博士論文

Web-based relapse prevention program for Japanese drug users: Program development and results of an intervention trial

（日本の薬物使用者に対するウェブ版再発予防プログラム：開発と介入試験実施結果）

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Contents

Abstract

Aims: This study evaluated the effectiveness of a newly developed web-based relapse prevention program (e-SMARPP) for people with methamphetamine and other drug problems.

Methods: The study was a multicenter randomized controlled trial comprised of 48 psychiatric outpatients diagnosed with drug use disorder who were randomly assigned to an eight-week, six-session web-based relapse prevention program (an intervention group) or a web-based self-monitoring only (a control group). The primary outcome was abstinence duration during the intervention and relapse risk assessed using the Stimulant Relapse Risk Scale. Secondary outcomes included motivation to change, self-efficacy, drug cost, quality of life, sense of coherence and abstinence. The outcomes, except duration of abstinence during the intervention, were assessed at baseline, 2-, 5-, and 8-months.

Results: No significant difference was observed between the intervention and control groups for the primary and the secondary outcomes. The effect size of abstinence during the intervention was comparable to previous studies. When participants were limited to those with a shorter history of outpatient treatment, abstinence from all drugs/alcohol were significantly longer in the intervention group. In the intervention group, about 26% dropped out from the intervention. About 31% did not complete the follow-ups among all participants.

Conclusions: The study failed to show that e-SMARPP was effective for improving abstinence duration or relapse risk, along with other outcomes, partly because of the small sample size. The findings of the study may warrant possible use of the program as an adjunct to drug addiction treatment, and some suggestions were proposed to refine the program and for further study.

Introduction

Drug use problems and treatment gap

Drug use problems have been a serious public health concern and illicit drug dependence is a global burden, accounting for 0.8% of global all-cause disability adjusted life years in 2010 (Degenhardt et al., 2013). Discrimination toward drug users is related to poor mental and physical health (Ahern, Stuber, & Galea, 2007). Stigma toward drug users has been identified as an important barrier to reducing substance use, improving mental health, and general health care (Calsyn et al., 2004). In Japan, drug use prevalence and drug-related health problems have been much lower than that of other countries (Kawakami et al., 2005; Tominaga et al., 2009; Wada, 2011). Lifetime prevalence of drug use was estimated at 2.6% for any drug (Wada, 2011), 6.4% for nonmedical use of prescription drugs, and 1.5% for cannabis (Tominaga et al., 2009). Cocaine, heroin and opioid abuse is low. However, there are high-risk groups with lifetime prevalence of any drug use estimated as 54.7% and 65.0% among HIV positive patients and men who have sex with men, respectively (Hidaka et al., 2006). Lifetime prevalence of cannabis use was reported as 32.7% among clubgoers (Shimane, Hidaka, Wada, & Funada, 2013). The most prevalent drug has been methamphetamine in the treatment population, estimated at about 40% of patients who received any treatment in psychiatry with dependence or related disorders (Matsumoto, Tachimori, Tanibuchi, Takano, & Wada, 2014).

Prescription drug abuse has been also prevalent, especially among females suffering from mental distress (Matsumoto et al., 2014).

The national drug policy for Japan is predicated on zero-tolerance. Initiatives have been called a “War on Drugs” and traditional treatment tends to be abstinence-oriented. This means that Japanese law is very strict regarding illicit drug use, even if limited to individual drug use. Furthermore, only abstinence has been thought as the best treatment goal. Such national policy has tended to cause a strong stigma towards drug use and drug users. For example, it is generally thought that drug use is not a medical issue, but a matter of self-responsibility. Indeed, many policies and practices intentionally or unintentionally create and exacerbate risks and harms toward drug users including discrimination, restrictive and punitive laws and policies, and the denial of life-saving medical care in the name of drug control and drug prevention (Harm Reduction International, 2017). Moreover, abstinence-oriented treatment tends to be mandatory and in an inpatient setting, which is more expensive, and not available to many drug users.

Many contemporary perspectives, however, view drug dependence as a chronic illness, comparable to diabetes, hypertension and asthma, rather than as an acute drug use problem (McLellan, McKay, Forman, Cacciola, & Kemp, 2005). At the same time, harm reduction, which is opposite to a zero-tolerance policy, is gaining popularity around the world.

A harm reduction approach consists of pragmatic policies, programs and practices for drug users. These efforts are aimed primarily at reducing the adverse health, social and economic consequences of the use of legal and illegal psychoactive drugs without necessarily reducing drug consumption (Harm Reduction International, 2017).

Harm reduction programs are provided based on the wants and needs of a drug user. There is also advocacy of human rights to improve drug users' quality of life, mental and physical health, and social function in employment, finance, family and social relationships. From this perspective, it is important to lower the threshold of treatment access with a non-punitive attitude and provide treatment widely, focused on not only abstinence, but also positive outcomes such as improvement of quality of life, subjective recovery, and socioeconomic status.

Based on scientific research on drug addiction since the 1970s, behavioral therapies are the most commonly used forms of treatment (National Institute on Drug Abuse, 2016). Despite evidence of the iveness of the interventions for substance use disorders, including cognitive behavioral therapy, there is a gap between potential treatment needs and available treatment services around the world (Kohn, Saxena, Levav, & Saraceno, 2004; The Substance Abuse and Mental Health Services Administration, 2015). Various reasons have been considered as barriers to treatment access: (1) limited availability (e.g., rigid session times,

inconvenient locations, cost for drug users), (2) concerns about confidentiality and stigmatization, and (3) economic and human-resource limitations for treatment providers (Rooke, Thorsteinsson, Karpin, Copeland, & Allsop, 2010; Rooke, Copeland, Norberg, Hine, & McCambridge, 2013; Sholomskas et al., 2005; Weissman et al., 2006). In a drug users survey, reasons for not receiving illicit drug use treatment among people who felt they needed treatment were non-readiness to stop using, no health coverage and unaffordable cost, concerns of negative effect for job and relationship, and no information (The Substance Abuse and Mental Health Services Administration, 2015).

In Japan, the situation around drug addiction treatment is very similar. Outpatient treatment and community-based support for drug users have been very poor (Matsumoto & Kobayashi, 2008). There are 12-step programs and self-help groups such as Narcotic Anonymous and Alcoholics Anonymous in the community. These self-help therapeutic programs have been popular, however, the treatment outcome evidence is unclear and only a small population of drug users engage in such programs. Group cognitive behavioral therapy programs, including relapse prevention, have gained in popularity and since April 2016 are covered by national health insurance. This is a landmark event because previously there was no specialized treatment for drug dependence. Dissemination of such treatment, however, is insufficient (Matsumoto & Kobayashi, 2008). In the coverage, two or more trained health

professionals (psychiatrist, nurse, or occupational therapist) provide a treatment program for a maximum of two years. The medical treatment fee for the program is defined as 340 points and the patient pays about 1,000 yen per visit if the patient uses national health insurance (Ministry of Health, Labour and Welfare, 2016). The program requires the involvement of trained professionals and outpatients diagnosed with drug dependence who regularly visit to hospital. These requirements pose challenges for a small hospital located in rural area because it is difficult to enroll outpatients that will continuously participate in the program. Moreover, patients that continue to work or have childcare needs cannot use the program unless they are absent from work or use childcare because the program is provided only during the day and on weekdays. The same thing happens at public psychiatric institutions that provide free treatment services.

As such, it is necessary to develop flexible, accessible and cost-effective treatment programs, especially in Japan, as outpatient treatment for drug users is very limited and societal drug-use stigma is strong.

Intervention using information and communication technology

Therapeutic interventions using information and communication technology have developed and adapted to various health problems to address challenges in treatment implementation (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Chebli, Blaszczynski, & Gainsbury, 2016).

There are pros and cons when we use such technologies for treatment. Positives include: easy accessibility, low cost for service users and providers, a lack of stigmatization, confidentiality, treatment consistency and standardization, and easy collection of data (Barak, Hen, Boniel-Nissim, & Shapira, 2008; Copeland & Martin, 2004; Moore, Fazzino, Garnet, Cutter, & Barry, 2011; Rooke, Thorsteinsson, Karpin, Copeland, & Allsop, 2010). Challenges include: lack of face-to-face and personalized contact (e.g., little non-verbal communication), ethical issues (e.g., information security, identity of patients and therapists, impersonation, emergency situations), legal issues (e.g., not covered by law and regulation, no insurance for negligence), and practical and technical issues (e.g., training online therapists, dependency on electricity and internet connection, complicated technology) (Barak et al., 2008; Copeland & Martin, 2004; Moore et al., 2011; Rooke et al., 2010). Many computer-assisted or web-, Internet- or mobile-based interventions for drug users that were developed based on psychosocial approaches have demonstrated benefits for abstinence, treatment retention and cost effectiveness with small to moderate effect sizes ranging from 0.19 to 0.54 (Moore, Fazzino, Garnet, Cutter, & Barry, 2011; Portnoy, Scott-Sheldon, Johnson, & Carey, 2008; Takano, Miyamoto, & Matsumoto, 2015). Various interventions were designed to use behavioral therapy approaches, e.g., cognitive behavioral therapy, motivational interviewing, as well as use in face-to-face interventions. In the studies, primary outcome was drug use

and/or abstinence assessed by self-report and/or urine test (Takano et al., 2015). Treatment retention, adverse events, relationship with therapists and engagement in the treatment were assessed as secondary outcomes (Takano et al., 2015). Most of these interventions have been developed for specific drugs, in particular cocaine, cannabis or opioid users in Western countries (Carroll et al., 2008, 2009; Kay-Lambkin, Baker, Lewin, & Carr, 2009; Kay-lambkin, Baker, Kelly, & Lewin, 2011; Ondersma, Svikis, & Schuster, 2007; Rooke et al., 2013). There are few programs that support various types of drug users including amphetamine-type-stimulant users and for populations in Asia with different social backgrounds (Tait et al., 2012, 2015; Takano et al., 2015). In Japan, there have been various web and mobile applications to assist in personal health care, however, evidence-based therapeutic interventions for drug users remains undeveloped.

Programs developed and tested in previous studies tended to target a specific drug use and have no or minimum involvement by a health professional (Bickel, Marsch, Buchhalter, & Badger, 2008; Carroll et al., 2014; Chopra et al., 2009; Kay-lambkin et al., 2009, 2011; Rooke et al., 2013; Tait et al., 2015). In Japan, however, most of the treatments using the basic elements and approaches of cognitive behavioral therapy such as problem solving and function analysis have been provided for people with problems for various types of substances in group therapy. This is because it is not feasible to gather a homogeneous

group of patients who use the same drug in Japan due to the small population of drug users. As such, it may be worthwhile to develop a program that is adaptable to problems for many types of drugs and which can cover a wide population and is feasible to implement, especially in settings with a small population. Also, it is necessary to develop a program that is better for multiple-drug users who use several kinds of drugs at the same time or who change the primary drug depending on situation. When considering approaches, a web-based program cannot provide personalized treatment based on the user's background and condition unless the program has very advanced technologies. Thus, it is necessary to evaluate the efficacy of a web or Internet-based program with involvement by a health care professional in order to provide personalized treatment. Additionally, evaluation of a Japan-based context is necessary to consider the local cultural background for drug use, treatment policy and community-based resources, which are different from other countries. The content of a web-based program in Japan may be different from content in other countries. As such, the author has developed a web-based program with personalized feedback for different drug users using content from an existing program in Japan for drug users who use various types of drugs.

Study 1: Development of e-SMARPP

Aims

The aims of this study were: 1) to describe the development of a new web-based relapse prevention program using existing evidence-based cognitive behavioral approaches, and 2) to examine the acceptance and usability of the prototype.

Development of the prototype

Structure and security

The author developed a prototype of a web-based program named "e-learning Serigaya Methamphetamine Relapse Prevention Program (e-SMARPP)" for Japanese drug users based on an existing face-to-face cognitive behavioral relapse prevention program (Takano, Miyamoto, Kawakami, & Matsumoto, 2016a), using Moodle version 2.6.1, which is an open-source web application for building e-learning websites ("Moodle", n.d.). Moodle is much less expensive than commercial e-learning systems provided by IT companies and it is easy to customize content depending on a developer's needs. The prototype was anticipated to require revision once or twice, so the author obtained an original domain name for the e-SMARPP website and developed all content. Moodle facilitates the ability to control access and set up different types of accounts with different authorizations. The author had an administrator account that allowed all functions, including user registration, customization of content, and entry of feedback comments. Co-researchers had a "teacher account" in which they could see users' progress and make feedback comments, however, they could not register a new user or

change the content. This “teacher account” is useful when the website has many classes (called “cohort” in Moodle) for managing a certain number of website users. If users of e-SMARPP increase or many settings are involved in e-SMARPP, the author can designate other health professionals as “teachers,” which represent web-therapists who provide interactive support. In the future, e-SMARPP can be used to provide adjunct or alternative treatment at different departments that drug users often visit such as a psychiatric hospital, HIV clinic, emergency room, and public healthcare center. The e-SMARPP website is designed to support any device, including personal computers, mobile phones and tablet computers with Internet access. The website is closed access and only the study participants were provided a login account from an administrator. Access security is protected by an individual login/password and secure socket layer technology.

Referenced program

The content of e-SMARPP was developed to be independent of the type of drug and was developed with versatility to assist in handling common problems among drug users. The referenced program was the Serigaya Methamphetamine Relapse Prevention Program (SMARPP), which was developed based on the Matrix Model for outpatients using stimulants in the United States. The Matrix Model is a packaged cognitive behavioral relapse prevention program constructed with treatment elements based on other evidence-based approaches such

as contingency management and motivational interviewing using detailed treatment manuals and demonstrated effectiveness for drug and alcohol reduction and risky sexual behaviors (Carrico et al., 2014; Rawson et al., 1995). The program is versatile and can be used for various drug problems. The program consists of a series of sessions based on educational components and practical relapse prevention exercises using a workbook. Since continuous drug-use monitoring is one of the important elements of treatment for drug addiction, participants of SMARRP check daily drug use and are encouraged to honestly convey their use to therapists and others. Urine tests/self-monitoring are only used to evaluate efficacy of the intervention and are kept confidential. Recently, SMARPP has been widely implemented at various settings including outpatient/community-based treatment, probation offices and correctional institutions in Japan (Kobayashi et al., 2007). In previous studies, about 60% of participants of SMARPP continued abstinence after 1-year follow-up among outpatients (Tanibuchi et al., 2016). SMARPP participants showed more frequent new enrollment in a self-help group than nonparticipants at community-based or outpatient treatment (Kondo et al., 2014). In addition, motivation for treatment and confidence dealing with drug cravings increased during intervention among inmates in a juvenile home and a prison that participated in the program (Matsumoto et al., 2014; Matsumoto, Chiba, Imamura, Kobayashi, & Wada, 2011).

Components of the prototype

The prototype of e-SMARPP consisted of five parts: 1) a relapse prevention program comprised of sessions (watching videos in a YouTube format, submitting exercises, and a weekly diary on the website); 2) self-monitoring (calendar that displays drug use status by color); 3) information (downloadable PDF information and website links to drug addiction support services), 4) user guide (how to use the system, frequently asked questions, and contact form to researchers); and (5) a survey (questionnaires for baseline and post surveys). The e-SMARPP content was intended to be user-friendly with minimal text and limited use of difficult Kanji characters referencing specialized medical terminology. User guides in each section supported use. Narration and subtitles in the videos helped users understand the content. In the web-based surveys, users clicked radio buttons or input brief text when answering. As for therapist involvement, tailored feedback comments from the health professional (the author) were provided after exercise answers were submitted and for the weekly diary. e-SMARPP had some automated functions, including tracking progress for users, and a notification email function for users when they received feedback, and for researchers indicating that users have submitted exercise answers, diary entries, and questionnaire answers. In the notification emails, a related web page link, for example, for a feedback comments page, is shown and users can access the web page directly.

The self-monitoring calendar in e-SMARPP was newly developed, using a plug-in from Moodle to provide a function that is similar to the self-monitoring process utilized in SMARPP. Participants of SMARPP put stickers of three colors (red, yellow, or blue) that indicate drug use condition on their calendar. The colors represent drug use as follows: red reflecting abuse of the primary drug; yellow reflecting secondary abuse of other drugs and alcohol use, or alcohol use; and blue indicating no drug or alcohol use. In e-SMARPP, participants clicked on a date in the calendar and selected one of the three colors, with that color subsequently displayed on the date. Instructions and a legend for the colors were not displayed on the web page to avoid concerns about confidentiality. Participants were provided an explanation about the colors and how to use the calendar at the time of study enrollment. During the intervention, participants were expected to check daily drug use and submit this at the weekly deadline. Additionally, this self-monitoring was also used in a manner similar to the Timeline FollowBack (TLFB) method. The TLFB method was developed to retrospectively record substance use (L. C. Sobell, Maisto, Sobell, & Cooper, 1979). Although the TLFB method was developed to obtain self-reports on alcohol use with a paper-and-pencil approach, it has been extended to other behaviors, and moreover, web-based versions have been developed with good reliability and usability (W Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Norberg, Mackenzie, & Copeland, 2012; Linda C. Sobell,

Brown, Leo, & Sobell, 1996). This self-monitoring was intended to record only presence or absence of drug use without quantity and frequency a day because primary abuse of a drug varies and it would not be possible to adequately compare total quantities. The TLFB method usually records daily quantity and frequency, however, we prioritized a user-friendly system that limited the presentation of complex options for drug names and units.

The development process was described previously in detail (Takano et al., 2016a).

Usability test of the prototype

Methods

The authors conducted a pilot study with a pre-post design to assess the usability and acceptance of the prototype of e-SMARPP among ten outpatients diagnosed as having a drug dependence and people who had recovered from drug dependence (Takano et al., 2016a). This was conducted at the outpatient department of the National Center of Neurology and Psychiatry (NCNP) and at nonprofit rehabilitation institutions called Drug Addiction Rehabilitation Center (DARC). DARC facilities are operated by peer educators who have themselves experienced drug dependence problems and who have recovered at a DARC. Because this study was a pilot and a first trial, we sought out a variety of comments from people dealing with drug problems at different stages of recovery. We felt that the opinions of persons who had experience with drug use and recovered from drug dependence were of some

help to developing an effective and user-friendly program. Therefore, we also invited DARC staff that had quit using drugs for more than a year to participate. In total, 12 people (NCNP=3 and DARC=9) volunteered to participate.

The participants used the prototype for four weeks and then evaluated usability. The intervention content consisted of four sessions of the relapse prevention program and self-monitoring. The participants were asked to complete each relapse prevention session in consecutive order and self-monitoring by each deadline (each Sunday). If they did not complete the session and/or the self-monitoring by each deadline, the author sent e-mails once or twice as a reminder. Usability was assessed by the Web Usability Scale (WUS) (Nakagawa, Suda, Zempo, & Matsumoto, n.d.). The WUS consist of 21 items measured on a 5-point scale (1: disagree to 5: agree) and seven subscales: Ease of use, Website structure, Visual, Response speed, Favorability, Helpfulness and Credibility. Subscale average scores were also calculated and a higher score indicated higher website usability. Additionally, original quantitative and qualitative questionnaires were used to evaluate detailed usability and acceptance of the prototype. Program completion rate was also assessed.

This pilot study was approved by the Ethics Committee of the Faculty of Medicine and Graduate School of Medicine of the University of Tokyo and the Ethics Committee and the Institutional Review Board of NCNP.

Results and discussion

Of the 12 eligible applicants, 83% completed the baseline assessment. There were two that were excluded because of poor health and an unknown reason. Most of the participants were male and recruited from DARC and accessed the Internet everyday primarily from a smartphone (70%). Primary drugs were methamphetamine (80%), cannabis (10%), and new psychoactive substances (10%). Most of the participants (90%) had maintained abstinence for more than a year.

Of the ten participants, the program completion rate was 60% (Takano et al., 2016a). The participants completed one relapse prevention session in about 60 minutes. The average number of days needed to complete one session was 2.15 days (median was 2). Most of the participants felt that the program volume and pace, a session per week, was suitable. A majority felt the content of the videos was helpful and submitting the exercises and diary were basically easy. The participants felt the feedback comments were adequate and a quick response was well received. All average scores of the subscales of the WUS were over 3 points. The results indicated good acceptance of e-SMARPP. However, they felt the length of a video was too long. Additionally, participants who had maintained abstinence for several years previous did not feel the self-monitoring was not helpful because it was boring to just record the same condition every day. Although there was no adverse effect during e-SMARPP

use, there were functional defects including compatibility in the character code for the iPhone e-mail application. One participant could not read notification e-mails regarding feedback comments.

Finalization of the program

Some improvements were suggested through the pilot study. In the revision process after the pilot study, the content of the videos was simplified to focus on problem-solving approaches rather than adverse drug effects. Videos were revised and shortened to be within a length of about 10 minutes (total time for watching videos per session: less than 30 minutes). Self-monitoring was improved to allow recording of detailed conditions about drug users (e.g., drug consumption, forms of used drugs, and triggers of drug use) depending on a user's needs, especially for drug users who had maintained abstinence for a long period of time. Programming bugs, including garbled characters on mobile phones, were fixed by excluding machine dependent characters. The author completed the revised version of e-SMARPP to conduct a subsequent randomized controlled trial (RCT) after the process of prototype development, the usability study, and revision (Takano, Miyamoto, Kawakami & Matsumoto, 2016b).

Study 2: Randomized controlled trial

Aims and hypothesis

The aim of this study was to examine the efficacy of a web-based cognitive behavioral relapse prevention program through a revised version of e-SMARPP, among Japanese psychiatric outpatients with methamphetamine and other drugs use problems with a multicenter RCT design at 8-month follow-up. The primary hypothesis was that participants assigned to e-SMARPP would maintain a longer duration of consecutive abstinence from a primary abused drug during the intervention and have reduced relapse risk compared to those who were randomized to web-based self-monitoring only. The secondary hypothesis was that participants in the e-SMARPP group would report positive changes in motivation to change, self-efficacy for drug craving, quality of life, sense of coherence, cost of drug, and abstinence in the past 28 days. In addition, completion, usability and satisfaction of the program were assessed for utilization and feasibility.

Methods

Trial design

As shown in Figure 1, this study was a two-arm (allocation ratio is one to one), parallel-group, non-blinded and multicenter randomized controlled trial. Eligible participants were asked to complete the baseline assessment and were randomly allocated to either the intervention group (e-SMARPP group) or the control group (self-monitoring group). All

participants in both groups were provided a login/password with instructions about how to access the website and used e-SMARPP during the study for eight weeks. The participants in the e-SMARPP group could access the complete contents of e-SMARPP, while the self-monitoring group could access a part of it: self-monitoring. Each individual access account was tied to either group, and as such participants could use e-SMARPP content included in their group only. Web-based follow-up assessments were conducted at 2, 5, 8 months after the baseline assessment. This study is reported based on the CONSORT checklist (Appendix 1). This study protocol was registered with the University Hospital Medical Information Network clinical trial registry (UMIN-CTR), number UMIN000016075 (https://upload.umin.ac.jp/cgi-open-bin/ctr/ctr_view.cgi?recptno=R000018484).

The RCT protocol was changed twice after study commencement. First, the inclusion criteria were extended from those who used a primary abused drug in the past month to those who used a primary abused drug in the past year because it was difficult to recruit outpatients who currently used drugs at the right time. Many patients tried to stop using drugs before their first visit. Patients admitted to an emergency department tended to drop out of the treatment, refer to another hospital or were hospitalized. Second, additional recruiting hospitals and clinics were added to recruit more patients (Takano et al., 2016c).

Participants and setting

The participants were recruited from five psychiatric hospitals and one clinic that provided treatment for people with substance use disorder in Japan (National Center of Neurology and psychiatry, Saitama Psychiatric Medical Center, Kanagawa Psychiatric Center, Okayama Psychiatric Medical Center, Tokyo Metropolitan Matsuzawa Hospital and APARI clinic). These institutions are located in cities with a large population. The inclusion criteria were: (1) outpatients who were diagnosed with substance use disorder assessed by DSM-IV or 5 by psychiatrists who were co-researchers (psychoactive substances other than alcohol and tobacco), (2) those who used a primary abused drug in the past year, and (3) those with access to the Internet via PC, smartphone or tablet computer and could exchange e-mail. The exclusion criteria were: (1) patients with severe physical diseases, (2) patients with high suicide risk, (3) patients with severe symptoms of substance-induced psychotic disorder, (4) patients with impaired cognitive function and (5) those who were judged ineligible to participate in the study by a psychiatrist (co-researcher). The participants were diagnosed using DSM IV or 5 criteria based on their complaints at a first visit by a psychiatrist who were certificated as a psychiatric specialist or a designated psychiatrist and had clinical experience of more than ten years. There was a limitation in terms of gaining a comprehensive diagnosis because a structured interview was not conducted. Various types of participants (type of drugs, previous and currently receiving treatment for drug dependence, psychiatric

comorbidity, pharmacotherapy and sexual orientation) were included to test adaptation of e-SMARPP to various drug users in a secondary analysis.

Randomization and blinding

Staff of recruiting institutions including co-researcher psychiatrists recruited outpatients who met the inclusion criteria by using flyers and posters. Psychiatrists with had lengthy experience in diagnosis and treatment of substance use disorders assessed a candidate's diagnosis and health condition, explained about the study, and then referred them to the author if the candidate indicated a willingness to participate in the study. It was difficult to count the number of all outpatients and eligible outpatients who met inclusion criteria because the psychiatrists examined many outpatients who had different diagnoses for a limited amount of time. Therefore, we did not know the number of total potential participants and eligible participants (Figure 1). Eligible participants were informed in advance that they would be randomly allocated to either the e-SMARPP group or the self-monitoring group. After baseline assessment, they were randomly assigned to either of the two groups using the method of permuted block, with a random block size of four, and they were informed about their assigned group by the author. Randomization was stratified by institution. The computer-generated allocation list was made by an independent researcher and concealed to other researchers and participants until the time of assignment. Enrollment was done by the author

and the intervention started immediately. The author managed study progress and sent e-mail reminders to participants who did not answer the assessments. Researchers and staff who worked for recruiting institutions were blinded. In addition, an independent researcher who did not analyze data downloaded data from the e-SMARPP database and an independent research assistant masked the group variable before analysis, then the author analyzed data that was already blinded to the group variable.

Interventions

Web-based relapse prevention program: e-SMARPP

The website of e-SMARPP was comprised of five modules: (1) cognitive behavioral relapse prevention sessions (watching videos, submitting exercises and a weekly dairy on the website), (2) self-monitoring, calendar that displays drug-use status by color, (3) information, downloadable PDFs and website links to drug addiction support services, (4) a user guide, how to use the system, frequently asked questions and a contact form to researchers, and (5) assessment, which were web-based questionnaires for baseline and three follow-up assessments.

The main intervention modules were the relapse prevention program sessions and self-monitoring. Content for the videos and exercises of the relapse prevention program were taken from the SMARPP workbook and can be adapted to any type of drug. Each session has

three videos, two exercises and a weekly diary activity (Appendix 2). Videos were made in a YouTube format and embedded in each session (Appendix 3). Videos were online, but were unlisted videos and restricted to people who have the link to the video, so only participants in the e-SMARPP group and researchers could view them. Narration and subtitles helped users understand the content. Exercises were related to the video content and users were expected to complete these after watching the video. Users wrote and submitted their own answers through an Internet text form (Appendix 4). In addition, users were expected to write down in the weekly diary their condition from the last week, current goals, and how they planned to spend time over the next week. Writing in the diary was also done on the Internet through the system. After submitting the exercise and the weekly diary, users received tailored feedback comments from qualified health care professionals (registered nurse/the author) trained to support patients with substance use disorders. Feedback comments were based on motivational interviewing skills to enhance user motivation and to provide individual support. The feedback comments for exercises were mixed common and personalized messages. In the common messages, the participants were provided examples of common triggers of drug use and ways of coping with drug craving. The personalized messages depended on each participant's comments and usually consisted of answers to questions and empathic, supportive, optimistic, yet directive advice according to an individual situation that utilized

motivational interviewing techniques, such as reflection, avoiding arguments, reframing, supporting self-efficacy, and developing discrepancy.

The self-monitoring was done in a calendar format like the Timeline FollowBack method (Fals-Stewart, O'Farrell, Freitas, McFarlin, & Rutigliano, 2000; Norberg, Mackenzie, & Copeland, 2012; Sobell, Maisto, Sobell, & Cooper, 1979; Sobell, Brown, Leo, & Sobell, 1996). Users clicked on a date in the calendar and selected one of three colors (red, yellow or blue), then that color subsequently displayed on the date (Appendix 5). The colors represented the user's drug use: red reflecting abuse of the primary drug; yellow reflecting secondary abuse of other drugs and/or alcohol use; and blue indicating no drug and alcohol use. An optional memo function was provided for personal user use that records detailed conditions (drug form, quantity and frequency, triggers, etc.).

Intervention group: e-SMARPP group

Participants who were assigned to the e-SMARPP group were provided access to the complete contents of e-SMARPP, including six sessions for cognitive behavioral relapse prevention and web-based self-monitoring. They were expected to complete each session over a week period in sequence order by each deadline (each Sunday). For an 8-week intervention period, they were expected to complete a total six sessions, but they had a 2-week grace period and were allowed to progress at their own pace. If they did not complete a session, the

session was carried over to the next week. Participants were expected to record their daily situation of drug use on the web-based self-monitoring calendar by each deadline (each Sunday). If they did not go through an expected session and/or self-monitoring by each deadline, the author sent an e-mail reminder on the next day (Monday). Participants continued to receive outpatient treatment as usual, including medication, face-to-face group or individual psychosocial treatment programs and counseling by psychologists and/or social workers. Provided treatment depended on individual condition. Even if participants stopped receiving outpatient treatment or changed their primary doctor and hospital, the web-based intervention was not cancelled.

Control group: self-monitoring group

Participants who were assigned to the self-monitoring group were provided access to a part of the contents of e-SMARPP, including the web-based self-monitoring and information content. The self-monitoring group participants did not have access to the cognitive behavioral relapse prevention sessions. Similar to the e-SMARPP group, they were expected to record their daily situation of drug use on the web-based self-monitoring calendar by each deadline (each Sunday). The e-mail reminder and outpatient treatment as usual were provided as well as the e-SMARPP group. After the study period, cognitive behavioral relapse prevention sessions were provided if requested.

In previous studies, there were a variety of control group conditions: treatment as usual, no treatment, face-to-face program, providing materials, or other web-based content. It would be possible to assess non-inferiority or equivalence of e-SMARPP compared to standard treatment (face-to-face relapse prevention), but it was difficult to randomly allocate outpatients into the two groups because they usually wanted to receive standard treatment. In this study, we needed to assess exact daily drug use during the intervention for two months, but drug users said in the pilot study that it was difficult to recall drug use history up to two month ago at the earliest. Additionally, we needed to maintain the participants in the control group in the study because drug users were generally likely to dropout from the study. We thought that we could send reminders often if the participants in the control group were provided any intervention and did not access the e-SMARPP website. Therefore, the control group did self-monitoring as a minimum intervention.

Measures

Data collection procedure

Data collection was conducted through web-based self-reported questionnaires on the e-SMARPP website at baseline (T1) and follow-up assessments at 2 (T2), 5 (T3) and 8 (T4) month after the randomization (Appendix 6). Participants were informed about the follow-up assessments via e-mail and asked to complete the questionnaire within one week. After one

week, an additional reminder email was sent to non-respondents. If a participant's e-mail address changed and an e-mail was not received, a postcard was sent as an extra reminder. Participants received a prepaid card for 1,000 yen as a reward for each assessment that they completed.

Primary outcome

The longest duration of consecutive abstinence

A primary outcome was the longest duration of consecutive abstinence (days), according to previous studies (Carroll et al., 2008, 2014). The longest duration of consecutive abstinence from the primary abused drug during eight-week intervention (56 days) was counted, using the self-monitoring calendar and the Timeline Follow Back method.

Previous studies have used a variety of definitions for abstinence, including: 1) consecutive abstinence or total days of abstinence in a certain period, and 2) abstinence from the most problematic drug, illicit drugs, or all substances including alcohol. We decided to use consecutive abstinence as a primary outcome because it was important to maintain a longer abstinence, rather than intermittent abstinence in terms of optimal recovery. Additionally, e-SMARPP content focused on recovery from the primary abused drug rather than all substances. As such, we employed abstinence from the primary abused drug.

Relapse risk

Another primary outcome was relapse risk, assessed using the Stimulant Relapse Risk Scale (SRRS) at 2-, 5, and 8-month follow-up (Ogai et al., 2007). The SRRS was developed to measure multidimensional relapse risk and consists of 30 items measured on a 3-point Likert scale. The total score ranges from 30 to 90. Higher scores for total and subscale items indicate higher relapse risk. Its reliability and validity was confirmed among stimulant drug users in Japan (Ogai et al., 2007).

Secondary outcome

Motivation to change

Motivation to change was measured with the Stage of Change Readiness and Treatment Eagerness Scale-8 version for Drug Use (SOCRATES-8D) (Kobayashi et al., 2010; Miller & Tonigan, 1996). The SOCRATES-8D consists of 19 items assessed on a 5-point Likert scale. The total score ranges from 19 to 95. Higher scores indicate a higher motivation to change. Positive correlations have been reported between high scores and the development of readiness for treatment (Mitchell, Angelone, & Cox, 2007) and engagement in treatment (Mitchell & Angelone, 2006). Reliability and validity of the Japanese version of the SOCRATES-8D has been confirmed (Kobayashi et al., 2010; Matsumoto, Chiba, Imamura, Kobayashi, & Wada, 2011).

Self-efficacy for handling drug use

Confidence (i.e., self-efficacy) in handling drug use and craving was measured with the Self-efficacy Scale for Drug Dependence (SSDD) (Morita et al., 2007). The SSDD has two domains: general self-efficacy (GE) and self-efficacy in specific situations (SS). The GE domain consists of five items assessed on a 5-point Likert scale from 1 (not confident) to 5 (confident). The SS domain consists of 11 items assessed on a 7-point Likert scale from 1 (not at all confident) to 7 (absolutely confident). The total score is summed the GE and the SS scores and ranged from 16 to 102. Higher score means more confidence in handling a drug craving.

Quality of life

Traditionally, addiction treatment has focused only on achieving abstinence from substances. However, this limited aim for treatment efficiency has recently been criticized. The addiction field has recognized that it is important to also focus on other positive treatment outcomes and subjective recovery such as quality of life, resilience and life satisfaction (Pasareanu, Opsal, Vederhus, Kristensen, & Clausen, 2015; Venner et al., 2006). Health related quality of life was measured with WHOQOL-26 (Skevington, Lotfy, & O'Connell, 2004), which consists of 26 items measured on a 5-point Likert scale. There are two items that ask about an individual's overall perception of quality of life (QOL) and their health. The remaining 24 items are divided into four domains: physical domain, psychological domain, social relationships and

environment. All items ask about the respondent's life over the last four weeks. Higher scores indicate a higher QOL.

Sense of coherence

Sense of coherence (SOC) is considered to be an individual's personality as a fundamental source of coping in stressful events (Antonovsky, 1987). The SOC of people with substance use disorder has been considered lower than that of healthy people (Arévalo, Prado, & Amaro, 2008). Among people with mental health problems and substance use disorders, previous studies have revealed that high SOC is associated with a better ability to cope with stressful life situations and improved life satisfaction (Arévalo et al., 2008; Langeland, Wahl, Kristoffersen, Nortvedt, & Hanestad, 2007) and high SOC is one of the predictors of treatment success: treatment retention and drug abstinence (Abramsohn, Peles, Potik, Schreiber, & Adelson, 2009). SOC can be considered as an important foundation for recovery from drug addiction. The University of Tokyo Health Sociology version of the SOC3 scale (SOC-3-UTHS) (Togari, Yamazaki, Nakayama, & Shimizu, 2007) was used, which consists of three items measured on a 7-point Likert scale. A higher score indicates a higher SOC.

Drug cost

There are many drug users that are unemployed, living alone, and lacking in positive social relationships. This economic situation is further degraded if they repeatedly buy and use

drugs, all the while without social support. Life stressors such as unemployment, economic hardship, and discrimination have been thought of as predictors of early relapse (Tate et al., 2008). Therefore, financial control is important for drug users. We assessed drug cost spent over the past month because it was difficult to assess the participant's entire financial history. Total cost of drug use (yen) in the past month was asked. Drug cost depended on type of drug, amount of drug, and the relationship between a drug user and a dealer. In Japan, amphetamine-type stimulants including methamphetamine and 3,4-methylenedioxymethamphetamine (MDMA) are more expensive than other drugs. Methamphetamine costs about 50,000 yen for use several times. MDMA called Ecstasy is a few thousand yen per one tablet. Other drugs including new psychoactive substances and cannabis are relatively cheap (about 2,000 to 5,000 yen for use several times). The outlier was defined if the cost variable was over 100,000 yen, even if the participant did not use a drug in the past month. There are also drug users who pay tens of thousands to prepare a place for drug use and to obtain drugs. It is possible that drug users have given up using a drug through self-control, although they may still buy drugs and leave drugs unused. Thus, the study did not exclude the cost variables even for users that maintained complete abstinence.

Abstinence

As mentioned in the primary outcome paragraph, there are several definitions for abstinence.

In this study, data for abstinence in the past 28 days was available at four points. We examined changes of abstinence over time by using different definitions in a sensitivity analysis. Abstinence in the past 28 days was repeatedly evaluated using the following four definitions. First: the longest duration of abstinence from the primary abused drug; second: the longest duration of abstinence from all drugs/alcohol; third: total abstinent days from the primary abused drug; and forth: total abstinent days from all drugs/alcohol. Abstinent days were recorded using the self-monitoring calendar during the intervention and retrospectively recorded using the Timeline Follow Back method at the baseline and at 5- and 8-month follow-up.

Process evaluation: usability and satisfaction

In addition, completion, usability and satisfaction of the program were assessed for utilization and through a feasibility test. The intervention completion rate of each group was assessed. Usability of the e-SMARPP website was assessed using the Web Usability Scale (WUS) (Nakagawa et al., n.d.) in the same way as in the pilot study. WUS consists of 21 items measured on a 5-point scale (1: disagree to 5: agree) and seven subscales: Ease of use, Website structure, Visual, Response speed, Favorability, Helpfulness and Credibility. Subscale average scores were also calculated higher score indicated higher website usability. The detailed usability of e-SMARPP content was also assessed using original quantitative and

qualitative questionnaires. Perceived program satisfaction was assessed using the Client Satisfaction Questionnaire 8-item version (CSQ-8) (Tachimori, & Ito, 1999). The CSQ-8 consists of eight items measured on a 4-point scale. A higher score indicates a higher satisfaction with service use. Additionally, participants' characteristics at the baseline were compared between those who completed an 8-month follow-up assessment and those who had dropped out from the follow-ups.

Adverse effects were also assessed. We asked the participants' primary doctor about their hospitalization, arrest, and death during the intervention. The participants were asked about harmful effects, for example, craving drugs or mental distress while using e-SMARPP in the 2-month assessment after the intervention.

Other covariates

At the baseline assessment, sociodemographic information was gathered including age, sex, marital status, cohabitation status, educational history, employment status and Internet use (use days per week, hours per day and main devices to access). Information about history of drug use was also asked. The primary problematic drug, drug use and abstinence in the past 28 days, age of first drug use, history of arrest and correctional facilities, and self-reported psychiatric comorbidity with an option to select a diagnosis based on the International Classification of Diseases-10 were collected. In order to assess the severity of drug use

problems, we use the Japanese version of the Drug Abuse Screening Test (DAST-20), which consists of 20 binary items (Skinner, 1982; Shimane et al., 2015). All items asked participants' about drug use condition over the past year. Total score ranges from 0 to 20 and a high score represents a severe condition. The cutoff score for drug use disorders is suggested as 5/6 with maximum sensitivity and specificity (Cocco & Carey, 1998; Gavin, Ross, & Skinner, 1989; Yudko, Lozhkina, & Fouts, 2007), although an optimal cutoff score has not confirmed in different populations and cultures, including Japan. It is also suggested that a score of 16 or greater indicates a very severe dependence condition (The European Monitoring Centre for Drugs and Drug Addiction, n.d.). Harmful alcohol use was assessed using the Alcohol Use Disorders Identification Test-Consumption (AUDIT-C) (Blank, Connor, Gray, & Tustin, 2015; Bush et al., 1998). Although the cutoff score for harmful alcohol use has not been confirmed in Japan, the cut-off points 3/4 for male and 2/3 for female were considered as harmful alcohol use in the study (Reinert & Allen, 2007). Furthermore, a Kessler-6 scale consisting of six items measured on a 5-point scale was used to assess psychological distress (Furukawa et al., 2008; Kessler et al., 2002). Total scores ranged from 0 to 24 and a high score indicates severe distress. The optimal cut-off point is considered 4/5 for a mood and anxiety disorder (Sakurai, Nishi, Kondo, Yanagida, & Kawakami, 2011). Additionally, history of treatment was assessed, including outpatient

treatment period, number of psychiatry hospitalizations, and previous use of face-to-face relapse prevention and self-help groups.

Sample size

A minimal sample size was calculated for the two primary outcome variables (the longest duration of abstinence and relapse risk) to detect a medium effect size of d = 0.4 based on previous studies for drug users. As for the first primary outcome (the longest duration of abstinence), the effect size between the intervention group and control group after the intervention was reported as d = 0.45 in a study conducted for computer-assisted cognitive behavioral therapy (Carroll et al., 2008). For another primary outcome (relapse risk), the effect size between pre and post intervention was d = 0.39 in a study conducting a relapse prevention program in Japan (Morita, 2013). We estimated a sample size of 100 per group (total 200), assuming $\alpha = 0.05$ and a power $(1 - \beta) = 0.8$. Attrition rate and non-completion rate was reported as relatively high (about 10-45 %) in previous studies of computer-assisted and web-based intervention for drug users (Carroll et al., 2008; Kay-Lambkin et al., 2009; Rooke et al., 2013). However, we did not include additional samples because we expected a low attrition rate because all the participants would be outpatients motivated to seek treatment and we would send email reminders to follow up. Moreover, it was difficult to recruit more than 200 drug users in a short period.

Statistical analysis

Primary analysis

The longest consecutive abstinent days from the primary abused drug during intervention was compared between the intervention and control groups using a t-test. A Cohen's d for the longest consecutive abstinent days was calculated. The values of 0.2, 0.5 and 0.8 were considered as small, medium and large effect, respectively (Cohen, 1992). The primary analysis for the repeated measures including the SRRS score was on an intention-to-treat (ITT) basis, using mixed-effect models. A fixed-effect model was employed when the mixed-effect model was not convergent. All participants at the baseline were included in the primary analysis. Missing values were estimated by using restricted maximum likelihood. We included the following variables as fixed effects: the group, time, the baseline scores and the interaction of group and time. We also included random effects of participants for intercept and time. The effect of the intervention was assessed by a test of hypothesis that a time and group interaction equals 0. To help in interpretation of the effect of e-SMARPP, effect sizes between groups were calculated at each assessment point by using estimated means based on the mixed-effect or fixed-effect model among all participants. The effect sizes were calculated by dividing differences of the estimated means between the intervention and control groups by pooled standard deviations, where the standard deviations were calculated by using raw

data of respondents who completed the questionnaire at baseline and at follow-up assessments in the total sample.

The missing data are often classified into three categories as follows based on how missing data are generated: 1) Missing Completely at Random (MCAR), 2) Missing at Random (MAR), and 3) Missing Not at Random (MNAR) (Dziura, Post, Zhao, Fu, & Peduzzi, 2013). MCAR that represents missing data does not depend on any observed and unobserved variables. The chance of missing data is the same for individuals in different treatment groups and those who have different disease severity. Typical examples are participants' moving and random failure of experimental instruments (e.g., test tube break). Study participants who dropout for this reason could be considered as a random and representative sample from the total study sample. Likelihood-based analysis (e.g., maximum likelihood estimation), multiple imputations (MI), Inversed Probability Weighting (IPW), or complete case analysis is acceptable. Last observation carried forward (LOCF) and worst observation carried forward (WOCF) are simple methods and tends to provide conservative estimates of the treatment effect, but these methods are not valid and not acceptable under MCAR. MAR in a case of missing data depends only on observed, but not unobserved variables. For example, dropout based on side effects or lack of treatment efficacy. Missing data can be estimated using the observed data. Likelihood-based analysis, IPW, or MI is

acceptable and consistent with the ITT principle because the methods do not exclude data from a participant with missing variables. However, likelihood-based analysis, IPW, or MI assumes people with missing data would have had the same outcome if they had completed the study as similar people without missing data (good adherence population). Sensitivity analysis is recommended to understand robustness. LOCF, WOCF, simple mean imputation, or complete case analysis is not acceptable because of selection bias. When missing data depends on unobserved variables, the data is classified as MNAR. In this scenario, future observation cannot be predicted without bias because unobserved variables are not available for analysis. For example, in a substance abuse trial to assess abstinence as an outcome, it is possible that dropout is higher for those who have relapsed. In this case, the missing data depends on relapse, which usually cannot be unobserved, but all missing variables are not the result of relapse. In a MNAR case, joint modeling of the outcome is done along with the missing data mechanism. This is very complicated because the missing data process is usually unknown and a valid assumption is not created. It is necessary to specify a strong relation between a missing variable and outcome. There are several ways to handle missing data in an intervention study (Dziura et al., 2013; Sterne et al., 2009). Some previous intervention studies in the field of addiction employed complete case analysis like ANOVA (Key-Lambiin, 2009). However, this method would decrease statistical power and may be vulnerable to a

selection bias. Single imputation of missing data was used in several studies (Kay-Lambikin, 2011; Omdersma, 2007), which may decrease statistical power. The likelihood-based imputation assuming MAR was most frequently used (Bickel, Marsch, Buchhalter, & Badger, 2008; Carroll et al., 2009, 2014; William Fals-Stewart & Lam, 2010; Rooke, Copeland, Norberg, Hine, & McCambridge, 2013). Thus, this method was applied to impute missing data in this study.

Analyses were conducted with a level of 5% in the two-sided test, using SPSS Statistics Ver. 23.

Subgroup analysis

The efficacy of the intervention was assessed by subgroups because the efficacy may vary depending on specific population. The participants were divided by the primary abused drug (methamphetamine or other drugs), previous face-to-face relapse prevention program (received or not received), and outpatient treatment period (long: more than 3 years, or short: less than 2 years). The abstinent duration and total days from the primary abused drug and all drugs/alcohol during intervention was evaluated using a t-test in each subgroup.

Complete case analysis

To assess efficacy among assessment or intervention completers, complete case analyses were conducted. First, we examined efficacy on relapse risk, motivation to change, self-efficacy for

handling drug use, QOL, SOC, and drug cost among the participants who completed the 2-, 5-, and 8-month assessment using a mixed-effect model or fixed-effect model. Subsequently, the longest period of consecutive abstinent days from the primary abused drug during intervention was compared by group among the participants who completed the intervention using a t-test.

Additionally, completers among the e-SMARPP group were analyzed in detail. First, baseline variables were compared between the intervention completers and dropouts. Then, the baseline variables were compared between the assessment completers and dropouts. These analyses employed t-test, chi-square test, and Fisher's exact test.

Process evaluation analysis

The intervention completion rate by intervention groups was described by calculating the progress of each session and thru weekly self-monitoring. The WUS and the CSQ-8 scores were compared between the intervention groups by t-test. To assess characteristics of those who completed the 8-month follow-up assessment and those who had dropped out from the follow-up, t-test, chi-square test or Fisher's exact test was conducted between the complete case and dropout case.

Ethical considerations

The Ethics Committee of the Faculty of Medicine and Graduate School of Medicine of the

University of Tokyo and the Institutional Review Board of each recruiting hospital and clinic approved this study. Before the baseline survey, candidates were fully informed that their participation was totally voluntary and could withdraw consent if they wanted and they could send a withdrawal e-mail to the researcher (the author) and also could indicate their intention to withdraw to their primary doctor. Even if they withdrew consent, there were no subsequent disadvantages. In addition, they were informed that the findings of this study would be disseminated without participants' personal information via publication and website. Face-to-face informed consent was conducted by the author and signed consent forms were obtained from all participants.

The participants were told that the web-based program did not provide emergency support verbally and on the website and were encouraged to use proper medical services or talk to their primary doctor in case of an emergency. If the author became aware of an emergency condition (e.g., imminent suicide intention, violence) through e-SMARPP, the author consulted with the participant's primary doctor. All data collected in this study was securely stored without the participants' personal information (name, address, etc.). Access to the data was encrypted and limited to research staff named on the ethics protocol.

Results

Participant description

Figure 1 is the participant flow diagram. In total, 48 outpatients were recruited from January 2015 to April 2016 and randomly assigned into either the e-SMARPP group or the self-monitoring group. No participant was recruited from one hospital. In the recruitment process, it was revealed that there were many outpatients who had already stopped using drugs for more than one year because they were on probation or after admission in a correctional institution. Thus, many of the outpatients were ineligible for this study. Additionally, although many outpatients who used new psychoactive substances (NPS) visited the hospitals until starting the recruitment, this quickly decreased because they could not buy NPS due to tightening of regulations for NPS by the Japanese government after April 2014. Thus, it was very difficult to efficiently recruit outpatients.

Table 1 shows the baseline demographics of the participants by group. Of these, 70% were male and average of age was in their middle 30s. Most participants (87.4%) were unmarried or divorced, but 77.3% lived with cohabiters. Over half (54.1%) were unemployed, although 60.1% had completed some college or higher education. The majority used the Internet every day and 2 hours or more a day via a smartphone. There was no significant difference by the intervention condition on these demographic variables, but the self-monitoring group was more male and higher educated than the e-SMARPP group.

Table 2 shows drug use characteristics of the participants. About half of the

participants used methamphetamine, 56.5% had substantial drug dependence severity, 66.8% had been arrested in the past, 37.8% had a psychiatric comorbidity, and 35.4% also had alcohol problems. About half of them had received outpatient treatment for more than three years and a face-to-face relapse prevention program in the past. About 20% had attended a self-help group before. The average number of hospitalizations was about 2.5 times. There was no significant difference by the intervention condition, but the e-SMARPP group had more amphetamine-type-stimulant (methamphetamine and MDMA) users and more psychiatric comorbidity than the self-monitoring group.

Abstinence during the intervention and relapse risk

Table 3 shows the raw scores of the primary and the secondary outcomes at baseline, 2-, 5-, and 8-month follow-up assessment by group. The e-SMARPP group maintained a longer abstinence duration from the primary abuse drug than the self-monitoring group during the follow-up with a moderate effect size ($d = 0.42$), while there was no significant difference between the groups (48.8 versus 41.2, $t = 1.446$, $p = 0.156$).

Table 4 and Figure 2 show the estimated efficacy of the e-SMARPP on the outcomes on the basis of the mixed- or fixed-effect model analyses. For the relapse risk, the SRRS scores had no significant difference for the interaction of group and time ($t = -0.23$, $p = 0.82$). At 2-, 5-, and 8-month follow-up assessments, the effect sizes were very small.

Motivation to change, self-efficacy, QOL, SOC and drug cost

The efficacy of e-SMARPP on all secondary outcomes were not significant in the interaction of group and time (Table 4). The effects sizes of motivation to change at the 2-month, self-efficacy at the 8-month, QOL at the 8-month, SOC at the 2-month, and drug cost at the 5-month were medium.

Abstinence

When the definition of abstinence was changed, the days of abstinence from the primary abused drug and all drugs/alcohol in the past 28 days increased in both groups over time until the 8-month follow-up (Table 3), but abstinence days tended to decrease after the 5-month. There were no significant differences for the interaction group and time (Table 4).

Subgroup analyses

The participants were divided by the primary abused drug, previous face-to-face relapse prevention program and outpatient treatment period. Table 5 shows the results of subgroup analyses on abstinent days from the primary abused drug and all drugs/alcohol during the intervention period.

Among the methamphetamine users and the participants who had never received face-to-face relapse prevention program, the e-SMARPP group maintained longer abstinence than the self-monitoring group with small to moderate effect sizes (d = 0.38 to 0.76), but there

was no significant difference between the groups. Among the participants with a short outpatient treatment period, the e-SMARPP group maintained a significantly longer duration of abstinence from the primary abused drug than the self-monitoring group ($t = 2.46$, $p = 0.03$) with a large effect size ($d = 0.96$). Also, the e-SMARPP group maintained a significantly longer duration and more total days of abstinence from all drugs/alcohol (abstinent duration: $t = 2.80$, $p = 0.01$; abstinent total days: $t = 3.18$, $p = 0.01$) with large effect sizes ($d = 1.20$ and 1.25, respectively). In comparison, among the participants who used other drugs, had received the relapse prevention program before, and had received long outpatient treatment, efficacy of e-SMARPP were likely to decrease.

Complete case analysis

Table 10 shows the efficacy of e-SMARPP on relapse risk, motivation to change, self-efficacy, QOL, SOC, and drug cost among assessment completers (e-SMARPP: n=13, self-monitoring: n=20). There were no significant differences for the interaction group and time. The effect sizes decreased or were opposite to our hypotheses compared to the results among the all participants. When participants were limited to those who completed the intervention (e-SMARPP: n=17, self-monitoring: n=25), the e-SMARPP group maintained a longer abstinence duration from the primary abuse drug than the self-monitoring group with a moderate effect size ($d = 0.49$), while there was no significant difference between the groups

(50.0 versus 41.2, t = 1.68, p = 0.10, data was not shown in the tables). The effect size increased slightly (all participants: effect size = 0.42).

Table 11 and 12 shows differences for the baseline variables between the intervention completers and dropouts among the e-SMARPP group (intervention completers: n = 17, 73.9%). Table 13 and 14 show differences for the baseline variables between the assessment completers and dropouts among the e-SMARPP group (assessment completers: n = 13, 56.5%). The results from these comparisons indicated significantly that the dropouts from both the intervention and the assessment tended to use drugs more at an earlier age, had a more severe condition in terms of drug addiction and psychological distress, had relapse, had less self-efficacy and QOL, and had criminal records. Additionally, dropouts were likely to use drugs other than methamphetamine, had more psychiatric comorbidity, and used outpatient treatment for a longer period.

Process evaluation

As shown in Table 6, the completion rate of the self-monitoring was over 80% in both groups. The relapse prevention session, which was the main content of e-SMARPP, was completed by about 70% of the participants of the e-SMARPP group. All of them completed at least two sessions. When intervention dropout rate was compared between the groups, the e-SMARPP group significantly had more dropouts (z = 2.73, p = 0.01).

As for e-SMARPP usability, all scores of the WUS subscales were over three points, except for the Favorability subscale in the self-monitoring group (Table 7). Among the e-SMARPP group, the subscales of Ease of use, Visual and Credibility were over four points. Among the self-monitoring group, only the Response speed sub-scale was over four points. The subscales of Favorability and Credibility of the e-SMARPP group were significantly higher than those of the self-monitoring group. Program satisfaction assessed by the CSQ in the e-SMARPP group was significantly higher than the self-monitoring group (Table 7).

Participants that mainly used methamphetamine, who had never received face-to-face relapse prevention program and with a short outpatient treatment period reported slightly better usability and higher satisfaction than the participants who used other drugs with a previous relapse prevention program and long-term outpatient treatment, but there were no significant differences between the subgroups (data was not shown).

Table 8 and 9 show comparisons of participants' characteristics at the baseline between the assessment complete cases and the dropout cases. The number of participants who dropped out from the follow-ups was 15 (31.3%) among the total sample. The dropout cases were significantly more female, more divorced, more arrested, had higher SRRS scores, and lower SOCRATES scores, self-efficacy for handling drug use, and SOC. In comparison, there were no significant differences in abstinent situation and drug dependence severity at the

baseline. When the assessment dropout rate was compared between groups, there was no significant difference ($z = 1.75$, $p = 0.08$).

There were no adverse effects such as hospitalization, arrest and death during the intervention. However, four participants (9.3%) reported that they felt drug craving and negative feelings. Their comments included, “The video included an image that was similar to the product package of new psychoactive substances.” “My uncomfortable memory came through and I felt lonely and anxiety when I thought about my triggers of drug use.”

Discussion

Main findings

A web-based relapse prevention program, e-SMARPP, was provided for Japanese drug users who used methamphetamine and other drugs and the efficacy were evaluated with an RCT design at 8-month follow-up. To our knowledge, this is the first RCT assessing the efficacy of a web-based program for Japanese drug users. No significant difference was observed between the intervention (e-SMARPP) and control (self-monitoring) groups on the two primary outcomes (duration of abstinence from the primary abused drug or the relapse risk). Also, all secondary outcomes were not significantly improved in the e-SMARPP group compared to the self-monitoring group. When the participants were limited to those who had received outpatient treatment for a shorter duration, abstinent durations from the primary drug

and all drugs/alcohol and abstinent total days from the all drugs/alcohol were significantly longer in the e-SMARPP group than the control group.

Participants' characteristics

Although as many outpatients as possible were recruited, only 48 participants were involved in the study. The participants' characteristics in this study were almost the same as those of drug users that received psychiatric treatment in Japan (Matsumoto, 2014). Meanwhile, the educational status of the participants (college or higher: 33%) was higher than general outpatients with drug use disorders in Japan (about 10%), although there were not great differences in other demographic variables (Matsumoto, 2014). The most prevalent abused drug of the participants in this study was methamphetamine (50%). The drug dependence severity assessed using DAST-20 was similar to those reported in previous studies among drug users that received face-to-face relapse prevention at the outpatient ward and community-based treatment (Kondo et al., 2014; Tanibuchi et al., 2016). The e-SMARPP group participants tended to be lower educated, more employed, more smartphone users, and more psychiatric comorbidity compared to the self-monitoring group.

In comparison with study participants in other countries, the participants in this study had been in outpatient treatment for several years, receiving a face-to-face relapse prevention program and maintaining a long abstinence prior to the intervention. On the other hand,

similar previous RCTs excluded drug users who were currently receiving any treatment for substance use disorders or were abstinent from drugs in the past month (Carroll et al., 2008, 2014; Kay-Lambkin et al., 2009; Rooke et al., 2013; Tait, 2014). For instance, the average days of the primary drug use and any drug and/or alcohol in the 28 days at the baseline were 3.9 and 6.2, respectively. These drug use days were less than the drug use days in previous studies in other countries (Carroll et al., 2008, 2014; Rooke et al., 2013; Tait, 2014). In this study, it was difficult to recruit drug users using exclusion criteria similar to the above-mentioned previous studies. These differences might cause a ceiling effect and lead to an attenuation of the intervention effect for abstinence, relapse, and other psychological outcomes compared to previous studies.

Efficacy on abstinence

The efficacy of e-SMARPP on abstinence were not significant. This might be because of the small sample size for effect size on abstinence. In this study, the sample size was almost quarter of the expected sample size of participants. However, the effect size of abstinence during the intervention in the study (d = 0.42) was moderate and comparable to the previous studies (Carroll et al., 2008; Portnoy et al., 2008; Rooke et al., 2013), so e-SMARPP had a reasonable efficacy for maintaining a lengthy abstinence. A further study with a large sample size will be needed to assess the exact efficacy on abstinence, but at the same time it is

important to make an effort to collect exact drug-use data without recall bias.

Additionally, the control group condition might have affected the results. In the Carroll study (Carroll et al., 2008), the condition of the control groups was treatment as usual. The effects of computer-assisted cognitive behavioral therapy (CBT) on self-reported longest continuous abstinence from all alcohol/drugs during the intervention was medium (d = 0.45). In Rooke's study (Rooke et al., 2013), the control group was provided with web-based information about cannabis. The effects of a web-based program based on CBT and motivational interviewing on cannabis smoking days at the 3-month follow-up was small (d = 0.31).

This study used an active control method; the control group was provided self-monitoring which was one of the important elements of CBT. The control group may have also received some benefit from the self-monitoring program. This may have attenuated the intervention effect. Therefore, the efficacy of e-SMARPP might be more underestimated when compared to previous studies. In fact, the program completion rate was 100% and program satisfaction was good in the self-monitoring group; in comparison, the completion rate was about 74% in the e-SMARPP group. A previous meta-analysis reported the same results that studies employing active treatment as comparison group demonstrated mostly an effect close to zero (Rooke et al., 2010).

Moreover, it was reported that offline computer programs produced significantly larger effect sizes than web-based programs regardless of monitoring setting at home or research setting (Rooke et al., 2010). Offline programs may offer a higher level of structure and require more dedication on the part of the participant, making the structure more effective and favorable compared to a web-based program. In this study, it is more difficult to obtain efficacy compared to Carroll's study, which used offline computers at the research clinics.

Regarding abstinence after the intervention, abstinence in the 28 past days at the follow-ups was not significantly improved. This suggested that e-SMARPP might improve abstinence during the intervention, but the efficacy are unlikely to be enduring. It is common to use drugs several times in the process of recovery among people with drug addiction. More longitudinal study is needed to assess drug users' long-term relapse and recovery.

Efficacy on relapse risk and positive psychological outcomes

All scales that assessed psychological factors related to relapse and positive outcomes were not significantly improved. The effect sizes of motivation to change at the 2-month, self-efficacy at the 8-month, QOL at the 8-month, SOC at the 2-month, and drug cost at the 5-month were medium. This suggested that e-SMARPP might improve some psychological factors, but the efficacy were unstable.

Motivation to change and self-efficacy among drug users have been reported to be

important predictors of abstinence, but may have a curvilinear relation with drug use behavior rather than a linear one (Crouch, DiClemente, & Pitts, 2015; Kobayashi et al., 2007; Kondo et al., 2014). Patients may be overconfident in their ability to abstain (Burling, Reilly, Moltzen, & Ziff, 1989). Self-efficacy is a more complex predictor. It is unclear whether higher self-efficacy is always better among substance users, and an optimal level of self-efficacy for abstinence is unknown (Kadden & Litt, 2011). Moreover, the motivational component, which was included in e-SMARPP, has been considered to increase the participant's ambivalence toward behavior change (Portnoy et al., 2008). It is necessary to carefully test the motivation to change and the self-efficacy using detailed subscales or a more longitudinal study.

The scores of QOL and SOC might be difficult to improve using a low intensity short-term relapse prevention program without face-to-face interaction between other drug users and professionals. The participants' QOL and SOC were relatively poorer than other populations. The QOL score, 2.86 at the baseline, was lower than 3.0-3.11 among people with schizophrenia and depression (Ishizaki, Kikuchi, Kinoshita, & Nakane, 2003; Kunikata, Mino, & Nakajima, 2006; Kunikata, Nakajima, & Numoto, 2008), 3.2 among caregivers such as family members of schizophrenia patients (Kunikata, 2005), and 3.18-3.29 among general population (Nakane, Tazaki, & Miyaoka, 1999). Also, the SOC score, 13.9 at the baseline, was lower than 14.3-16.4 among the general population (Togari, 2008, 2011). It was reported

that drug users have difficulties functioning in daily life even if they quit drugs (Kamioka & Oshima, 2010). Recovering from QOL and SOC is usually assumed to take a long time. Referral to human services including a self-help group or rehabilitation services in the web-based program is important to support the various difficulties encountered in a drug user's entire life.

Regarding reduction of drug cost, drug cost in the past month at the 5-month follow-up tended to be lower in the e-SMARPP group. This was on average a reduction of about 15,000 yen in the e-SMARPP group compared to the baseline. No previous study has examined the efficacy of a web-based drug relapse prevention program on drug cost. e-SMARPP might have an efficacy in reducing drug cost among drug users. This is important to maintain a social life, especially for drug users that are unemployed and without financial support. In an adverse financial situation, a drug user is likely to become a drug dealer to obtain money and drugs, making it even more difficult to quit drugs.

e-SMARPP allows the participants to recognize at a glance their condition of daily drug use via the self-monitoring calendar, and may also assist in increasing understanding about the benefit of quitting a drug. The relapse prevention included a function analysis that assessed the pros and cons of drug use and quitting drugs. Many participants might feel the benefit of saving on this cost and use the money for other activities. Another possible reason

is the primary abused drug. In the e-SMARPP group, 68.5% of the participants used amphetamine-type stimulants, which are more expensive than other drugs in Japan, and their abstinent days increased. This probably leads to the e-SMARPP group showing a great improvement for drug cost.

However, there was some question on data reliability because some participants reported that they paid more than 100,000 yen even though they did not use drugs. The data collection methods of drug cost should be refined. A detailed analysis of the cost-effectiveness of e-SMARPP will be evaluated with incremental cost-effectiveness ratio in a future study.

Efficacy for specific groups

From the results of the subgroup analyses, outpatients with a short duration of treatment maintained significantly longer abstinence in the e-SMARPP group than in the control. Outpatients who start receiving treatment and maintained abstinence are considered to have better self-efficacy. Self-efficacy is one of the strong predictors of abstinence (Adamson, Sellman, & Frampton, 2009; Ilgen, McKellar, & Tiet, 2005), because people make an effort to cope with high-risk situations and successful coping leads to increased self-efficacy (Crouch et al., 2015). Their confidence and accomplishment of abstinence leads to additional abstinence. On the other hand, outpatients who received long outpatient treatment may have other reasons requiring long treatment, for example severe dependence, comorbidity, poly

drug use and switching of abused drugs. These patients might decrease self-efficacy and motivation to change because motivation for change builds when individuals start to perceive an ambivalent condition between current and desired behavior and then options to resolve the cognitive dissonance experience are identified (Miller & Rollnick, 2002). An additional intensive treatment rather than web-based program may be needed. Another possible reason is that the outpatients with long treatment might have been satisfied with the current treatment and/or have enough self-efficacy, so they did not think that they needed to change.

Efficacy in complete case

When the participants were limited to assessment completers, the efficacy of e-SMARPP decreased compared to the results among the all participants (Table 4 and 10). This might be because the ceiling effect increased since the dropout participants tended to have lower scores for outcome variables at the baseline (Table 9). When the participants were limited to intervention completers, the longest abstinence during the intervention was longer and the effect size was larger than among all participants (effect size, intervention completers: 0.49 vs. all participants: 0.42). These results suggested that not only intervention completion, but also assessment completion was important to accurately evaluate the efficacy of e-SMARPP. It might be necessary to provide more reminders for the assessments and to add incentives to answer the assessment.

In the e-SMARPP group, participants who dropped out from both the intervention and the assessment were likely to deal with psychological problems inappropriately and had used drugs since their late teens and had less confidence about recovery due to a lack of feelings of improvement. It might be better to enhance their self-efficacy and confidence in dealing with drug problems. As such, a longer web-based program might not be effective for such participants. However, the results of the complete case analyses might not be accurate because the analyses were conducted using bivariate analysis methods. Multivariate analysis and more samples are needed to evaluate predictors of the dropouts.

Program and process evaluation

The program completion rate was better or comparable to previous studies (Carroll et al., 2008, 2014; Rooke et al., 2013; White et al., 2010). Program usability and satisfaction was good especially in the e-SMARPP group. The e-SMARPP group users gave comments such as “the video and homework of the relapse prevention sessions were the most useful.” Programs with interactive functions, multimedia and human involvement have been thought to have more effectiveness and satisfaction (Barak et al., 2008; Rooke et al., 2010). The all subscale scores of the WUS in this study were better than those in the pilot study using the prototype of e-SMARPP (Takano et al., 2016a). This means the revision of the prototype was beneficial. These results suggested e-SMARPP is feasible for Japanese drug uses. However, it

is unclear that e-SMARPP is feasible and effective for active drug users who are not receiving treatment.

About 30% of the participants dropped out from the study follow-up. These participants were likely to be arrested, have more relapse risk, were less motivated, and had less self-efficacy and SOC regardless of drug use condition and drug dependence severity. Continuance of the treatment is important for patients with drug addiction because the effects of short-term treatment usually do not endure for long time. It might be necessary to revise the e-SMARPP content to enhance motivation and self-efficacy. Additionally, it might be effective to share e-SMRPP user information with hospital staff and support them directly. As for a comparison of dropout rate between groups, the dropouts from the intervention were significantly observed in the e-SMARPP group. This might be because of the volume of the intervention. An excessive volume of intervention causes an additional strain on the participants.

There were no serious adverse effects although some participants felt drug cravings and uncomfortable feelings while they were doing a relapse prevention session included in e-SMARPP. When a web-based program is provided, provision of information about emergency services in the program is essential because the web-based program did not have emergency support. Also, it is better to recruit outpatients without a serious traumatic experience and who

are allowed to participate by their medical doctors because some drug users have serious trauma related to drug use and may recall a severe experience when they think about situations regarding drug use. Additionally, when e-SMARPP is implemented in the real world, terms of service and disclaimer are needed to avoid legal liabilities.

Regarding the program structure of e-SMARPP, the number of the sessions (six sessions) and the intervention period (eight weeks) were shorter than the face-to-face program in Japan (Tanibuchi et al., 2016). However, the efficacy of web-/Internet-based treatment length and volume was inconsistent among previous meta-analysis studies (Carey, Scott-Sheldon, Elliott, Garey, & Carey, 2012; Portnoy et al., 2008; Rooke et al., 2010). The volume of one session might be large with the time needed to complete the session being more than 60 minutes compared to previous computer-assisted/web-based programs (Takano et al., 2015). Some patients reported that it was hard to complete one session, which included three videos and three assignments. A reduced volume per session might be easier to complete and more feasible for e-SMARPP users and the web-therapists, however, this is likely to require a larger number of sessions. Longer-term intervention might cause more dropouts. The optimum number of sessions, length of a program (intervention), and volume of one session should be carefully considered to prevent dropouts and increase the completion rate.

Future direction

As for revision of e-SMARPP, some possible suggestions were considered to prevent dropout from the intervention. First, it could be effective to add feedback comments and reminder emails to enhance a participant's motivation to continue the intervention. One of the possible means to do this is to add support from therapists, such as a web-therapist who provides support and guidance via emails and telephone. In previous studies that assessed the efficacy of internet-based CBT programs for depression and anxiety or alcohol and tobacco use, more therapist support was associated with higher effect sizes (Spek et al., 2007; Andersson & Cuijpers, 2009; Rooke et al., 2010; Sundström et al., 2016). These results suggest that more therapist support can prevent dropout from the intervention and make the program more effective. As an additional option, an automated reminder function could also be effective. Artificial intelligence, machine learning, and gamification could be utilized to provide feedback and reminders depending on a participant's background and responses (Brown et al., 2016; Fitzpatrick, Darcy, & Vierhile, 2017; Bakker, Kazantzis, Rickwood, & Rickard, 2016). Second, e-SMARPP included a section on major depression that is frequently comorbid with substance use, and it may be effective to add some components of other psychiatric comorbidities to e-SMARPP. A mismatch may arise between the needs of users who had psychiatric comorbidities, because e-SMARPP did not provide broad support to patients with other psychiatric problems, such as schizophrenia and posttraumatic stress disorder.

Meanwhile, however, users felt a strong need to cope with these problems. Thus, it may be useful to provide users with basic information on psychiatric disorders other than substance use disorders. The other option is to inform e-SMARPP users in advance during recruitment that e-SMARPP does not cover all psychiatric problems. It might be better for them to consult a doctor about complex psychiatric problems. Third, modifying e-SMARPP to specifically target users of methamphetamine may improve the effect of the program, because it is generally expected that specific messages to a selected condition might work better than general messages to a broad range of conditions. However, in order to develop such a program targeting methamphetamine, further extensive research on specific behaviors and problems of methamphetamine users is needed.

Several improvements are needed for future research. First, an open trial among the targeted population is essential to confirm the scale of a subsequent RCT and the required trial period that calculates the rate of participation and dropout from the intervention. Moreover, it is necessary to consider an adequate endpoint of an RCT with a limited sample size. As mentioned in the introduction, because Japan has a drug use situation that is very different from other countries (e.g., number of drug users, type of drug, frequency of use), previous results including effect size in other countries might not be appropriate as a comparison. It is important to consider a valuable clinical endpoint that suits the Japanese

situation and to then calculate a feasible sample size. Because frequency and quantity of drug use among Japanese drug users was much lower than frequency among drug users in other countries (Carroll et al., 2008; 2014) and more than half of the participants were able to maintain abstinence at the baseline in this study, it was difficult to find an improvement for abstinent days between pre- and post-intervention in Japan. In previous meta-analysis, studies measuring abstinence tended to have low effect sizes compared to studies measuring post-intervention drug use or reduction of drug use (Rooke, 2010). This result suggests that reduction of drug use is more sensitive than detection of improvement in a drug use situation. Possible endpoints related to abstinence or drug use in Japan might be as follows: reduction of drug use by at least 50%, increase in abstinent days by more than one day, and maintenance of complete abstinence. Second, clinical research coordinators are necessary to improve outreach and recruitment, especially when conducting a multicenter RCT. Support from a contract research organization might also be helpful because RCT involves considerable management, such as central registration of the study participants, randomization, communications, etc. Importantly, extensive outreach is required to find many research settings to complete the RCT when limiting study participants. Moreover, a research budget is essential to conduct such studies. Third, it might be better that the control group is not an active control condition, but treatment as usual, when the research aim is to assess if e-

SMARPP has any effect. In this study, web-based self-monitoring was provided to gather correct data of drug use situation in the control group during the intervention. However, when collecting data regarding drug use, another improved approach might be considered; for example, having both groups report on the situation of drug use retrospectively every month, even if the e-SMARPP group does self-monitoring during the intervention. Fourth, it might be better to limit the study participants to patients with methamphetamine use disorder although e-SMARPP targets all drug users regardless of type of drug. In this study, patients who used drugs other than methamphetamine tended to drop out from the intervention in the intervention group. However, there is a detriment in limiting the type of drugs used among the study participants. This approach may limit the efficacy of the study, which would be different from real-world scenarios. Additionally, it may be better to exclude other patients who tended to drop out using criteria from the various scales, such as patients who started drugs at an early age, those who have a high relapse risk, those who with low self-esteem or QOL, etc. Fifth, stratified randomization or dynamic allocation which use factors that cause dropout or affect efficacy of the intervention might be considered as an alternative method for reducing the effects of dropout (McEntegart, 2003).

Dissemination of e-SMARPP

The ability to apply e-SMARPP to a larger number of patients is limited due to the inclusion

of personalized feedback from a health care professional. Personalized and quick feedback requires more web-therapists or would entail additional costs to add an advanced automated function if the program is used widely. The author thinks that e-SMARPP will be used as a partial replacement of standard treatment or an extension of care in programs such as the "Therapeutic Education System (TES)" by Marsch et al. and "CBT4BT" Carroll et al. (Carroll et al., 2008; Marsch, Carroll, & Kiluk, 2014).

In the future, e-SMARPP can be used as adjunct or alternative treatment at different departments (psychiatric hospital, HIV clinic, emergency room, and public healthcare center, etc.). In the real world, there are different types of drug users with varying issues of drug dependence severity, physical comorbidity, and socioeconomic status. This study did not include various types of drug users because we only recruited outpatients who visited a psychiatric hospital within a limited area. Additionally, strategies to prevent dropouts (e.g., email reminder) were taken in this RCT. In other words, this RCT was an efficacy study, but not an effectiveness study. When e-SMARPP is widely provided in different settings, it is necessary to consider and develop more feasible methods to provide e-SMARPP and carefully assess the efficacy and generalizability of e-SMARPP.

Limitations

Some possible limitations are considered. First, the sample size was very small and the

statistical power was limited. In future research, a larger sample size is required to identify the efficacy and effectiveness of e-SMARPP. This can be done with expanded multicenter collaboration involving a far greater number of collaborative institutes. Second, the follow-up term was relatively short. Recovery is long process, and as such, future studies need a longer follow-up to evaluate long-term effects. Third, generalization of the findings is limited. The participants were recruited from only five large-scale psychiatric hospitals with many patients with drug addiction in an area with a large population. Although the participants' characteristics in this study were almost the same as those of outpatients receiving outpatient treatment for drug use disorder in Japan, the participants were more educated and may have been more motivated and engaged in outpatient treatment. It is unclear whether e-SMARPP is effective for outpatients with low motivation. Also, the efficacy of e-SMARPP for drug users who do not receive outpatient treatment were not confirmed. Future study should be conducted to evaluate the efficacy and effectiveness of e-SMARPP among different populations in various areas, such as drug users who live in a remote area, those who seek any support, but do not have time to continue to visit a hospital, and those who have dropped out of treatment early for any reason. Fourth, it was possible that the efficacy of e-SMARPP were not accurately assessed because this RCT was not blinded. A blinded RCT using other web-based minimal interventions in the control group (e.g., provision of information about

diseases caused by drugs) might be acceptable and feasible in future study. Lastly, the reliability of the collected data was uncertain because the all outcomes and confounders were self-reported. Some variables, e.g., drug use and motivation to change, might be influenced by social desirability bias. Also, some variables might be difficult to answer for patients, for example diagnosis of comorbidity. Provision of user support, e.g., a pop-up user guide for answering the questionnaires, may facilitate better answers.

Conclusion

The author evaluated the efficacy of a newly developed low intensive web-based relapse prevention program for Japanese drug users, e-SMARPP, among psychiatric outpatients with a multicenter RCT design on duration of abstinence, relapse risk, and other outcomes at 8-month follow-up. The study failed to show significant differences in any of these outcomes between the intervention and control groups. However, the effect size for duration of abstinence from the primary abused drug during the intervention was moderate and similar to those reported previously in other countries. Duration and total days of abstinence from all drugs/alcohol were significantly longer in the intervention group when the participants were limited to those who had shorter duration of medical treatment. The e-SMARPP program may be promising as an effective, safe, and feasible relapse prevention program for drug users,

while further research with a larger sample and longer follow-up term should be conducted in different future settings.

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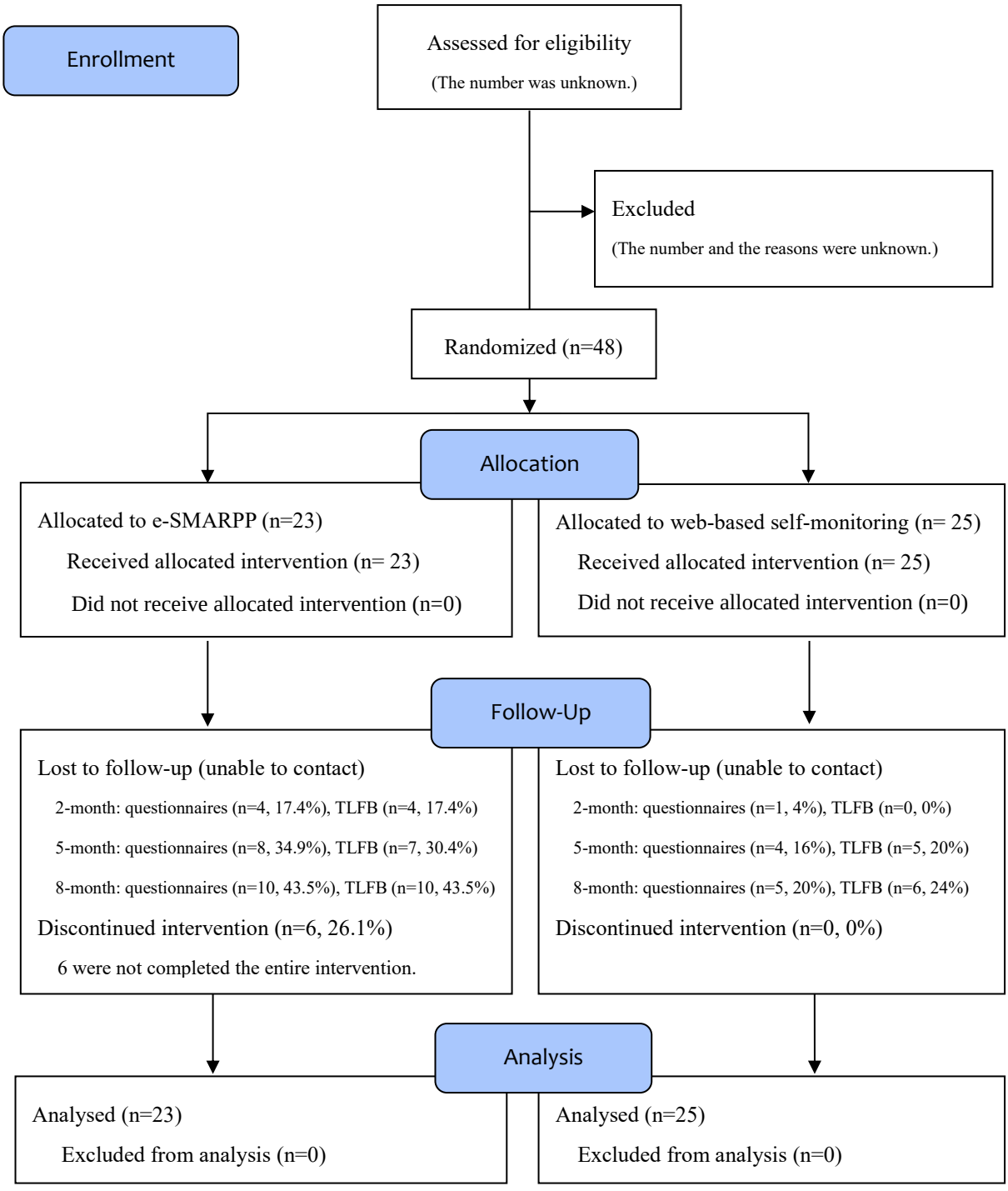
Tables and figures

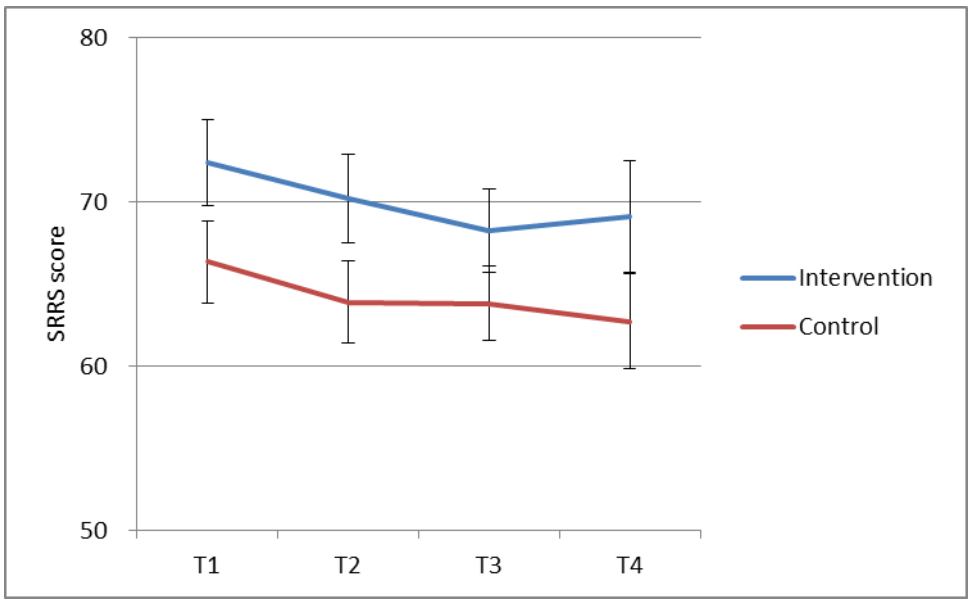


TLFB: The TimeLine Follow Back method to assess the participants' drug use condition

Figure 1. Participant flow diagram

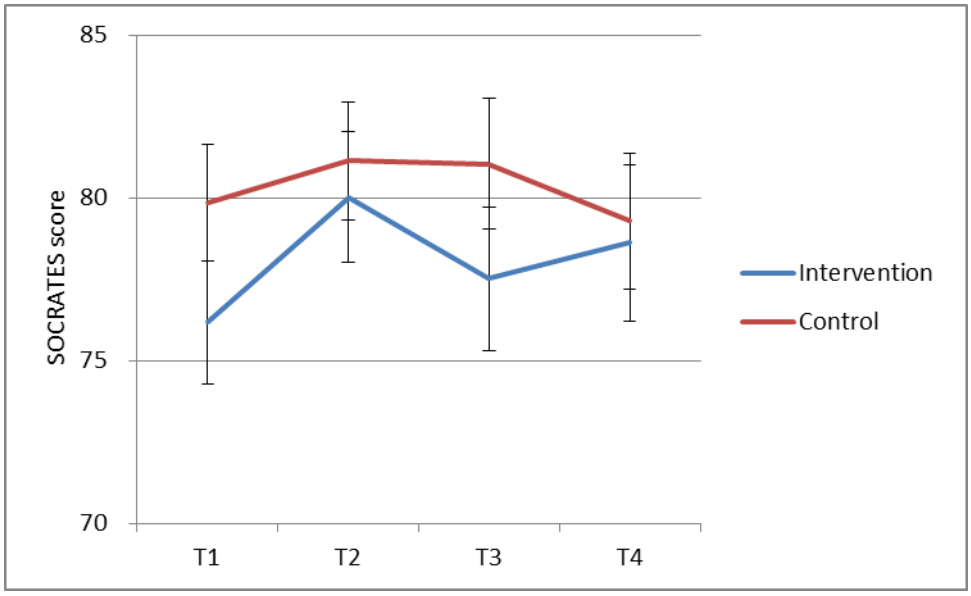
Figure 2. Estimated means of outcomes calculated by mixed or fixed model for repeated measures ANOVA model analysis (N=48)

Error bars in the figures indicate standard errors.



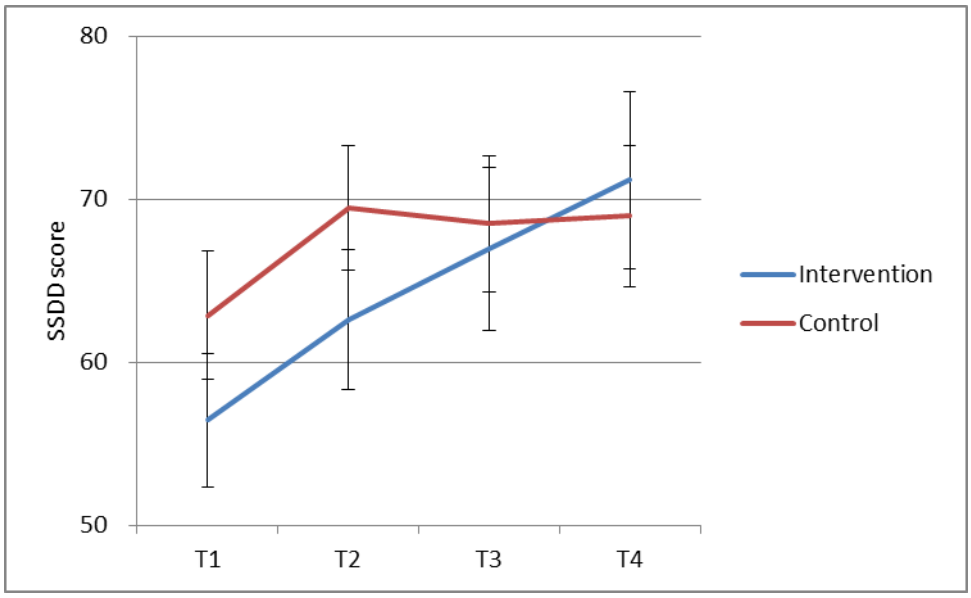
Relapse risk

SRRS: Stimulant Relapse Risk Scale



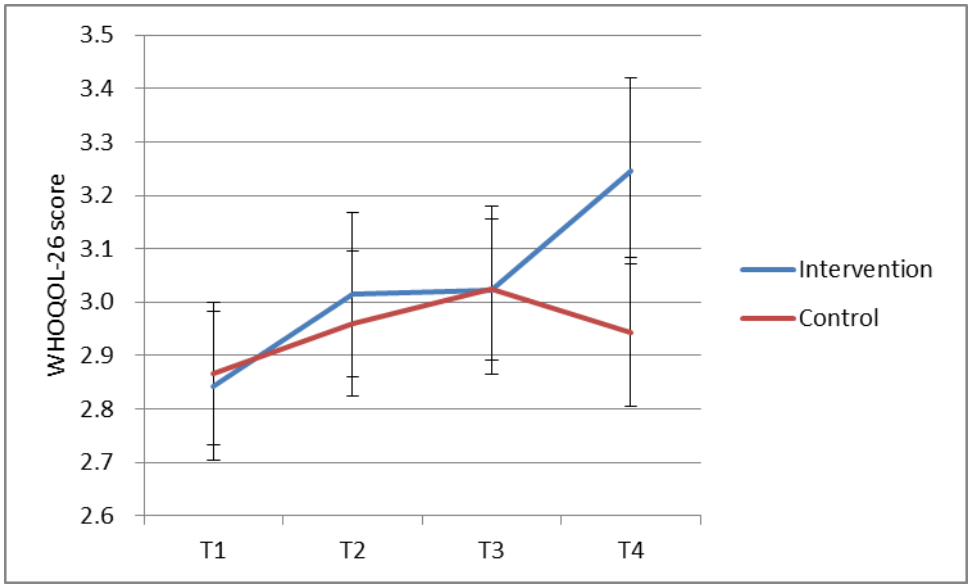
Motivation to change

SOCRATES: Stage of Change Readiness and Treatment Eagerness Scale

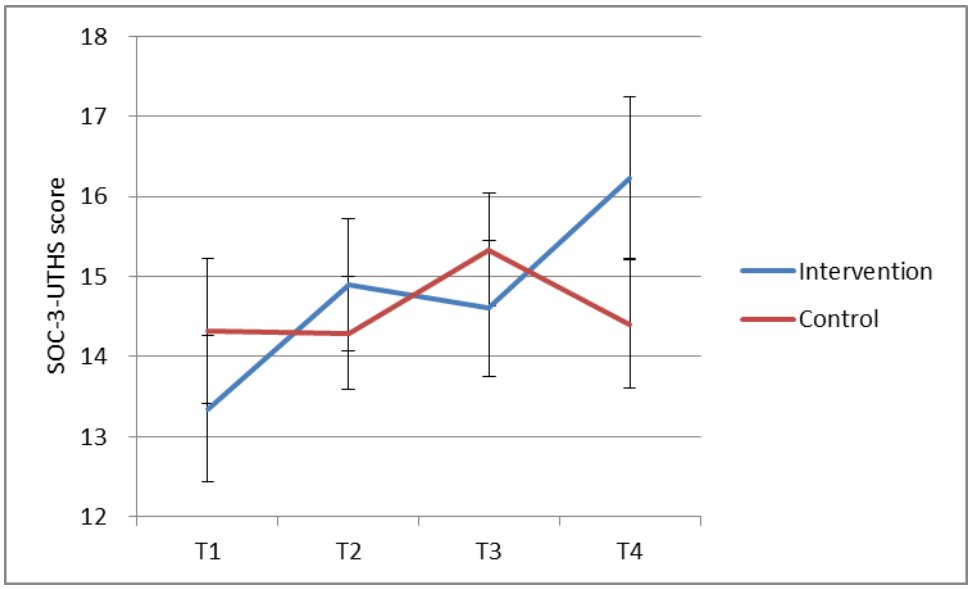


Self-efficacy for handling drug use

SSDD: Self-efficacy Scale for Drug Dependence

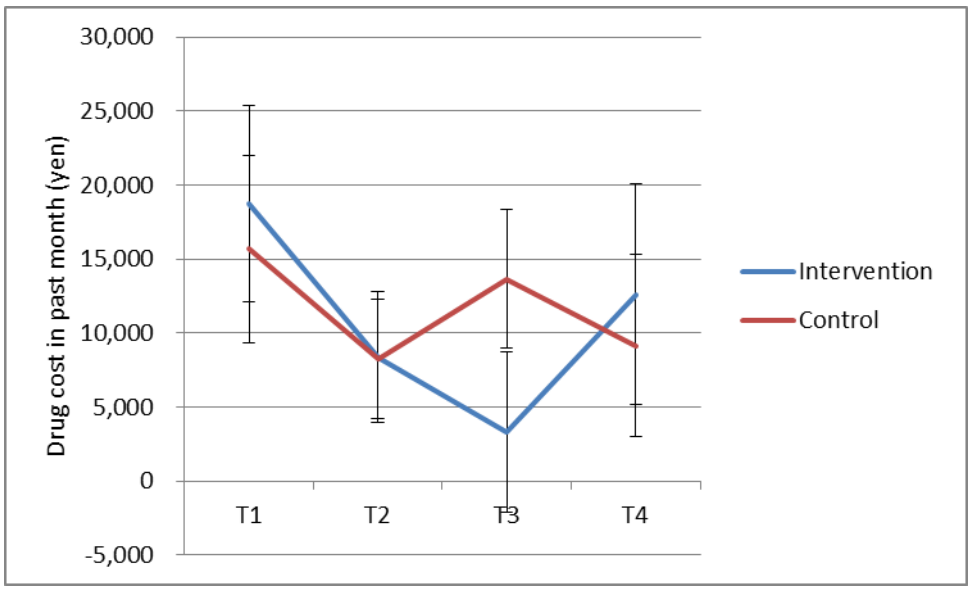


Quality of life



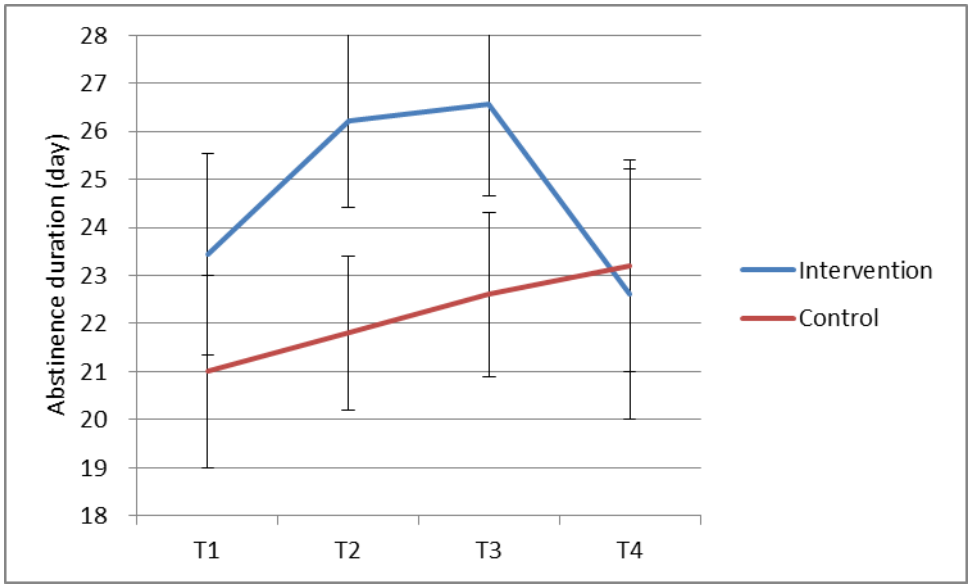
Sense of coherence

COC-3-UTHS: The University of Tokyo Health Sociology version of the SOC3 scale

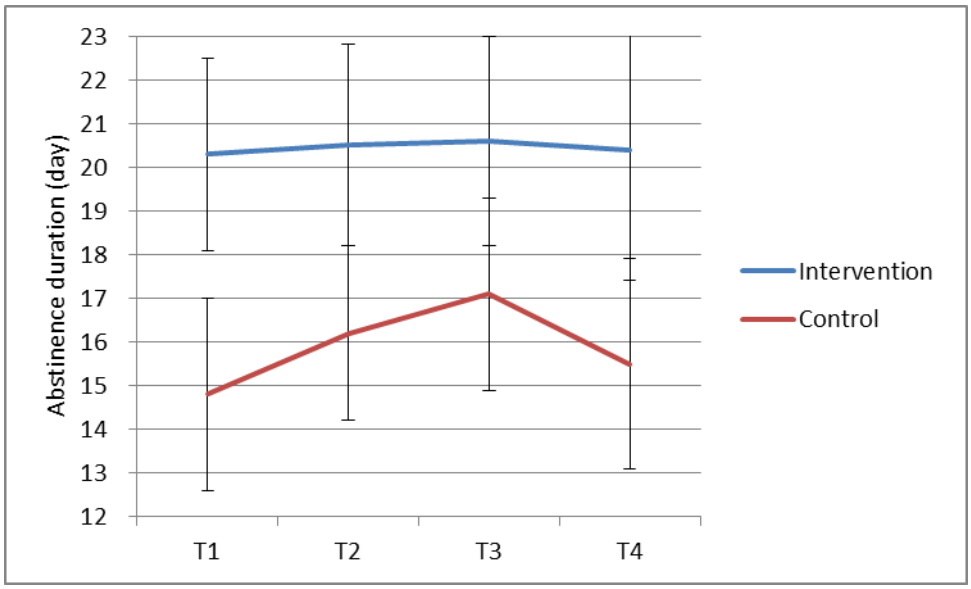


Drug cost in past month (yen)

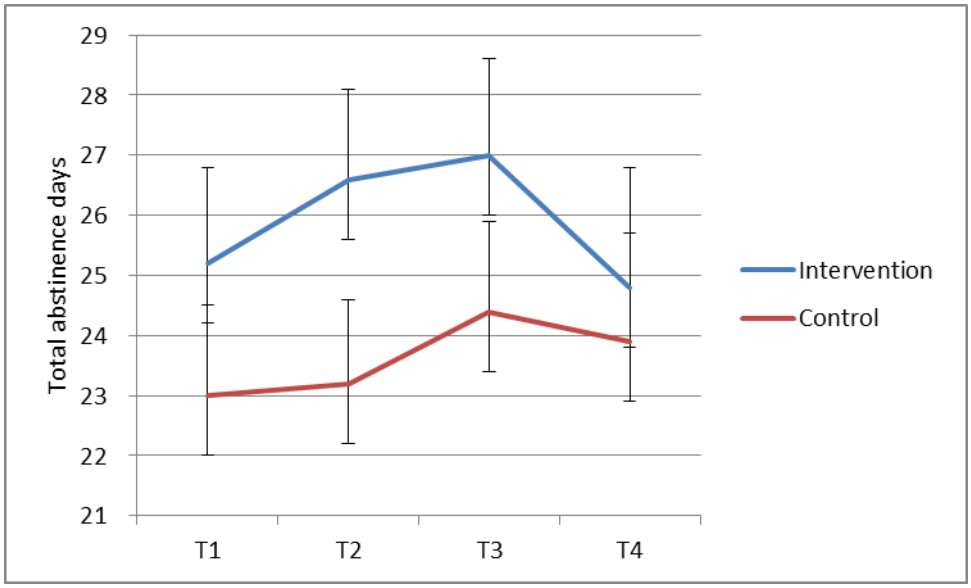
Sample size varied because of excluding outliers.



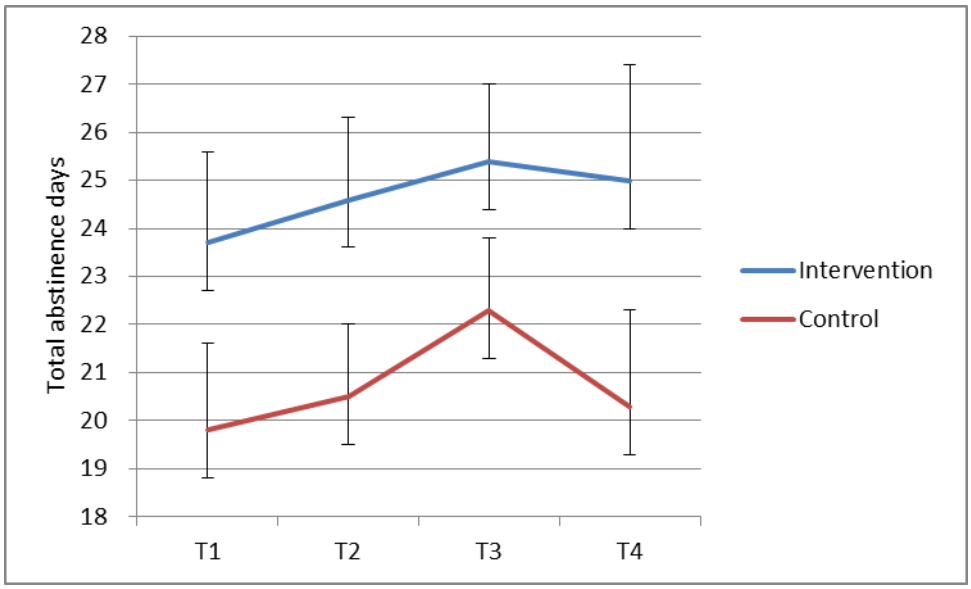
Longest duration of abstinence from primary drug in past 28 days



Longest duration of abstinence from all drugs/alcohol in past 28 days



Total abstinent days from primary drug in past 28 days



Total abstinent days from all drugs/alcohol in past 28 days

Table 1. Participants' demographic characteristics and Internet use at baseline

		Intervention (n=23)		Control (n=25)	
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)
Age		*37.0*	*(7.3)*	*39.5*	*(7.5)*
Sex	Male	14	60.9	19	76.0
Marital status	Currently married	4	17.4	5	20.0
	Never married	15	65.2	17	68.0
	Divorced	4	17.4	3	12.0
Cohabiter	Single	4	17.4	7	28.0
Education	Middle school	2	8.7	4	16.0
	High school	9	39.1	4	16.0
	Some college	6	26.1	7	28.0
	College or higher	6	26.1	10	40.0
Job	Full-time	4	17.4	3	14.6
	Part-time	5	21.7	2	8.0
	Unemployed	12	52.2	14	56.0
	Sick leave	0	0	2	8.0
	Housewife/other	2	8.7	4	16.0
Internet use	Every day	19	82.6	21	84.0
	2 hours or more/day	15	65.2	18	72.0
Internet device (most use)	Smartphone	18	78.3	17	68.0
	Personal computer	4	17.4	7	28.0
	Tablet/mobile phone	1	4.3	1	4.0
Internet access	Home	16	69.6	23	92.0

Table 2. Participants' characteristics related to drug use

		Intervention (n=23)		Control (n=25)	
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)
Primary abused drug	Methamphetamine	13	56.5	11	44.0
	NPS	1	4.3	5	20.0
	MDMA	3	13.0	2	8.0
	Hypnotics/anxiolytics	1	4.3	3	12.0
	Cough medicine	2	8.7	2	8.0
	Heroine	0	0	2	8.0
	Inhalant	1	4.3	0	0
	Poly drug	2	8.7	0	0
Age of first drug use		*21.3*	*(7.6)*	*21.5*	*(5.6)*
Arrest in past		16	69.6	16	64.0
Jail in past		4	17.4	6	24.0
Drug dependence severity (DAST-20)	Total score	*13.2*	*(3.6)*	*11.7*	*(3.9)*
	Low (1-5)	1	4.3	3	12.0
	Intermediate (6-10)	4	17.4	4	16.0
	Substantial (11-15)	14	60.9	13	52.0
	Severe (16-20)	4	17.4	5	20.0
Psychiatric comorbidity		10	43.5	8	32.0
Harmful alcohol use (AUDIT-C)		8	34.8	9	36.0
Psychological distress (K6)		*11.1*	*(6.2)*	*9.8*	*(6.5)*
Outpatient treatment period	< 1 year	8	34.8	7	28.0
	1-3 years	2	8.7	5	20.0
	> 3 years	13	56.5	13	52.0
Number of hospitalization		*2.9*	*(6.4)*	*2.2*	*(6.3)*
Previous face-to-face relapse prevention		11	47.8	13	52.0
Previous self-help group		6	26.1	8	32.0

NPS: New psychoactive substances
MDMA: 3,4-methylenedioxymethamphetamine
DAST-20: Drug Abuse Screening Test
AUDIT-C: The Alcohol Use Disorders Identification Test-Consumption, harmful alcohol use (total score) = male > 3, female > 2

Table 3. Average abstinence days and scores of primary and secondary outcomes by treatment condition

Primary outcome	Intervention (N=23)								Control (N=25)							
Longest duration of abstinence from primary drug in intervention period (56 days)	mean		SD		median		(n=19)		mean		SD		median		(n=25)	
	48.8		14.7		56				41.2		20.3		56		t=1.446 p=0.156 d=0.42	
	Baseline (n=23)		2 months (n=19)		5 months (n=15)		8 month (n=13)		Baseline (n=25)		2 months (n=24)		5 months (n=21)		8 month (n=20)	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
Relapse risk (SRRS)	72.4	13.1	68.0	13.7	64.2	11.5	64.4	15.0	66.3	12.0	63.5	10.9	63.7	10.5	62.7	12.9
Secondary outcome																
Motivation to change (SOCRATES)	76.2	7.5	80.9	8.1	79.2	7.1	80.4	7.4	79.8	9.9	81.1	10.1	82.2	9.0	80.3	11.0
Self-efficacy for handling drug use	56.4	21.2	62.6	21.7	66.9	18.0	71.2	18.8	62.9	18.1	69.5	15.9	68.5	20.3	69.0	19.6
Quality of life (WHOQOL26)	2.84	0.74	3.01	0.69	3.02	0.66	3.25	0.60	2.87	0.59	2.96	0.66	3.02	0.57	2.94	0.64
Sense of coherence	13.4	4.7	14.9	3.6	14.6	3.9	16.2	3.3	14.3	4.3	14.3	3.6	15.3	2.8	14.4	3.9
Drug cost in past month (yen)	39695.6	106512.2	8368.4	21294.9	3333.3	10465.4	12615.4	29250.5	55040.4	198390.2	12062.5	25450.9	17781.0	31640.3	23700.0	69525.5
Drug cost in past month (yen, exclude outlier) [a]	(n=22)		(n=19)		(n=15)		(n=13)		(n=24)		(n=23)		(n=20)		(n=19)	
	18772.7	36564.3	8368.4	21294.8	3333.3	10465.4	12615.4	29250.5	15667.1	25068.2	8239.1	17618.3	13670.0	26081.0	9157.9	25257.0
Abstinence in 28 days	Baseline (n=23)		2 months (n=19)		5 months (n=16)		8 month (n=13)		Baseline (n=25)		2 months (n=25)		5 months (n=20)		8 month (n=19)	
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
Longest duration of abstinence from primary drug	23.4	9.2	26.2	4.4	26.6	3.9	22.6	8.6	21.0	10.7	21.8	9.7	22.6	9.5	23.2	10.0
Longest duration of abstinence from all drugs/alcohol	20.3	10.3	20.5	9.3	20.6	8.5	20.4	9.1	14.8	11.2	16.2	10.8	17.1	10.9	15.5	11.6
Total abstinent days from primary drug	25.2	7.0	27.3	1.9	27.7	1.0	25.5	6.2	23.0	9.3	23.3	8.4	24.7	7.3	24.4	8.4
Total abstinent days from all drugs/alcohol	23.7	7.9	24.6	5.0	25.4	4.1	25.0	6.0	19.8	10.1	20.5	8.9	22.3	7.9	20.3	10.0

SRRS: Stimulant Relapse Risk Scale

SOCRATES: Stage of Change Readiness and Treatment Eagerness Scale

a: Cost variable was excluded if the variable was over 100,000 (yen) even the participant did not use primary abused drug in the past month. Sample size varies because of excluding outliers.

Table 4. Efficacy of e-SMARPP on relapse risk, motivation to change, self-efficacy, quality of life, sense of coherence, drug cost, and abstinence among the all participants (intervention: n=23, control: n=25)

Primary outcome	Estimates of fixed effects		(95% CI)	t	p	Difference of estimated means (intervention - control)	Pooled SD	Effect size
Relapse risk (SRRS)	2 months [c]	0.29	(-4.96 to 5.53)	0.11	0.91	0.29	8.41	0.03
	5 months [c]	-1.61	(-7.57 to 4.35)	-0.55	0.59	-1.61	9.06	-0.18
	8 month [c]	0.34	(-7.76 to 8.45)	0.09	0.93	0.34	11.90	0.03
	Pooled [d]	-0.28	(-2.73 to 2.17)	-0.23	0.82			
Secondary outcome	Estimates of fixed effects		(95% CI)	t	p	Difference of estimated means (intervention - control)	Pooled SD	Effect size
Motivation to change (SOCRATES)	2 months [a]	2.55	(-1.19 to 6.29)	1.37	0.18	2.55	5.97	0.43
	5 months [a]	0.14	(-4.51 to 4.79)	0.06	0.95	0.14	7.30	0.02
	8 month [a]	3.00	(-2.14 to 8.13)	1.17	0.25	3.00	8.56	0.35
	Pooled [b]	0.98	(-0.92 to 2.87)	1.05	0.30			
Self-efficacy for handling drug use	2 months [c]	-0.38	(-16.42 to 15.66)	-0.05	0.96	-0.38	15.60	-0.02
	5 months [c]	4.90	(-12.38 to 22.18)	0.57	0.57	4.90	15.46	0.32
	8 month [c]	8.65	(-9.13 to 26.43)	0.97	0.34	8.65	14.77	0.59
	Pooled [b]	-0.91	(-4.08 to 2.26)	-0.58	0.56			
Quality of life (WHOQOL26)	2 months [c]	0.08	(-0.48 to 0.64)	0.28	0.78	0.08	0.46	0.17
	5 months [c]	0.02	(-0.54 to 0.58)	0.08	0.94	0.02	0.58	0.04
	8 month [c]	0.32	(-0.26 to 0.91)	1.10	0.27	0.32	0.59	0.55
	Pooled [b]	-0.01	(-0.13 to 0.12)	-0.09	0.93			
Sense of coherence	2 months [a]	1.58	(-1.74 to 4.89)	0.94	0.35	1.58	3.15	0.50
	5 months [a]	0.24	(-3.10 to 3.58)	0.14	0.89	0.24	3.90	0.06
	8 month [a]	2.80	(-0.81 to 6.41)	1.55	0.13	2.80	3.84	0.73
	Pooled [b]	0.37	(-0.50 to 1.23)	0.86	0.40			
Drug cost in past month (exclude outlier)	2 months [c]	-2976.35	(-24821.23 to 18868.53)	-0.27	0.79	-2976.35	25658.81	-0.12
	5 months [c]	-13442.31	(-36610.06 to 9725.44)	-1.16	0.25	-13442.31	26346.53	-0.51
	8 month [c]	351.85	(-26269.32 to 26973.01)	0.03	0.98	351.85	22341.46	0.02
	Pooled [d]	-2113.85	(-10084.20 to 5856.43)	-0.53	0.60			

Longest duration of abstinence from primary drug in past 28 days	2 months [c]	1.94	(-5.53 to 9.04)	0.52	0.61	1.98	6.28	0.31
	5 months [c]	1.54	(-6.10 to 9.17)	0.40	0.69	1.53	7.20	0.21
	8 month [c]	-3.02	(-11.95 to 5.91)	-0.67	0.50	-3.02	8.17	-0.37
	Pooled [b]	-0.71	(-2.48 to 1.07)	-0.81	0.43			
Longest duration of abstinence from all drugs/alcohol in past 28 days	2 months [c]	-1.19	(-9.92 to 7.55)	-0.27	0.79	-1.20	8.40	-0.14
	5 months [c]	-1.96	(-10.95 to 7.04)	-0.43	0.67	-2.00	9.72	-0.21
	8 month [c]	-0.56	(-10.42 to 9.30)	-0.11	0.91	-0.60	7.73	-0.08
	Pooled [d]	-0.29	(-3.30 to 2.73)	-0.19	0.85			
Total abstinent days from primary drug in past 28 days	2 months [a]	1.24	(-1.62 to 4.10)	0.88	0.38	1.20	4.29	0.28
	5 months [a]	0.42	(-2.78 to 3.61)	0.27	0.79	0.40	5.22	0.08
	8 month [a]	-1.23	(-5.72 to 3.27)	-0.56	0.58	-1.30	6.27	-0.21
	Pooled [b]	-0.3	(-1.63 to 1.04)	-0.45	0.66			
Total abstinent days from all drugs/alcohol in past 28 days	2 months [c]	0.12	(-6.81 to 7.05)	0.03	0.97	0.20	5.32	0.04
	5 months [c]	-0.84	(-7.64 to 5.96)	-0.25	0.81	-0.80	6.32	-0.13
	8 month [c]	0.71	(-7.43 to 8.84)	0.17	0.86	0.80	4.53	0.18
	Pooled [d]	0.06	(-2.37 to 2.49)	0.05	0.96			

SRRS: Stimulant Relapse Risk Scale
SOCRATES: Stage of Change Readiness and Treatment Eagerness Scale
a: A mixed model for repeated measures ANOVA model analysis was conducted.
b: A mixed model for repeated measures conditional growth model was conducted.
c: A fixed model for repeated measures ANOVA model analysis was conducted.
d: A fixed model for repeated measures conditional growth model was conducted.

Table 5. Subgroup analyses on abstinence during the intervention (56 days)

Subgroup			Abstinent duration from the primary abused drug						Abstinent duration from all drugs/alcohol						Abstinent total days from the primary abused drug						Abstinent total days from all drugs/alcohol					
			n	Mean	SD	t	p	d	n	Mean	SD	t	p	d	n	Mean	SD	t	p	d	n	Mean	SD	t	p	d
All participants		I	19	48.8	14.7	1.45	0.16	0.42	19	34.2	20.3	1.11	0.27	0.34	19	53.3	5.9	1.71	0.10	0.47	19	48.4	9.8	1.68	0.10	0.47
		C	25	41.2	20.3				25	27.1	21.4				25	47.6	15.2				25	41.4	17.5			
Primary abused drug	Meth amphetamine	I	12	51.2	11.6	1.48	0.17	0.76	12	38.7	18.9	0.84	0.41	0.38	12	53.5	5.9	1.19	0.25	0.54	12	50.4	7.2	1.42	0.19	0.76
		C	8	38.9	21.5				8	30.4	25.1				8	48.1	14.0				8	40.8	18.3			
	Other drugs	I	5	40.2	21.7	-0.07	0.94	-0.04	5	22.6	20.9	-0.34	0.74	-0.18	5	51.6	7.4	0.70	0.49	0.37	5	41.6	14.2	0.13	0.90	0.07
		C	13	41.0	21.1				13	26.5	22.0				13	45.7	18.0				13	40.3	20.1			
Previous face-to-face relapse prevention	Received	I	10	52.5	11.1	1.39	0.18	0.29	10	33.9	19.6	1.39	0.18	0.09	10	54.6	4.4	1.24	0.19	0.38	10	49.8	7.1	1.64	0.09	0.26
		C	13	42.8	21.7				13	22.2	20.5				13	47.8	16.9				13	40.3	17.1			
	Not receive	I	9	44.7	17.7	0.65	0.53	0.54	9	34.4	22.2	0.21	0.84	0.58	9	51.8	7.2	0.87	0.39	0.52	9	46.9	12.3	0.59	0.56	0.69
		C	12	39.3	19.4				12	32.4	21.9				12	47.3	13.9				12	42.7	18.7			
Outpatient treatment term	Long: > 3 years	I	9	40.8	18.7	0.08	0.94	0.03	9	22.6	16.1	-1.15	0.27	-0.47	9	50.2	7.6	0.76	0.46	0.33	9	42.1	10.9	-0.04	0.97	-0.02
		C	13	40.1	21.9				13	32.0	22.6				13	45.4	18.0				13	42.4	20.5			
	Short: < 2 years	I	10	56.0	0.0	2.46	**0.03**	0.96	10	44.6	18.4	2.80	**0.01**	1.20	10	56.0	0.0	1.79	0.10	0.69	10	54.1	3.1	3.18	**0.01**	1.25
		C	12	42.3	19.2				12	21.8	19.6				12	49.9	11.8				12	40.4	14.5			

I: intervention (e-SMARPP group), C: control (self-monitoring group)

Table 6. Intervention completion rate

Intervention (n=23)			Control (n=25)		
Self-monitoring (week)	n	%	Self-monitoring (week)	n	%
1	23	100.0	1	25	100.0
2	23	100.0	2	25	100.0
3	23	100.0	3	25	100.0
4	21	91.3	4	25	100.0
5	21	91.3	5	25	100.0
6	20	87.0	6	25	100.0
7	20	87.0	7	25	100.0
8	19	82.6	8	25	100.0
Relapse prevention session	n	%			
1	23	100.0			
2	23	100.0			
3	22	95.7			
4	21	91.3			
5	20	87.0			
6	17	73.9			

Table 7. Program usability and satisfaction

	Total (N=43)		Intervention (n=19)		Control (n=24)		
Web usability scale	Mean	SD	Mean	SD	Mean	SD	p
Total	3.8	0.5	3.9	0.3	3.7	0.6	0.08
Ease of use	3.9	0.8	4.0	0.7	3.9	0.9	0.71
Website structure	3.7	0.9	3.7	0.9	3.7	0.9	0.98
Visual	3.7	0.8	4.0	0.8	3.6	0.8	0.14
Response speed	4.0	0.9	3.8	1.0	4.2	0.9	0.14
Favorability	3.2	1.0	3.7	0.6	2.9	1.0	**0.002**
Helpfulness	3.8	0.5	3.9	0.5	3.8	0.6	0.41
Credibility	4.0	0.8	4.4	0.5	3.6	0.8	**0.001**
CSQ-8	23.1	4.2	25.9	2.5	21.0	4.1	**< 0.001**

Web usability scale: Higher score indicates higher usability assessed on 5-point Likert scale (1: disagree to 5: agree)
CSQ-8: Client Satisfaction Questionnaire 8-item version. Higher score indicates higher satisfaction.

Ease of use: 操作のわかりやすさ, Website structure: 構成のわかりやすさ, Visual: 見やすさ, Response speed: 反応の良さ, Favorability: 好感度, Helpfulness: 役立ち感, Credibility: 内容の信頼性

Table 8. Comparison of participants' demographic characteristics at the baseline between survey completers and dropout participants

		Completer (n=33)		Dropout (n=15)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Age		*38.2*	*(7.0)*	*38.5*	*(8.6)*	.90
Sex	Male	26	78.8%	7	46.7%	**.03**
Marital status	Currently married	6	18.2%	3	20.0%	**.04**
	Never married	25	75.8%	7	46.7%	
	Divorced	2	6.1%	5	33.3%	
Cohabiter	Single	8	24.2%	3	20.0%	.53
Education	Middle school	3	9.1%	3	20.0%	.28
	High school	7	21.2%	6	40.0%	
	Some college	9	27.3%	4	26.7%	
	College or higher	14	42.4%	2	13.3%	
Job	Full-time	6	18.2%	1	6.7%	.49
	Part-time	6	18.2%	1	6.7%	
	Unemployed	16	48.5%	10	66.7%	
	Sick leave	2	6.1%	0	0%	
	Housewife/other	3	9.1%	6	22.5%	
Internet use	Every day	27	81.8%	13	86.7%	.44
	2 hours or more/day	11	63.6%	12	80.0%	.18
Internet device (most use)	Smartphone	8	24.2%	10	66.7%	.20
	Personal computer	25	75.8%	3	20.0%	
	Tablet/mobile phone	0	0%	2	13.4%	
Internet access	Home	26	78.8%	13	86.7%	.35

a: t-test, chi-square, Fisher's exact test

Table 9. Comparison of participants' characteristics related to drug use at the baseline between survey completers and dropout participants

		Completer (n=33)		Dropout (n=15)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Primary abused drug	Methamphetamine	17	51.5%	7	46.7%	.22
	NPS	6	18.2%	0	0%	
	MDMA	4	12.1%	1	6.7%	
	Hypnotics/anxiolytics	3	9.1%	1	6.7%	
	Cough medicine	2	6.1%	2	13.3%	
	Heroine	1	3.0%	1	6.7%	
	Inhalant	0	0.0%	1	6.7%	
	Poly drug	0	0.0%	2	13.3%	
Age of first drug use		*21.8*	*(6.6)*	*20.5*	*(6.4)*	.53
Arrest in past		25	75.8%	7	46.7%	**.05**
Jail in past		10	30.3%	0	0.0%	**.03**
Drug dependence severity (DAST-20)	Total score	*12.2*	*(3.6)*	*13.1*	*(4.2)*	.44
	Low (1-5)	3	9.1%	1	6.7%	.81
	Intermediate (6-10)	6	18.2%	2	13.3%	
	Substantial (11-15)	19	57.6%	8	53.3%	
	Severe (16-20)	5	15.2%	4	26.7%	
Psychiatric comorbidity		12	36.4%	6	40.0%	.53
Harmful alcohol use (AUDIT-C)	Total score	*2.4*	*(2.8)*	*3.6*	*(4.0)*	.24
	yes	10	30.3%	7	46.7%	.22
Psychological distress (K6)		10.0	6.0	11.3	7.1	.54
Outpatient treatment period	< 1 year	13	39.4%	2	13.3%	.17
	1-3 years	3	9.1%	4	26.7%	
	> 3 years	17	51.5%	9	60.0%	
Number of hospitalization		*1.7*	*(5.3)*	*4.5*	*(8.0)*	.15
Previous face-to-face relapse prevention		17	51.5%	7	46.7%	.50
Previous self-help group		12	36.4%	2	13.3%	.10
Relapse risk (SRRS)		*66.5*	*(12.8)*	*75.1*	*(10.9)*	**.03**
Motivation to change (SOCRATES)		*79.8*	*(8.4)*	*74.2*	*(9.1)*	**.04**
Self-efficacy for handling drug use		*63.6*	*(18.7)*	*51.3*	*(19.6)*	**.04**
Quality of life (WHOQOL26)		*3.0*	*(0.6)*	*2.6*	*(0.7)*	.08
Sense of coherence		*14.7*	*(4.1)*	*11.9*	*(4.3)*	**.04**
Drug cost in past month (yen, exclude outlier) [b]		*18331.0*	*(32967.8)*	*14716.7*	*(26594.7)*	.71
Abstinence in 28 days						
Longest duration of abstinence from primary drug		*22.3*	*(9.8)*	*21.8*	*(10.7)*	.87
Longest duration of abstinence from all drugs/alcohol		*18.1*	*(10.4)*	*16.0*	*(12.5)*	.55
Total abstinent days from primary drug		*24.5*	*(7.6)*	*23.3*	*(9.8)*	.65
Total abstinent days from all drugs/alcohol		*23.0*	*(7.9)*	*18.8*	*(11.4)*	.15

a: t-test, chi-square, Fisher's exact test
b: Cost variable was excluded if the variable was over 100,000 (yen) even the participant did not use primary abused drug in the past month. Sample size varies because of excluding outliers.
NPS: New psychoactive substances
MDMA: 3,4-methylenedioxymethamphetamine
DAST-20: Drug Abuse Screening Test
AUDIT-C: The Alcohol Use Disorders Identification Test-Consumption, harmful alcohol use (total score) = male>3, female>2
SRRS: Stimulant Relapse Risk Scale
SOCRATES: Stage of Change Readiness and Treatment Eagerness Scale

Table 10. Efficacy of e-SMARPP on relapse risk, motivation to change, self-efficacy, quality of life, sense of coherence, and drug cost among the assessment completers (intervention: n=13, control: n=20)

Primary outcome	Estimates of fixed effects		(95% CI)	t	p	Difference of estimated means (intervention - control)	Pooled SD	Effect size
Relapse risk (SRRS)	2 months [c]	0.97	(-5.22 to 7.17)	0.32	0.75	0.97	8.40	0.12
	5 months [c]	-0.27	(-7.22 to 6.69)	-0.08	0.94	-0.27	9.43	-0.03
	8 month [c]	1.57	(-7.20 to 10.34)	0.37	0.72	1.57	11.90	0.13
	Pooled [b]	0.26	(-2.50 to 3.02)	0.19	0.85			
Secondary outcome	Estimates of fixed effects			t	p	Difference of estimated means (intervention - control)	Pooled SD	Effect size
Motivation to change (SOCRATES)	2 months [a]	2.16	(-2.53 to 6.85)	0.94	0.36	2.16	6.26	0.35
	5 months [a]	-0.83	(-6.03 to 4.36)	-0.33	0.75	-0.83	7.21	-0.12
	8 month [a]	2.25	(-3.30 to 7.79)	0.81	0.42	2.25	8.56	0.26
	Pooled [b]	0.50	(-1.51 to 2.51)	0.51	0.62			
Self-efficacy for handling drug use	2 months [c]	-7.17	(-24.97 to 10.64)	-0.81	0.42	-7.17	15.08	-0.48
	5 months [c]	-6.10	(-24.383to 12.64)	-0.65	0.52	-6.10	15.95	-0.38
	8 month [c]	-5.12	(-24.25 to 14.01)	-0.54	0.59	-5.12	14.77	-0.35
	Pooled [d]	-1.38	(-7.32 to 4.56)	-0.46	0.65			
Quality of life (WHOQOL26)	2 months [c]	-0.03	(-0.65 to 0.59)	-0.10	0.92	-0.03	0.48	-0.07
	5 months [c]	-0.29	(-0.86 to 0.29)	-0.99	0.32	-0.29	0.60	-0.48
	8 month [c]	-0.06	(-0.67 to 0.54)	-0.21	0.83	-0.06	0.59	-0.11
	Pooled [b]	-0.05	(-0.19 to 0.09)	-0.67	0.51			
Sense of coherence	2 months [c]	0.86	(-3.04 to 4.77)	0.44	0.66	0.86	2.98	0.29
	5 months [c]	-0.98	(-4.67 to 2.70)	-0.53	0.60	-0.98	4.07	-0.24

	8 month [c]	1.13	(-2.82 to 5.08)	0.57	0.57	1.13	3.84	0.29
	Pooled [b]	0.13	(-0.82 to 1.08)	0.29	0.78			
Drug cost in past month (exclude outlier)	2 months [c]	-530.51	(-29697.86 to 28636.83)	-0.04	0.97	-530.51	29246.15	-0.02
	5 months [c]	-15577.88	(-44933.32 to 13777.56)	-1.07	0.29	-15577.88	27645.43	-0.56
	8 month [c]	-1577.07	(-32998.72 to 29844.58)	-0.10	0.92	-1577.07	22341.46	-0.07
	Pooled [b]	-2411.95	(-11612.25 to 6788.34)	-0.52	0.60			

SRRS: Stimulant Relapse Risk Scale
SOCRATES: Stage of Change Readiness and Treatment Eagerness Scale
a: A mixed model for repeated measures ANOVA model analysis was conducted.
b: A mixed model for repeated measures conditional growth model was conducted.
c: A fixed model for repeated measures ANOVA model analysis was conducted.
d: A fixed model for repeated measures conditional growth model was conducted.

Table 11. Comparison of participants' demographic characteristics at the baseline between intervention completers and dropout participants among the intervention group (completer: n=17, dropout: n=6)

		Intervention Completer (n=17)		Dropout (n=6)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Age		*38.71*	*6.20*	*32.33*	*8.59*	0.06
Sex	Male	12	70.6%	2	33.3%	0.16
Marital status	Currently married	3	17.6%	1	16.7%	0.48
	Never married	12	70.6%	3	50.0%	
	Divorced	2	11.8%	2	33.3%	
Cohabiter	Single	4	23.5%	0	0.0%	0.54
Education	Middle school	1	5.9%	1	16.7%	0.21
	High school	5	29.4%	4	66.7%	
	Some college	6	35.3%	0	0.0%	
	College or higher	5	29.4%	1	16.7%	
Job	Full-time	3	17.6%	1	16.7%	0.51
	Part-time	4	23.5%	1	16.7%	
	Unemployed	9	52.9%	3	50.0%	
	Sick leave	0	0.00%	0	0%	
	Housewife/other	1	5.9%	1	16.7%	
Internet use	Every day	13	76.5%	6	100.0%	0.64
	2 hours or more/day	10	58.8%	5	83.3%	0.17
Internet device (most use)	Smartphone	13	76.5%	5	83.3%	0.83
	Personal computer	3	17.6%	1	16.7%	
	Tablet/mobile phone	1	5.9%	0	0.0%	
Internet access	Home	11	64.7%	5	83.3%	0.28

a: t-test, chi-square, Fisher's exact test

Table 12. Comparison of participants' characteristics related to drug use at the baseline between intervention completers and dropout participants among the intervention group (completer: n=17, dropout: n=6)

		Intervention Completer (n=17)		Dropout (n=6)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Primary abused drug	Methamphetamine	11	64.7%	2	33.3%	0.47
	NPS	1	5.9%	0	0.0%	
	MDMA	2	11.8%	1	16.7%	
	Hypnotics/anxiolytics	1	5.9%	0	0.0%	
	Cough medicine	1	5.9%	1	16.7%	
	Heroine	0	0.0%	0	0.0%	
	Inhalant	0	0.0%	1	16.7%	
	Poly drug	1	5.9%	1	16.7%	
Age of first drug use		*23.12*	*8.01*	*16.17*	*1.72*	**0.05**
Arrest in past		13	76.5%	3	50.0%	0.32
Jail in past		3	17.6%	1	16.7%	0.23
Drug dependence severity (DAST-20)	Total score	*12.18*	*3.52*	*16.17*	*1.83*	**0.02**
	Low (1-5)	1	5.9%	0	0.0%	0.39
	Intermediate (6-10)	4	23.5%	0	0.0%	
	Substantial (11-15)	10	58.8%	4	66.7%	
	Severe (16-20)	2	11.8%	2	33.3%	
Psychiatric comorbidity		6	35.3%	4	66.7%	0.34
Harmful alcohol use (AUDIT-C)	Total score	*1.94*	*2.22*	*5.50*	*4.72*	0.13
	yes	4	23.5%	4	66.7%	0.13
Psychological distress (K6)		*9.47*	*5.75*	*15.67*	*5.47*	**0.03**
Outpatient treatment period	< 1 year	8	47.0%	0	0.0%	0.18
	1-3 years	2	11.8%	0	0.0%	
	> 3 years	7	41.2%	6	100.0%	
Number of hospitalization		*3.24*	*7.42*	*2.00*	*2.10*	0.70
Previous face-to-face relapse prevention		8	47.1%	3	50.0%	1.00
Previous self-help group		6	35.3%	0	0.0%	0.14
Relapse risk (SRRS)		*68.82*	*13.08*	*82.33*	*6.47*	**0.03**
Motivation to change (SOCRATES)		*77.12*	*7.64*	*73.50*	*7.06*	0.32
Self-efficacy for handling drug use		*61.65*	*20.33*	*41.67*	*17.20*	**0.04**
Quality of life (WHOQOL26)		*3.02*	*0.70*	*2.33*	*0.67*	**0.05**
Sense of coherence		*14.12*	*3.44*	*11.17*	*6.18*	0.16
Drug cost in past month (yen, exclude outlier) [b]		*11937.50*	*32766.79*	*37000.00*	*42965.10*	0.16
Abstinence in 28 days						
Longest duration of abstinence from primary drug		*23.47*	*8.68*	*23.33*	*11.43*	0.98
Longest duration of abstinence from all drugs/alcohol		*21.06*	*9.62*	*18.00*	*12.84*	0.55
Total abstinent days from primary drug		*25.88*	*4.96*	*23.33*	*11.43*	0.46
Total abstinent days from all drugs/alcohol		*24.94*	*6.16*	*20.33*	*11.54*	0.39

a: t-test, chi-square, Fisher's exact test

b: Cost variable was excluded if the variable was over 100,000 (yen) even the participant did not use primary abused drug in the past month. Sample size varies because of excluding outliers.

NPS: New psychoactive substances

MDMA: 3,4-methylenedioxymethamphetamine

DAST-20: Drug Abuse Screening Test

AUDIT-C: The Alcohol Use Disorders Identification Test-Consumption, harmful alcohol use (total score) = male>3, female>2

Table 13. Comparison of participants' demographic characteristics at the baseline between assessment completers and dropout participants in the intervention group (survey completer: n=13, dropout: n=10)

		Assessment Completer (n=13)		Dropout (n=10)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Age		*38.38*	*7.48*	*35.30*	*6.99*	0.32
Sex	Male	10	76.9%	4	40.0%	0.10
Marital status	Currently married	1	7.7%	3	30.0%	0.31
	Never married	10	76.9%	5	50.0%	
	Divorced	2	15.4%	2	20.0%	
Cohabiter	Single	2	15.4%	2	20.0%	1.00
Education	Middle school	1	7.7%	1	10.0%	0.08
	High school	3	23.1%	6	60.0%	
	Some college	3	23.1%	3	30.0%	
	College or higher	6	46.2%	0	0.0%	
Job	Full-time	4	30.8%	0	0.0%	0.10
	Part-time	4	30.8%	1	10.0%	
	Unemployed	5	38.5%	7	70.0%	
	Sick leave	0	0.0%	0	0.0%	
	Housewife/other	0	0.0%	2	20.0%	
Internet use	Every day	10	76.9%	9	90.0%	0.64
	2 hours or more/day	7	53.9%	8	80.0%	0.43
Internet device (most use)	Smartphone	11	84.6%	7	70.0%	0.47
	Personal computer	2	15.4%	2	20.0%	
	Tablet/mobile phone	0	0.0%	1	10.0%	
Internet access	Home	8	61.5%	8	80.0%	0.34

a: t-test, chi-square, Fisher's exact test

Table 14. Comparison of participants' characteristics related to drug use at the baseline between assessment completers and dropout participants in the intervention group (survey completer: n=13, dropout: n=10)

		Assessment Completer (n=13)		Dropout (n=10)		p [a]
		n/*mean*	%/(*SD*)	n/*mean*	%/(*SD*)	
Primary abused drug	Methamphetamine	10	76.9%	3	30.0%	0.09
	NPS	1	7.7%	0	0.0%	
	MDMA	2	15.4%	1	10.0%	
	Hypnotics/anxiolytics	0	0.0%	1	10.0%	
	Cough medicine	0	0.0%	2	20.0%	
	Heroine	0	0.0%	0	0.0%	
	Inhalant	0	0.0%	1	10.0%	
	Poly drug	0	0.0%	2	20.0%	
Age of first drug use		*23.92*	*8.95*	*17.90*	*3.14*	0.06
Arrest in past		12	92.3%	4	40.0%	**0.02**
Jail in past		4	30.8%	0	0.0%	**0.02**
Drug dependence severity (DAST-20)	Total score	*11.85*	*3.53*	*15.00*	*2.98*	**0.03**
	Low (1-5)	1	7.7%	0	0.0%	0.08
	Intermediate (6-10)	3	23.1%	1	10.0%	
	Substantial (11-15)	9	69.2%	5	50.0%	
	Severe (16-20)	0	0.0%	4	40.0%	
Psychiatric comorbidity		4	30.8%	6	60.0%	0.22
Harmful alcohol use (AUDIT-C)	Total score	*1.85*	*1.91*	*4.20*	*4.37*	0.14
	yes	3	23.08%	5	50.0%	0.22
Psychological distress (K6)		*8.92*	*5.45*	*13.90*	*6.24*	**0.05**
Outpatient treatment period	< 1 year	7	53.9%	1	10.0%	
	1-3 years	0	0.0%	2	20.0%	
	> 3 years	6	46.2%	7	70.0%	
Number of hospitalization		*0.92*	*1.89*	*5.50*	*9.12*	0.09
Previous face-to-face relapse prevention		8	61.5%	3	30.0%	0.21
Previous self-help group		4	30.8%	2	20.0%	0.67
Relapse risk (SRRS)		*66.62*	*13.05*	*79.80*	*9.00*	**0.01**
Motivation to change (SOCRATES)		*78.54*	*8.00*	*73.10*	*5.84*	0.08
Self-efficacy for handling drug use		*68.08*	*17.57*	*41.30*	*15.30*	**0.001**
Quality of life (WHOQOL26)		*3.19*	*0.54*	*2.39*	*0.75*	**0.01**
Sense of coherence		*15.15*	*3.53*	*11.00*	*4.37*	**0.02**
Drug cost in past month (yen, exclude outlier) [b]		*21416.67*	*41740.45*	*15600.00*	*31138.40*	0.72
Abstinence in 28 days						
Longest duration of abstinence from primary drug		*23.77*	*8.35*	*23.00*	*10.64*	0.85
Longest duration of abstinence from all drugs/alcohol		*20.23*	*8.92*	*20.30*	*12.44*	0.99
Total abstinent days from primary drug		*26.15*	*4.85*	*24.00*	*9.24*	0.48
Total abstinent days from all drugs/alcohol		*25.31*	*4.84*	*21.70*	*10.60*	0.29

a: t-test, chi-square, Fisher's exact test

b: Cost variable was excluded if the variable was over 100,000 (yen) even the participant did not use primary abused drug in the past month. Sample size varies because of excluding outliers.

NPS: New psychoactive substances

MDMA: 3,4-methylenedioxymethamphetamine

DAST-20: Drug Abuse Screening Test

AUDIT-C: The Alcohol Use Disorders Identification Test-Consumption, harmful alcohol use (total score) = male>3, female>2

Appendix

1. CONSORT check list

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	Title page
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	p.1-2
Introduction			
Background and	2a	Scientific background and explanation of rationale	p.3-10
objectives	2b	Specific objectives or hypotheses	p.20
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	p.20-21
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	p.22
Participants	4a	Eligibility criteria for participants	p.22
	4b	Settings and locations where the data were collected	p.22
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	p.24-28
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	p.28-36, Appendix 6

			(p.107)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	p.37
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	p.23
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p.23
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	p.23
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p.23-24
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	p.23-24
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	p.37-41
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p.41-42
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	p.43-45, Figure 1 (p.88)
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1 (p.88)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	p.43
	14b	Why the trial ended or was stopped	N/A

Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	p.43-44 Table 2 and 3 (p.95-96)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1 (p.80)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	p.44-45, Table 3 and 4 (p.96-98)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	p.46-49, Table 5 (p.99)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	p.50
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	p.66-68
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p.67
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	p.50, 68
Other information			
Registration	23	Registration number and name of trial registry	p.21
Protocol	24	Where the full trial protocol can be accessed, if available	p.21
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p.69

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

2. Content for relapse prevention session of e-SMARPP

1. What is drug dependence?		
Video	➢	Mental and physical consequences caused by drug use (11' 02")
	➢	Change in the brain (11' 39")
	➢	How to stop drug craving (7' 43")
Exercise	■	Think about your pros and cons for drug use and quitting drug.
	■	Define your drug use situation: when, where, who, why, what and emotion.
2. Triggers of drug use		
Video	➢	Process of craving and drug use (5' 27")
	➢	Various internal and external triggers of drug craving (11' 00")
	➢	Anchors keeping you from drug use (5' 01")
Exercise	■	Define your internal and external triggers.
	■	Who and what are your anchors?
3. Recovery process; "Just for today"		
Video	➢	Process and stage of recovery (12' 38")
	➢	Safe lifestyle and signs of relapse (10' 19")
	➢	How to plan a safe daily life (9' 27")
Exercise	■	Think of your signs of relapse and barriers to recovery.
	■	Plan a safe daily life schedule without drugs.
4. Features of dependence symptoms		
Video	➢	Typical features of dependence (9' 05")
	➢	Typical thoughts and behaviors when people fall for drugs (12' 32")
	➢	Justification for relapse (9' 21")
Exercise	■	Think of your patterns of thinking and behavior during drug use
	■	Think of your possible justification for relapse
5. Supporters for recovery		
Video	➢	Typical internal triggers: "HALT" (hungry, angry, lonely and tired) (10' 05")
	➢	To trust and be honest to yourself and others (5' 41")
	➢	Support from peers and professionals (13' 39")
Exercise	■	Think of ways to handle internal triggers.
	■	Think of your supporters. Who? How to find?
6. No need to be strong, be smart and practiced		
Video	➢	Tips for recovery (6' 04")
	➢	Review of skills to handle triggers and relapse (12' 21")
	➢	To accept the way you are, messages from peers (4' 32")
Exercise	■	Think of crisis plans when you relapse into drug use.
	■	Think of your future when you recover from drug addiction.

Each session additionally has a weekly diary activity.
Parentheses indicate minutes and seconds of each video.

Reference: Takano A, Miyamoto Y, Kawakami N, Matsumoto T, Shinozaki T, Sugimoto T. Web-based cognitive behavioral relapse prevention program with tailored feedback for people with methamphetamine and other drug use problems: protocol for a multicenter randomized controlled trial in Japan. BMC Psychiatry. 2016, 16:87.

3. Video screenshot

動画3-1　回復のステージ

どのように回復していくのか、回復には何が必要かを考えていきます。

動画を見終わったら、課題3-1「かべ期の症状を考えよう」に進んでください。

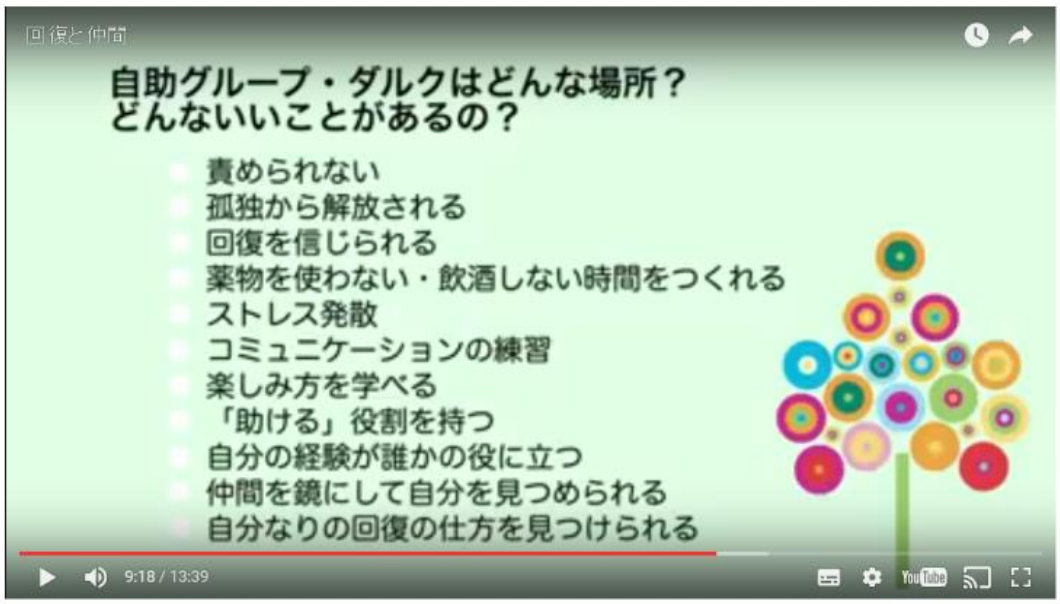
動画4-1　依存症の7つの特徴

依存症という病気の特徴を説明します。

動画5-3　回復と仲間

あなたを支えてくれる仲間がいると回復がぐっとスムーズになります。

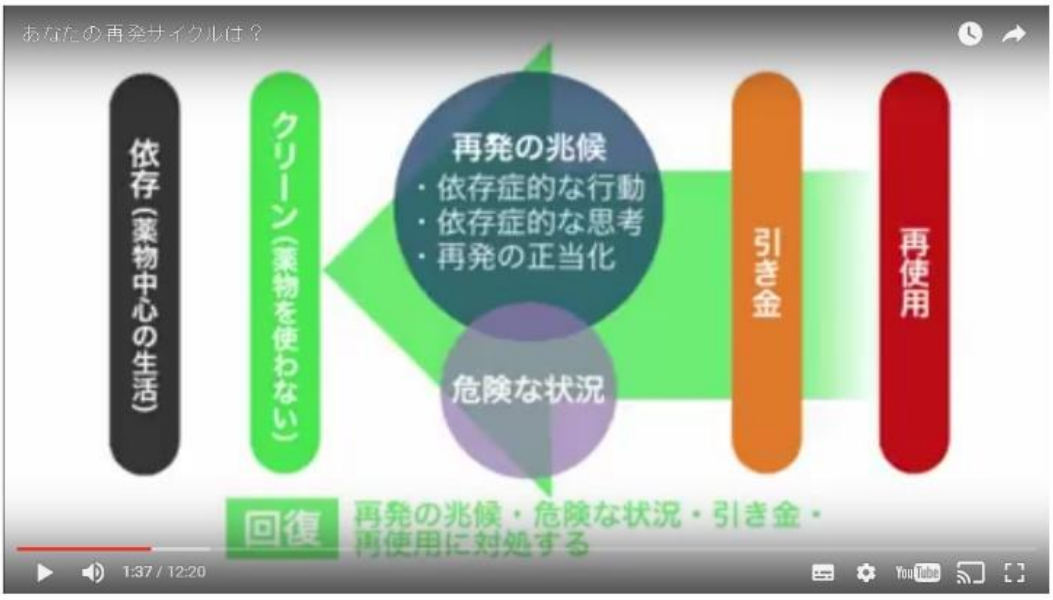
動画を見終わったら、課題5-3「支えになってくれる人はいますか？」に進んでください。



動画6-2　あなたの再発サイクルは？

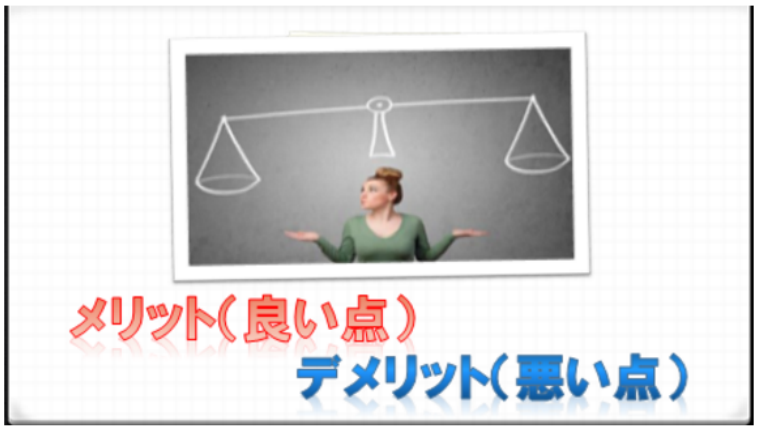
あなたにとって特に危険な再発サインを考えてみましょう。

動画を見終わったら、課題6-2「再使用した時の対処法を考えよう」に進んでください。



4. Assignment screenshot

課題1-1　使う？やめる？メリット・デメリット



あなたにとって、クスリやアルコールを使うことには、どんなメリット（良い点）とデメリット（悪い点）がありますか？
また、クスリやアルコールをやめるとしたら、どんなメリット（良い点）とデメリット（悪い点）がありますか？
1. 使うメリット・デメリット
2. やめるメリット・デメリット
をそれぞれ書いてみてください。

課題1-2　どんなとき使っていましたか？

あなたはどんなときに、薬物・アルコールを使っていましたか？
どんなときに使いたいという気持ちが強くなりましたか？
何曜日の何時頃でしょうか？
何をしているとき、何かをする前、何かをした後でしょうか？
誰かと一緒に使っていましたか？それとも一人のときですか？
どんな気分のときでしたか？
具体的な**時間帯や状況、気分**について、思いつくだけ書いてみてください。

課題2-2　引き金を考えよう

1. 外的な引き金は、何ですか？
あなた自身の引き金（＝クスリを使うきっかけとなるもの）を考えてみてください。
下の表を参考にして、引き金となっていた、もしくは、なりそうな「人・場所・状況」をふりかえってみてください。

＜外的な引き金＞

人	場所	状況	
クスリ仲間	自分の部屋	一人のとき	仕事の前後
飲み仲間	友達の家	デート	セックス
売人	クラブ	ミネラルウォーター	注射器
恋人	トイレ	夜または朝	休日
愛人	ホテル	お金があるとき	イベント
同僚	車の中	飲酒	たばこ
	繁華街	自動販売機	パイプ
	居酒屋	映画	音楽
	コンビニ	疲れ	空腹
		太った	ギャンブル

2. 内的な引き金は、ありますか？
使用につながってしまうそうな感情や気持ちがある場合は、どんな気持ちか教えてください。
使っていたときはあまり意識していなかったとしても、「今思い返せばあてはまりそう」といった感情はありませんか？
下の表を参考にして、思いつくだけ記入してみましょう。

＜内的な引き金＞

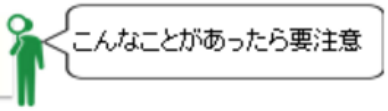
喜び	怒り	悲しみ	恐れ	不愉快
うれしい	怒り	悲しい	恐い	不愉快
愛情	嫉妬	申し訳ない	恥ずかしい	嫌悪
希望	ねたみ	後悔	心配	がっかり
得意	失望	落胆	不安	ゆううつ
愉快	うんざり	絶望	モヤモヤ	苦しい
安心	イライラ	情けない	焦り	痛い
楽しい	不満	切ない	困った	きつい
しあわせ	緊張	むなしい	混乱	疲れた
満足	憎い	あきらめ	とまどい	つらい
幸福	無視された	さみしい	プレッシャー	欲求不満
高揚		自信がない	罪悪感	つまらない

課題3-1「かべ」期の症状を考えよう

「かべ」期は、誰にでもおとずれるスリップの危険が高まる時期です。

1. あなたの「かべ」期には、どんな症状があらわれると思いますか？
   下の表を参考にして、思いつくだけ書いてみてください。
2. そのような症状があらわれたら、どのように対処しようと考えていますか？
   すでに行っていること、これから行おうと思っていることを教えてください。

「かべ」の症状を理解しよう



「かべ」の症状	
気分	うつ　イライラ　不安　焦り　気分の変動　頭がボーっとする
考え	クスリの欲求　治療を受けたくない　失敗をくよくよ悩む しらふのメリットを感じない　物事に関心がない 希望がないと感じる　考えがあいまいになる　忘れっぽい
行動	クスリの使用　治療や自助グループに行かない　治療ルール違反 人間関係トラブル　約束のキャンセル　治療の中断　ひきこもり 運動をやめる　引き金に近づく　クスリ仲間と会う・連絡を取る

課題4-2　あなたの依存症的な行動と思考は？

1. あなたにとって危険な依存症的な行動と思考は何ですか？
   それぞれ最低2つずつ挙げてください。

2. そのような行動や思考が出てきたら、どのように対処しますか？
   自分の経験を振り返って、なるべく具体的に考えるのがポイントです。

課題5-3　支えになってくれる人はいますか？

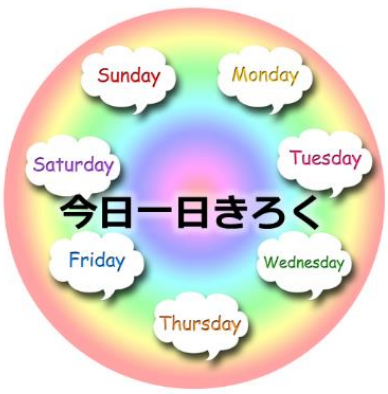
1. あなたには、回復の支えとなってくれる人は何人いますか？それは、どのような人ですか？

2. 支えとなってくれる人や頼る先を増やすために、どのようなことができますか？

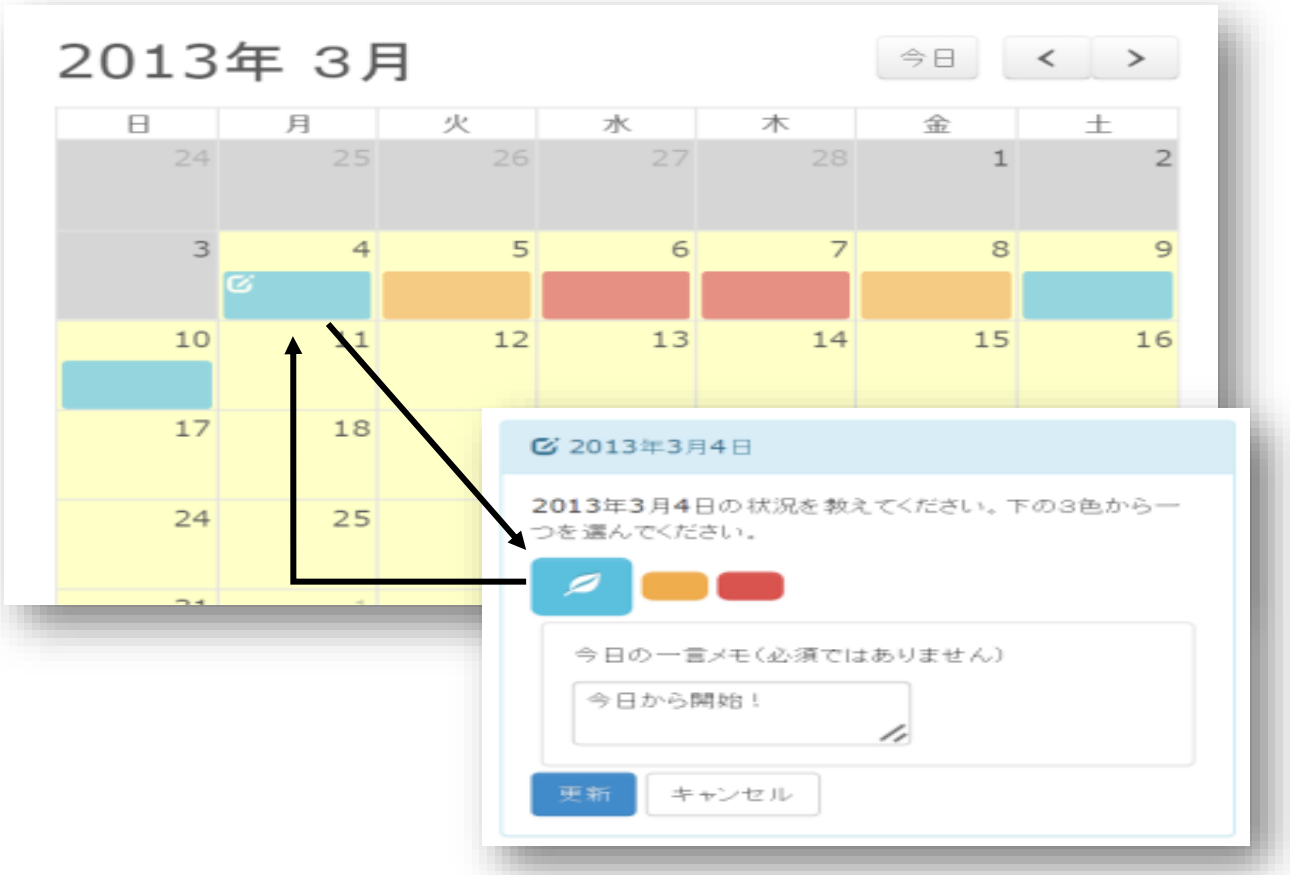
課題6-2　再使用した時の対処法を考えよう

再使用してしまった時、あなたはどう対処しますか？これまでの経験を振り返り、どのように行動すれば、悪循環に陥らずに済むかを考えてみてください。

5. Self-monitoring calendar screenshot



クスリのない生活は、一日一日の積み重ねです。
いろいろ悩みはあるけれど、とりあえず「今日一日」は使わない！
明日のこと、1年先のことは、ひとまず考えるのをやめて、「今日一日」を大切に過ごしましょう。



1. カレンダーの日付をクリックする
2. 色選択画面が表示される
3. 薬物使用状況を 3 色から 1 色を選択する
   青：薬物使用も飲酒もなし、黄：メイン以外の薬物使用または飲酒、赤：メインの薬物使用
4. 選択した色がカレンダー上に表示される

6. Assessment schedule of primary and secondary outcomes

Outcome		Measurement	Baseline	Follow-up		
			(T1)	2-month (T2)	5-month (T3)	8-month (T4)
Primary outcome						
1	Relapse risk	SRRS	x	x	x	x
2	Longest consecutive abstinent days	Longest consecutive abstinent days during the intervention #		x		
Secondary outcome						
1	Motivation to change	SOCRATES	x	x	x	x
2	Self-efficacy for handling drug use and craving	Self-efficacy Scale for Drug Dependence	x	x	x	x
3	Abstinent days (total or duration)	Abstinent days in the past 28 or 56 days #	x	x	x	x
4	Health related quality of life	WHOQOL26	x	x	x	x
5	Sense of coherence	3-item sense of coherence scale	x	x	x	x
6	Cost of drug	Self-report cost of drugs in the last month (yen)	x	x	x	x
7	Treatment retention	Yes or no	x	x	x	x
8	Self-help group use	Yes or no	x	x	x	x
9	Psychiatric medical cost	Self-reported medical use in the past six months	x			x
Feasibility and usability outcome						
1	Program completion rate	Number of completed weeks		x		
2	Satisfaction	CSQ-8		x		
3	Usability and usefulness	Original questionnaire		x		

Reference: Takano A, Miyamoto Y, Kawakami N, Matsumoto T, Shinozaki T, Sugimoto T. Web-based cognitive behavioral relapse prevention program with tailored feedback for people with methamphetamine and other drug use problems: protocol for a multicenter randomized controlled trial in Japan. BMC Psychiatry. 2016, 16:87.

7. Questionnaires

e-SMARPP 利用前アンケート

※　ベースライン時に調査

A．あなたについての情報

1. 今回あなたはどちらのグループになりましたか。

   Web-CBT グループ

   セルフモニタリング・グループ

2. あなたの通院している病院はどれですか。

   国立精神・神経医療研究センター病院

   埼玉県立精神医療センター

   神奈川県立精神医療センター（せりがや病院）

   岡山県精神科医療センター

   東京都立松沢病院

   アパリクリニック

3. 性別　　男　・　女

4. 年齢　　　　歳

5. 婚姻状況　　配偶者なし　・　配偶者あり　・　離婚　・　死別

6. 最終学歴　　中学　・　高校　・　専門学校／短期大学　・　大学　・　大学院

7. 就労状況

   学生　・　常勤　・　非常勤　・　パートタイム　・　アルバイト　・無職　・　その他

   （　　）

8. 同居者　　親兄弟　・　配偶者　・　子供　・　その他（　　）

9. インターネット利用の頻度（パソコン、携帯等含めて）　週　　日　1 日　　時間

10. インターネットにアクセスするのにもっともよく利用する手段

    パソコン　・　携帯　・　スマートフォン　・　タブレット端末　・　その他（

11. もっともよくインターネットにアクセスする場所

    自宅　・　外出先　・　仕事先　・　ネットカフェ　・　その他（　　）

B．薬物使用に関する情報

1．主たる使用薬物（ひとつ）

覚せい剤 ・大麻 ・危険ドラッグ・処方薬（病院でもらう薬）・有機溶剤（シンナーなど）・コカイン・幻覚剤（LSD・ケタミンなど）・ RUSH ・5-meo ・ヘロイン ・MDMA 市販薬（ドラッグストアなどで買える薬）・多剤 ・その他

2．これまで使用したことのある薬物（複数可）

覚せい剤 ・大麻 ・危険ドラッグ・処方薬（病院でもらう薬）・有機溶剤（シンナーなど）・コカイン・幻覚剤（LSD・ケタミンなど）・ RUSH ・5-meo ・ヘロイン ・MDMA 市販薬（ドラッグストアなどで買える薬）・その他

3．多剤乱用の有無　なし ・ あり

4．初回薬物使用年齢（何らかの薬物の初めて乱用した年齢）　歳

5．薬物の入手経路（複数可）

友人 ・ 家族 ・ 売人 ・ インターネット ・ その他（ ）

6．薬物使用に関連した逮捕歴　なし ・ あり

7．通院歴　過去 回 ・ 最大期間（ 年 か月）

8．入院歴　過去 回 ・ 最大期間（ 年 か月）

9．専門治療を受けた経験　なし ・ あり

（具体的に：どこで ／何を ／期間 年 か月）

10．現在の自助グループ（NA, AA など）の参加

なし ・ あり（具体的に ）

11.民間回復施設(DARC, MACなど)の利用　なし ・ あり(具体的に)

12．過去 1 ヶ月間で、薬物にいくらお金を使いましたか。数字を入力してください。薬物にお金を使っていない場合は、0 と入力してください。

C．飲酒に関する事項

1．初回飲酒年齢　歳

2．習慣飲酒（機会飲酒以外に自分の意志でほぼ毎日飲酒する）の有無

なし ・ あり（ 歳から）

3．通院歴　過去 回 ・ 最大期間（ 年 か月）

4．入院歴　過去 回 ・ 最大期間（ 年 か月）

5．専門治療を受けた経験　なし ・ あり

（具体的に：どこで ／何を ／期間 年 か月）

D．他の精神疾患

１．他の精神疾患の併存　　なし　・　あり

認知症・アルコール依存症・統合失調症・妄想性障害・うつ病・双極性障害・不安障害・強迫性障害・適応障害・PTSD・解離性障害・摂食障害・睡眠障害・人格障害・性同一性障害・ 知的障害・ 発達障害（自閉症、アスペルガー症候群など）・ADHD・行為障害・その他

わからない

E．アルコール使用障害スクリーニングテスト（Alcohol Use Disorder Identification Test-consumption: AUDIT-C）

		0	1	2	3	4
1	あなたはアルコール含有飲料をどのくらいの頻度で飲みますか？	飲まない	1カ月に1度以下	1カ月に2～4度	1週に2～3度	1週に4度以上
2	飲酒するときには通常どのくらいの量を飲みますか？	1～2ドリンク	3～4ドリンク	5～6ドリンク	7～9ドリンク	10ドリンク以上
3	1 度に 6 ドリンク以上飲酒することがどのくらいの頻度でありますか？	ない	1カ月に1度未満	1カ月に1度	1週に1度	毎日あるいはほとんど毎日

日本酒 1 合＝ 2 ドリンク、ビール大瓶 1 本＝ 2.5 ドリンク、ウイスキー水割りダブル 1 杯＝ 2 ドリンク、焼酎お湯割り 1 杯＝ 1 ドリンク、ワイングラス 1 杯＝ 1.5 ドリンク位、梅酒小コップ 1 杯＝ 1 ドリンク（ 1 ドリンク＝純アルコール 9 ～ 12 g ）

F．うつ・不安（K６）

あなたの現在のストレスの程度について教えてください。過去 30 日の間にどれくらいの頻度で次のことがありましたか。あてはまる欄の数字に○をつけてください。

	全くない	少しだけ	ときどき	たいてい	いつも
神経過敏に感じましたか。	1	2	3	4	5
絶望的だと感じましたか。	1	2	3	4	5
そわそわ、落ち着かなく感じましたか。	1	2	3	4	5
気分が沈み込んで、何が起こっても気が晴れないように感じましたか。	1	2	3	4	5
何をするのも骨折りだと感じましたか。	1	2	3	4	5
自分は価値のない人間だと感じまし	1	2	3	4	5

たか。					

G. 薬物問題の重症度（Drug Abuse Screening Test 日本語版）

注意事項：ここでいう「薬物使用」とは、以下の 1～3 のいずれかを指します（使用回数に関わらず）。
1. 違法薬物（大麻、有機溶剤、覚せい剤、コカイン、ヘロイン、LSD など）を使用すること
2. 危険ドラッグ（ハーブ、リキッド、パウダーなど）を使用すること
3. 乱用目的で処方薬・市販薬を不適切に使用すること（過量摂取など）
※飲酒は「薬物使用」に含みません。

過去 12 ヶ月間で当てはまるものに◯を付けてください。	当てはまる方に〇をつけてください	
(1) 薬物使用しましたか?（治療目的での使用を除く）	はい	いいえ
(2) 乱用目的で処方薬を使用しましたか?	はい	いいえ
(3) 一度に 2 種類以上の薬物を使用しましたか？	はい	いいえ
(4) 薬物を使わずに 1 週間を過ごすことができますか?	はい	いいえ
(5) 薬物使用を止めたいときには、いつでも止められますか?	はい	いいえ
(6) ブラックアウト（記憶が飛んでしまうこと）やフラッシュバック（薬を使っていないのに、使っているような幻覚におそわれること）を経験しましたか？	はい	いいえ
(7) 薬物使用に対して、後悔や罪悪感を感じたことはありますか？	はい	いいえ
(8) あなたの配偶者（あるいは親）が、あなたの薬物使用に対して愚痴をこぼしたことがありますか？	はい	いいえ
(9) 薬物使用により、あなたと配偶者（あるいは親）との間に問題が生じたことがありますか?	はい	いいえ
(10) 薬物使用のせいで友達を失ったことがありますか?	はい	いいえ
(11) 薬物使用のせいで、家庭をほったらかしにしたことがありますか?	はい	いいえ
(12) 薬物使用のせいで、仕事（あるいは学業）でトラブルが生じたことがありますか?	はい	いいえ
(13) 薬物使用のせいで、仕事を失ったことがありますか?	はい	いいえ
(14) 薬物の影響を受けている時に、ケンカをしたことがありますか?	はい	いいえ
(15) 薬物を手に入れるために、違法な活動をしたことがありますか?	はい	いいえ
(16) 違法薬物を所持して、逮捕されたことがありますか?	はい	いいえ

(17)　薬物使用を中断した時に、禁断症状（気分が悪くなったり、イライラがひどくなったりすること）を経験したことがありますか?	はい	いいえ
(18)　薬物使用の結果、医学的な問題（例えば、記憶喪失、肝炎、けいれん、出血など）を経験したことがありますか？	はい	いいえ
(19) 薬物問題を解決するために、誰かに助けを求めたことがありますか?	はい	いいえ
(20) 薬物使用に対する治療プログラムを受けたことがありますか?	はい	いいえ

H. 刺激薬物再使用リスク評価尺度（Stimulant Relapse Risk Scale: SRRS）

ここ一週間のあなたの状態についてお聞きします。

下に出てくる文章について、自分にあてはまるところを○で囲んでください。

質問項目中の「薬物」「薬」は、<u>あなたが問題にしている薬物</u>のことを思い浮かべてお答えください。

×，△，○のうち，どれかひとつを○でかこんでください

	あてはまらない	あまりあてはまらない	どちらともいえない	ややあてはまる	あてはまる
例）よく眠れる		×	△		○
1) 薬物を使用していたときの感覚がよみがえることがある		×	△		○
2) 薬物を使用したいと思ったことがある		×	△		○
3) 口さみしくてしょうがない			×		△ ○
4) 自分の力だけで薬物をやめられると思う		×	△		○
5) まわりの人の言葉がわずらわしいと思う		×	△		○
6) また使ってしまうのではないかと心配になる		×	△		○
7) いらいらしている		×	△		○
8) 薬物を使用するためならほとんど何でもするだろう		×	△		○
9) 以前より気持ちが軽くなったと感じている		×	△		○
10) 何に対してもやる気がない		×	△		○
11) ずっと薬を使わないでやっていくことができそうだ		×	△		○
12) 家族のことを考えるともう使えないと思う		×	△		○
13) もう大丈夫だと思う		×	△		○
14) 幻覚・妄想状態になるのが怖い		×	△		○
15) もう薬物を使わないという自信がある		×	△		○
16) 孤独でさみしいと感じている		×	△		○
17) もし、薬物を使ったら、すぐにまともな行動がとれなくなってしまうと思う			×		△ ○
18) 目の前で薬を誘われたら、NO とはいえない		×	△		○

19) 将来にたいして不安を感じている …… × △ ○
20) ひとりになったら使ってしまう …… × △ ○
21) もし薬物を使ったら、仕事に影響が出ると思う …… × △ ○
22) 病院の中でも友達に誘われれば使ってしまう …… × △ ○
23) 自分の気持ちがコントロールできないと感じている …… × △ ○
24) 目の前に実際に薬物があれば使ってしまう …… × △ ○
25) 気持ちがあせって疲れていると感じている …… × △ ○
26) 自分は依存症だと思う …… × △ ○
27) まとまったお金が入れば薬を買いたい …… × △ ○
28) 薬物を買うお金をかせぐためならなんでもしようと思う …… × △ ○
29) 薬物を使ったら、いらいらがなくなるように感じるだろう …… × △ ○
30) 薬を使うと、なんでも物事がスムーズにいくように感じる …… × △ ○

31) 盗んででも薬がほしいと思うことがある …… × △ ○
32) 薬物を使うと元気になれる気がする …… × △ ○
33) 近い将来、薬物を使う気がする …… × △ ○
34) 法に触れる仕事をしてでも薬物を手に入れたいと思う …… × △ ○
35) 今度使ったら逮捕されるとわかっていても使ってしまう …… × △ ○

I. Stage of Change Readiness and Treatment Scale（SOCRATES-8D）日本語版

以下の質問文をよく読んで下さい。あなたが**自分の薬物使用に関して**感じていること（または感じていないこと）が書かれています。ひとつひとつの質問に対して、あなたが**今現在**そう思うか、またはそうは思わないかを、その度合いに応じて１から５までの数字のうち、どれか一つに○をつけて下さい。各質問に対して当てはまる数字を一つだけ選び、○をつけてください。

		絶対にそうは思わない	そうは思わない	どちらともいえない	そう思う	絶対そう思う
1	自分が薬物を使うことを何とか変えたいと真剣に思っている	1	2	3	4	5
2	ときどき自分は薬物依存なのではないかと思うことがある	1	2	3	4	5
3	すぐに薬物をやめなければ、自分の問題は悪くなる一方だと思う	1	2	3	4	5
4	私はすでに自分の薬物の使い方を少し変えようとし始めている。	1	2	3	4	5
5	昔、自分は薬をたくさん使っていたけれど、	1	2	3	4	5

		絶対にそうは思わない	そうは思わない	どちらともいえない	そう思う	絶対そう思う
	その後、何とかそのような使い方を変えることができた。					
6	ときどき、自分が薬物を使うことで他の人たちを傷つけているかもしれないと思うことがある。	1	2	3	4	5
7	自分には薬物の問題がある。	1	2	3	4	5
8	自分は薬物を使うことを変えようと頭で考えているだけではなくて、実際に行動に移し始めている	1	2	3	4	5
9	自分はすでに以前のような薬物の使い方はやめている。そして昔のような使い方に戻ってしまわない方法を探している。	1	2	3	4	5
10	自分は深刻な薬物の問題を抱えている。	1	2	3	4	5
11	ときどき自分は薬物の使用をコントロールできているのだろうかと疑問に思うことがある。	1	2	3	4	5
12	自分が薬物を使用することで、たくさんの害が生じている。	1	2	3	4	5
13	自分は今、薬物の使用を減らすか、薬物の使用をやめるために積極的に行動している。	1	2	3	4	5
14	自分は以前のような薬物の問題に戻ってしまわないように、誰かに助けてもらいたいと思っている。	1	2	3	4	5
15	自分には薬物の問題があると分かっている。	1	2	3	4	5
16	自分は薬物を使いすぎなのではないかと思うことがある。	1	2	3	4	5
17	自分は薬物依存者だ。	1	2	3	4	5
18	自分は薬物の使用を何とか変えようと努力している。	1	2	3	4	5
19	自分は薬物の使い方を少し変えてみた。そして以前のような使い方に戻ってしまわないように助けてもらいたいと思っている。	1	2	3	4	5

J. 薬物使用に関する自己効力感尺度

Ⅰ. 以下の文章について自分がどれくらいあてはまるかを考え、番号に○をつけて下さい。

Ⅰ		あてはまらない	あまりあてはまらない	どちらともいえない	ややあてはまる	あてはまる
1	自分が薬物を使いたくなるきっかけをわかっていて、それをできるだけ避けるように注意できる	1	2	3	4	5
2	今後、もし薬物を使いたくなることがあっても、何とか使わないでその場を切り抜ける準備ができている	1	2	3	4	5
3	薬物がなくても生活していける自信がある	1	2	3	4	5
4	困った時にも薬に頼らず、周りの人に助けを求めることができる	1	2	3	4	5
5	何かあっても、あわてずやっていける落ち着いた気持ちをもてる	1	2	3	4	5

Ⅱ. 以下のような状況やできごとのときに、薬物を使わない自信は、どれくらいありますか？

薬物を使わない自信のレベルを１（全然自信がない）から７（絶対の自信がある）で表すとすれば、今のあなたの自信のレベルに近い数字を１つ選んで、○をつけてください。

Ⅱ		全然自信がない	少ししか自信がない	やや自信がある	どちらともいえない	少し自信がある	だいぶ自信がある	絶対の自信がある
1	薬物を使うことに誘われた時	1	2	3	4	5	6	7
2	他の人が薬物を使っているところを見た時	1	2	3	4	5	6	7
3	ちょっとなら大丈夫と試したくなった時	1	2	3	4	5	6	7

Ⅱ		全然自信がない	少ししか自信がない	やや自信がある	どちらともいえない	少し自信がある	だいぶ自信がある	絶対の自信がある
4	セックスしたい気持ちから薬物を用いたくなった時	1	2	3	4	5	6	7
5	ストレスや疲れにより薬物が欲しくなった時	1	2	3	4	5	6	7
6	よく眠れず薬物が欲しくなった時	1	2	3	4	5	6	7
7	身体の不調や苦痛により薬物を使いたくなった時	1	2	3	4	5	6	7
8	人間関係の悩みで薬物を使いたくなった時	1	2	3	4	5	6	7
9	落ちこみや不安により薬物が欲しくなった時	1	2	3	4	5	6	7
10	腹が立って薬物が欲しくなった時	1	2	3	4	5	6	7
11	孤独で、さみしくて薬物が欲しくなった時	1	2	3	4	5	6	7

K. 生活の質（WHOQOL26）

1. 自分の生活の質をどのように評価しますか
<まったく悪い・悪い・ふつう・良い・非常に良い>
2. 自分の健康状態に満足していますか
<まったく不満・不満・どちらでもない・満足・非常に満足>

次の質問は、過去２週間にあなたが、どのくらい経験したか、あるいはできたかについてお聞きするものです。
<まったくない・少しだけ・多少は・かなり・非常に>

3. 体の痛みや不快感のせいで、しなければならいことがどのくらい制限されますか
4. 毎日の生活の中で治療（医療）がどのくらい必要ですか
5. 毎日の生活をどのくらい楽しくすごしていますか
6. 自分の生活をどのくらい意味あるものと感じていますか
7. 物事にどのくらい集中することができますか
8. 毎日の生活はどのくらい安全ですか
9. あなたの生活環境はどのくらい健康的ですか
10. 毎日の生活を送るための活力はありますか
11. 自分の容姿（外見）を受け入れることができますか
12. 必要なものが買えるだけのお金を持っていますか

13. 毎日の生活に必要な情報をどのくらい得ることができますか
14. 余暇を楽しむ機会はどのくらいありますか
15. 家の周囲を出まわることがよくありますか

次の質問は、過去２週間にあなたが、どのくらいできたか、あるいは満足したかについてお聞きするものです。
<まったく不満・不満・どちらでもない・満足・非常に満足>

16. 睡眠は満足のいくものですか
17. 毎日の活動をやり遂げる能力に満足していますか
18. 自分の仕事をする能力に満足していますか
19. 自分自身に満足していますか
20. 人間関係に満足していますか
21. 性生活に満足していますか
22. 友人たちの支えに満足していますか
23. 家と家のまわりの環境に満足していますか
24. 医療施設や福祉サービスの利用しやすさに満足していますか
25. 周辺の交通の便に満足していますか
26. 気分がすぐれなかったり、絶望、不安、落ち込みといったいやな気分をどのくらいひんぱんに感じますか

L. Sense of Coherence (The University of Tokyo Health Sociology version of the SOC3 scale)

あなたの人生に対する感じ方についてうかがいます。
それぞれ１～７までのうち、あなたの感じ方をもっともよくあらわしている数字１つに○をつけてください。（○はそれぞれにつき１つ）

	よくあてはまる ← → まったくあてはまらない						
1. 私は、日常生じる困難や問題の解決策を見つけることができる	1	2	3	4	5	6	7
2. 私は、人生で生じる困難や問題のいくつかは、向き合い、取り組む価値があると思	1	2	3	4	5	6	7

う。							
3．私は日常生じる困難や問題を解決したり予測したりできる	1	2	3	4	5	6	7

e-SMARPP フォローアップ調査

※2 か月後、5 か月後、8 か月後に調査

1. 定期的な通院をしていますか？　はい　・　いいえ
2. 自助グループ（NA, AA など）に参加していますか？　はい　・　いいえ
3. 民間回復施設（DARC, MAC など）を利用していますか？　はい　・　いいえ
4. 過去 1 ヶ月間で、薬物にいくらお金を使いましたか。数字を入力してください。薬物にお金を使っていない場合は、0 と入力してください。

I. Stage of Change Readiness and Treatment Scale（SOCRATES-8D）日本語版

H. 刺激薬物再使用リスク評価尺度（Stimulant Relapse Risk Scale: SRRS）

J. 薬物使用に関する自己効力感尺度

K. 生活の質（WHOQOL26）

L. Sense of Coherence (The University of Tokyo Health Sociology version of the SOC3 scale)

医療費に関する調査

※ベースライン時と 8 か月後に調査

過去半年間における医療の利用状況などについてうかがいます。
思い出せる限りでかまいませんので、できるだけ正確に回答してください。

1. 過去半年の間に、精神科に入院しましたか。精神科以外の入院は含めません。
   入院なし・入院あり
2. 過去半年の間に、何回精神科に入院しましたか。数字を入力してください。
3. 過去半年間で精神科病院に入院した際、1 回の入院あたり何日間入院しましたか。入院日数の平均を教えてください。数字を入力してください。
4. 過去半年の間に、救急車で病院に運ばれたことはありますか。回数を入力してください。ない場合は、0 と入力してください。
5. 過去半年間で、精神科に通院していた合計の期間を教えてください。過去半年間に複数の精神科病院に通院した場合は、各病院の通院期間を合計してください。過去半年間に通院を中断したことがある場合は、中断する前の期間と現在の通院期間を合計してください。次の中からあてはまるものを 1 つ選んでください。
   1 ヶ月未満・1 ヶ月～2 ヶ月未満・2 ヶ月～3 ヶ月未満・3 ヶ月～4 ヶ月未満・4 ヶ月～5 ヶ月未満・5 ヶ月～6 ヶ月未満
6. 過去半年の間で、平均して月に何回精神科に通院しましたか。数字を入力してください。
7. 過去半年の間で、精神科に通院中、薬の処方はありましたか。必須入力フィールド
   処方なし・処方あり
8. 過去半年間に、処方薬のためにいくら支払いましたか。金額の合計を入力してください（数字のみ記入）。1 回に支払う金額や過去 1 ヶ月間に支払った金額を思い出して、計算してください。

9. 精神科に通院するのに、どのぐらい時間がかかりますか。病院にいる時間と病院への行き帰りの時間も含めて、分単位でお答えください。数字を入力してください。
10. 病院で行っている外来プログラム（スマープ、ライフ、ステム）に参加していますか。または、過去半年の間に、参加していましたか。入院中のプログラムは含みません。
    参加していない・参加している（参加していた）
11. 過去半年の間で、病院で行っている外来プログラムには、平均して月に何回参加していますか（参加していましたか）。数字を入力してください。過去半年の間で、病院で行っている外来プログラムに参加していた期間はどのぐらいですか。
    1 ヶ月未満・1 ヶ月～2 ヶ月未満・2 ヶ月～3 ヶ月未満・3 ヶ月～4 ヶ月未満・4 ヶ月～5 ヶ月未満・5 ヶ月～6 ヶ月未満
12. 先月のあなたの収入はいくらでしたか。自分で働いて得たお金の金額を、次の中から 1 つ選んでください。
    生活保護・年金・雇用保険（失業給付）・収入なし・月 7.5 万円未満・月 7.5 万円～15 万円未満・月 15 万円～30 万円未満・月 30 万円以上
13. 医療や薬物の費用に関する質問で、回答に困った質問や回答できなかった質問があれば教えてください。（自由回答）

e-SMARPP 利用後調査

※2 か月後に調査

1．e-SMARPP へのアクセスについて、うかがいます。

1) e-SMARPP にアクセスするのに、もっともよく利用した手段は、次のうちどれですか。
パソコン ・スマートフォン ・タブレット端末 ・その他

2) もっともよく e-SMARPP にアクセスした場所は、どこですか。必須入力フィールド
自宅 ・外出先 ・職場 ・ネットカフェ ・その他

2．e-SMARPP の使いやすさについて、うかがいます。（Web Usability Scale）

※(1) そう思わない、(2) あまりそう思わない、(3) どちらともいえない、(4) まあそう思う、(5) そう思う」から一つ選んで回答

1) このウェブサイトの操作手順は、シンプルでわかりやすい。
2) このウェブサイトの使い方は、すぐに理解できる。
3) このウェブサイトでは、次に何をすればよいか迷わない。
4) このウェブサイトには、統一感がある。
5) このウェブサイトは、メニューの構成がわかりやすい。
6) 自分がこのウェブサイト内のどこにいるのか、わかりやすい。
7) このウェブサイトの文章は読みやすい。
8) このウェブサイトの絵や図表は見にくい。
9) このウェブサイトを利用していると、目が疲れる感じがする。
10) このウェブサイトでは、操作に対してすばやい反応が返ってくる。
11) このウェブサイトを利用しているときに、画面が正しく表示されないことがある。
12) このウェブサイトを利用しているときに、表示が遅くなったり、途中で止まってしまうことがある。
13) このウェブサイトのビジュアル表現は楽しい。

14) このウェブサイトは、印象に残る。

15) このウェブサイトには、親しみがわく。

16) このウェブサイトでは、すぐにわたしのほしい情報が見つかる。

17) このウェブサイトには、わからない言葉が多く出てくる。

18) このウェブサイトを利用するのは、時間の浪費である。

19) このウェブサイトに掲載されている内容は、信頼できる。

20) このウェブサイトは、信頼できる。

21) このウェブサイトの文章表現は、適切である。

3．セルフモニタリング「今日一日」きろくについて、うかがいます。

1) 「今日一日」きろくは、使いやすかったですか。
使いにくかった ・少し使いにくかった ・どちらともいえない ・まあまあ使いやすかった ・使いやすかった

2) 「今日一日」きろくは、役に立ちましたか。必須入力フィールド
役に立たなかった（役に立たなそう）・あまり役に立たなかった（あまり役に立たなそう）・どちらともいえない ・まあまあ役に立った（まあまあ役に立ちそう） ・役に立った（役に立ちそう）

3) 「今日一日」きろくについて、感想・ご意見・ご要望がありましたら、教えてください。(自由回答)

4．情報ボックスについて、うかがいます。

1) 情報ボックスを利用しましたか。必須入力フィールド
利用しなかった ・使用した

2) 情報ボックスは、使いやすかったですか。
使いにくかった ・少し使いにくかった ・どちらともいえない ・まあまあ使いやすかった ・使いやすかった

3) 情報ボックスは、役に立ちましたか。
役に立たなかった（役に立たなそう）・あまり役に立たなかった（あまり役に立たなそう）・どちらともいえない ・まあまあ役に立った（まあまあ役に立ちそう） ・役に立った（役に立ちそう）

4) 情報ボックスについて、感想・ご意見・ご要望がありましたら、教えてください。（自由回答）

５．よくある質問・お問い合わせについて、うかがいます。

1) よくある質問・お問い合わせを利用しましたか。必須入力フィールド
利用しなかった ・使用した

2) よくある質問・お問い合わせは、使いやすかったですか。
使いにくかった ・少し使いにくかった ・どちらともいえない ・まあまあ使いやすかった ・使いやすかった

3) よくある質問・お問い合わせは、役に立ちましたか。
役に立たなかった（役に立たなそう）・あまり役に立たなかった（あまり役に立たなそう）・どちらともいえない ・まあまあ役に立った（まあまあ役に立ちそう） ・役に立った（役に立ちそう）

4) よくある質問・お問い合わせについて、感想・ご意見・ご要望がありましたら、教えてください。（自由回答）

６．e-SMARPP について、ご意見を教えてください。（Client Satisfaction Questionnaire 8-item version）

皆様から頂いたご意見やご提案を参考に、より良いプログラムのあり方を検討し、実行していきたいと考えております。次の質問に対し率直にお答えください。

1) サービスの内容・質はいかがでしたか
- 非常に良い
- 良い
- 普通
- 良くない

2) ご期待通りの内容でしたか
- 期待はずれだった
- やや期待に反した
- ほぼ期待通りだった
- 期待通りだった

3) どの程度、皆さまのニーズにお応えできましたか
- ほぼすべてのニーズを満たした
- 大体のニーズを満たした
- いくつかのニーズを満たした

- ニーズは満たされなかった

4) あなたのお友達が同じような状況にいたら、このプログラムを勧めますか
   - 絶対に勧めない
   - たぶん勧めない
   - たぶん勧める
   - 絶対に勧める
5) あなたが受けたサービスに対して、量的に満足していますか
   - 非常に不満足
   - 関心がない、またはやや不満足
   - ほぼ満足
   - 非常に満足
6) あなたが受けたサービスは、あなたがより効果的に問題に対処するのに役立ちましたか
   - 非常に役立った
   - どちらかというと役立った
   - あまり役に立たなかった
   - 問題が悪化した
7) 当プログラムに対する総体的なあなたの満足度は
   - 非常に満足
   - ほぼ満足
   - 関心がない、またはやや不満足
   - 非常に不満足
8) 将来問題が起きた時、当プログラムを再度利用しますか必須入力フィールド
   - 二度と利用しない
   - たぶん利用しない
   - たぶん利用する
   - また利用する
9) ご意見がありましたら、以下の欄にご記入お願いします。

   私が受けたこのサービスに関して最も気に入った点は：

   提供されたサービスの何かをもしも変えることができるとすれば、私だったらここを変える：

7．ウェブサイトを利用して、思ったこと・感じたことを教えてください。

1) ウェブサイトを利用していて、薬物を使用したくなったり、具合が悪くなったり、不快な気分になることは、ありましたか。
なかった ・あった ・どちらともいえない

2) 前の質問で、サイト利用中に薬物を使用したくなったり、具合が悪くなったり、不快な気分になることが「あった」と回答した方にうかがいます。具体的に、どのような状況でどのような症状があったのか、教えてください。

3) これまで回答いただいた以外にも、感想・ご意見・ご要望がありましたら、教えてください。(自由回答)

※以下は介入群のみが回答

1. e-SMARPP について、うかがいます。

1) 一番役に立ったコンテンツはどれですか。ひとつ選んでください。
- (Re:boot)+の動画
- (Re:boot)+の課題
- (Re:boot)+のぼちぼち日記
- お役立ち情報
- 「今日一日」きろく
- 情報ボックス

2) 1 でそのコンテンツを選んだ理由を教えてください。(自由回答)

3) 一番役に立たなかったコンテンツはどれですか。ひとつ選んでください。
- (Re:boot)+の動画
- (Re:boot)+の課題
- (Re:boot)+のぼちぼち日記
- お役立ち情報
- 「今日一日」きろく
- 情報ボックス

4) 3 でそのコンテンツを選んだ理由を教えてください。(自由回答)

2. (Re:boot)+についてうかがいます。

1) セッションの回数は、適切でしたか。
- 6 回でちょうどよかった
- 6 回より少ない方がよかった
- 6 回より多い方がよかった

- わからない

2) 週に 1 回ずつ進めるという回数設定は、適切でしたか。
   - ちょうど良かった
   - 週 1 回より少ない方が良かった（例：2 週に 1 回）
   - 週 1 回より多い方が良かった（例：1 週に 2 回）
   - わからない
3) 1 回のセッションを平均して何日かけて行いましたか。1 つ選んでください。
   - 1 日
   - 2 日
   - 3 日
   - 4 日
   - 5 日
   - 6 日
   - 7 日
4) 動画は、使いやすかったですか。
   - 使いにくかった
   - 少し使いにくかった
   - どちらともいえない
   - まあまあ使いやすかった
   - 使いやすかった
5) 動画は、役に立ちましたか。
   - 役に立たなかった
   - あまり役に立たなかった
   - どちらともいえない
   - まあまあ役に立った
   - 役に立った
6) 1 回あたりの動画の長さは、適切でしたか。
   - ちょうどよかった
   - もっと短い方がよかった
   - もっと長い方がよかった
   - わからない
7) 動画の内容は、難しかったですか。

- 難しかった
- 少し難しかった
- どちらともいえない
- あまり難しくなかった
- 難しくなかった

8) 課題は、使いやすかったですか。
   - 使いにくかった
   - やや使いにくかった
   - どちらともいえない
   - まあまあ使いやすかった
   - 使いやすかった

9) 課題は、役に立ちましたか。
   - 役に立たなかった
   - あまり役に立たなかった
   - どちらともいえない
   - まあまあ役に立った
   - 役に立った

10) 課題に回答するのは、難しかったですか。
   - 難しかった
   - 少し難しかった
   - どちらともいえない
   - あまり難しくなかった
   - 難しくなかった

11) 1 つの課題に書き込んで提出するのに、平均して何分かかりましたか。数字を入力してください。

12) 「ぼちぼち日記」は、使いやすかったですか。
   - 使いにくかった
   - 少し使いにくかった
   - どちらともいえない
   - まあまあ使いやすかった
   - 使いやすかった

13) 「ぼちぼち日記」は、役に立ちましたか。

- 役に立たなかった
- あまり役に立たなかった
- どちらともいえない
- まあまあ役に立った
- 役に立った

14) 「ぼちぼち日記」を書くのは、難しかったですか。
- 難しかった
- 少し難しかった
- どちらともいえない
- あまり難しくなかった
- 難しくなかった

15) 1 つの「ぼちぼち日記」に書き込んで提出するのに、平均して何分かかりました。数字を入力してください。

16) (Re:boot)+について、感想・ご意見・ご要望などありましたら、教えてください。(自由回答)

3．感想やご意見を教えてください。

「こんな機能がほしい」「ここを改善してほしい」「こんな情報を入れてほしい」などの要望やご意見がありましたら、教えてください。（自由回答）