engagement is not uncommon in FEP digital interventions, reflects patient preferences and may still yield psychosocial benefits (Schlosser et al., 2018; Steare et al., 2020). To further enhance future intervention engagement, preferred features like personalized content, flexible goal-setting tools, and peer support should be explored (Oakley-Girvan et al., 2021; Tatar et al., 2021). Understanding which users benefit from these tools—and why others may disengage—may clarify what drives suboptimal app uptake. An ongoing ancillary qualitative study with CHAMPS participants and clinicians aims to explore experiences, satisfaction and engagement barriers to inform future refinement. Other factors such as low motivation or interest may also explain intervention use patterns and merit further exploration.

Given the challenges of engaging young adults with FEP and the novelty of CHAMPS, retention concerns were anticipated. In-person cannabis interventions in this population reported retention ranging between 41 % and 100 % (Barrowclough et al., 2014; Bonsack et al., 2011; Edwards et al., 2006; Fischer et al., 2022). The CHAMPS trial retention at week 6 was at the higher end of the range for this population (83/101, 82.2 %). Post-trial debriefing with staff identified key strategies supporting retention, including strong interpersonal collaboration and appointment reminders. Control group retention may have been further facilitated by the option to access CHAMPS app at week 18 if still participating. Participants also received up to $150 CAD, which may have contributed to overall engagement. Employing these strategies in future trials may contribute to satisfactory retention in future trials.

For app-based interventions like CHAMPS, designed to support people with FEP within clinical services, clinicians can be key to trial success through their support with onboarding and technical assistance, highlighting the importance of their involvement in digital intervention delivery (Graham et al., 2020). Future research should explore how varying levels of clinician support influence implementation, as refining these approaches may enhance intervention effectiveness and participant retention and can facilitate the transition of such interventions into clinical settings.

This pilot trial follows best practices for evaluating new interventions and this precludes conclusions on efficacy-related outcomes of the intervention (Abbott, 2014). Observed changes in secondary and exploratory outcomes signaled potential improvement in the intervention arm. However, the intervention arm had fewer participants at later timepoints than the control arm, many participants used the app briefly, and our findings reflected only available data. This potentially exaggerated differences between groups and timepoints, as participants at later timepoints may have been particularly motivated or may have represented those deriving greater benefit from the app. That said, our findings regarding cannabis harm reduction practices, motivation to change behaviors, cannabis-related problems and cannabis use frequency suggest the potential of CHAMPS in addressing cannabis use in this population. While mechanisms driving potential benefits are yet unclear, it is possible that CHAMPS is influencing multiple facets

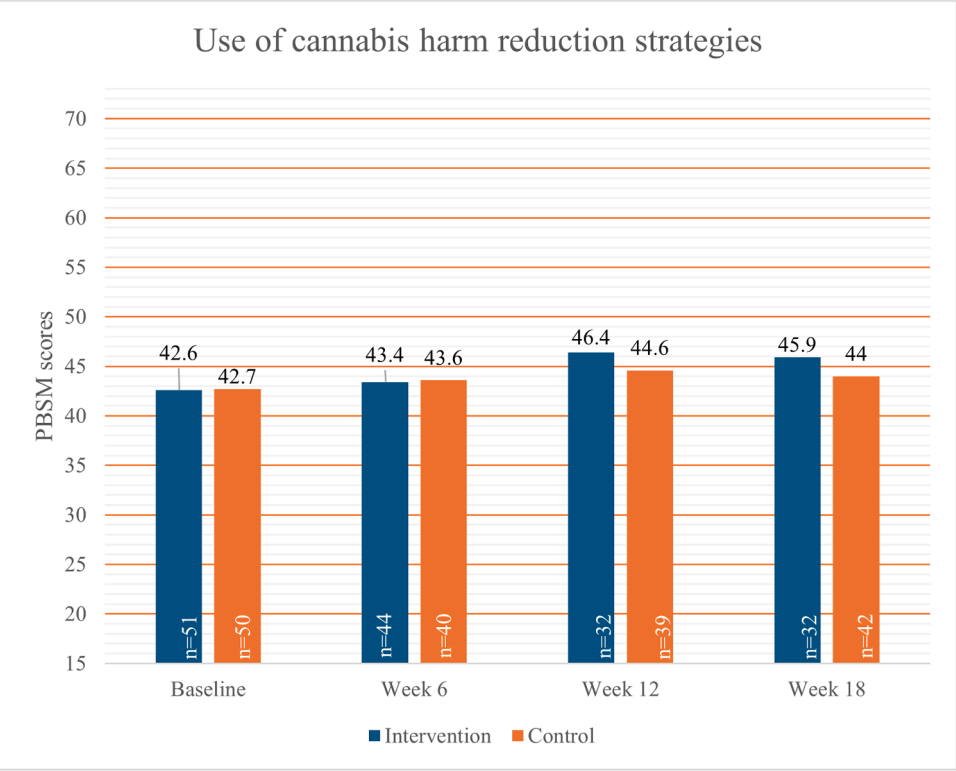

Fig. 3. Use of cannabis harm reduction practices.

Table 5
Motivation to change cannabis practices.

Participants in each stage of change[ab]		
Study arm	Intervention	Control
Timepoint		
Baseline	n = 51	n = 50
Precontemplation	8 (15.7%)	5 (10.0%)
Contemplation	11 (21.6%)	16 (32.0%)
Action	32 (62.7%)	29 (58.0%)
Week 6	n = 44	n = 39
Precontemplation	3 (6.8%)	4 (10.3%)
Contemplation	10 (22.7%)	14 (35.9%)
Action	31 (70.5%)	21 (53.8%)
Week 12	n = 32	n = 39
Precontemplation	5 (15.6%)	4 (10.3%)
Contemplation	4 (12.5%)	9 (23.1%)
Action	23 (71.9%)	26 (66.7%)
Week 18	n = 32	n = 42
Precontemplation	3 (9.4%)	3 (7.1%)
Contemplation	1 (3.1%)	10 (23.8%)
Action	28 (87.5%)	29 (69%)

Footnotes: a, The number of participants at each timepoint reflect the number of participants who answered the assessment at that particular timepoint; b, n (%)

surrounding an individual's cannabis habits, not just their harm reduction practices. These preliminary findings may provide initial support for harm reduction interventions in improving behaviors and related outcomes (e.g., cannabis use), although proper evaluation in future trials is still needed.

Certain limitations may have impacted our findings. First, participants were not blinded to group assignment, potentially biasing assessment responses. Second, clinician-referred recruitment could have introduced selection bias, although most sites aimed to identify all using cannabis. Third, although EIS are high-intensity care settings, participation in the intervention arm may have impacted results, either through increased clinical attention from CHAMPS-related support or reduced attention given participant access to CHAMPS. The following factors may limit study generalizability. This study occurred during the COVID-19 pandemic, a period of increased telehealth services and societal distress, both of which may have influenced engagement and outcomes. This trial was conducted in Canada, where cannabis use is legal since 2018; the clinician support of our harm reduction approach may not reflect contexts in countries with stricter cannabis laws. Finally, although the study spanned two provinces, our sample was predominantly Quebec-based, which differs socioculturally from other provinces; differences include higher minimum age for cannabis use (21 vs. 18) and lower youth use rates (Conus, 2023), potentially limiting applicability to other provinces.

4.1. Conclusion

Despite a glaring need for interventions that address continued cannabis use and related harms in young adults with FEP, treatment alternatives such as harm reduction interventions for this population are limited. Our study found that the CHAMPS app was acceptable to this population and that retention of young adults with FEP in this trial was satisfactory, suggesting that conducting a full-scale RCT of this digital harm reduction intervention is feasible. Preliminary results of secondary and exploratory outcomes suggest that EIS+CHAMPS may have possibly conferred some benefit, underlining the need to conduct a full-scale efficacy trial of the CHAMPS intervention. Future research may also focus on additional features (e.g., peer support) that may improve uptake, retention and efficacy of such interventions for young adults with FEP and persistent cannabis use. The findings of this trial lend preliminary support to the potential of digital interventions to enhance health care service delivery for vulnerable, difficult-to-engage populations and to promote safer cannabis practices through harm reduction approaches. Promising results from pilot trials like this one may

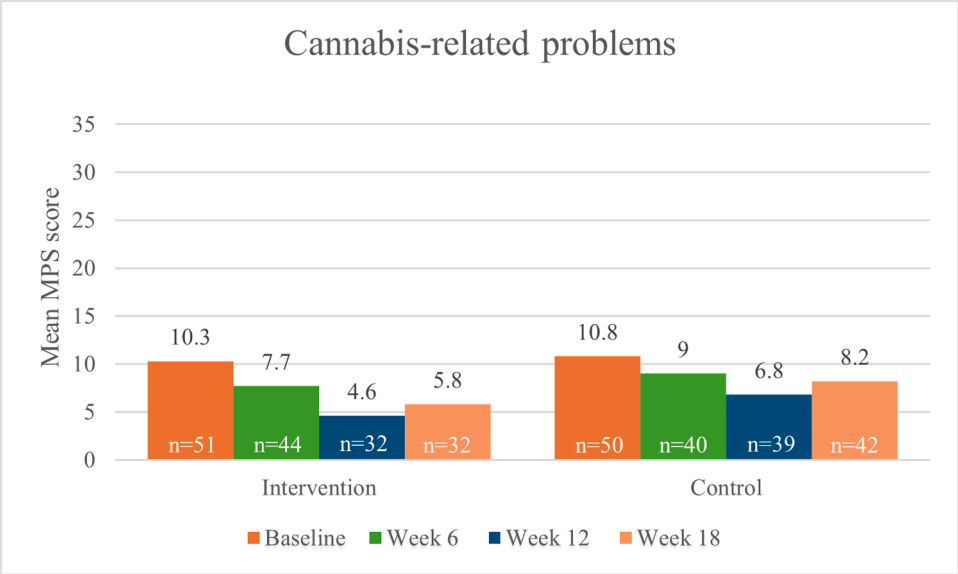

Fig. 4. Cannabis-related problems in past two weeks.

Table 6
Cannabis use and cannabis use frequency over time.

Cannabis use and cannabis use frequency over time[a]		
Study arm	Intervention	Control
Baseline	*n* = 51	*n* = 50
Cannabis use in the past 14 days, n (%)	49 (96.1 %)	49 (98 %)
Number of days of cannabis use over 14 days, mean ± SD	9.2 ± 5.2	10.7 ± 4.4
Week 6	*n* = 42	*n* = 40
Cannabis use in the past 14 days, n (%)	39 (92.9 %)	37 (92.5 %)
Number of days of cannabis use over 14 days, mean ± SD	9.2 ± 5.2	9.6 ± 5.4
Week 12	*n* = 32	*n* = 39
Cannabis use in the past 14 days, n (%)	29 (90.6 %)	36 (92.3 %)
Number of days of cannabis use over 14 days, mean ± SD	8.0 ± 5.3	9.5 ± 5.0
Week 18	*n* = 32	*n* = 42
Cannabis use in the past 14 days, n (%)	29 (90.6 %)	36 (85.7 %)
Number of days of cannabis use over 14 days, mean ± SD	7.8 ± 5.4	9.7 ± 5.3

[a] The number of participants at each timepoint reflect number of participants who answered the assessment at that specific timepoint

Abbreviations: SD: standard deviation.

provide initial justification for future development and evaluation of digital harm reduction tools that can eventually expand the spectrum of care.

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CRediT authorship contribution statement

Stephanie Coronado-Montoya: Writing – review & editing, Writing – original draft, Conceptualization. **Amal Abdel-Baki:** Writing – review & editing, Investigation, Conceptualization. **Paule Bodson-Clermont:** Writing – review & editing, Formal analysis, Conceptualization. **David Boucher-Roy:** Writing – review & editing, Formal analysis, Conceptualization. **José Côté:** Writing – review & editing, Conceptualization. **Candice E. Crocker:** Writing – review & editing, Investigation, Conceptualization. **David Crockford:** Writing – review & editing, Investigation, Conceptualization. **Jean-Gabriel Daneault:** Writing – review & editing, Investigation, Conceptualization. **Simon Dubreucq:** Writing – review & editing, Investigation, Conceptualization. **Maxime Dussault-Laurendeau:** Writing – review & editing, Investigation, Conceptualization. **Benedikt Fischer:** Writing – review & editing, Conceptualization. **Pamela Lachance-Touchette:** Writing – review & editing, Conceptualization. **Tania Lecomte:** Writing – review & editing, Investigation, Conceptualization. **Sophie L'Heureux:** Writing – review & editing, Investigation, Conceptualization. **Clairélaine Ouellet-Plamondon:** Writing – review & editing, Investigation, Conceptualization. **Marc-André Roy:** Writing – review & editing, Investigation, Conceptualization. **Ovidiu Tatar:** Writing – review & editing, Conceptualization. **Philip G Tibbo:** Writing – review & editing, Investigation, Conceptualization. **Marie Villeneuve:** Writing – review & editing, Investigation, Conceptualization. **Anne Wittevrongel:** Writing – review & editing, Conceptualization. **Didier Jutras-Aswad:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization.

Declaration of competing interest

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

Didier Jutras-Aswad reports financial support was provided by Quebec Ministry of Health and Social Services (Public Health Division). Philip G. Tibbo reports a relationship with Otsuka Lundbeck that includes: consulting or advisory. Philip G. Tibbo reports a relationship with AbbVie that includes: consulting or advisory. Philip G. Tibbo reports a relationship with Boehringer Ingelheim that includes: consulting or advisory. Didier Jutras-Aswad reports a relationship with Cardiol Therapeutics that includes: non-financial support. If there are other authors, they 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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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.psychres.2025.116553.

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