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Cochrane Database of Systematic Reviews 2012, Issue 8. Art. No.: CD010032.

DOI: [10.1002/14651858.CD010032](https://doi.org/10.1002/14651858.CD010032).

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[Intervention Protocol]

Music therapy for attention deficit hyperactivity disorder (ADHD) in children and adolescents

Fan Zhang¹, Kun Liu², Ping An³, Chao You⁴, Liangzhu Teng¹, Qingwei Liu⁵

¹Department of Neurosurgery, Shandong Provincial Hospital, Shandong University, Jinan, China. ²Department of Respiratory Medicine, West China Hospital, Sichuan University, Chengdu, China. ³Department of Otorhinolaryngology, West China Hospital, Sichuan University, Chengdu, China. ⁴Department of Neurosurgery, West China Hospital, Sichuan University, Chengdu, China. ⁵Department of Medical Imaging, Shandong Provincial Hospital, Shandong University, Jinan, China

Contact address: Liangzhu Teng, Department of Neurosurgery, Shandong Provincial Hospital, Shandong University, No. 44, Wenhua Xi Road, Jinan, Shandong, 250012, China. tengliangzhu@126.com.

Editorial group: Cochrane Developmental, Psychosocial and Learning Problems Group.

Publication status and date: New, published in Issue 8, 2012.

Citation: Zhang F, Liu K, An P, You C, Teng L, Liu Q. Music therapy for attention deficit hyperactivity disorder (ADHD) in children and adolescents. *Cochrane Database of Systematic Reviews* 2012, Issue 8. Art. No.: CD010032. DOI: [10.1002/14651858.CD010032](https://doi.org/10.1002/14651858.CD010032).

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ABSTRACT

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

To assess the effects of music therapy for ADHD in children and adolescents.

BACKGROUND

Description of the condition

Attention deficit hyperactivity disorder (ADHD) is a prominent neurobehavioral disorder in childhood and adolescence (APA 2000). The defining features of ADHD are inattention (or attention-deficit), hyperactivity (or overactivity) and impulsivity (APA 2000). The result is maladaptive behaviors that are inconsistent with age and developmental level. Studies in neuropsychology, pharmacology and neuroimaging indicate potential impairment in the neurotransmitter systems (dopamine and norepinephrine) in the pathophysiology of ADHD (Nigg 1999; Durston 2003; Seidman 2005). Extremely low birth weight (less than 1000 g), head trauma and genetic factors also appear to be associated with symptoms of ADHD (Hille 2001; Castellanos 2002). The *Diagnostic and Statistical Manual of Mental Disorders, 4th edition - text revision* (DSM-IV-TR; APA 2000) classifies ADHD into three subtypes according to the symptoms: (1) mainly inattentive type (ADHD-I); (2) mainly hyperactive-impulsive type (ADHD-HI) and (3) combined type (ADHD-C). The inattentive subtype consists of individuals who exhibit inattentive behaviors but not hyperactive/impulsive behaviors, whereas the hyperactive/impulsive subtype consists of the reverse, and individuals with the combined subtype have both. The DSM-IV-TR diagnosis of ADHD requires the behavior to last for at least six months to a degree that is maladaptive and inconsistent with developmental level. Moreover, the behavior should be present in two or more different settings since inattention, hyperactivity or impulsivity are not pathological per se and can be triggered by a demanding environment.

Generally, ADHD is associated with impairment across a range of domains. More specifically, it is associated with educational underachievement (Wilson 1996), family problems, peer relationship problems (Erhardt 1994; August 1998; Bagwell 2001) and increased antisocial and delinquent activity (Satterfield 1994). Long-term adverse outcomes include increased risk of substance abuse (Biederman 1998), decreased vocational opportunities (Barkley 2006) and increased criminal activity (Satterfield 1997). ADHD is often comorbid with other disorders such as oppositional defiant disorder (ODD), conduct disorder (CD), depression and anxiety (Biederman 1992; Biederman 2006).

Epidemiological studies have claimed ADHD occurs in 6% to 8% of children and 4% to 5% of adults worldwide (Faraone 2003; Kessler 2006; Polanczyk 2007), and is most frequently diagnosed between the ages five and 10 years (Costello 1989; APA 2000; Parr 2003). Some researchers have reported even higher morbidity for ADHD, ranging from 9% to 19% (Paule 2000). This range may be attributed to the nation and race of participants selected, the inclusion and exclusion criteria used or the diagnostic criteria or definition used. Though ADHD is a chronic condition with symptoms experienced over a lifetime, ADHD mainly affects children and adolescents. It is observed in clinical practice that children aged six to 13 years have more serious and more obvious symptoms than older individuals. The psychology and physiology in childhood are quite different from that in adulthood and the symptoms and behaviors experienced are not the same. For example, alcoholism and drug abuse can be issues for adults with ADHD. For this reason, we will confine our review to children and adolescents.

Pharmacological interventions and behavior therapy are the main treatments for ADHD (MTACG 1999a; MTACG 1999b; Abikoff

2004; Pliszka 2007). Medications include psychostimulants (for example, amphetamine and methylphenidate), nonstimulant-norepinephrine reuptake blockers (for example, atomoxetine) and α -agonist antihypertensive agents. Amphetamine and methylphenidate are still the first-line agents for the management of ADHD (AACAP 1997). In 1994, about 80% (Efron 1998) of all children in the US who were diagnosed with ADHD were treated with stimulant medication (68% to 80% reported in Spencer 2000, AAP 2001a and Rappley 2005).

Behavior therapy using modifications of the physical and social environment in order to alter behavior is important in treating children with ADHD. It is also important to incorporate changes such as more structure, closer attention and limiting of distractions (AAP 2001b). Parent training in behavior modification techniques may be helpful (Zwi 2011). Psychological interventions may also be directed at the child and designed to change the child's emotional status (for example, play therapy) or thought patterns (for example, cognitive therapy or cognitive-behavior therapy). In addition, brain biofeedback training (Lansbergen 2011), Chinese medicine and acupuncture (Li 2009; Zhang 2000) seemingly demonstrate a beneficial effect on ADHD in some studies.

Description of the intervention

Music is an intrinsic part of human existence in terms of responses such as pulse, rhythm, breathing and movement, and the whole range of emotions. These connections with music can remain despite disability and illness and so music therapists and counselors can use music to help children (and adults) with a wide range of needs arising from various causes such as learning disabilities, mental and physical illness, physical and sexual abuse, stress and terminal illness. Emotional, cognitive and developmental needs can be addressed through interactive musical experiences (Hadley 2001).

Music therapy is a type of psychotherapy. It is defined as "a systematic process of intervention wherein the therapist helps the client to promote health, using musical experiences and the relationships that develop through them as dynamic forces of change" (Bruscia 1998). Central working modalities in music therapy include free and structured improvisation, listening to music, re-creating music/playing previously composed music on instruments, singing and writing or improvising songs, and verbal discussion of these music experiences (Baker 2005; Gold 2009). Improvisation is perhaps "the most prominent form of musical interaction in music therapy. It has been described as central in many music therapy models" (Gold 2009).

Music therapy approaches can be described in terms of three distinct aspects: whether the active or receptive mode is used, the level of structure and the focus of therapeutic attention (Drieschner 2001).

The active mode includes such activities as free improvisation or reproduction of songs or playing music on instruments and singing. Receptive techniques may involve, for example, the use of pre-composed music for relaxation or listening to recorded music selected by either therapist or client.

The level of structuring refers to how much direction is given by the music therapist. A higher level of structuring might include pre-selection of activities by the therapist, whereas a lower level would

involve the activities being negotiated with the client in the session. The level of structuring varies between music therapy models and depending on client need.

The focus of attention may be on the processes occurring within the musical interaction itself or on the verbal reflection of the client's issues brought forth by the musical processes.

How the intervention might work

Music therapy is targeted at: (a) evoking responses of alertness, relaxation, satisfaction, self-confidence and enthusiasm; (b) creating a condition wherein the client can reveal problems, feelings and thoughts; and (c) helping to uncover unconscious attitudes or hidden memories and feelings (Harper 1989). One remarkable aspect of music therapy is its ability to address a wide spectrum of needs in people of all ages – physical, mental, social, emotional, spiritual – often working with multiple needs simultaneously. Music therapy may decrease the frequency of maladaptive behaviors of ADHD (Jackson 2003; Rickson 2003) and reduce other mental health conditions that mimic or coexist with ADHD (for example, learning disorders, ODD, CD, depression, tic disorder, adjustment disorder) (Baker 2005; Maratos 2008; Gold 2009) by providing people with "a safe, structuring and socially acceptable form in which they can express feelings which otherwise might be too overwhelming to express" (Gold 2009). A music therapy program promoting autonomy and creativity may help children and adolescents to interact more appropriately with others, though it might also lead to a temporary mild increase in disruptive behavior in the classroom (Rickson 2003). Music therapists use a number of methods to lead to outcomes that are generally perceived to be favorable in the treatment of children with ADHD (Jackson 2003). Rickson 2006 concluded that music therapy could contribute to a reduction in a range of ADHD symptoms in the classroom and improvement in a range of developmental areas.

Why it is important to do this review

ADHD is a chronic health condition that not only affects individuals in the childhood and adolescent period but also into adulthood. Studies indicate behaviors of ADHD may overlap or coexist with other mental health conditions (learning and language disorders, ODD, CD, anxiety and depression, as well as bipolar, post-traumatic stress, tic and adjustment disorders) (Green 1999). Academic work is often poor quality or cannot be completed, and relationships with family, teachers and peers may worsen due to ADHD. Ultimately, it may lead to delinquency, even criminality (Sibley 2010). Music therapy is potentially a highly effective treatment that could address the core symptoms of ADHD and of the multiple disorders that can coexist with ADHD.

To our knowledge, systematic reviews of trials of music therapy in ADHD have not been conducted. Whether or not music therapy for children and adolescents is effective in producing a reduction in core ADHD symptomatology or improving engagement or enhancing in learning as well as other beneficial outcomes is still unknown. We plan to conduct a well-designed systematic review of music therapy for ADHD that will further the research agenda and provide guidance for clinical practice.

OBJECTIVES

To assess the effects of music therapy for ADHD in children and adolescents.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials (RCT) and quasi-randomized trials in which participants are randomized by methods such as alternate allocation, date of birth or case number.

Types of participants

Studies of adolescents and children aged 18 years or under and diagnosed with ADHD will be included. Adults (people over 18 years old) will be excluded. Studies including participants under and over the age of 18 will be included if data for those participants aged 18 years and under are separately provided or can be obtained.

Types of interventions

Any form of music therapy that meets the definition in Bruscia 1998 (see Background) will be included, compared to a no treatment control or to conventional treatment, whether pharmacological or psychological.

Trials in which music therapy is added to another treatment will be included provided that any such intervention is identical in the experimental and control groups.

Studies using music carried out by nonmusic therapists or studies that are not specifically using music in a music therapy context will be excluded.

Types of outcome measures

Primary outcomes

1. Incidence or severity of the core symptoms

- Inattention
- Impulsivity
- Hyperactivity

2. Adverse outcome

- Disruptive behavior

The primary outcomes will be obtained directly from child, parent, teacher or other professional reports on interviews or validated symptoms rating scales, including: the revised Conners' Parent Rating Scale (CPRS-R) (Conners 1997; Conners 1998a), Conners Teacher Rating Scale (CTRS-R) (Conners 1998b), the SNKL-IV Teacher and Parent Rating Scale (Swanson 2001), Clinical Global Impressions Scale-Severity (CGI-S), Clinical Global Impressions Scale - Improvement (CGI-I) and Continuous Performance Test (CPT). The reliability and validity of this evidence will be discussed due to the possible variability in quality. All the measures will be considered and discussed to avoid any possible biases.

Secondary outcomes

1. School/academic performance

2. Family and social outcomes
3. Quality of life scale
4. Disorders relevant to ADHD

- Learning disability
- Oppositional defiant disorder
- Conduct disorder
- Emotional disorder
- Tic disorder
- Adjustment disorders
- Substance abuse
- Dysgenopathy
- Somnipathy

5. Interpersonal relationships

6. Any adverse events of music therapy reported in the trials

The secondary outcomes will be measured by official medical records, school records or validated symptoms rating scales, such as the Wechsler Individual Achievement Test (WIAT) (Wechsler 1992) or the Parenting Scale for Parents of Children with ADHD (Harvey 2001).

Outcome time periods will be recorded and then grouped as appropriate, for example, short term, medium term and long term.

The 'Summary of findings' tables will include the primary outcomes and the following secondary outcomes: school/academic performance, family and social outcomes, quality of life and adverse events.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases:

1. Cochrane Central Register of Controlled Trials (CENTRAL)
2. MEDLINE
3. EMBASE
4. CINAHL
5. PsycINFO
6. ERIC
7. Social Science Citation Index (SSCI)
8. Science Citation Index (SCI)
9. RILM Abstracts of Music Literature
10. SCOPUS
11. Wanfang data (in Chinese)
12. CNKI (in Chinese)
13. Vip information (in Chinese)
14. ClinicalTrials.gov
15. WHO International Clinical Trials Registry Platform (ICTRP)
16. metaRegister of Controlled Trials

The following search strategy will be used to search Ovid MEDLINE. No language or study methods filters will be used.

- 1 exp "Attention Deficit and Disruptive Behavior Disorders"/
- 2 adhd.tw.
- 3 addh.tw.

- 4 adhs.tw.
- 5 "add".tw.
- 6 "ad/hd".tw.
- 7 hyperactiv\$.tw.
- 8 hyper-activ\$.tw.
- 9 overactiv\$.tw.
- 10 over-activ\$.tw.
- 11 Hyperkinesis/
- 12 hyperkin\$.tw.
- 13 hyper-kin\$.tw.
- 14 hkd.tw.
- 15 (minimal adj3 brain\$ adj3 (damag\$ or disorder\$ or dysfunc\$)).tw.
- 16 (attention\$ adj3 (deficit\$ or dysfunc\$ or disorder\$)).tw.
- 17 (behav\$ adj3 (dysfunc\$ or disorder\$)).tw.
- 18 impulsiv\$.tw.
- 19 (inattentiv\$ or inattention\$).tw.
- 20 disruptiv\$.tw.
- 21 (overactiv\$ or over-activ\$).tw.
- 22 or/1-21
- 23 Music Therapy/
- 24 Music/
- 25 music\$.tw.
- 26 improvis\$.tw.
- 27 Percussion/
- 28 percussion\$.tw.
- 29 Pitch Perception/
- 30 Pitch Discrimination/
- 31 pitch.tw.
- 32 rhythm\$.tw.
- 33 harmon\$.tw.
- 34 (melody or melodies).tw.
- 35 timbre.tw.
- 36 (vibroacoustic\$ or vibro-acoustic\$).tw.
- 37 (sing or singing or song\$ or choral or choir or orchestra).tw.
- 38 (Bonny\$ or GIM or BMGIM).tw.
- 39 Dalcroze\$.tw.
- 40 kodaly\$.tw.
- 41 (Nordoff adj Robbins).tw.
- 42 orff\$.tw.
- 43 suzuki\$.tw.
- 44 or/23-43
- 45 22 and 44
- 46 exp infant/
- 47 exp child/
- 48 adolescent/
- 49 (baby or babies or infant\$ or child\$ or pre-school\$ or preschool\$ or schoolchild\$ or teen\$ or adolescen\$ or young adult\$ or young people or youth\$).tw.
- 50 or/46-49
- 51 45 and 50

The search strategy will be modified as necessary when searching other databases.

Searching other resources

Handsearching

We will do handsearches following the electronic searches, particularly where abstracts from relevant neuropsychological and associated meetings are not available electronically. Conference proceedings relevant to this topic will be handsearched. Any books

and conference proceedings that are in the music and expressive arts area will also be handsearched. Journals and conferences to be handsearched will include:

1. *Journal of Clinical Pediatrics*;
2. *Chinese Journal of Pediatrics*;
3. *Chinese Journal of Contemporary Pediatrics*;
4. The 1st National Academic Conference on ADHD, 1986 Nov 24-25, Beijing;
5. The 2st National Academic Conference on ADHD, 1991 Aug 23-24, Beijing;
6. The 3st National Academic Conference on ADHD, 2004 Aug 23-25, Beidaihe.

Additional searches

We will check the reference lists of identified RCTs and review articles in order to find RCTs not identified by the electronic or handsearches.

Correspondence

We will request information on unpublished or ongoing trials from authors of published studies and from experts (academics working in music therapy such as Professor Nigel Osbourne at Edinburgh University, UK). We will also search the websites of organizations involved in music therapy, for example, Nordoff-Robbins (www.nordoff-robbins.org.uk).

Data collection and analysis

Selection of studies

Two review authors (FZ and KL) will independently screen the titles and abstracts obtained by the search strategies against the eligibility criteria. Potentially relevant papers (that is, those in the music, expressive arts or relevant neuropsychology area) will be obtained. Any disagreement will be resolved through discussion or consultation, or both, with LT and QL. At all stages, reasons for inclusion and exclusion of articles will be noted.

Data extraction and management

Data about the participants, the intervention, sample size, blinding, randomization, outcome, follow-up survey, missing data and analytical procedure will be independently extracted by FZ and KL using a data extraction form, and saved electronically. The data collection form will be pilot tested for clarity, relevance to the study questions and completeness. The comparison of extracted data will be done by each author independently. Any disagreements will be resolved by discussion with LT and QL. Clarification will be sought from the trial investigators when necessary.

All relevant data will be entered into Review Manager 5 (RevMan) ([RevMan 2011](#)) by FZ and rechecked by KL for accuracy. The reliability of data extraction and data entry will be examined throughout the process.

Assessment of risk of bias in included studies

Two review authors (FZ and KL) will independently assess the risk of bias within each included study, using the Cochrane Collaboration's tool for assessing risk of bias ([Higgins 2011](#)). We will assess risk of bias in relation to the following seven domains, with our judgments categorized as 'low risk' of bias, 'high risk' of bias

and 'unclear' risk of bias. Disagreements will be resolved through consensus, or referred for arbitration by the editorial base of the Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG) if needed.

Random sequence generation

Random sequence generation will be judged as follows:

- low when computer-generated random numbers, a random numbers table or coin-tossing were used to assign participants to treatment conditions;
- unclear when random sequence generation were not clearly described;
- high when none above was used for randomization.

Allocation concealment

Allocation concealment will be judged as defined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)):

- low when participants and researchers were unaware of participants' future allocation to condition until after decisions about eligibility were made and informed consent was obtained;
- unclear when allocation concealment measures were not clearly described;
- high when allocation was not concealed from either participants before informed consent or from researchers before decisions about inclusion were made (this will always be the case for quasi-randomized studies).

All three categories are eligible for inclusion as this review aims to include randomized and quasi-randomized studies. The rating is only used as a descriptive measure of study risk of bias.

Blinding of participants and personnel

It is not possible to blind either those who deliver music therapy or those who receive it owing to the nature of the intervention. We will take into account the likely impact of not being able to blind the therapists or participants. The assessments of risk of bias resulting from lack of blinding may will be made separately for different outcomes, if necessary.

Blinding of outcome assessment

Quality of blinding will be determined primarily by whether those who assessed and coded outcome measures were blind to whether a participants was in the treatment or control condition, and the quality of blinding be judged as follows:

- low when the assessor was blind to condition;
- unclear when blinding of assessor was not reported and information is not available from researchers;
- high when assessor was not blind to condition.

Incomplete outcome data

Whether researchers applied intention-to-treat (ITT) analysis to estimate the missing data will be taken in to account and will receive the following judgments:

- low when all randomized participants were included in the analyses or ITT analysis can be applied using available data;

- unclear when ITT analyses was not reported and information not available from the researchers of the study or the numbers randomized into each intervention group and the number of participants included in the analysis is not clearly described;
- high when ITT analyses were not used or cannot be performed with available data.

Selective outcome reporting

The studies where the authors selectively withheld the nonsignificant results from publication or omitted part of the research data will be identified and will be judged as follows:

- low when all collected results seems to be reported;
- unclear when it is difficult to determine whether some results was collected but not reported;
- high when the outcomes used in the trial are unpublished.

Any other sources of bias

Other potential threats to validity

The steps taken to ensure studies kept fidelity to the protocol will be checked to see if the methods (for example, training sessions and supervision) were appropriate.

Other potential sources of bias

Assessment will determine whether any other bias is present in the trial, such as stopping the trial early, changing methods during the trial or using different type of music therapy. The particular biases in different types of trials will also be considered, such as recruitment bias, baseline imbalance and loss of clusters in cluster-randomized trials.

Measures of treatment effect

Dichotomous data

Risk ratio (RR) and number needed to treat to benefit statistics with 95% confidence intervals (CI) for binary outcomes will be calculated, partly because RR is the concept more familiar to readers such as patients and health professionals than odds ratio (OR).

Continuous data

When means and standard deviations are available in the paper or calculable from the available data (standard deviations will be obtained from standard errors, CIs, t values and P values using the formula outlined in [Higgins 2011](#)) continuous data will be analyzed. Continuous outcomes will be summarized as mean differences (MD) where all data are from the same scale, or as standardized mean differences (SMD) where similar data from different scales are combined. 95% CIs will be calculated for each effect estimate.

Multiple outcomes

When a study provides multiple, interchangeable measures of the same construct at the same point in time, the conversion formula that is outlined in [Higgins 2011](#) will be used to translate the treatment effect to desired format and a sensitivity analysis will also be performed to examine the heterogeneity.

Unit of analysis issues

The unit of analysis of the trials will be taken into account to determine whether individuals were randomized in groups (that is, cluster-randomized trials), whether individuals may have undergone more than one intervention at once and whether there were multiple observations for the same outcome.

Cluster-randomized trials

If participants of the trials were randomized to groups in clusters, either when data from multiple children in each family are included (creating a cluster within the family), or when participants are randomized by schools, classes, medical practices or families, the results should be presented with proper controls for clustering (robust standard errors or hierarchical linear models). If appropriate controls are not used and it is impossible to obtain the full set of individual participant data, the data will be controlled for clustering using the procedures outlined in [Higgins 2011](#). That is, if outcome measures are dichotomous, the number of events and number of participants per trial will be divided by the design effect $[1 + (M - 1) ICC]$, where M is the average cluster size and ICC is the intra-cluster correlation coefficient. If outcome measures are continuous, the number of participants per trial will be divided by the design effect, while leaving the mean values and standard deviations unchanged. To determine the ICC, the review authors will use estimates in the primary trials on a study-by-study basis. However, if these values are not reported, the review authors will use external estimates of the ICC that are appropriate to each trial context and average cluster size by contacting the trialists. A common approach is to use external estimates obtained from similar studies, and several resources are available that provide examples of ICCs ([Ukoumunne 1999](#); [Campbell 2000](#); [Health Services Research Unit 2004](#)). If they are not available, the review authors will seek statistical assistance from the Cochrane Statistical Methods Group ([Higgins 2011](#)).

Studies with multiple treatment groups

Data from the same group will not be analyzed twice for trials where there are multiple treatment groups. The treatment condition will be selected for meta-analysis according to which ones match the inclusion criteria. The comparison condition will be conventional treatment or the least active treatment offered. The relevant control groups will be combined into a single control group and the efforts will be made to avoid a loss of information when a study with multiple intervention groups is included. A sensitivity analysis will be performed when the control studies are combined to avoid the heterogeneity in the relevant control groups.

Dealing with missing data

All missing data will be described, together with drop-outs and attrition for each included study in the 'Risk of bias' tables. We will investigate and summarize the reasons, number and characteristics of the missing data. We will contact the authors using every means available (email, formal letter, facsimile, telephone call) if there are missing data and drop-outs, or no information is provided about adverse events. All the attempts to secure missing data will be reported. A sensitivity analysis will be done to assess bias in the analysis if the missing data are not available and the extent to which the results might be biased by missing data will be discussed.

Assessment of heterogeneity

The Chi^2 test will be employed to determine the strength of the evidence that heterogeneity is genuine. In addition, heterogeneity will be assessed by examining I^2 (Higgins 2011), a quantity that describes the approximate percentage of variability in point estimates due to heterogeneity rather than sampling error. Sensitivity analysis will be conducted when the necessary data are available.

Assessment of reporting biases

If sufficient studies are available, publication bias and other reporting biases will be addressed by drawing funnel plots (Light 1984; Egger 1997). If a relationship between effect size and standard error is found, clinical diversity will be examined as a possible explanation. Asymmetric funnel plots may be caused by publication bias and other bias.

Data synthesis

If the necessary statistics (for example, event rates, means or standard deviations) are available or can be calculated and studies include homogeneous clinical factors (participants, such as similar age range and distribution, interventions, such as music therapy versus a no treatment control, and outcome measurement) and methodological factors (for example, randomization, measurements), meta-analysis will be used. When the Chi^2 test or the I^2 statistic indicate heterogeneity, a random-effects meta-analysis will be used and where studies appear to be homogeneous according to known characteristics and the values of the Chi^2 test or the I^2 statistic, a fixed-effect meta-analysis will be used. The decision to use fixed-effect versus random-effects models will be justified conceptually by heterogeneity not only by those values of the statistics. If suitable numerical data are not available for meta-analysis, or if meta-analyses are considered inappropriate, a descriptive paragraph will be provided for the results from each study, although general conclusions about the effectiveness of music therapy would not be possible in that case. The narrative description will be done consistently, including the same elements of information for each study, presented in the same order. We will organize the studies into groupings if a large number of studies have been included in the review to make the process of describing the results narratively more manageable.

Subgroup analysis and investigation of heterogeneity

Further investigation of the causes of heterogeneity may be conducted using subgroup analyses. The data may be analyzed in subgroups according to the following categories:

- age (< 13 years vs \geq 13 years);
- different types of music therapies (for example, improvisation vs listening to recorded music);
- different subtypes of ADHD (ADHD-I, ADHD-HI, ADHD-C);
- different control interventions (for example, pharmacological vs psychological);
- treatment duration.

Sensitivity analysis

Sensitivity analyses will be conducted to explore the impact of studies at high risk of bias (the eligibility criteria, analysis or methodology in these studies may possibly have affected the robustness of the results) by removing these studies lacking specific quality attributes from the analysis and re-analyzing the remaining studies. This will be undertaken on the following dimensions:

1. studies with heterogeneity in the definition, measurement or reporting of results (for example, if the number of participants varies in the report);
2. studies with interventions that are composed of music therapy plus another treatment;
3. studies with multiple treatment groups;
4. missing data that are not available and different ways to estimate the values for missing data;
5. use of different analytical methods (for example, a fixed-effect meta-analysis vs a random-effects model, OR vs RR).

ACKNOWLEDGEMENTS

We are grateful for the guidance and editorial comments from Professor Geraldine Macdonald and Laura MacDonald and other members of the CDPLPG. We appreciate the help and advice of Margaret Anderson in the development of the search strategy. We would also like to thank the members of our Steering Group, Qi Pang, Chao You, Ping An, Jing Chen, Jianguo Xu and Ming He, for their help in the design of this proposed review. Lastly, we would like to thank Professor Christian Gold for useful guidance.

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CONTRIBUTIONS OF AUTHORS

All authors contributed to the development of this protocol. FZ drafted the protocol, with substantial input from KL, PA, CY, LT and QL. FZ, KL, PA, CY, LT and QL devised the search strategy. FZ and KL will screen the abstracts and titles and retrieve potentially eligible papers. FZ

and KL will review the papers and make decisions about eligibility in discussion with LT and QL. FZ will extract data, which will be double-checked by KL. FZ will draft the full review with regular input from all authors at every stage.

DECLARATIONS OF INTEREST

- Fan Zhang - none known.
- Kun Liu - none known. KL is a qualified music therapist.
- Ping An - none known.
- Chao You - none known.
- Liangzhu Teng - none known.
- Qingwei Liu - none known.

SOURCES OF SUPPORT

Internal sources

- Shandong University, China.
- Department of Neurosurgery, Shandong Provincial Hospital Affiliated to Shandong University, China.
- School of Medicine, Shandong University, China.

External sources

- Chinese Cochrane Centre, West China Hospital, China.
- Department of Neurosurgery, West China Hospital, China.
- Sichuan University, China.