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Relapse prevention group therapy via video-conferencing for substance use disorder: protocol for a multicentre randomised controlled trial in Indonesia

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ABSTRACT

Background Substance use disorder (SUD) is a leading contributor to the global burden of disease. In Indonesia, the availability of formal treatment for SUD falls short of the targeted coverage. A standardised therapeutic option for SUD with potential for widespread implementation is required, yet evidence-based data in the country are scarce. In this study, we developed a cognitive behavioural therapy (CBT)-based group telemedicine model and will investigate effectiveness and implementability in a multicentre randomised controlled trial.

Methods A total of 220 participants will be recruited from the social networks of eight sites in Indonesia: three hospitals, two primary healthcare centres and three rehabilitation centres. The intervention arm will participate in a relapse prevention programme called the Indonesia Drug Addiction Relapse Prevention Programme (Indo-DARPP), a newly developed 12-week module based on CBT and motivational interviewing constructed in the Indonesian context. The programme will be delivered by a healthcare provider and a peer counsellor in a group therapy setting via video-conferencing, as a supplement to participants' usual treatments. The control arm will continue treatment as usual. The primary outcome will be the percentage increase in days of abstinence from the primarily used substance in the past 28 days. Secondary outcomes will include addiction severity, quality of life, motivation to change, psychiatric symptoms, cognitive function, coping, and internalised stigma. Assessments will be performed at baseline (week 0), post-treatment (week 13), and 3 and 12 months post-treatment completion (weeks 24 and 60). Retention, participant satisfaction, and cost-effectiveness will be assessed as the implementation outcomes.

Ethics and dissemination The study protocol was reviewed and approved by the Ethics Committees of Universitas Indonesia and Kyoto University. The results will be disseminated via academic journals and international conferences. Depending on trial outcomes, the treatment programme will be advocated for adoption as a formal healthcare-based approach for SUD.

Trial registration number UMIN000042186.

Strengths and limitations of this study

- The proposed study will be the first to establish high-quality evidence for a cognitive behavioural therapy-based relapse prevention programme for substance use disorder (SUD) in Indonesia.
- Telemedicine enables far-reaching, nationwide participation, connecting participants from across the nation with providers in major cities.
- A successful outcome may produce a new SUD treatment module in Indonesia and pave the way for its adoption by national guidelines.
- Study limitations include risk of recall and social desirability bias, heterogeneous control conditions, and possible variability in treatment provision.

INTRODUCTION

Substance use disorder (SUD) is characterised by the inability to control the use of psychoactive substances, such as alcohol and psychotropic drugs, which disrupt daily living. SUD remains a significant and growing health problem worldwide. According to the 2016 Global Burden of Disease survey, SUD contributed to 131 million disability-adjusted life years (DALYs) or 5.5% of all DALYs,[1] and its prevalence has been increasing since the 1990s.[2] While substance use itself is more widespread in high-income countries, low-income and middle-income countries (LMICs) had disproportionately high SUD mortality rates. The absolute mortality rate due to SUD was greatest in LMICs with large populations,[3] and people with economic disadvantages were more likely to develop SUD.[4] The Movement for Global Mental Health and the WHO have found substantial treatment gaps in LMICs. For instance, the number of individuals with SUD far exceeds the availability of formal treatment services.[5–7] While these numbers do not take traditional care into account, it is

still concerning that only 1% of individuals with SUD in LMICs have reported receiving government-standardised treatment.[8]

In Indonesia, the world's third most populous LMIC, government statistics have estimated the prevalence of drug use to be 1.8% or 3.3 million residents, with the most used substance being marijuana (68%), followed by amphetamine-type stimulants (ATS, 42%), opioids (38%), and sedatives (35%).[9 10] While injecting drug use decreased by 80% between 2002 and 2016,[10] unprescribed use of psychoactive medications like benzodiazepines has become significant.[11] Similar to other Muslim majority countries,[12] alcohol consumption is comparatively low in Indonesia, with alcohol use disorder being prevalent only among 0.8% residents in 2016, much lower than the overall rate in Southeast Asia (3.9%).[13] However, new psychoactive substances (NPS) have entered the country in the last decade.[14] Moreover, the COVID-19 pandemic may further complicate the SUD situation in Indonesia, as has been observed in other countries.[15] For instance, unpublished data from our coauthor (KS) revealed that since the pandemic began in early April 2020, both drug and alcohol use have increased in Indonesia by up to 2.5%. Increased drug use might have been influenced by lockdown isolation, socioeconomic issues due to unemployment, and severe psychological burden.

In Indonesia, formal mental health providers and facilities are severely lacking. In a nation of 267 million people, only 773 psychiatrists (0.32/100 000 people) are employed—the second lowest proportion in Southeast Asia[16]—across hospitals with psychiatric care, half of which are located in the capital island of Java.[17] Among the ~1700 government-run primary healthcare centres (abbreviated as *Puskesmas* in Indonesian), only a fifth actively provide mental healthcare.[17 18] Current formal treatment options for SUD include one-on-one supportive psychotherapy, symptomatic pharmacotherapy, peer counselling, and opioid substitution. Methadone maintenance therapy (MMT) has been available in Puskesmas since 2006, but as of 2012, its coverage was only 5%,[19] due to methadone cost, reliance on subsidisation, lack of programme sustainability,[20] and the tendency to incarcerate patients under the 'war on drugs' policy.[19 21] The 3-month retention rate of MMT was only 60%–74%.[22 23] Psychiatric comorbidities and lower quality of life are common among MMT recipients.[24] Most concerningly, insufficient formal treatment coverage and the lack of standardised care for SUD have prompted policymakers to enact punitive criminalisation practices, which are even more stringent under the current administration, instead of a comprehensive mental healthcare approach.[25 26]

Behavioural therapies in many forms are commonly administered for SUD, the most popular method being cognitive behavioural therapy (CBT). There is strong evidence supporting the efficacy of CBT in treating SUD. A meta-analysis reported a moderate overall effect size (d=0.45) of CBT treatments, with outcomes such as self-reported abstinence, drug-free urine at treatment exit, and increased retention in therapy.[27 28] CBT strategies include: (a) contingency management (CM),[29] which introduces rewards for abstinence, (b) motivational interviewing (MI), which explores and resolves ambivalence,[30 31] (c) relapse prevention (RP), which helps participants to identify high-risk triggers and prevent cravings, or (d) combinations thereof.[32] Therapy can be delivered individually or in groups; the latter has reportedly increased adherence and self-disclosure, and decreased the treatment duration by 40%.[33 34] CBT (particularly MI and RP) is relatively low-cost and can be delivered by non-specialists, making it adaptable to and beneficial in settings with limited formal mental health professionals.[35 36] In LMICs, while ample randomised controlled trials (RCTs) have supported the efficacy of CBT in reducing alcohol use,[37 38] evidence for treating drug use disorders is limited, with only five RCTs published so far.[39–43] Among these, three were inpatient-based, even though SUD management mandates sustainable outpatient care in community settings.

Telemedicine has the potential to improve SUD treatment coverage in Indonesia. Internet communication overcomes the geographical barriers of the Indonesian archipelago and saves time as well as transportation costs for both patients and providers, both in remote areas where health services are sparse,[44] and in major cities with heavy traffic, such as Jakarta.[45] Privacy is also better ensured online as opposed to in visiting clinics, where there is a greater risk of inappropriate disclosure of SUD diagnoses, which is one of the most stigmatised health conditions.[46] Synchronous telemedicine via live video feed connects participants in real-time, improving rapport and potentially adherence, as compared with asynchronous telemedicine (eg, through text messages or web application). Video-conferencing has been effectively used in SUD treatment;[47–52] however, recent systematic reviews[53–58] have revealed three gaps in research: (1) previous reports have only focused on alcohol and opioid use,[47 50–52] (2) group therapy was investigated by only one small-scale pilot RCT,[51] and (3) no studies have been conducted in LMICs. This latter gap is particularly relevant because the use of internet devices has been rapidly expanding in LMICs, including Indonesia. Smartphone users accounted for 74% of the Indonesian population in 2019, possibly reaching 89% by 2025.[59] The COVID-19 pandemic has further elevated telemedicine from an accessory to a necessity, including for psychiatric care.[60] Its accessibility and acceptance among patients with SUD, as shown in a recent survey,[61] may potentially sustain telemedicine as the 'new normal' even in the post-pandemic world.[62 63]

Given the above challenges and opportunities, we propose a clinical trial to evaluate a RP telemedicine programme for SUD in Indonesia. We have developed a new 12-week CBT-based group therapy called *the Indonesia Drug Addiction Relapse Prevention Programme* (Indo-DARPP), which will be delivered via video conference (tele-Indo-DARPP). The primary objective will be to evaluate the effectiveness of tele-Indo-DARPP in addition

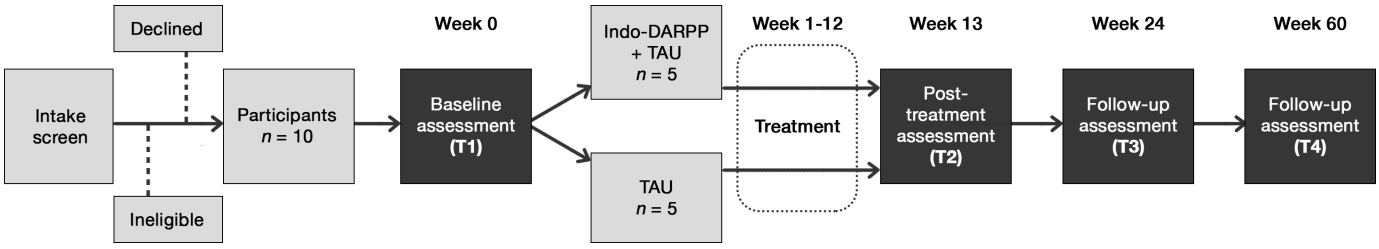

Figure 1 Study flowchart for each site. A total of 20 or 30 participants will be recruited through the social network of each site. After 10 participants have been recruited to constitute one wave, they will be randomly allocated into two arms: intervention (Indo-DARPP +TAU) and control (TAU only), with five participants in each arm. Recruitment will be continued until another 10 or 20 participants (second or third wave) join, in a similar procedure. Treatment period will be 12 weeks. Assessments will be conducted four times: T1 (week 0) during baseline or before randomisation, T2 (weeks 13–16) during postassessment or 1–4 weeks after treatment period ends, T3 (week 24) at 3 months after treatment ends and T4 (week 60) at 12 months after treatment ends. DARPP, Drug Addiction Relapse Prevention Programme; TAU, treatment as usual.

to treatment as usual (TAU) towards increasing abstinence from primarily used substances, as compared with the effectiveness of TAU only. The secondary objectives will be to assess impacts on quality of life, motivation to change, psychological symptoms, cognitive function, coping, and internalised stigma. Retention, participant satisfaction, and group cohesion will be assessed as implementation outcomes, and cost-effectiveness analyses will be conducted to inform health policy investments.

METHODS

Trial design

This trial is a parallel-group, two-arm, assessor-blinded, multicentre RCT. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (online supplemental file 1). We designed the study as a pragmatic type 1 hybrid effectiveness-implementation trial,[64] which allows concurrent investigation of intervention effectiveness as well as implementation in clinical practice, focusing on the former. After intake screening, participants will undergo baseline assessment (T1) and be randomly allocated in a 1:1 ratio, either to the intervention arm receiving tele-Indo-DARPP in addition to TAU, or the control arm receiving TAU only. Treatment will be administered for 12 weeks, followed by a post-treatment assessment (T2) at week 13, and follow-up assessments (T3) at week 24 and (T4) at week 60 (figure 1).

Participants and settings

Participants will be recruited across Indonesia via social networks of eight sites: two primary health centres (Puskesmas), three referral hospitals, and three drug rehabilitation services (table 1). These facility types constitute the community-based treatment model for SUD in Indonesia,[65] encompassing patients with diverse motivations for behavioural change, substance use histories, comorbidities, and stages of treatment. Recruitment will be conducted via online advertisements (ie, on social networking services, group chat, website) and through consecutive sampling by directly approaching current and former clients through outpatient services. Although all targeted facilities are located in urban settings, the recruitment process will include social media services of each site, particularly rehabilitation centres, which have nationwide coverage. Hence, we expect that participants will be recruited from anywhere in Indonesia and will not be limited to the physical scope of each site.

The services offered by each type of site vary. Puskesmas provide general primary care, pharmacotherapy for cases without complications and MMT. Referral hospitals provide psychotherapy, pharmacotherapy, opioid substitution therapy using buprenorphine/naloxone, and specialised care for cases with complications, such as severe psychiatric disorders. Rehabilitation services provide long-term psychosocial care, typically in a mutual-aid group. Sites were selected based on feasibility, client demographics, recruitment potential, and availability of providers. While recruited participants may not be undergoing treatment at these sites at the time, facilitators for tele-Indo-DARPP will be staff members of the respective sites: general practitioners in Puskesmas, psychiatrists in referral hospitals, and counsellors in rehabilitation centres.

Inclusion criteria will be those who: (1) be aged 18–65 years old; (2) be diagnosed with SUD based on DSM-5; (3) have used primarily used substances for at least 1 day in the past year; (4) have access to electronic devices (ie, smartphone, mobile tablet, personal computer) with internet connection and (5) be proficient in Indonesian. Individuals who (1) have severe comorbidities that hinder informed consent or group therapy participation and (2) are hospitalised or using residential care, will be excluded.

We set a broad inclusion criterion, that is, substance use in the past 1 year, for two reasons. First, proportional hazard models have showed that the probability of relapse remains high before achieving 1 year of abstinence, and declines substantially only after 16 months.[66 67] Thus, it is clinically important to examine treatment efficacy for people who have not achieved 1-year abstinence.[67] Second, in this pragmatic effectiveness study,[68] we designed eligibility criteria to accurately represent the population encountered in real-world Indonesian clinical

Table 1 Recruitment sites in this study

Name	Location	Type	Treatment as usual	Most reported primarily used substance
Cipto Mangunkusumo Hospital	Jakarta	Tertiary national general hospital	Individual psychotherapy, symptomatic pharmacotherapy	Benzodiazepine
Aceh Mental Hospital	Aceh	Tertiary provincial mental hospital	Individual psychotherapy, symptomatic pharmacotherapy	Methamphetamine
Duren Sawit Regional Hospital	Jakarta	Tertiary regional general hospital	Individual psychotherapy, symptomatic pharmacotherapy, opioid substitution therapy (buprenorphine, naloxone)	Opioid
Karisma Foundation	Jakarta	Rehabilitation centre	Individual and group peer counselling	Methamphetamine, opioid
Kapeta Foundation	Banten	Rehabilitation centre	Individual and group peer counselling	Methamphetamine, benzodiazepine, synthetic cannabinoids
Kios Atma Jaya	Jakarta	Rehabilitation centre and regional HIV clinic	Individual psychotherapy, group peer counselling, outreach programme	Opioid
Puskesmas Jatinegara	Jakarta	Primary healthcare	Counselling, symptomatic pharmacotherapy, methadone maintenance therapy	Heroin
Puskesmas Gambir	Jakarta	Primary healthcare	Counselling, symptomatic pharmacotherapy, methadone maintenance therapy	Heroin

Counselling focuses on education and giving advice.
Symptomatic pharmacotherapy gives medication for helping patients with specific psychopathologies.
Psychotherapy aims to help a person identify and change their emotions, thoughts, and behaviour.

practice. Indeed, patients treated at the collaborating clinical sites include those who have been abstinent for more than 1 month but still experience cravings and a tendency to relapse.

Recruitment

Patient eligibility will be assessed by collaborating staff at the respective sites. Addiction psychiatrists will conduct clinical assessments via video calls for those who have never been diagnosed with SUD. The consent form in English is provided in online supplemental file 2. For urine tests, explanations will be given immediately after post-treatment (T2) assessment, as anticipation for urine tests may influence substance use behaviour. Consent to urine tests or absence thereof will not affect study participation.

Randomisation and blinding

Depending on the study site, participants will be randomly allocated to either the intervention (tele-Indo-DARPP+TAU) or the control (TAU only) arm. Each site will conduct two or three waves of recruitment, with 10 participants in each wave. For each wave at a site, we will randomly allocate five participants to either the intervention or control arm. All participants in each tele-Indo-DARPP group will belong to the same recruitment site. Allocation will be performed using computer-generated random numbers by a researcher who will be blinded to the participants' information, except for ID. Data will be collected by researchers who are blinded to participants' study conditions. Participants and treatment providers will not be blinded, as it would not be possible given the psychotherapeutic nature of the intervention.

Development of the Indo-DARPP

The Indo-DARPP is based on the Serigaya Methamphetamine Relapse Prevention Programme (SMARPP), a face-to-face CBT-based group intervention developed by a coauthor (TM) in Japan,[69] which itself is based on the Matrix Model developed in the USA.[70] It has demonstrated efficacy in increasing abstinence duration, motivation to change, and participation in self-help groups.[71–73] SMARPP is covered by the national insurance scheme and has been widely implemented as a psychotherapy for SUD in psychiatric clinics and in primary healthcare

centres, rehabilitation centres, and probation offices in Japan. SMARPP has excellent scalability as it is delivered through workbooks and can be facilitated by non-specialists who have received brief training.

The contents of Indo-DARPP are based on the RP model, where participants are guided to learn about high-risk situations for substance use, and coping strategies. Elements of MI are incorporated in the earlier parts of the workbook in a form of open questions to assess participants' ambivalence and motivation to change. The programme also includes psychoeducation on substances, SUD and common comorbidities. While CM could also be added, it increases cost and may not be effective in the longer term;[74] thus, only MI and RP approaches will be used in this study. Adaptations from SMARPP were determined via focus group discussions involving Japanese researchers and psychiatrists, general practitioners, and peer counsellors based in Indonesia, all of whom have extensive experience ranging from 4 to 20 years in the addiction field. The substances discussed in the module are ATS, benzodiazepines and other prescribed medicines, opioids, marijuana, NPS, and alcohol. Indo-DARPP is designed to be delivered in a small group format using a workbook (see online supplemental file 3 for the table of contents of the workbook). Sessions will be delivered by one facilitator and one peer counsellor with lived experiences of SUD as cofacilitator.

A pilot test was conducted at Site 1, with nine patients with SUD recruited for a 12-week tele-Indo-DARPP to check content acceptability and feasibility of the online delivery format. Further adjustments were made based on pilot results and patient feedback.

Intervention via video conference: tele-Indo-DARPP

Tele-Indo-DARPP will be delivered as group therapy for 12 weeks in weekly 2-hour sessions over the online videoconferencing application Zoom, with a maximum of five participants. The research team will provide video conference links to participants and two providers. Participants who agree to share their contact information will receive the links on an online group chat, while others will be notified via personal messages. Each Indo-DARPP session consists of three parts: (1) 'check-in', where participants share history of substance use and craving in the past week, and analyse high-risk situations and coping actions taken; (2) 'today's topic', where providers guide discussions of specific workbook chapters and participants complete exercises, and (3) 'check-out', where providers give summary and invite feedback, and participants anticipate triggers and coping strategies for the following week.

Providers of tele-Indo-DARPP

At least two persons from each site will serve as facilitators, who meet either of the following criteria: psychiatrists with at least a year of experience in treating patients with SUD, healthcare providers with at least 2years of experience in providing care for patients with SUD, or peer counsellors with at least 2 years of involvement with any organisations providing services for patients with SUD. The roles of facilitators are to: (1) lead and moderate Indo-DARPP sessions, (2) elaborate on chapter contents, (3) manage participants to follow rules, (4) establish a safe and warm environment, (5) provide consultation, including out-of-session, and (6) contact absent participants to encourage attendance.

Similarly, at least two persons from each site will serve as cofacilitators for the tele-Indo-DARPP. Cofacilitators will be peer counsellors who have also experienced SUD and recovered, with at least 6 months of involvement with any organisations providing services for patients with SUD. The role of cofacilitators is to: (1) share personal experiences relevant to discussion topics, (2) assist facilitators in ensuring a safe and warm environment, (3) provide general support to the Indo-DARPP process, and (4) provide counsel, both in and out of sessions.

Training and supervision

Prior to recruitment, all providers will receive two full-day online training sessions on basic knowledge of SUD treatment, Indo-DARPP content, principles of MI (eg, empathy, reflective listening, empowering affirmations), video demonstrations, hands-on role play, discussion of difficult cases, and study-related quality control. Workbooks and manuals will be handed to all providers, and close communication with the research team will be maintained via a WhatsApp group chat throughout the research period. To maintain treatment fidelity and quality control, during actual tele-Indo-DARPP sessions, addiction psychiatrists from the research team (KS and EH) will randomly select and observe at least two sessions per Indo-DARPP group. Observations will be conducted at each wave at each site, constituting 16.7% of all sessions, and will be reviewed using a structured checklist.

Control condition

Participants who received treatment before the study will continue to receive TAU, regardless of group allocation. TAU was chosen as the control condition because it is expected to complement the existing treatment services for SUD at every level of care. The TAU differs according to service location (table 1). Individual psychotherapy is typically conducted via in-person short consultations (~15min) with clinical psychiatrists. Pharmacotherapy is used to alleviate symptoms, by prescribing medications such as anxiolytics for conditions such as anxiety. Patients undergoing MMT visit their sites almost every day to receive their daily doses, while patients undergoing substitution therapy with buprenorphine with naloxone visit every week. All participants will be able to continue any outpatient pharmacological treatment (eg, MMT, antidepressants) and psychotherapy (eg, 12-step group sessions).

Primary outcome

Abstinence from primarily used substance

The primary outcome is the percentage of days of abstinence from the primarily used substance in the past 28 days. Per cent days of abstinence have been shown to be

Table 2 Outcome and measurement

Outcome	Measurement	Data for analysis	Type and score range	Hypothesis for intervention (vs control)	Assessment time point			
					T1	T2	T3	T4
Primary outcome								
Abstinence from primary substance	TLFB for the past 28 days	Number of days being abstinent from primary substance divided by 28 (%).	Continuous, 0 (no use) to 100 (used every day).	Higher	✔	✔ *	✔	✔
Secondary outcomes								
Addiction severity	ASI	7 composite scores: medical, employment, alcohol use, drug use, legal, family/social and psychiatric status. Each composite score calculated using standard formula.	Continuous, 0 (no problems) to 1 (severe problems).	Lower	✔	✔	✔	✔
Health-related quality of life	EQ-5D-5L	Health utility score, calculated from 5 items on mobility, self-care, usual activities, pain/discomfort and anxiety/depression, using Indonesian value set.	Continuous, −0.865 (impaired health) to 1 (full health).	Higher	✔	✔	✔	✔
Motivation to change	URICA	Action stage subscale, sum of 8 items.	Continuous, 8 (not active in behavioural change) to 40 (highly active in behavioural change).	Higher	✔	✔	✔	✔
Coping	Brief COPE	Sum of substance use coping (2 items)	Continuous, 2 (low substance use coping) to 8 (high substance use coping).	Lower	✔	✔	✔	✔
Psychiatric symptoms	SCL-90-R	GSI, average of 90 items.	Continuous, 0 (no symptoms) to 4 (severe symptoms).	Lower	✔	✔	✔	✔
Cognitive function	RAVLT	3 test results; immediate, learning and recalling.	Continuous, 0 (low functioning) to 15 (high functioning).	Higher	✔	✔	✔	✔
Internalised stigma	ISMI	Sum of 4 subscales: alienation, stereotype endorsement, social withdrawal and stigma resistances.	Continuous, 24 (low internalised stigma) to 96 (high internalised stigma).	Lower	✔	✔	✔	✔
Implementation outcomes								
Retention in treatment	Self-reporting for the past 3 months	Coded as 'retained' if they had therapeutic contacts in at least 75% of the planned number of therapeutic contacts.	Categorical, 'retained'=1, 'not retained'=0.	More 'retained'		✔	✔	✔
Treatment satisfaction	CSQ-3	Sum of 3 items.	Continuous, 4 (not satisfied) to 12 (satisfied).	Higher		✔		
Group cohesion	GTES	Sum of 16 items.	Continuous, 16 (poor cohesion) to 80 (great cohesion).	Not applicable: measured only in intervention arm		✔		

*Objective validation by urine drug test for eight substances: alcohol, amphetamine, morphine, cannabinoids, methamphetamine, benzodiazepine, cocaine, synthetic cannabinoids.
ASI, Addiction Severity Index; COPE, Coping Orientation to Problems Experienced; CSQ-3, Client Satisfaction Questionnaire-3; EQ-5D, EuroQol-5D; GSI, Global Severity Index; GTES, Group Therapy Experience Scale; ISMI, Internalised Stigma of Mental Illness; RAVLT, Rey Auditory Verbal Learning Test; SCL-90-R, Symptom Checklist-90 Revised; TLFB, timeline follow-up; URICA, University of Rhode Island Change Assessment.

sensitive to the effects of CBT and are good predictors of SUD treatment follow-up.[75] Data on the use of primarily used substances each day (measured in a yes/no format) for 28 days will be retrospectively collected on a weekly basis using the timeline follow-up (TLFB) method (table 2), which has good validity and high test-retest reliability in measuring substance consumption.[76 77] The participants will be asked to recount every week to reduce the risk of recall bias. The primarily used substance refers to the most problematic substance for participants, which has driven them to seek care at T1.

Urine samples will be collected to test for the presence of the primarily used substance once at T2. Thresholds for a positive result are >100 ng/mL for ethyl glucuronide (alcohol), >300 ng/mL for ATS (ie, d-methamphetamine and 3,4-methylenedioxymethamphetamine), >100 ng/mL for diacetylmorphine (heroin), cocaine and benzodiazepine, >50 ng/mL for synthetic cannabis (K2),

and >25 ng/mL for tetrahydrocannabinol (marijuana). Urine tests in this study will only serve to corroborate the data of self-reported substance use at the primary endpoint (T2), not as an objective substitute of all self-reported substance use data at every time point. This was planned to improve feasibility for participants and minimise dropout due to the burden of data collection (urine test needs in-person assessment, unlike all other measurements in this study), especially among participants who reside in remote areas who are deemed to benefit the most from online therapy.

Secondary outcomes

Addiction severity

The Addiction Severity Index (ASI) is the most widely used measure in the field of addiction.[78] Internal consistency, test-retest reliability and scale independence of ASI to measure substance use have long been established.[79 80] The Treatnet ASI V.3.0 by the United Nations Office on Drugs and Crime will be used; the scale is available in Indonesian, and one addiction treatment centre in Indonesia was included in its development trial.[81]

Health-related quality of life

The five-level version of the five-dimensional EuroQoL (EQ-5D)[82 83] will be used to assess health-related quality of life, which has been used before for patients with SUD with confirmed construct validity.[84 85] The total utility score will be obtained using the already established value set in Indonesia.[86]

Motivation to change

Motivation to change will be assessed by the Action subscale of the University of Rhode Island Change Assessment (URICA)[87] which has been shown to have good validity. Higher scores indicate that the person has committed to develop positive behavioural changes.[88]

Coping

Types of engaged stress coping will be assessed by the Brief Coping Orientations to Problems Experienced,[89] which is commonly used for patients with SUD.[90] Higher scores for specific types indicate that patients have adopted them more frequently.

Psychiatric symptoms

Psychiatric symptoms will be evaluated by the Symptom Checklist 90 R.[91] The Global Severity Index will be used, which is widely used for measuring psychiatric symptoms among patients with SUD.[92]

Cognitive function

Cognitive function will be assessed by the Rey Auditory Verbal Learning Test,[93] which is useful for diagnosing cognitive impairment as well as post-treatment improvement in patients with SUD.[94 95]

Internalised stigma

Internalised stigma will be assessed using the Internalised Stigma of Mental Illness scale.[96] The term 'mental illness' in the statements will be replaced with 'substance addiction'.

Implementation outcomes

Retention in treatment

Participants will be coded as 'retained in treatment' if they have had therapeutic contact, including attending tele-Indo-DARPP and visiting any outpatient clinic for TAU, in at least 75% of planned contacts in the previous 3 months.

Treatment satisfaction

The Client Satisfaction Questionnaire-3[97] will be used, as it is commonly used for treatment programmes, including for SUD.[98]

Group cohesion

The Group Therapy Experience Scale will be used to measure the level of group cohesion and self-disclosure in group therapy, as implementation outcomes of tele-Indo-DARPP.[99]

Indo-DARPP attendance

Attendance of each session will be recorded by the facilitator.

Cost effectiveness

Cost-effectiveness will be assessed from patient, provider, and societal perspectives. Cost data will be calculated by multiplying the quantity of used resources by the unit price. Data on quantity and unit price will be obtained from within the trial or estimated from relevant data sources. For effectiveness data, both clinical and economic indices will be used. The clinical index will be based on days of abstinence from the primarily used substance in the previous 28 days, which will be converted into years of abstinence. The economic index will be based on the quality-adjusted life year (QALY) calculated from the utility score of the EQ-5D.

Feedback interviews

Semistructured interviews will be conducted with both participants and providers to assess the following: satisfaction with content quality, comprehensibility, technical experience regarding video-conferencing, comfort, module practicability, language barriers and participants' perception of the credibility of providers. Interviews will be audio-recorded with the interviewees' consent.

Participant characteristics

The following data will be obtained via a self-administered questionnaire: age, gender, approximate residential location, marital status, household cohabitants, ethnicity, religion, highest education level, employment status, individual and household income, type of internet device used, frequency of video calls in the past year, age during first instance of drug use, primarily used substance, inpatient history or incarceration in the past month, types of treatments received, treatment locations in the past

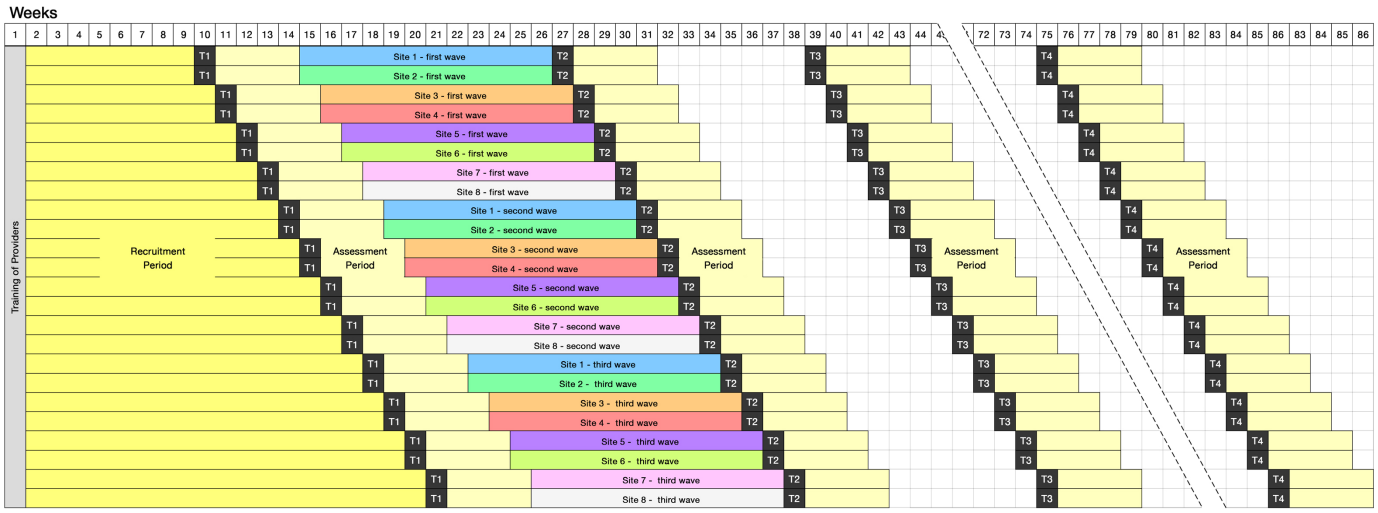

Figure 2 Planned trial schedule across all eight research sites. Staggered schedules were designed to spread the assessment workload of providers and research staff. After training the providers, all sites will be given approximately 1–2 months to recruit participants. Sites with relatively higher potential to recruit faster, that is, those with higher rates of patient turnover, have been selected first in the schedule. Each site will have two or three waves of recruitment and treatment periods.

3 months, status of current outpatient care (voluntary or involuntary, legal or non-legal) and transportation time and cost from residence to outpatient locations.

Data collection procedure

Researchers blinded to the treatment allocation will collect data at four different time points: at baseline (week 0, T1), the week after the completion of treatment (week 13, T2), 3 months after the completion of treatment (week 24, T3), and 12 months after the completion of treatment (week 60, T4), using self-answered questionnaires and online one-on-one interviews. For the primary outcome, participants will be asked to recall weekly drug use using the TLFB, with a period of approximately 4 weeks between each assessment. Urine specimens will be collected only at T2 and at the final 2 weeks within the TLFB assessment period. The assessment schedule is presented in table 2 and figure 2. To facilitate honest disclosure from participants, we will not record any Indo-DARPP video-conferencing sessions throughout the study.

Sample size

The sample size was calculated for the primary outcome to detect a medium effect size of d=0.50, which is slightly more modest than that of a previous study examining the efficacy of telemedicine for people with SUD in an LMIC (d=0.59).[100] Using α=0.05, power=0.80, a simple t-test requires n=64 per arm. We estimated the design effect of clustering within the Indo-DARPP group using the formula $D=1+(m-1)\rho$,[101] assuming intraclass correlation within Indo-DARPP groups or ρ=0.05, and group size or m=5, which yielded a design effect of D=1.2. We then multiplied n=64 by D=1.2, which yielded the minimal number of participants in the data analysis: n=77 per arm. Assuming an attrition proportion of 30% which is more conservative than a previous similar study (26%),[102] the sample size for enrolment was set as 110 per arm, or 220 in total.

Statistical analysis

A detailed statistical analysis plan will be developed by a statistician who is blinded to the patient allocation prior to data analysis. Baseline data description and main analyses will be conducted on an intention-to-treat basis; that is, participants' data will be handled according to their initially assigned arms, regardless of the actual received treatment. Analyses will be conducted with a significance level of 5% in the two-sided test, using Stata/SE V.16.1.

Consideration for correlated outcome data

The correlation within sites for the control arm will be ignored, as the TAU within one site varies per patient and some participants may not receive any treatment. For the intervention arm, the correlation within each Indo-DARPP group due to the nature of group therapy needs to be considered. We define a new variable termed 'clustering group identification' (CID), in which the control arm will be coded as a unique CID for each person, while the intervention arm will be coded based on the tele-Indo-DARPP group, hence assigning the same CID for all five participants.

Main analysis

The primary endpoint has been set at T2. The mean of the outcome changes from T1 to T2 will be compared between the intervention and control arms using a linear model. To investigate the durability of the treatment effect, outcome changes from T1 to T3 and T4 will also be compared between the two arms. We will account for the aforementioned correlations by clustering data based on CID in the generalised estimation equations (GEE). To help interpret the effect size, Cohen's d between the arms will be calculated.

Missing values

A complete case analysis will be performed, which will only include participants with no missing values in the variables of interest. Sensitivity analysis for missing values will be conducted by either inverse probability-weighted GEE[103] or multiple imputation.

Subgroup analysis

Effects of the intervention will be investigated by subgroups, as the observed effect may vary depending on the specific population. Participants will be divided by the types of primarily used substance, gender, previous and current utilisation of other SUD treatment, high and low values in clinical characteristics at T1 (eg, per cent days of abstinence, ASI drug use composite score, URICA readiness score, and cognitive function). Specifically, based on previous studies which showed that treatment effectiveness varied depending on baseline severity levels,[104 105] we hypothesised that participants assigned to tele-Indo-DARPP with more severe levels of substance use at T1 would report more increase in days of abstinence at T2, T3, and T4.

Implementation evaluation

χ^2 tests and *t*-tests will be performed to compare retention in treatment and treatment satisfaction between the arms, exclusively for participants who are already receiving SUD treatment at T1. Group cohesion and Indo-DARPP attendance will be descriptively reported by means and SD. For cost-effectiveness analysis, the incremental cost-effectiveness ratios will be calculated, which will yield costs per QALY and abstinent year. Feedback interviews will be transcribed, and thematic analysis will be conducted.

Compensations

Participants in both the control and intervention groups will receive 300 000 IDR (~US$21.3) to compensate for their transportation to treatment sites for TAU throughout the 12 weeks, and 98 000 IDR (≈US$7.0) every time they completed an online video assessment as compensation for internet data and 2-hour data collection. Participants from the intervention group will further receive internet mobile data equivalent to 50 000 IDR (≈US$3.5) before the first session of tele-Indo-DARPP, and subsequently every time they attend four sessions of tele-Indo-DARPP. For providers, compensation of 170 000 IDR (≈US$12.1) and 150 000 IDR (≈US$10.7) will be provided for each tele-Indo-DARPP session to the facilitator and cofacilitator, respectively.

Data monitoring

Data on adverse events, including hospitalisation, arrest, and death, will be collected from the participants' treating psychiatrists or medical staff. In addition, participants will be interviewed at T2 to determine whether they have experienced any subjective harmful effects (eg, withdrawal syndrome, increased cravings) after joining Indo-DARPP. An independent data monitoring committee will not be convened, as the study involves short-term, non-invasive psychotherapeutic intervention. No interim analysis was planned due to the short duration of the intervention. Completeness and accuracy of data collection will be checked by Japanese coinvestigators, and there will be no auditing process by independent investigators.

Data publication

The results of the study will be published in scientific publications and reported to relevant government bodies in Indonesia to advocate adopting the treatment module.

Ethical consideration and dissemination

The study protocol was approved by the Research Ethical Committee of Faculty of Medicine, Universitas Indonesia (approval number: KET-1175/2019) and the Ethics Committee of the Graduate School and Faculty of Medicine, Kyoto University (approval number: C1483). The study protocol was registered at the University Hospital Medical Information Network Clinical Trial Registry (UMIN-CTR) (registry number: UMIN000042186).

The consent process will be conducted carefully to ensure that all potential participants fully understand the research objectives, procedures, risks, benefits, costs, and alternatives. It will be emphasised that study participation is voluntary, and consent can be withdrawn at any time before publication. We will allocate participants to treatment arms only when written informed consent for participation is obtained. Likewise, urine specimens will only be collected if written informed consent for urine collection is obtained. Participants will not be influenced when deciding on study participation and/or urine collection. Personal data will be protected by separating the study data from the participants' identifiable information. To quickly respond to adverse events arising when outpatient visits are not possible, a dedicated phone number and WhatsApp account for the study will be opened to ease communication with the research team. Participants will be instructed to text or call when experiencing adverse events. Importantly, written agreement will be obtained from participants to never share others' information with any third party. This regulation will be enforced both during and outside tele-Indo-DARPP sessions, in any medium, including video conference and group chat.

The results of this study will be disseminated via peer-reviewed journals and international academic conferences. Depending on trial outcomes, Indo-DARPP will be advocated to the Indonesian government for adoption as a nationwide formal treatment programme.

Patient and public involvement

Patient feedback during the pilot study was incorporated into the Indo-DARPP module design. In addition, patients and/or the public will not be involved in conducting, reporting, or disseminating this study.

DISCUSSION

At the time of writing, nine RCTs from LMICs had reported the effectiveness of digital delivery of interventions for SUD. The used formats were telephone calls,[106–109] webpages,[110–112] and mobile applications.[100 113] However, no study in LMICs has so far investigated the effectiveness of video conference-based psychotherapy. The latter may facilitate honest, interactive discussions on personal substance use and cravings, founded on better rapport between providers and patients,[114] all of which are integral to CBT for SUD. One meta-analysis concluded that web-based mental health interventions had better retention rates and treatment outcomes when therapists were synchronously involved.[115]

This study has several strengths. This will be the first RCT to investigate the effectiveness of video conference-based psychotherapy in any LMIC, as well as the first study to establish quality evidence on psychotherapy for SUD in Indonesia. Recruitment will be done throughout multiple levels of care, that is, tertiary (referral hospitals), primary (Puskesmas), and community (rehabilitation centres). The latter have extensive reach encompassing all major Indonesian islands, and social media advertising will facilitate recruitment across the nation. While effectiveness of CBT is the primary outcome, the study allows examinations of real-world implementation and cost-effectiveness in a hybrid effectiveness-implementation design.[64] This is particularly true in Puskesmas, where the providers will be general practitioners, and in rehabilitation centres, where the providers will be peer counsellors. This pragmatic RCT aims to mimic usual clinical practice, and we hope that the results may be used to inform decision-making by patients, providers and policymakers.[116]

This study has several limitations. All data from participants will be self-reported and prone to recall and social desirability bias. Urine tests will be performed to corroborate subjective data but will not constitute a full validation, as they will only be performed once to represent substance-detectable period. The test was planned only at T2 to improve feasibility for participants and reduce the risk of drop-outs. Control conditions will be heterogeneous, as the study will include participants who use various substances at multiple sites, where TAU differs or may not even be provided. Variability in the providers' background may create inconsistency in CBT delivery, even though training and treatment manuals will be introduced to standardise care. Treatment delivery via online videoconferencing might have poor generalisability towards people with low internet literacy, as well as people in low socioeconomic strata who cannot afford smartphones, although entry-level Android-based smartphones (less than US$100) are available nationwide in Indonesia. Psychotherapy will be provided in Bahasa Indonesia; hence, its effectiveness would not be generalisable to people with limited proficiency in the language.

Efforts to establish evidence-based treatment for SUD should be scaled up in Indonesia and LMICs in general, where effectiveness data are sparse. The proposed study may present high-quality evidence, and a successful outcome may result in a new SUD treatment module in Indonesia, paving the way for the adoption of Indo-DARPP into the national guidelines. We hope that our efforts may further promote a comprehensive healthcare approach, as opposed to repressive antidrug policies, for the SUD population.

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Reporting checklist for protocol of a clinical trial.

Based on the SPIRIT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SPIRITreporting guidelines, and cite them as:

Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A, Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586

		Reporting Item	Page Number
Administrative information			
Title	#1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	#2a	Trial identifier and registry name. If not yet registered, name of intended registry	4, 23
Trial registration: data set	#2b	All items from the World Health Organization Trial Registration Data Set	n/a, trial already registered as described in 2a.
Protocol version	#3	Date and version identifier	23
Funding	#4	Sources and types of financial, material, and other support	26-27
Roles and	#5a	Names, affiliations, and roles of protocol	26

responsibilities: contributorship		contributors	
Roles and responsibilities: sponsor contact information	#5b	Name and contact information for the trial sponsor	n/a, no trial sponsor.
Roles and responsibilities: sponsor and funder	#5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	n/a, no involvement of funders in the study design.
Roles and responsibilities: committees	#5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	n/a, no direct intervention in the study design by the host universities.
Introduction			
Background and rationale	#6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	6-9
Background and rationale: choice of comparators	#6b	Explanation for choice of comparators	15
Objectives	#7	Specific objectives or hypotheses	9
Trial design	#8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	9-10

Methods: Participants, interventions, and outcomes			
Study setting	#9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	10-11
Eligibility criteria	#10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	11
Interventions: description	#11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	13
Interventions: modifications	#11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease)	22-23
Interventions: adherance	#11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests)	22-23
Interventions: concomitant care	#11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	15
Outcomes	#12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome.	15-19

		Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	
Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	10, 19, 26
Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	20
Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	11
Methods: Assignment of interventions (for controlled trials)			
Allocation: sequence generation	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	12
Allocation concealment mechanism	#16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	12
Allocation:	#16c	Who will generate the allocation sequence,	12

implementation		who will enrol participants, and who will assign participants to interventions	
Blinding (masking)	#17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	12, 19
Blinding (masking): emergency unblinding	#17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a, only assessors are blinded
Methods: Data collection, management, and analysis			
Data collection plan	#18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-19
Data collection plan: retention	#18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	19, 22-23
Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the	23

		protocol	
Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	20-22
Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	21-22
Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	21
Methods: Monitoring			
Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	23, DMC will not be convened as the intervention involves a short-term psychotherapy with known minimal risk.
Data monitoring: interim analysis	#21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	23, interim analysis is not planned due to the short duration of intervention.
Harms	#22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	22-23
Auditing	#23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	23, there will be no auditing process by independent investigators.

Ethics and dissemination			
Research ethics approval	#24	Plans for seeking research ethics committee / institutional review board (REC / IRB) approval	23, 28
Protocol amendments	#25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	23
Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	23
Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	23
Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	23
Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	28
Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	15, CBT intervention will be made available for control group after the end of the study.

Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
Dissemination policy: authorship	#31b	Authorship eligibility guidelines and any intended use of professional writers	26-27
Dissemination policy: reproducible research	#31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	28
Appendices			
Informed consent materials	#32	Model consent form and other related documentation given to participants and authorised surrogates	11, 23
Biological specimens	#33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	16

Notes:

- 2b: n/a, trial already registered as described in 2a.
- 5b: n/a, no trial sponsor.
- 5c: n/a, no involvement of funders in the study design.
- 5d: n/a, no direct intervention in the study design by the host universities.
- 17b: n/a, only assessors are blinded
- 21a: 23, DMC will not be convened as the intervention involves a short-term psychotherapy with known minimal risk.
- 21b: 23, interim analysis is not planned due to the short duration of intervention.

- 23: 23, there will be no auditing process by independent investigators.
- 30: 15, CBT intervention will be made available for control group after the end of the study. The SPIRIT Explanation and Elaboration paper is distributed under the terms of the Creative Commons Attribution License CC-BY-NC. This checklist was completed on 15. February 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

Supplementary file 2

Research Participation Consent Form

Title of the Research:

Effectiveness of a cognitive behavioral therapy for drug use disorders in Indonesia: A randomized controlled trial

(Collaboration research between the Faculty of Medicine, University of Indonesia and Kyoto University)

An explanation has been given which includes the following discussion :

1. Research Title
2. Research Clearance
3. Research institutes and researchers
4. Research purposes
5. Research procedure
6. Research period
7. Inclusion Criteria
8. Risks, benefits, and side effects
9. Right to refuse and drop out
10. Voluntary participation and risk of involvement
11. Research data publication
12. How to access research-related materials for participants
13. Privacy of personal data
14. Research data storage
15. Research funds and conflicts of interest
16. Researcher contact list
17. Remuneration for participants
18. General management of drug addiction patients outside of research interventions
19. Follow up management after the research ends
20. Report of the participant's genetic information
21. Compensation for illness related to research and invasive procedures
22. Secondary research data for other institutions
23. Samples and participant information related to invasive procedures
24. Name, position, and affiliation of the person in charge of managing data and information related to research
25. CBT group participant commitments and drop out possibility of research participation

Explanations have been given according to the explanation sheet, and consent has been obtained voluntarily.

Date of consent : _____ / _____/ 20 ___

Researcher's affiliation : _____

Researcher's Name :

Researcher's Signature :

Acknowledged by:

1. Dean of the Faculty Medicine, University Indonesia
2. Director of the *Center for South East Asian Studies, Kyoto University*

Supplementary file 2

CBT-Group Participation Consent Form

I, the undersigned, hereby acknowledge, consent and agree to fulfill the following matters during my participation in CBT group therapy, in order to ensure the safe and secure continuation of the program:

1. I will not divulge information about other participants in the group to external parties without the consent of the parties concerned.
2. I will not record audio, video, or take camera pictures without the permission of the parties concerned and the research team.
3. I will not use drugs during the CBT session.
4. I will not divulge links (URL), ID, and passwords for online meetings in the Zoom application to external parties, without the approval of the research team.
5. I will not harass, say offensive words related to ethnicity,religion and race, or commit acts of violence for any reason to any party related to the research, whether other participants or the research team.

If I infringe the points of the agreement above, I will be given 1 (one) warning. If I do not show any improvement after being warned, or infringe it for the second time, or it is deemed that my participation will interfere with the continuation of CBT therapy in the future, I have no objection to my participation being unilaterally terminated.

I, the undersigned, hereby declare that I have understood the explanation given and agree to my participation in the research mentioned above.in my behavior after being warned, or infringe it for the second time, or it is deemed that my participation will interfere with the continuation of CBT therapy in the future, I have no objection to my participation being unilaterally terminated.

Date of Consent : ____ / _____ / 20 ___

Name : _____

Signature : _____

Supplementary file 2

Urine Test Informed Consent

Title of Research:

Effectiveness of a cognitive behavioral therapy for drug use disorders in Indonesia: A randomized controlled trial

(Collaboration research between the Faculty of Medicine, University of Indonesia and Kyoto University)

An explanation has been given which includes the following discussion:
1. Purpose of the urine sampling
2. Urine test procedure
3. Analysis of urine test results data and maintaining data confidentiality

Explanations have been given according to the explanation sheet, and consent has been obtained voluntarily.

I, the undersigned, declare that I

Agree / do not agree

*please circle one of these options above

…to provide the urine sample to be tested for the research team, and I have acknowledged and understood the purposes, procedures and data analysis as described previously.

Date of consent : ____ / _____ / 20 ___

Name : _____

Signature : _____

Supplementary file 2

Withdrawal of Informed Consent for Urine Test

Title of the research:

Effectiveness of a cognitive behavioral therapy for drug use disorders in Indonesia: A randomized controlled trial

(Collaboration research between the Faculty of Medicine, University of Indonesia and Kyoto University)

I,the undersigned,hereby wish to withdraw my prior consent to participate in the urinary test for this research by signing this form.

Withdrawal Date : ____ / _____ / 20 ___

Participant's Name : _____

Participant's Signature : _____

Supplementary file 3

Table of contents of Indo-DARPP (English translation)