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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
BACKGROUND	1
OBJECTIVES	3
METHODS	3
ACKNOWLEDGEMENTS	7
REFERENCES	8
APPENDICES	9
CONTRIBUTIONS OF AUTHORS	13
DECLARATIONS OF INTEREST	13
SOURCES OF SUPPORT	14

[Intervention Protocol]

Music therapy for people with substance use disorders

Claire Ghetti¹, Xi-Jing Chen², Jorg Fachner³, Christian Gold⁴

¹GAMUT - The Grieg Academy Music Therapy Research Centre, Grieg Academy, University of Bergen, Bergen, Norway. ²CAS Key Laboratory of Mental Health, Institute of Psychology, Chinese Academy of Science, Beijing, China. ³Music and Performing Arts, Anglia Ruskin University, Cambridge, UK. ⁴GAMUT - The Grieg Academy Music Therapy Research Centre, Uni Research Health, Uni Research, Bergen, Norway

Contact address: Claire Ghetti, GAMUT - The Grieg Academy Music Therapy Research Centre, Grieg Academy, University of Bergen, Postboks 7805, Bergen, 5020, Norway. claire.ghetti@uib.no.

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ABSTRACT

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

Main objective

To assess the effects of music therapy, as a primary or a supportive intervention, compared to standard care, wait-list control or no treatment, for people with substance use disorders, to reduce substance use, the severity of substance dependence/abuse, psychological symptoms, and substance craving; to enhance motivation for change/treatment; and for retention in treatment.

Secondary objective

To assess the impact of the number of music therapy sessions on study outcomes.

BACKGROUND

Description of the condition

Substance abuse and related high-risk behaviour have a negative impact on individuals, families, and global public health. The World Health Organization's (WHO) *Global Status Report on Alcohol and Health 2014* cites 3.3 million deaths in 2012 attributable to the harmful use of alcohol, representing 5.9% of all deaths (WHO 2014, p.48). In addition, 5.1% of the global burden of disease, expressed as 139 million net disability-adjusted life years, can be attributed to alcohol consumption (WHO 2014, p.16).

Problematic use of drugs and alcohol is a widespread issue, with approximately 27 million people worldwide engaging in problem drug use (range 15.7 to 39 million) (UNODC 2015), and 4.1% of the world's population aged 15 years or older demonstrating either harmful use of alcohol or alcohol dependence (WHO 2014). 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 cognitive, behavioural, physiological or social functioning (DSM-V, APA 2013). People who inject drugs are at higher risk of death due to the transmission of infectious diseases, most notably HIV, and the possibil-

ity of fatal overdose (UNODC 2015). An estimated one in every six problem drug users worldwide receives the necessary treatment; if all problem drug users 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 and healthcare provision for untreated problem drug use remain far higher than that of prevention and treatment (INCB 2013).

Longer lengths of stay in substance abuse treatment are associated with better engagement in aftercare programmes and lower levels of substance use at long-term follow-up (Arbour 2011). Better 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 treatment remains a crucial aspect of addressing the harms caused by SUDs, but remains one of the greatest challenges. In the United States, approximately 26% of problem substance users drop out of public treatment programmes (SAMHSA 2014). Problem substance users who have co-occurring mental health disorders demonstrate low treatment retention rates. Gender-specific treatment retention strategies are also important for this subgroup (Choi 2015).

Description of the intervention

Music therapy is “a systematic process of intervention wherein the therapist helps the person to promote health, using music experiences and the relationships that develop through them as dynamic forces of change” (Bruscia 1998, p.20). During this process, a trained music therapist engages with the participant in a range of active and receptive approaches to listening to, discussing, creating, improvising and performing music. Music therapy may incorporate varying levels of verbal processing, depending upon client need 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 of song lyrics, instrumental or vocal improvisation, or both, music performance, and music-assisted relaxation. Music therapy may be practised from a variety of theoretical orientations, and in the setting of substance abuse treatment may include elements of cognitive-behavioural, humanistic, psychodynamic and/or neurobiological theory, among others. Music therapists work with abstinence-based, controlled use, and in harm reduction contexts (Aldridge 2010; Ghetti 2004), in inpatient treatment centres, community mental health centres, adult day healthcare centres, state and general hospitals, therapeutic communities, and aftercare programmes (Aldridge 2010; Ghetti 2004; Silverman 2009).

The modern profession of music therapy began in the 1940s and 1950s, with the establishment of academic and clinical training programmes in the United States, Austria, and the United Kingdom, 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 music therapy.

The music therapy process is potentially well-positioned to meet the needs of people in substance abuse treatment. Within each music therapy session, interactions between therapist and participant are designed to “motivate and sustain the client’s engagement in the therapeutic music process” and to move them closer to therapeutic goals (Bruscia 2014, p.37). Furthermore, sessions and music therapy approaches are sequenced over time in direct relation to the participant’s needs and readiness, building upon their resources and introducing therapeutic challenges when appropriate (Bruscia 2014).

How the intervention might work

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 abuse treatment, and resistance represents scepticism toward 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 provides a broad range of effects for people with SUDs, from neurobiological to social and cultural levels (Aldridge 2010). Music therapists are informed by an awareness of the neurobiological impacts of music on human emotions and behaviour, and consider this level of influence as they engage with participants in music-making. The social and interpersonal benefits of engaging in music help provide communal experiences that offer opportunities for connection and expression.

At a neurobiological level, music that provokes peak experiences stimulates neural reward and emotion systems similar to those that are activated by drugs of abuse (Blood 2001). Due to these similar patterns of neural activity, music has the potential to promote positive mood states, including euphoria, and to enable emotional regulation (Koelsch 2015; 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).

Since music readily acts upon neural activity, special consideration is necessary when using music therapeutically with 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, gaining awareness of healthy and unhealthy uses of music, and of the context of how music is perceived are important aspects of music therapy within substance abuse treatment (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 music therapy (Horesh 2010). Individuals learn to recognise, retrain and integrate state-specific emotional responses to music as part of their lifestyle.

People with SUDs who participate in music therapy may experience increased motivation to engage in treatment, which may then generalise to other facets of substance abuse treatment (Horesh 2010). Active engagement in music therapy can alleviate anxiety and depression in people with serious mental disorders (Mössler 2011), and a reduction in such symptoms may then improve adherence to treatment and promote improved general functioning. By motivating engagement in treatment, facilitating development of therapeutic rapport, and musically approaching strong emotions as a means of expanding coping skills (Ghetti 2013), music therapy may promote readiness for treatment and reduce resistance, thereby promoting treatment retention and the subsequent reduction of substance use.

Why it is important to do this review

Music therapy is used as a non-pharmacological psychotherapeutic intervention within acute-phase treatment for detoxification, and in community aftercare programmes for people with substance use disorders (Aldridge 2010; Silverman 2009), with individual studies demonstrating improvements in motivation to engage in treatment and reduction in psychological symptoms (Albornoz 2011; Silverman 2012). Previous reviews (Mays 2008; Silverman 2003) of music therapy for substance use disorders are either out of date or did not include meta-analysis of study outcomes. Due to the increasing volume of international research into music therapy for substance use disorders, and the need to establish an evidence base for practice and policy, a rigorous and comprehensive systematic review of randomised controlled trials specific to this topic is warranted.

OBJECTIVES

Main objective

To assess the effects of music therapy, as a primary or a supportive intervention, compared to standard care, wait-list control or no

treatment, for people with substance use disorders, to reduce substance use, the severity of substance dependence/abuse, psychological symptoms, and substance craving; to enhance motivation for change/treatment; and for retention in treatment.

Secondary objective

To assess the impact of the number of music therapy sessions on study outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant parallel-group randomised controlled trials (RCTs), including the first phase of cross-over trials.

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). Diagnosis of substance use disorder will be based upon diagnostic criteria from DSM-IV-TR (APA 2000) or DSM-V (APA 2013), and from the International Classification of Diseases 10 Version: Online 2016 (ICD-10) (WHO 2016), codes F10 to F16 (mental and behavioural disorders due to use of alcohol, opioids, cannabinoids, sedatives or hypnotics, cocaine, stimulants, or hallucinogens), and F18 to F19 (mental and behavioural disorders due to use of volatile solvents or multiple drug use and use of other psychoactive substances), with the exclusion of caffeine (part of F15). There will be no restrictions by age or other participant characteristics. Participants may be dual-diagnosed with mental health problems. Participants may receive intervention in inpatient, outpatient, therapeutic community, or supportive aftercare settings.

Types of interventions

Experimental intervention:

Music therapy or music therapy added to standard care.

The intervention should be labeled 'music therapy' (MT), and should be conducted by a trained music therapist. MT involves

a music therapist and one or more participants, mindfully engaging in music experiences as a means of helping them to 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 on 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 music therapy interventions. MT may be integrated with a specific treatment approach (e.g. cognitive behaviour therapy), and can be any length of session and course of treatment. MT may be offered either with or without standard care (as defined below).

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 substance use disorders include: counselling, case management, pharmacotherapy including methadone maintenance treatment, pharmacological detoxification, etc.

Wait-list control:

Wait list consists of participants assigned to a waiting list to receive MT after the active treatment group. Wait-list control may be presented with or without standard care.

Types of comparisons:

- MT plus standard care versus standard care alone (including wait list for MT)
- MT with no additional treatment versus no treatment (including wait list for MT)

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 rater (i.e. not the music therapist).

Primary outcomes

1. Reduction in substance use in terms of amount, frequency, or peak use (as measured by self-report, report by independent evaluators, urine analysis or blood samples).

2. Retention in treatment (based on reported study dropout rates).

3. Severity of substance dependence/abuse, as measured by validated scales (e.g. Addiction Severity Index (ASI), Drinking Inventory Consequences (DrInC), or the Severity of Dependence Scale (SDS)).

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

1. Cessation of substance use (as measured by self-report, report by independent evaluators, urine analysis, or blood samples).
2. Reduction of 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.
3. Improvement in 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.
4. Substance craving, e.g. measured by Brief Substance Craving Scale (BSCS), or visual analogue scales.
5. Serious adverse events (e.g. relapse requiring hospitalisation, suicide attempts, or suicide).

Some people with SUDs have personal goals of reducing harm from substance use, but do not have a goal of maintaining abstinence. For this reason, we propose cessation of substance use as a secondary outcome. 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 music therapy. 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 internet searches of the following sites:

- 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. [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. Two review authors and content area experts (two of the following: XJC, JF, CGh) will independently examine each title and abstract to remove obviously irrelevant reports, and a third review author and methodologist (CGo) will resolve disagreements. We will then obtain full texts for all potentially relevant reports, and link together 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 the third and fourth review authors (JF, CGo). We will contact investigators when necessary, to clarify study eligibility.

Data extraction and management

Two review authors (CGh, XJC) will independently perform data extraction using Covidence, and will export data to Review Manager 5. When necessary, we will contact investigators to obtain

missing data. We will resolve disagreements in consultation with the remaining two review authors (JF, 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;
- outcomes and time points;
- results;
- key conclusions/remarks 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. We will resolve disagreements through consultation with a third review author and methodologist (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*, 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. reduction or cessation of substance use measured by urine analysis or blood samples, retention in treatment, serious adverse events) and subjective outcomes (e.g. participant self-report of substance use/cessation, severity of substance dependence, psychological symptoms, motivation for treatment/change, substance craving). 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. For attrition bias, we will consider the

impact of high attrition rates, i.e. studies with attrition rates greater than 20%.

Measures of treatment effect

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 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). 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. We will standardise SMDs by pooling standard deviations between participants, rather than standard deviations of the differences within participants.

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 music therapy, 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 music therapy intervention, we will combine all such experimental groups into a single group, as recommended by the Cochrane Handbook (Higgins 2011). Similarly, when studies have more than one relevant control group, we will combine these into a single control group.

Dealing with missing data

We will make 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. substance use disorder 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/abuse, cessation of substance use, serious adverse events).

Sensitivity analysis

We plan to perform a series of sensitivity analyses of the review outcomes, removing trials with high attrition rates (i.e. studies with attrition rates higher than 20%), and trials with a high risk of detection bias.

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 (GRADE 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:

- a list of all important outcomes, both desirable and undesirable;
- a measure of the typical burden of these outcomes (e.g. illustrative comparative risk);
- absolute and relative magnitude of effect;
- number of participants and studies addressing these outcomes;
- a rating of the overall quality of evidence for each outcome;
- space for comments.

The 'Summary of findings' table will include all primary outcomes (substance use, retention in treatment, severity of substance dependence/abuse) and four secondary outcomes of the review (reduction of psychological symptoms, improvement in motivation for treatment/change, substance craving, serious adverse events). We will use GRADEprofiler (GRADEpro) to assist in the preparation of the 'Summary of findings' table.

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* Indicates the major publication for the study

APPENDICES**Appendix I. 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 marijuana[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. abstain*[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

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'
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, web-based, and pharmacy-controlled randomisation); sequentially-numbered drug containers of identical appearance; sequentially-numbered, opaque, sealed envelopes

(Continued)

		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

(Continued)

		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) Subjective outcomes	Low risk	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
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

(Continued)

		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 pre-specified (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
	High risk	There is at least one important risk of bias. For example, 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

CONTRIBUTIONS OF AUTHORS

Claire Ghetti:

developing protocol

securing funding

Xi-Jing Chen

developing protocol

Jörg Fachner

developing protocol

Christian Gold

developing protocol

securing funding

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Claire Ghatti: None known

Xi-Jing Chen: None known

Jorg Fachner: None known

Christian Gold: None known

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