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Music therapy for people with substance use disorders (Protocol)

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[Intervention Protocol]

Music therapy for people with substance use disorders

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

Main objective

To compare the effect of music therapy (MT) in addition to standard care versus standard care alone, or to standard care plus an active control intervention, on psychological symptoms, substance craving, motivation for treatment, and motivation to stay clean/sober.

Secondary objective

To assess the impact of the number of MT sessions on study outcomes.

BACKGROUND

Description of the condition

Problematic substance use and related high-risk behaviour have a negative impact on individuals, families, and global public health. The burden of problematic substance use to systems such as healthcare, criminal justice, and unemployment/welfare is substantial (WHO 2018). The World Health Organization (WHO) *Global Status Report on Alcohol and Health 2018* cites 3.0 million deaths in 2016 were attributable to the harmful use of alcohol, representing 5.3% of all deaths (WHO 2018, p.63). In addition, 5.1% of the global burden of disease, expressed as 132.6 million net disability-adjusted life years, can be attributed to alcohol consumption (WHO 2018, p.64). Problematic use of drugs and alcohol is a widespread issue, with approximately 30.5 million people worldwide (range 16.7 to 44.4 million), amounting to 0.62% of the adult population (15 to 64 years), engaging in problematic drug use in 2016 (UNODC 2018), and 4.9% of the world's population aged 15 years or older demonstrating either harmful use of alcohol or alcohol dependence (WHO 2018). While both the number of deaths related to alcohol use and the number of people engaging in harmful alcohol consumption appear to have stabilised from 2013 to 2018, the number of people engaging in problematic drug use has increased by approximately 10% since 2013 (UNODC 2018). This increase is mainly attributed to the increase in opioid use, where global opium production has more than doubled between 2015 and 2017 (UNODC 2018). Opioids also continue to cause the most harm, as 76% of deaths that are directly drug-related are caused by opium and its derivatives (UNODC 2018).

Substance use disorders (SUDs) may be defined as the use of one or more psychoactive substances, medically prescribed or not (WHO 1994), in a manner that results in continued use despite significant substance-related problems in areas of the person's cognitive, behavioural, physiological, or social functioning (Diagnostic and Statistical Manual of Mental Disorders [DSM-5], APA 2013). People who inject drugs are at higher risk of death. This harm is partly due to fatal overdoses or the transmission of lethal infectious diseases (UNODC 2018). More than half of people who inject drugs live with hepatitis C and approximately 12% of them are diagnosed with HIV (UNODC 2018). Worldwide, an estimated one in every six people with problematic drug use receives necessary treatment; if all people with problematic drug use sought treatment, the resulting cost would represent 0.3% to 0.4% of the global gross domestic product (INCB 2013). Although the economic burden of treatment is considerable, the costs of crime-related law enforcement and judiciary services and healthcare provision for untreated problematic drug use remain far higher than that of prevention and treatment (INCB 2013).

Research-based principles of substance use addiction treatment suggest that SUD is a complex but treatable disease (NIDA 2018). Successfully treating people who have SUDs demands a diversity of treatment procedures and areas of treatment focus, due to the diversity of personal characteristics and substance(s) used. Treatment must meet the complex biopsychosocial needs of the person involved, and thus must be multidisciplinary in nature. Longer lengths of residential substance use treatment are associated with better engagement in aftercare programmes and lower levels of substance use at long-term follow-up (Arbour 2011; Moos 2007). Improved treatment retention also predicts lower recidivism rates in criminally-convicted individuals with co-occurring substance use and mental health disorders (Jaffe 2012). Supporting retention in multidisciplinary treatment remains a crucial aspect of addressing the harms caused by SUDs, but at the same time remains one of the greatest challenges. In the USA, approximately 26% of people with problematic substance use drop out of public treatment programmes (SAMHSA 2014). People with problematic substance use who have co-occurring mental health disorders demonstrate even lower treatment retention rates. Gender-specific retention strategies are an important means of promoting treatment retention among people with problematic substance use with co-occurring mental health disorders (Choi 2015).

People with SUDs often experience emotional dysfunction, which can contribute to the development of the disorder. People with SUDs commonly experience co-occurring affective disorders such as depression and anxiety (London 2004), as well as posttraumatic stress disorder (Ouimette 2005; van Dam 2012). In addition, people with SUDs demonstrate dysfunction in emotion regulation, such as dampened inhibition of intense affects and abnormal emotional reactions to emotional stimuli (Chen 2018; O'Daly 2012; Wilcox 2016). Research demonstrates functional changes in emotion-related brain areas in people with SUDs, including abnormalities in the activation of the insula and amygdala, as well as hypoactivity in the anterior cingulate cortex and ventromedial prefrontal cortex (Gilman 2008; Salloum 2007).

Description of the intervention

Music therapy (MT) is "the systematic use of specific musical interventions (based upon musical, aesthetic, clinical, scientific, and practice-based research as well as tacit knowledge) by an accredited music therapist to realise individual treatment goals within a therapeutic alliance" (NVvMT 2017, p.11-2). In MT, therapeutic change occurs via engagement in musical experiences and by the relationships that develop through them (Bruscia 1998). Music therapists engage participants in a range of active and receptive approaches to listening to, discussing, creating, improvising, and performing music. MT may incorporate varying levels of verbal processing, depending upon the needs of the participant(s) and the theoretical orientation of the music therapist. Sessions can occur with individuals, groups, or with communities, and may include various approaches such as songwriting; discussion and analysis of song lyrics; instrumental or vocal improvisation, or both; music performance; and music-assisted relaxation. MT may be practised from a variety of theoretical orientations, and in the setting of substance use treatment may include elements of cognitive-behavioural; humanistic; psychodynamic or neurobiological theory, or both; among others. MT is an integrated part of multidisciplinary substance use treatment in many countries. Music therapists work within abstinence-based, controlled use, and harm reduction contexts (Aldridge 2010; Ghetti 2004), in inpatient treatment centres, community mental health centres, adult day and ambulant healthcare centres, state and general hospitals, therapeutic communities, and aftercare programmes (Aldridge 2010; Ghetti 2004; Silverman 2009).

The modern profession of MT began in the 1940s and 1950s, with the establishment of academic and clinical training programmes in the USA, Austria, and the UK, followed by developments in other parts of Europe, North and South America, Africa, Australia, and Asia (Bunt 2014). The academic preparation required for

professional practice currently varies by country, although many countries require master's level training in MT.

How the intervention might work

MT addresses the biopsychosocial needs of people undergoing multidisciplinary substance use treatment. Various forms of engagement in musical experiences are systematically and intentionally employed by music therapists to trigger specific neurological, biological, psychological, and social mechanisms. Music therapists understand and utilise the various ways that music induces emotions, including via brain stem reflexes, rhythmic entrainment, evaluative conditioning, emotional contagion, visual imagery, episodic memory, musical expectancy, and aesthetic judgment (Juslin 2013). This emotional activation and improved emotion regulation can then lead to increased motivation and sustained engagement in the therapeutic music process, enabling progress towards therapeutic goals (Bruscia 2014). MT approaches are sequenced over time in direct relation to participants' needs and readiness, building upon their resources and introducing therapeutic challenges when appropriate (Bruscia 2014).

Music therapy as emotion regulation

Music therapists are informed by an awareness of the neurobiological impacts of music on human emotions, and consider this level of influence as they engage with participants in music-making. At a neurobiological level, music that provokes peak experiences stimulates neural reward and emotion systems similar to those that are activated by (illicit) drug use (Blood 2001), which can result in dopamine release (Salimpoor 2011). Owing to these patterns of neural activity, music can be shaped by a qualified music therapist to promote positive mood states, including euphoria, and to enable emotion regulation (Koelsch 2015; Salimpoor 2011; Sena Moore 2013). As music provides a means of promoting positive mood states (Koelsch 2014), it may consequently buffer against the risk of relapse that is associated with negative mood states (Koob 2013). Furthermore, pleasurable music can promote the release of dopamine to positively affect the reward system (Blum 2010), and can inhibit activity in areas of the limbic system in a way that inhibits transmission of pain perception (Neugebauer 2004). Music therapists intentionally utilise musical experiences to enable these mechanisms of emotion regulation, reward, and pain relief.

People with SUD often use substances as a strategy for coping with difficult emotions. In addition to impacting neurological systems associated with emotion regulation and reward, MT enables the development of a broader and more flexible array of strategies for coping with emotions (Dijkstra 2010). MT offers a means for expressing and working through a broad range of emotions in an adaptive way, which is particularly helpful for participants who have difficulty expressing emotions verbally (Baker 2007). Some participants may need to experience and work through emotions nonverbally as a prerequisite to being able to benefit from verbal forms of therapy.

Music therapy and substance craving

Since music readily acts upon neural activity, special consideration is necessary when using music therapeutically in people with SUDs. Individuals with SUDs can experience a decrease in substance craving after listening to songs they identify as helping them stay clean/sober, but they may also experience an increase in substance craving after listening to songs they identify as making them want to use substances (Short 2015). Thus, important aims of MT within substance use treatment include gaining awareness of healthy and unhealthy uses of music, and understanding how context impacts perception of the music (McFerran 2016). Furthermore, strong personal associations between music and substance use, some of which can contribute to relapse when left unexamined, can be successfully addressed and reversed in MT (Horesh 2010). Individuals learn to recognise, retrain, and integrate state-specific emotional responses to music as part of their lifestyle (Fachner 2017).

Music therapy for motivation

People with SUDs who participate in MT may experience increased motivation to engage in treatment, which may then generalise to other facets of substance use treatment (Horesh 2010). Gains in motivation for change are also evident in people with co-occurring mental health disorders who engage in MT (Ross 2008). Motivation for treatment may be understood in terms of the distinct dimensions of readiness and resistance, where readiness represents the level of interest in and commitment to substance use treatment, and resistance represents scepticism towards the potential benefits of treatment or opposition to engaging in treatment (Longshore 2006). The degree of readiness serves as a significant predictor of treatment retention, while the level of resistance predicts actual drug use (Longshore 2006). Promoting treatment retention as a means of enabling better overall outcomes therefore requires improving readiness for treatment and reducing resistance to treatment.

Music therapy for social engagement

MT provides a broad range of effects for people with SUDs, from neurobiological to social and cultural levels (Aldridge 2010). The social and interpersonal benefits of engaging in music provide communal experiences that offer opportunities for connection and expression, while also enabling coping, stress reduction, and re-activation. MT in group settings enables participants to become aware of maladaptive coping and interpersonal patterns, to have these challenged within a supportive context, and to practice new ways of relating to their emotions and to other people (Dijkstra 2010). Participants who have difficulty forming relationships with others may find that MT offers a non-verbal means of being with and relating to others. Expansion of positive social experiences through MT can be an essential factor in increasing motivation for continued treatment.

In summary, MT has a direct neurobiological impact on areas of the brain implicated in substance use, including emotion regulation and reward. MT also indirectly impacts substance use behaviour by supporting social engagement, improving coping skills, and increasing motivation for treatment. As a large number of people with SUD also have co-occurring mental health disorders, the effects of MT for mental health disorders may have relevance in the context of substance use treatment. Active engagement in MT can alleviate anxiety and depression in people with serious mental health disorders (Geretsegger 2017), and those with depression, where it can also improve global functioning (Aalbers 2017). A reduction in depression and anxiety, and improvement in social, occupational, and psychological functioning may then improve adherence to treatment and enable better outcomes for substance users. By motivating engagement in treatment, facilitating development of therapeutic rapport, and musically

approaching strong emotions as a means of expanding coping skills (Dijkstra 2010; Ghetti 2013) and attention span (van Alphen 2019), MT may promote readiness for treatment and reduce resistance, while also equipping people with emotional, interpersonal, cognitive, and musical skills that can help them positively manage their SUD.

Why it is important to do this review

MT is used as a non-pharmacological psychotherapeutic intervention in a variety of multidisciplinary substance use treatment settings ranging from acute-phase treatment for detoxification through community aftercare programmes for people with SUDs (Aldridge 2010; Silverman 2009). Individual studies demonstrate improvements in motivation to engage in treatment and reduction in psychological symptoms (Albornoz 2011; Silverman 2012). Previous systematic reviews of MT for SUDs are either out of date or did not include quantitative meta-analysis of study outcomes (Carter 2020; Hohmann 2017; Mays 2008; Megranahan 2018; Silverman 2003). Due to the increasing volume of international research into MT for SUDs, and the need to establish an evidence base for practice and policy, a rigorous and comprehensive systematic review of randomised controlled trials specific to MT within multidisciplinary treatment is warranted.

OBJECTIVES

Main objective

To compare the effect of music therapy (MT) in addition to standard care versus standard care alone, or to standard care plus an active control intervention, on psychological symptoms, substance craving, motivation for treatment, and motivation to stay clean/sober.

Secondary objective

To assess the impact of the number of MT sessions on study outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs), including the first phase of cross-over trials, and cluster-RCTs.

Types of participants

People with problem substance use, with a formal diagnosis of substance use disorder (SUD). Substances to be considered are illicit drugs, medication, and alcohol. We exclude nicotine addiction, due to the dissimilar impact on social and functional domains. We exclude non-substance addiction (e.g. internet addiction, gambling addiction). We will base the diagnosis of SUD upon diagnostic criteria from DSM-IV-TR (APA 2000) or DSM-5 (APA 2013), and from the International Classification of Diseases 10 Version: Online 2019 (ICD-10) (WHO 2019), codes F10 to F16 (mental and behavioural disorders due to psychoactive substance use) [with the exclusion of caffeine (part of F15)], and F18 to F19 (mental and behavioural disorders due to use of volatile solvents or multiple drug use and use of other psychoactive substances). There will be no restrictions by age or other participant characteristics, thus we will include both adolescents and adults. Participants may be dual-diagnosed with mental health problems or learning problems. Participants may receive intervention in inpatient, outpatient, therapeutic community, or supportive aftercare settings.

Types of interventions

Experimental intervention

MT added to standard care.

To be included, the intervention must be labelled 'music therapy' (MT), and conducted by a qualified music therapist. MT involves a music therapist and one or more participants, engaging in specifically created music experiences to help them achieve their highest potentials of health (Bruscia 2014). MT interventions may consist of a variety of receptive or active approaches that use music to promote therapeutic change. Receptive approaches may include listening to music as a basis for guided discussion and examination of feelings and thoughts or to impact mood, as well as other aims. Active approaches may include opportunities for the participant to interact with music and music-making processes through songwriting, singing, or playing instruments. We will include both individual and group MT interventions. MT is most commonly offered as a part of multidisciplinary substance use treatment, and it may be practised from an integrated treatment orientation (e.g. cognitive behaviour therapy). MT can be any length of session and course of treatment.

Control intervention

Standard care alone

Standard care represents treatment as usual, and includes any conventional treatment (including pharmacotherapy) offered at the treatment setting as long as that treatment does not involve MT. Examples of services offered as part of standard care for SUDs include: psychotherapy, relapse prevention counselling, peer-led groups including 12-step programmes, case management, pharmacological detoxification, pharmacotherapy including methadone maintenance treatment, recreational and sports activities, etc. Wait-list control occurs in conjunction with standard care, and consists of participants assigned to a waiting list to receive MT after the active treatment group.

Active control intervention

Participants allocated to an active control intervention receive a structurally equivalent condition that lasts the same duration as the MT intervention and controls for nonspecific effects of the therapist's presence and attention, presence of the music, or presence of some other therapeutic element. Only participants assigned to the active control intervention receive this particular intervention. An example of an active control intervention is verbal therapy that is provided in addition to standard care, and consists of discussion of themes related to motivation for change, relapse prevention, and managing substance use triggers. In this case, verbal therapy serves to control for the presence of the therapist and the discussion of treatment-related themes, but it lacks a key proposed element of therapeutic change, namely musical engagement.

Types of comparisons

- MT plus standard care versus standard care alone;

- MT plus standard care versus standard care plus another active intervention.

Types of outcome measures

Outcomes can be measured and reported either dichotomously or continuously. Data sources may include both standardised and non-standardised instruments. We will include data from rating scales when they are from participant self-report or rated by an independent evaluator (i.e. not the music therapist).

Primary outcomes

- Psychological symptoms (e.g. depression, anxiety, anger), e.g. measured by Beck Depression Inventory (BDI), Brief Symptom Inventory (BSI), state portion of the State-Trait Anxiety Inventory (STAI), or visual analogue scales;
- substance craving, e.g. measured by Brief Substance Craving Scale (BSCS), or visual analogue scales;
- motivation for treatment/change, e.g. measured by Readiness to Change Questionnaire (RCQ), Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES), University of Rhode Island Change Assessment Scale (URICA), or visual analogue scales;
- motivation to stay sober/clean, e.g. measured by Commitment to Sobriety Scale (CSS), or visual analogue scales.

We will collect outcomes reported immediately following completion of the intervention, short-term follow-up up to three months after completion of the intervention, and long-term follow-up at more than three months after completion of the intervention.

Secondary outcomes

- Alcohol or substance use, or both, in terms of amount, frequency or peak use (as measured by self-report, report by independent evaluators, urine analysis, or blood samples, as appropriate);
- retention in treatment (as measured by number of participants remaining in treatment at the end of the study);
- severity of substance dependence/use, as measured by validated scales (e.g. Addiction Severity Index (ASI), Drinking Inventory Consequences (DrInC), or the Severity of Dependence Scale (SDS));
- serious adverse events (e.g. relapse requiring hospitalisation, suicide attempts, or suicide).

We will measure serious adverse events as a binary variable related to the presence or absence of adverse events, including relapse requiring hospitalisation, suicide attempts, or suicide.

Search methods for identification of studies

Electronic searches

The electronic searches will include the following databases:

- the Cochrane Drugs and Alcohol Group's Specialised Register of Trials;
- the Cochrane Central Register of Controlled Trials (CENTRAL, most recent issue);
- MEDLINE (PubMed) (January 1966 to present);
- Embase (embase.com) (January 1974 to present);
- CINAHL (EBSCOhost) (1982 to present);
- ERIC (eric.ed.gov) (1964 to present);
- ISI Web of Science;
- PsycINFO (EBSCOhost) (1872 to present);
- International Bibliography of the Social Sciences (IBSS) (1951 to present);
- ProQuest Dissertations & Theses (1997 to present);
- Google Scholar.

We will not impose any restrictions by language, date, gender, age, or tag terms. We will search databases by selecting medical subject heading (MeSH) terms and free-text terms relating to substance use and to MT. The PubMed search strategy is given in Appendix 1. We will model search strategies for the remaining databases after the strategy for PubMed, with variations as required by each additional database. The Information Specialist of the Cochrane Drugs and Alcohol Group (CDAG) will develop and apply search strategies for electronic searches.

In addition, we will search for ongoing clinical trials and unpublished studies via searching the following registries:

- ClinicalTrials.gov (www.clinicaltrials.gov);
- World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (apps.who.int/trialsearch/).

Searching other resources

Handsearching and reference searching

We will handsearch the reference lists of all included studies. We will also examine the reference lists of relevant review articles (e.g. Hohmann 2017; Mays 2008; Silverman 2003).

Data collection and analysis

Selection of studies

We will use the Covidence software platform for citation screening, including merging search results and removing duplicates, and for full-text review (Covidence). Two review authors and content area experts (XJC, CGh) will independently examine each title and abstract to remove obviously irrelevant reports, and a third review author (CGo or LH) will resolve disagreements. We will then obtain full texts for all potentially relevant reports, and link multiple reports of the same study when applicable. Two review authors (XJC, CGh) will independently examine each full-text report to determine eligibility, resolving disagreements in consultation with two other review authors (LH, CGo). We will contact study investigators when necessary, to clarify study eligibility. We will illustrate the study selection process in a PRISMA diagram.

Data extraction and management

Two review authors (XJC, CGh) will independently perform data extraction using Covidence (Covidence), and will export data to Review Manager 5 (Review Manager 2014). When necessary, we will contact study investigators to obtain missing data. We will resolve disagreements in consultation with two review authors (LH, CGo), and will archive their content and resolution. We will extract information from each study regarding:

- methods (including design and aspects related to assessing risk of bias);
- country and setting;

- characteristics and number of participants;
- characteristics of experimental and comparison groups, including the number of participants allocated to each, and length of MT in minutes/hours/sessions;
- outcomes and time points;
- results;
- funding of the study;
- conflict of interest of study authors.

Assessment of risk of bias in included studies

Two review authors (XJC, CGh) will independently assess risks of bias using the Cochrane 'Risk of bias' tool (Higgins 2011), in conjunction with the Covidence software platform (Covidence). We will resolve disagreements by consulting two review authors (AB, CGo). The first part of the tool describes what was reported to have happened in the study, while the second part assigns a judgement relating to the risk of bias for that entry, as low, high, or unclear risk. We will make such judgements using the criteria indicated by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), adapted to the addiction field. Appendix 2 includes a detailed description of the 'Risk of bias' criteria to be used. The seven domains to be assessed include:

- sequence generation (selection bias);
- allocation concealment (selection bias);
- blinding of participants and providers (performance bias);
- blinding of outcome assessors (detection bias);
- incomplete outcome data (attrition bias);
- selective outcome reporting (reporting bias);
- other potential sources of bias.

We will consider blinding of participants and providers, and blinding of outcome assessors (avoidance of performance bias and detection bias) separately for objective outcomes (e.g. alcohol or substance use, or both, as measured by urine analysis or blood samples; retention in treatment; serious adverse events) and subjective outcomes (e.g. psychological symptoms, substance craving, motivation for treatment/change, motivation to stay sober/clean, participant self-report of substance use, participant self-report of severity of substance dependence/use). We will assess incomplete outcome data for each outcome (avoidance of attrition bias), with the exception of 'retention in treatment'. Other potential threats to validity could include contamination of conditions, differences between groups at baseline, or bias introduced by elements of study design. We plan to include all eligible studies, regardless of the level of the risks of bias, when presenting main findings for each outcome; however, we will discuss the risks of bias and provide a cautious interpretation within the 'Discussion' and 'Conclusions' sections of the review. Studies with attrition rates greater than 20% will be rated as at high risk of attrition bias.

Measures of treatment effect

We will assess serious adverse events and retention in treatment at the end of treatment, while we will measure efficacy measures at three different time points: immediately post-intervention, short-term follow-up (up to three months after completion of the intervention), and long-term follow-up (more than three months after completion of the intervention).

Dichotomous data

We will calculate the risk ratio (RR) and corresponding 95% confidence interval (95% CI) for dichotomous data.

Continuous data

For continuous data from parallel-group RCTs, we will select the mean and standard deviation (SD) end-point data for experimental and control groups. When outcomes are measured on the same scale or can be transferred to the same scale in all studies, we will calculate the mean difference (MD) on the original metric. When studies use different scales to measure the same outcome, we will calculate the standardised mean difference (SMD) and corresponding 95% CI for continuous outcomes.

Unit of analysis issues

Cross-over trials

When appropriate, we will combine results of cross-over trials with those of parallel-group trials. Due to the likelihood of carry-over effects in cross-over trials of MT, we will only analyse data from the first phase (i.e. before cross-over) of any included cross-over trial.

Cluster-randomised trials

When studies account for clustering in their analysis, inclusion of the data in meta-analysis is straightforward. If clustering is not accounted for in an included study, we will attempt to contact the study investigators to obtain the intra-class correlation coefficient (ICC) of their clustered data, and will use accepted methods for handling such data. If we are unable to obtain the ICC, we will use external estimates from similar studies (Higgins 2011).

Studies with multiple treatment groups

When studies have more than one relevant MT intervention, we will combine all such experimental groups into a single group, as recommended by the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

Dealing with missing data

We will undertake up to three attempts to contact investigators by email to request missing data. We intend to follow intention-to-treat principles and to include all known data from all randomised participants. We will use the following sensitivity analyses to examine the impact of missing data. For continuous outcomes, we will remove studies with high attrition (more than 20%). For dichotomous outcomes, we will assume that the unobserved cases have a negative outcome. We will report on the potential impact of missing data when assessing risks of bias.

Assessment of heterogeneity

If the number of included studies is low or studies have small sample size, or both, statistical tests for heterogeneity may have low power and be difficult to interpret (Higgins 2011). We plan to conduct descriptive analyses of heterogeneity, by visually examining forest plots for consistency of results and by calculating the I^2 statistic, which represents the percentage of effect estimate variability that is due to heterogeneity instead of sampling error (Higgins 2011). We plan to supplement the I^2 statistic with a calculation of the Chi^2 statistic to assess the likelihood that the heterogeneity was genuine, and to consider possible sources of heterogeneity.

Assessment of reporting biases

We plan to test for asymmetry of funnel plots when at least 10 studies are included in a meta-analysis, and to explore likely reasons for asymmetry when it is present.

Data synthesis

We will combine the outcomes from the individual trials through meta-analysis where possible (comparability of intervention and outcomes between trials), using a random-effects model, because we expect a certain degree of heterogeneity among trials. In cases where meta-analysis is not appropriate, we will report results for each individual study.

Subgroup analysis and investigation of heterogeneity

When we detect heterogeneity, we plan to use subgroup analyses to examine the impact of the number of sessions, type of substance, and presence of dual-diagnosis (i.e. SUD and mental disorder). For subgroup analysis of the number of sessions, we will use the following cut-off points for respective subgroups: three sessions or more versus one or two sessions for outcomes that might show an effect of short intervention, such as are found in detoxification settings (i.e. retention in treatment, reduction in psychological symptoms, improvement in motivation for treatment/change, substance craving); and 10 or more sessions versus fewer than 10 sessions for outcomes typically requiring longer-term treatment, such as those within rehabilitation settings (i.e. reduction in substance use, severity of substance dependence/use, cessation of substance use, serious adverse events).

Sensitivity analysis

We plan to perform a sensitivity analysis of the review outcomes, removing trials at high risk of attrition bias, as unequal attrition from studies may indicate unsatisfactory or intolerable treatment.

Summary of findings and assessment of the certainty of the evidence

Grading of evidence

We will assess the overall quality of evidence for the primary outcome using the GRADE system. The GRADE Working Group has developed a system for grading the quality of evidence (Atkins 2004; Guyatt 2008; Guyatt 2011), which takes into account issues related both to internal and external validity, such as directness, consistency, imprecision of results, and publication bias.

The GRADE system uses the following criteria for assigning grades of evidence:

- high: we are very confident that the true effect lies close to that of the estimate of the effect;
- moderate: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different;
- low: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect;
- very low: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Grading is decreased for the following reasons:

- serious (-1) or very serious (-2) study limitation for risk of bias;
- serious (-1) or very serious (-2) inconsistency between study results;
- some (-1) or major (-2) uncertainty about directness (the correspondence between the population, the intervention, or the outcomes measured in the studies actually found and those under consideration in our systematic review);
- serious (-1) or very serious (-2) imprecision of the pooled estimate (-1);
- publication bias strongly suspected (-1).

'Summary of findings' table

We will include a 'Summary of findings' table to present the main findings of the review in a transparent and simple tabular format. The 'Summary of findings' table will include:

- main findings from the primary outcomes: psychological symptoms, substance craving, motivation for treatment/change, motivation to stay sober/clean; and findings from outcomes that might reflect undesirable effects: retention in treatment, and serious adverse events;
- a measure of the typical burden of these outcomes (e.g. illustrative comparative risk);
- absolute and relative magnitude of effect;
- number or participants and studies addressing these outcomes;
- a rating of the overall quality of evidence for each outcome;
- space for comments.

We will use GRADEprofiler (GRADEpro) to prepare the 'Summary of findings' table(s) (GRADEpro GDT).

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APPENDICES

Appendix 1. PubMed search strategy

1. Substance-Related Disorders[MeSH]
2. Amphetamines[MeSH] OR Cannabis[MeSH] OR Cocaine[MeSH] OR Designer Drugs[MeSH] OR Heroin[MeSH] OR Methamphetamine[MeSH] OR Narcotics[MeSH] OR Street Drugs[MeSH] OR amphetamine*[tiab] OR drug*[tiab] OR polydrug[tiab] OR substance[tiab] OR cannabis[tiab] OR cocaine[tiab] OR "hash oil*"[tiab] OR hashish[tiab] OR heroin[tiab] OR lsd[tiab] OR marihuana[tiab] OR marijuana[tiab] OR methadone[tiab] OR mdma[tiab] OR morphine[tiab] OR ecstasy[tiab] OR methamphetamine*[tiab] OR narcotics[tiab] OR opioid*[tiab] OR opiate*[tiab] OR opium[tiab]
3. #1 OR #2
4. abstin*[tiab] OR abstain*[tiab] OR abuse*[tiab] OR addict*[tiab] OR dependen*[tiab] OR misuse[tiab] OR overdose[tiab] OR withdrawal*[tiab] OR disorder*[tiab]
5. #3 AND #4
6. Alcohol Drinking[MeSH]
7. ((alcohol*[tiab] AND (abstain*[tiab] OR abstin*[tiab] OR abus*[tiab] OR addict*[tiab] OR consum*[tiab] OR dependen*[tiab] OR disorder*[tiab] OR drink*[tiab] OR excess*[tiab] OR misus*[tiab] OR problem*[tiab] OR risk*[tiab] OR withdrawal*[tiab]))
8. #5 OR #6 OR #7
9. "Music Therapy"[Mesh]
10. "Music"[Mesh]
11. music*[tiab]
12. sing[tiab] OR singing[tiab] OR song*[tiab] OR choral*[tiab] OR choir*[tiab] OR melod*[tiab] OR lyric*[tiab]
13. #9 OR #10 OR #11 OR #12
14. randomized controlled trial[pt]
15. controlled clinical trial[pt]
16. randomized[tiab]
17. placebo[tiab]
18. drug therapy[sh]
19. randomly[tiab]
20. trial[tiab]
21. groups[tiab]
22. groups[tiab]
23. #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22
24. (animals[mh] NOT humans[mh])
25. #23 NOT #24
26. #8 AND #13 AND #25

Appendix 2. Criteria for the assessment of risk of bias

No.	Item	Judgement	Description
1	Random sequence generation (selection bias)	Low risk	The investigators describe a random component in the sequence generation process such as: random-number table; computer random-number generator; coin tossing; shuffling cards or envelopes; throwing dice; drawing of lots; minimisation
		High risk	The investigators describe a non-random component in the sequence generation process such as: odd or even date of birth; date (or day) of admission; hospital or clinic record number; alternation; judgement of the clinician; preference of the participant; results of a laboratory test or a series of tests; availability of the intervention
		Unclear risk	Insufficient information about the sequence generation process to permit judgement of 'low risk' or 'high risk'

(Continued)

2	Allocation concealment (selection bias)	Low risk	Investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation: central allocation (including telephone, internet-based, and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes
		High risk	Investigators enrolling participants could possibly foresee assignments and thus introduce selection bias because one of the following methods was used: open random allocation schedule (e.g. a list of random numbers); assignment envelopes without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered); alternation or rotation; date of birth; case record number; any other explicitly unconcealed procedure
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement
3	Blinding of participants and providers (performance bias) Objective outcomes	Low risk	No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken
		High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'; the study did not address this outcome
4	Blinding of participants and providers (performance bias) Subjective outcomes	Low risk	Blinding of participants and providers ensured, and unlikely that the blinding could have been broken
		High risk	No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'; the study did not address this outcome
5	Blinding of outcome assessor (detection bias) Objective outcomes	Low risk	No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; blinding of outcome assessment ensured, and unlikely that the blinding could have been broken
		High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'; the study did not address this outcome
6	Blinding of outcome assessor (detection bias)	Low risk	Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken

(Continued)

	Subjective outcomes	High risk	No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'; the study did not address this outcome
7	Incomplete outcome data (attrition bias) For all outcomes except retention in treatment	Low risk	No missing outcome data; reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; missing data have been imputed using appropriate methods; all randomised participants are reported/analysed in the group they were allocated to by randomisation, irrespective of noncompliance and co-interventions (intention-to-treat)
		High risk	Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across interventions groups; for dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; for continuous outcome data, plausible effect size (difference in means or standardised difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; 'as-treated' analysis done with substantial departure of the intervention received from that assigned at randomisation
		Unclear risk	Insufficient reporting of attrition/exclusions to permit judgement of 'low risk' or 'high risk' (e.g. number randomised not stated, no reasons for missing data provided; the study did not address this outcome)
8	Selective reporting (reporting bias)	Low risk	The study protocol is available and all of the study's prespecified (primary and secondary) outcomes that are of interest in the review have been reported in the prespecified way; the study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were prespecified (convincing text of this nature may be uncommon)
		High risk	Not all of the study's prespecified primary outcomes have been reported; one or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not prespecified; one or more reported primary outcomes were not prespecified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); one or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; the study report fails to include results for a key outcome that would be expected to have been reported for such a study
		Unclear risk	Insufficient information to permit judgement of 'low risk' or 'high risk'
9	Other sources of bias	Low risk	The study appears to be free of other sources of bias

(Continued)

High risk	There is at least one important risk of bias; e.g. the study had a potential source of bias related to the specific study design used; or has been claimed to have been fraudulent; or had some other problem
Unclear risk	There may be a risk of bias, but there is either: insufficient information to assess whether an important risk of bias exists; or insufficient rationale or evidence that an identified problem will introduce bias

WHAT'S NEW

Date	Event	Description
10 September 2020	New citation required and major changes	Changes to Background information, Objectives and to authorship.

HISTORY

Protocol first published: Issue 2, 2017

CONTRIBUTIONS OF AUTHORS

Claire Ghetti, Xi-Jing Chen, Annette Brenner, Laurien Hakvoort, Lars Lien, Jörg Fachner, and Christian Gold developed the protocol and drafted the protocol text. All authors read and approved the final protocol version.

Claire Ghetti and Christian Gold secured funding for undertaking this systematic review.

DECLARATIONS OF INTEREST

Claire Ghetti: none known

Xi-Jing Chen: none known

Annette Brenner: none known

Laurien Hakvoort: none known

Lars Lien: none known

Jörg Fachner: none known

Christian Gold: none known

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NOTES

In this updated version of the protocol, we have revised wording of the main objective, provided more specificity regarding control intervention, and re-organised the placement of primary and secondary outcomes. The aforementioned revisions adhere to editorial requirements initiated after publication of the original protocol.