

Promoting social communication through music therapy in children with autism spectrum disorder

Multidimensional investigation: Systematic review, RCT study protocol, treatment guide, feasibility study

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DOI (link to publication from Publisher):
[10.5278/vbn.phd.hum.00010](https://doi.org/10.5278/vbn.phd.hum.00010)

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Unspecified

Publication date:
2015

Document Version
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

Citation for published version (APA):
Geretsegger, M. (2015). *Promoting social communication through music therapy in children with autism spectrum disorder: Multidimensional investigation: Systematic review, RCT study protocol, treatment guide, feasibility study*. Aalborg Universitetsforlag. <https://doi.org/10.5278/vbn.phd.hum.00010>

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PROMOTING SOCIAL COMMUNICATION THROUGH MUSIC THERAPY IN CHILDREN WITH AUTISM SPECTRUM DISORDER

MULTIDIMENSIONAL INVESTIGATION:
SYSTEMATIC REVIEW, RCT STUDY PROTOCOL,
TREATMENT GUIDE, FEASIBILITY STUDY

**BY
MONIKA GERETSEGGER**

DISSERTATION SUBMITTED 2015



AALBORG UNIVERSITY
DENMARK

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AALBORG UNIVERSITY
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Thesis submitted for the degree of Doctor of Philosophy

Thesis submitted: January 05, 2015

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PhD Series: Faculty of Humanities, Aalborg University

ISSN: 2246-123X
ISBN: 978-87-7112-211-4

Published by:
Aalborg University Press
Skjernvej 4A, 2nd floor
DK – 9220 Aalborg Ø
Phone: +45 99407140
aauf@forlag.aau.dk
forlag.aau.dk

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Printed in Denmark by Rosendahls, 2015



CV

Monika Geretsegger was born in Salzburg in 1978, and lives in Vienna, Austria. She studied psychology and linguistics at the Universities of Salzburg and Vienna, and music therapy at the University of Music and Performing Arts Vienna. She gained her Master equivalent degrees in 2005 (music therapy, *Magistra artium*), 2008 (linguistics, *Magistra philosophiae*), and 2009 (psychology, *Magistra rerum naturalium*). In addition, she completed an academic supplement study for interdisciplinary communication at the Faculty of Interdisciplinary Research and Continuing Education (IFF) in Vienna in 2004. She is a certified music therapist and a certified clinical and health psychologist.

In her clinical work, she specialises in children and adolescents with developmental disorders, working in private practice in Vienna for ten years, and in adults with mental health problems, working in an Austrian hospital department for social psychiatry for almost nine years so far.

She received a PhD Mobility Fellowship from Aalborg University in 2010, and in connection with this has been employed at University of Vienna's Faculty of Psychology for four years. From Nov. 2014, she also works at GAMUT, Uni Research Health, in Bergen, Norway.

She has been serving as president of the Austrian Association of Music Therapists since 2010. She so far presented various aspects of her clinical, scientific, and advocacy work within music therapy at congresses and universities in nine European countries, South Korea, and Australia.

DECLARATION

I hereby declare that neither this thesis nor part of the thesis have previously been submitted for a higher degree to any other university or institution in Denmark or abroad.

Monika Geretsegger

Date

ENGLISH SUMMARY

This PhD study explores music therapy as a means to promote social communication in children with autism spectrum disorder (ASD) by examining outcome- and process-related dimensions of this complex field. Previous research had suggested that music therapy may positively influence core areas in ASD such as social interaction and communication. However, since these studies were limited in either methodology or the clinical relevance of their approach, the evidence was difficult to generalise and not robust enough for music therapy to be recognised as a recommended intervention for individuals with ASD. Moreover, previous studies on music therapy for ASD were typically conducted as single-site studies which limits the achievable sample size, and no consistent but sufficiently flexible treatment guidelines were available to allow for reliable implementation of comparable music therapy interventions in several countries.

To address these issues, four articles are presented within this study: In a systematic review (Cochrane review), the current research evidence on overall effects of music therapy for individuals with ASD was synthesised. The findings summarising results from 10 studies with a total of 165 participants provide evidence that compared to ‘placebo’ therapy or standard care, music therapy may help children with ASD to improve in primary outcome areas that constitute the core of the condition such as social interaction, non-verbal and verbal communicative skills, initiating behaviour, and social-emotional reciprocity. Music therapy was also superior to ‘placebo’ therapy or standard care in the secondary outcome areas social adaptation, joy, and the quality of parent-child relationships.

In a study protocol, the design of TIME-A, a large randomised controlled trial (RCT) examining effects of improvisational music therapy on social communication skills in children with ASD aged four to seven is specified. Using rigorous methodology including blinded assessment of outcomes measuring generalised effects, assessment of treatment fidelity, and follow-up measures seven months after therapy has ended, its findings will also be easily applicable to clinical practice due to broad eligibility criteria and common treatment techniques and durations.

An international consensus model of improvisational music therapy for children with ASD is described in a treatment guide specifying unique and essential, essential, and compatible principles of this approach. These resulted from a survey and focus groups with experienced music therapists in a total of

eleven countries worldwide. A related tool to evaluate treatment adherence was successfully applied to assess treatment fidelity.

Finally, data on implementation procedures from the pilot cohort ($n = 15$) of the TIME-A project, an international multi-centre RCT, are summarised in an article addressing the scarcity of feasibility studies on trials examining complex interventions. Feasibility and acceptability of study components were evaluated by examining recruitment, implementation of interventions and control conditions, assessment procedures, safety, and retention. Findings suggest that overall, the study was designed appropriately regarding the feasibility of study components. Additionally, descriptions of three participants' development within therapy related to independent observations by blinded assessors provide insight into the complexity of individual developmental trajectories and the challenges involved in interpreting results on individual and generalised levels.

Overall, this PhD study contributes to the collaborative efforts of understanding and developing music therapy as a means to promote social communication in individuals with ASD (i) by presenting a solid base of current evidence, (ii) by specifying detailed requirements for research in this area, and by providing (iii) a treatment guide and (iv) feasibility data as integral components for large-scale research projects on complex interventions such as music therapy.

DANSK RESUME

Denne ph.d.-afhandling udforsker musikterapi som middel til at fremme social kommunikation hos børn med autismespektrumforstyrrelse (ASF) ved at undersøge effekt- og procesrelaterede dimensioner af dette komplekse område. Tidligere forskning har vist, at musikterapi positivt kan påvirke kerneområder i ASF så som social interaktion og kommunikation. Men da kvaliteten af denne forskning er begrænset rent metodologisk eller i forhold relevansen af den kliniske indfaldsvinkel, er den påviste evidens vanskelig at generalisere, og ikke stærk nok til at kunne få musikterapi anerkendt som en anbefalet intervention for mennesker med ASF. Hidtidig forskning har typisk været udført med udgangspunkt i et enkelt sted (eng. single-site studies), hvilket begrænser det opnåelige deltagerantal, og der har ikke været ensartede og samtidig tilstrækkeligt fleksible retningslinjer for behandling til rådighed, som kunne sikre en pålidelig anvendelse af sammenlignelige musikterapiinterventioner på tværs af landegrænser.

Disse problemer er blevet adresseret i fire artikler, som indgår i denne ph.d.-afhandling: I en systematisk litteraturgennemgang (Cochrane review) blev den foreliggende evidens for den samlede effekt af musikterapi med personer med ASF sammenholdt. Konklusionen sammenfatter resultater fra 10 forskningsstudier med i alt 165 deltagere og viste, at musikterapi sammenlignet med 'placebo'- eller standardbehandling kan hjælpe børn med ASF til at blive bedre inden for de primære områder, der udgør kernen i ASF, så som social interaktion, nonverbale og verbale kommunikative færdigheder, initierende adfærd og social-emotionel gensidighed. Musikterapi var også bedre end 'placebo'- eller standardbehandling i forhold til sekundære områder så som social tilpasning, glæde samt kvaliteten af forældre-barn relationer.

I en forskningsprotokol beskrives forskningsdesignet for TIME-A, som er en international multi-center randomiseret, kontrolleret undersøgelse (RCT) af effekten af improvisatorisk musikterapi på sociale kommunikationsfærdigheder hos børn med ASF i alderen 4-7 år. Ved at anvende en stringent forskningsmetodologi med blindede målinger af effektmål, vurdering af behandlingsnøjagtighed (eng. treatment fidelity), og follow-up målinger syv måneder efter behandlings afslutning, formodes undersøgelsens resultater at være letanvendelige i klinisk praksis pga. vide egnethedskriterier og ensartede behandlingsteknikker og -varighed.

En international konsensusmodel over improvisatorisk musikterapi med børn med ASF er blevet udviklet og beskrevet i en behandlingsguide, der præciserer

henholdsvis unikke og essentielle, essentielle men ikke unikke og endelig kompatible principper inden for denne indfaldsvinkel samt forbinder dem med typisk adresserede områder og musikterapiteknikker anvendt i forhold til ASF. Principperne blev udformet vha. en spørgeskemaundersøgelse samt inddragelse af fokusgrupper med erfarne musikterapeuter i samlet set elleve lande verden over. Et lignende redskab blev med succes anvendt til at vurdere om behandlingsprincipperne blev overholdt.

Endelig blev data vedrørende gennemførelsesprocedurer (eng. implementation procedures) fra pilot kohorten ($n = 15$) af TIME-A studiet sammenfattet i en artikel, der adresserer knapheden af undersøgelser af gennemførligheden (eng. feasibility) af forskning rettet mod komplekse behandlingsformer. Gennemførlighed og acceptabilitet af undersøgelsens bestanddele blev vurderet ved at undersøge rekruttering, implementering af interventioner og kontrolforhold, diagnostiske assessmentprocedurer, tryghed og fastholdelse. Resultaterne indikerer overordnet set, at pilotstudiet var designet hensigtsmæssigt i forhold til gennemførligheden af undersøgelsens dele. I tillæg blev beskrivelser af tre deltageres udvikling i musikterapien sammenholdt med uafhængige observationer foretaget af blindede bedømmere med henblik på at give indsigt i kompleksiteten i de enkelte deltageres udviklingsbaner samt udfordringerne ved at fortolke resultater på henholdsvis individuelt og generelt niveau.

Samlet set bidrager denne ph.d.-afhandling til en fælles indsats i forhold til at forstå og udvikle musikterapi som et middel til at fremme social kommunikation hos personer med ASF, (i) ved at præsentere en solid base af den foreliggende evidens, (ii) ved at angive detaljerede krav til forskning på dette område, og ved at (iii) fremlægge behandlingsguide og (iv) data om gennemførlighed som integrerede dele af store (eng. large-scale) forskningsprojekter med komplekse behandlingsinterventioner som fx musikterapi.

ACKNOWLEDGEMENTS

I am grateful for many people's valuable support and precious company during the time of my PhD study:

First of all, I am thankful to all the children and families who participated in this study's clinical trial for devoting many hours of their time to this study, and for sharing with me their views and experiences of living with a diagnosis of autism.

I would like to say thank you to my two fabulous supervisors, Ulla Holck and Christian Gold. I feel very fortunate to have had them as supervisors and see both of them as ideal mentors for me on my path of development, caringly supporting me in all kinds of ways as well as gently challenging me to expand my methodological and reflexive abilities.

It was Christian Gold who initially sparked off the idea that I could embark on this PhD study, and he generously devoted much of his limited time and vast knowledge to guide and support me all along the way. Through the whole course of the study and beyond, he continued to open up opportunities for me to utilise my interest in research, and to expand my skills in doing it. He also made me more aware of where a detail-focussed way of working is beneficial, and where it may be a hindrance in getting the full picture.

Accompanying me through the many steps and levels of this study, Ulla Holck was always ready to support me by sharing her expert knowledge in clinical practice, empirical research, and in combining the two. She encouraged me to develop more thoroughness in argumentation and critical thinking, and she also provided essential support in coping with the administrative requirements and pitfalls that a PhD study naturally involves. I also want to thank her for translating this PhD study's abstract to Danish, and for many helpful comments in other matters of language.

My sincere thanks go to the late Tony Wigram who made this study possible in the first place. The mobility fellowship position that I was granted gave me the invaluable opportunity to become a PhD student in the extraordinary research milieu that he had created at Aalborg University. Even ahead of admission to the programme, Tony Wigram went out of his way to support me in my plans for the study. I miss his voice both literally and in scientific debate, and he continues to inspire me through his writings and the memory of his unparalleled personality and passion for music therapy.

At Aalborg University's Doctoral Programme in Music Therapy, I want to express my gratitude to the extremely dedicated faculty team, skilfully and caringly led by Hanne Mette Ochsner Ridder, and to visiting guest teachers, for the constructive, collaborative and supportive atmosphere of learning that characterised our times together at the PhD courses and that continues to inspire me in my work.

I also wish to thank all the students of the Doctoral Programme that I had the pleasure of meeting there in the past few years. I treasure the opportunities to exchange ideas and support each other, to share the delights and struggles of developing PhD research, and to spend time together in joy and sorrow. I am thankful for the friendships and professional collaboration that developed through this and that I look forward to continue beyond my time at the programme. In a similar way, I also want to thank the international colleagues of the TIME-A project for sharing their enthusiasm, passion, and expertise. Becoming a part of both these international scientific communities has truly broadened my horizons.

Thanks also go to music therapists in many countries who participated in the survey and focus groups that were part of this study, for sharing their expertise and experiences in the field of improvisational music therapy and autism spectrum disorder; and to Carolin Steidl and Sonja Metzler, clinical psychologists in Vienna, who supported this study's clinical trial with their diagnostic expertise in many hours of conducting and evaluating assessments.

I would like to acknowledge the support of the Faculty of Psychology, University of Vienna, who acted as local collaborating institution for this PhD study in Austria. My thanks go to the faculty's dean Germain Weber, and to Esther Schmidt who provided much-needed support in coming to terms with the red tape of regulations, forms, and contracts.

Many thanks to my parents Erika and Hans Geretsegger for backing me in my scientific interests and for being so reliable in their support during the many years of my studies.

I am also grateful for dear friends in Vienna and all around the world who sustained our long-time friendships despite decreasing amounts of time spent together, and who keep my mind open for other important matters in life besides music therapy, research, and academia.

Finally, my heartfelt thanks go to Thomas Stegemann, for supporting my work on this study in numerous direct and indirect ways, for his patience and sagacity, and for joining me in developing fulfilling forms of shared work and life.

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PART A: THESIS FRAMEWORK

1. BACKGROUND & CONTEXT

1.1. INTRODUCTION

Impairments in competencies of social interaction and communication are at the core of autism spectrum disorder (ASD) by definition (American Psychiatric Association, 2000, 2013). Based on interaction and the relationship between client and therapist where music is used as an expressive and communicative means, music therapy shows great potential to be utilised as an intervention method within ASD aimed at reducing those impairments and fostering growth in related abilities. What sounds plausible in theory and has been practised for decades is, however, difficult to document and evaluate reliably and with the methodological rigour demanded in contemporary health care settings and clinical research. Due to the complexity of the condition and the broad variety in both the clinical presentation of ASD and music therapy techniques applied, generalisable knowledge about effects and specific working mechanisms of music therapy in ASD is still limited.

At the outset of this PhD study, its focus was on conducting a randomised controlled trial (RCT) examining effects of improvisational music therapy on social communication in children with ASD. This aim was based on the need for more rigorously designed trials examining specific outcomes of music therapy in ASD (Wheeler, Williams, Seida, & Ospina, 2008), and built upon previous findings suggesting that music therapy in general, and improvisational approaches specifically, may facilitate skills in those areas typically affected by ASD. During the process of this PhD study, its focus broadened to include important aspects surrounding this RCT, and the aim of evaluating effectiveness was transferred to a large international research endeavour beyond the scope of, but connected to this PhD study (see 3.1.1.). From the beginning, I also intended to systematically summarise the evidence to date on effects of music therapy for individuals with ASD, to develop a treatment guide for improvisational music therapy in that area, and to examine the feasibility of implementing a rigorously designed trial using a complex intervention within everyday clinical settings.

This PhD study is based upon the articles that originated from these aims. Their contents are presented in section 1.4., and summarised in Chapter 4. For some readers, perusing the articles reprinted in Part B first might be a good way of approaching this thesis' contents.

Taken together, the four articles of this PhD study and the linking text of this book may lay the groundwork for more valid and reliable investigations into efficacy, effectiveness, and processes of promoting social communication in individuals with ASD through music therapy and other complex interventions.

1.2. TERMINOLOGY

The expression autism spectrum disorder, or ASD, is used throughout this thesis due to the framework that its articles are situated in. I am aware of the societal dimension and potential negative impact of labels like “disorder”, potentially implying that something is viewed as pathology and in need of being “put right”. Using the term “autism spectrum condition” instead of “disorder” is one way of indicating that those affected do not need to get “cured” from something, but rather that they present with a specific neurodevelopmental constitution that might require some specific consideration and support if it causes difficulties for them. The notion of neurodiversity as a broad spectrum of natural neurological variation including individuals of mild to pronounced autism features as well as “neurotypical” individuals is another way of emphasising a less deficit-centred view of autism. However, with the articles of this PhD study referring to the paradigm of evidence-based practice and to health care contexts, it seems appropriate to employ a term from established classification systems (e.g., American Psychiatric Association, 2013) in order to enhance visibility and accessibility of findings for those working in the same contexts.

Nonetheless, it is important to me to mention that as a clinician, it is not my goal to “normalise” individuals, but to enable them to feel better in their personal way of being, and to collaborate on finding ways to interact with the world and those around them that are effective to them. Also as a researcher, it is important for me to use language that is both efficient regarding the respective text’s goals and also respectful towards those addressed. Although the choice of using “person-first” language (i.e., “child with autism/ASD” instead of “autistic child”) is also contested by some as disregarding the option of viewing a disability as a valued part of identity (e.g., Bakan, 2014), in this thesis, person-first constructions are used throughout following current conventions within scientific writing in health care contexts.

1.3. PERSONAL MOTIVATION

In general, the decision to embark on a PhD study itself as well as the area of research and the research paradigm chosen in this project may be viewed as corresponding to some of my essential personal needs and primary interests:

- to understand reasons why people interact with each other – reasons both in a phylogenetic and an ontogenetic, individual-based sense –, and how they do it;
- to understand fundamental elements of communication, and what the human phenomena of music and language have in common;
- to accompany people on their path of development through building relationships;
- to find ways of being clear and precise in what I do and say (without losing vitality or becoming rigid);
- to acquire new skills and insights that might open up previously unknown areas through interacting with others.

In my experience over the last four years of my study, I find all of these reflected both in the nature of the chosen therapy approach and in the process of doing PhD research in itself, thus making it a rewarding and enriching experience. Using music in improvisational ways as described below (cf. section 1.8. and Part B, II and III) complies with my perception of communication as a more or less structured and improvised flow of interaction. In that way, I see music therapy as a means to facilitate music experiences within a therapeutic relationship that emanate from interests and interactions of those involved, thus making them meaningful. Through those meaningful experiences and interactions, a sense of relatedness may occur which in turn may serve as a basis for building relationships, expanding capabilities, and developing new skills.

More specific motives to design and develop my PhD study the way it is now presented in this volume are detailed below.

1.3.1. CLINICAL FIELD OF AUTISM SPECTRUM DISORDER

As for my personal background within the field of ASD, it is interesting to see for myself in hindsight how this topic and people associated with it kept turning up in my life over the years: I have been working with individuals with ASD in different settings and in different countries for many years: supervising

and helping school children with ASD in their everyday activities as a voluntary care worker in a boarding school in the UK, working with children and adolescents with ASD as a music therapy student within training placements in Austria and also in South Africa, conducting autism spectrum diagnostics, family counselling and classroom support as a trainee in clinical and health psychology, and seeing children and adolescents with ASD in my private music therapy practice for ten years. I developed a special interest in the concept of theory of mind (fuelled by attending lectures held by Heinz Wimmer and Josef Perner, formative empirical researchers on false belief, in the first semesters of my study of psychology at the University of Salzburg) and experienced later on that seemingly well-established areas of research like this one example are rarely reflected upon in music therapy practices in an explicit way. Additionally, while receiving my music therapy training within the at that time mainly practice- and theory-based programme at the University of Music and Performing Arts Vienna, there were times when I found it difficult to integrate scientific approaches and research-oriented thinking that I had learned to value with the individualised approaches of clinical practice. With my combination of studies (psychology, linguistics, and music therapy) I sometimes felt like some sort of commuter between various disciplines and models all circling around the same objects. While engaged in this commuting, I always felt a bit dissatisfied with what seemed to me to be (perhaps necessary) disregard of important other aspects when acquiring a certain perspective. This eventually led to an effort to draw connections between neuropsychological models of autism and current clinical practice in music therapy within my music therapy diploma thesis at the University of Music and Performing Arts Vienna (Geretsegger, 2005).

In music therapy with people affected by autism, I was often struck by the experience that musical interplay can be a much more feasible way for them to interact with others than “normal” verbal or non-verbal communication. However, the challenges of working with those children and adolescents have at times also brought about moments where I experienced a certain sense of aimlessness, uncertain of whether perceived moments of synchronicity or reciprocity were really shared experiences or rather effects of chance or of me over-interpreting a certain course of events, struggling with the impression that any progress seemed slow and fleeting. In moments like this, fundamental questions tend to come to mind: Does all this work that we are doing here have an effect at all, one that is perceivable – for me, for the person with ASD, for the people around that person? How much progress do I need to observe to be convinced (and be able to communicate to others, e.g. the child’s parents) that this is worth all the time that is invested here on both sides? Do these moments of relatedness, shared emotions, or interaction that the person

with ASD may have experienced within music therapy translate to any other areas of their life outside the therapy room?

With this in mind, conducting this study (and being involved in the actual clinical work myself, see section 3.2.2.) also served as a way for me to strengthen my understanding of relevant processes within my own practical work, of music therapy's effects on specific areas of development, and of relevant factors moderating those outcomes. In other words, it helped making the clinical, sometimes implicit and procedural knowledge about effective ways of working with people with ASD more explicit.

As for the clinical approach applied in this study, it may be stated that improvisational music therapy is not only a method that has been found effective in the treatment of people with ASD in previous research (see sections 1.7., 1.8.; Part B, I, II, and III), but is also the music therapy method that has been the dominant approach within my own training and clinical work and which I therefore felt competent of working in and also doing research upon. Additionally, using improvisational techniques attuned to the client's behaviour and expression allows for flexibly integrating the experiential and relational context much more than using, for example, behaviouristic approaches. I deem it essential for therapists to bear in mind this context of interaction and the client's motivation to engage in interaction in order to effect enduring change in fundamental skills of communication, and to facilitate transfer of changes to other contexts. A preliminary definition of improvisational music therapy as used within this study is given in section 1.8.

1.3.2. FOCUS ON QUANTITATIVE METHODS

Given my interest for effects of music therapy combined with being a person who enjoys uncovering relations between things, events, human experiences and human behaviour, who likes dealing with logic and numeric data, and who – not unlike individuals with an autism condition – has a propensity to high levels of structure, I might be considered naturally drawn towards quantitative methods in research. This corresponds to my experience as a student and researcher so far where I have been primarily involved in projects and collaborations using quantitative methodology. In this PhD study, the fixed, quantitative design characterising three articles (the RCT protocol, the systematic review, and the feasibility study) is complemented by a more flexible approach containing qualitative methods in the article on the development of a treatment guide, and also in the brief case descriptions within the feasibility study.

Doing this study in the way that is presented here is based on my genuine interest to conduct research that has a clear relevance to and stays true to clinical work as it is carried out in “everyday” clinical practice, without compromising methodological accuracy at the same time. In this way, doing this study helped me not only to acquire solid research skills, but also to explore ways how to best apply research findings to clinical work, or to feed findings of practice-based research back to everyday work.

Producing solid quantitative results that are clinically relevant and applicable in daily practice also responds to contemporary requirements within health care settings to provide evidence-based services and interventions. While it is important to retain both freedom in scientific research and clinical, experience-based expertise in practice, I also consider it necessary to find feasible and responsible ways of quantitatively investigating complex interventions.

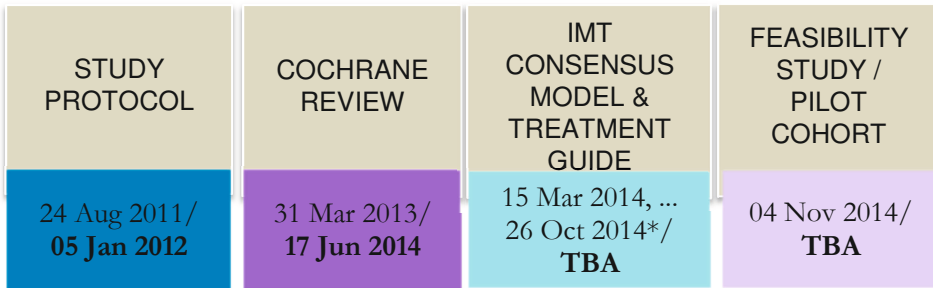
1.3.3. ARTICLE-BASED TYPE OF THESIS

One recommendation of the Doctoral Programme in Music Therapy at Aalborg University is to aim at publishing journal articles not only after completion of the PhD, but also during one’s enrolment. In accordance with this, and also based on my personal working style of moving along step-by-step rather than starting from a larger scope, doing my thesis in an article-based way was appealing and seemed logical to me in relation to my aims. I also appreciated the possibility of writing an article-based thesis as it provided me with useful experience in the practices of scientific publishing including correspondence with editors and reviewers of international peer-reviewed journals.

1.4. OVERALL STRUCTURE OF THE THESIS

The whole PhD thesis is structured around articles to be published. As planned in my elaborate proposal for the PhD study submitted to the Doctoral Programme nine months into the study period, four manuscripts have been submitted for publication in peer-reviewed journals over the course of my four-year study. At the time of submitting this thesis, two of them have been published, while the other two are still in review (see Figure 1-1).

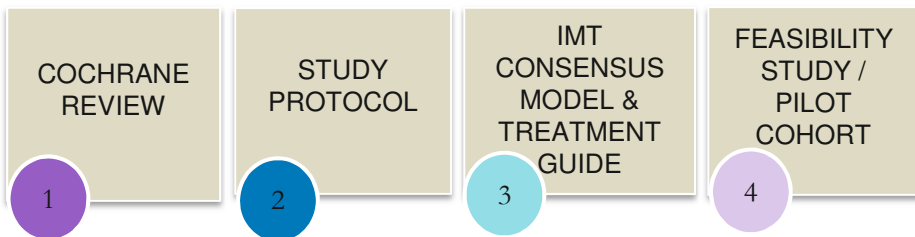
Figure 1-1 *Time-based sequence of this PhD study's four articles (submission/publication date)*



* *Note.* The ‘IMT consensus model & treatment guide’ manuscript was first submitted on 14 March 2014 and after rejection consecutively submitted to other journals; the latest submission was on 26 October 2014.

However, within the context of this thesis, the manuscripts will be presented in the common order of background (systematic review), methods (study protocol and treatment guide), results and discussion (feasibility study) to preserve the “logical” sequence of study components within reports of research (see Figure 1-2).

Figure 1-2 *Sequence of this PhD study's four articles in the order presented in this book (cf. Chapter 4 and Part B)*



As mentioned in section 1.1., the main focus of the PhD study has changed across the time of the study starting from preparatory work in spring 2010 and the official starting date of November 1, 2010. While initially, the PhD research was planned to primarily focus on the quantitative results of the RCT outlined in the study protocol, over the course of the four years of enrolment,

proportions of research questions within the study changed. In constant consultation with my supervisors, and documented in the half-year reports submitted to and approved by Aalborg University's Faculty of Humanities, the change that occurred may be described as in the following two figures:

Figure 1-3 Initial idea of main focus and proportions of research parts within PhD study

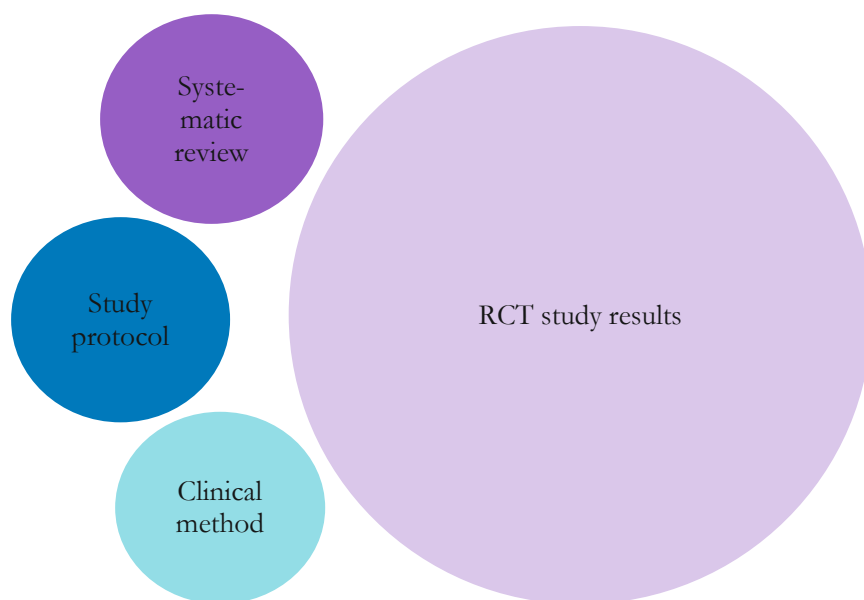
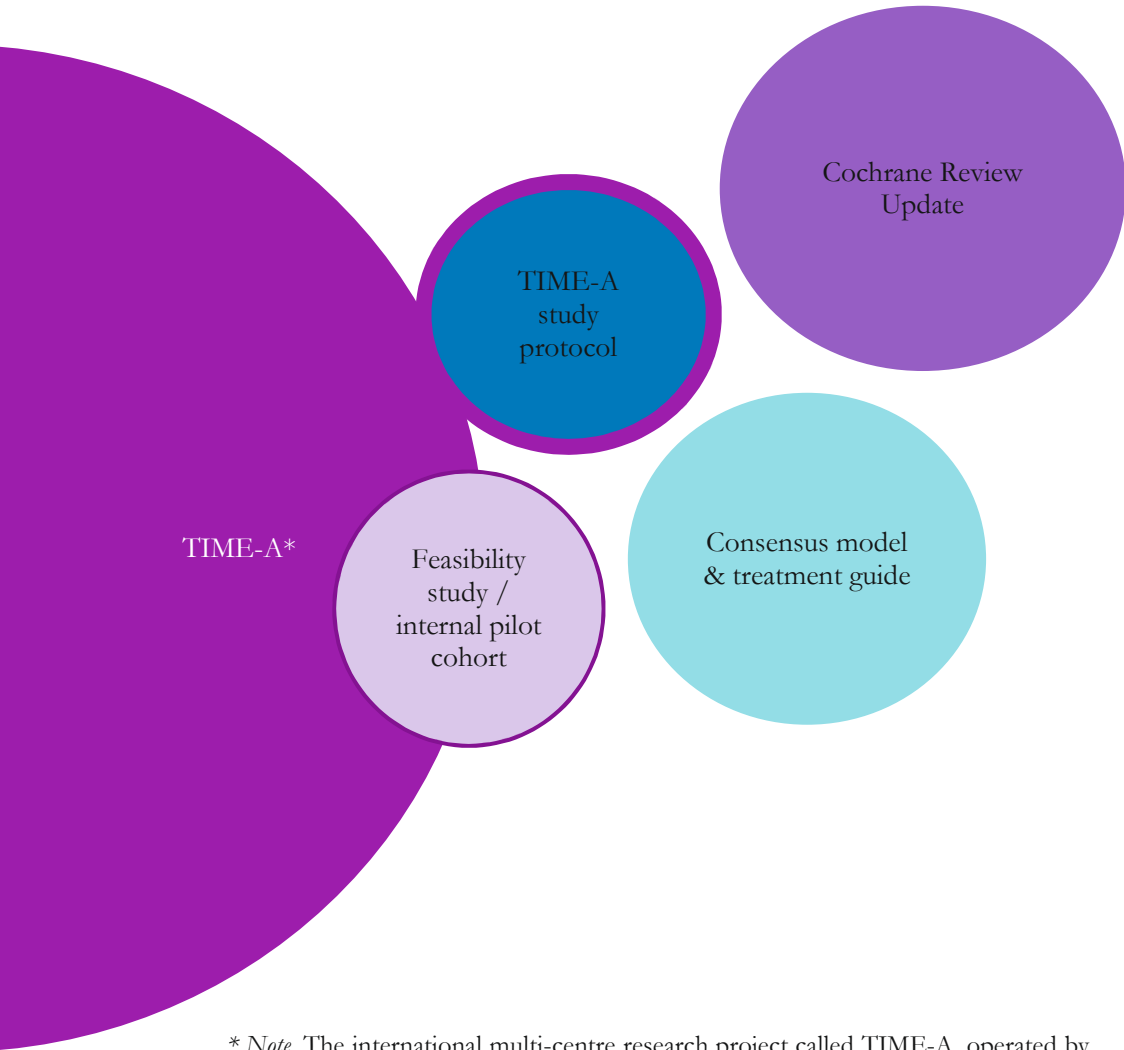


Figure 1-4 *Proportions of research parts within (and beyond) PhD study after completion*



** Note.* The international multi-centre research project called TIME-A, operated by GAMUT, Bergen/Norway, started in 2012 and will include a sufficient number of participants to evaluate improvisational music therapy's effectiveness for children with ASD. TIME-A is based on the published RCT study protocol (Geretsegger, Holck, & Gold, 2014) that has also been followed in this PhD study, and will incorporate data collected in the internal pilot cohort presented in the feasibility study article.

1.5. STRUCTURE OF LITERATURE REVIEW

Within the following sections (1.6. to 1.8.), an overview is given on literature relevant to this study's core topic, effects of music therapy for individuals with ASD. A summary of evidence of the very focus of this study, that is, a systematic review of music therapy outcome studies within ASD, has been performed as an update of the Cochrane Review on music therapy for autistic spectrum disorder published by Christian Gold, Tony Wigram, and Cochavit Elefant in 2006 (Part B, I; Geretsegger, Elefant, Mössler, & Gold, 2014).

Apart from research on effects of music therapy within ASD, other, more general realms such as outcome research on (other) psychosocial interventions for ASD and research on normal and impaired development of social communicative skills, as well as in areas relating to singular aspects of this research project (e.g., music therapy methods within ASD, outcome measures targeting social communicative skills) are considered pertinent to this study and are summarised below.

The following sections are structured as follows: After a description of main characteristics of the clinical condition, the nature of social communicative skills and their role in ASD will be addressed together with available evidence on interventions targeting these skills; section 1.6. will conclude with a brief assessment of outcome measures for psychosocial interventions in ASD. In section 1.7., the application of music therapy within ASD will be described, discussing different approaches, settings, and types of evidence related to effects of music therapy on various aspects of the disorder. The section on improvisational music therapy (1.8.) will give a working definition for this specific method and present a provisional rationale for its application within ASD by outlining findings from infant research, developmental psychology, and previous music therapy research.

1.6. AUTISM SPECTRUM DISORDER (ASD)

Autism spectrum disorder as defined by the American Psychiatric Association (2013) in DSM-5, and by the World Health Organization (1993) in ICD-10 (therein still separated into distinct diagnoses of childhood autism, Asperger syndrome, atypical autism, and other pervasive developmental disorders) is currently considered to be a set of complex neurodevelopmental disorders that are defined and diagnosed behaviourally and usually become manifest from early childhood on, persisting throughout life.

ASD is generally characterised by impairments in social interaction and communication combined with restrictive repetitive or stereotypic patterns of behaviour. Disorders on the so-called autistic spectrum – a term coined by Lorna Wing (1995) – cover a wide range of clinical presentations and a large variety of levels of individual abilities. For clinical diagnosis as well as for therapeutic intervention, this diversity within and across individuals affected by ASD poses particular challenges.

While the prevalence of pervasive developmental disorders (PDD)/ASD was previously assumed to be around 21 in 10,000 (Wing & Gould, 1979), more recent estimates ranged from 51.5 to 116.1 out of 10,000 (Baird et al., 2006; Fombonne, 2009; Williams, Thomas, Sidebotham, & Edmond, 2008); an estimate of a total population sample even places the prevalence of ASD in the range of 2% to 3% (Kim et al., 2011), but various possible risks of over- and underestimation are reported that result from the large number of methodological choices necessary in determining prevalence estimates.

In his review of 43 surveys on prevalence of PDD, Fombonne (2009) concludes that

[i]n some countries, and in some US states, recent prevalence estimates are above the 1% mark. Current evidence does not strongly support the hypothesis of a secular increase in the incidence of autism but power to detect time trends is seriously limited in existing datasets. Although it is clear that prevalence estimates have gone up over time, this increase most likely represents changes in the concepts, definitions, service availability, and awareness of autistic-spectrum disorders in both the lay and professional public. (p. 597)

In the same review of prevalence studies (Fombonne, 2009), the mean male-to-female ratio of PDD is reported as 4.2:1.

1.6.1. SOCIAL COMMUNICATIVE SKILLS IN ASD

What will be condensed as “social communicative skills” in this study is in fact a multitude of partly rather complex abilities. Apart from dividing them into broad areas such as social interaction, language and communication, several abilities such as joint attention behaviours, imitation, emotion recognition, reciprocity, intersubjectivity, and pretend play may be discriminated. Joint attention behaviours in turn, to take just one example, may be broken down

into behaviours initiating vs. responding to joint attention, and into further partial skills such as pointing to objects, showing items to another person, and following eye gaze.

Evolution and gradual advancement of these skills in typical development has been an area of substantial research efforts over the last decades, and questions as to specific definitions and time frames of occurrence of certain skills continue to be a matter under discussion. It is widely accepted however that all these skills play decisive roles as precursors in the development and as integral components of social competency and language (Bruner, 1995; Gergely & Watson 1999; Meltzoff & Gopnik, 1993; Mundy & Stella, 2000; Trevarthen & Aitken, 2001). They have been confirmed to be impaired in children diagnosed with ASD early on in their lives (e.g., Crais, Watson, Baranek, & Reznick, 2006; Dawson, Meltzoff, Osterling, Rinaldi, & Brown, 1998; Dawson et al., 2004; Sigman, Dijamco, Gratier, & Rozga, 2004), and may therefore be regarded as primary goal areas for attempts to facilitate developmental change in children with ASD. This is reflected in the large amount of literature published in this field in recent decades which will be addressed in the following section.

1.6.2. INTERVENTIONS TARGETING SOCIAL COMMUNICATIVE SKILLS IN ASD

In their comprehensive article on challenges in evaluating psychosocial interventions for ASD, Lord et al. (2005) write that

[t]he deficits in very basic skills that are usually present in typical infants and toddlers that define ASD [...], the pervasiveness of these deficits across contexts, and the very early onset noted in most children also affect the design and selection of treatments, in that interventions are needed that are as comprehensive as the disorders are pervasive, and that begin as early as the disorders are recognized. (p. 696)

Through early intervention, it is hoped that the negative feedback loop of impaired basic skills hampering the development of higher-level skills of social communication might be avoided, and that in this way, children with ASD might be enabled to be more successful in their development of social interaction, communication, and language.

As defining features of ASD, qualitative impairments in social interaction and problems with the social aspects of communication can be regarded as the most important targets of interventions for individuals with ASD: In their review of measures and measurement practices in intervention research with young children with autism, Wolery and Garfinkle (2002) differentiate between seven skill domains targeted by interventions (social skills, communication, adaptive skills, engagement or attending, play, imitation, and reducing problem behaviours); they report social and communicative domains as being well represented in intervention studies, but skill areas such as imitation, attention, engagement, and play appearing under-studied in spite of the fact that they may be regarded as core areas of difficulties for young children with ASD.

A few years on, interventions tailored to facilitate these particular skills have been the focus of a number of studies: Connie Kasari and her colleagues conducted randomised controlled trials on joint attention and symbolic play (Kasari, Freeman, & Paparella, 2006; Kasari, Paparella, Freeman, & Jahromi, 2008). They reported findings that suggest clinically significant benefits of interventions targeting those skills in young children with autism, including greater language growth in children randomised to joint attention, but (contrary to previous expectations) also symbolic play intervention groups compared to controls. Other studies investigated interventions targeting skills such as initiating joint attention (Yoder & Stone, 2006), imitation (Ingersoll & Gergans, 2007), and socially synchronous engagement within ASD (Landa, Holman, O'Neill, & Stuart, 2011).

A reasonable approach in facilitating social communication skills of children affected by ASD is by involving their parents or family members in programmes where they get assistance or training to promote those skills when interacting with their children. Recent rigorous studies on those parent-mediated interventions have been carried out by Kasari, Gulsrud, Wong, Kwon, and Locke (2010) and Green et al. (2010), reporting sustained benefits for social communication between parent and child. Furthermore, parent-mediated behavioural interventions are also among the few interventions evaluated as displaying statistically significant improvements for communication skills in children with ASD in Wheeler et al.'s (2008) overview of reviews.

There are also several music therapists (Oldfield, 2006; Thompson, 2012; Thompson, McFerran, & Gold, 2013; Warwick, 1995; Wimpory & Nash, 1999) who have employed this approach of involving parents of children with ASD in treatment in order to facilitate generalisation of improvements within therapy to everyday settings.

1.6.3. OUTCOME MEASURES FOR PSYCHOSOCIAL INTERVENTIONS WITHIN ASD

There is a wide range of outcome measures in research on interventions for ASD, ranging “from very specific (e.g., asking a certain kind of question) to very general (e.g., full inclusion in a regular school program; looking indistinguishable from normal)” (Lord et al., 2005, p. 697).

Another important distinction is between outcome measures that are applied within therapy sessions and those that evaluate change outside of the intervention context, that is, examining generalised behaviour.

Wheeler et al. (2008) have argued that “[r]esearchers must attend closely to trial quality and ensure the use of valid outcome measures that are sensitive to change and measure outcomes that are important to individuals and their families” (p. 13). They report that the large number of different outcome measures applied across studies investigated in their overview of reviews severely hampered processes of data synthesising and thus conclusions about treatment efficacy in an area of research where sample sizes are typically low.

They also observed that types of outcome measures available and applied in trials are often neither designed nor considered suitable to monitor change over time, even less so for the short time periods that are often reported in trials within the area of ASD. However, Lord et al. (2005) comment on ways to overcome such limitations, for example by broadening ranges of scores in the instruments, resulting in an enhanced sensitivity to change. The Autism Diagnostic Observation Schedule (Lord, Rutter, DiLavore, & Risi, 2001), which is also employed as an outcome measure in the present study’s clinical trial, is such an instrument that was initially developed as a diagnostic measure. It is widely used in diagnosis both in research and clinical practice, but has also been utilised to measure change in previous intervention studies (see section 3.2.3., *Outcome measures*).

Outcomes that are rarely measured after interventions within ASD, but may be considered relevant to clients and their families as well as service providers, include quality of life, cost-effectiveness and parental satisfaction with treatment (Charman & Howlin, 2003; Wheeler et al., 2008).

Wolery and Garfinkle (2002) present some family-related outcomes applied in some programmes for children with autism such as the *Parent Stress Index* (Abidin, 1983), the *Family Environment Scale* (Moos & Moos, 1981), and the *Child Improvement and Locus of Control* (DeVellis et al., 1985), but criticise that

these outcomes were less well developed and measured with less sophistication than child-specific outcomes. A more recent measure within this area, the *Family Quality of Life Questionnaire* was published by Brown et al. (2006) who also report families' quality of life to be related to the social competences of disabled children.

1.7. MUSIC THERAPY WITHIN ASD

1.7.1. DEFINITIONS OF MUSIC THERAPY

There are numerous interventions using music to facilitate change in individuals. Not all of them are appropriately termed as music therapy. For this study, it is considered important to define music therapy as approach that incorporates musical experiences (which includes music making as well as perception of music) and relational experiences, both gained within a therapeutic relationship, to promote the client's health and to decrease impairments in behaviour and mental processes (cf. Bruscia, 1998). This means that purely music-oriented interventions where music or musical stimuli are solely used to facilitate learning of specific skills do not fall under this definition. Especially when focusing on changes within fundamental social communication skills, it is deemed necessary to reflect on the relational framework in which an intervention is used with a client and to integrate this experiential context into the theoretic model of the intervention; otherwise, the risk of any progress remaining limited to the confines of the concrete therapy setting may be assumed to be even greater than is the case in any treatment approach within ASD anyway.

This stands in stark contrast to definitions of music therapy (as applied within the field of ASD) that can be found elsewhere: In a report on the evidence of treatment options for ASD, the National Autism Center (2009) assigns the term music therapy to interventions that “seek to teach individual skills or goals through music. A targeted skill (e.g., counting, learning colors, taking turns, etc.) is first presented through song or rhythmic cuing and music is eventually faded” (p. 64), thus limiting the term music therapy to behavioural approaches of using music to change behaviour.

In the definition of music therapy as issued by the World Federation of Music Therapy in May, 2011, an attempt was made to include a large range of diverse practices that utilise music in connection with health and wellbeing:

Music therapy is the professional use of music and its elements as an intervention in medical, educational, and everyday environments with individuals, groups, families, or communities who seek to optimize their quality of life and improve their physical, social, communicative, emotional, intellectual, and spiritual health and wellbeing. [...] (p. 1)

As this definition also lacks a relational component, it is considered too broadly phrased for this study's context.

Another definition that adequately captures the musical as well as the relationship-based element of music therapy (in addition to the one by Bruscia, 1998, as mentioned above) is the one provided in the Austrian Music Therapy Act that came into force in July 2009, governing the practice of music therapy within Austria where the data collection for this study's clinical trial has taken place:

[Music therapy] consists in the deliberate and planned treatment of persons with behavioural disorders and conditions induced by emotional, somatic, intellectual or social factors by means of musical interventions in a therapeutic relationship between one or more clients and one or more therapists with the objective of:

1. preventing, mitigating or eliminating symptoms or
2. changing behaviours and attitudes requiring treatment or
3. promoting and maintaining or restoring the development, maturity and health of the client. (Federal Ministry of Health, 2013)

A further defining characteristic that is considered important to distinguish this study's notion of music therapy from other interventions using music or musical stimuli is that music therapy needs to be conducted by people trained in this profession (as opposed to lay people or people from other professions using selected techniques). This also complies with the qualification requirements for music therapists in Austria as regulated within the Music Therapy Act mentioned above.

1.7.2. APPROACHES OF MUSIC THERAPY APPLIED IN ASD

In her review of the history of music therapy research and treatment of children with autism, Reschke-Hernández (2011) states that documents of music therapy as applied in autism in early years (mid-1940s to early 1960s) are

rare. She subsequently reports that early music therapy approaches within autism predominantly built on children's salient musical abilities and interest in music, e.g. as used by Hollander and Juhrs (1974) utilising the "Orff-Schulwerk" philosophy of music education in their work within a group setting with children with autism. Other techniques such as vocal or dance exercises (Goldstein, 1964), or rhythmical and singing activities to stimulate vocalisation and increase attention skills (Stevens & Clark, 1969; Mahlberg, 1973) were also reported by clinicians during the 1960s and 1970s.

Aside from those mostly structured techniques, more child-centered approaches with a primary goal of establishing communication through musical activities also began to appear in the late 1960s and 1970s. Pioneers such as Alvin (1978) and Nordoff and Robbins (1977) paved the way for many ensuing approaches employing improvisational techniques attuned to the child's behaviour to facilitate motivation and attention skills as well as interpersonal communication and social interaction (cf. Wigram & Gold, 2006; for more details on improvisational music therapy, see section 1.8.).

In the period from the early 1980s until the end of the century, published approaches of music therapy applied in the field of ASD include works by Bryan (1989), Di Franco (1999), Robarts (1998), Schumacher (1999), Thaut (1984), and Warwick (1984, 1995); further contributions are listed in narrative reviews by Accordino, Comer, and Heller (2007), Simpson and Keen (2011), and Wigram (2002) as well as by Reschke-Hernández (2011), who notices a lack of detail in the description of most techniques during that time that impeded replication in practice or subsequent research.

Furthermore, Reschke-Hernández (2011) points out that "[i]t is likely that many music therapists working with children with autism have not engaged in clinical research or published their work; therefore, the literature may not be representative of current clinical practice" (p. 199).

Apart from being influenced by their respective personal background, for instance as musicians, as was the case with French/British cellist Juliette Alvin, American composer and pianist Paul Nordoff, or the Austrian violinist Editha Koffer-Ullrich (cf. Mössler, 2011), music therapists working with clients affected by pervasive developmental disorders have always been influenced by a variety of theories from different fields. Within the last three decades, these include educational and medical contexts, but also developmental psychology, neuropsychology, musicology, and psychotherapy (cf. Dimitriadis & Smeijsters, 2011). However, summarising almost 60 years of music therapy practice in the field of ASD, Reschke-Hernández (2011) argues that it is now especially

important to reinforce techniques unique to music therapy such as improvisation. Newer research illustrates efforts to closely examine both process and efficacy of such approaches (Kim, Wigram, & Gold, 2008, 2009; Thompson, McFerran, & Gold, 2013), and in recent years also research in neighbouring areas such as developmental psychology (e.g., Stern, 2010; Trevarthen, 1999) produced empirical support for ideas developed by music therapy pioneers decades ago.

1.7.3. SETTINGS OF MUSIC THERAPY APPLIED IN ASD

Gold, Wigram, and Elefant (2006) have mentioned that “[m]usic therapy for individuals with autistic spectrum disorders is usually provided as individual therapy” (p. 2). However, also other contexts of intervention have been reported, e.g. by Bryan (1989) who employed an improvisational music therapy group approach, by Oldfield (2006), Warwick (1995), and Wimpory and Nash (1999), where children with autism received music therapy with their mothers involved in treatment, or by Kaplan and Steele (2005) who comment on a variety of session types for individuals with ASD in a music therapy department (i.e., individual, but also partner, small groups of three to five subjects, large groups of six and above, and peer model).

Apart from providing music therapy in a dedicated (and, ideally, appropriately equipped) therapy room, music therapists may also embed their intervention into classroom, community, or home settings (e.g., Kern & Aldridge, 2006; Kern, Wolery, & Aldridge, 2007; Pasiali, 2004, although these studies do not comply with the narrower definition of music therapy used in this study as described in section 1.7.1.). Family-centred music therapy in the home environment is also described in the study of Thompson (2012).

Within this study’s RCT, music therapy for children with ASD was provided in an individual setting in a private music therapy practice in Vienna, Austria.

1.7.4. RESEARCH ON MUSIC THERAPY FOR ASD

Music therapy has been applied for people with ASD for decades, but there is still only limited evidence showing its effects in generalisable ways – even though the same is true for most of the many other intervention techniques reported, as Wheeler et al. (2008) conclude in their overview of Cochrane reviews:

There is as yet no clear evidence of benefit following treatment for ASD reported in any Cochrane review. Research in autism is in a period of growth and development, and more good quality trials are needed to clarify if this means that the treatments that are the subject of this overview are not effective or that there is insufficient evidence to show true treatment effectiveness. (p. 13)

As can be seen from several reviews of publications on music therapy for ASD (Accordino et al., 2007; Reschke-Hernández, 2011; Wigram, 2002), and as is the typical case in emerging forms of treatment, most of the early music therapy literature on autism was published in clinical reports, case studies, or case control studies (e.g., Alvin, 1978; Goldstein, 1964; Mahlberg, 1973; Nordoff & Robbins, 1977; Saperston, 1973; Stevens & Clark, 1969).

Single case or small group studies conducted until today continue to contribute to the understanding of relevant processes within therapy, to inform clinical practice, and to provide evidence as to what kind of intervention may be appropriate for more rigorous, large-scale, and typically more expensive research efforts. For instance, in a thorough account of relationship patterns observed in children with ASD, qualitative investigations into children's changes within music therapy were presented by Schumacher (1999) and Schumacher and Calvet-Kruppa (1999); Holck (2002, 2004) presented findings based on video micro-analysis that showed specific characteristics and functions of interaction between child and therapist in music therapy; Carpenter (2009) presented detailed descriptions of four children's development within Nordoff-Robbins music therapy; Plahl (2000) conducted detailed investigations on different areas of development in music therapy such as pre-verbal communication, also utilising detailed video analysis as well as other sources of information such as rating scales, psychological tests, and interviews with parents.

Edgerton (1994) presented evidence from a study involving 11 subjects suggesting improvisational music therapy's effectiveness in increasing communicative behaviour of children with autism. Edgerton's study can be viewed as influential in terms of conducting empirical research involving higher numbers of participants on highly individualised techniques such as music therapy because, as Accordino et al. (2007) comment, "[t]his empirical investigation shows that such studies can effectively take place in the field without diminishing the individual nature of the therapy" (p. 107).

Other studies of a more experimental nature include Brownell (2002), Buday (1995), Farmer (2003), Hairston (1990), and Pasiali (2004), but various

methodological flaws such as low sample sizes, inadequate designs, and high variability in interventions applied seriously limit the interpretation of the results within a larger context.

To examine possibly relevant factors found in case and small group studies in a broader context, research strategies need to avoid inherent bias by employing suitable designs and statistical analyses to test the significance of any changes through interventions. The most rigorous way to deal with unmeasured confounding factors is a randomised controlled trial (RCT).

Consistent with the definition of music therapy for this study as given above, the remaining part of this section will present approaches that use music as a means within a relationship-oriented context and delivered by trained music therapists; it will not include any details on interventions that involve only listening to music such as auditory integration training or other sound therapies (for an overview, see Sinha, Silove, Williams, & Hayen, 2004), or interventions where music is used as auditory stimulus to regulate behaviour (e.g., Orr, Myles, & Carlson, 1998).

Following systematic reviews in the field of music therapy and other interventions (Gold, Wigram, & Elefant, 2006; Wheeler et al., 2008) that highlighted important directions for future research in the field of music therapy for ASD, there have been increased efforts to conduct more rigorous studies within recent years (Kim, Wigram, & Gold, 2008, 2009; Gattino, Riesgo, Longo, Leite, & Faccini, 2011; Thompson, McFerran, & Gold, 2013).

An comprehensive analysis of relevant outcome studies (RCTs and controlled clinical trials/CCTs) of music therapy within ASD is presented in the systematic review that is part of this thesis (cf. section 4.1. & Part B, I).

An interesting feature of previous research on music therapy for ASD is the age distribution of participants under investigation: Simpson & Keen (2011) report that in their review of 20 studies of music interventions which also included music therapy studies, “[t]he use of music interventions with individuals with autism predominantly focused on young children (3–11 years), with only 2 of the 106 participants in the adolescent age range (12–18 years)” (p. 1512). While it is reasonable to provide interventions as early as possible to optimise developmental outcomes, with the present study following the same rationale, the scarcity of published research involving older individuals with ASD leaves much uncertainty as to music therapy’s effectiveness for adolescents and beyond.

1.8. IMPROVISATIONAL MUSIC THERAPY (IMT)

Communication relies on a shared context. Without some kind of basic common ground and shared “channels”, individuals will not be able to create meaning through shared interactions. In the beginning of a human being’s life, infants are helped by their caregivers to get to know this specific shared context and to learn about it through continual interaction which provides endless amounts of social stimuli. Typically developing children display selective orientation to and often surprisingly coordinated responses to those stimuli. In that way, they can readily make use of them, gradually acquiring increasingly effective ways of communicating their needs, sharing their emotional states, and influencing their surroundings, thus developing a sense of self-efficacy.

Trevarthen (1999) writes that “[t]he core of being human is living in a fabric of meaning generated by others of our kind” (p. 170). Improvisational music therapy has been noted for its potential to utilise such a jointly developed context of meaning, thus offering a framework for developmental progress.

Gold, Wigram, and Elefant (2006) have commented on improvisational music therapy as effective medium not only to engage individuals with autism in social interaction, but also to provide opportunities for various communicative behaviours through active music making between the child and the therapist. As already mentioned above, the joint context in a relationship between music therapist and client is similar to early mother-infant interaction in presenting features that are relevant to social interaction: a shared history of interaction, plenty of opportunities to establish joint attention, reciprocity and turn-taking, and musical and emotional attunement (cf. Holck, 2002; Kim, 2006; Wigram & Gold, 2006; Wigram & Elefant, 2008). In this sense, it is also important to note that in developmental approaches such as improvisational music therapy, the client’s behaviour is usually seen as communication and/or a means of self-regulation (cf. Casenhiser, Shanker, & Stieben, 2013; Schumacher, 1999; Stern, 2010).

Although improvisational forms of music therapy have been applied in the treatment of individuals with ASD over decades, and have been described by clinicians and researchers from various countries, common characteristics of this approach in its various manifestations have not been succinctly summarised as yet.

For the present study's RCT with its context of pre-school aged children with ASD in an individual setting, initially the following working definition of improvisational music therapy was used (also see the description within the study protocol, Part B, II):

Improvisational music therapy is a child-centred approach where a trained therapist uses music experiences and the relationship that develops through them to facilitate growth in the child's social communicative skills and promote development in other areas of need, such as developing awareness and attention, a sense of self, or promoting self-efficacy; it is based on active, spontaneous music making with the therapist generally following the child's focus of attention, behaviours, and interests.

In his/her musical expression, the therapist is closely attuned to the child's immediate display of (musical or other) behaviour and/or emotional expression. Improvisational techniques may involve imitation, variation, elaboration, regulation, support, responding, or contextualization; in musical terms, this may involve matching, sustaining, or complementing "musical" features of the child's behaviour (pulse, rhythmic pattern, dynamic or melodic contour, timbre), thus creating moments of synchronisation and "meeting" (adopted from Bruscia, 1998; Kim, 2006; Schumacher, 1999; Wigram, 2002; Wigram & Gold, 2006).

During the course of the study, this preliminary definition was elaborated by developing an international consensus model and treatment guide as described extensively in the third article presented in this volume (see Part B, III).

2. RESEARCH QUESTIONS

Based on previous research findings and gaps in knowledge as described in Chapter 1 and the background sections of this thesis' articles (see Part B), this PhD study was aimed at investigating the following main research question:

- 1) Does music therapy positively influence social communication in children with autism spectrum disorder?

As almost every component of this combination (“music therapy”, “promote”, “social communication”, “autism spectrum disorder”) relates to a broad concept comprising various presentations, it is impossible to address this overall question in an exhaustive manner. Therefore, the corresponding subquestions that were guiding the study were specified as follows:

- 2a) Is music therapy superior to standard care in improving social communicative skills in children with ASD as assessed by independent clinicians at the end of the treatment period?
- 2b) Is music therapy superior to standard care in improving social responsiveness in children with ASD as assessed by parents/caregivers at the end of the treatment period?
- 2c) Does the response to music therapy vary with variation of treatment intensity (i.e., number of music therapy sessions per week)?
- 2d) Are any differences in social communicative skills between the music therapy and standard care groups retained at follow-up twelve months after randomisation?

Complementing these questions on effects of music therapy, methodological aspects were addressed by research questions 3) to 5):

- 3) How can the clinical method of improvisational music therapy as applied within ASD be adequately described in a treatment guide to be flexibly applied in research on clinical practice?
- 4) Which developmental pathways of individual children can be discerned within the setting of a rigorously designed study involving a predefined treatment duration?

- 5) Which obstacles and benefits are encountered when implementing an RCT that is designed as a pragmatic trial closely linked to actual clinical practice and conducted in collaboration with various institutions and experts?

In addition to these questions presented above that were formulated at the outset of the PhD study, two additional questions developed during the study:

- 6) What is the evidence about the overall effects of music therapy in people with ASD when comparing music therapy or music therapy in addition to standard care to no therapy, similar treatment without music ('placebo' therapy), or standard care?
- 7) How do recruitment, implementation of intervention and control conditions, assessment procedures, safety, and retention turn out in the present pilot cohort?

The research questions were addressed in several articles:

- I. A systematic review (update of a Cochrane Review) was performed to synthesise the overall worldwide evidence to date on effects of music therapy for individuals with ASD.
- II. The design of TIME-A, an RCT examining effects of improvisational music therapy on social communication skills in children with ASD aged 4 to 7, was specified in a study protocol.
- III. An international consensus model of improvisational music therapy for children with ASD was described in a treatment guide.
- IV. Data from this PhD study's clinical trial, which also serves as the internal pilot cohort of the ongoing international multi-centre project TIME-A, were summarised in a feasibility study.

2.1. EPISTEMOLOGICAL & ONTOLOGICAL PERSPECTIVES

As described above in section 1.3.2., as a student and researcher I have been dealing with quantitative research methodology much more than with qualitative approaches. However, it is my firm belief and also reflects my experience of discussing other researchers' projects that design and methods chosen within a study are naturally determined by the type of questions researchers want to examine through their study (cf. Bonde, 2014; Wigram, Pedersen, & Bonde, 2002).

Thus, in this PhD study, quantitative methodology using fixed designs (research questions 2, 6 & 7), and qualitative approaches of a more evolutionary, flexible nature (research questions 3, 4 & 5) were combined (Robson, 2002) in order to explore the overall question.

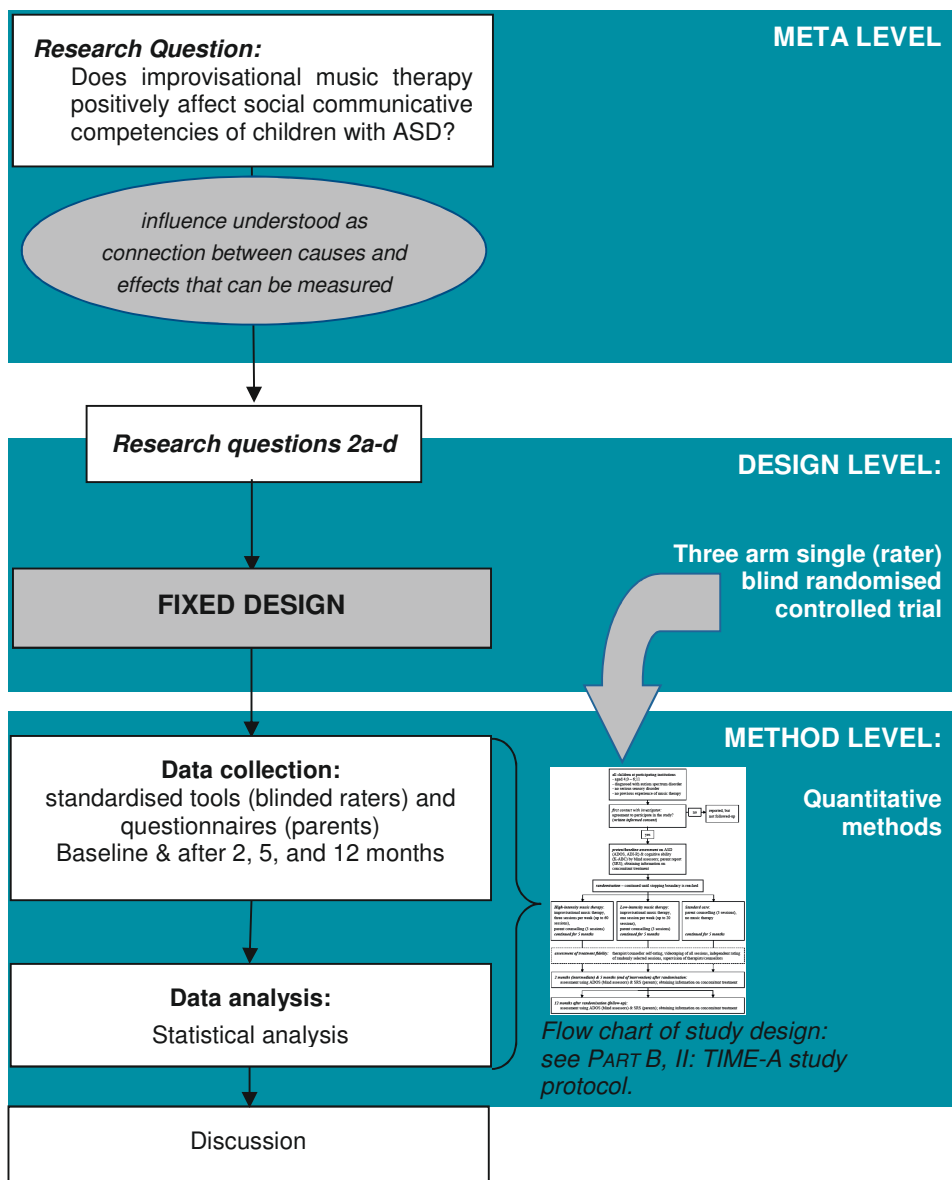
Music therapy as a profession has developed out of empirical practice, generating theory and knowledge both from within itself and by integrating ideas and models from other disciplines (Wigram, 1999; cf. also sections 1.7.2. and 1.7.4.). As an own branch of research at a scientific level, and as an established health care profession, music therapy today finds itself within a field where evidence-based practice (EBP) has become a weighty issue in clinical research and health care policies. It is, however, crucial to note that the best available scientific evidence, which is sometimes mistakenly seen as the decisive component of EBP, has two equally important companions in evidence-based treatment of clients: the therapist's clinical expertise, and client values and wishes (cf. Vink & Bruinsma, 2003).

With this in mind, it was important in developing this study that although rigorous methodological standards are followed in the research design of the RCT, the subject matter of it is music therapy as it is conducted in the field of children with ASD in everyday clinical practice (as opposed to highly experimental conditions), emphasising the pragmatic orientation of the study as presented in the study protocol and feasibility study (see Part B).

Firmly rooted in clinical practice with the aim of generating findings of high clinical relevance, the study's overall question is centred on whether music therapy may help to promote social communication in children with ASD. Especially in the part of the study that was initially its centre and later moved on to be addressed within the international multi-site research project TIME-A, i.e. the RCT (see research questions 2a to 2d above), the main question is not about processes, but about effects of a certain approach (improvisational music therapy) on social communication skills in children with ASD. Thus, these questions clearly require a quantitative approach and a fixed design as illustrated in Figure 2-1 (see next page).

As within any research, careful consideration is needed regarding validity and reliability of findings, i.e. ensuring that the study is able to answer the questions initially posed and that findings are not based on random variation; efforts undertaken in the RCT study design to fulfil these requirements are described in the study protocol (see Part B, II), along with considerations and definitions of social communicative skills and improvisational music therapy given in sections 1.6.1 and 1.8.

Figure 2-1 *Graphic overview (simplified) of the RCT research design*
(adopted from Bonde, 2014)



Quantitative methods corresponding to the same meta level (“influence understood as connection between causes and effects that can be measured”; cf. Bonde, 2014) were also employed in the systematic review (see research question 6, and Part B, I).

In the development of the treatment guide (see Part B, III), a flexible design was used to incorporate expertise from experienced clinicians and researchers in the field, and to find appropriate links between improvisational music therapy techniques and related areas typically targeted in ASD. The design included a survey and focus groups yielding some numeric, but mainly descriptive data. In this study, the treatment guide and the resulting tool to assess treatment fidelity were preliminarily evaluated concerning feasibility and applicability. An extensive integration of this qualitative part with quantitative data from this PhD study’s RCT or other sources is beyond the scope of this thesis and remains to be examined in other studies.

Descriptive data addressing research questions 4 and 5 about individual children’s development and RCT implementation issues are presented within the feasibility study (Part B, IV). They provide possible explanations and validation for the quantitative findings on feasibility and acceptability.

3. METHOD AND DESIGN SPECIFICS OF THIS PHD STUDY

For the clinical trial (articles II and IV in Part B), the rationale behind choices made in the design, protocol modifications necessary to fit this PhD project's scale and scope, and details with regard to the local implementation of the protocol are explained in the following sections. A description of methodological aspects of the development of the treatment guide (article III in Part B) is given in section 3.3. Details of the methodology used for the systematic review (article I in Part B) are specified therein.

3.1. PRACTICAL ASPECTS OF THE RCT

The overall design that was followed within this PhD study's clinical trial is described in the study protocol article as reprinted in Part B, I (Geretsegger, Holck, & Gold, 2012). The protocol defined in this article addresses an international multi-site RCT (principal investigator: Christian Gold, who also served as one of the two supervisors of this PhD study) to be conducted in several countries with a targeted sample size of $n = 300$. This international RCT called TIME-A is still ongoing at the time of this PhD thesis' submission, and to date includes a total of nine countries worldwide. As no major protocol amendments were required (cf. Part B, IV), data collected during this PhD study's internal pilot RCT in Vienna/Austria will be included in the main TIME-A study (see also section 3.1.1.).

3.1.1. RELATION OF THIS PILOT STUDY TO THE INTERNATIONAL STUDY TIME-A

It was self-evident from the beginning that the sample size as resulting from the power calculation in the study protocol ($n = 300$, cf. Part B, II) could not be achieved within the time, budget, and personnel bounds of this PhD study. In lieu thereof, the rationale for the number of participants aimed for within this study was initially given as follows: As there is evidence suggesting that improvisational music therapy for children with ASD be beneficial with regard to improvement in social communication skills (Kim, 2006; Kim, Wigram, & Gold, 2008, 2009), one-sided hypothesis testing will be applied. With a targeted

effect size of $d = 0.8$ between ADOS scores of both music therapy groups taken together compared to the control group (a strong assumption, but viewed as possible), and based on approximately 80% power to detect a significant difference ($P < 0.05$), a total of 45 participants would have been required. With an assumed drop-out and loss-to-follow-up rate of around 10%, 50 participants would have been required for randomisation.

Since the estimated costs for assessments and therapies of this number of participants still exceeded the funds available for this PhD study, it was started with a target sample of 16 participants (four children per intervention group; eight children in the standard care condition) and with myself conducting all music therapy and parent counselling sessions. With this sample size, test power was considered limited; the trial's results would however be valuable as an exploratory study examining feasibility and acceptability of the study protocol, and as an internal pilot cohort for the large-scale multi-centre RCT TIME-A.

3.1.2. FUNDING

The majority of the research costs of this PhD study were covered by a PhD Mobility Fellowship from the Doctoral Programme of Music Therapy, Faculty of Humanities, Aalborg University, which was awarded to the researcher for the period from November 1, 2010 until October 31, 2014.

The trial's main cost factors were assessments (fees for clinical psychologists conducting external ASD diagnostics and outcome assessments) and interventions (fees for the person administering music therapy and parent counselling). As I carried out all music therapy as well as counselling sessions myself (see previous section and Part B, IV), the interventions incurred no additional expenses.

Acquiring additional third-party funding from research councils, local authorities, or other parties within Austria or abroad were considered beneficial for the study; improvements considered possible included recruiting a higher number of participants to increase statistical power, and employing an additional music therapist to conduct some of the therapies, thus enhancing external validity.

Two grant proposals were submitted in January and April 2011, respectively (one in response to the Austrian Science Fund's call within its clinical research funding initiative, and one to the Andreas-Tobias-Kind Foundation based in Hamburg, Germany), but were rejected.

More funding became available for the RCT within this PhD study however when the main trial TIME-A received funding from The Research Council of Norway in 2011. As a consequence, all costs involved in data collection could be covered, and acquiring further third-party funding for this PhD study was not considered necessary anymore.

3.2. IMPLEMENTATION OF THE STUDY PROTOCOL FOR THIS PILOT STUDY

3.2.1. DATA COLLECTION

Regarding the data collection for the RCT part of this study, eligibility criteria for children to participate in the study are defined and explained in the study protocol (see Part B, II). It was decided to choose relatively broad selection criteria (e.g., including children regardless of any cognitive and/or language impairment) in order to comply with the study's primary orientation towards research that is closely linked with, based on, and relevant to clinical practice as opposed to more experimental forms of research where it is usually attempted to exclude any potentially confounding variables.

Similarly, no specific requirements were defined for participants with regard to their use of any other services or concomitant treatment, be it medication or other therapeutic or educational interventions, although this might be connected to a decrease in statistical power. Apart from ethical considerations (it would be questionable to ask participants to refrain from intervention measures that might be beneficial to them), this decision also enhances the trial's primary orientation as a more "pragmatic" than "explanatory" study (cf. Thorpe et al., 2009) in that restrictions on participant selection are minimised and the full range of variety within the population may be represented in the sample.

Before formal enrolment, participants' diagnosis of ASD needed to be reconfirmed in the baseline assessment with children fulfilling diagnostic criteria for ASD on both the Autism Diagnostic Interview-Revised (ADI-R) and the Autism Diagnostic Observation Schedule (ADOS; cf. section 3.2.3., *Outcome measures*, and Part B, II), and informed consent by the child's parents/caregivers had to be obtained (see *Ethical aspects*, section 3.2.5.). If from non-German speaking backgrounds, parents' knowledge of German had to be sufficient for them to understand the information form, consent to participation, attend and contribute to baseline and follow-up assessments, and participate in parent counselling sessions.

Participants were recruited in Vienna/Austria from several institutions (a major national autism help organisation, children's development centres, and hospital departments; see details below). Parents in the greater area of Vienna with a child who is supposed to have some kind of developmental disorder are usually referred to one of these institutions e.g. by their general practitioner or a (kindergarten) teacher, or turn to one of these institutions themselves to seek advice, counselling and/or diagnostics. Children referred from these institutions were candidates for inclusion in the study if the eligibility criteria as defined in the study protocol were confirmed by myself, either during an initial telephone conversation, or in the introductory discussion that preceded informed consent and baseline assessments.

At the outset of this study, the following institutions consented to assist in recruitment by referring potential study participants:

- (1) **ÖAH – Österreichische Autistenhilfe** [Austrian Autistic People's Aid]
1010 Vienna, Eßlinggasse 17
www.autistenhilfe.at
Contact person: Mag. Carolin Steidl
- (2) **Universitätsklinik für Kinder- und Jugendheilkunde** [Department of Paediatrics and Adolescent Medicine at the Medical University of Vienna/Vienna General Hospital]
1090 Vienna, Währinger Gürtel 18-20
www.meduniwien.ac.at/kinderklinik
Contact person: Dr. Kathrin Hippler
- (3) **Ambulatorium Fernkorngasse der VKKJ**, Zentrum für Entwicklungsneurologie und Sozialpädiatrie [Outpatient clinic, Centre of developmental neurology and social paediatrics]
1100 Vienna, Fernkorngasse 91
www.vkkj.at/ambulatorien/fernkorgasse
Contact person: Prim. Dr. Klaus Vavrik
- (4) **Kinder- und Jugendpsychiatrische Abteilung, Neurologisches Zentrum Rosenhügel** [Department of Child and Adolescent Psychiatry, Neurological Hospital Rosenhügel]
1130 Vienna, Riedelgasse 5/Pavillon C
www.wienkav.at/kav/khl/medstellen_anzeigen.asp?ID=84
Contact person: Prim. Dr. Ralf Gößler

- (5) **Ambulatorium Strebersdorf der VKKJ**, Zentrum für Entwicklungsneurologie und Sozialpädiatrie [Outpatient clinic, Centre of developmental neurology and social paediatrics]
1210 Vienna, Jara-Benes-Gasse 16
www.vkkj.at/ambulatorien/strebersdorf
Contact person: Prim. Dr. Lenka Stejfova

- (6) **ZEF – Zentrum für Entwicklungsförderung** [Centre of development advancement]
1220 Vienna, Langobardenstraße 189
www.wienersozialdienste.at/unsere-dienstleistungen/foerderung-und-begleitung/zentren-fuer-entwicklungsforderung.html
Contact person: Prim. Dr. Friedrich Brandstetter

One further local development centre that I had contacted decided not to collaborate with this study, as the fixed duration of music therapy of no longer than five months did not fit the centre's approach of building relationships with and providing services for children with ASD for longer periods of time.

3.2.2. INTERVENTIONS

As mentioned above, I acted as the music therapist providing improvisational music therapy sessions for participants of this pilot cohort. According to the requirements of the study protocol (Part B, II), all sessions were videotaped. Two cameras in opposite corners of the room were used to cover as much of the session as possible. After each session, I completed a brief self-developed form of session notes (see Appendix F) including ratings of frequency for several categories of intervention techniques applied, the child's vocal expression and use of instruments, and the child's social communication behaviour; additionally, I noted down interaction themes, difficult situations that might have occurred, and significant moments during the session. Apart from fulfilling the occupational duty of documentation, these session notes served as memory aid for the therapist herself and also as a basis for evaluation over the course of therapy.

I also acted as the parent counsellor for all families within the pilot cohort. Parent counselling sessions were conducted as described in the study protocol (Part B, II); for parents whose children were receiving music therapy, sessions could also be used to discuss their child's experience within and outside of music therapy sessions.

3.2.3. OUTCOME MEASURES

Measures applied for evaluating outcome are described in the study protocol (Part B, II). As specified therein, the ADOS (Lord, Rutter, DiLavore, & Risi, 2001) as a widely used and validated scale was chosen as primary outcome. It is a standardised observation instrument in which core features of ASD are assessed through play-based interactions between a child and a trained clinician. Although the ADOS was initially developed for the purpose of diagnosis, it has been used as measure of change in previous studies (e.g., Aldred, Green, & Adams, 2004; Green et al., 2010; Owley et al., 2001). Adaptations to the scoring procedure applied in order to increase sensitivity to change are described in the study protocol.

At the time during the course of data collection for this pilot cohort when the TIME-A study protocol was also starting to be implemented in other countries, a factor that was not initially considered became apparent: While in Austria, the ADOS scoring sheet applied in clinical practice based on the German ADOS version (Rühl, Bölte, Feineis-Matthews, & Poustka, 2005) still yielded a score called “Communication + Social Interaction”, ADOS versions commonly used in other countries (i.e., the revised ADOS-G; Gotham, Risi, Pickles, & Lord, 2007) resulted in the “Social Affect” score which comprised a similar, but not completely congruent selection of items from the domains “Communication” and “Reciprocal Social Interaction”. Hence, a minor protocol modification was necessary for the international study, and items included in the “Social Affect” score that were not part of the “Communication + Social Interaction” algorithm and therefore not scored for the first few participants in Austria needed to be scored retrospectively where possible or resulted in missing values (cf. Part B, IV, Figure 4).

3.2.4. DATA ANALYSIS

Methods of data analysis used within the systematic review (Part B, I) and the feasibility study (Part B, IV) are described in detail therein, respectively.

Complementing these analyses, some additional data were analysed for this thesis and are presented in Chapter 5: In order to examine proportions of various techniques applied within improvisational music therapy sessions provided for this study’s participants, ratings in the corresponding section of the session notes form (see Appendix F) were counted and pooled across all sessions.

Additionally, data from the therapist's self-ratings regarding the amount of structuring and/or directive activities provided during sessions, and regarding the therapist's experience of how demanding the sessions were for her were analysed graphically.

In order to examine characteristics of the children's behaviour within music therapy sessions, proportions of therapist ratings of their vocal expression, their use of instruments, and their social-communicative behaviour were also analysed by pooling scores across all sessions.

3.2.5. ETHICAL ASPECTS

The study protocol was approved by the Faculty of Humanities' Human Research Ethics Board (HREB) at Aalborg University, Denmark, "to project a low-risk research project with adequate ethical considerations taken into account" (HREB #201107, date of approval: August 8, 2011; see Appendix A).¹

For participant recruitment at two collaborating institutions, an additional approval from the Medical University of Vienna's ethics commission was necessary; they approved the study on January 12, 2012 (EK number 238/2011, see Appendix B).

3.3. METHODOLOGICAL ASPECTS OF DEVELOPING THE TREATMENT GUIDE

Methods applied in the process of developing the consensus model and treatment guide for improvisational music therapy for children with ASD are described in the corresponding article (Part B, III); some additional information is given below.

¹ Earlier attempts to receive ethics approval from local (Austrian) ethics committees had turned out unsuccessful due to diverse reasons: the Faculty of Psychology's Ethics Committee at the University of Vienna ceased to exist on December 31, 2010, with its projected successive board (University of Vienna's Ethics Committee) still not operating in August 2011; a submission for ethical approval at the Ethikkommission der Stadt Wien [Ethics Committee of the City of Vienna] on April 18, 2011, was refused a formal review with the committee claiming not to be in charge for this type of (non-pharmaceutical/non-biomedical) study as this project was not subject to Austrian regulatory requirements for clinical trials (Medicinal Products Act; Medical Devices Act).

Following the approach of Waltz, Addis, Koerner, and Jacobson (1993) of establishing core principles that are guiding an intervention, we initially collected and extracted relevant items from existing literature on improvisational music therapy techniques for ASD. After relating them to areas typically targeted in ASD, I drafted a treatment guide that listed preliminary principles and for each stated its purpose/rationale within the context of children with ASD, corresponding attitudes of the therapist, categories of activities, and brief examples from clinical practice. Together with the co-authors collaborating on this study (Christian Gold, Ulla Holck, John Carpenter, Cochavit Elefant, and Jinah Kim), we discussed and refined this systematisation and from that developed a survey about comprehensibility, clinical validity, and acceptability of each principle. Appendix H presents the questionnaire used for the survey, and an example of the invitation letter to prospective survey participants is reproduced in Appendix G.

The invitation to participate in the survey was sent out to a total of 42 music therapists experienced in using improvisational music therapy techniques. Music therapists with a strong background in research and/or clinical practice were contacted to help making the treatment guide meaningful and appropriate for research contexts as well as everyday clinical practice. Addressees were identified using the TIME-A network of collaborators: site managers of participating countries (Australia, Brazil, Israel, Italy, Norway, Korea, United Kingdom, and USA) were requested to nominate eligible colleagues and to provide contact details where available. In addition, contact persons related to this study in Denmark and Germany were contacted with the same request.

In addition to the survey, focus groups with experienced clinicians were conducted in Austria, Italy, and Korea. Participants were recruited in a similar way. Procedures applied within the focus group workshops included assigning principles to categories of “unique”, “essential”, “compatible” and “proscribed”, discussing the proposed principles and connected attitudes and techniques in the context of case vignettes provided by the group participants, and collecting aspects that group participants felt were missing from the preliminary treatment guide.

4. SUMMARY OF ARTICLES INCLUDED IN THIS THESIS

Following the order of articles described above (see 1.4.), the contents of published and submitted manuscripts are summarised below.

4.1. SYSTEMATIC REVIEW

This review (Geretsegger, Elefant, Mössler, & Gold, 2014) was conducted following the requirements of the Cochrane Collaboration and summarises the worldwide evidence of effects of music therapy for individuals with autism spectrum disorder to date. It is an update of the initial Cochrane review entitled 'Music therapy for autistic spectrum disorder' published in 2006 by Christian Gold, Tony Wigram, and Cochavit Elefant, and generally followed the same protocol (Gold & Wigram, 2003) with due consideration given to necessary amendments such as added search terms or adapted categories of outcome measures.

Relevant databases and other sources of pertinent references were searched in July 2013. All RCTs or controlled clinical trials comparing music therapy, or music therapy added to standard care, to 'placebo' therapy, no treatment, or standard care were considered for inclusion. Ten studies with a total number of 165 participants were included. The studies examined the short- and medium-term effect of music therapy interventions of one week to seven months for children with ASD.

Music therapy was superior to 'placebo' therapy or standard care with respect to core features of ASD including social interaction, non-verbal and verbal communicative skills, initiating behaviour, and social-emotional reciprocity. Music therapy was also superior to 'placebo' therapy or standard care in the secondary outcome areas social adaptation, joy, and the quality of parent-child relationships. None of the included studies reported any adverse effects.

The quality of the evidence was moderate for social interaction outside of the therapy context, initiating behaviour, social adaptation, and the quality of the parent-child relationship, and low for the other three main outcomes (non-verbal communicative skills outside of the therapy context, verbal communicative skills outside of the therapy context, and social-emotional reciprocity). Reasons for limited quality of the evidence were issues with study methodology and the small sample sizes of the studies.

In summary, the findings of this updated review provide evidence that music therapy may help children with ASD to improve their skills in primary outcome areas that constitute the core of the condition. In contrast to the studies included in an earlier version of this review published in 2006, the new studies included in this update enhanced the applicability of findings to clinical practice. More research using larger samples and generalised outcome measures is still needed to corroborate these findings and to examine whether the effects of music therapy are enduring.

When applying the results of this review to practice, it is important to note that the application of music therapy requires specialised academic and clinical training.

4.2. TIME-A STUDY PROTOCOL

This article (Geretsegger, Holck, & Gold, 2012) presents the rationale and design for a study examining the effects of improvisational music therapy on social communication skills of children with ASD. Additional aims of the study are to examine if variation in dose of treatment (i.e., number of music therapy sessions per week) affects outcome of therapy, and to determine cost-effectiveness.

The protocol provides for children aged between 4;0 and 6;11 years who are diagnosed with ASD to be randomly assigned to one of three conditions. Parents of all participants are to receive three sessions of parent counselling (at 0, 2, and 5 months). In addition, children randomised to the two intervention groups are to be offered individual, improvisational music therapy over a period of five months, either one session (low-intensity) or three sessions (high-intensity) per week. Generalised effects of music therapy are to be measured using standardised scales completed by blinded assessors (Autism Diagnostic Observation Schedule, ADOS) and parents (Social Responsiveness Scale, SRS) before and 2, 5, and 12 months after randomisation. Cost effectiveness is to be calculated as man years. A group sequential design with first interim look at $n = 235$ is to be applied to ensure both power and efficiency.

Responding to the need for more rigorously designed trials examining the effectiveness of music therapy in autism spectrum disorders, this pragmatic trial was designed to generate findings that are well generalisable to clinical practice. Addressing the issue of dose variation, this study's results will also provide information on the relevance of session frequency for therapy outcome.

4.3. IMT CONSENSUS MODEL / TREATMENT GUIDE

This manuscript submitted for publication (Geretsegger, Holck, Carpenter et al., 2014) presents the delineation of improvisational music therapy (IMT) as a relationship-based treatment approach within ASD. This approach has been widely used for children with ASD for several decades, and parts of it have been described by clinicians and researchers from various countries. However, common characteristics of its various manifestations in various countries worldwide have not been succinctly summarised as yet.

The aims of the study were to identify those common characteristics of IMT as practiced internationally in ASD, to describe a consensus model defining its core principles compared to general approaches within ASD interventions, and based on these to create and preliminarily evaluate a treatment guide that can be used within future research, clinical practice, and training.

A survey conducted in ten countries, supplemented with focus group workshops, yielded eight core principles defining IMT. The resulting treatment guide, along with a tool to assess treatment fidelity, operationalises these principles.

Findings suggest that the treatment guide can be successfully used to rate therapists' adherence to and competence in IMT, making it ready for assessing treatment fidelity, and for being applied to facilitate future research, clinical practice, and training. Thus, this study introduces more standardisation into a complex and flexible intervention approach, and may serve as a model to develop similar therapy guidelines in other areas of intervention.

4.4. FEASIBILITY STUDY / PILOT COHORT

This study (manuscript submitted for publication; Geretsegger, Holck, Bieleninik, & Gold, 2014) aimed to address the scarcity of feasibility studies on trials examining complex interventions. Feasibility and acceptability of study procedures from this PhD study's clinical trial, the internal pilot cohort of a multi-centre RCT on improvisational music therapy for ASD, were evaluated by examining recruitment, implementation of intervention and control conditions, assessment procedures, safety, and retention. Additionally, clinical outcomes for individual children were described to illustrate developmental trajectories with and without music therapy.

Randomisation, treatment fidelity, safety, and blinded assessment turned out as expected, and retention was perfect (attrition rate = 0%). However, recruitment turned out slower than expected, and acceptability was limited related to the high-intensity condition (i.e., three therapy sessions per week in locations other than the children's care facilities).

Clinical descriptions of three children's development within therapy related to independent observations by blinded assessors provided some insight into the complexity of individual developmental trajectories. This underlines the challenges involved in determining appropriate outcome measures and in interpreting results on individual and generalised levels.

Findings suggest that overall, the study was designed appropriately regarding the feasibility of study components. For future research on complex interventions, more reports on feasibility of study procedures are called for.

5. ADDITIONAL RESULTS

In addition to the results described within the articles, supplementary results are presented in this section. Therapist's ratings from session note forms (see Appendix F) on various aspects of the session, the therapist's experience, and the child's behaviour (cf. 3.2.4.) were pooled across all sessions provided for the seven children receiving music therapy in this PhD study's clinical trial.

With regard to the question also raised in the treatment guide article of whether what was provided within this study's clinical trial may be accurately called 'improvisational music therapy' (i.e., treatment fidelity), the therapist's self-reported ratings of broad therapeutic techniques (improvisation using instruments, improvisation using voice, techniques using movement or the body, etc.) as documented in the regularly completed session notes forms (see Appendix F) were pooled across all 175 sessions for which data were available (data for four sessions are missing because this part of the form had been left blank). Ratings were scored as follows: 0 = 'not at all', 1 = 'a little/sometimes', 2 = 'a lot/often'.

Results are presented in Table 5-1 below: Techniques that were applied most often included improvisation on instruments (mean = 1.43), improvisation using voice and instruments together (1.42), verbal techniques (1.14), and vocal improvisation (0.98). These were followed by allowing for pauses (0.69) and techniques that centred on movement or the child's or therapist's body parts without being necessarily accompanied by music (0.55). Other techniques such as playing with books or picture cards were only rarely applied (0.14). Overall, this brief analysis supports the findings reported in the treatment guide article where material from this PhD study's clinical trial was used (see Part B, III) indicating the therapist's sufficient adherence to improvisational music therapy.

Table 5-1 *Therapist-reported frequency ratings for techniques applied within music therapy sessions*

	mean	standard deviation
improvisation on instrument(s)	1.43	.52
voice improvisation	.98	.52
improvisation using voice and instrument(s)	1.42	.53
movement/body	.55	.55
pause	.69	.47
verbal	1.14	.35
other	.14	.37

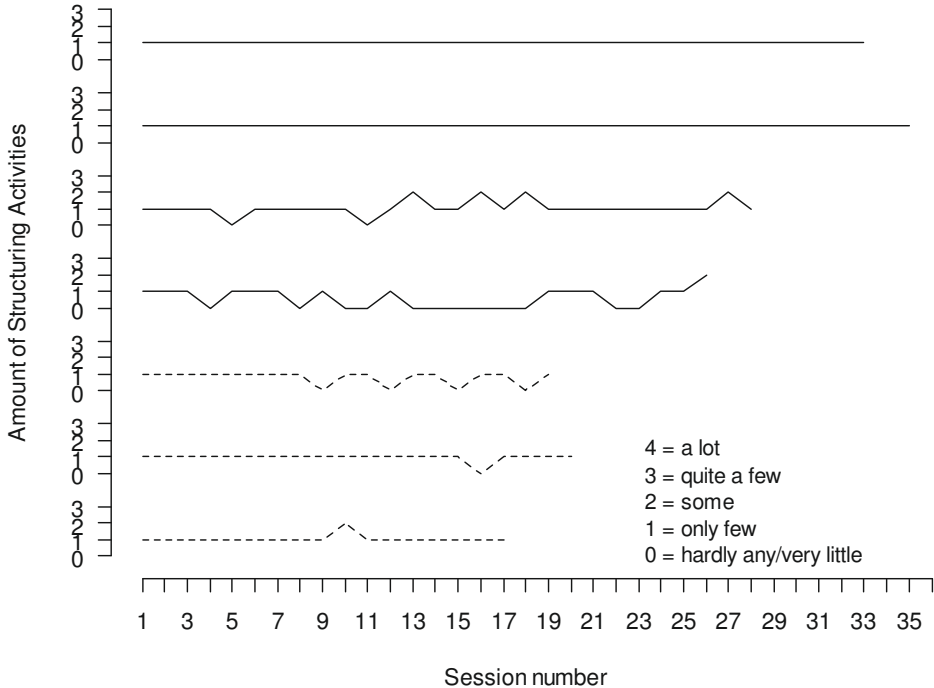
Note. Ratings of 0 corresponded to ‘not applied at all’, 1 to ‘applied a little/sometimes’, and 2 to ‘applied a lot/often’.

Concerning the therapist’s self-ratings of the amount of structuring and/or directive activities provided during sessions, data were processed graphically resulting in Figure 5-1 (see below).

Examples for structuring/directive activities are offering the child a choice of instrument or activity, preventing the child from hurting him/herself, or guiding the child back to the therapy room if s/he has left the room ahead of the scheduled time.

Predominantly, the therapist used ‘only few’ structuring/directive activities (corresponding to a rating of 1), and never used the scores 3 or 4 (‘quite a few’ and ‘a lot’, respectively) to describe the level of structuring/directive activities within a session. This is in line with the child-centred orientation of the approach and further emphasises the therapist’s adherence to its principles, in this case to the one categorised as essential (Geretsegger, Holck, Carpenste et al., 2014), “follow the child’s lead”.

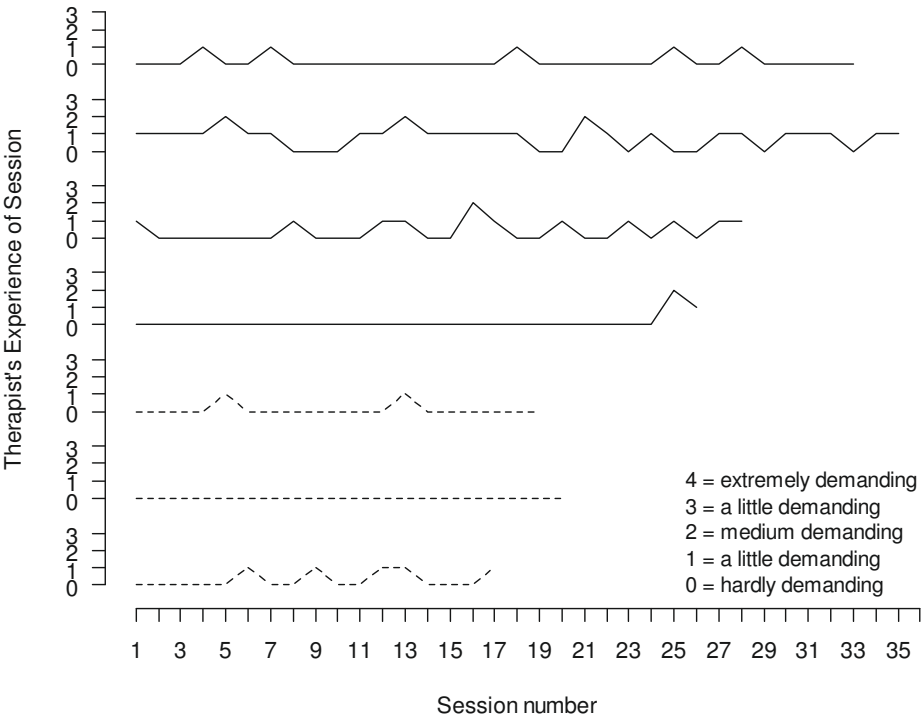
Figure 5-1 *Therapist's self-rated scores regarding amount of structuring/directive activities provided during session by participant*



Note. Solid lines represent participants in the high-intensity condition (who were offered 3 sessions of music therapy per week), dashed lines represent participants in the low-intensity condition (offered 1 session of music therapy per week). For purposes of readability and because it was never used, the possible score of 4 is not displayed on the y-axis.

Regarding the therapist's experience of how demanding the sessions were for her, scores from 0 ('hardly demanding') to 2 ('medium demanding') were used, see Figure 5-2 below. Like in the previous figure, it is interesting but not surprising to see that with some children, therapeutic challenges seem to have been very low throughout, while in others, there is some variability in the level of demand on the therapist and in the required level of directive activities.

Figure 5-2 *Therapist’s self-rated scores regarding levels of demand during session by participant*



Note. Solid lines represent participants in the high-intensity condition (who were offered 3 sessions of music therapy per week), dashed lines represent participants in the low-intensity condition (offered 1 session of music therapy per week). For purposes of readability and because it was never used, the possible score of 4 is not displayed on the y-axis.

Means of therapist ratings of the children’s behaviour within music therapy sessions are presented in the following Tables 5-2, 5-3, and 5-4.

Table 5-2 *Therapist's ratings of the children's vocal expression within music therapy sessions*

	mean	standard deviation
cooing / babbling / vocalising	.85	.88
single syllables / (proto-)words	.66	.71
multi-word phrases	.81	.89
echolalia	.21	.41
humming / singing	.64	.60
screaming / crying	.08	.30
other	.07	.27

Note. Ratings of 0 corresponded to 'not at all', 1 to 'a little/sometimes', and 2 to 'a lot/often'.

Proportions of therapist ratings from 179 available sessions show that the most frequent modes of children's vocal expression were 'cooing / babbling / vocalising' (mean = .85), and 'multi-word phrases' (.81); it is plausible that those ratings mostly refer to the subgroups of so-called "non-verbal" children and those children that have already developed verbal language, respectively. The types of vocal expression that followed in frequency were 'single syllables / (proto-)words' (.66) and 'humming / singing' (.64). Echolalia only occurred to a small extent (.21), and there was almost no 'screaming / crying' (.08) or other form of vocal expression (.07).

Regarding the children's use of instruments during sessions, therapist ratings reflect not only frequency of use, but also whether the instrument was used in a 'sensorial' manner (i.e., a sometimes mechanical way of use where the child seems focussed on for example tactile sensation or the instrument's construction), or more 'musically', as a means of expression. Ratings presented in Table 5-3 below show that drums tended to be used in an expressive manner the most (mean = 1.40), followed by keyboard instruments (1.15), small percussion instruments (1.05), and stringed instruments (1.00). Mean ratings below 1.00 indicate that instruments or other objects were either not used in the majority of sessions, or used in a way that focussed on object properties (e.g., taking apart a xylophone, scratching the ribbed surface of a radiator).

Table 5-3 *Therapist's ratings of the children's use of instruments within music therapy sessions*

	mean	standard deviation
small percussion	1.05	.78
drums	1.40	.81
xylophones etc.	.99	.91
string instruments	1.00	.84
keyboard instruments	1.15	.85
furniture	.16	.38
other	.39	.60

Note. Ratings of 0 corresponded to 'not used', 1 to 'sensorially' / focussing on object properties', and 2 to 'musically / as a means of expression'.

Finally, pooled data from 178 available sessions on children's social-communicative behaviour within sessions indicate the highest frequencies for 'reaction to therapist or joint activity' (mean = 1.26), 'joint attention' (1.03), and imitation (1.00). Children were only rarely observed to initiate interaction (.31), which is in line with common symptomatology associated with ASD (see Table 5-4 below).

Table 5-4 *Therapist's ratings of the children's social-communicative behaviour within music therapy sessions*

	mean	standard deviation
stereotyped behaviour	.75	.54
reaction to therapist or joint activity	1.26	.50
emotional sharing / shared affect	.75	.58
imitation	1.00	.51
joint attention	1.03	.54
expectation towards therapist	.62	.51
initiation of interaction	.31	.48
other	.01	.08

Note. Ratings of 0 corresponded to 'not at all', 1 to 'a little/sometimes', and 2 to 'a lot/often'.

6. DISCUSSION

6.1. MAIN FINDINGS

This PhD study aimed to investigate if and how music therapy promotes social communication skills in children with autism spectrum disorder.

Consistent with the fact mentioned above (see Chapter 2) that by addressing this topic, several complex and comprehensive areas need to be interrelated with each other, this study may be considered as a connecting link within the large and long-term collaborative efforts to understand and develop music therapy as a means to promote social communication in individuals with ASD.

As this PhD study was conducted as an article-based thesis, its main findings may be outlined by interconnecting its articles' findings. They are summarised as follows:

The results of the systematic review (Geretsegger, Elefant, Mössler, & Gold, 2014) provided evidence for the effectiveness of music therapy for core areas of ASD including social interaction, non-verbal and verbal communicative skills, initiating behaviour, and social-emotional reciprocity. Benefits of music therapy were also found for areas that may be considered particularly important for individuals with ASD and those around them such as social adaptation, joy, and the quality of parent-child relationships.

Despite these promising results, the evidence provided is still considered as being of only low to moderate quality due to methodological limitations of the studies included in this review such as small sample sizes, use of non-standardised outcome measures, or lack of blinding.

In the light of this, the study protocol for an RCT on improvisational music therapy's effectiveness for children with ASD called TIME-A (Geretsegger, Holck, & Gold, 2012) was designed to combine high clinical relevance (using broad inclusion criteria, and music therapy as usually applied in everyday practice) with rigorous methodology, including computer-generated randomisation, concealed allocation to study conditions, blinding of primary outcome assessors, and standardised measures.

In order to specify the intervention procedures within this RCT, and to allow for training of staff and replication of treatment, a treatment guide for improvisational music therapy for children with ASD was devised

(Geretsegger, Holck, Carpenste et al., 2014). It needs to be administered flexibly according to the requirement of the respective situation and needs of the client within the therapy process, and can only be applied in combination with and relying on the clinical expertise of an experienced music therapist. It consists not of a strict manual to be followed, but rather of core principles of improvisational music therapy for which consensus has been ascertained within music therapists experienced in this field from a total of eleven countries worldwide. Principles that are unique and essential to improvisational music therapy in this area include facilitating musical and emotional attunement, musically scaffolding the flow of interaction, and tapping into the shared musical history of interaction between child and therapist. Despite its flexible outline, a tool based on this treatment guide to assess treatment fidelity has successfully been applied to evaluate treatment adherence and competence.

Finally, findings from the process of implementing the study protocol for TIME-A using a pilot cohort showed that the study had been designed appropriately regarding feasibility and acceptability of study components (Geretsegger, Holck, Bieleninik, & Gold, 2014). With a final sample of $n = 15^2$, an analysis of effects was not possible; the trial's results are however valuable as an exploratory study, and as an internal pilot cohort for the large-scale multi-centre RCT TIME-A. Additionally, descriptions of children's developmental trajectories during their study participation yield insight into the multitude of challenges involved when examining effects of a complex intervention, thus underlining the need for a large sample to account for the high number of possibly influencing factors.

With regard to the study questions (see Chapter 2), answers may be concluded as follows:

- 2a) *Is music therapy superior to standard care in improving social communicative skills in children with ASD as assessed by independent clinicians at the end of the treatment period?*
- 2b) *Is music therapy superior to standard care in improving social responsiveness in children with ASD as assessed by parents/ caregivers at the end of the treatment period?*
- 2c) *Does the response to music therapy vary with variation of treatment intensity (i.e., number of music therapy sessions per week)?*
- 2d) *Are any differences in social communicative skills between the music therapy and standard care groups retained at follow-up twelve months after randomisation?*

² By the time of writing this, the sample size of the Austrian site has increased to $n = 16$. Since the last participant has not yet completed the 12-month follow-up period at the time of submitting this thesis, it had been decided earlier on to limit the sample for analysis in all parts of this thesis to 15 participants.

Questions 2a) to 2d) had initially been posed with relation to the RCT part of this study. Since the final sample size turned out to be too low to apply inferential statistics for analysing effects, data from the present pilot cohort could not be used for answering these questions, leaving those open until data from the international study TIME-A with a sufficiently large sample will be ready for analysis.

However, questions 2a) and 2b) relate to effects of music therapy on social communication compared to standard care, a comparison that was also examined within the systematic review (Part B, I). Originally, this review was conducted to provide a solid basis for the current RCT, and for addressing research question 6 regarding overall effects of music therapy. However, while finalising this study, and also in view of the small sample size of the present RCT cohort preventing analysis of effects, I realised that data from the systematic review also have potential to address research questions 2a) and 2b), all the more as all studies included in the systematic review had focused on children (not adolescents or adults) with ASD, thus in line with the focus of questions 2a) and 2b).

Studies that contributed to the systematic review's outcome of "social interaction" used the 'Social communication' domain of the CARS-BR (Childhood Autism Rating Scale, Brazilian version; Gattino et al., 2011), and the social approach subscale of the PDDBI (Pervasive Developmental Disorder Behavior Inventory, Korean version; Kim et al., 2008) which were applied by blinded assessors. Additionally, parents who were not blinded to the allocation of their child also completed the Vineland SEEC (Vineland Social Emotional Early Childhood Scales) and the SRS-PS (Social Responsiveness Scale Preschool Version; Thompson et al., 2013). When synthesising the studies' results for social interaction as assessed by independent assessors and parents, music therapy was superior compared to standard care or 'placebo' therapy with a mean difference of 0.71 standard deviations and a 95% confidence interval ranging from 0.18 to 1.25. Thus, these findings preliminarily suggest a positive answer to research questions 2a) and 2b) regarding benefits of music therapy for improving social communication skills in children with ASD, although it remains to be examined in the multi-centre trial TIME-A whether these findings will be corroborated when ratings from blinded assessors and parents are analysed separately within one single study.

Similarly, questions 2c) and 2d) regarding effects of treatment intensity and at 12-month follow-up also cannot be answered until data from the TIME-A study with a sufficiently large sample will be available.

- 3) *How can the clinical method of improvisational music therapy as applied within ASD be adequately described in a treatment guide to be flexibly applied in research on clinical practice?*

Answering research question 3), the treatment guide presented in Part B, III, provides detailed yet flexible principles of improvisational music therapy as applied within ASD to be followed by qualified clinicians.

- 4) *Which developmental pathways of individual children can be discerned within the setting of a rigorously designed study involving a predefined treatment duration?*

Research question 4) focused on the individual level of RCT study participants and on their developmental pathways during therapy. Descriptions included in the pilot cohort report (Part B, IV) documented that during the five months of music therapy, both therapist and parents observed improvements in various areas of children's social communication skills, although these changes were not consistently detected by the standardised measures applied.

- 5) *Which obstacles and benefits are encountered when implementing an RCT that is designed as a pragmatic trial closely linked to actual clinical practice and conducted in collaboration with various institutions and experts?*

Research question 5) regarding implementation of a pragmatic RCT protocol was also addressed in the pilot cohort's feasibility report (Part B, IV). As I acted as local coordinator of study procedures and site management, participating families' main contact person, music therapist, and parent counsellor, no time was lost for transferring information between these areas which facilitated smooth succession of study events for each participant. In this way, burden of study participation for families involving more extra appointments than would be usual in practice outside of research conditions was minimised. In some cases, possibilities for conducting assessment appointments in a timely manner were limited due to difficulties in coordinating families' and assessors' schedules. Overall, the present study suggests that it is feasible to conduct an RCT using rigorous methodology without compromising clinical validity.

- 6) *What is the evidence about the overall effects of music therapy in people with ASD when comparing music therapy or music therapy in addition to standard care to no therapy, similar treatment without music ('placebo' therapy), or standard care?*
- 7) *How do recruitment, implementation of intervention and control conditions, assessment procedures, safety, and retention turn out in the present pilot cohort?*

These two additional research questions that developed during the study were also addressed and answered in two of the articles included in this volume: The overall effects of music therapy in people with ASD when comparing music therapy or music therapy in addition to standard care to no therapy, similar treatment without music, or standard care were analysed and summarised in the systematic review as described above (see section 4.1.). Recruitment, implementation of intervention and control conditions, assessment procedures, safety, and retention in the present pilot cohort were examined in the feasibility study (see section 4.4.).

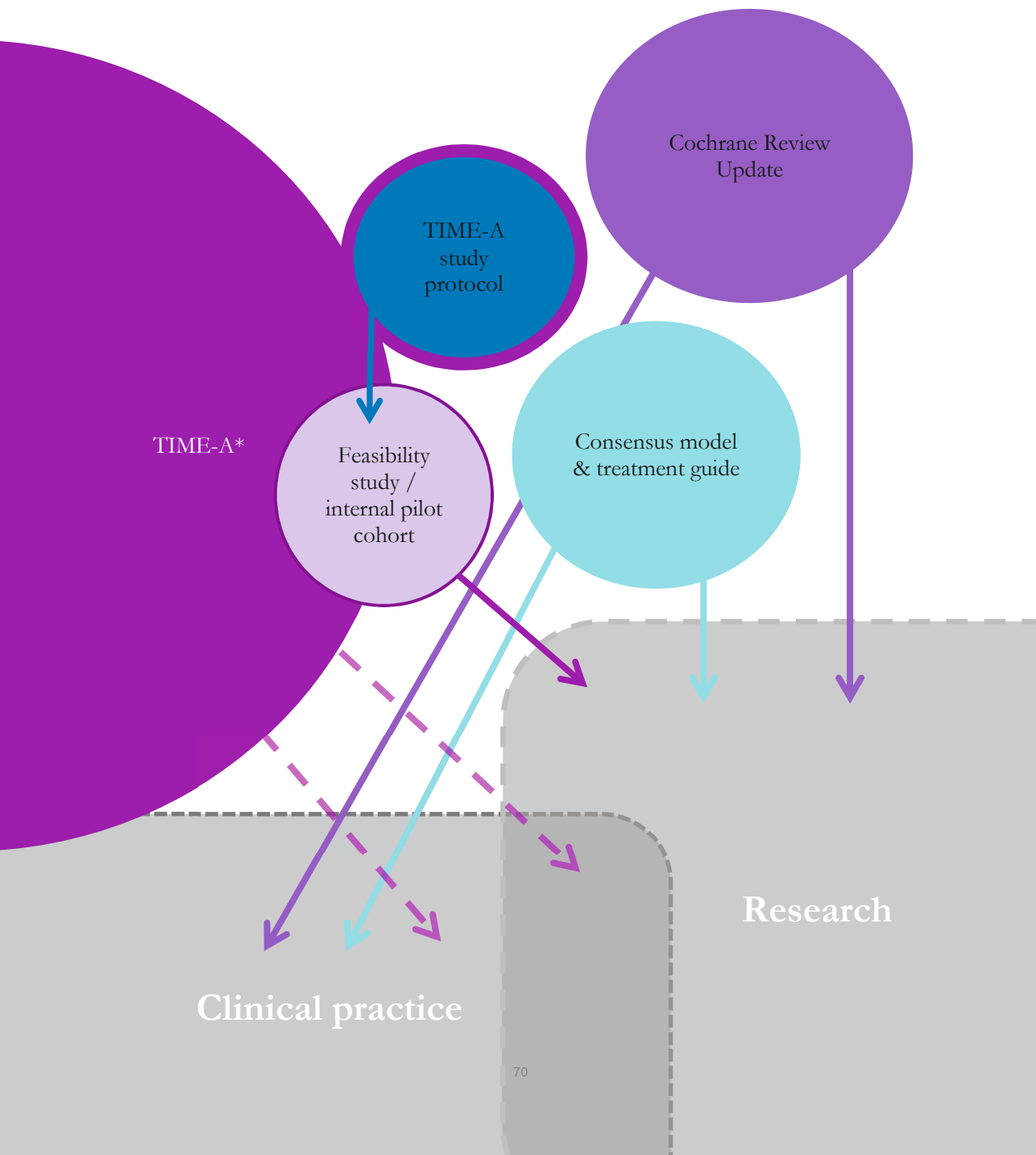
Overall, the main findings of this PhD study may contribute to efforts of integrating research evidence and clinical practice expertise within the field of music therapy for children with ASD and other areas of practice and research (see Figure 6-1, and sections 6.3. and 6.4. below):

Evidence from the Cochrane review update supporting music therapy as an effective means to promote core areas of ASD may lead to changes in provision of services for individuals with ASD. At the same time, its findings, conclusions, and recommendations may also lead to improved methodological quality of future studies in the field of music therapy and/or ASD.

The consensus model and treatment guide for improvisational music therapy for children with ASD may serve to facilitate clinical practice and training in this field through its basic principles that enable music therapists to develop and reflect upon their own ways of practicing. In other fields of music therapy practice, the treatment guide might instigate similar efforts of developing consensus models to facilitate exchange between therapists and other professionals. In research contexts, the treatment guide allows for standardising interventions while retaining flexibility for individualised work, and the tool to assess treatment adherence and competence may also serve as a model for developing measures of treatment fidelity in other areas.

Findings from the internal pilot cohort study may support appropriate design choices of future outcome research on complex interventions such as music therapy by providing detailed information on feasibility and acceptability of study components and procedures as described in the TIME-A study protocol.

Figure 6-1 *Directions of possible influence of PhD study components' findings on clinical practice and research within and outside of music therapy (dashed lines represent future findings expected from the TIME-A project)*



6.2. ADDITIONAL FINDINGS

Analysis of data from session notes forms that were completed after each music therapy session in this PhD study's clinical trial provided some insight into overall characteristics of both the therapist's and study participants' behaviour within music therapy sessions. Although these data are subject to a certain risk of bias due to self-reporting, the therapist interacting with the child in assessed situations, and the double role of researcher-therapist, findings are considered to add relevant background information illustrating the results presented in the pilot cohort article (Part B, IV).

Regarding the general approach of improvisational music therapy, the therapist's self-ratings of broad categories indicated that improvisational techniques were applied most frequently, thus supporting results presented in the treatment guide article (Part B, III) about the therapist's sufficient adherence to the approach.

Regarding levels of structure and directives provided by the therapist, it could have been expected that at the beginning of a therapy process, more "structuring/directive activities" might be applied by the therapist, gradually decreasing in amount over time. Self-ratings of the therapist however were mostly steady throughout, with a tendency to slightly more structuring in some children who had more difficulty than others to settle in with the time and space frame required (i.e., wanting to leave the therapy room ahead of time). The most frequent rating of 1 ("only few structuring/directive activities provided by therapist") can be considered as being in line with the non-directive orientation of the IMT approach.

In terms of the therapist's subjective appraisal of the therapy session as a more or less demanding experience, assessments showed predominantly low levels of demand with small variations of ratings for sessions with some of the children.

Analysing and interpreting variation in these three types of ratings related to outcome variables could allow for hypotheses about influencing factors and specific effects for therapeutic techniques and types of interaction that could then be systematically explored in further studies. However, this would necessitate further data from single sessions and therapy processes over time (including the therapist's condition on each particular day, indicators of the relationship developing between therapist and individual children, etc.) and a larger sample, both of which were beyond the scope of this thesis.

Regarding the children's behaviour within sessions (vocal expression, use of instruments, social-communicative behaviour), available therapist ratings provide additional descriptive information on the group of children receiving music therapy in this study. Results indicate a typical range and variety of behaviours for children with ASD including large amounts of either vocalising (in children that have not developed spoken language yet) or multi-word phrases (in so-called verbal children), musical and non-musical uses of instruments, and few occurrences of initiating behaviour.

6.3. IMPLICATIONS FOR CLINICAL PRACTICE

The findings of the systematic review (Part B, I) suggest that therapy approaches that emphasise relational aspects of music and integrate children's specific interests and motivations might be especially effective in fostering social communication abilities. Although these findings still need to be corroborated in future investigations, this is in line with the rationale of many descriptions of clinical music therapy in the literature (e.g., Carpente, 2009; Holck, 2004; Kim et al., 2009; Schumacher, 1999; Thompson et al., 2013). Incorporating a child with ASD's focus of attention and interest to promote social communication has also been found to be effective and appropriate in other approaches, for example in those that may be termed as developmental social pragmatic interventions (cf. Casenhiser et al., 2013): Rather than aiming at specific behaviours per se (e.g., eye contact), social communicative functions of such behaviours (e.g., the ability to engage in joint attention) in pragmatically appropriate contexts are focussed in the process of developing social communication abilities.

On a more overarching level, the systematic review's results provide evidence for the effectiveness of music therapy for children with ASD that could lead health care providers to consider providing music therapy, or strengthening available services, for families affected by this condition.

From the delineation of improvisational music therapy for children with ASD given in the treatment guide (Part B, III), it is clear that this approach is considered a comprehensive one addressing various dimensions of core characteristics of ASD simultaneously. It is however important to note that the principles, purposes, rationales, therapeutic attitudes, and activities are not intended to be best suited to any situation within any music therapy session with any child with ASD. It is crucial to only use the treatment guide based on one's own clinical expertise, and considering individual needs of the respective child as well as circumstances within which the therapy takes place. For

example, different stages of the therapeutic process, comorbidities such as ADHD or depression, or life events such as loss of a family member or birth of a sibling, are expected to present specific requirements that the therapist certainly needs to be responsive to.

6.4. IMPLICATIONS FOR FUTURE RESEARCH

In the light of this study's process and findings, it seems appropriate to recommend further collaborative efforts in facing the challenges of providing evidence for music therapy in ASD. This will enable researchers to reach larger sample sizes that are necessary to achieve robust results when investigating complex interventions and heterogeneous conditions, and will also enhance external validity of findings by integrating a broader variety of clinical and scientific approaches and expertise.

In music therapy research, it is not common practice yet to publish a protocol presenting a study's design ahead of its results, or to publish information on feasibility and acceptability of trial procedures. Both types of publications serve to introduce more rigour into the process of conducting and reporting on trials, and may help to work against publication bias (i.e., the tendency to publish only favourable results). The two related articles included in this PhD thesis (Part B, II & IV) might serve as reference examples for similar publications within future trials in the field which may help to further establish music therapy as a scientific discipline using rigorous methodology.

Although this study's systematic review (Part B, I) has added to and corroborated previous findings of positive effects of music therapy for social communication skills in children with ASD, more research is still needed to address further questions. These include unresolved issues of types, methods, and techniques of music therapy applied, appropriate outcomes that are relevant for those affected, potentially relevant subgroups of children with ASD as well as adolescents and adults, long-term impacts of music therapy for these groups, and mechanisms of change in music therapy for ASD. Implications for specific components of future research are detailed below.

6.4.1. STUDY DESIGN AND PROCEDURES

Designed as a pragmatic study, this PhD study's clinical trial aimed at examining the effectiveness of music therapy for children with ASD, that is, whether the intervention works under "usual conditions" (Thorpe et al., 2009).

Consequently, practical arrangements were tailored to approximate everyday circumstances in clinical practice. Inclusion criteria were broad (including all types of ASD, and all children irrespective of their verbal ability), intervention was applied in an individualised and flexible way, and like in other recent RCTs on music therapy for ASD (Gattino et al., 2011; Kim et al., 2008; Thompson et al., 2013), treatment was offered for a period of several months.

Due to these characteristics, the findings on effects of improvisational music therapy on generalised social communication skills of children with ASD that are expected from the TIME-A study will be well transferable to general clinical practice. For questions addressing effects of music therapy under specified “ideal” conditions, a more explanatory approach involving more specific conditions will be appropriate, for example with therapists that have received specialised training providing treatment for a subgroup of children with ASD, looking at direct consequences of the intervention, etc.

The fixed treatment duration of five months generally worked well in the pilot cohort described in Part B, IV, particularly as it often coincided with semesters (e.g., summer until the end of the year, or winter until start of families’ summer holidays). However, it was usually decided to randomise children as soon as possible after inclusion to avoid waiting time, so in some cases, holiday periods were included in the treatment phase, naturally resulting in lower numbers of sessions attended. Another possibility would have been to wait for a group of children to be randomised at once, however this could have led to baseline assessment data becoming out of date and unwanted times of waiting for individual families. Future studies will have to carefully consider which of these procedures will work best in given local circumstances, and with given study requirements.

As the approach applied in this trial is expected to have more than just immediate effects, the parallel group design was chosen to avoid uncertainties usually involved in the interpretation of data from cross-over trials (e.g., Arezina, 2011; Kim et al., 2008). However, to ensure sufficient test power, larger samples are required for parallel design, thus further underlining the need to conduct collaborative research involving more than one site.

The treatment guide for improvisational music therapy for children with ASD developed within the framework of this study and described in Part B, III, serves as a means to specify treatment procedures, ensuring the trial’s validity and replicability, while still retaining flexibility and openness to emerging procedures within the therapy process (Rolvjord, Gold, & Stige, 2005; also cf. Part B, II). As a first step in the challenge of introducing more standardisation into a highly individualised, flexible, and complex intervention, it needs to be

followed up with further research on the applicability of this and similar tools, and on its possible uses for explaining mechanisms of change more precisely. Researchers in other fields of practice might also use it as a model for developing similar guidelines to allow for standardisation in the application of complex interventions, and for assessment of treatment fidelity.

Findings gained through the application of a treatment guide may help to enrich future training and education of music therapists and other health care professionals working in the field of ASD, and to further specify music therapy treatment guidelines for specific populations.

6.4.2. CHOICE OF OUTCOME MEASURES

As can be seen from the long list of outcome measures enumerated within the results section of the systematic review (Part B, I), it is all but a straightforward task to choose adequate measures for capturing the effects of music therapy for children with ASD. Some researchers aim to measure effects on generalised behaviour (i.e., behaviour outside of the immediate treatment context), while others look at changes in the same setting where the intervention takes place, as for example by counting the frequency of certain behaviours within therapy sessions.

On the continua from very specific to very general, and proximal to distal, the study protocol presented in this PhD study (Part B, II) adopts an intermediate position by utilising the observation tool ADOS applied by blinded assessors as primary outcome measure, and the parents questionnaire SRS as secondary outcome measure: Both instruments focus on combinations of defining characteristics of ASD, and both measure generalised behaviour, rather than outcomes proximal to music therapy.

Generally, choosing a distal outcome measure increases the “noise” within analysis, as it may be more heavily influenced by variables that are not directly associated with treatment. On the other hand, distal measures provide information about effects that may be more relevant to those affected than changed behaviour within therapy, since the ultimate goal of any intervention within ASD is to effect improvements in generalised settings such as daily life.

The two main outcome measures chosen for the TIME-A study design (Part B, II), ADOS and SRS, are also two instruments that are standardised and validated in several languages. This was important for achieving valid data in all participating countries that can be combined for analysis to examine effects.

Preliminary findings presented in the feasibility study (Part B, IV) indicate that both instruments are sufficiently sensitive to change to be used as measures of effects. For the ADOS, this is consistent with earlier outcome studies on interventions in ASD (Aldred et al., 2004; Green et al., 2010; Owley et al., 2001) where it was also used to measure change over time. However, there is some variety in versions applied in different countries (its second edition, ADOS-2, has become available for some languages during the time of this study), and in the selection of items included in algorithms reported in the literature (e.g., Gotham et al., 2008; Lord et al., 2000). Developed for diagnostic purposes, ADOS was originally designed to discriminate between children with and without ASD. It still remains to be examined which combination of items or scores yields the most valid estimation of a child with ASD's skills and competencies within social communication, and of changes over time. Within the TIME-A study, a sum score consistently available in all participating countries (using all available information from the ADOS domains "Language and Communication" and "Reciprocal Social Interaction") was chosen for application throughout. Since the need to score all available items only became apparent while data collection for this PhD study was already underway in Austria, there are some missing data for the first couple of children (cf. Part B, IV).

In line with the recommendation to also include family-related outcomes in studies on ASD (cf. section 1.6.3.), the TIME-A project also provides for data collection on the child's individual as well as the family's quality of life (see Part B, IV). In order to limit burden on participating families, we refrained from adding another elaborate and time-consuming questionnaire and instead used a simple scale from 0 to 100 where parents were asked to assess current quality of life from 'worst imaginable' to 'best imaginable'. While this simple procedure possibly involves some threat to validity as people may interpret the concept 'quality of life' quite differently, it still serves as a means to indicate change over time in an important family-related variable.

In general, it seems appropriate to recommend for future studies on music therapy and other interventions for ASD to choose measures that address areas at the core of ASD such as social communication in generalised settings (cf. Part B, I), and to also consider outcomes addressing family stress and quality of life. Additionally, measures covering longer follow-up periods are necessary to examine whether an intervention has lasting effects.

6.5. LIMITATIONS OF THIS STUDY

Constituting a common methodological weakness of music therapy research, small sample sizes led to limitations in both the systematic review and this PhD study's clinical trial. With a total of just 165 participants and sample sizes of 4 to 50 participants in the 10 studies included in the review (Part B, I), future research is needed to improve the quality of the evidence for some of the outcomes, especially for generalised non-verbal and verbal communicative skills, and social-emotional reciprocity within the therapy setting.

Other limitations present in the systematic review, such as non-standardised measurement tools and lack of blinding in some of the included studies, were sought to be avoided in the design for this PhD study's clinical trial (Part B, II): The TIME-A study protocol provided for using standardised, validated outcome measures and blind assessment of the primary outcome in addition to secondary, parent-rated measures. As mentioned in the study protocol, specific characteristics of study design that might be considered weaknesses (e.g., broad inclusion criteria, the heterogeneity of standard care as a control condition, lack of outcome measures proximal to music therapy) were deliberately chosen to allow for enhanced feasibility and pragmatic study orientation (Thorpe et al., 2009).

Regarding the consensus model of improvisational music therapy for children with ASD (Part B, III), its scope is inevitably limited to the views and practices represented by the participants in the survey and focus groups that were conducted in selected countries. More discussion and research will be necessary to evaluate whether the described principles need to be further refined and/or amended to reflect the “common ground” of clinical practice in improvisational music therapy for ASD internationally.

Since recruitment for this PhD study's trial turned out much lower than initially expected (cf. section 1.4., and Part B, IV), using inferential statistics for data analysis was not possible, thus also leaving research questions 2a) to 2d) about effects of music therapy on social communicative skills and social responsiveness, effects of dosage, and long-term effects unaddressed. However, by providing detailed information about successes and difficulties in the trial's implementation, it is hoped that findings from this pilot cohort will nonetheless be valuable in planning and designing future effectiveness studies on music therapy.

Finally, it is important to note that participating in an RCT like this is not necessarily viable for every family eligible for participation. Therefore, although

broad eligibility criteria were applied to enhance the study's pragmatic orientation, the fact that some eligible families eventually did not participate still somewhat limits the scope of generalising findings to the general population of children with ASD. However, as also mentioned by Thorpe and colleagues (2009), it seems impossible to conduct a “purely” pragmatic trial that would provide ultimate evidence for users to choose between options for care.

6.6. DEVELOPMENT PROCESS OF THE ARTICLES

As mentioned in sections 1.3.3. and 1.4. above, the plan to write this thesis as an article-based one took shape within the first year of my PhD studies. The design and structure for two of those planned articles was rather clear-cut: It was obvious that the study protocol for the RCT had to address key components of study design, and that it would follow common standards and recommendations for RCT reporting such as the CONSORT guidelines (Schulz, Altman, Moher, & the CONSORT Group, 2010). For the systematic review, it seemed appropriate to conduct an update of the first Cochrane review on music therapy for ASD (Gold, Wigram, & Elefant, 2006), which necessitated that the strict procedures specified by the Cochrane Collaboration (cf. Higgins & Green, 2011) had to be followed.

For the other two articles, it took some time to conceive appropriate concepts and procedures for the intentions of describing the clinical approach of improvisational music therapy, and sharing information from this PhD study's clinical trial, respectively.

In the development of the treatment guide, I started off by discussing ways of summarising improvisational approaches of music therapy for children with ASD with my two PhD supervisors (Christian Gold and Ulla Holck) and consulting with one further expert in the field and co-author-to-be, John Carpente. After some time of exchanging our own ideas and pertinent literature, and following several attempts of synopsising them, it became clear that an overall description needed to be independent from training backgrounds in music therapy to be flexible enough to fit practices in different countries. Helped by previous studies on specifying guidelines for therapy (Rolvsjord, Gold, & Stige, 2005; Waltz et al., 1993) and inspired by the Delphi method, a communication technique to reach consensus by collating expert opinions in structured rounds of responding to questionnaires, we devised a survey about basic principles of the approach. As the international group of collaborators for the TIME-A study had been established by then, we decided

to use this network of experts for the purpose of finding respondents for our survey. It was important for us to have a broad range of music therapy backgrounds represented in the survey sample (Nordoff-Robbins training, anthroposophical orientation, developmental approaches, etc.), and we asked collaborators to nominate experienced clinicians in their respective countries with expertise in the areas of ASD and improvisation music therapy. Further steps in developing the treatment guide are described in the corresponding manuscript (Part B, III). As we considered this description of developing treatment guidelines for an individualised, flexible approach pertinent also to areas beyond music therapy, we initially submitted our manuscript to general ASD journals. However, it proved difficult to adapt the study's qualitative approach and the manuscript's structure to the usual sequence of study report components common in those journals, resulting in repeated rejections of our manuscript. It seems an important issue, particularly in a complex and interdisciplinary field like ASD, to further explore ways of making findings from studies that do not fit regular publishing conventions available for wide audiences.

Regarding the article describing the pilot cohort, the initial plan of examining effects of music therapy had to be dismissed due to the small number of participants recruited during the period of study (cf. section 3.1.1.). However, it was considered viable and valuable to explore feasibility and acceptability aspects of the RCT study protocol for TIME-A (Part B, II), which also addresses the current scarcity of pilot and feasibility studies within music therapy. As there are no general guidelines on the reporting of feasibility yet, an attempt was made to find a form that allows for structured analysis of common aspects of feasibility, while also providing some insight into participants' changes over time. It is hoped that the combination of qualitative evaluation and narrative description of individual children's development will prove useful for further considerations of practice-based research.

6.7. REFLECTIONS OF THE PHD PROCESS

As is not unusual within doctoral studies, I acted in multiple roles within this PhD process. Apart from being responsible for overall design and conducting the study, I also acted as primary contact person for referrers, families interested in participation, and collaborating assessors in this study's clinical trial, and as music therapist and parent counsellor. I enjoyed taking on those different perspectives and variety in tasks and challenges, as I felt it provided me with valuable insight into the individual experiences of all those involved in

this research project – including everyday hassles of scheduling appointments in due time, discussions with parents from many different backgrounds about their concerns and hopes for their child’s future, precious moments of shared enjoyment in music therapy sessions, collaborating with local clinical experts as well as researchers around the world. This gave me a fuller understanding of what participating in this study meant for all involved, and made me more sensitive to tensions between usual practice, individual needs, and research requirements, therefore also obliging me to act responsibly in each of the roles.

These multiple roles might also have caused some bias in the way I acted in the clinical setting. However, as described in Part B, IV, the risk of potential influence towards desired results is considered low, since improving social communication skills may be seen as primary goal of music therapy for children with ASD regardless of research context, and also because outcome measures examined generalised behaviour rather than observations within music therapy sessions.

My double role of researcher and clinician that this PhD study entailed was made known to families eligible for participation right from the start. For some, this might have seemed advantageous in terms of the quality of services that they would receive. At the same time, it might also have aroused some concerns whether their child’s needs would have utmost priority in relation to research interests. I made sure that family’s and child’s safety and well-being were always paramount, and that study requirements were not in the way of providing appropriate high-quality treatment according to each child’s needs.

The double role of music therapist and parent counsellor that I had for families in the music therapy conditions is not unusual for my own clinical practice outside the framework of research, where parent sessions are often scheduled at regular intervals to discuss a child’s development within and outside of music therapy.

The ratings that I recorded in the session notes forms (see sections 3.2.4. and 6.2.) might also have been influenced by the fact that I was simultaneously working on developing the treatment guide, and that I later on used these notes myself for examining treatment fidelity. Also to provide a remedy for this risk of bias in ratings of levels of structure and applied activities, additional fidelity checks were conducted by external, independent raters assessing randomly selected video excerpts (see Part B, III). It still remains to be investigated in detail how combinations of therapeutic techniques and levels of structure provided relate to therapy outcomes on individual and generalised levels.

6.8. PERSONAL EXPERIENCE GAINED FROM DOING THIS RESEARCH

As described in the previous section, I was grateful for the opportunity to be involved in the full range of study procedures of the clinical trial which provided me with a deeper understanding and appreciation of the interrelations between research aims, practical requirements, and individual needs of participants.

Developing the treatment guide in collaboration with co-authors and in consultation with many experts world-wide has both widened my perspectives on various manifestations of improvisational music therapy, and made me more aware of the many facets and implications of clinical techniques when applying (my rendition of) this approach. As hoped for, the thorough examination of those techniques in ASD and exchange with experienced colleagues also increased my confidence as a clinician within this field.

The fact that this type of thesis implicated the development and submission of manuscripts suitable for publication provided me with valuable experiences in presenting my work to editors and anonymous reviewers. In the correspondences discussing necessary amendments and revisions, I learned a lot about the importance of taking an external reader's view when devising a text. In addition, developing a certain routine in responding to reviewers' comments also led me to deal with feedback in a more factual and constructive way than I had available initially, when critique sometimes caused subtle feelings of being offended personally.

The many possibilities for collaborative work involved in this study, including my participation in the international TIME-A project, and co-authoring articles, have deepened my appreciation for developing joint perspectives on research and clinical practice in music therapy. Similar to previous experiences such as co-developing conference contributions with colleagues, I value those opportunities for their potential to enhance both the quality of resulting work and my motivation to embark on such endeavours in the first place.

Last but not least, the different types of articles, and other forms of dissemination that developed during this study such as conference contributions and lectures for students, have increased my awareness of distinct language requirements for different contexts and target groups. To give an example, specific 'codes' of expression such as the phrasing common in Cochrane reviews might cause confusion or misunderstanding if summarised accounts of findings do not include appropriate background

information: For instance, a statement in such a context that an intervention “might help” may indicate quite good evidence, and not serious doubts about its benefits. As Sven Bölte writes in a recent editorial on the significance and limitations of systematic reviews and related communication “traps”, “Different audiences need different information” (Bölte, 2015, p. 4). It is a constant challenge worth taking up to communicate research and its findings to various groups, and to translating scientific jargon to comprehensible information without simplifying too much, or distorting meaning.

6.9. CONCLUSIONS

In this PhD study which used fixed designs of examination supplemented by flexible methods of investigation, music therapy was explored as a complex and flexible intervention that is applied to meet the requirements of children with ASD, constituting a complex and varied condition.

This study provides a solid base of current evidence on music therapy demonstrating benefits for core areas of ASD, specifies detailed requirements for effectiveness research in this area, provides an international consensus of standardised guidelines for treatment, and presents feasibility data for a pilot cohort of an RCT investigating effects of improvisational music therapy on children’s social communication abilities in ASD. In this way, this study presents feasible ways of applying rigorous research methods to investigate a highly individualised approach.

Collaboration on practical, theoretical and research-related levels has been pointed out as essential ingredient of doing research in this complex field.

The realms of research and clinical practice in music therapy are often perceived as separated from each other. By finding ways to combine clinical relevance and rigorous research methodology without compromising either, concerns on both “sides” may be reduced. Furthermore, feeding back and integrating findings from clinical research into clinical work is crucial in order to put these findings to use for those it is about.

Taken together, I hope that this PhD study adds to enhanced communication and knowledge transfer between research and practice in music therapy. Constructive collaboration between experts in both fields is essential for the common goal of more effective and more substantiated health care services for individuals with ASD and other conditions.

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Appendix A. Ethical approval: Human Research Ethics Board, Aalborg University

HREB # 201107

Ethical approval

We have evaluated the protocol for Monika Geretsegger's PhD-project "Effects of improvisational music therapy on social communication skills in pre-school children with autism – a randomized controlled trial" as described in the application to HREB and amendment of July 31, 2011 and found it to project a low-risk research project with adequate ethical considerations taken into account.

Ethical approval granted:

Date: August 8, 2011 pp. HREB: Tia Hansen

Signature: 

**Appendix B. Ethical approval:
Ethikkommission der Medizinischen
Universität Wien**

**ETHIK-KOMMISSION
DER MEDIZINISCHEN UNIVERSITÄT WIEN**

Borschkegasse 8b/6 - A-1090 Wien, Austria
☎ 0043 1 404 00 – 2147, 2244 & 📠 0043 1 404 00 – 1690
**E-Mail: ethik-kom@meduniwien.ac.at
ethikkommission.meduniwien.ac.at**

Sitzung der Ethik-Kommission am 06. Dezember 2011, TOP 20 :

EK Nr: 938/2011

Antragsteller: MMMag. Monika Geretsegger(1), Univ.Prof.Dr. Christian Popow(2)

Einreichende Institution: Inst.f.Klin., Biol. u. Diff.Psychologie(1), Univ.Klin.f. Psychiatrie d. Kindes- u. Jugendalters(2)

Projekttitel: Effects of Improvisational Music Therapy on Social Communication Skills in Pre-school Children with Autism - a Randomised Controlled Trial

Die Stellungnahme der Ethik-Kommission erfolgt aufgrund folgender eingereichter Unterlagen:

Dokument	Version/Nr	Datiert
Originalprotokoll:		Oktober 2011/Dezember 2011
Kurzfassung:		undatiert
Patienteninfo./Einverständniserklrg.: HREB#201107	2.0	2011-08-08
Elterninformation:	3/4	2011-11-30/2011-12-28
CRF's:		undatiert
Voten anderer EK's: Denmark		2011-08-08
Qualifikation: CV, Conflict of Interest-Erklärung		undatiert
Sonstiges: Aushang		undatiert

Dieser Antrag wurde in folgender(n) Sitzung(en) behandelt: 08.11.2011

Die Kommission fasst folgenden Beschluss (mit X markiert):

- ☒ Es besteht kein Einwand gegen die Durchführung der Studie.
- ☐ Die unten bezeichneten Punkte des Antrages sind entweder noch unerledigt bzw sollten von den Antragstellern geändert/ nachgereicht werden. Nach entsprechender Vorlage/Erledigung kann auch vor der nächsten Ethik-Kommissions Sitzung ein endgültig positiver Beschluss ausgefertigt werden. Der Antrag wird in der nächsten Sitzung der Kommission nicht mehr behandelt.
Achtung: Werden die geforderten Unterlagen von den Antragstellern nicht innerhalb von 3 Sitzungsperioden (ab Datum dieser Sitzung) nachgereicht, gilt der Antrag ohne weitere Benachrichtigung als zurückgezogen und muss gegebenenfalls als Neuantrag eingereicht werden.
- ☐ Es bestehen Einwände gegen die Durchführung der Studie in der eingereichten Form. Die unten angeführten Punkte sollten von den Antragstellern entsprechend geändert und der Kommission neu vorgelegt werden. Der Antrag wird in der nächsten Sitzung der Kommission nochmals behandelt.
Achtung: Werden die geforderten Unterlagen von den Antragstellern nicht innerhalb von 3 Sitzungsperioden (ab Datum dieser Sitzung) nachgereicht, gilt der Antrag ohne weitere Benachrichtigung als zurückgezogen und muß gegebenenfalls als Neuantrag eingereicht werden.
- ☐ Der Antrag wird von der Ethik-Kommission abgelehnt.
- ☐ Der TOP wird bis zur nächsten Sitzung vertagt (Begründung siehe unten)

Kommentare:

Zum Prüfplan : **Die Ethik-Kommission kann die Studie als Pilotstudie akzeptieren, dies müsste bereits aus dem Titel ersichtlich sein.**

Eine Bezahlung der studienbedingten Musiktherapie durch die Studienteilnehmer ist nicht akzeptabel.

Da die Studienleiterin die Studie möglicherweise vorzeitig verlässt, ist dafür Sorge zu tragen, dass diese lokal unter anderer Verantwortung zu Ende geführt werden kann.

Zur Patienteninformation : **Der Briefkopf der „Aalborg Universiteit“ ist zu ersetzen durch den der jeweiligen Prüfstelle.**

Punkt 1 ist laienverständlich, unter Vermeidung von Fremdwörtern, Fachausdrücken und Fachjargon abzufassen.

In Punkt 2 ist anzugeben, ob die jeweiligen Studienbesuche die Eltern und Kinder betreffen, und wie lange die Besuche jeweils dauern (für Eltern bzw. für Kinder).

Hinweise auf Kosten, die den Teilnehmern durch die Musiktherapie entstehen, sind zu entfernen.

In Punkt 10 wird den Eltern angeboten, sich bei „Fragen oder ethischen Bedenken“ an eine Stelle in Dänemark zu wenden. Es kann nicht vorausgesetzt werden, dass die Eltern der englischen Sprache im erforderlichen Ausmaß mächtig sind.

Es ist anzugeben, was mit den erhobenen Daten bzw. den Filmaufnahmen bei vorzeitigem Austritt aus der Studie geschieht.

Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Patienteninformationen Versionsbezeichnungen anzugeben und ein Exemplar mit hervorgehobenen Änderungen beizulegen.

Zur Versicherungsbestätigung : **nicht erforderlich**

Andere : **Der Tagesordnungspunkt wird vertagt.**

Ergänzender Beschluss der Sitzung vom 06.12.2011:

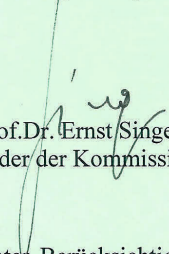
Die Antragsteller legen am 1.12.11 überarbeitete Unterlagen vor.

Das Projekt wird nach Erhalt der Stellungnahme ausführlich diskutiert. Da allein schon auf Grund der geringen Fallzahl die wissenschaftliche Aussagekraft der Studie stark beeinträchtigt ist, kann die Ethik-Kommission nur zustimmen, wenn den Teilnehmern aus der Studienteilnahme keine Kosten erwachsen.

Nachtrag vom 12. Jänner 2012: Die Antragsteller legen am 29.12.11 überarbeitete Unterlagen vor, die von der Ethik-Kommission akzeptiert werden.

Die Ethik-Kommission geht - rechtlich unverbindlich – davon aus, daß es sich um keine klinische Prüfung gemäß AMG/MPG handelt.

Mitgliederliste der Ethik-Kommission (aktueller Stand am Sitzungstag) beiliegend. Mitglieder der Ethik-Kommission, die für diesen Tagesordnungspunkt als befangen anzusehen waren und daher laut Geschäftsordnung an der Entscheidungsfindung/Abstimmung nicht teilgenommen haben: **keine**


Univ. Prof. Dr. Ernst Singer
Vorsitzender der Kommission

ACHTUNG: Unter Berücksichtigung der „ICH-Guideline for Good Clinical Practice“ gilt dieser Beschluß **ein Jahr ab Datum der Ausstellung**. Gegebenenfalls hat der Antragsteller eine Verlängerung der Gültigkeit mittels Formular für „Meldungen“ rechtzeitig vorzulegen.

Appendix C. Information leaflet about the RCT for parents (German)

Verdacht auf Autismus-Spektrum-Störung? Diagnostik, Beratung, Therapie | TeilnehmerInnen gesucht!

Im Rahmen einer internationalen Studie („TIME-A“, <http://helse.uni.no/timea>) untersuchen wir Auswirkungen von Therapie- und Beratungsangeboten auf sozial-kommunikative Fähigkeiten von Kindern mit einer Autismus-Spektrum-Störung.

Wir suchen Familien mit **Kindern im Kindergarten- und Vorschulalter** im Raum Wien, die sich über einen Zeitraum von 5 Monaten an dieser Studie beteiligen können.

Der Einstieg in die Studie ist jederzeit möglich.

Wenn Sie sich – nach einem einführenden Informationsgespräch – für eine Teilnahme entscheiden, so können Sie **kostenfrei** eine **ausführliche klinisch-psychologische Autismus-Spektrum-Diagnostik** in Anspruch nehmen und von **individuell angepasster Elternberatung und/oder musiktherapeutischer Behandlung** profitieren.

Darüber hinaus leisten Sie durch Ihre Teilnahme einen wertvollen Beitrag zur Autismusforschung und zur Bewertung wirksamer Behandlungsmethoden im Bereich Autismus-Spektrum-Störungen.

Über die Ergebnisse der Studie erhalten Sie selbstverständlich Rückmeldung.

WIE, WAS, WER, WO?

- Am Beginn der Studienteilnahme wird eine umfassende klinisch-psychologische Autismus-Spektrum-Diagnostik durchgeführt.
- Der weitere Ablauf sieht regelmäßige Therapie-Einheiten und/oder Beratungstermine vor. Näheres dazu erfahren Sie im ausführlichen Erstgespräch.
- Alle Therapien und Beratungen werden ausschließlich von erfahrenen Expertinnen durchgeführt.
- Die Diagnostik-, Therapie- und Beratungstermine finden in Wien in Einrichtungen im 1. und 16. Bezirk statt.

Die Teilnahme an der Studie ist anonym, d.h. alle Daten der teilnehmenden Kinder und ihrer Eltern werden für die Auswertung anonymisiert.

Videoaufzeichnungen von Therapie- und Beratungseinheiten werden zu Dokumentations- und Auswertungszwecken angefertigt und lediglich von Projektmitarbeiter/innen verwendet.

Sollten Sie an einer **Teilnahme** interessiert sein oder noch weitere **Informationen** benötigen, stehen wir Ihnen gerne jederzeit per E-Mail (monika.geretsegger@univie.ac.at) oder auch telefonisch unter +43 [redacted] zur Verfügung.

lokale Studienleitung:

MMMag. Monika Geretsegger | Musiktherapeutin, klinische und Gesundheitspsychologin, Doktorandin/Projektangestellte

beteiligte Institutionen:

Grieg Academy Music Therapy Research Centre (GAMUT),
Uni Health, Uni Research, Bergen/Norwegen

Faculty of Humanities, Aalborg University/Dänemark,
Department of Communication and Psychology,
Doctoral Programme in Music Therapy

Fakultät für Psychologie der Universität Wien,
Institut für Angewandte Psychologie:
Gesundheit, Entwicklung und Förderung



Appendix D. Information and consent form (English version)

Version 1.0 as submitted to Aalborg University's Human Research Ethics Board on June 22, 2011.

Doctoral Programme in Music Therapy

Information and Consent Form for participation in the clinical study

Effects of Improvisational Music Therapy on Social Communication Skills in Pre-school Children with Autism – a Randomised Controlled Trial

Institute for Communication
and Psychology
**International PhD
programme in
MusicTherapy**
Prof. Tony Wigram &
Assoc. Prof. Hanne Ridder
Krogstræde 6
9220 Aalborg Øst
Denmark
hanne@hum.aau.dk
www.mt-phd.aau.dk
Tlf. 45 9940 9120
Fax 45 9815 4594

Dear participant,

We invite you and your child to participate in the clinical study with the above title. You will receive detailed information about the study and your potential participation in this form and in an interview with the principal researcher, Ms. Monika Geretsegger.

Your participation in this clinical study is voluntary. You are free to withdraw your consent to participate at any time without giving reasons. Rejection of participation or dropping out of the study ahead of schedule will not have any adverse consequences on the care and support you receive or on the treatment of your child.

The principal researcher (Monika Geretsegger) is a qualified music therapist and psychologist and has been working with children with autism spectrum disorders since 2002. She is currently enrolled at Aalborg University/Denmark (Doctoral Programme in Music Therapy) as a PhD Research Fellow; this involves conducting this clinical study which is supervised by Assoc. Prof. Dr. Ulla Holck, Aalborg University, Aalborg/Denmark, and Prof. Dr. Christian Gold, Grieg Academy Music Therapy Research Centre, Bergen/Norway, and is conducted in cooperation with the Department of Clinical, Biological and Differential Psychology at Faculty of Psychology, University of Vienna.

Clinical studies are necessary in order to gain reliable research findings. It is an indispensable requirement for conducting a clinical study that you as a participant give your written consent for participation in this clinical study. In addition to the interview with the principal researcher, please read the following information carefully and do not hesitate to ask questions.

Please sign this consent form only

- if you have fully understood the clinical study's nature and procedures,
- if you are willing to consent to participate, and
- if you are aware of your rights as a participant in this clinical study.

This clinical study and this information and consent form have been approved by the responsible ethics committee (Human Research Ethics Board, Aalborg University, Denmark).

1. What is the purpose of this clinical trial?

The purpose of this clinical trial is to determine effects of music therapy on social communicative skills of pre-school aged children with autism spectrum disorders. Furthermore, effects of varying frequency of music therapy sessions and the development of these skills over a longer period of time are investigated.

Early social communicative skills provide the basis for language development, for the development of social competences, and also for emotional and cognitive development. In children with autism spectrum disorders, these social communicative skills often show significant impairments.

There are some studies and numerous reports from clinical practice indicating that improvisational music therapy can help children with autism spectrum disorders to express and share feelings and to interact with others. To this end, the music therapist reacts musically and verbally to musical and other expressions of the child and thus creates an environment where contact and interaction are facilitated.

Another aim of this study is to better specify music therapy treatment guidelines which may improve autistic children's access to music therapy services. Thus, findings from this study will be valuable not only for future research efforts within the field of intervention methods of autism, but also for families with children with autism spectrum disorders who are interested in effective and feasible ways of supporting their children's development.

2. What are this clinical trial's procedures?

This clinical trial will be conducted in Vienna in several locations, and approximately 16 children will be participating. Your participation in this clinical trial will take 5 months. In addition, a follow-up examination will be conducted one year after the start of your participation.

During this clinical trial, the following assessments and interventions will be conducted:

at the beginning:

ADI-R (*Autism Diagnostic Interview-Revised*); this is a detailed interview on particular areas of the child's development which will be conducted with you as parent/guardian.

K-ABC (*Kaufman Assessment Battery for Children*); this is a test where through different tasks, the child's cognitive developmental level is determined.

ADOS (*Autism Diagnostic Observation Schedule*); this is a semi-structured, standardised observation instrument where the assessor interacts with the child in a playful manner by creating various play situations and dialogues.

SRS (*Social Responsiveness Scale*); this is a questionnaire in which you are asked to answer questions on different areas of everyday life, behaviour, and skills of your child.

Parent counselling (approx. 60 minutes), where you will be provided with information on autism spectrum disorders, early child development, and social communicative skills, as well as with support in current difficulties, problems, or worries regarding your child's development.

after 2 months: ADOS, SRS; parent counselling (approx. 60 minutes)

after 5 months: ADOS, SRS; parent counselling (approx. 60 minutes)

after 12 months: ADOS, SRS

For these appointments, you will be asked to visit the institution as notified. Overall, approximately six visits will be needed.

In addition (according to random assignment), your child might receive **music therapy for a period of five months**, either once or three times per week.

One music therapy session lasts 30 minutes.

All music therapy and parent counselling sessions will be video-recorded. Video recordings will be used for research purposes only, and will be deleted 4 years and 11 months after the end of the research project.

3. What is the benefit of participating in this trial?

Through participation in the clinical trial, you will receive extensive diagnostics on autism spectrum disorder free of charge, conducted by a clinical psychologist well experienced in this area.

In parent counselling sessions (also free of charge), you will receive detailed information on autism spectrum disorders and assistance with current worries and problems.

Within music therapy, your child will have the opportunity to work on difficulties associated with autism spectrum disorders through individual facilitation, e.g. expanding his/her social communicative skills, enhance his/her self-confidence, and develop his/her creativity and flexibility. All therapy and counselling sessions will be conducted solely by experts with several years' clinical experience in the field of autism spectrum disorders.

During and after your participation, you will receive detailed information on test results concerning your child's respective current level of development, and on this research project's findings.

4. Are there any risks, discomforts, and side effects?

No risks or undesired side effects have been reported neither from previous research on methods and interventions applied in this study nor from clinical practice.

5. Additional utilisation of other treatment methods?

There is no restriction on other therapy methods and interventions that you and your child might receive for the period of your participation in this clinical study, but your child should not receive any (other) music therapy treatment within the period of participation (including follow-up assessment).

6. What needs to be done if additional symptoms, side effects, and/or injuries occur?

If any undesired effects, accompanying symptoms, or injuries should occur during the course of the clinical study, you need to inform the principal researcher about this, if necessary by phone (for contact details, see page 5).

7. In what case will the clinical study be quit prematurely?

You are free to withdraw your consent to participate and drop out of the study at any time, and without giving reasons, without any adverse consequences on the care and support you receive or on the treatment of your child.

On very rare occasions, it is possible that the principal researcher decides to end your participation in the clinical trial ahead of time without obtaining your permission beforehand. Reasons for this may be the following:

- You are not able to comply with the clinical trial's requirements;
- The principal researcher is under the impression that continuing your participation is not in your interest;
- Participating institutions decide to terminate the entire clinical trial, or just to end your participation prematurely.

8. How will data collected within this clinical trial be used?

Only the principal researcher and her co-workers will have access to confidential data where you are mentioned by name. These persons are subject to confidentiality.

Disclosure of information will take place for statistical purposes only, and you will not be mentioned by name therein without exception. Likewise, in any publications of this clinical trial's data, you will not be mentioned by name.

9. Are there any costs for participants? Is there any reimbursement of costs?

If your child does not receive music therapy, then your participation in this clinical trial does not involve any costs.

If your child is assigned to music therapy (either once or three times per week, total duration of therapy: five months), then a **contribution to therapy costs** in the amount of **400,- €** applies, payable as total sum after the first month of participation, or by instalments of 100,- € at the respective end of the month of the first four months of participation.

In well-founded circumstances (low household income, unemployment, etc.), and depending on budgetary feasibility, travel reimbursements may be granted for travelling to music therapy sessions. The amount of this allowance is determined by the level of socio-economic need¹. Travel allowances will be paid at the end of the month.

10. Discussing further questions

If you have any further questions regarding this clinical study, you are welcome to contact the principal researcher. We are also happy to answer any questions relating to your rights as participant in this clinical trial.

name of contact person: Mag.art. Mag.phil. Mag.rer.nat. Monika Geretsegger
available on: monika.geretsegger@univie.ac.at
Tel: +43-664-1556144

If you have any questions or concerns about the conduct of this research project, you can also contact the following position:

Executive Officer
Human Research Ethics Board
Aalborg University, Faculty of Humanities
Kroghstræde 3
DK – 9220 Aalborg
Denmark

¹ *Calculation example:* annual gross household income < 35.000,- € in a four-person household yields travel allowances of 36,- € per month if attending music therapy three times per week.

11. Consent form

Parent's/guardian's name in print:

.....

Date of birth: Code:

I consent to participate in the clinical trial "Effects of Improvisational Music Therapy on Social Communication Skills in Pre-school Children with Autism – a Randomised Controlled Trial", conducted by MMMag. Monika Geretsegger, supervised by Assoc.Prof. Dr. Ulla Holck and Prof. Dr. Christian

Gold, together with my child, born 20.....

Ms. MMMag. Monika Geretsegger has explained clearly and in detail possible implications and risks as well as type, relevance, and scope of the clinical trial, and ensuing requirements. In addition, I have read the text of this information and consent form which includes 7 pages in total. Questions that have occurred have been answered by the principal researcher adequately and comprehensibly. I have had enough time to make my decision. I do not have further questions at the moment.

I will adhere to directions given by the principal researcher that are required for the conduct of the clinical trial, but reserve my right to terminate my voluntary participation at any time, without any adverse consequences on the care and support I receive or on the treatment of my child.

I also agree to the recording of my data within this clinical trial.

In handling the data, regulations of the Data Protection Act are adhered to.

I have received a copy of this information and consent form. The original is retained by the principal researcher.

.....

(Date and participant's signature)

.....

(Date and principal researcher's signature)

12. Video recordings consent form

I agree that video recordings of my child may be taken within this research project and may be used for research purposes.

yes ☐

no ☐

I agree that video recordings of my child within this research project may be used at professional congresses, conferences, and in further education of professionals.

yes ☐

no ☐

Child's name:

Parent's/guardian's name:

Parent's/guardian's signature:

Date: 201 ...

Appendix E. Information and consent form (German version)

Version 4 as submitted to the Medical University of Vienna's ethics commission on December 28, 2011.



universität
wien

Universität Wien

Fakultät für Psychologie

Institut für Angewandte Psychologie: Gesundheit, Entwicklung und Förderung
Liebiggasse 5, 1010 Wien



Aalborg University

Department of Communication and Psychology

Doctoral Programme in Music Therapy

Kroghstræde 6, 9220 Aalborg Øst
Dänemark

Teilnehmer/innen-Information und Einwilligungserklärung zur Teilnahme an der klinischen Studie

Effekte improvisationsbasierter Musiktherapie auf sozial-kommunikative Fähigkeiten von Vorschulkindern mit Autismus – eine randomisierte kontrollierte Pilotstudie

[Effects of Improvisational Music Therapy
on Social Communication Skills in Pre-school Children with Autism
– a Randomised Controlled Pilot Trial]

Sehr geehrte Eltern/Erziehungsberechtigte!

Wir laden Sie und Ihr Kind ein, an der oben genannten klinischen Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen Informationsgespräch mit der Studienleiterin, MMMag. Monika Geretsegger. **Ihre Teilnahme an dieser klinischen Studie erfolgt freiwillig. Sie können jederzeit, auch ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre Betreuung oder die Behandlung Ihres Kindes.**

Die Studienleiterin (Monika Geretsegger) ist Musiktherapeutin sowie klinische und Gesundheitspsychologin und arbeitet seit dem Jahr 2002 mit Kindern mit Autismus-Spektrum-Störung. Derzeit ist sie als PhD Research Fellow an der Universität Aalborg/Dänemark (Doctoral Programme in Music Therapy) tätig; dies umfasst die Durchführung dieser klinischen Studie, die von Assoc.Prof. Dr. Ulla Holck, Aalborg University, Aalborg/Dänemark, und Prof. Dr. Christian Gold, Grieg Academy Music Therapy Research Centre, Bergen/Norwegen supervidiert wird und in Kooperation mit dem Institut für Angewandte Psychologie: Gesundheit, Entwicklung und Förderung der Fakultät für Psychologie, Universität Wien, durchgeführt wird.

Klinische Studien sind notwendig, um verlässliche neue Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit der Studienleiterin sorgfältig durch und zögern Sie nicht, Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur,

- wenn Sie Art und Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer/in an dieser klinischen Studie im Klaren sind.

Zu dieser klinischen Studie sowie zur Teilnehmer/innen-Information und Einwilligungserklärung wurden von der zuständigen Ethik-Kommission der Medizinischen Universität Wien sowie vom Human Research Ethics Board der Universität Aalborg/Dänemark befürwortende Stellungnahmen abgegeben.

1. Was ist der Zweck der klinischen Studie?

Wir wollen mit dieser klinischen Studie herausfinden, welche Auswirkungen Musiktherapie auf sozial-kommunikative Fähigkeiten von Vorschulkindern mit Autismus-Spektrum-Störung hat. Außerdem untersuchen wir, wie sich die Häufigkeit von Musiktherapie-Einheiten auf die Entwicklung dieser Fähigkeiten auswirkt.

Frühe sozial-kommunikative Fähigkeiten bilden die Grundlage für die Sprachentwicklung, die Entwicklung sozialer Kompetenzen und auch für die emotionale und kognitive Entwicklung eines Kindes. Bei Kindern mit Autismus-Spektrum-Störung (ASS) zeigen sich bezüglich dieser sozial-kommunikativen Fähigkeiten meist deutliche Einschränkungen.

Einige Forschungsergebnisse und zahlreiche Berichte aus der Praxis weisen darauf hin, dass improvisationsbasierte Musiktherapie Kindern mit Autismus-Spektrum-Störung helfen kann, Gefühle auszudrücken und mit anderen zu teilen sowie mit anderen in Interaktion zu treten. Dabei bezieht sich die Musiktherapeutin mit improvisierter Musik und auch verbal auf musikalische und sonstige Äußerungen des Kindes und schafft so ein Umfeld, in dem Kontakt und Interaktion ermöglicht wird.

Ziel dieser Studie ist es auch, musiktherapeutische Behandlungsrichtlinien besser zu bestimmen, was dazu führen kann, dass Kinder mit ASS leichter Zugang zu musiktherapeutischer Behandlung bekommen. So werden die Ergebnisse dieser Studie für künftige Forschungsbemühungen im Bereich der Behandlungsmethoden von ASS wertvoll sein, ebenso aber auch für Familien von Kindern mit ASS, die an wirksamen und praktikablen Möglichkeiten zur Entwicklungsförderung ihrer Kinder interessiert sind.

2. Wie läuft die klinische Studie ab?

Diese klinische Studie wird in Wien an mehreren Orten durchgeführt, und es werden insgesamt ca. 16 Kinder daran teilnehmen. Ihre Teilnahme an dieser klinischen Studie wird 5 Monate dauern. Ein Jahr nach dem Beginn Ihrer Teilnahme wird außerdem noch eine Nachuntersuchung durchgeführt.

Während dieser klinischen Studie werden die folgenden Untersuchungen bzw. Interventionen durchgeführt:



zu Beginn:

ADI-R (*Diagnostisches Interview für Autismus-Revidiert*); dies ist ein ausführliches Interview zu einzelnen Entwicklungsbereichen des Kindes, das mit Ihnen durchgeführt wird.

K-ABC (*Kaufman Assessment Battery for Children*); dies ist ein Verfahren, bei dem mittels verschiedener Aufgaben der kognitive Entwicklungsstand des Kindes bestimmt wird.

ADOS (*Diagnostische Beobachtungsskala für Autistische Störungen*); dies ist ein halbstrukturiertes, standardisiertes Beobachtungsverfahren, bei dem die Untersucherin mit dem Kind mittels unterschiedlicher Spielsituationen und Dialogen in spielerische Interaktion tritt.

SRS (*Skala zur Erfassung sozialer Reaktivität – Dimensionale Autismus-Diagnostik*); dies ist ein Fragebogen, bei dem Sie gebeten werden, Fragen zu verschiedenen Bereichen des Alltags, des Verhaltens und der Fähigkeiten Ihres Kindes zu beantworten.

Elternberatung (ca. 60 Minuten), in der Ihnen Informationen zu Autismus-Spektrum-Störungen, frühkindlicher Entwicklung und sozial-kommunikativen Fähigkeiten vermittelt sowie Hilfestellungen bei aktuellen Schwierigkeiten, Problemen oder Sorgen bezüglich der Entwicklung Ihres Kindes angeboten werden.

nach 2 Monaten: ADOS, SRS; Elternberatung (ca. 60 Minuten)

nach 5 Monaten: ADOS, SRS; Elternberatung (ca. 60 Minuten)

nach 12 Monaten: ADOS, SRS

Sie werden gebeten, hierzu jeweils in die Einrichtung zu kommen, die Ihnen bei der Terminvereinbarung mitgeteilt wird.

Insgesamt sind ca. sechs Besuche notwendig: ca. drei Besuche zu Beginn der Studienteilnahme (Dauer jeweils ca. 90 Minuten; davon betrifft ein Termin nur Sie als Eltern/Erziehungsberechtigte, die anderen beiden Sie gemeinsam mit Ihrem Kind), und je ein Termin nach 2, 5 und 12 Monaten (Dauer jeweils ca. 60 Minuten; an diesen drei Terminen nehmen Sie gemeinsam mit Ihrem Kind teil).

Zusätzlich kann es (je nach zufälliger Zuteilung) sein, dass Ihr Kind **fünf Monate lang Musiktherapie** erhält, wobei dies entweder einmal oder dreimal pro Woche stattfinden wird.

Eine Musiktherapie-Einheit dauert 30 Minuten.

Alle Musiktherapie-Einheiten sowie auch die Elternberatung werden per Videokamera aufgezeichnet.

Die **Videoaufnahmen** werden ausschließlich für Forschungszwecke verwendet und 4 Jahre und 11 Monate nach Ende des Forschungsprojektes gelöscht werden.

3. Worin liegt der Nutzen einer Teilnahme an der klinischen Studie?

Durch die Teilnahme an der klinischen Studie erhalten Sie eine kostenlose ausführliche Autismus-Spektrum-Diagnostik ihres Kindes, die von einer in diesem Bereich erfahrenen klinischen Psychologin durchgeführt wird.

In den Elternberatungen (ebenso kostenlos) erhalten Sie ausführliche Informationen zu Autismus-Spektrum-Störungen sowie Hilfestellungen bei aktuellen Sorgen und Problemen.

Im Falle der Zuteilung zur für Sie kostenfreien Musiktherapie hat Ihr Kind durch die individuell abgestimmte Förderung die Möglichkeit, durch eine Autismus-Spektrum-Störung bedingte Schwierigkeiten zu bearbeiten, bspw. seine sozial-kommunikativen Fähigkeiten auszubauen, sein Selbstbewusstsein zu steigern und seine Kreativität und Flexibilität zu entwickeln. Alle Therapien und Beratungen werden ausschließlich von Expertinnen mit mehrjähriger Erfahrung im Bereich Autismus-Spektrum-Störung durchgeführt.

Während und nach Ihrer Teilnahme erhalten Sie ausführliche Informationen über Untersuchungsergebnisse zum jeweiligen Entwicklungsstand Ihres Kindes sowie zu Ergebnissen dieses Forschungsprojektes.

4. Gibt es Risiken, Beschwerden und Begleitscheinungen?

Aus bisherigen Forschungsergebnissen sowie der klinischen Praxis der in der Studie gesetzten Maßnahmen und Interventionen sind keine Risiken oder unerwünschten Begleitscheinungen bekannt.

5. Zusätzliche Inanspruchnahme anderer Behandlungsmaßnahmen?

Es besteht für Sie und Ihr Kind keinerlei Einschränkung bezüglich anderer therapeutischer Maßnahmen und Interventionen, die Sie für die Dauer Ihrer Teilnahme an dieser klinischen Studie in Anspruch nehmen möchten, jedoch soll Ihr Kind für die Dauer der Teilnahme (inkl. Nachuntersuchung) keine (andere) musiktherapeutische Behandlung erhalten.

6. Was ist zu tun beim Auftreten von zusätzlichen Symptomen, Begleitscheinungen und/oder Verletzungen?

Sollten im Verlauf der klinischen Studie irgendwelche negativen Effekte, Begleitscheinungen oder Verletzungen auftreten, müssen Sie diese der Studienleiterin mitteilen, ggf. telefonisch (Kontaktdaten siehe Seite 5).

7. Wann wird die klinische Studie vorzeitig beendet?

Sie können jederzeit, auch ohne Angabe von Gründen, Ihre Teilnahmebereitschaft widerrufen und aus der klinischen Studie ausscheiden, ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere Betreuung oder die Behandlung Ihres Kindes entstehen. Erhobene Daten und Filmaufnahmen werden bei vorzeitigem Austritt aus der Studie auf Anfrage vernichtet.

In sehr seltenen Fällen ist es möglich, dass die Studienleiterin entscheidet, Ihre Teilnahme an der klinischen Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

- Sie können den Erfordernissen der klinischen Studie nicht entsprechen;
- die Studienleiterin hat den Eindruck, dass eine weitere Teilnahme an der klinischen Studie nicht in Ihrem Interesse ist.

8. In welcher Weise werden die im Rahmen dieser klinischen Studie gesammelten Daten verwendet?

Nur die Studienleiterin und deren Mitarbeiter/innen haben Zugang zu den vertraulichen Daten, in denen Sie namentlich genannt werden. Diese Personen unterliegen der Verschwiegenheitspflicht. Die Weitergabe der Daten erfolgt ausschließlich zu statistischen Zwecken, und Sie werden ausnahmslos darin nicht namentlich genannt. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Studie werden Sie nicht namentlich genannt.

9. Entstehen für die Teilnehmer/innen Kosten? Gibt es einen Kostenersatz?

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie keine zusätzlichen Kosten.

In begründeten Fällen (geringes Haushaltseinkommen, Arbeitslosigkeit o.ä.) kann bei einer Teilnahme an dieser klinischen Studie im Hinblick auf die budgetäre Bedeckbarkeit ein Fahrtkostenzuschuss für die Fahrten zu den Musiktherapie-Einheiten gewährt werden. Die Höhe des Zuschusses richtet sich nach dem Grad der sozialen Bedürftigkeit¹. Der Fahrtkostenzuschuss wird jeweils am Ende eines Monats ausbezahlt.

10. Möglichkeit zur Diskussion weiterer Fragen

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie steht Ihnen die Studienleiterin gern zur Verfügung. Auch Fragen, die Ihre Rechte als Teilnehmer/in an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Name der Kontaktperson: Mag.art. Mag.phil. Mag.rer.nat. Monika Geretsegger

erreichbar unter: monika.geretsegger@univie.ac.at

Tel: +43-

¹ **Berechnungsbeispiel:** Bruttohaushaltseinkommen jährlich < 35.000,- € bei einem 4-Personen-Haushalt ergibt einen Fahrtkostenzuschuss von 36,- € im Monat bei dreimal wöchentlich stattfindender Musiktherapie.

11. Einwilligungserklärung

Name des Erziehungsberechtigten in Druckbuchstaben:

.....

Geb.Datum: Code:

Ich erkläre mich bereit, gemeinsam mit meinem Kind,

geb. am 20....., an der klinischen Studie „Effects of Improvisational Music Therapy on Social Communication Skills in Pre-school Children with Autism – a Randomised Controlled Trial“, die von MMMag. Monika Geretsegger unter der Supervision von Assoc.Prof. Dr. Ulla Holck und Prof. Dr. Christian Gold durchgeführt wird, teilzunehmen.

Ich bin von Frau MMMag. Monika Geretsegger ausführlich und verständlich über mögliche Belastungen und Risiken sowie über Wesen, Bedeutung und Tragweite der klinischen Studie und die sich für mich daraus ergebenden Anforderungen aufgeklärt worden. Ich habe darüber hinaus den Text dieser Teilnehmer/innen-Information und Einwilligungserklärung, die insgesamt 7 Seiten umfasst, gelesen. Aufgetretene Fragen wurden mir von der Studienleiterin verständlich und genügend beantwortet. Ich hatte ausreichend Zeit, mich zu entscheiden. Ich habe zur Zeit keine weiteren Fragen mehr.

Ich werde den Anordnungen der Studienleiterin, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile für meine weitere Betreuung oder die Behandlung meines Kindes entstehen. Ich bin zugleich damit einverstanden, dass meine im Rahmen dieser klinischen Studie ermittelten Daten aufgezeichnet werden. Beim Umgang mit den Daten werden die Bestimmungen des Datenschutzgesetzes beachtet (siehe www.dsk.gv.at/site/6200/default.aspx).

Eine Kopie dieser Teilnehmer/innen-Information und Einwilligungserklärung habe ich erhalten. Das Original verbleibt bei der Studienleiterin.

.....
(Datum und Unterschrift des/der Erziehungsberechtigten).....
(Datum und Unterschrift der Studienleiterin)

12. Einwilligungserklärung zu Videoaufnahmen

Ich erkläre mich damit einverstanden, dass in diesem Forschungsprojekt Videoaufnahmen meines Kindes angefertigt und für Forschungszwecke verwendet werden.

ja ☐nein ☐

Ich erkläre mich damit einverstanden, dass Videoaufnahmen meines Kindes in diesem Forschungsprojekt innerhalb von Fachkongressen, Fachtagungen und Weiterbildungsseminaren verwendet werden.

ja ☐nein ☐

Name des Kindes:

Name des/der Erziehungsberechtigten:

Unterschrift des/der Erziehungsberechtigten:

Datum: 201 ...

Appendix F. Music therapy session notes form

MUSIC THERAPY — DOCUMENTATION FORM				
client:			therapist:	
session #	date:		starting time:	duration:
	Mon	Tue		

goals:	
--------	--

amount of structuring/directive activities provided by therapist:				
hardly any / very little	<input type="checkbox"/>	only few	<input type="checkbox"/>	some
			<input type="checkbox"/>	quite a few
				<input type="checkbox"/>
				a lot
				<input type="checkbox"/>

therapist assessing the session as...				
hardly demanding	<input type="checkbox"/>	a little demanding	<input type="checkbox"/>	medium demanding
			<input type="checkbox"/>	quite demanding
				<input type="checkbox"/>
				extremely demanding
				<input type="checkbox"/>

intervention techniques applied:			
	not at all	a little / sometimes	a lot / often
improvisation on instrument(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
voice improvisation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
improvisation using voice and instrument(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
movement/body	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
pause	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
verbal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

interaction theme(s):	
difficult situation(s):	
significant moment(s):	

child's vocal expression:			
	not at all	a little / sometimes	a lot / often
cooing / babbling / vocalizing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
single syllables / (proto-) words	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
multi-word phrases	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
echolalia	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
humming / singing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
screaming / crying	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
no vocal utterances	<input type="checkbox"/>		

child's use of instruments:			
type of instrument:	not used	sensorially / focusing on object properties	musically / as a means of expression
small percussion	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
drums	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
xylophones etc.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
string instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
keyboard instruments	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
furniture	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
no instruments used	<input type="checkbox"/>		

child's social-communicative behaviour:			
	not at all	a little / sometimes	a lot / often
stereotyped behaviour	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
reaction to therapist or joint activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
emotional sharing / shared affect	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
imitation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
joint attention	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
expectation towards therapist	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
initiation of interaction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
other:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix G. Treatment guide survey: Invitation letter

Von: Monika Geretsegger <mg@hum.aau.dk>

Gesendet: Freitag, 07. Juni 2013 14:42

An: [REDACTED]

Betreff: treatment guide for improvisational MT in ASD - survey participation request

Anlagen: treatment-guide-IMT-ASD_v1.pdf; IMT-ASDprinciples+examples_survey_may2013.docx

Dear [REDACTED],

I'm a music therapist writing to you from Vienna/Austria where I'm currently involved in the research project [TIME-A](#) as part of my PhD studies in Aalborg/Denmark.

[REDACTED] has passed on your email address to me so that I can contact you as an expert experienced in improvisational music therapy (IMT) in the field of autism spectrum disorder (ASD).

I would like to kindly ask for your help and invite you to take part in a **survey about a treatment guide for IMT for children with ASD** that Ulla Holck (DK), John Carpente (USA), Christian Gold (NOR), Cochavit Elefant (ISR), Jinah Kim (KOR) and myself have developed in the context of TIME-A.

The treatment guide aims at concisely summarising the most important common characteristics of IMT for children with ASD as applied across various countries. Unlike a manual with fixed sequences of steps and techniques, this treatment guide focuses on basic principles of the approach and is designed to be applied flexibly by trained music therapists according to the particular circumstances and needs of the client within the therapy process.

The survey is sent out to IMT/ASD experts in eleven countries worldwide, and we look forward to all your valuable feedback that will help us to validate and refine the treatment guide so that it appropriately reflects clinical practice and knowledge across countries and individual music therapists' backgrounds.

In order to participate in the survey, I recommend that you first read the treatment guide itself (i.e., the PDF file attached), and then use the attached text file to assess comprehensibility, accuracy, and importance of the ten therapy principles suggested and their related examples. When you have completed the survey, please save it locally and then return it to me via email. If you experience

any technical difficulties accessing or editing the survey file, please let me know so that we can find another feasible option. Please also get in touch if you have any queries or would like to have any further information.

We greatly appreciate any input, and I thank you in advance for your time and efforts and for sharing your expertise!

With my best wishes from Vienna,
Monika.

...

Mag.art. Mag.phil. Mag.rer.nat.

Monika Geretsegger | music therapist · clinical & health psychologist ·
PhD fellow at Aalborg University · project employee at University of Vienna

...

T: +43 [REDACTED]

...

Doctoral Programme in Music Therapy · Department of Communication and Psychology

Aalborg University | Kroghstræde 6 · 9220 Aalborg Øst · Denmark

Email: mg@hum.aau.dk | Web: <http://personprofil.aau.dk/profil/122893>

...

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Appendix H. Treatment guide survey: Questionnaire

TIME-A | TREATMENT GUIDE SURVEY • Improvisational music therapy (IMT) for children with autism spectrum disorder (ASD)

Below you see an overview of principles considered important in IMT for children with ASD, and their corresponding rationale, therapist's attitude, activity category, and examples. Please use the fields marked in green to assess for each of the rows whether you find the items and their sequence understandable (a), whether you agree with them (b), and how important you think they are (c). If you have any suggestions for changes or other additional comments, please add them under (d) and (e). To suggest any additional items for a category (unique & essential / essential / compatible / proscribed), please use the empty row provided at the end of the respective category.

	<i>principle</i>	<i>purpose / rationale</i>	<i>attitude</i>	<i>category of activities</i>	<i>example / technique</i>	
	1	FACILITATE MUSICAL & EMOTIONAL ATTUNEMENT	increase opportunities for awareness of self, shared attention, social reciprocity, and relationship building	follow the child's focus of attention, behaviours, and interests; meet the child where s/he is musically and/or emotionally	create moments of musical attunement / synchronicity that may develop into emotional attunement / emotional sharing; incorporate the child's interests and skills	respond to the child's utterances and behaviour using improvised music (e.g., by holding, mirroring, matching techniques)
	1a) Do you understand this item? (no / somewhat / yes)					
	1b) Do you agree with this item? (no / somewhat / yes)					
	1c) How important is this item? (not important / somewhat important / very important)					
	1d) What changes would you suggest, if any?					
1e) Any additional thoughts?						
	2	SCAFOLD INTERACTIONS DYNAMICALLY	increase opportunities for the child to comprehend, engage in, and initiate interaction	meet the child's initiatives / behaviour as communicatively intended	while following the child's lead and musical ideas, form the child's expressions into recognisable musical forms, patterns, or motifs	apply improvisational music therapy techniques (e.g., rhythmic grounding, shaping, exaggerating, extemporising, frameworking)
	2a) Do you understand this item? (no / somewhat / yes)					
	2b) Do you agree with this item? (no / somewhat / yes)					
	2c) How important is this item? (not important / somewhat important / very important)					
	2d) What changes would you suggest, if any?					
2e) Any additional thoughts?						

unique & essential

unique & essential				

	<i>principle</i>	<i>purpose / rationale</i>	<i>attitude</i>	<i>category of activities</i>	<i>example / technique</i>
5	PROVIDE A SECURE ENVIRONMENT	facilitate predictability/ feeling safe and secure: keep the child's anxiety low	present as reliable and responsible interaction partner	provide for consistency in therapy settings	maintain same therapy room and equipment
				respond to the child's behaviour in consistent ways	avoid retreating from interaction partner into "observer" role
				comment on/ explain interruptions and unexpected events	if it is necessary to terminate the session, explain why you find it necessary to do so
				prepare for beginnings and endings	use hello and goodbye songs or rituals
5a) Do you understand this item? (no/ somewhat/ yes)					
5b) Do you agree with this item? (no/ somewhat/ yes)					
5c) How important is this item? (not important/ somewhat important/ very important)					
5d) What changes would you suggest, if any?					
5e) Any additional thoughts?					
6	BUILD AND MAINTAIN A POSITIVE THERAPEUTIC RELATIONSHIP	enable rapport and continuation of therapy	present with interest, respect, confidence	understand / reflect upon meanings of the child's and the therapist's behaviour	display empathy during (musical) interaction
6a) Do you understand this item? (no/ somewhat/ yes)					
6b) Do you agree with this item? (no/ somewhat/ yes)					
6c) How important is this item? (not important/ somewhat important/ very important)					
6d) What changes would you suggest, if any?					
6e) Any additional thoughts?					

essential (but not unique to IMT)

essential (but not unique to IMT)

<i>essential (but not unique to IMT)</i>							
	principle		purpose / rationale		attitude	category of activities	example / technique
7	FOLLOW THE CHILD'S LEAD (NON-DIRECTIVE APPROACH)		facilitate intrinsic motivation		follow the child's focus of attention, behaviours, and interests; meet the child where s/he is musically and/or emotionally	incorporate the child's interests and motivations match level of session / interaction structure to child's needs	relate to a child's preference for numbers in making up a "number song" allow the child to control certain aspects of the interaction; allow the child to functionalise the therapist; offer choices
			keep the child's anxiety/low				
7a) Do you understand this item? (no / somewhat / yes)							
7b) Do you agree with this item? (no / somewhat / yes)							
7c) How important is this item? (not important / somewhat important / very important)							
7d) What changes would you suggest, if any?							
7e) Any additional thoughts?							
8	SET TREATMENT GOALS		meet the individual child's needs; guide and evaluate the therapy process		enable the child to reach the respective next developmental stage in a certain skill area	assess the child's competences, emerging abilities, and needs; choose an intervention strategy and technique according to an assessed need in a specific area	if the child is aware of his/her own and the therapist's (musical) actions, foster reciprocal interactions
8a) Do you understand this item? (no / somewhat / yes)							
8b) Do you agree with this item? (no / somewhat / yes)							
8c) How important is this item? (not important / somewhat important / very important)							
8d) What changes would you suggest, if any?							
8e) Any additional thoughts?							
Would you suggest any additional items (principles) in this category?							
➔							

	<i>principle</i>	<i>purpose / rationale</i>	<i>attitude</i>	<i>category of activities</i>	<i>example / technique</i>
9	ADJUST SETTING ACCORDING TO FAMILIES' NEEDS, CLINICAL JUDGEMENT, AND PRACTICAL POSSIBILITIES	facilitate generalisation of skills to everyday settings; support families in building safe relationships among family members	consider the whole range of settings of the child's everyday life	allow for participation of parents / caregivers or other family members in therapy session employ family member-mediated intervention strategies	improvise together with the child and a family member in home environment discuss with family members how they can employ musical experiences in interacting with the child; encourage parents to sing and vocalise together with their child
<p>9a) Do you understand this item? (no / somewhat / yes)</p> <p>9b) Do you agree with this item? (no / somewhat / yes)</p> <p>9c) How important is this item? (not important / somewhat important / very important)</p> <p>9d) What changes would you suggest, if any?</p> <p>9e) Any additional thoughts?</p>					
Would you suggest any additional items (principles) in this category?					
→					

compatible
(efficient but not necessary)

		<i>principle</i>	<i>purpose / rationale</i>	<i>attitude</i>	<i>category of activities</i>	<i>example / technique</i>
	10	ADHERE TO PREDETERMINED TREATMENT SCHEDULE	implement distinct skills and behaviours	purely directive, educational	use explicit demands that the child complies to task requirements ; use extrinsic means of reinforcement	apply an imitation task (model and prompt to imitate) without reference to the child's expression
<i>proscribed</i>	10a)	Do you understand this item? (no / somewhat / yes)				
	10b)	Do you agree with this item? (no / somewhat / yes)				
	10c)	How important is this item? (not important / somewhat important / very important)				
	10d)	What changes would you suggest, if any?				
	10e)	Any additional thoughts?				
	Would you suggest any additional items (principles) in this category?					
	→					

SOURCES: Carpente (2009); Holick (2004); Kim (2006); Kim, Wigram, & Gold (2009); Schumacher (1999); Thompson (2012a, 2012b); Wigram (2004); Wigram & Elefant (2009); & the authors' (JC, UH, CE, MG, CG) clinical experience

PART B: ARTICLES

CO-AUTHOR STATEMENTS IN CONNECTION WITH SUBMISSION OF PHD THESIS

CO-AUTHORS' STATEMENT # 1

Paper title:

Music therapy for people with autism spectrum disorder

Authors:

Monika Geretsegger, Cochavit Elefant, Karin A. Mössler, Christian Gold

Status:

Published in *The Cochrane Library* (2014).

Description of authors' contributions:

C. Gold had designed the protocol and co-ordinated the reviewing for the initial review published in 2006. M. Geretsegger co-ordinated this review's update and drafted the manuscript. M. Geretsegger and C. Gold searched for studies. M. Geretsegger, C. Elefant, and C. Gold screened search results. All authors extracted data, analysed data, wrote the report, and approved the full review.

We hereby confirm the statement above is true and accurate.

Monika Geretsegger

Cochavit Elefant

Karin A. Mössler

Christian Gold

CO-AUTHORS' STATEMENT # 2

Paper title:

Randomised controlled trial of improvisational music therapy's effectiveness for children with autism spectrum disorders (TIME-A): Study protocol

Authors:

Monika Geretsegger, Ulla Holck, Christian Gold

Status:

Published in *BMC Pediatrics* (2012).

Description of authors' contributions:

M. Geretsegger and C. Gold conceived the study and developed the study design. M. Geretsegger drafted the manuscript. C. Gold did the power calculation and helped to draft the manuscript. U. Holck contributed to the development of the study design and helped to draft the manuscript. All authors approved the final manuscript.

We hereby confirm the statement above is true and accurate.

Monika Geretsegger

Ulla Holck

Christian Gold

CO-AUTHORS' STATEMENT # 3

Paper title:

Defining improvisational music therapy: Development of a treatment guide for children with autism spectrum disorder

Authors:

Monika Geretsegger, Ulla Holck, John Carpenté, Cochavit Elefant, Jinah Kim, Christian Gold

Status:

Submitted to a peer-reviewed journal. Under review.

Description of authors' contributions:

M. Geretsegger was the main researcher responsible for designing and conducting the study, conducting the survey and co-ordinating focus groups, collecting and analysing data and writing the article. U. Holck and C. Gold supervised the designing and conducting of the study and provided expert advice during data analysis and writing up. C. Gold contributed to data collection. J. Carpenté, C. Elefant, and J. Kim provided expert advice during designing the survey and writing up the manuscript. All authors approved the final draft of this article.

We hereby confirm the statement above is true and accurate.

Monika Geretsegger

Ulla Holck

John Carpenté

Cochavit Elefant

Jinah Kim

Christian Gold

CO-AUTHORS' STATEMENT # 4

Paper title:

Feasibility of a trial on improvisational music therapy for children with autism spectrum disorder: An internal pilot cohort

Authors:

Monika Geretsegger, Ulla Holck, Łucja Bieleninik, Christian Gold

Status:

Submitted to a peer-reviewed journal. Under review.

Description of authors' contributions:

M. Geretsegger and C. Gold conceived the study and developed the study design. U. Holck contributed to the development of the study design.

M. Geretsegger was the main researcher responsible for conducting the study, implementing study procedures, collecting and analysing data and writing the article. U. Holck and C. Gold supervised the designing and conducting of the study. C. Gold provided statistical support. U. Holck, Ł. Bieleninik, and C. Gold provided expert advice during data analysis and writing up. All authors approved the final manuscript.

We hereby confirm the statement above is true and accurate.

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I. SYSTEMATIC REVIEW

Geretsegger, M., Elefant, C., Mössler, K. A., & Gold, C.
Music therapy for people with autism spectrum disorder.
Cochrane Database of Systematic Reviews 2014, Issue 6.
Art. No.: CD004381. DOI: 10.1002/14651858.CD004381.pub3.
(<http://dx.doi.org/10.1002/14651858.CD004381.pub3>)

This Cochrane Review is published in the *Cochrane Database of Systematic Reviews* 2014, Issue 6. Cochrane Reviews are regularly updated as new evidence emerges and in response to feedback, and the *Cochrane Database of Systematic Reviews* should be consulted for the most recent version of the Review.

Music therapy for people with autism spectrum disorder (Review)

Geretsegger M, Elefant C, Mössler KA, Gold C



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Music therapy for people with autism spectrum disorder

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

Publication status and date: New search for studies and content updated (conclusions changed), published in Issue 6, 2014.

Review content assessed as up-to-date: 2 December 2013.

Citation: Geretsegger M, Elefant C, Mössler KA, Gold C. Music therapy for people with autism spectrum disorder. *Cochrane Database of Systematic Reviews* 2014, Issue 6. Art. No.: CD004381. DOI: 10.1002/14651858.CD004381.pub3.

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ABSTRACT

Background

The central impairments of people with autism spectrum disorder (ASD) affect social interaction and communication. Music therapy uses musical experiences and the relationships that develop through them to enable communication and expression, thus attempting to address some of the core problems of people with ASD. The present version of this review on music therapy for ASD is an update of the original Cochrane review published in 2006.

Objectives

To assess the effects of music therapy for individuals with ASD.

Search methods

We searched the following databases in July 2013: CENTRAL, Ovid MEDLINE, EMBASE, LILACS, PsycINFO, CINAHL, ERIC, ASSIA, Sociological Abstracts, and Dissertation Abstracts International. We also checked the reference lists of relevant studies and contacted investigators in person.

Selection criteria

All randomised controlled trials (RCTs) or controlled clinical trials comparing music therapy or music therapy added to standard care to 'placebo' therapy, no treatment, or standard care for individuals with ASD were considered for inclusion.

Data collection and analysis

Two authors independently selected studies, assessed risk of bias, and extracted data from all included studies. We calculated the pooled standardised mean difference (SMD) and corresponding 95% confidence interval (CI) for continuous outcomes to allow the combination of data from different scales and to facilitate the interpretation of effect sizes. Heterogeneity was assessed using the I^2 statistic. In cases of statistical heterogeneity within outcome subgroups, we examined clients' age, intensity of therapy (number and frequency of therapy sessions), and treatment approach as possible sources of heterogeneity.

Main results

We included 10 studies (165 participants) that examined the short- and medium-term effect of music therapy interventions (one week to seven months) for children with ASD. Music was superior to 'placebo' therapy or standard care with respect to the primary outcomes social interaction within the therapy context (SMD 1.06, 95% CI 0.02 to 2.10, 1 RCT, n = 10); generalised social interaction outside of the therapy context (SMD 0.71, 95% CI 0.18 to 1.25, 3 RCTs, n = 57, moderate quality evidence), non-verbal communicative skills within the therapy context (SMD 0.57, 95% CI 0.29 to 0.85, 3 RCTs, n = 30), verbal communicative skills (SMD 0.33, 95% CI 0.16 to 0.49, 6 RCTs, n = 139), initiating behaviour (SMD 0.73, 95% CI 0.36 to 1.11, 3 RCTs, n = 22, moderate quality evidence), and social-emotional reciprocity (SMD 2.28, 95% CI 0.73 to 3.83, 1 RCT, n = 10, low quality evidence). There was no statistically significant difference in non-verbal communicative skills outside of the therapy context (SMD 0.48, 95% CI -0.02 to 0.98, 3 RCTs, n = 57, low quality evidence). Music therapy was also superior to 'placebo' therapy or standard care in secondary outcome areas, including social adaptation (SMD 0.41, 95% CI 0.21 to 0.60, 4 RCTs, n = 26), joy (SMD 0.96, 95% CI 0.04 to 1.88, 1 RCT, n = 10), and quality of parent-child relationships (SMD 0.82, 95% CI 0.13 to 1.52, 2 RCTs, n = 33, moderate quality evidence). None of the included studies reported any adverse effects. The small sample sizes of the studies limit the methodological strength of these findings.

Authors' conclusions

The findings of this updated review provide evidence that music therapy may help children with ASD to improve their skills in primary outcome areas that constitute the core of the condition including social interaction, verbal communication, initiating behaviour, and social-emotional reciprocity. Music therapy may also help to enhance non-verbal communication skills within the therapy context. Furthermore, in secondary outcome areas, music therapy may contribute to increasing social adaptation skills in children with ASD and to promoting the quality of parent-child relationships. In contrast to the studies included in an earlier version of this review published in 2006, the new studies included in this update enhanced the applicability of findings to clinical practice. More research using larger samples and generalised outcome measures is needed to corroborate these findings and to examine whether the effects of music therapy are enduring. When applying the results of this review to practice, it is important to note that the application of music therapy requires specialised academic and clinical training.

PLAIN LANGUAGE SUMMARY

Music therapy for people with autism spectrum disorder

Review Question

We reviewed the evidence about the effect of music therapy in people with autism spectrum disorder (ASD). We compared music therapy or music therapy in addition to standard care to no therapy, similar treatment without music ('placebo' therapy), or standard care.

Background

People with ASD have difficulties with social interaction and communication. Music therapy uses musical experiences and the relationships that develop through them to enable people to relate to others, to communicate, and to share their feelings. In this way, music therapy addresses some of the core problems of people with ASD. We wanted to discover whether music therapy helps people with ASD compared to other alternatives.

Study Characteristics

We included 10 studies with a total number of 165 participants. The studies examined the short- and medium-term effect of music therapy interventions (one week to seven months) for children with ASD.

Key Results

Music therapy was superior to 'placebo' therapy or standard care with respect to social interaction, non-verbal and verbal communicative skills, initiating behaviour, and social-emotional reciprocity. Music therapy was also superior to 'placebo' therapy or standard care in the areas of social adaptation, joy, and the quality of parent-child relationships. None of the included studies reported any side effects caused by music therapy.

Quality of the Evidence

The quality of the evidence was moderate for social interaction outside of the therapy context, initiating behaviour, social adaptation, and the quality of the parent-child relationship, and low for the other three main outcomes (nonverbal communicative skills outside of the therapy context, verbal communicative skills outside of the therapy context, and social-emotional reciprocity). Reasons for limited quality of the evidence were issues with study design and small number of patients who participated in the studies.

Authors' Conclusions

Music therapy may help children with ASD to improve their skills in important areas such as social interaction and communication. Music therapy may also contribute to increasing social adaptation skills in children with ASD and to promoting the quality of parent-child relationships. Some of the included studies featured interventions that correspond well with treatment in clinical practice. More research with adequate design and using larger numbers of patients is needed. It is important to specifically examine how long the effects of music therapy last. The application of music therapy requires specialised academic and clinical training. This is important when applying the results of this review to practice.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Music therapy compared to 'placebo' therapy or standard care for autism spectrum disorder			
Patient or population: Individuals with autism spectrum disorder Settings: Outpatient therapy centre, hospital, school, or home Intervention: Music therapy Comparison: 'Placebo' therapy or standard care			
Outcomes	Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)
	Music therapy versus 'placebo' therapy or standard care		
Social interaction - Generalised (outside sessions, daily life) CARS, PDDBI, Vineland SEEC, SRS Follow-up: 4 to 7 months	The mean social interaction - 57 generalised (outside sessions, daily life) in the intervention groups was 0.71 standard deviations higher (0.18 to 1.25 higher)	(3 studies)	⊕⊕⊕○ moderate ^{1,2,4}
Communicative skills: non-verbal - Generalised (outside sessions, daily life) CARS, ESCS, MBCDI-W&G Follow-up: 4 to 7 months	The mean communicative skills: 57 non-verbal - generalised (outside sessions, daily life) in the intervention groups was 0.48 standard deviations higher (0.02 lower to 0.98 higher)	(3 studies)	⊕⊕○○ low ^{3,4}
Communicative skills: verbal - Generalised (outside sessions, daily life) CARS, MBCDI-W&G Follow-up: 4 to 7 months	The mean communicative skills: 47 verbal - generalised (outside sessions, daily life) in the intervention groups was 0.30 standard deviations higher (0.28 lower to 0.89 higher)	(2 studies)	⊕⊕○○ low ^{3,4}
Initiating behaviour - Non-generalised Requesting (initiating joint attention), imitation of engagement frequency, requesting behaviour Follow-up: 5 weeks to 4 months	The mean initiating behaviour - 22 non-generalised in the intervention groups was 0.73 standard deviations higher (0.36 to 1.11 higher)	(3 studies)	⊕⊕⊕○ moderate ^{1,2,4}
Social-emotional reciprocity - Non-generalised Emotional and musical synchronicity, frequency, and duration	The mean social-emotional reciprocity - non-generalised in the intervention groups was 2.28 standard deviations higher	10 (1 study)	⊕⊕⊕○ low ^{2,4,5}

Follow-up: 4 months	(0.73 to 3.83 higher)	
Social adaptation - Non-generalised Interaction (engaging in joint attention), compliant or non-compliant response frequency, no response frequency, on-task behaviour Follow-up: 5 weeks to 4 months	The mean social adaptation - non-generalised in the intervention groups was 1.15 standard deviations higher (0.69 to 1.61 higher)	⊕⊕⊕○ moderate ^{1,2,4}
Quality of parent-child relationship MPIP, PCRI Follow-up: 4 months	The mean quality of parent-child relationship in the intervention groups was 0.82 standard deviations higher (0.13 to 1.52 higher)	⊕⊕⊕○ moderate ^{2,4}

CI: Confidence interval

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

¹ Limitations in the designs such as poorly reported randomisation and blinding of outcomes.

² The estimated effect was in the large or close to the large range according to [Cohen 1988](#).

³ 95% confidence interval includes no effect and the upper confidence limit crosses an effect size of 0.5 ([GRADEpro 2008](#)).

⁴ Total number of participants in this outcome is lower than 400.

⁵ Only one study within this outcome.

BACKGROUND

Description of the condition

Autism spectrum disorder (ASD), as defined by the International Classification of Diseases and Related Health Problems, 10th edition (ICD-10) ([WHO 1992](#)), and the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM-5) ([APA 2013](#)), is considered to be a complex neurodevelopmental disorder that is defined and diagnosed behaviourally, and usually manifests in early childhood persisting throughout life.

Individuals with ASD have difficulties in various aspects of social communication. They also have a restricted imagination and social repertoire, the latter characteristically displayed as what seems to others to be obsessional behaviour and rigidity in their own behaviour as well as in the behaviour they require from others in response to their own. In the last two decades, the key construct has been the 'triad of impairment', which affects social interaction, language and communication, and behaviour and imagination ([Wing 1997](#)), that can be identified through examination of early development and current presentation ([Wing 2002](#)). Within the ICD-10 ([WHO 1992](#)), and the DSM-IV-TR ([APA 2000](#)), the last leg of the triad was defined as restricted repetitive and stereotyped patterns of behaviour, interests, and activities. However, in

new editions of the classification systems, the recently published DSM-5 and the forthcoming ICD-11, the first two areas have been merged resulting in only two core domains of ASD: (1) social communication or social interaction and (2) restricted, repetitive behaviours and interests (Lord 2012). People with ASD also present with pervasive difficulties to 'mind-read', where a lack of perception and understanding of other people's feelings, beliefs or emotions results in a consequential inability to respond appropriately (Baron-Cohen 1995). This has particular impacts on social skills and interactions (Howlin 1998).

The clinical picture varies because individuals have different levels of ability, from profound learning disability to a spiky cognitive profile where superior skills are present in some areas of functioning. At the high-functioning end of the autism spectrum is a condition known as Asperger's syndrome, with the same fundamental core impairments as autism but also some differences in language development, motor skills, and originality of thought (Asperger 1979); with the changes in DSM-5, Asperger's syndrome was merged into the single diagnostic category of ASD (APA 2013). Recent prevalence estimates for autism spectrum conditions vary according to factors such as method of case identification, age range, or standardisation of diagnostic measures, and range from 60 to 157 children per 10,000 (Baird 2006; Baron-Cohen 2009; Fombonne 2009; Fombonne 2010), suggesting much higher prevalence rates than estimates from older studies (Chakrabarti 2001; Fombonne 1999).

Description of the intervention

Music therapy has been 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, p. 20). Central music therapy techniques include free and structured improvisation, singing songs and vocalisation, and listening to both pre-recorded and live music.

Music therapy for individuals with ASD is usually provided as individual therapy, although there are also reports of group-based and peer-mediated interventions (Boso 2007; Kern 2006; Kern 2007). In recent years, family-centred approaches, where parents or other family members are included in therapy sessions, have increasingly become an important part of music therapy for children with ASD (Oldfield 2012; Pasiali 2004; Thompson 2012a; Thompson 2012b).

How the intervention might work

The processes that occur within musical interaction may help people with ASD to develop communication skills and the capacity for social interaction. Musical interaction in music therapy, in particular musical improvisation, can be understood and described as

a non-verbal and pre-verbal language that enables verbal people to access pre-verbal experiences, enables non-verbal people to interact communicatively without words, and enables all to engage on a more emotional, relationship-oriented level than may be accessible through verbal language (Alvin 1991). Listening to music within music therapy also involves an interactive process that often includes selecting music that is meaningful for the person (e.g. relating to an issue that the person is occupied with) and, where possible, reflecting on personal issues related to the music or associations brought up by the music. For those with verbal abilities, verbal reflection on the musical processes is often an important part of music therapy (Wigram 2002).

A rationale for the use of music therapy for individuals with communication disorders is based on the findings of infancy researchers such as Stern and Trevarthen who describe sound dialogues between mothers and infants using 'musical' terms (Stern 1985; Stern 1989; Stern 2010; Trevarthen 2000). When describing tonal qualities, researchers use the terms pitch, timbre, and tonal movement, and when describing temporal qualities, they speak of pulse, tempo, rhythm, and timing (Wigram 2002). Trevarthen 1999 describes the sensitivity of very young infants to the rhythmic and melodic dimensions of maternal speech, and to its emotional tone, as demonstrating that we are born ready to engage with the 'communicative musicality' of conversation, and this premise allows music to act as an effective medium for engaging in non-verbal social exchange for children and adults with ASD. Necessary communicative behaviours, such as joint attention, eye contact, and turn-taking, are characteristic events in shared, active music making and therefore inherent components of music therapy processes. In addition to music's potential to stimulate communication, Wigram and Elefant also explain how music therapists can use music, especially improvisational music-making, to provide children with ASD with opportunities to experience foundation-giving structure combined with measured flexibility, thus helping them to find ways of coping in less predictable situations that will typically pose challenges for them (Wigram 2009).

The potential for predictability and anticipation brought about by musical structures is an element also used in behavioural approaches where music is utilised as a stimulus facilitating the perception and production of speech and language and enhancing communication skills. Another rationale for using music in this way is the increased attention and enjoyment observed in individuals when presented with musical as opposed to verbal stimuli (Buday 1995; Lim 2010; Lim 2011).

Why it is important to do this review

This is an update of a Cochrane review first published in 2006 (Gold 2006). Before the original version of this review was published, clinical reports and pre-experimental studies had suggested that music therapy may be an effective intervention for people with ASD. For example, Edgerton 1994 examined the development of

communicative skills in 11 children with autism over the course of music therapy sessions, finding a continuous increase of communicative acts and responses in all subjects (Edgerton 1994). Schumacher described qualitatively how relationship patterns of children with autism changed and developed during long-term music therapy (Schumacher 1999a; Schumacher 1999b). Two earlier systematic reviews pertaining to the scope of this review yielded conflicting results. Whipple 2004 concluded that music therapy was effective for people with ASD. However, interventions and study designs were too heterogeneous to allow clinically meaningful and methodologically strong conclusions. Ball 2004 concluded that effects of music therapy were unclear. However, this review failed to identify many possibly relevant studies (Ball 2004). Thus, a more comprehensive systematic review of controlled studies in this area was deemed necessary.

The first version of this review concluded that music therapy may help children with ASD to improve their communicative skills, but also noted that more research was needed to investigate the effects of music therapy in typical clinical practice and within longer periods of observation (Gold 2006). A recent systematic review suggested that music therapy may be an effective treatment for young children with ASD for developing communication, interpersonal abilities, personal responsibility, and play skills (Whipple 2012). However, as in the author's previous review (Whipple 2004), the designs of the included studies lacked homogeneity and entailed various risks of bias (e.g. sample sizes of only one, lack of blinded observations).

We conducted the current update to summarise and evaluate new studies of music therapy for ASD published since the 2006 version of this review in order to provide comprehensive and up-to-date conclusions, as well as implications for practice and research that are based on recent findings.

OBJECTIVES

To review the effects of music therapy, or music therapy added to standard care, for individuals with ASD.

METHODS

Criteria for considering studies for this review

Types of studies

All relevant randomised controlled trials (RCTs) and controlled clinical trials (CCTs) were considered for inclusion. Studies using single-case experimental designs were included if they also met the definition of RCTs or CCTs. That is if the different interventions

were provided in a different order to different participants i.e. (cross-over RCTs/CCTs). Studies in which all participants received interventions in the same order (i.e. case series) were excluded.

Types of participants

Individuals of any age who are diagnosed with a pervasive developmental disorder, as defined in ICD-10 or DSM-IV or DSM-IV-TR, whether identified by a psychological assessment or a psychiatric diagnosis were considered inclusion. This includes childhood autism (F84.0 in ICD-10), atypical autism (F84.1), Asperger's syndrome (F84.5), and pervasive developmental disorder not otherwise specified (F84.9). Individuals with Rett's disorder (F84.2) or childhood disintegrative disorder (F84.3) were not included as they do not conventionally fall within the autism spectrum disorders, given their significantly different clinical course.

Types of interventions

Interventions included music therapy (i.e. regular sessions of music therapy as defined above), delivered by a professional music therapist, compared with either 'placebo' therapy (the concept of attention placebo in psychotherapy research is discussed in Kendall 2004), no-treatment, or standard care control; or music therapy added to standard care compared with standard care (with or without 'placebo').

Types of outcome measures

We regarded outcome measures in all areas of social communication as primary outcomes as they refer to the core characteristics defining ASD. We regarded commonly examined outcome measures in areas not specific to defining ASD characteristics as secondary outcomes.

Primary outcomes

Primary outcomes included the following.

- Social interaction.
- Communicative skills (non-verbal and verbal).
- Initiating behaviour.
- Social-emotional reciprocity.
- Adverse effects.

Secondary outcomes

Secondary outcomes included the following.

- Social adaptation skills (including outcomes that were summarised as behavioural problems, such as stereotypic behaviour, in the 2006 version of this review).
- Quality of life in school, home, and other environments.
- Quality of family relationships.
- Cognitive ability (including attention, concentration).

- Hyperacusis (hypersensitivity to sound).

Data sources could have included non-standardised or standardised instruments (for a review of relevant standardised instruments see [Ozonoff 2005](#)), parent or teacher report, or school records. Data from rating scales were only included if the instrument was either a self report or completed by an independent rater or relative (i.e. not the therapist). We also included outcomes initially rated by the therapist and reconfirmed by an independent rater.

Changes in generalised skills that are measured outside of the immediate treatment context pose the biggest challenge for any interventions for ASD ([Warren 2011](#)). Generalised outcomes refer to changes that generalise to other behaviours and to other contexts across settings, people, or materials. Because of the importance of generalised improvements for people with ASD, we reported the results that focus solely on 'within sessions' change (hereafter referred to as 'non-generalised' outcome measures) separately from those that assess the impact of music therapy broadly in other contexts (referred to as 'generalised' outcome measures).

In the [Summary of findings for the main comparison](#), we report the results of the three generalised outcomes: social interaction, non-verbal communicative skills, verbal communicative skills; three non-generalised outcomes that relate to core areas of difficulty for children with ASD: initiating behaviour, social-emotional reciprocity, and social adaptation. Given its importance for children and their families, we also report the quality of the parent-child relationship ([Wheeler 2008](#)).

Where outcomes were measured at multiple time points during the course of therapy, we used mean values of all data from the second therapy session onwards. We determined a small effect size (i.e. 0.2) as the minimally important threshold for appreciable change for each outcome ([Cohen 1988](#); [Gold 2004](#)). If follow-up data were included, we planned to group outcome time points as follows: immediately post-intervention, one to five months post-intervention, six to 11 months post-intervention, 12 to 23 months post-intervention, and 24 to 35 months post-intervention.

Search methods for identification of studies

We ran the searches for this update in September 2011 and again on 29 July 2013. We revised the original search strategy by adding new search terms to increase the sensitivity of the search. Searches were limited to the period since the original review (2004 onwards). We also searched the databases for the period before 2004 using only the new search terms, to be sure we had not missed any relevant studies.

Electronic searches

We searched the following databases:

- Cochrane Central Register of Controlled Trials (CENTRAL) 2013, Issue 6, part of The Cochrane Library;

- Ovid MEDLINE 1948 to July week 3 2013;
- EMBASE 1980 to 2013 week 30;
- LILACS 1982 to current;
- PsycINFO 1806 to July week 3 2013;
- CINAHL 1937 to current;
- ERIC 1966 to current;
- ASSIA 1987 to current;
- Sociological Abstracts 1952 to current;
- Dissertation Abstracts International.

Detailed search strategies are reported in [Appendix 1](#). Search terms from the original version of the review are reported in [Appendix 2](#)

Searching other resources

We searched the following specific sources for music therapy literature:

- musictherapyworld.net. (this website, formerly maintained by the Institute for Music Therapy at the University of Witten Herdecke, Germany, was last accessed in July 2004 but was no longer being maintained at the time of this update);
- Music Therapy Research CD ROM ([AMTA 1999](#)); and
- Music Therapy World Info-CD ROM IV ([Aldridge 2002](#)).

In addition, we searched the reference lists of the studies included in this review as well as relevant review articles ([Accordino 2007](#); [Ball 2004](#); [Reschke-Hernández 2011](#); [Simpson 2011](#); [Whipple 2004](#); [Whipple 2012](#)), and proceedings of music therapy conferences to identify additional studies.

Data collection and analysis

Selection of studies

Three authors (CE, CG, MG) independently inspected all titles and abstracts identified from the search. We obtained potentially relevant papers and resolved any disagreement about eligibility through discussion or consultation with the other authors. If non-English study reports had been found, we would have provided for their translation. We recorded the reasons for excluding trials.

Data extraction and management

Two reviewers (CG, MG) independently performed data extraction using a data collection form. When necessary, we contacted the study authors to provide missing data.

Assessment of risk of bias in included studies

Two authors (KM, MG) assessed methodological quality independently using the Cochrane risk of bias tool ([Higgins 2011a](#)). Any

disagreements were resolved by discussion, or consultation with the other reviewers, or both.

For each included study, we presented the risk of bias assessments in a table where the judgement of the review authors (low, high or unclear risk of bias) was followed by a text box providing details on the available information that led to each judgement.

We assessed the following items:

- Random sequence generation;
- Allocation concealment;
- Blinding of participants and personnel;
- Blinding of outcome assessment;
- Completeness of outcome data;
- Selective reporting; and
- Other sources of bias.

Randomisation

We judged the risk of bias for random sequence generation as follows.

- Studies were judged to be at low risk of bias if participants were allocated to treatment interventions using randomisation such as computer-generated random numbers, a random numbers table, or coin-tossing.
- Studies were judged to be at unclear risk of bias if the randomisation method was not clearly stated or was unknown.
- Studies were judged to be at high risk of bias if the method sequence generation was non-random.

Randomised as well as quasi-randomised trials were included in the review, as noted above.

Allocation concealment

We judged the risk of bias for allocation concealment as follows.

- Studies were judged to be at low risk of bias if allocation concealment was adequate; participants and researchers were unaware of participants' future allocation to an intervention until after decisions about eligibility were made and informed consent was obtained.
- Studies were judged to be at unclear risk of bias if the methods used for allocation concealment were not described in detail.
- Studies were judged to be at high risk of bias if allocation concealment was inadequate; 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-randomised studies).

As this review aimed to include randomised and quasi-randomised studies, all three categories were eligible for inclusion; we only used the rating as a descriptive measure of study quality.

Blindness of participants and personnel

Due to the nature of the intervention it was not possible to blind those who delivered music therapy or those who received it. Consequently, neither participants nor personnel of the studies under review can be declared to be blinded. However, although children with ASD were not blinded, this was unlikely to introduce bias as they are usually not fully aware of available treatment options or study design (Cheuk 2011). The possible risk of bias introduced by therapists administering the intervention was unknown. Therefore, we judged the risk of performance bias as unclear in all studies in the review.

Blinding of outcome assessors

We determined whether those who assessed and coded the outcome measures were blind to treatment assignment using the following categories.

- Studies were judged to be at low risk of bias if the assessor was blind to treatment assignment.
- Studies were judged to be at unclear risk of bias if blinding of assessor not reported and information not available from researchers.
- Studies were judged to be at high risk of bias if the assessor was not blind to treatment assignment.

All of the above were included in the review.

Attrition bias

We assessed whether authors adequately dealt with missing data as follows.

- Studies were judged to be at low risk of bias if the number of participants randomised to groups was clear and it was clear that all participants completed the trials in all participant groups. Studies were also judged to be at low risk of bias if outcome data were missing in both intervention groups, but reasons for these were both reported and balanced across groups.
- Studies were judged to be at unclear risk of bias if information about which participants completed the study could not be acquired by contacting the study authors.
- Studies were judged to be at high risk of bias if there was clear evidence of attrition or exclusion from analysis in at least one participant group that was likely related to the true outcome.

Reporting bias

We judged the risk of selective outcome reporting as follows.

- Studies were judged to be at low risk of bias if all collected data seem to be reported and all expected outcomes were reported.
- Studies were judged to be at unclear risk of bias if it was not clear whether other data were collected and not reported.

- Studies were judged to be at high risk of bias if data for one or more expected outcomes were missing.

Other bias

Through assessment, we determined whether any other bias was present in the trial including inadequate music therapy methods or inadequate music therapy training of therapists delivering the intervention.

Measures of treatment effect

Binary data

We had planned to calculate the risk ratio and corresponding 95% confidence interval (95% CI) for binary outcomes. The number needed to treat for an additional beneficial outcome was to be calculated where appropriate. However, no binary data were available from the included studies.

Continuous data

For studies where outcomes were measured on several occasions during each treatment intervention, we used the mean of all measurements from the second occasion onwards. Where raw data were available, the distributions of values were visually checked for skewness. Where skewness was found, we attempted to remove it by log-transformation. We then examined how log-transformation influenced the effect size estimate and used the more conservative estimate. We calculated the standardised mean difference (SMD) and corresponding 95% CI for all continuous outcomes. When combining different scales for the same outcome, it was necessary to standardise the effects in order to make them comparable. When combining results for the same scale, either the mean difference (MD) or SMD could have been used. We decided to use SMD in order to facilitate the interpretation of effect sizes as small (up to 0.2), medium (around 0.5) or large (0.8 and above) based on guidelines that are commonly used in the behavioural sciences (Cohen 1988; Schünemann 2011). It is noted that the choice of SMD or MD does not usually affect the significance level of the results and the authors cautiously assessed whether this was the case.

All SMDs, regardless of whether the study was a parallel or a cross-over design, were standardised by the pooled standard deviation between participants, rather than the standard deviation of the difference within participants. This is the standard procedure, which enables comparisons of different scales and facilitates interpretation of the magnitude of effects (Cohen 1988; Gold 2004). The calculation of the standard error then depended on the study design. For parallel designs, the standard error was calculated using the standard formulae for SMDs as implemented in RevMan and described in the RevMan handbook (Review Manager 2012). For

cross-over studies, we took into account the correlations within the participants as recommended and described in the literature on meta-analysis of cross-over studies (Elbourne 2002; Higgins 2011b).

Unit of analysis issues

Where appropriate, we combined the results of cross-over trials with the results of parallel-group trials. Data from washout periods in cross-over studies were excluded from the analysis. For studies comparing more than two experimental groups, such as a music therapy intervention, a comparable non-music intervention, and an independent play condition, we compared the music therapy intervention with the non-music intervention as its 'placebo' condition.

Dealing with missing data

We assessed loss to follow-up and drop-outs in the included studies as reported in the 'Risk of bias' tables. All but two of the included studies had complete data for all participants and therefore an intention-to-treat analysis was straightforward. We did not impute missing values. For analyses containing studies where drop-outs occurred (Kim 2008; Thompson 2012a), we examined the impact of studies with high drop-out rates using sensitivity analyses where these studies were excluded.

Assessment of heterogeneity

Because statistical tests of heterogeneity have low power, particularly when the number of studies is low, we relied primarily on descriptive analyses of heterogeneity. We visually inspected forest plots for consistency of results and calculated the I^2 statistic (Higgins 2002), which describes the proportion of variation in point estimates that is due to heterogeneity rather than sampling error. We supplemented this by calculating the χ^2 statistic to determine the strength of evidence that the heterogeneity was genuine. We investigated possible sources of heterogeneity when it was detected.

Assessment of reporting biases

We planned to use funnel plots to investigate any relationship between effect size and study precision in cases where 10 or more studies were pooled for an outcome.

Data synthesis

We conducted a meta-analysis utilising available or calculated SMDs. A fixed-effects model was used for all analyses. If a common effect size was not tenable due to heterogeneity, we considered a random-effects model. In addition to the fixed-effects analyses, we also examined whether random-effects analyses would have

altered the statistical significance of the results and reported any such difference.

Subgroup analysis and investigation of heterogeneity

When heterogeneity was identified, we examined the impact of clients' age, intensity of therapy (i.e. number and frequency of music therapy sessions), and treatment quality in subgroup analyses.

Sensitivity analysis

We conducted sensitivity analyses to determine the impact of study quality on outcome for included studies of different quality (e.g. studies with high attrition rates, see above).

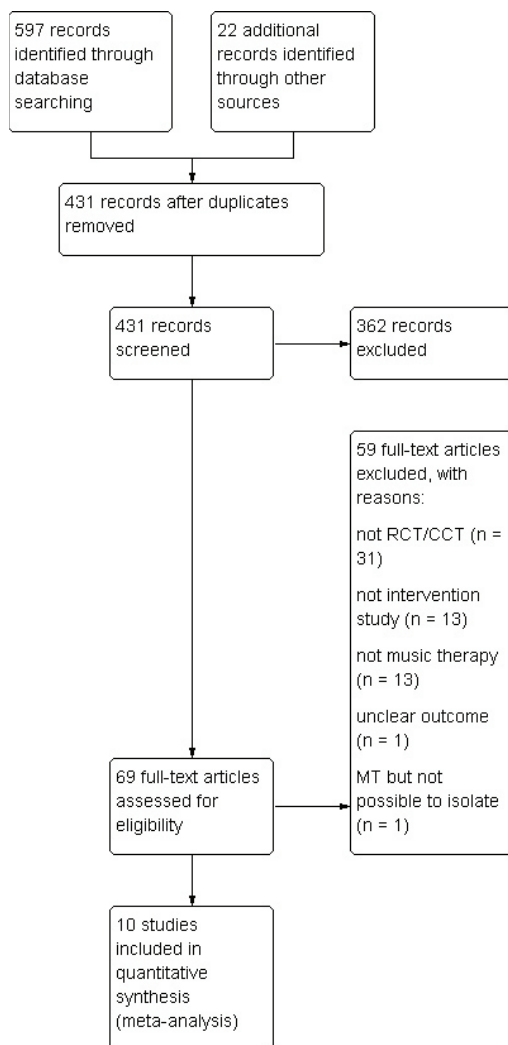
RESULTS

Description of studies

Results of the search

Electronic searches conducted in July 2013 yielded a total of 431 records after deduplication. Sixty-nine of these were deemed potentially relevant and selected for closer inspection. Thirty-one studies were excluded because they were not RCTs or CCTs. Thirteen studies were excluded because they evaluated an assessment rather than an intervention. Thirteen studies were excluded because the intervention was not music therapy. One study was excluded because the outcome measure was unclear, and another study was excluded because it was not possible to isolate music therapy from other interventions. Ten studies met the inclusion criteria for this review. One relevant ongoing study was identified. [Figure 1](#) shows a flow diagram of search results.

Figure 1. Study flow diagram.



Included studies

Ten studies met the criteria for the review (see [Characteristics of included studies](#)). Of these, three studies were included in the first version of this review ([Brownell 2002](#); [Buday 1995](#); [Farmer 2003](#)), and seven studies were added for this update ([Arezina 2011](#); [Gattino 2011](#); [Kim 2008](#); [Lim 2010](#); [Lim 2011](#); [Thomas 2003](#); [Thompson 2012a](#)). Nine were randomised trials. One study utilised a 'counterbalanced' sequence generation ([Brownell 2002](#)). Seven of the trials were short-term studies comparing music therapy to a 'placebo' type therapy, and were conducted in the USA ([Arezina 2011](#); [Brownell 2002](#); [Buday 1995](#); [Farmer 2003](#); [Lim 2010](#); [Lim 2011](#); [Thomas 2003](#)). A medium-term Korean study also compared music therapy to a 'placebo' condition of play sessions ([Kim 2008](#)). Two medium-term studies from Brazil ([Gattino 2011](#)), and Australia ([Thompson 2012a](#)), compared music therapy to standard care. Other characteristics of these studies are described below.

Length of trials

The period under investigation in the included studies ranged from one week ([Farmer 2003](#); [Lim 2010](#)), to eight months ([Kim 2008](#)).

The duration of each treatment intervention was one week in four studies ([Brownell 2002](#); [Buday 1995](#); [Farmer 2003](#); [Lim 2010](#)), and two weeks in another study ([Lim 2011](#)). In the other studies, music therapy was applied for a period varying from five weeks ([Arezina 2011](#)), to seven months ([Gattino 2011](#)). No later follow-up assessments were included in any of the studies.

Participants

The participants in the included studies were between two and nine years of age, with the majority being boys (range 80% to 100%). All participants had received a diagnosis of ASD. Both non-verbal and verbal children were included. In six studies symptom severity or levels of cognitive abilities, or both, were also specified ([Arezina 2011](#); [Buday 1995](#); [Gattino 2011](#); [Kim 2008](#); [Lim 2010](#); [Thompson 2012a](#)). Standardised tools for diagnosis were used in [Buday 1995](#) (i.e. participants ranging from mildly to moderately autistic according to the Childhood Autism Rating Scale, CARS), [Kim 2008](#) (i.e. participants meeting criteria for the Korean version of the CARS), [Lim 2010](#) (i.e. participants classified as being of high or low functioning level according to the CARS or the Autism Diagnostic Interview Revised), and [Thompson 2012a](#) (i.e. participants' severity of symptoms ranging from moderate to severe according to the Social Responsiveness Scale, SRS; [Constantino 2005](#)). With regard to cognitive level, [Buday 1995](#) reported participants to be ranging from mildly to severely mentally retarded

(according to DSM III-R), and [Gattino 2011](#) specified the participants' level of intelligence as ranging from intellectual disability to above average intelligence according to the Brazilian version of Raven's Coloured Progressive Matrices ([Pasquali 2002](#)).

Setting

The participants received therapy either at home ([Thompson 2012a](#)), at school ([Brownell 2002](#); [Buday 1995](#)), in hospital ([Gattino 2011](#)), at outpatient therapy centres ([Arezina 2011](#); [Kim 2008](#)), or a combination thereof ([Farmer 2003](#); [Lim 2010](#)). For [Lim 2011](#) and [Thomas 2003](#), the therapy setting was not reported.

Study size

Six of the studies had extremely small sample sizes, varying from four to ten participants per study ([Arezina 2011](#); [Brownell 2002](#); [Buday 1995](#); [Farmer 2003](#); [Kim 2008](#); [Thomas 2003](#)). [Farmer 2003](#) was the only study that did not use a cross-over design. Cross-over designs were used in the other studies to partly compensate for the small sample sizes. Three studies had slightly larger sample sizes of 24, 22, and 23 respectively ([Gattino 2011](#); [Lim 2011](#); [Thompson 2012a](#)). [Lim 2010](#) had a sample size of 50.

Interventions

Music therapy

The majority of studies included in this review examined music therapy in an individual (i.e. one-to-one) setting. [Thompson 2012a](#) applied a family-based setting where parents or other family members were also involved in therapy sessions.

In five studies music therapy was provided on a daily basis ([Brownell 2002](#); [Buday 1995](#); [Farmer 2003](#); [Lim 2010](#); [Lim 2011](#)). The duration of the music therapy intervention was only one or two weeks in all those studies. In the other studies ([Arezina 2011](#); [Gattino 2011](#); [Kim 2008](#); [Thomas 2003](#); [Thompson 2012a](#)), music therapy was provided on a weekly basis for periods ranging from five weeks ([Arezina 2011](#)) to seven months ([Gattino 2011](#)).

[Brownell 2002](#), [Buday 1995](#), [Farmer 2003](#), [Lim 2010](#), and [Lim 2011](#) utilised a highly structured approach to music therapy using mostly receptive techniques (i.e. listening to live or, in the case of [Lim 2010](#), pre-recorded music presented by the therapist). Songs sung by the music therapist were composed or chosen individually for the participants and were usually used with specific aims. For example, songs were based on a social story addressing a central problem behaviour of the particular individual in treatment

(Brownell 2002); they contained signs and words to be learned (Buday 1995; Lim 2010; Lim 2011); or they were used to build a relationship and to provide a safe and understandable structure for the participants in the study (Farmer 2003). Active music-making by the participants, which is often typical for music therapy in clinical practice (Wigram 2006), was reported in only one of those studies (Farmer 2003). Participants were allowed to play guitar and drums. Playing instruments was partly used to reinforce adjusted behaviour. The report did not specify whether, or in what ways, the therapist improvised or otherwise played music together with the client.

In the other five studies particular emphasis was put on the interactive and relational aspects of music therapy (Arezina 2011; Gattino 2011; Kim 2008; Thomas 2003; Thompson 2012a). Music therapy techniques included improvisation, songs, and structured musical games. Interventions followed a non-directive approach and focused on engaging the child in musical interaction, offering opportunities for the child to make choices and to initiate contact. Generally, the therapist's interventions were depicted as drawing on the individual child's skills, interests, preferences, and motivations as well as on their immediate expression and behaviour. By attuning to the child musically and emotionally, the therapists create moments of synchronisation that help the child to experience and recognise core elements of reciprocal communication (Kim 2008; Schumacher 1999a; Schumacher 1999b; Stephens 2008; Thompson 2012a; Wigram 2009).

Some of the studies employed specifically developed treatment guidelines in the form of a treatment contingency plan (Thompson 2012a), or a treatment manual (Kim 2008). In these protocols, principles and procedures of therapy are specified whilst allowing the therapist to adapt interventions flexibly according to the child's needs and the specific requirements of the situation.

'Placebo' therapy

Six of the studies included in this review compared music therapy to some kind of 'placebo' activity to control for the non-specific effects of therapeutic attention. Since in all of these studies music was considered as the specific ingredient of music therapy, the placebo conditions were constructed to closely match the music therapy condition, only that music was not used. For example, a social story was read instead of sung to the participants (Brownell 2002); rhythmic or normal speech was used instead of singing (Buday 1995; Lim 2010; Lim 2011); the same play activities were offered without using songs or music instruments (Farmer 2003); or the therapist engaged in interaction with the child by responding to the child's behaviour non-musically and using non-music toys (Arezina 2011; Kim 2008; Thomas 2003).

Other conditions

Two of the included studies compared music therapy to standard care (Gattino 2011; Thompson 2012a). In the Thompson 2012a

study, participants received varying forms of services and support from early childhood intervention centres. Gattino 2011 reported that participants received routine clinical services, including medical examinations and consultations.

In addition to the music therapy and non-music interventions, Brownell 2002 reported outcomes during a baseline and a washout period with no intervention. These data were not used in this review. Arezina 2011 also observed behaviour in an 'independent play' group, which we considered was neither 'placebo' therapy nor 'standard care'. Therefore, data from this group were not included in this review. Lim 2010 and Lim 2011 compared music training to both a speech training and a 'no training' group. For this review, we included data from the comparison between the music and the non-music groups.

Outcome measures

Both generalised and non-generalised outcomes were used in the included studies. Non-generalised outcomes refer to changes in the child's non-generalised behaviour in the same setting where the intervention takes place, as opposed to generalised outcomes which are observed in other settings (Warren 2011).

Primary outcomes

Social interaction

Social interaction skills were examined in three studies (Gattino 2011; Kim 2008; Thompson 2012a). All three studies measured this outcome outside of the treatment context using published scales. Gattino 2011 utilised the 'social communication' domain of the Childhood Autism Rating Scale, Brazilian version (CARS-BR; Pereira 2008; Rapin 2008), a diagnostic behaviour observation tool administered by investigators blind to group allocation. Kim 2008 used the 'social approach' subscale of the Pervasive Developmental Disorder Behavior Inventory, Korean version (PDDBI; Cohen 1999), which was filled out by professionals (i.e. a teacher or a therapist of the child) who were blind to experimental condition. Thompson 2012a utilised social interaction measures, including the Social Responsiveness Scale (SRS; Constantino 2005), rated by parents, and the 'Interpersonal Relationships' and 'Play and Leisure Time' subscales of the Vineland Social-Emotional Early Childhood Scales (Vineland SEEC; Sparrow 1998), rated by the therapist following an interview with parents.

Kim 2008 also investigated behaviours related to social interaction in the intervention setting. These measures included frequency and duration of the child's turn-taking and frequency of imitation behaviours. The coding procedure was conducted by the lead investigator by microanalytically (second by second) observing DVD recordings, with subsequent coding supplemented by a trained research assistant who was blind to session order.

Communicative skills: non-verbal

Nonverbal (i.e. gaze-related and gestural) communicative skills were examined in five studies (Buday 1995; Farmer 2003; Gattino 2011; Kim 2008; Thompson 2012a). Three studies addressed the participants' behaviour within therapy sessions (Buday 1995; Farmer 2003; Kim 2008). Independent observers counted the number of communicative gestures (e.g. imitating a sign or motion, eye contact) in the session. In the Buday 1995 study, the outcome consisted simply of the frequency count of appropriate gestures within a session. In the Farmer 2003 study, a completed gesture was given a score of two, and an attempt a score of one, and the outcome consisted of the sum of these scores for all attempted and completed gestures within a session. In the Kim 2008 study, frequency and duration of eye contact (i.e. the child looking at the therapist) was coded by microanalytic analysis of the session material. The exact criteria for what was seen as a non-verbal communicative skill were different between the three studies. The measures used for this outcome in these three studies were not published separately.

Three studies used published instruments for measuring generalised non-verbal communicative skills (Gattino 2011; Kim 2008; Thompson 2012a). Gattino 2011 applied the 'nonverbal communication' subscale of the CARS-BR as described above. Kim 2008 used the abridged version of the Early Social Communication Scales (ESCS; Mundy 2003), a structured toy play assessment yielding frequency scores of behaviours such as 'initiation of joint attention' and 'responding to joint attention'. The scoring was administered by the researcher and by two trained research assistants who were blind to group assignment. Thompson 2012a utilised the MacArthur-Bates Communicative Development Inventories - Words and Gestures (MBCDI-W&G; Fenson 2007), a parent-report measure assessing early communication skills. The subscale 'actions and gestures used' was also included in this outcome category.

Communicative skills: verbal

Communicative skills in verbal communication were addressed in six studies (Buday 1995; Farmer 2003; Gattino 2011; Lim 2010; Lim 2011; Thompson 2012a). For Buday 1995, Farmer 2003, Lim 2010, and Lim 2011, independent observers rated in-session behaviour by counting the frequency of appropriate verbal responses in a manner similar to the previous outcome. The non-generalised outcome measures used in four studies were unpublished (Buday 1995; Farmer 2003; Lim 2010; Lim 2011). The other two studies used published instruments for measuring generalised verbal communicative skills. Gattino 2011 used the 'verbal communication' subscale of the CARS-BR as described above. Thompson 2012a used the subscales 'phrases understood', 'words understood' and 'words produced' of the MBCDI-W&G as described for the previous outcome.

Initiating behaviour

Three studies investigated children's initiating behaviour as observed within the intervention setting using unpublished measures (Arezina 2011; Kim 2008; Thomas 2003). In Arezina 2011, the researcher coded videotaped sessions for 'requesting (initiating joint attention)' behaviours such as pointing, giving an object to the therapist, or touching the therapist while making eye contact; an independent observer additionally coded a third of the session material. In Kim 2008, the frequency of 'initiation of engagement' behaviours was coded as described above (microanalysis of DVD recordings by the researcher, supplemented by coding by a research assistant who was blind to session order). In the Thomas 2003 study, 'requesting behavior' was defined in a manner similar to the Arezina 2011 study, and coded by a trained music therapy intern using video recordings.

Social-emotional reciprocity

Skills related to social-emotional reciprocity were addressed in the Kim 2008 study using behaviours within the treatment context that were coded through microanalytic analysis using unpublished measures. Child behaviours included in this outcome category were frequency and duration of both 'emotional synchronicity' and 'musical synchronicity'.

Secondary outcomes

Social adaptation

Three studies investigated behaviours related to social adaptation within the interventions setting (Arezina 2011; Kim 2008; Thomas 2003). In Arezina 2011 and Thomas 2003, videotaped sessions were coded for 'interaction (engaging in joint attention)' and 'on-task behavior', respectively; this included activities such as following a direction, physically manipulating a toy in a functional manner, and imitating a movement or vocal sound. In Kim 2008, sessions were scored by frequencies of 'compliant response', 'non-compliant response', and 'no response'. Brownell 2002 addressed individually targeted repetitive behaviours. This outcome was categorised as 'Behavioural problems' in the first version of this review. Occurrence of behaviour was assessed outside therapy sessions. Independent observers (i.e. teachers) counted how often the targeted behaviour occurred in the classroom. The frequency count was used as the outcome measure. No published scale was used.

Joy

Behaviours associated with the frequency and duration of joy (i.e. smiling and laughing) on the part of the child were addressed in one study (Kim 2008). The researcher described occurrences of joy as a clinically significant motivational factor for the child to join in shared activities with the therapist. Scores were determined through microanalytic observation of videotaped sessions.

Quality of parent-child relationship

In two studies, features of the quality of parent-child relationships were examined (Kim 2008; Thompson 2012a). Kim 2008 used the Mother Play Intervention Profile (MPIP), a measure specifically developed for her study to assess characteristics of interactions between mothers and children with ASD during a casual play situation at their home. Features such as the amount of initiation of interaction by the child and the mother and the degree of structuring activities introduced by the mother were scored on a four-point Likert scale. Scores were based on video observations conducted by the researcher, supplemented by an independent observer's coding for a third of the sessions. Thompson 2012a used the Parent-Child Relationship Inventory (PCRI; Gerard 2005), a self report questionnaire for parents to assess the parent-child relationship and parents' attitudes towards parenting.

Excluded studies

Fifty-nine studies were excluded. Thirty-one studies were excluded because they did not have an RCT or CCT design (20 case series, i.e. studies comparing different treatments that all participants received in the same order; 11 case studies). Thirteen studies were excluded because these studies involved an assessment rather than an intervention (e.g. assessing traits of people with ASD using music therapy techniques). Thirteen studies were excluded because the intervention was not music therapy (e.g. auditory integration training). One study was excluded because the outcome measure was unclear; and one study was excluded because it was not possible to isolate music therapy from other interventions (see [Characteristics of excluded studies](#)).

Ongoing studies

One relevant, longer-term study of improvisational music therapy was still ongoing when this review was written ([ISRCTN78923965](#)); see [Characteristics of ongoing studies](#).

Awaiting assessment

We were able to assess all studies for eligibility. No studies were awaiting assessment.

Risk of bias in included studies

A visual representation of the included studies' risk of bias for each domain, as specified below, is shown in [Figure 2](#). [Figure 3](#) provides a summary of the risk of bias results for each included study.

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

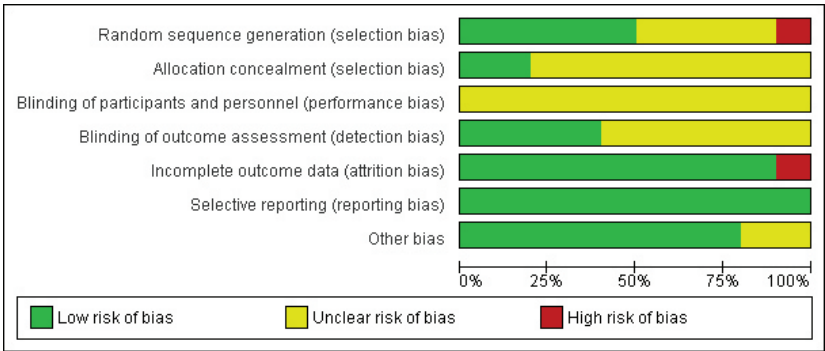


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Arezina 2011	+	?	?	?	+	+	+
Brownell 2002	-	?	?	?	+	+	+
Buday 1995	?	?	?	+	+	+	?
Farmer 2003	?	?	?	?	+	+	+
Gattino 2011	+	+	?	+	+	+	+
Kim 2008	+	?	?	?	-	+	+
Lim 2010	?	?	?	+	+	+	?
Lim 2011	+	?	?	+	+	+	+
Thomas 2003	?	?	?	?	+	+	+
Thompson 2012a	+	+	?	?	+	+	+

Allocation

Seven of the included studies stated explicitly that randomisation was used to assign participants to treatment groups (Arezina 2011; Buday 1995; Farmer 2003; Gattino 2011; Kim 2008; Thomas 2003; Thompson 2012a). Methods of randomisation included using computer-generated random sequences for determining allocation to experimental condition (Gattino 2011; Kim 2008; Thompson 2012a), and a Latin Square for determining session order (Arezina 2011). In three studies, methods of randomisation and allocation concealment were not specified (Buday 1995; Farmer 2003; Thomas 2003). The remaining study used the term 'counterbalanced' to describe an assignment that was either random or quasi-random, but intended to be random (Brownell 2002).

Blinding

Four of the included studies were single-blind, with blinded assessors (Buday 1995; Gattino 2011; Lim 2010; Lim 2011). In Kim 2008, some outcomes were coded by blinded assessors, while non-generalised outcome measures and two of the measures assessing generalised skills (ESCS, MPPI) were rated by the researcher and complemented by independent coders (inter-rater reliability ranging from 0.70 to 0.98). In Thompson 2012a, measures were based on parent reports; however, they contained internal safe-guards to address bias as evidenced by high correlations with non-parent rated measures and high test-retest correlations (e.g. Pearson's $r = 0.70$, P value = 0.01, for the SRS's one-month test-retest reliability). No details about blinding of outcome assessment were reported in the other studies (Arezina 2011; Brownell 2002; Farmer 2003; Thomas 2003).

Five studies used more than one rater to independently assess outcomes. All of those studies reported a high inter-rater reliability for the assessment of outcomes (Arezina 2011: inter-observer agreement ranging from 85.7% to 98.9%; Brownell 2002: inter-rater reliability 0.86 to 0.94; Buday 1995: agreement rate 98%; Farmer 2003: agreement rate 91%; Kim 2008: inter-rater reliability 0.70 to 0.98, as reported above).

Incomplete outcome data

Drop-outs were reported in two of the ten studies. In Kim 2008, five of the 15 participants initially enrolled dropped out, and data from drop-outs were excluded, yielding a high risk of bias due to attrition for this study. In Thompson 2012a, two of 23 participants dropped out, and an intention-to-treat analysis was applied, so we consider the related risk of bias to be low.

Selective reporting

There was no evidence of selective reporting of outcomes in the included studies. In the Kim 2008 study, some outcomes were only reported in the thesis but not in the journal articles, but we included all outcomes in the meta-analysis.

Other potential sources of bias

We considered inadequate music therapy methods and inadequate music therapy training of therapists as additional potential sources of bias. With the exception of Buday 1995, where we found music therapy methods and the training of the person delivering the intervention to be of unclear adequacy, we detected none of these sources of bias in the included studies.

Preparation of data for meta-analysis

Buday 1995 reported means, standard deviations, and F test results for the outcomes described above. From these statistics it was possible to calculate a SMD and standard error as appropriate for cross-over studies. Similarly, we calculated SMDs from data reported in Arezina 2011, Kim 2008, Thomas 2003, and Thompson 2012a. For the other studies individual patient data were extracted from tables or graphs (Brownell 2002; Farmer 2003; Gattino 2011). We screened the data for skewness before data synthesis. Data from the Farmer 2003 study showed a skewed distribution. A log transformation would have removed the skewness, but would also have increased the effect size estimate. Therefore, we decided to use the more conservative original scale. Similarly, we found skewed distributions in 13 of the 15 non-generalised outcomes in the Kim 2008 study (all except 'compliant response frequency' and 'no response frequency'). We calculated SMDs both using log-transformed scores and raw scores and used the smaller effect size. The raw-score-based effect size was smaller than the log-transformed effect size in three of the 13 outcomes: 'frequency of eye contact', 'duration of eye contact', and 'frequency of initiation of engagement'.

Effects of interventions

See: [Summary of findings for the main comparison Music therapy compared to 'placebo' therapy or standard care for autism spectrum disorder](#)

We used fixed-effects analysis for all outcomes, but checked whether the effect size estimate changed if a random-effects model was used. P values for each outcome indicate that results remained statistically significant using random-effects analysis. They are reported below.

Primary outcomes

Social interaction

Kim 2008 assessed social interaction skills within the intervention context. Post-treatment difference between the music therapy and the control group yielded an SMD effect size of 1.06 (95% CI 0.02 to 2.10), indicating a large effect (Cohen 1988; Schünemann 2011).

Three studies measured generalised social interaction skills using standardised scales (Gattino 2011; Kim 2008; Thompson 2012a). The SMD in generalised social interaction between music therapy and control groups was 0.71 (95% CI 0.18 to 1.25), indicating a moderate to large effect (Cohen 1988; Schünemann 2011). We checked whether the results changed when using a random-effects model, and found no difference (SMD 0.71, 95% CI 0.18 to 1.25, P value = 0.009). The results were homogeneous ($\text{Chi}^2 = 1.41$, P value = 0.49, $I^2 = 0\%$) and do not require examination of moderators (see Analysis 1.1).

We conducted a sensitivity analysis excluding data from the high-attrition study (Kim 2008), and found that the effect for generalised skills remained statistically significant (P value = 0.03). No heterogeneity was detected for this analysis ($\text{Chi}^2 = 1.38$, P value = 0.24, $I^2 = 28\%$).

Communicative skills: non-verbal

Three studies used measures of non-generalised non-verbal communicative skills through continuous scales addressing observed behaviour (Buday 1995; Farmer 2003; Kim 2008). The effect size for difference in non-generalised non-verbal communicative skills between music therapy and control groups was 0.57 (95% CI 0.29 to 0.85), indicating a moderate effect. We checked whether the results changed when using a random-effects model, and found that the effect remained statistically significant (SMD 1.00, 95% CI 0.10 to 1.90, P value = 0.03). Statistically significant heterogeneity was detected for this pooled analysis ($\text{Chi}^2 = 5.15$, P value = 0.08, $I^2 = 61\%$). This heterogeneity may be related to the relatively high attrition rate in Kim 2008, or the unclear quality of music therapy methods and therapist's training in Buday 1995. When excluding data from either of the studies, the overall effect remained statistically significant (SMD 0.50, 95% CI 0.22 to 0.79, P value = 0.0006; and SMD 1.56, 95% CI 0.61 to 2.50, P value = 0.001, respectively), resulting in the decision to keep these studies in the pooled analysis.

Three studies assessed generalised non-verbal communicative skills using published standardised scales (Gattino 2011; Kim 2008; Thompson 2012a). The effect size for difference between music therapy and control groups was 0.48 (95% CI -0.02 to 0.98), suggesting that children receiving music therapy had similar non-verbal communicative skills after treatment as children receiving 'placebo' therapy or standard care (Analysis 1.2). Changing the

model of analysis to random-effects did not change the statistical significance of the results (SMD 0.48, 95% CI -0.02 to 0.98, P value = 0.06). No heterogeneity was detected for this comparison ($\text{Chi}^2 = 1.33$, P value = 0.51, $I^2 = 0\%$).

A sensitivity analysis excluding the study with a high drop-out rate (Kim 2008) did not change the statistical significance of the results for generalised non-verbal communicative skills (SMD 0.31, 95% CI -0.28 to 0.89, P value = 0.31). However, the overall effect across domains (then calculable as none of the remaining studies is represented in both domains) was significant (SMD 0.47, 95% CI 0.21 to 0.73; $\text{Chi}^2 = 1.32$, P value = 0.72, $I^2 = 0\%$), indicating a moderate effect.

Communicative skills: verbal

Four studies investigated non-generalised verbal communicative skills using continuous scales addressing observed behaviour (Buday 1995; Farmer 2003; Lim 2010; Lim 2011). The effect size for difference in non-generalised verbal communicative skills was 0.33 (95% CI 0.16 to 0.50), indicating a small to moderate effect favouring music therapy over the 'placebo' intervention, suggesting that improvement in verbal communicative skills was more likely to occur with music therapy. The results did not change when using a random-effects model (SMD 0.33, 95% CI 0.16 to 0.50, P value = 0.0002). No heterogeneity was detected for this comparison ($\text{Chi}^2 = 0.72$, P value = 0.87, $I^2 = 0\%$).

Generalised verbal communicative skills were assessed in two studies using standardised scales (Gattino 2011; Thompson 2012a). The effect size for difference in generalised non-verbal communicative skills was 0.30 (95% CI -0.28 to 0.89), suggesting that children receiving music therapy had similar verbal communicative skills after treatment as children receiving standard care. No heterogeneity was detected for this comparison ($\text{Chi}^2 = 0.01$, P value = 0.93, $I^2 = 0\%$), and using a random-effects model did not change the results (SMD 0.30, 95% CI -0.28 to 0.89, P value = 0.31).

The overall effect size for difference in verbal communicative skills between music therapy and control groups was 0.33 (95% CI 0.16 to 0.49), indicating a small to moderate effect (see Analysis 1.3).

Initiating behaviour

Three studies reported measures of non-generalised initiating behaviour using continuous scales (Arezina 2011; Kim 2008; Thomas 2003). For Arezina 2011 and Thomas 2003, we averaged participants' behaviour over all therapy sessions except the first one and calculated an SMD with a standard error. The effect size was 0.73 (95% CI 0.36 to 1.11), which indicates a close to large effect in favour of music therapy (see Analysis 1.4). Possible heterogeneity was detected for this analysis ($\text{Chi}^2 = 3.91$, P value = 0.14, $I^2 = 49\%$), but when the high-attrition study (Kim 2008) was excluded from analysis, the overall effect remained statistically

significant (P value = 0.009) and heterogeneity was no longer detected ($\text{Chi}^2 = 0.18$, P value = 0.67, $I^2 = 0\%$). Using a random-effects model did not change the results (SMD 0.80, 95% CI 0.19 to 1.41, P value = 0.01).

Social-emotional reciprocity

Kim 2008 applied measures of social-emotional reciprocity within the intervention context using continuous scores for the child displaying 'emotional synchronicity' (frequency and duration) and 'musical synchronicity' (frequency and duration). Post-treatment difference between the music therapy and the control group yielded an effect size of 2.28 (SMD 95% CI 0.73 to 3.83), indicating a large effect (see Analysis 1.5). However, this result must be interpreted with caution since data came from a study with a small sample size and a high drop-out rate.

Adverse events

No deterioration on a primary outcome or other adverse events were reported as a result of treatment in any of the included studies.

Secondary outcomes

Social adaptation

Three studies used continuous scales addressing observed behaviour for examining social adaptation of children within the intervention setting (Arezina 2011; Kim 2008; Thomas 2003). This was done by observing behaviours of 'interaction (engaging in joint attention)' (Arezina 2011), 'on-task behavior' (Thomas 2003), and frequencies of 'compliant response', 'non-compliant response', and 'no response' (Kim 2008). As described above, we averaged participants' behaviour over all therapy sessions except the first one for Arezina 2011 and Thomas 2003. Data from Kim 2008 were also synthesised by calculating an SMD with a standard error. The effect size for difference in non-generalised social adaptation between music therapy and 'placebo' therapy groups was 1.15 (95% CI 0.69 to 1.61), indicating a large effect. No heterogeneity was detected for this comparison ($\text{Chi}^2 = 2.87$, P value = 0.24, $I^2 = 30\%$). Using a random-effects model did not change the results (SMD 1.23, 95% CI 0.61 to 1.86, P value = 0.0001). The effect on non-generalised social adaptation remained statistically significant ($P < 0.00001$) in a sensitivity analysis excluding the high drop-out study (Kim 2008). Heterogeneity increased to 65%, but the effect remained statistically significant also when a random-effects analysis was used (SMD 1.50, 95% CI 0.24 to 2.76), P value = 0.02).

Data for generalised social adaptation were available from only one study using measures of a continuous scale for observed behaviour (Brownell 2002). We averaged participants' behaviour over all days

in therapy except the first one and calculated an SMD with a standard error. The resulting SMD effect size was 0.24 (95% CI 0.02 to 0.46), indicating a small effect, which suggests that music therapy may be slightly more beneficial than a similar verbal therapy in increasing social adaptation outside the therapy context.

The overall effect size for difference in social adaptation between music therapy and control groups was 0.41 (95% CI 0.21 to 0.60), indicating a small to moderate effect. The Chi^2 and I^2 statistics showed heterogeneity of studies across subcategories ($\text{Chi}^2 = 15.34$, P value = 0.002, $I^2 = 80\%$), indicating that the Brownell 2002 study examining generalised skills was different from the more recent studies measuring non-generalised social adaptation abilities. Applying a random-effects model did not change the results (SMD 0.95, 95% CI 0.22 to 1.68, P value = 0.01).

Quality of life in school, home and other environments

One study used an outcome that can be related to quality of life in the treatment environment by measuring frequency and duration of 'joy' displayed by the child within the therapy setting (Kim 2008). We combined data (frequency and duration) by calculating an SMD with a standard error. The resulting effect size was 0.96 (95% CI 0.04 to 1.88), indicating a large effect that suggests that an increase in displays of joy was more likely to occur in music therapy than in 'placebo' therapy. However, this result must be interpreted with considerable caution since data came from only one study with a small sample size and a high drop-out rate.

Quality of family relationships

Two studies included measures connected to the quality of family relationships (Kim 2008; Thompson 2012a). The effect size across studies was 0.82 (95% CI 0.13 to 1.52), with no indication of heterogeneity between studies ($\text{Chi}^2 = 0.03$, P value = 0.87, $I^2 = 0\%$). The results did not change when a random-effects model was calculated (SMD 0.82, 95% CI 0.13 to 1.52, $P = 0.02$). However, when excluding data from the study with high attrition (Kim 2008), the effect was no longer statistically significant (P value = 0.11), suggesting that these data must be interpreted with caution.

Cognitive ability

None of the included studies investigated change in cognitive abilities such as concentration or intelligence.

Hyperacusis

We did not find any reports on children's hypersensitivity to sound in any of the included studies.

DISCUSSION

Summary of main results

We found 10 RCTs that evaluated the effects of music therapy for children with ASD aged two to nine years using non-generalised and generalised outcomes. Non-generalised outcomes refer to changes of behaviour as observed in the treatment context, while generalised outcomes are measured outside of the therapy environment in the child's daily life. Music therapy was compared to standard care, or to a 'placebo' therapy which attempted to control for all non-specific elements of music therapy, such as the attention of a therapist or the client's motivation to participate in therapy. We calculated SMDs and conducted meta-analyses using a fixed-effect model on five primary outcomes and three secondary outcomes. The effect sizes found can be interpreted in accordance with common guidelines for interventions in the behavioural sciences (Cohen 1988; Schünemann 2011), where effect sizes of up to 0.2 are considered small, those around 0.5 are moderate, and those at 0.8 and above are large. The results show evidence of moderate to large effects of music therapy for the primary outcomes non-generalised social interaction skills, generalised social interaction skills, non-generalised non-verbal communicative skills, initiating behaviour, and social-emotional reciprocity, and for the secondary outcomes joy and quality of parent-child relationships. Small to moderate effect sizes resulted for the primary outcome verbal communicative skills and the secondary outcome social adaptation. It is interesting to note that non-verbal communicative skills, which may be more closely related to non-verbal communication within music therapy, appeared to show greater change than verbal communicative skills. However, it may also be that non-verbal communicative skills are relatively easier to address than verbal communicative skills especially in low-functioning children and through short- to medium-term interventions, and particularly regarding skills to be generalised beyond the treatment context. Results were statistically significant for all but two outcome categories under investigation, suggesting a beneficial effect of music therapy when compared to 'placebo' therapy or standard care. The only two sub-categories where the effect was not statistically significant were generalised non-verbal and generalised verbal communicative skills. Using the GRADE system (GRADEpro 2008), we rated the qual-

ity of the evidence as 'moderate' for four outcomes and 'low' for three outcomes included in the [Summary of findings for the main comparison](#). Even with Bonferroni correction, which is known to be overly conservative when outcomes are correlated, all primary outcomes that showed significant effects remained statistically significant (all P values were below Bonferroni-corrected alpha level $0.05/5 = 0.01$). Therefore, alpha error accumulation can be excluded as a source of error.

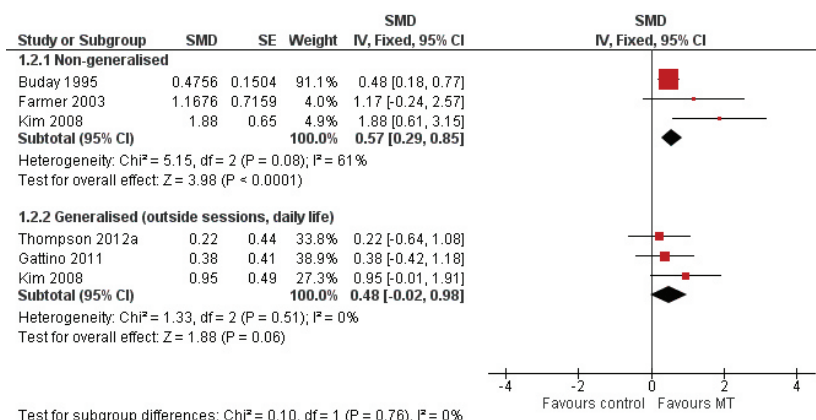
Overall completeness and applicability of evidence

Music therapy conditions

Three studies that were included in the first version of this review (Gold 2006), were of limited generalisability to clinical practice (Brownell 2002; Buday 1995; Farmer 2003). These studies only used a limited subset of the music therapy techniques described in the clinical literature in the experimental treatment conditions. Receptive music therapy techniques with a high level of structuring predominated in those interventions; improvisational techniques were not utilised. However, improvisational techniques are widely used in many parts of the world (Edgerton 1994; Gattino 2011; Holck 2004; Kim 2006; Schumacher 1999a; Schumacher 1999b; Thompson 2012a; Thompson 2012b; Wigram 2006; Wigram 2009). Five of the studies added in this review update (Arezina 2011; Gattino 2011; Kim 2008; Thomas 2003; Thompson 2012a), reflect and emphasise improvisational and relational approaches to music therapy, thus considerably increasing the applicability of findings to clinical practice and hence the external validity of this review.

The findings of this review may suggest that more flexible, child-led approaches yield better outcomes, as indicated by the results for non-generalised non-verbal communicative skills, where receptive techniques as applied in Buday 1995 and Farmer 2003 yielded smaller effects than the improvisational method provided in Kim 2008 (see [Figure 4](#)). This complies with findings about musical interactions by Stephens who states that, "children with autism related reciprocally to others when they engaged in pleasurable, child-led, shared attention routines" (Stephens 2008, pp. 667-8).

Figure 4. Forest plot of comparison: I Music therapy vs. 'placebo' therapy or standard care, outcome: 1.2 Communicative skills: non-verbal.



Generally speaking, music therapy for children with ASD should be backed by research evidence from both music therapy and related fields, aiming at cooperation with others involved in treatment and care of clients, active engagement of clients, and establishing structure, predictability, and routines. It is important to note that providing structure does not equal rigidity within interventions. Music contains rhythmic, melodic, harmonic, and dynamic structure which, when applied systematically and skillfully, can be effective in engaging children with ASD. Intervention strategies employing music improvisation are usually not pre-structured in the sense of a fixed manual. In recent years, flexible but systematic treatment protocols for music therapy have been developed in clinical practice and research investigations in ASD (Geretsegger 2012; Kim 2006; Thompson 2012a; Wigram 2006) as well as in other fields (Rolvsjord 2005). As described above (see *Included studies*), two of the studies in this review have successfully applied such guidelines (Kim 2008; Thompson 2012a). More studies employing therapy approaches, which are close to those applied in clinical practice, will be needed in order to improve the clinical applicability of research findings.

Control conditions

Eight of the included studies used a dismantling strategy to isolate the effect of the specific 'ingredients' of music therapy by setting up comparison conditions, which were very similar to the music therapy interventions, excluding only the music component (Arezina 2011; Brownell 2002; Buday 1995; Farmer 2003; Kim 2008; Lim 2010; Lim 2011; Thomas 2003). Any conclusion from

such comparisons will therefore address the effects of specific music therapy techniques, rather than the absolute effects of music therapy in general. This type of design is justified when exploring music therapy intervention strategies. However, such comparison conditions may introduce some artificiality into the studies through selecting out and applying a single intervention strategy. This is not typically undertaken in clinical treatment, although it does isolate specific components of music therapy. In the broader field of psychotherapy research, similar constructions of 'placebo' therapy to control for the therapist's attention and the non-specific elements have been broadly used (Kendall 2004, pp. 20-1). However, research on common factors in psychotherapy raise the question of how adequate it is conceptually, and also whether it is technically possible to separate the active from the non-active elements of therapy (Lambert 2004, pp. 150-2).

Duration, population, and outcomes

ASD as a pervasive developmental disorder is a chronic condition, which requires sustained therapeutic intervention starting as early as possible. In clinical reports for ASD, music therapy is usually described as a longer-term intervention, and given the typical emergence of entrenched and deteriorating behaviour, therapeutic intervention relies on consolidating progress over time. With the treatment duration of included studies ranging up to seven months, we consider this review's findings as sufficiently applicable to clinical contexts.

With regards to the population addressed, the applicability of the

findings is limited to the age groups included in the studies. No direct conclusions can be drawn about music therapy in adults with ASD.

The outcomes addressed in the included studies cover areas that form the core of the condition and that we consider as highly relevant to individuals with ASD and their families.

Quality of the evidence

As indicated by the ratings of evidence presented in the [Summary of findings for the main comparison](#) ('moderate' for four, 'low' for three of the relevant outcomes), the body of evidence identified allows for fairly robust conclusions regarding this review's objectives. Limitations to the methodological strength of the evidence are due to the small sample sizes of the 10 included studies (4 to 50 participants) and the small total number of individuals under review ($n = 165$). Additionally, only some of the outcomes used in the studies were published measurement tools, which hampers replicability of findings. Moreover, some of the measures in the included studies relied on reports from parents who were aware of their children's group allocation. However, change in children's skills as assessed by parents may reflect effects of interventions that are meaningful and relevant to clients and their families.

Potential biases in the review process

One can never be completely sure that all relevant trials have been identified. However, our searches included not only exhaustive electronic and hand searches, but relied additionally on an existing international network of leading researchers in the field. Therefore, it seems unlikely that an important trial exists that did not come to our attention. Furthermore, this field does not seem to be characterised by strongly selective publication. The trials that were unpublished or published only in the grey literature tended to have positive results and were either unpublished for reasons unrelated to study results ([Arezina 2011](#); [Thomas 2003](#)), or because they were too new ([Thompson 2012a](#)).

Agreements and disagreements with other studies or reviews

This review's findings about music therapy's effectiveness for children with ASD fit well into the context of previous evidence in this area ([Gold 2006](#); [Wheeler 2008](#); [Whipple 2004](#); [Whipple 2012](#)), but add considerably to the external validity of previous results by including trials that employed settings and methods utilised in clinical practice. Additionally, the robustness of findings is increased by following rigorous methodology and covering a larger total sample size than previous reviews.

AUTHORS' CONCLUSIONS

Implications for practice

The findings of this review provide evidence that music therapy may have positive effects on social interaction and communication skills of children with ASD. Music therapy has been shown to be superior to standard care and to similar forms of therapy where music was not used, which may be indicative of a specificity of the effect of music within music therapy. In addition, the results of this review suggest that therapy approaches that focus on the relational qualities of music within interactions and on the client's own interests and motivations ([Gattino 2011](#); [Kim 2008](#); [Thompson 2012a](#)), may be effective in increasing basic skills of social communication, such as keeping eye contact or initiating interaction. However, these findings need to be corroborated by future research involving larger samples. Children and adults with ASD frequently pose considerable behavioural challenges to their parents and other family members ([Oono 2013](#)). Therefore, the increases in social adaptation skills of children and in the quality of parent-child relationships through music therapy as found in this review may be highly relevant findings for families affected by ASD. As only short- to medium-term effects have been examined, it remains unknown how enduring the effects of music therapy on social interaction, communication, and related skills are in the long term.

When applying the results of this review to practice, it is important to note that the application of music therapy requires academic and clinical training in music therapy. Trained music therapists and academic training courses are available in many countries, and information is usually accessible through professional associations. Training courses in music therapy teach not only the clinical music therapy techniques as described in the background of this review, but also aim at developing the therapist's personality and clinical sensitivity, which is necessary to apply music therapy responsibly.

Implications for research

Future research on music therapy for people with ASD will need to pay close attention to sample size and power. Sample sizes in all included studies were small, and test power was only discussed in three studies ([Gattino 2011](#); [Kim 2008](#); [Thompson 2012a](#)). Limited sample size remains a common problem in research on interventions for ASD. As there is a lack of studies for older individuals with ASD, research is needed examining effects of music therapy for adolescents and adults with ASD. Furthermore, we recommend that future trials on music therapy in this area should be: (1) pragmatic; (2) parallel; (3) conscious of types of music therapy; (4) conscious of relevant outcome measures; and (5) include long-term follow-up assessments.

(1) Pragmatic trials of effectiveness: The earliest trials on music therapy for ASD were efficacy trials, characterised by "inflexible

experimental intervention, with strict instructions for every element”; “restricted flexibility of the comparison intervention ... [e.g.] placebo”; and a primary outcome that was “a direct and immediate consequence of the intervention ... [e.g.] a surrogate marker of another downstream outcome of interest” (Thorpe 2009, Table 1). More recent trials (Thompson 2012a; Gattino 2011) have started to use more flexible interventions, standard care comparisons, and downstream outcomes. More pragmatic trials are needed to address the question of effectiveness (i.e. whether music therapy works ‘under usual conditions’, Thorpe 2009).

(2) Parallel trials: Many of the trials to date used cross-over designs. These designs are appropriate for early trials because they have the compelling advantage of higher test power even with small sample sizes. However, this advantage is bought at the expense of additional uncertainty (Elbourne 2002). Cross-over trials are only adequate for chronic conditions (this criterion is met in ASD) and for interventions with only short-acting effects. The duration of effect is presently unknown for music therapy, where learning effects may be lasting. Parallel design trials avoid these problems but require far greater resources. The present findings appear to justify such large-scale trials in the future.

(3) Types of music therapy: As discussed in this review, various types of music therapy have been proposed. Future trials should continue to be conscious of the quality, clinical applicability and link to usual practice, and type of music therapy examined. Future trials might entail comparisons between types of music therapy, but should also continue to investigate music therapy compared to other interventions or standard care.

(4) Relevant outcome measures: There is currently no consensus about the most pertinent outcome measures to be used in ASD intervention research (Warren 2011; Wheeler 2008). However, in line with recommendation (1) above, future trials should include outcomes that address the core problems of ASD in a generalised

setting utilising standardised scales.

(5) Long-term follow-up assessments: The most notable gap in this review was a lack of trials with longer follow-up periods. Future trials should consider long-term follow-up assessments of a year or more.

ACKNOWLEDGEMENTS

Tony Wigram, a co-author of the 2006 version of this review, passed away in June 2011. The work on the 2014 update began after his decease. His legacy in music therapy research, both in ASD (Gold 2011a) and other fields (Gold 2011b), will remain influential.

We thank Margaret Anderson, Trials Search Coordinator of the Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG), for undertaking the searches for this update, Laura MacDonald and Joanne Wilson, Managing Editors of the CDPLPG, for their assistance and guidance throughout the review process, and Geraldine Macdonald, Co-ordinating Editor of the CDPLPG, for valuable comments on an earlier draft of this update.

We also thank study authors Clare Arezina and Jinah Kim for kindly providing additional data from their respective studies, and would like to acknowledge the help of Hanne Cecilie Braarud in assessing the quality of the evidence, and the help of Jörg Assmus in addressing statistical questions.

In relation with the 2006 version of this review, we would like to thank Jane Dennis and Jo Abbott of the CDPLPG for their help throughout the process, and Lisa Tjosvold of the Cochrane Child Health Field for her help in retrieving additional unpublished studies; we also acknowledge Sogn og Fjordane University College, Norway, and Aalborg University, Denmark, as previous sources of support.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Arezina 2011

Methods	Allocation: session order randomised using Latin Square Blindness: unclear; random sub-sample (33.33% of sessions) assessed by independent observer Duration: 5 weeks Design: cross-over	
Participants	Diagnosis: autism spectrum disorder N = 6 Age: range 36 to 64 months Sex: 5 males, 1 female Setting: child development program	
Interventions	1. Interactive MT (musical instrument play, songs, music books, sung and verbal responses to verbalisations), 6 ten-minute sessions, n = 6 2. Non-music interactive play (non-music toys and books, verbal responses to verbalisations), 6 ten-minute sessions, n = 6 3. Independent play, 6 ten-minute sessions, n = 6	
Outcomes	Behaviour observation of videotaped sessions: a) Interaction or engaging in joint attention (percent of 15-second intervals engaged in interaction) b) Requesting or initiating joint attention (number of requests during a given time period)	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Order of sessions (including different therapeutic approaches) was randomised for each child using a Latin Square
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details about blinding reported; however, a random subsample (33.33%) was assessed by an independent observer (inter-observer agreement ranged from 85.7% to 98.9%)
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Brownell 2002

Methods	Allocation: quasi-randomised, possibly randomised ('counterbalanced') Blindness: independent assessor (teacher), blinding not reported Duration: 4 weeks Design: cross-over
Participants	Diagnosis: autism N = 4 Age: range 6 to 9 years Sex: 4 males, 0 females Setting: elementary school
Interventions	1. Structured receptive MT (songs with social stories), 5 individual daily sessions, n = 4 2. Structured receptive 'story therapy' (reading of social stories), 5 individual daily sessions, n = 4 3. No intervention, 2 x 5 days, n = 4
Outcomes	Repetitive behaviours outside therapy sessions (in classroom) Inter-rater reliability 0.86 to 0.94
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Assignment to a counterbalanced treatment order (either ABAC or ACAB)
Allocation concealment (selection bias)	Unclear risk	No details given

Brownell 2002 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outcomes were assessed by a teacher or instructional associate assigned to the participant No details given on blinding of assessors
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcomes (targeted behaviours) of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Buday 1995

Methods	Allocation: randomised Blindness: assessor blinded to the nature of the hypothesis and to treatment condition Duration: 2 weeks Design: cross-over	
Participants	Diagnosis: autism N = 10 Age: range 4 to 9 years Sex: 8 males, 2 females Setting: public school	
Interventions	1. Structured receptive MT (songs used to teach signs), 5 individual sessions, n = 10 2. 'Rhythm therapy' (rhythmic speech used to teach signs), 5 individual sessions, n = 10	
Outcomes	Imitating behaviour in sessions (rating of a video recording with sound turned off to ensure blinding of raters; inter-rater agreement 98%): a) Sign imitation b) Speech imitation	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Buday 1995 (Continued)

Random sequence generation (selection bias)	Unclear risk	Randomised, no further details given Additionally, counterbalancing of target signs for each treatment condition
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessments were conducted by a person blinded to the nature of the hypothesis and to treatment condition
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Unclear risk	Adequate music therapy method: unclear Adequate music therapy training: unclear

Farmer 2003

Methods	Allocation: randomised Blindness: not known Duration: 5 days Design: parallel group
Participants	Diagnosis: autism N = 10 Age: range 2 to 5 years Sex: 9 males, 1 female Setting: homes and therapy centres
Interventions	1. Music therapy sessions (combined active and receptive: guitar playing, songs), n = 5 2. Placebo (no music) sessions, n = 5 Mostly individual sessions of 20 minutes
Outcomes	Responses within sessions (inter-rater agreement 91%): a) Verbal responses b) Gestural responses
Notes	

Farmer 2003 (Continued)

<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details given
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear if assessors were masked to the randomisation result
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Gattino 2011

Methods	Allocation: balanced randomisation using a table of random numbers Blindness: assessors blinded Duration: 7 months Design: parallel group
Participants	Diagnosis: autism spectrum disorder N = 24 Age: range 7 to 12 years (mean 9.75 years) Sex: 24 males, 0 females Setting: hospital
Interventions	1. Relational music therapy (improvisation not using a structured protocol; 3 assessment sessions, 16 intervention sessions, 1 final assessment session) in addition to standard treatment, 20 thirty-minute sessions, scheduled weekly, n = 12 2. Standard treatment (clinical routine activities including medical examinations and consultations), n = 12

Outcomes	a) Verbal communication (Childhood Autism Rating Scale, Brazilian version, CARS-BR) b) Nonverbal communication (CARS-BR) c) Social communication (CARS-BR)	
Notes	Funding sources: Fund of Incentive to Research of Porto Alegre Clinical Hospital (project no. 08006), Brazilian Research Council (CNPq)	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised (computer-generated random sequence)
Allocation concealment (selection bias)	Low risk	Allocation was conducted by an external investigator
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were blinded to the randomisation result
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Kim 2008

Methods	Allocation: randomised Blindness: assessors were blinded to the treatment condition, except for parent-based measures conducted by mothers Duration: 8 months Design: cross-over
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Participants	Diagnosis: autism N = 15 at entry; N = 10 for analysis Age: range 39 to 71 months (mean 51 months) Sex: 13 males, 2 females at entry; 10 males, 0 females for analysis Setting: private practice clinic	
Interventions	1. Improvisational music therapy, 12 thirty-minute sessions, scheduled weekly, n = 10 2. Play sessions with toys, 12 thirty-minute sessions, scheduled weekly, n = 10	
Outcomes	<i>Social interaction:</i> - social approach subscale (Pervasive Developmental Disorder Behavior Inventory, PDDBI); completed by parents (not blind) and independent observers (blinded) - turn-taking duration <i>Non-verbal communicative skills:</i> - Early Social Communication Scale, ESCS, abridged version - eye contact frequency and duration <i>Initiating behaviour:</i> - initiation of engagement frequency <i>Social-emotional reciprocity:</i> - emotional synchronicity frequency and duration - musical synchronicity frequency and duration <i>Social adaptation:</i> - compliant response frequency - non-compliant response frequency - no response frequency <i>Joy:</i> - joy frequency and duration	
Notes	Funding source: Aalborg University, Denmark	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised (picking the randomisation result from an opaque box)
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Assessors were blinded to the randomisation result, except for non-generalised measures, ESCS, and MPIP, where a random subsample (30%) was additionally assessed by independent observers (inter-rater reliability ranging from 0.70 to 0.98)
Incomplete outcome data (attrition bias) All outcomes	High risk	High drop-out rate (5 of 15 participants dropped out) Data from drop-outs were excluded
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Lim 2010

Methods	Allocation: randomised Blindness: assessors were blind to the purpose of the study Duration: 5 days Design: parallel group	
Participants	Diagnosis: autism spectrum disorder N = 50 Age: range 3 to 5 years (mean 4.8 years) Sex: 44 males, 6 females. Setting: recruiting site (schools, therapy centres, etc.)	
Interventions	1. Music training ('Developmental Speech and Language Training through Music'; videotaped songs with target words), 6 individual sessions within 3 days, n = 18 2. Speech training (videotaped spoken stories with target words), 6 individual sessions within 3 days, n = 18 3. No training, n = 14	
Outcomes	Behaviour observation of videotaped post-test sessions: verbal response. Inter-rater reliability 0.999	
Notes		
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details given

Lim 2010 (Continued)

Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were blind to the purpose of the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Unclear risk	Adequate music therapy method: unclear Adequate music therapy training: unclear

Lim 2011

Methods	Allocation: training order randomised Blindness: assessors were blind to the purpose of the study Duration: 2 weeks Design: cross-over	
Participants	Diagnosis: autism spectrum disorder, N = 22 Age: range 3 to 5 years (mean 4.3 years) Sex: 17 males, 5 females Setting: no details given	
Interventions	1. Music training ('music incorporated Applied Behavior Analysis Verbal Behavior'; sung instructions, songs with target words), 6 individual sessions within 2 weeks, n = 22 2. Speech training (Applied Behavior Analysis Verbal Behavior; spoken instructions, sentences with target words), 6 individual sessions within 2 weeks, n = 22 3. No training, n = 22	
Outcomes	Behaviour observation of videotaped post-test sessions: verbal production	
Notes		
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement

Lim 2011 (Continued)

Random sequence generation (selection bias)	Low risk	Order of sessions (including different therapeutic approaches) was randomised for each child using a random number chart
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Assessors were blind to the purpose of the study
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Thomas 2003

Methods	Allocation: randomised order of treatment Blindness: no blinding Duration: 12 weeks Design: cross-over (within each session)
Participants	Diagnosis: autism, N = 6 Age: range 2 to 3 years Sex: 5 males, 1 female Setting: not known
Interventions	1. Music therapy (using songs, instruments, vocal sounds and movement to interact with the child and musically or verbally respond to the child's verbal or non-verbal behaviour) , twelve 15-minute session parts, immediately following or preceding playtime session parts, n = 6 2. Playtime (attempts to interact with the child using toys and verbally responding to the child's non-verbal or verbal behaviour), twelve 15-minute session parts, immediately following or preceding music therapy session parts, n = 6

Thomas 2003 (Continued)

Outcomes	Behaviour observation of videotaped sessions a) On-task behaviour (percentage of session time) b) Requesting behaviour (percentage of session time)	
Notes	Funding source: Mid-Atlantic Region of the American Music Therapy Association	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomised, no further details given
Allocation concealment (selection bias)	Unclear risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention was unknown
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details given if the assessor was blinded to the randomisation result
Incomplete outcome data (attrition bias) All outcomes	Low risk	No drop-outs No missing data reported
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

Thompson 2012a

Methods	Allocation: randomised Blindness: no blinding Duration: 16 weeks Design: parallel group
Participants	Diagnosis: ASD N = 23 Age: range 3 to 6 years Sex: 19 males, 4 females Setting: participants' homes

Interventions	1. Home-based, family-centred music therapy (using songs, improvisation, structured music interactions), in addition to standard care, 16 sessions, scheduled weekly, n = 12 2. Standard care, n = 11	
Outcomes	a) Vineland Social Emotional Early Childhood Scales (Vineland SEEC) b) Social Responsiveness Scale Preschool Version (SRS-PS), rated by parents c) MacArthur-Bates Communicative Development Inventories - Words and Gestures (MBCDI-W&G), rated by parents d) Parent-Child Relationship Inventory (PCRI), rated by parents e) Music Therapy Diagnostic Assessment (MTDA): not used since rated for music therapy group only	
Notes	Funding source: Department of Education and Early Childhood Development, Victoria	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised (computer-generated random sequence)
Allocation concealment (selection bias)	Low risk	An independent statistician prepared opaque, numbered allocation envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The fact that children with ASD participating in the study were not blinded was considered unlikely to introduce bias The possible risk of bias introduced by therapists administering the intervention is unknown
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Parent-report based measures were used However, measures contain internal safeguards to address bias as evidenced by high correlations with non-parent rated measures or high test-retest correlations
Incomplete outcome data (attrition bias) All outcomes	Low risk	Low drop-out rate Intention-to-treat analysis
Selective reporting (reporting bias)	Low risk	All outcome measures of interest were considered in the analysis
Other bias	Low risk	Adequate music therapy method: yes Adequate music therapy training: yes

MT - music therapy; ABAC, ACAB - type of trial where interventions A, B, and C are given in this order

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Applebaum 1979	Not intervention study (assessment)
Bettison 1996	Not MT (AIT - only music listening)
Blackstock 1978	Not intervention study (assessment)
Bonnel 2003	Not intervention study (assessment)
Boso 2007	Not RCT or CCT (case series)
Brown 1994	Not RCT or CCT (case series)
Brown 2003	Not intervention study (assessment)
Bruscia 1982	Not RCT or CCT (case study)
Carroll 1983	Not MT (only sung instructions)
Chilcote-Doner 1982	Not MT (rhythmic strobe and drumbeat)
Clauss 1994	Not RCT or CCT (case series, ABACA design)
Cooley 2012	Not MT (speech and language training with music)
Dawson 1998	Not intervention study (assessment)
Diez Cuervo 1989	Not intervention study (assessment)
Edelson 1999	Not MT (AIT - only music listening)
Edgerton 1994	Not RCT or CCT (case series)
Finnigan 2010	Not RCT or CCT (case study)
Frissell 2001	Not intervention study (assessment)
Goldstein 1964	Not RCT or CCT (case study)
Gore 2002	No usable data (unclear outcome measure)
Griggs 1997	Not RCT or CCT (case study) Not intervention study (assessment)

(Continued)

Hadsell 1988	Not RCT or CCT (case series) Not ASD (Rett syndrome)
Hairston 1990	Not RCT or CCT (case series)
Heaton 1999	Not intervention study (assessment)
Heaton 2003	Not intervention study (assessment)
Hillier 2012	Not RCT or CCT (case series)
Kern 2006	Not RCT or CCT (case series)
Kern 2007	Not RCT or CCT (case study)
Kolko 1980	Not intervention study (assessment)
Krauss 1982	Not RCT or CCT (case series) Not ASD (apraxia, language delay)
Laird 1997	Not RCT or CCT (uncontrolled design)
Lee 2004	Not RCT or CCT (case series)
Li 2011	Not possible to isolate MT from other interventions
Lim 2007	Not MT (speech training with music)
Litchman 1976	Not MT (listening to recorded nursery rhymes)
Lundqvist 2009	Not MT (presentation of preset vibroacoustic stimuli)
Ma 2001	Not RCT or CCT (case series)
Mahlberg 1973	Not RCT or CCT (case study)
Miller 1979	Not RCT or CCT (case study)
Mortron 2000	Not intervention study (assessment)
Mudford 2000	Not MT (AIT/only music listening)
O'Connell 1974	Not RCT or CCT (case study)
O'Dell 1998	Not MT (music listening)

(Continued)

O'Loughlin 2000	Not RCT or CCT - includes three case series where all received the same treatment (no. 1, 3, 4) and one case series with an ABA design (no. 2)
Pasiali 2004	Not RCT or CCT (case series, ABAB design)
Rao 2001	Not MT (headphones with versus without music)
Sandiford 2013	Not MT (speech training with music)
Saperston 1973	Not RCT or CCT (case study)
Schmidt 1976	Not RCT or CCT (case series, AB design)
Starr 1998	Not RCT or CCT (case series)
Staum 1984	Not RCT or CCT (case study)
Stephens 2008	Not RCT or CCT (case series)
Stevens 1969	Not RCT or CCT (case series)
Thaut 1987	Not intervention study (assessment)
Thaut 1988	Not intervention study (assessment)
Toolan 1994	Not RCT or CCT (case series)
Watson 1979	Not RCT or CCT (case series, ABCA design)
Wimporoy 1995	Not RCT or CCT (case study)
Wood 1991	Not MT (music listening)

MT - music therapy; AIT - auditory integration training; RCT - randomised controlled trial; CCT - controlled clinical trial; ASD - autism spectrum disorder; ABA, ABAB, AB - type of trial where interventions A and B are given in this order; ABCA, ABACA - type of trial where interventions A, B, and C are given in this order

Characteristics of ongoing studies *[ordered by study ID]*

ISRCTN78923965

Trial name or title	Randomised controlled trial of improvisational music therapy's effectiveness for children with autism spectrum disorders (TIME-A)
Methods	Allocation: randomised Blindness: assessors of primary outcome blinded Duration: 12 months Design: parallel group
Participants	Diagnosis: autism spectrum disorder N = 300 Age: range 4 years to 6 years, 11 months
Interventions	1. Individual improvisational music therapy over a period of five months, 3 sessions per week (high-intensity), plus standard care (see below) 2. Individual improvisational music therapy over a period of five months, 1 session per week (low-intensity), plus standard care (see below) 3. Standard care: 3 sessions of parent counselling at 0, 2, and 5 months
Outcomes	a) Autism Diagnostic Observation Schedule (ADOS) b) Social Responsiveness Scale (SRS) c) Cost-effectiveness
Starting date	01/08/2011
Contact information	christian.gold@uni.no
Notes	http://www.controlled-trials.com/ISRCTN78923965

DATA AND ANALYSES

Comparison 1. Music therapy vs. 'placebo' therapy or standard care

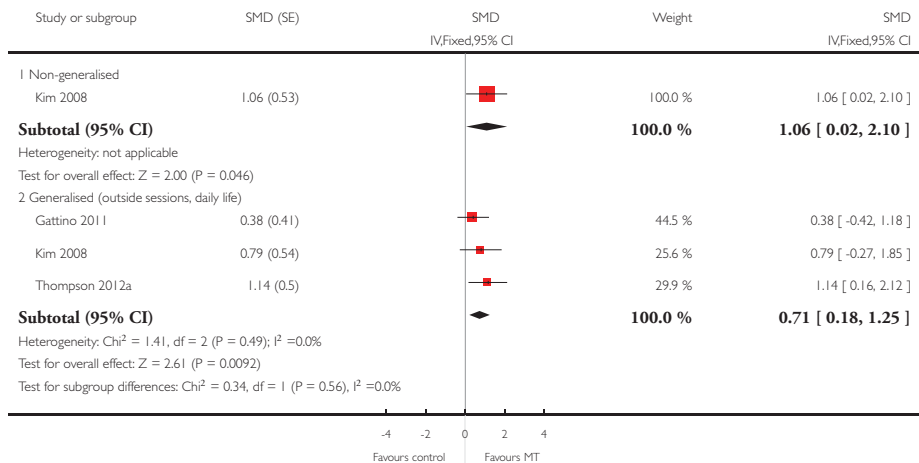
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Social interaction	3		SMD (Fixed, 95% CI)	Subtotals only
1.1 Non-generalised	1		SMD (Fixed, 95% CI)	1.06 [0.02, 2.10]
1.2 Generalised (outside sessions, daily life)	3		SMD (Fixed, 95% CI)	0.71 [0.18, 1.25]
2 Communicative skills: non-verbal	5		SMD (Fixed, 95% CI)	Subtotals only
2.1 Non-generalised	3		SMD (Fixed, 95% CI)	0.57 [0.29, 0.85]
2.2 Generalised (outside sessions, daily life)	3		SMD (Fixed, 95% CI)	0.48 [-0.02, 0.98]
3 Communicative skills: verbal	6		SMD (Fixed, 95% CI)	0.33 [0.16, 0.49]
3.1 Non-generalised	4		SMD (Fixed, 95% CI)	0.33 [0.16, 0.50]
3.2 Generalised (outside sessions, daily life)	2		SMD (Fixed, 95% CI)	0.30 [-0.28, 0.89]
4 Initiating behaviour	3		SMD (Fixed, 95% CI)	Subtotals only
4.1 Non-generalised	3		SMD (Fixed, 95% CI)	0.73 [0.36, 1.11]
5 Social-emotional reciprocity	1		SMD (Fixed, 95% CI)	Subtotals only
5.1 Non-generalised	1		SMD (Fixed, 95% CI)	2.28 [0.73, 3.83]
6 Social adaptation	4		SMD (Fixed, 95% CI)	0.41 [0.21, 0.60]
6.1 Non-generalised	3		SMD (Fixed, 95% CI)	1.15 [0.69, 1.61]
6.2 Generalised (outside sessions, daily life)	1		SMD (Fixed, 95% CI)	0.24 [0.02, 0.46]
7 Joy	1		SMD (Fixed, 95% CI)	0.96 [0.04, 1.88]
8 Quality of parent-child relationship	2		SMD (Fixed, 95% CI)	0.82 [0.13, 1.52]

Analysis 1.1. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 1 Social interaction.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 1 Social interaction

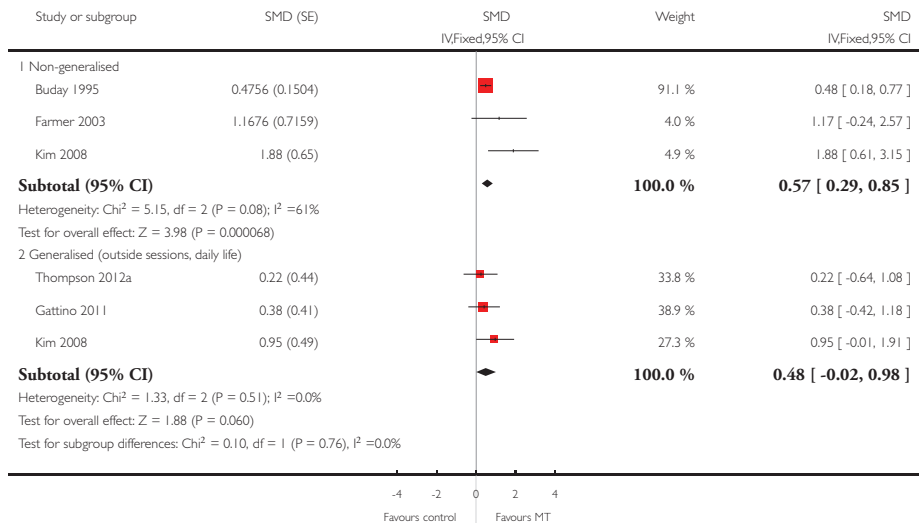


Analysis 1.2. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 2 Communicative skills: non-verbal.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 2 Communicative skills: non-verbal

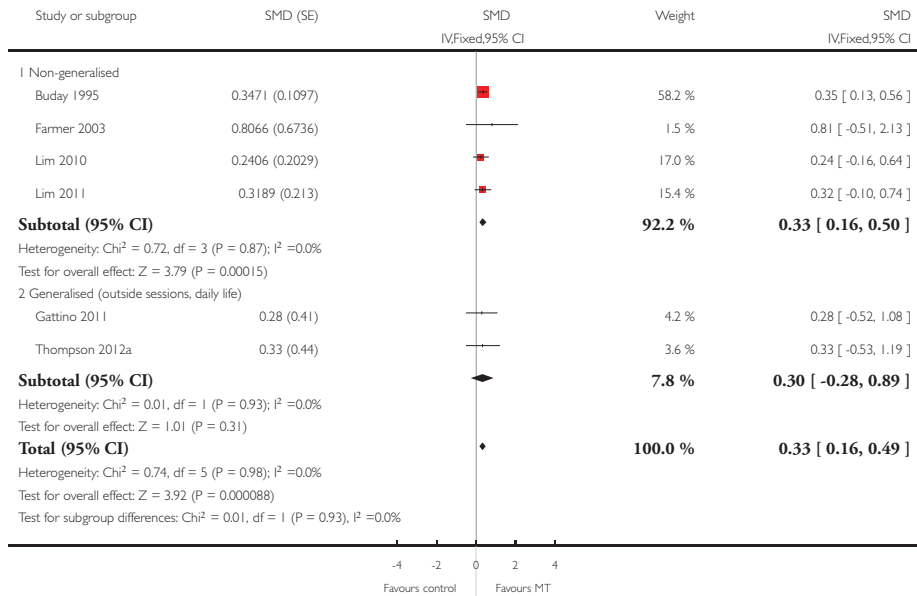


Analysis 1.3. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 3 Communicative skills: verbal.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 3 Communicative skills: verbal

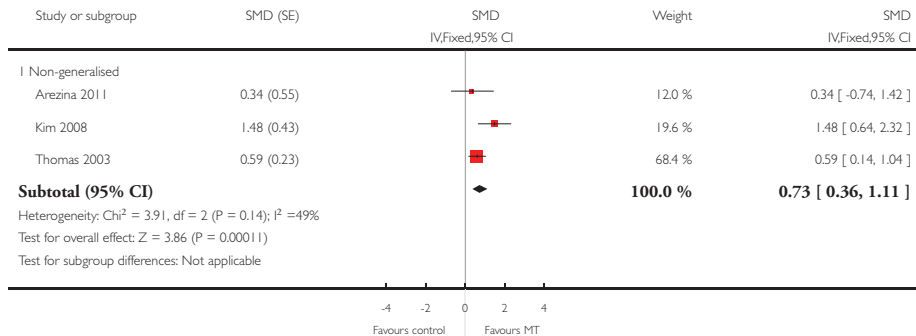


Analysis 1.4. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 4 Initiating behaviour.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 4 Initiating behaviour

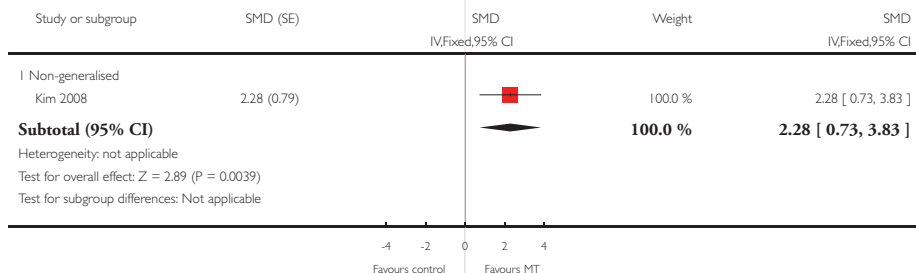


Analysis 1.5. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 5 Social-emotional reciprocity.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 5 Social-emotional reciprocity

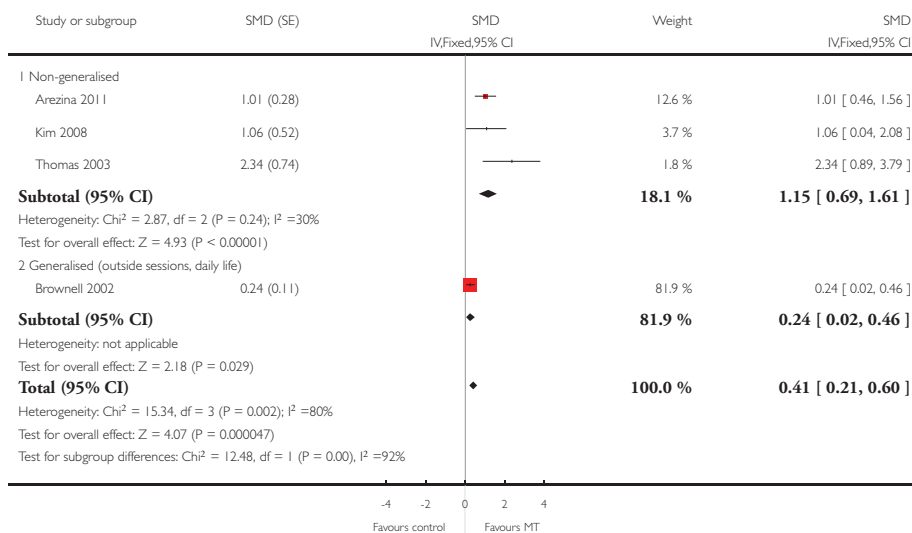


Analysis 1.6. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 6 Social adaptation.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 6 Social adaptation

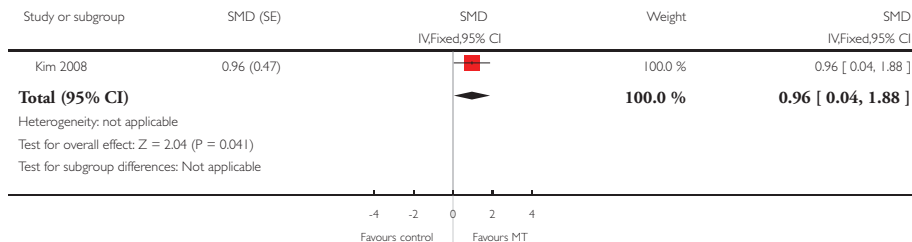


Analysis 1.7. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 7 Joy.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 7 Joy

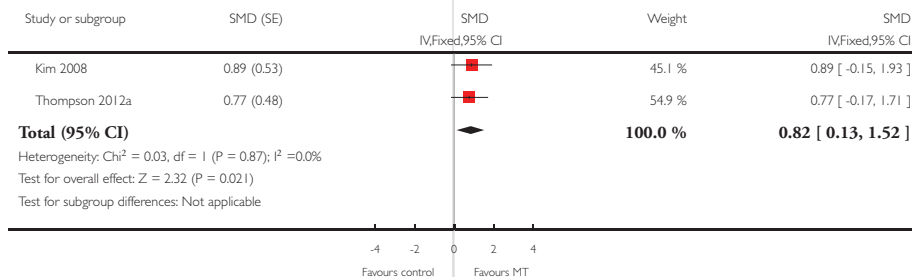


Analysis 1.8. Comparison 1 Music therapy vs. 'placebo' therapy or standard care, Outcome 8 Quality of parent-child relationship.

Review: Music therapy for people with autism spectrum disorder

Comparison: 1 Music therapy vs. 'placebo' therapy or standard care

Outcome: 8 Quality of parent-child relationship



APPENDICES

Appendix 1. Search strategies 2004-2013

For this update, the following search terms were added to the original strategy (reported in [Appendix 2](#)) to increase the sensitivity of the search:

(sing or singing or song* or choral* or choir*)

(percussion* or rhythm* or tempo*)

improvis*

melod*

Nordoff-Robbins

Bonny

(auditory or acoustic or sound*) adj5 (stimulat* or cue*)

CENTRAL

2011 Issue 3 Limited by year 2004 to 2011. Searched 7 September 2011 plus new terms for all years pre-2004 [61 records]

2013 Issue 6 Limited by year 2011 to 2013. Searched 29 July 2013 [8 records]

#1MeSH descriptor: [Music] this term only

#2MeSH descriptor: [Music Therapy] this term only

#3music*

#4((guided next imagery) near music)

#5GIM

#6vibroacoustic

#7vibro-acoustic

#8(sing or singing or song* or choral* or choir*)

#9(percussion* or rhythm* or tempo* or melod*)

#10improvis*

#11(Nordoff-Robbins or bonny*)

#12((auditory or acoustic or sound*) near/5 (stimulat* or cue*))

#13(#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12)

#14MeSH descriptor: [Child Development Disorders, Pervasive] 1 tree(s) exploded

#15asperg* or autis* or kanner* or (childhood next schizophren*)

#16(speech near disorder*)

#17(language near delay*)

#18ASD or ASDs or PDD or PDDs

#19(#14 or #15 or #16 or #17 or #18)

#20(#13 and #19) in Trials

Ovid MEDLINE

Ovid MEDLINE 1948 to August Week 4 2011. Searched 6 September 2011. Limited by year 2004 to 2011 plus new terms for all years pre-2004 [93 records]

Ovid MEDLINE 1946 to July Week 3 2013. Searched 29 July 2013 Limited to ed=20110831 to 20130729 [24 records]

1 music therapy/

2 music\$.tw.

3 (guided imagery adj3 music).tw.

4 gim.tw.

5 (vibro-acoustic\$ or vibroacoustic\$).tw.

6 music/

7 (sing or singing or song\$ or choral\$ or choir\$).tw.

8 (percussion\$ or rhythm\$).tw.

9 melod\$.tw.
 10 improvis\$.tw.
 11 (Nordoff-Robbins\$ or bonny\$).tw.
 12 ((auditory or acoustic or sound\$) adj5 (stimulat\$ or cue\$)).tw.
 13 or/1-12
 14 exp child development disorders, pervasive/
 15 pervasive development\$ disorder\$.tw.
 16 (PDD or PDDs or ASD or ASDs).tw.
 17 autism\$.tw.
 18 asperg\$.tw.
 19 kanner\$.tw.
 20 childhood schizophreni\$.tw.
 21 (speech adj3 disorder\$).tw.
 22 (language adj3 delay\$).tw.
 23 or/14-22
 24 randomized controlled trial.pt.
 25 controlled clinical trial.pt.
 26 randomi#ed.ab.
 27 placebo\$.ab.
 28 drug therapy.fs.
 29 randomly.ab.
 30 trial.ab.
 31 groups.ab.
 32 or/24-31
 33 exp animals/ not humans.sh.
 34 32 not 33
 35 13 and 23 and 34

Embase (OVID)

Embase 1980 to 2011 Week 35. Searched 7 September 2011. Limited to year=2004 to 2011 plus new terms for all years pre-2004 [133 records]

Embase 1980 to 2013 Week 30. Searched 29 July 2013. Limited to year=2011 to 2013 [54 records]

1 exp music/
 2 music therapy/
 3 music\$.tw.
 4 (guided imagery adj3 music).tw.
 5 GIM.tw.
 6 (guided imagery adj3 music).tw.
 7 (vibro-acoustic therapy or vibroacoustic therapy).tw.
 8 (sing or singing or song\$ or choral\$ or choir\$).tw.
 9 (percussion\$ or rhythm\$).tw.
 10 melod\$.tw.
 11 improvis\$.tw.
 12 (Nordoff-Robbins\$ or bonny\$).tw.
 13 ((auditory or acoustic or sound\$) adj5 (stimulat\$ or cue\$)).tw.
 14 or/1-13
 15 exp autism/
 16 pervasive development\$ disorder\$.tw.
 17 (PDD or PDDs or ASD or ASDs).tw.
 18 autism\$.tw.
 19 asperg\$.tw.

20 kanner\$.tw.
 21 childhood schizophreni\$.tw.
 22 (speech adj3 disorder\$).tw.
 23 (language adj3 delay\$).tw.
 24 or/15-23
 25 exp Clinical trial/
 26 Randomized controlled trial/
 27 Randomization/
 28 Single blind procedure/
 29 Double blind procedure/
 30 Crossover procedure/
 31 Placebo/
 32 Randomi#ed.tw.
 33 RCT.tw.
 34 (random\$ adj3 (allocat\$ or assign\$)).tw.
 35 randomly.ab.
 36 groups.ab.
 37 trial.ab.
 38 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw.
 39 Placebo\$.tw.
 40 Prospective study/
 41 (crossover or cross-over).tw.
 42 prospective.tw.
 43 or/25-42
 44 14 and 24 and 43

PsycINFO (OVID)

PsycINFO 1806 to August Week 5 2011. Searched 7 September 2011. Limited to 2004 to 2011 plus new terms for all years pre-2004 [33 records]

PsycINFO 1806 to July Week 3 2013. Searched 29 July 2013. Limited to 2011 to current [14 records]

1 exp music/
 2 music therapy/
 3 music\$.tw.
 4 (guided imag\$ adj3 music*).tw.
 5 GIM.tw.
 6 (vibroacoustic\$ or vibro-acoustic\$).tw.
 7 rhythm/ or tempo/
 8 (percussion\$ or rhythm\$ or tempo).tw.
 9 singing/
 10 (sing or singing or song\$ or choral\$ or choir\$).tw.
 11 melod\$.tw.
 12 improvis\$.tw.
 13 (Bonny or Nordoff\$).tw.
 14 ((auditory or acoustic or sound\$) adj5 (stimulat\$ or cue\$)).tw.
 15 or/1-14
 16 exp pervasive developmental disorders/
 17 pervasive development\$ disorder\$.tw.
 18 (PDD or PDDs or ASD or ASDs).tw.
 19 autis\$.tw.
 20 asperg\$.tw.
 21 kanner\$.tw.

22 childhood schizopreni\$.tw.
 23 (speech adj3 disorder\$).tw.
 24 (language adj3 delay\$).tw.
 25 or/16-24
 26 Clinical Trials/
 27 Random Sampling/
 28 Placebo/
 29 treatment effectiveness evaluation/ or mental health program evaluation/
 30 evaluation/ or program evaluation/
 31 educational program evaluation/
 32 ((clinical or control\$) adj5 trial\$).tw.
 33 placebo\$.tw.
 34 randomi#ed.tw.
 35 (random\$ adj3 (assign\$ or allocat\$)).tw.
 36 (singl\$ adj3 (mask\$ or blind\$)).tw.
 37 (doubl\$ adj3 (mask\$ or blind\$)).tw.
 38 ((tripl\$ or trebl\$) adj3 (mask\$ or blind\$)).tw.
 39 (crossover\$ or cross-over\$).tw.
 40 ((evaluat\$ or effectiveness\$) adj3 (study or studies or research\$)).tw.
 41 or/26-40
 42 15 and 25 and 41

CINAHL Plus (EBSCOhost)

CINAHL 1937 to current. Searched 7 September 2011. Limited to year=2004 to 2011 plus new terms for all years pre-2004 [50 records]

CINAHL 1937 to current. Searched 29 July 2013. Limited to year=2011 to 2013 [25 records]

S42 S21 AND S41
 S41 S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 OR S31
 OR S32 OR S33 OR S34 OR S35 OR S36 OR S37 OR S38 OR S39 OR S40
 S40 placebo*
 S39 (MH "Placebos")
 S38 (MH "Evaluation Research") OR (MH "Summative Evaluation Research")
 OR (MH "Program Evaluation")
 S37 (MH "Treatment Outcomes")
 S36 (MH "Comparative Studies")
 S35 TI (compar* stud* or compar* research*) or AB (compar* stud* or
 compar* research*) or TI (evaluat* study or evaluat* research) or AB
 (evaluat* study or evaluat* research) or TI (effectiv* study or
 effectiv* research) or AB (effectiv* study or effectiv* research) OR TI
 (prospectiv* study or prospectiv* research) or AB(prospectiv* study or
 prospectiv* research) or TI (follow-up study or follow-up research) or
 AB (follow-up study or follow-up research)
 S34 crossover* or "cross over"
 S33 (MH "Crossover Design")
 S32 (trebl* N3 mask*) or (trebl* N3 blind*)
 S31 (tripl* N3 mask*) or (tripl* N3 blind*)
 S30 (doubl* N3 mask*) or (doubl* N3 blind*)
 S29 (singl* N3 mask*) or (singl* N3 blind*)
 S28 (clinic* N3 trial*) or (control* N3 trial*)
 S27 (random* N3 allocat*) or (random* N3 assign*)
 S26 randomis* or randomiz*

S25 (MH "Meta Analysis")
 S24 randomis* or randomiz*
 S23 (MH "Clinical Trials+")
 S22 MH random assignment
 S21 S14 AND S20
 S20 S15 OR S16 OR S17 OR S18 OR S19
 S19 speech N3 disorder* or language N3 delay*
 S18 (PDD or PDDs or PDD-NOS or ASD or ASDs)
 S17 pervasive development* disorder*
 S16 autis* or asperger* or childhood schizophre* or kanner*
 S15 (MH "Child Development Disorders, Pervasive+")
 S14 S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR
 S12 OR S13
 S13 (auditory N3 cue* or auditory N3 stimul*) OR (acoustic N3 cue* or
 acoustic N3 stimul*) or (sound N3 cue* or sound N3 stimul*)
 S12 Nordoff* or Bonny*
 S11 improvis*
 S10 percussion* or rhythm* or melod* or tempo
 S9 sing or singing or song* or choral or choir*
 S8 (MH "Singing")
 S7 vibro-acoustic* or vibroacoustic*
 S6 GIM
 S5 (guided imagery) N3 (music*)
 S4 (MH "Guided Imagery")
 S3 music*
 S2 MH music therapy
 S1 MH music

ERIC (Proquest)

ERIC 1966 to current. Limited to year=2004 to 2011. Searched 9 September 2011 Limited to 2004 to 2011 plus new terms for all years pre-2004 [67 records]

ERIC 1966 to current. Limited to year=2011 to 2013. Searched 30 July 2013 [31 records]

(SU.EXACT.EXPLODE("Music") OR SU.EXACT("Music Therapy") OR SU.EXACT.EXPLODE("Music Activities") OR (music* OR guided imag* OR GIM OR vibro-acoustic therapy* OR vibroacoustic therapy* OR

Bonny* OR Nordoff* OR singing OR song* OR choral* OR choir* OR percussion* OR rhythm* OR improvis*) OR ((auditory OR acoustic OR sound*) NEAR/5 (stimulat* OR cue*)) AND (SU.EXACT.EXPLODE

("Pervasive Developmental Disorders") OR (autism* OR asperg* OR "pervasive development* disorder*" OR "childhood schizophrenia*" OR Kanner*)) AND (SU.EXACT.EXPLODE("Pervasive Developmental

Disorders") OR (autism* OR asperg* OR "pervasive development* disorder*" OR "childhood schizophrenia*" OR Kanner*)) AND (SU.EXACT("Experimental Groups") OR SU.EXACT("Control Groups") OR

random* OR control* or group* or placebo* OR trial* OR blind*)

Sociological Abstracts (Proquest)

1952 to current. Limited to year=2004-2011. Searched 8 September 2011. Limited to year=2004 to 2011 plus new terms for all years pre-2004 [4 records]

1952 to current. Limited to year=2011-2013. Searched 30 July 2013. Limited to year=2011 to 2013 [0 records]

((su.EXACT("Music")or ((music* or guided imag* or GIM or vibro-acoustic therapy* or vibroacoustic therapy* or Bonny* or Nordoff* or singing or song* or choral* or choir* or percussion* or

rhythm* or improvis* or ((auditory or acoustic or sound*) near/5 (stimulat* or cue*)))) and (su.EXACT(("autism")) or (autism* or asperg* or pervasive development* disorder* or childhood

schizophrenia* or Kanner*)) AND (random* or placebo* or trial* or blind*)

LILACS

All available years searched 9 September 2011 [2 records]

Searched 30 July 2013. Limited to year=2011 to 2013 [0 records]

((Pt randomized controlled trial OR Pt controlled clinical trial OR Mh randomized controlled trials OR Mh random allocation OR Mh double-blind method OR Mh single-blind method) AND NOT (Ct

animal AND NOT (Ct human and Ct animal)) OR (Pt clinical trial OR Ex E05.318.760.535\$ OR (Tw clin\$ AND (Tw trial\$ OR Tw ensa\$ OR Tw estud\$ OR Tw experim\$ OR Tw investiga\$)) OR ((Tw singl\$

OR Tw simple\$ OR Tw doubl\$ OR Tw doble\$ OR Tw duplo\$ OR Tw trebl\$ OR Tw trip\$) AND (Tw blind\$ OR Tw cego\$ OR Tw ciego\$ OR Tw mask\$ OR Tw mascar\$)) OR Mh placebos OR Tw placebo\$ OR (Tw

random\$ OR Tw randon\$ OR Tw casual\$ OR Tw acaso\$ OR Tw azar OR Tw aleator\$) OR Mh research design) AND NOT (Ct animal AND NOT (Ct human and Ct animal)) OR (Ct comparative study OR Ex

E05.337\$ OR Mh follow-up studies OR Mh prospective studies OR Tw control\$ OR Tw prospectiv\$ OR Tw volunt\$ OR Tw volunteer\$) AND NOT (Ct animal AND NOT (Ct human and Ct animal))) [Words] and

(Mh MUSIC OR Mh MUSIC therapy OR (musi\$ OR GIM OR vibro-acoustic therapy OR vibroacoustic therapy)) [Words] and (Mh autistic disorder OR Mh asperger syndrome OR autis\$ OR asperg\$ or PDD

or PDDs or ASD or ASDs)

ASSIA (Proquest)

ASSIA 1987 to current. Searched 8 September 2011. Limited to year=2011-2014 plus new terms for all years pre-2004 [4 records]

ASSIA 1987 to current. Searched 29 July 2013.

((su.EXACT("Music" or "Drumming" or "Melodies" or "Singing" or "Songs" or su.EXACT(("Music therapy")) or ((music* or guided image* or GIM or vibro-acoustic therapy* or vibroacoustic

therapy* or Bonny* or Nordoff* or singing or song* or choral* or choir* or percussion* or rhythm* or improvis* or ((auditory or acoustic or sound*) near/5 (stimulate* or cue*)))) AND

(EXACT(("autism" or "Infantile autism")) or EXACT(("Asperger's syndrome" or "autistic spectrum disorders" or "Pervasive developmental disorders")) or (autism* or asperg* or pervasive

development* disorder* or childhood schizophrenia* or kanner*)) AND ((EXACT(("Clinical randomized controlled trials" or "Cluster randomized controlled trials" or "Double blind randomized

controlled trials" or "Randomized consent design" or "Randomized controlled trials" or "Single blind randomized controlled trials" or "Urn randomization")) or randomised or randomized or

randomly or trial*))

ClinicalTrials.gov

Searched 9 September 2011 and 30 July 2013 [0 records]

Conditions: autism OR autistic or asperger or aspergers or pervasive or ASD or ASDs or PDD or PDDS

Interventions: music

ICTRP

Searched 9 September 2011 and 3 July 2013 [3 records]

Condition: autism OR autistic or asperger or aspergers or pervasive or ASD or ASDs or PDD or PDDS

Intervention: music

Appendix 2. Search strategies up to 2004

Searches for the original review were based on the following Ovid MEDLINE strategy:

#1 MUSIC

#2 MUSIC THERAPY

#3 musi*

#4 gim

#5 ((guided imagery) near music)

#6 vibroacoustic

#7 vibro-acoustic

#8 (#1 or #2 or #3 or #4 or #5 or #6 or #7)

#9 (asperger next syndrome)

#10 autis*

#11 kanner*

#12 (childhood near schizophren*)

#13 (speech near disorder*)

#14 (language near delay*)

#15 pdd

#16 CHILD DEVELOPMENT DISORDERS, PERVASIVE

#17 (#9 or #10 or #11 or #12 or #13 or #14 or #15 or #16)

#18 (#8 and #17)

The search terms were modified to suit the requirements of the other databases searched. An optimal sensitive search strategy for randomised controlled trials was also used where necessary.

WHAT'S NEW

Last assessed as up-to-date: 2 December 2013.

Date	Event	Description
2 December 2013	New search has been performed	A search for new studies was conducted, resulting in the inclusion of seven new studies; based on the added studies' findings, the categories of outcome measures were revised, new meta-analyses were performed, and pre-existing results and conclusions were modified
31 March 2013	New citation required and conclusions have changed	Updated review with two new authors.

HISTORY

Protocol first published: Issue 3, 2003

Review first published: Issue 2, 2006

Date	Event	Description
5 November 2009	Amended	Minor edit in background.
10 November 2008	Amended	Converted to new review format.
21 February 2006	Amended	Minor update
29 January 2006	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

CG designed the protocol and co-ordinated the reviewing. MG co-ordinated this review's update. CG and MG searched for studies. CE, CG, and MG screened search results. CE, CG, KM, and MG extracted data, analysed data, wrote the report, and approved the full review.

Contribution of previous authors: Tony Wigram, co-author of the 2006 version of this review, contributed to the development of the protocol, extracted and analysed data, and helped with writing the original report.

DECLARATIONS OF INTEREST

The authors of this review are clinically trained music therapists.

Christian Gold is an Associate Editor of the Cochrane Developmental, Psychosocial and Learning Problems Group, and has been involved in publications from two studies included in this review (Kim 2008;Thompson 2012a), none of which supported or influenced his work on this review.

Christian Gold and Karin Mössler's institute (GAMUT) received a grant to support the preparation of this manuscript from The Research Council of Norway (grant no. 213844, The Clinical Research and The mental Health Programmes). Support for the manuscript was also received through Monika Geretsegger's PhD Mobility Fellowship, which was funded by a grant from the Danish Council for Independent Research/Humanities (FKK) to Aalborg University.

Cochavit Elefant - none known.

SOURCES OF SUPPORT

Internal sources

- Aalborg University, Denmark.
- University of Vienna, Austria.
- University of Haifa, Israel.
- Grieg Academy Music Therapy Research Centre (GAMUT), Uni Health, Uni Research, Bergen, Norway.

External sources

- The Research Council of Norway, Norway.
(grant no. 213844, The Clinical Research and The Mental Health Programmes)
- The Danish Council for Independent Research/Humanities (FKK), Denmark.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In compliance with the developments in systematic review methods since publication of the first version of this review (Gold 2006), a distinction was made between primary and secondary outcome measures, and 'Risk of bias' tables and a 'Summary of findings' table were included in this update.

INDEX TERMS

Medical Subject Headings (MeSH)

Autistic Disorder [*rehabilitation]; Child Development Disorders, Pervasive [*rehabilitation]; Communication; Music Therapy [*methods]; Randomized Controlled Trials as Topic

MeSH check words

Child; Humans

II. TIME-A STUDY PROTOCOL

Geretsegger, M., Holck, U., & Gold, C. (2012).
Randomised controlled trial of improvisational music therapy's
effectiveness for children with autism spectrum disorders (TIME-A):
Study protocol. *BMC Pediatrics*, 12(2). DOI:10.1186/1471-2431-12-2.
(<http://www.biomedcentral.com/1471-2431/12/2>)

STUDY PROTOCOL

Open Access

Randomised controlled trial of improvisational music therapy's effectiveness for children with autism spectrum disorders (TIME-A): study protocol

Monika Geretsegger^{1,2}, Ulla Holck¹ and Christian Gold^{3*}

Abstract

Background: Previous research has suggested that music therapy may facilitate skills in areas typically affected by autism spectrum disorders such as social interaction and communication. However, generalisability of previous findings has been restricted, as studies were limited in either methodological accuracy or the clinical relevance of their approach. The aim of this study is to determine effects of improvisational music therapy on social communication skills of children with autism spectrum disorders. An additional aim of the study is to examine if variation in dose of treatment (i.e., number of music therapy sessions per week) affects outcome of therapy, and to determine cost-effectiveness.

Methods/Design: Children aged between 4;0 and 6;11 years who are diagnosed with autism spectrum disorder will be randomly assigned to one of three conditions. Parents of all participants will receive three sessions of parent counselling (at 0, 2, and 5 months). In addition, children randomised to the two intervention groups will be offered individual, improvisational music therapy over a period of five months, either one session (low-intensity) or three sessions (high-intensity) per week. Generalised effects of music therapy will be measured using standardised scales completed by blinded assessors (Autism Diagnostic Observation Schedule, ADOS) and parents (Social Responsiveness Scale, SRS) before and 2, 5, and 12 months after randomisation. Cost effectiveness will be calculated as man years. A group sequential design with first interim look at N = 235 will ensure both power and efficiency.

Discussion: Responding to the need for more rigorously designed trials examining the effectiveness of music therapy in autism spectrum disorders, this pragmatic trial sets out to generate findings that will be well generalisable to clinical practice. Addressing the issue of dose variation, this study's results will also provide information on the relevance of session frequency for therapy outcome.

Trial Registration: Current Controlled Trials ISRCTN78923965.

Background

Impairments or delayed development in skills concerning social interaction and communication are at the core of autism spectrum disorders (ASD) [1]. The attempts to help children with ASD develop meaningful language and social communication skills cover a wide

range of different approaches. Yet, for most of the various intervention methods available and reported within ASD that are designed to improve communication and social interaction, only insufficient evidence of effectiveness exists [2]. Some favourable results can be found for approaches such as early behavioural interventions [3,4] and augmentative communication [5]. However, if methodologically rigorous standards are applied, statistically significant improvements in communication and speech could hitherto only be ascertained in a parent-mediated

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communication-focused intervention [6], parent-mediated behavioural interventions [2], and music therapy [2,7]. Similarly, in a review of "novel and emerging treatments" for ASD [8] including several nutritional supplements, diets, medications, and nonbiological treatments, it was found that the only treatment options that reached the highest ranking in an evidence-based grading system were melatonin, acetylcholinesterase inhibitors, naltrexone, and music therapy. Considering that pharmacological treatments typically target symptoms such as hyperactivity, agitation, or sleep disorders rather than core symptoms of ASD, and may have adverse effects [2,8], music therapy can be viewed as a promising, but not yet sufficiently evidenced treatment for improving social interaction and communication skills within ASD. Due to various methodological quality limitations of previous studies [2], further high quality randomised controlled trials (RCTs) on common interventions for ASD have been found to be urgently needed.

Music therapy has a long tradition within ASD [9,10], and there are many clinical reports, case studies, and single group studies (e.g. [11-13]; for an overview, see [14]) suggesting that music therapy may enhance skills of social communication such as initiating and responding to communicative acts. In recent years, increased efforts have been made to conduct more rigorous studies in this area. A Cochrane review combining the findings of three small controlled studies of music therapy in children with ASD [7] concluded that this type of intervention may have positive effects on the communicative skills of children with ASD, but also noted limited applicability of the studies' results to clinical practice due to very short duration of treatment conditions and low flexibility in music therapy techniques applied.

Following this review, some RCTs were conducted that strived for improved clinical relevance by applying treatment durations of several months as well as improvisational, flexible, child-centred methods of music therapy provided by trained therapists [15-17].

Improvisational music therapy for children with ASD may generally be described as a child-centred approach making use of the potential for social engagement and expression of emotions occurring through improvisational music making. Instead of practising targeted skills in an abstract manner, improvisational music therapy has been noted for its potential to provide a meaningful framework that, similar to early mother-infant interaction, encompasses relevant features of social communication such as being embedded in a shared history of interaction, having a common focus of attention, turn-taking, and musical and emotional attunement [15-18]. In the first of these newer RCTs on child-centred music therapy methods [15], it was suggested that improvisational

music therapy may facilitate skills fundamental to social interaction in children with autism and proves to be effective in improving lower levels of initiating joint attention and responding to joint attention bids. Despite this trial's significant results, some methodological constraints such as its small sample size ($N = 10$) and large number of outcome measures limited the generalisability of its findings. Recent RCTs with slightly larger sample sizes of $N = 23$ (unpublished report, Thompson, McFerran, and Wigram, 2011) and $N = 24$ [16], respectively, also investigated effects of improvisational, child-centred music therapy approaches on social communication skills of young children with ASD, but were still seriously limited in sample size and test power. A large pragmatic RCT is needed to decide if improvisational music therapy improves core symptoms of ASD in a generalised setting.

Objectives

The objectives of this study are as follows:

- 1.) To determine whether music therapy is superior to standard care in improving social communicative skills in children with ASD as assessed by independent clinicians at the end of the treatment period.
- 2.) To determine whether music therapy is superior to standard care in improving social responsiveness in children with ASD as assessed by parents/guardians at the end of the treatment period.
- 3.) To determine whether the response varies with variation of treatment intensity.
- 4.) To determine how the development of social communicative skills proceeds until follow-up twelve months after the start of treatment.

It is predicted that children's social communicative ability will increase over time, that social communicative skills may be better in music therapy conditions than in the standard care condition, and that more frequent music therapy may intensify the improvement in the skills assessed. Assessing participants' social communicative skills seven months after ending of treatment (12 months after randomisation) will yield important information on whether any effects in the skills investigated will be sustained.

Methods/Design

Participants

The study will include children referred from participating institutions (hospital departments, development centres, parents' support groups) who comply with the following criteria:

Inclusion criteria

(a) *Aged 4;0 to 6;11*: At their respective time of randomisation, the participants' age ranges between 4;0 and 6;11. Given the nature of basic social communication skills that are targeted in this study as occurring early in

development, inclusion of young children is considered necessary; as it will be desirable for children to be able to attend therapy sessions without their parents, the lower age boundary was chosen based on the experience that children will usually be able to attend therapy in a one-to-one setting at that age; a further reason for setting the lower boundary at 4 years is that one of the scales measuring outcome (SRS, see below) is standardised for children from age 4. The upper age boundary was chosen in order to limit the sample to a group sharing similar everyday life conditions in preschool settings and/or around the time of transfer to school.

(b) Diagnosis of autism spectrum disorder: Participants must have a diagnosis of an autism spectrum disorder as assessed by a child psychiatrist or clinical psychologist according to ICD-10 criteria before their respective baseline assessment. Participants' diagnosis of ASD needs to be reconfirmed in the baseline assessment with children fulfilling diagnostic criteria for ASD on the Autism Diagnostic Observation Schedule (ADOS) [19] and on two of three domains of the Autism Diagnostic Interview-Revised (ADI-R) [20].

Exclusion criteria

(a) Serious sensory disorder: Children participating in the study must not be affected by serious sensory disorders such as blindness or deafness as this would alter the aim, course, and implementation of therapy.

(b) Previous experience of music therapy: Children having had music therapy sessions prior to study enrolment will not be included as this would be likely to have a strong influence on the course of therapy.

Non-verbal children as well as children with language skills may be included. Parents/guardians must give informed consent for their children to be involved in the study. Participants must be able to attend up to three weekly music therapy sessions. In cases where transportation to and from locations where the therapy sessions take place might be difficult to provide by parents/guardians, travelling allowances may be made available to avoid bias or drop-out due to any family's financial restrictions.

Baseline assessment

To support the diagnosis of autism, and to establish a baseline of the respective outcome measure, the Autism Diagnostic Observation Schedule (ADOS) [19] will be administered to potential participants. Additionally, the Autism Diagnostic Interview-Revised (ADI-R) [20] will be administered to parents/guardians to acquire data not only on the behaviour displayed during baseline assessment, but also on the history of development of each child, and to avoid loss of specificity [21,22]. The children's level of cognitive ability will be assessed using the Kaufman Assessment Battery for Children (K-ABC)

[23]. In cases where the application of the K-ABC is not possible due to the respective child's limitations in complying with the requirements of the testing situation, children's level of cognitive functioning will be estimated by the assessor to fall into one of three categories (no mental retardation vs. mild mental retardation vs. moderate to profound mental retardation according to ICD-10 criteria) using clinical judgment. To establish the baseline of the secondary outcome measure, parents/guardians will be asked to complete the Social Responsiveness Scale (SRS) [24]. In addition, standard demographic parameters (gender, age, first language, family size, parents' educational background), comorbidities, and information on concomitant treatment will be recorded.

Interventions

Participants will be randomly assigned to one of the following three conditions:

(1) High-intensity music therapy: Improvisational music therapy sessions in an individual setting thrice weekly for five months (i.e., a total of up to 60 sessions, depending on possible omission of single sessions due to sickness or holidays), and three sessions of parent counselling as a "standard care condition" (one session at baseline, one after two months, and a third one after five months).

(2) Low-intensity music therapy: Improvisational music therapy sessions in an individual setting once a week for five months (i.e., a total of up to 20 sessions), and three sessions of parent counselling (at baseline, two months, and five months).

(3) Standard care: Three sessions of parent counselling (at baseline, after two months, and after five months).

Concomitant treatment

Any concomitant treatment or therapeutic interventions that participating children might receive outside the trial will be recorded during assessment sessions before randomisation and after 2, 5, and 12 months, specifying the kind and amount or frequency of intervention.

We consider a treatment duration of five months to be sufficient for detectable developments in children's social communication skills. Some of the earlier RCTs on music therapy in autism [15-17] were able to identify effects with shorter or similar duration; see also a meta-analysis of the dose-effect relationship in music therapy [25]. Additionally, we believe this time frame not to be overly long for being able to sustain parents'/guardians' motivation to participate in the study.

Description of music therapy

The duration of music therapy sessions will be 30 minutes. Therapists conducting the music therapy sessions will be trained music therapists (master's level or

equivalent) with clinical experience of working with children with ASD.

The music therapy approach applied in this study is based on the ideas and principles of improvisational music therapy [26,27], findings from previous music therapy research [13,15-17,28], and developmental psychology [29]. The music played or sung by the therapist is generally attuned to the child's (musical or other) behaviour and expression and includes various improvisational techniques to engage the child and establish contact with the child. To this end, "musical" features of the child's expression (pulse, rhythmic, dynamic or melodic patterns, timbre etc.) may be mirrored, reinforced, or complemented, thus allowing for moments of synchronisation between child and therapist and giving the child's expressions a pragmatic meaning within the context. To allow elicitation of specific social communicative behaviours, the therapist may also gently provoke the child e.g. by violating expectations or jointly developed patterns. While engaging in joint musical activities within a shared history of interaction, the child is offered opportunities to develop and enhance skills such as affect sharing, joint attention, imitation, reciprocity, and turn-taking, all of which are associated with later development in language and social competency [30,31].

Description of parent counselling

Parent counselling sessions will be approximately 60 minutes and will be conducted by a music therapist and/or clinical psychologist experienced in the field of ASD. Counselling sessions will comprise supporting conversations with a focus on current concerns, problems, and difficulties arising from the child's diagnosis, behaviour, and development over time as well as providing information about ASD, child development, and social communication relevant to the families' everyday life situations.

Treatment guide for music therapy and parent counselling

Music therapy and parent counselling sessions will both be provided in accordance with a treatment guide devised for this study in order to specify the treatment procedures and to allow for training of staff and replication of treatment. Within this guide, the setting, general goals, and basic principles of the intervention as well as exemplifications will be outlined. The guidelines are to be administered flexibly according to the requirements of the respective situation and needs of the client or parent within the therapy process or counselling session and can only be applied in combination with and relying on the clinical expertise of the therapist or counsellor.

While the treatment guide will help to ensure the trial's validity and replicability, it is also important to retain flexibility and openness to emerging procedures within music therapy in clinical practice [32]. Keeping enough "space" for flexible adaptation within the

treatment guide according to the child's spontaneous social behaviours will also ensure that the intervention will be shaped in a way that is tailored to the individual strengths and needs of each child, thus addressing the great variability of developmental profiles present in children on the autism spectrum. The treatment guide will be described in a separate paper.

Assessment of treatment fidelity

To determine if the treatment is conducted as intended, fidelity check measures will be applied as follows: after every session, the therapist/counsellor will document significant events, notable child/parent behaviours, and interventions applied. In addition to these self-reports, all therapy and parent counselling sessions will be videotaped to allow for assessment by independent raters [33]. As in a previous RCT in music therapy [34], adherence to the method and competence in its application will also be monitored and sustained through clinical supervision of music therapists/counsellors, utilising the therapists' clinical notes and video-recordings of sessions where necessary.

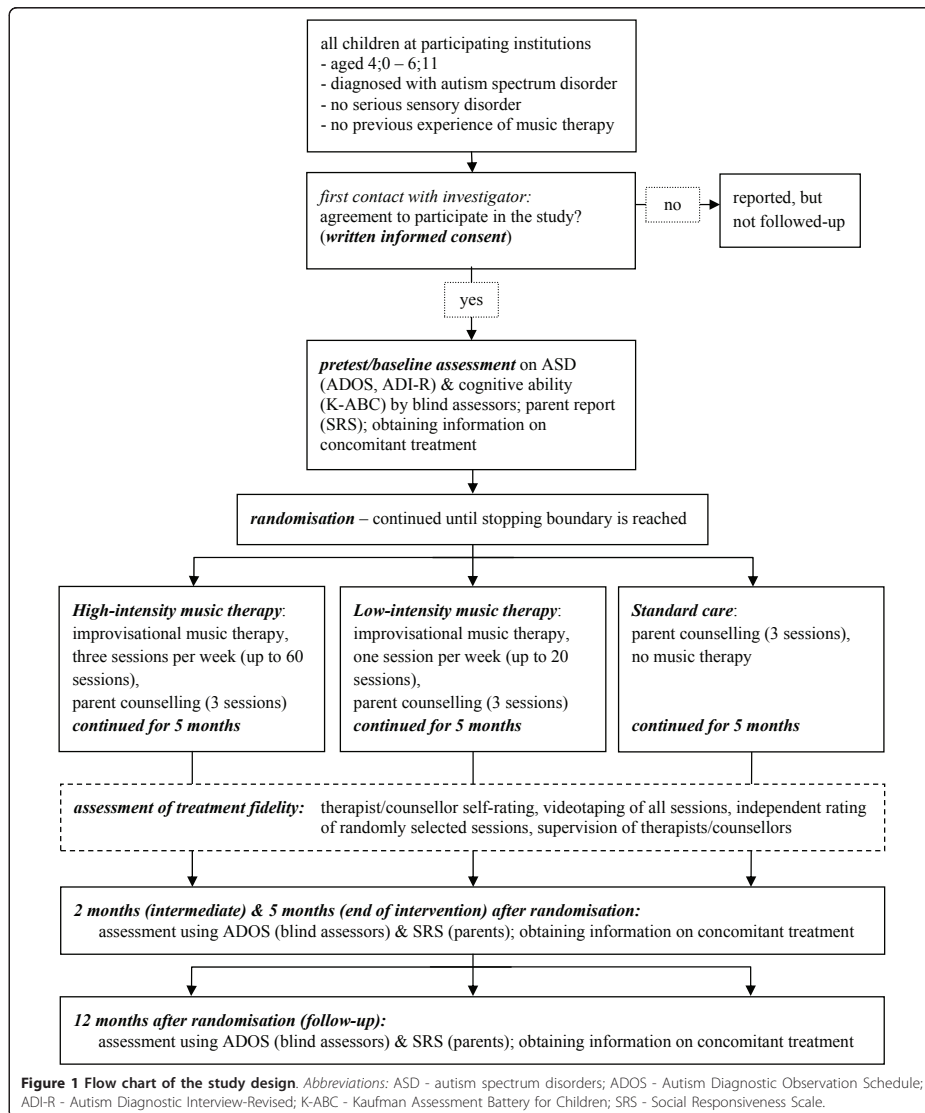
Study design

The study will be a pragmatic international multicentre single-blind (assessor-blinded) randomised controlled trial with three parallel arms. After inclusion in the study and baseline assessment, participants will be assigned to one of the music therapy conditions or the standard care condition on an individual basis according to a computer generated randomisation list. The allocation ratio of intended numbers of participants in the comparison groups will be 1:1:2 so that the number of children receiving music therapy will be similar to the number of participants in the standard care condition. To this end, randomisation will be made in blocks with random sequences of block sizes of 4 or 8 respectively (a separate list for each site) to avoid possible guessing of some allocations. Before random assignment is performed, it has to be confirmed by the investigator recruiting participants that the eligibility criteria have been met and participants are formally enrolled. Once recruitment and data collection at baseline are complete and informed consent to participate in the study by the parents/guardians has been obtained, the respective randomisation code will be revealed to the investigator by an administrative person at the central randomisation office who will have no contact to participants. An overview of the study design is shown in Figure 1.

Power calculation and sample size

Estimate of effect size

A Cochrane review on music therapy for ASD found effect sizes (standardised mean differences) of $d = 0.50$ and 0.36 for gestural and verbal communicative skills,



respectively [7]. However, these figures were derived from small studies with low precision and using unpublished scales [7]. A more precise estimate using the ADOS scale may be derived from the PACT trial [6]

where an effect of $d = 0.24$ was found. That study was more similar in design to the present study but used a different behavioural intervention. In summary, an effect size in the small ($d = 0.20$) to medium ($d = 0.50$) range

may be expected [35], corresponding to a 1 to 2.5 points difference on the ADOS scale that typically has SD = 5 [6]. An effect size in this range would be clinically meaningful as the ADOS scale measures the core symptoms of ASD which are difficult to influence with any treatment.

Parameters for sample size calculation

The two music therapy arms (high- and low-intensity) will be taken together for the primary analysis to answer the question if music therapy in general is superior to standard care. Half of all participants will be assigned to music therapy. In light of the uncertainty around the true effect size and the difficulty of recruiting large samples, a group sequential design (GSD, [36]) will ultimately ensure 80% power (two-sided alpha 0.05) even for a small effect, while avoiding excessively large sample size if there is in fact a medium effect. We used the common Lan-DeMets alpha spending function and a Pocock boundary to make early stopping likely. Calculations and simulations were made for up to four equally spaced looks, using East 5.4 software by Cytel Inc., 2010.

Results

Table 1 shows that if there is a medium effect of music therapy, power at the first interim look (usable N = 235) will be 93%. Power will also be acceptable (76%) if the effect is slightly smaller than medium. If there is only a small effect size, power can still be retained by recruiting more participants. An independent data monitoring committee will perform the interim look. We will aim to randomise N = 300 participants (150 to standard care and 75 to each type of music therapy) to account for possible drop-outs and clustering within sites [37]. However, the actual interim look may be taken at a different sample size, depending on recruitment progress and funding.

Outcomes

The study will use assessments by blinded clinicians as well as reports by parents/guardians. Outcome variables will be assessed at several time points: after the baseline assessment (taking place before each individual's randomisation), the outcome measures will be reapplied after an interval of two months (intermediate), once again after an interval of five months (end of intervention),

and finally at follow-up twelve months after randomisation. Thus, requirements such as close analysis of the mechanism of action (i.e. how long an intervention is required to begin to have an effect) and investigation on maintenance of any observed changes over a longer period of time [2] can be met.

Primary outcome

To allow for potential comparison with studies investigating similar interventions as well as for potential inclusion in later reviews, a validated scale widely used in research and academic practice will be used for assessing social communication skills: The Autism Diagnostic Observation Schedule (ADOS) is a semi-structured, standardised observation instrument designed to assess communication, social interaction, and play or imaginative use of materials using 28 to 31 specific behavioural criteria in one of four modules chosen individually depending on the respective child's expressive language level and chronological age [19]. Inter-rater reliability, test-retest reliability, and internal validity have been demonstrated for the ADOS [19]. The ADOS is viewed especially suitable for this study considering that, although standardised, its assessment is based on play-based interactions between assessor and child, thus similar in its setting to the music therapy situation. This study's primary outcome will be the ADOS social communication algorithm score which has been used as an outcome measure in previous RCTs investigating effects of interventions for autism [6,38,39]. In order to improve sensitivity to change, the scoring procedure will be modified as in an earlier RCT on treatment effects [6], i.e. the module applied to each child will be the same across assessment points (instead of adjusting the module to potentially developed expressive language skills) to avoid discontinuity of scores, and the full range of scores will be retained (instead of recoding 3's to 2's as in the standard diagnostic algorithm) [40].

To avoid bias in observation and assessment, assessors administering the instrument will be blinded to group allocation of the children to be assessed. This will be secured for example by having the assessments take place in another location than music therapy sessions. Success of blinding will be verified by asking assessors

Table 1 Sample size and power under different scenarios

Raw difference on the ADOS scale (SD = 5)	Standardised effect size (Cohen's d)	Power at first interim look ¹	Test power over all 4 interim looks ²
2.5	0.5 (medium effect)	93%	100%
2	0.4	76%	100%
1.5	0.3	47%	99%
1	0.2 (small effect)	20%	80%

Note. Based on 10000 simulations for each scenario. ¹Usable N = 235 (300 randomised). ²Maximum usable N = 939.

whether or not they inadvertently found out about the child's allocation.

Secondary outcomes

In order to supplement the assessment, parents/guardians will be asked to complete the Social Responsiveness Scale (SRS) [24] at baseline, and two, five, and twelve months after randomisation. The 65-item rating scale measures the severity of autism spectrum symptoms occurring in natural social settings, assessing social awareness, social information processing, capacity for reciprocal social communication, social anxiety/avoidance, and autistic preoccupations and traits. Defined as suitable for assessing treatment response [41], these five subscales seem appropriate as secondary outcome measures. The scale features high inter-rater and test-retest reliability as well as internal validity rates and may be completed in 15 to 20 minutes [42-44], thus easily applicable during appointments.

Cost-effectiveness of music therapy will be compared to standard care. Cost will be measured as real resources used in treatment, in terms of personnel hours of work. Effectiveness is measured by ADOS, and cost-effectiveness ratios and incremental cost-effectiveness ratios for the different alternatives can be calculated. Gains for the general health care sector and society will be more long term, and can hardly be included in this project. However, some consideration will be made as to possible effects on school attainment. Costs can be made comparable across countries using purchasing power parity measures.

Statistical analyses

The primary analysis will be undertaken on an intention-to-treat basis, and two-sided tests will be applied at a 5% alpha level. Following assessment of normality, treatment effects will be analysed using a generalized estimating equations (GEE) approach that allows for analysis of longitudinal data while accounting for the correlation among the repeated observations for each subject [45]. GEE analyses will also be used to examine dose-effect relationships and to explore possible confounding effects of site or relevant subgroups such as age or ASD subtype.

Ethical issues

The study protocol was approved by the Faculty of Humanities' Human Research Ethics Board (HREB) at Aalborg University, Denmark. Freely given, written informed consent will be obtained from participant's parents/guardians prior to study enrolment in accordance with regulatory requirements. Random allocation of participants to study groups is considered reasonable as no adverse effects are expected in any of the

conditions. Inconveniences caused by the necessity to attend three weekly sessions of music therapy for the families assigned to this study group are considered tolerable in view of the anticipated benefit for the child receiving therapy.

Discussion

High clinical applicability of this RCT's findings is to be achieved through therapy conditions that are close to clinical practice in terms of broad eligibility criteria (verbal and non-verbal children, all types of ASD), treatment duration (several months), and therapy techniques (improvisational music therapy conducted by experienced therapists in a typical setting).

The study's limitations are also its strengths: The absence of outcomes proximal to music therapy [15,17]; the heterogeneity of standard care as a control condition; and the heterogeneity of the population [46] may be seen as limitations, but are features that will improve feasibility and that are in line with pragmatic trials of effectiveness whose focus is to help users choose between options [47].

Conclusions that will emerge from this study are expected to contribute to the evidence base of treatment options for children with ASD. The results of the trial will provide evidence on the effectiveness of music therapy as a treatment for ASD and will also provide information on the relevance of session frequency for therapy outcome. Furthermore, findings gained through the application of a treatment guide within this study may help to further specify music therapy treatment guidelines for this population and to enrich future training and education of music therapists and other health care professionals working in the field of ASD.

Findings of this study will also be relevant for other fields where music therapy is applied, such as adult mental health [10,25], and for basic research into the musical qualities of early mother-infant communication providing a rationale for music therapy [18,29]. Music therapy in general is an intervention that focuses on developing social and emotional abilities, and ASD is a case in point because impairments in these abilities are central for ASD.

Acknowledgements

This trial is funded by The Research Council of Norway, programmes Clinical Research and Mental Health (Research Council of Norway project number 213982). The development of this study protocol was supported by the Department of Communication and Psychology, Aalborg University, Aalborg, Denmark (MG, UH); the Department of Applied Psychology: Health, Development, Enhancement and Intervention, Faculty of Psychology, University of Vienna, Vienna, Austria (MG); and the Grieg Academy Music Therapy Research Centre, Uni Health, Uni Research, Bergen, Norway (CG). The funding sources had no role in the study design; in the writing of the manuscript; and in the decision to submit the manuscript for publication.

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Authors' contributions

MG and CG conceived the study and developed the study design. MG drafted the manuscript. CG did the power calculation and helped to draft the manuscript. UH contributed to the development of the study design and helped to draft the manuscript. All authors read and approved the final manuscript.

Competing interests

MG, UH, and CG are clinically trained music therapists.

Received: 24 August 2011 Accepted: 5 January 2012
Published: 5 January 2012

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Pre-publication history

The pre-publication history for this paper can be accessed here:
<http://www.biomedcentral.com/1471-2431/12/2/prepub>

doi:10.1186/1471-2431-12-2

Cite this article as: Geretsegger et al: Randomised controlled trial of improvisational music therapy's effectiveness for children with autism spectrum disorders (TIME-A): study protocol. *BMC Pediatrics* 2012 **12**:2.

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III. IMT CONSENSUS MODEL / TREATMENT GUIDE

Manuscript submitted for publication.

Defining improvisational music therapy: Development of a treatment guide for children with autism spectrum disorder

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Funding

This study was funded through a PhD fellowship awarded to MG from Aalborg University, and through The Research Council of Norway (grant no. 213844, The Clinical Research and The Mental Health Programmes).

Acknowledgments

We would like to thank all music therapists who kindly provided their expert feedback in response to our survey. Special thanks go to Gustavo Gattino, Ferdinando Suvini, and Grace Thompson for their help in developing certain aspects of the treatment guide, and to Maj-Britt Posserud and Łucja Bieleninik for valuable comments on the manuscript.

Abstract

Background: Improvisational methods of music therapy have been increasingly applied in the treatment of individuals with autism spectrum disorder (ASD) over the last decades in many countries world-wide.

Objective: This study aimed at developing a treatment guide based on the most important common characteristics of improvisational music therapy (IMT) with children affected by ASD as applied across various countries.

Methods: After initial development of treatment principle items, a survey among music therapy professionals in ten countries and focus group workshops with experienced clinicians in three countries were conducted to evaluate the items and formulate a revised treatment guide. To check usability, a treatment fidelity assessment tool was subsequently used to rate therapy excerpts.

Results: Survey findings and feedback from the focus groups corroborated most of the initial principles for IMT. Unique and essential principles include facilitating musical and emotional attunement, musically scaffolding the flow of interaction, and tapping into the shared musical history of interaction between child and therapist. Raters successfully used the tool to evaluate treatment adherence and competence.

Conclusions: Summarizing an international consensus about core principles of IMT for children with ASD, this treatment guide can be used to assess treatment fidelity, and may be applied to facilitate future research, clinical practice, and training.

Keywords

improvisation; music therapy; treatment guide; autism spectrum disorder

Background

Introduction

Autism spectrum disorder (ASD) is comprised of a group of conditions in which impairments in communication and social interaction are core features of the diagnosis (cf. American Psychiatric Association, 2013; World Health Organization, 1993). Important areas of difficulty within communication and social interaction, and therefore targeted areas of interventions for individuals with ASD, include imitation (e.g., Hobson & Hobson, 2008; Landa, 2007), joint attention (Leekam, López, & Moore, 2000), reciprocity (Landa, 2007), affective sharing (Wetherby et al., 2004), and initiation of interaction (Landa, 2007; Landa, Holman, & Garrett-Mayer, 2007).

Developmental interventions in ASD may be defined as a group of relationship-based approaches that are guided by typical child development and target underlying functions of social-emotional interactions rather than specific behaviors (cf. Casenhiser, Shanker, & Stieben, 2013; Ingersoll, Dvortcsak, Whalen, & Sikora, 2005; Mahoney & Perales, 2003). Also defined as social-pragmatic (Prizant & Wetherby, 1998), these interventions share characteristics such as following the child's lead, encouraging initiations from the child, responding to all types of communicative behavior as if it was purposeful, focusing on emotional expression, and adjusting any language and social input to the child's developmental stage and attentional focus (Ingersoll et al., 2005).

Improvisational music therapy (IMT) is described as a client-centered intervention making use of the potential for social engagement and expression of emotions occurring through improvisational music making (Geretsegger, Holck, & Gold, 2012). In ASD, IMT may be depicted as a child-centered approach where a trained music therapist uses active, spontaneous music making and the relationship that develops through this. The therapist generally follows the child's focus of attention, behaviors, and interests to facilitate growth in the child's social communicative skills and promote development in other areas of need, such as awareness and attention, sense of self, or self-efficacy (Bruscia, 1998; Kim, 2006; Kim, Wigram, & Gold, 2008, 2009; Wigram, 2002). When working with children with ASD, there are specific aspects that need to be addressed in addition to the core areas (i.e., communication and social interaction): Children with ASD often perceive their environment as chaotic and confusing and therefore require routines and predictability of interactions and surroundings (e.g., Schuler, Prizant, & Wetherby, 1997). In balancing between this need and the tendency to "get lost" in repetitive behaviors, improvised music can be made to be very predictable containing repetitions at different levels while at the same time providing "controlled" flexibility in the form of

variations in melody, harmony, rhythm, phrasing, or dynamics (Wigram, 2004; Wigram & Elefant, 2009), as for example through commonly developed “interaction themes” (Holck, 2004a). Involving parents/caregivers in the process can support both children and parents in building interactions with one another, and facilitates generalization of therapy outcomes into the child’s and caregivers’ everyday life (Oldfield, 2006; Warwick, 1995). Some music therapists do this by including family members directly in therapy sessions (Thompson, McFerran, & Gold, 2013), whereas others meet with parents separately.

History

The diagnosis of autism and the music therapy profession emerged during the same time period (Gold, 2011; Reschke-Hernández, 2011). Documentation of music therapy as an applied intervention in autism in early years (mid-1940s to early 1960s) is rare. The earliest reported examples used mostly structured techniques (e.g., vocal or dance exercises and rhythmical and singing activities); more child-centered approaches (e.g., responding musically to the child’s utterances) began to appear in the literature in the late 1960s and 1970s (Reschke-Hernández, 2011). This also implied a turn towards goals at the core of ASD, such as fostering communication and interaction. Some of the earliest formative influences in IMT were introduced by Paul Nordoff and Clive Robbins (1964, 1968), Mary Priestley (1975), Juliette Alvin (1978), and Kenneth Bruscia (1987). Since then, improvisational techniques employed in the assessment and treatment of individuals with ASD have been described by various authors (e.g., Carpenter, 2011; Edgerton, 1994; Holck, 2004a; Kim et al., 2008, 2009; Oldfield, 2006; Schumacher & Calvet-Kruppa, 1999; Wigram & Gold, 2006; Wigram & Elefant, 2009). All of these authors describe processes of musical attunement to the child’s behavior to facilitate interpersonal communication and social interaction. While also contributing to the knowledge about processes and effects of music therapy in general, these authors specifically focused on the relevance and the specific advantages of improvisation for children’s social and communicative skills, as well as on its use in the assessment of these skills.

Evidence of effectiveness

Several systematic reviews and meta-analyses have indicated positive effects of music therapy on areas central to ASD, such as non-verbal and verbal communicative skills, social interaction, and play (Geretsegger, Elefant, Mössler, & Gold, 2014; Rossignol, 2009; Wheeler, Williams, Seida, & Ospina, 2008; Whipple, 2012).

Effects of IMT were investigated systematically for the first time in 1994 when Edgerton presented evidence from a study involving eleven children aged 6 to 9 that suggested IMT’s effectiveness in increasing the communicative behavior of children with ASD. Since then, three randomized controlled trials (RCTs) conducted in various parts of the world (Australia,

Brazil, Korea) have indicated IMT's effectiveness for non-verbal communication skills (Gattino, Riesgo, Longo, Leite, & Faccini, 2011; Kim et al., 2008), joint attention (Kim et al., 2008), affective sharing and initiating behavior (Kim et al., 2009), social interactions (Kim, 2006; Kim et al., 2008), and the parent-child relationship (Thompson et al., 2013).

Need for consensus definition

To develop and apply treatment guidelines that are both scientifically sound and clinically useful not only serves the purpose of ensuring replicability of research studies, but may also help to ensure a method's comprehensibility, transparency, and training (Hillecke & Wilker, 2009). However, trying to standardize and manualize a highly individualized approach like IMT might appear paradoxical at first. One might ask whether it is reasonable and feasible to generalize pathways of intervention in a field with such a diverse clinical presentation and for a method based on emerging interactions as the treatment proceeds. Can the need for standardized guidelines be met without weakening the integrity of the approach? Accordino, Comer and Heller (2007) argued that although IMT is tailored according to patients' responses, it can be replicated across a number of participants, even in a highly individualized way, "without diminishing the individual nature of the therapy" (p. 107). Similarly, Rolvsjord, Gold, and Stige (2005) have suggested that the demands for research rigor and therapeutic flexibility can be reconciled by retaining openness to emerging procedures as an essential part of a therapy manual.

Objectives

This study aimed to (1) identify the common characteristics of IMT, based on targeted areas of development and core guiding principles; (2) if possible, describe an international consensus model in a way that balances sufficient standardization with sufficient flexibility to accommodate individual client needs and varying therapy contexts or settings; and (3) create a treatment guide based on these principles, and evaluate its feasibility as a tool to assess adherence and competence in IMT.

Methods

Identification of relevant items

Based on existing literature on IMT for ASD (Carpente, 2011; Edgerton, 1994; Gattino et al., 2011; Holck, 2004a, 2004b; Kim, 2006; Kim et al., 2008, 2009; Nordoff & Robbins, 1964, 1968; Oldfield, 2001; Schumacher & Calvet-Kruppa, 1999; Stephens, 2008; Thompson et al., 2013; Wigram & Gold, 2006; Wigram & Elefant, 2009), core features, principles, and techniques of improvisational approaches of music therapy were identified, collated, and related to target areas typically addressed in working with children with ASD.

Initial development

In order to facilitate a synoptic view of the approach pivotal characteristics of IMT, as described in various authors' works, were systemized. From the items initially identified, we developed a treatment guide to be followed by trained music therapists building upon research evidence (Gattino et al., 2011; Kim, 2006; Kim et al., 2008, 2009; Thompson et al., 2013; Wigram & Gold, 2006), the authors' clinical experience, as well as other treatment guides developed for previous interventional RCTs for children with ASD (Aldred et al., 2010; Kasari, Freeman, & Paparella, 2006; Kim, 2006). A draft version was formulated by four of the authors (first, second, third, and last author). Subsequent steps included further refinement and developing a consensus version among all authors.

Survey

In order to ensure validity of the treatment guide and compatibility of the proposed model with IMT as practiced internationally, we collected feedback from a larger group of experts and sought to determine if there was a consensus. Music therapy clinicians and researchers from ten different countries (Australia, Brazil, Denmark, Germany, Israel, Italy, Norway, Korea, United Kingdom, and USA) experienced in employing improvisational techniques in the treatment of children with ASD were requested to act as an expert group to validate the treatment guide. In the survey that was conducted via email from May to July 2013, 42 recipients were asked to read the treatment guide draft and to indicate for each proposed principle of IMT whether they understood it (no / somewhat / yes), 2) whether they agreed or disagreed with it, and 3) how important they considered the proposed principle (not important / somewhat important / very important). The principles were categorized into four groups: 1) unique and essential, 2) essential but not unique, 3) compatible, and 4) proscribed (cf. Waltz, Addis, Koerner, & Jacobson, 1993). In addition, respondents were encouraged to propose amendments and to suggest any key components that in their opinion had been missing from the proposed principles.

Focus groups

We conducted focus group workshops in three countries (Austria, Italy, Korea) to further evaluate the treatment guide draft using clinical case material. The focus groups were led by music therapy researchers and consisted of three to four music therapy clinicians experienced in the field of ASD (total $n = 11$). Verbal accounts and video excerpts from clinical practice were set in relation to the treatment guide's principles, and any suggestions for amendments and additional topics were discussed and forwarded to the authors.

Revision of items based on survey and focus group results

The responses and comments gathered from the survey and focus groups were incorporated into the final version of the treatment guide by following three steps: (i) extracting and collating topics raised by respondents (first author); (ii) developing suggestions which topics should be integrated and how (first author); (iii) discussing suggestions and reaching agreement (all co-authors).

Development of a tool to assess treatment fidelity

Finally, we attempted to quantify adherence to the treatment guide and evaluate the feasibility of this newly developed tool (see Table 1). Items derived from the IMT principles were coded on a 6-point scale (cf. Casenhiser et al., 2013): 0 = no evidence of interactions appropriate to IMT; 1 = interactions appropriate to IMT are rarely observed; 2 = interactions appropriate to IMT are sometimes observed; 3 = interactions appropriate to IMT are frequently observed; 4 = full competence: most observed interactions are appropriate to IMT; 5 = mastery: all observed interactions are appropriate to IMT. We prepared sixteen three-minute videotaped sequences from IMT sessions to be rated by first-year music therapy students, nine three-minute sequences to be rated by Master students, and ten three-minute sequences to be rated by experienced music therapists. Raters did not receive any further contextual information (on diagnosis, therapy process, etc.), and every sequence was assessed by two independent raters.

Table 1

Results

Initial version

In an effort to summarize and systematize key characteristics of IMT to be utilized in the clinical practice of treating children with ASD, the initial version of the treatment guide was developed to contain information about the setting, musical media, and general goals of the approach, as well as basic principles representing criteria that need to be present in order to fulfill our definition of IMT for children with ASD. The initial version of the treatment guide comprised of:

- four unique and essential principles: facilitate musical and emotional attunement; scaffold interactions dynamically; tap into shared history of musical interaction; facilitate enjoyment;
- four essential principles: provide a secure environment; build and maintain a positive therapeutic relationship; follow the child's lead; set treatment goals;
- one compatible principle: adjust setting according to families' needs, clinical judgment, and practical possibilities;
- one proscribed principle: adhere to predetermined treatment schedule.

Tabularized descriptions and explanations of basic principles included the purpose/rationale for each principle within IMT for children with ASD, the therapist's attitude related to that principle, categories of activities that may be associated with the respective principle, and some examples/techniques of how each principle may be operationalized within therapy. Overlaps were possible – for example, one activity could be based on more than one principle, or several principles could share the same rationale. Table 2 shows an example of how the basic principles were described in the initial version of the treatment guide – here the first unique and essential principle: facilitate musical and emotional attunement. The full initial version of the treatment guide can be obtained from the first author.

Table 2

Survey results and feedback from focus group workshops

We received feedback from 30 music therapists (response rate 71%) from all ten countries. The expert group consulted in the survey generally understood the items and their descriptions well, agreed with most of them, and considered most of them as “very important” to IMT for children with ASD. All of the thirty respondents confirmed that they understood the items “facilitate enjoyment”, “provide a secure environment”, “build and maintain a positive therapeutic relationship”, and “follow the child’s lead”. Ratings for understanding of the other items ranged from 81 to 96%. Agreement ratings ranged from 85 to 96%, except for the “proscribed” principle, “adhere to predetermined treatment schedule” (59%). Regarding the question of how important respondents found the respective items for the approach, ratings of “very important” ranged from 81 to 100% for all of the “essential” and “essential and unique” principles (100% for “facilitate musical and emotional attunement”). The “compatible” and “proscribed” principles were endorsed as “very important” somewhat less often (by 79% and 74% of the respondents, respectively). Feedback from focus group members was generally supportive of the selection and description of the treatment guide’s principles.

The main points of critique, suggested changes, and suggestions for additional principles by survey respondents and focus group members may be summarized as follows:

Issues that some of the experts felt were missing included a reference to managing challenging/disruptive/destructive/harmful behavior;
 references to the importance of affect regulation, body awareness, and the integration of sensory perceptions by creating connections between different perceptual channels;
 specific references to other emotions apart from enjoyment;
 the importance of finding a balance between “following the child” and “initiating”;

music as a means of self-expression and emotional release; and a reference to different phases of therapy (i.e., beginning of treatment vs. later development).

Five survey respondents suggested that the principle “facilitate enjoyment” be moved from the “unique and essential” to the “essential” category, as it also applies to many other relationship-based approaches. Some respondents found that the “proscribed” principle was too harshly formulated and/or confusing as it was phrased inversely to the other nine principles (i.e., delineating activities, a therapeutic attitude, and purpose that are considered contradictory to IMT). In response to this feedback, we adapted the treatment guide as follows.

Managing challenging/disruptive/destructive/harmful behavior: was incorporated within “facilitate musical and emotional attunement”.

Affect dysregulation, body awareness, integration of sensory perceptions and emotions apart from enjoyment: were incorporated within “facilitate musical and emotional attunement”.

Balance between “child-led” and directing/structuring: was incorporated within “follow the child’s lead”.

Music as a means of self-expression and emotional release: was incorporated within “facilitate musical and emotional attunement”.

Differentiate between beginning of therapy and sessions later on: was incorporated within “provide secure environment” and “set treatment goals” (by adding “and evaluate progress” to the principle’s title).

The item “facilitate enjoyment” was moved from the “unique” to the “essential” category of principles because it is shared by other relationship-based approaches. Since the “proscribed” principle led to more confusion than added clarity, we decided to incorporate the underlying contents of this principle within several other items. Additionally, we rephrased the item “scaffold interactions dynamically” into “scaffold the flow of interaction musically”, in order to clarify the primary mode of interaction. Furthermore, we added using toys or media that are not primarily musical as another example within the “compatible” principle of adjusting the setting (cf. Gold, Wigram, & Voracek, 2007). Finally, we returned to the purely narrative form of principle description (as opposed to the additional, more complex tabularized display used for the survey) in order to facilitate comprehension.

The final treatment guide

Figure 1 provides an overview of the essential, unique, and setting-related (“compatible”) principles, respectively, defining the international consensus model of IMT for children with ASD as described below. It is important to note that the order of the principles is not supposed to indicate a certain hierarchy; all items are considered equally important.

Figure 1

Unique and essential principles within IMT for children with ASD:

- Facilitate musical and emotional attunement

The music played or sung by the therapist is closely attuned to the child's immediate display of (musical or other) behavior, focus of attention, and/or emotional expression. In doing so, the therapist creates moments of musical attunement that may develop into affective and emotional attunement and emotional sharing. This increases opportunities for the child to improve his/her awareness of self, to experience shared attention and social reciprocity, and to engage in communication; it also facilitates the process of relationship building between the child and the therapist, and encourages the child to utilize music as a means of emotional expression and emotional release. In case of high levels of arousal and affective expression including tantrums or disruptive behaviors, musical attunement and subsequent regulation might also serve to promote the child's ability of emotional self-regulation. The therapist is required to choose and adapt the intervention techniques to specifically fit the child's current abilities of social responsiveness. Improvisational techniques may involve imitation, mirroring, variation, elaboration, regulation, support, responding, or contextualization; in musical terms, this may involve matching, sustaining, or complementing "musical" features of the child's behavior (pulse, rhythmic pattern, dynamic or melodic contour, timbre), thus creating an integration of sensory perceptions, and moments of synchronization and "meeting".

- Scaffold the flow of interaction musically

The therapist meets the child's behavior and initiatives as having meaning and as being related to assumed intentions, even if the child's signals may be scarce, weak, or poorly timed. By meeting the child's behavior as communicatively intended, the therapist increases opportunities and uses supportive techniques (e.g., complementing the child's utterances) for the child to comprehend, engage in, and initiate interaction. In order to encourage the child to participate in musical interactions, the therapist uses musical means (e.g., matching volume, timbre, or rhythm; forming the child's expressions into recognizable musical forms, patterns, or motifs), but also verbal, visual, or physical cues, such as anticipatory gestures or facial expressions. These various types of adaptive support lead to expectation on the part of those involved in the interplay, thus acting as a scaffold which supports the musical interaction and enables the child to actively engage in the interaction. If the child displays signs of newly emerging communicative skills, the therapist gently reinforces them and expands on them in a playful and encouraging way; for example, if the child becomes aware of his/her own playing, the therapist may communicate that s/he is also aware of the child's playing by imitating, exaggerating and augmenting the child's musical utterances. The therapist may also model or suggest activities or introduce new musical instruments to the child as necessary to involve the child or keep him/her engaged. Whenever introducing new material, the

therapist follows the child's focus of attention and range of interest and pays special attention to the child's own initiatives and ideas. IMT techniques for musically scaffolding interventions include rhythmic grounding, shaping, extemporizing, or frameworking.

- Tap into the shared history of musical interaction

In order to facilitate both a feeling of safety and predictability and the capacity for flexibility and coping with change, particular consideration is given to specific characteristics of the joint history of musical interaction developing over time between the therapist and the child. Within the shared context, a shared musical repertoire and interaction themes may develop, that is, musical or movement-based forms of interplay that arise from joint improvisation between the play partners. The therapist presents as a playful and reliable interaction partner who forms the child's expressions into recognizable musical forms, patterns, or motifs which can be repeated and varied as needed to foster interaction. Thus, meaningful chains of interaction may emerge that allow for both partners to develop expectancies on musical, action-related, or intersubjective levels. If joint routines of actions have developed, using and elaborating them may lead to opportunities to assess the child's level of participation by making an unexpected musical action in a humorously teasing way (e.g., by unexpected pauses or dynamic variation) which in turn may enable the child to anticipate, actively participate in, or initiate interaction. IMT techniques that tap into the shared history of musical interaction between child and therapist include building up and drawing upon a joint repertoire of interaction themes, variation, and playing with musical expectations.

Essential (but not unique) principles within IMT for children with ASD:

- Build and maintain a positive therapeutic relationship

The therapeutic relationship acts as key component of developmental interventions, including IMT. Purposes of building and maintaining a positive therapeutic relationship are to enable rapport and to help making the child prepared to attend therapy in the first place in order to facilitate positive outcomes of therapy. Within IMT, the therapeutic relationship is the sphere within which musical, emotional, and intersubjective experiences may be shared, developed, and built upon. The general attitude of the therapist is to present with interest, respect, and confidence. S/he creates a supportive atmosphere where the child feels welcome and valuable. S/he reflects upon and tries to understand the meaning(s) of the child's and his/her own behavior and the relationship that develops between the child and him/herself.

- Provide a secure environment

As with any other intervention offered to children with ASD, it is important to conduct IMT within a safe environment that keeps the child's anxiety low

and helps the child to experience a feeling of security. Strategies to convey reliability and predictability are, for instance, providing for consistency in therapy settings (e.g., maintaining the same therapy room and equipment), responding to the child's behavior in consistent ways, using the structure of music to convey safeness, explaining purpose and scheduling of therapy sessions, commenting on interruptions, explaining unexpected events, and preparing the child for endings or any breaks within the therapy process, for instance by using goodbye songs or musical rituals to help the child in managing transitions. Some of these strategies may be more needed at the beginning of therapy than in later stages when a feeling of security and trust has been established.

- Follow the child's lead

The general approach is to follow the child's focus of attention, behaviors, and interests, and to incorporate his/her interests and motivations into meaningful sequences of interaction. In IMT, this is done by meeting the child where s/he is, especially with regard to his/her musical and emotional expression. This facilitates the child's intrinsic motivation to engage in social exchange and also keeps any anxiety on the part of the child on a low level. To that effect, the therapist balances the type of therapeutic techniques so that the child feels safe and reassured, and has ample opportunities to engage in, respond to, and initiate social interaction and communication. Furthermore, the therapist structures the session according to his/her own clinical judgment and the child's needs. Sometimes, some structure might be deemed necessary for preventing the child to feel insecure or lost in aimlessness, while in other situations, presenting the child with too many structured activities might restrain their own initiatives. At the same time, it is of key importance that the therapist pays close attention to adapting his/her communicative actions to the child's current level of interactional competence. *Examples:* Relating to a child's preference for numbers in making up a "number song"; allowing the child to control certain aspects of the interaction; offering various types of choices.

- Set treatment goals and evaluate progress

It is important to assess specific competences and needs of each child initially and throughout the course of the therapy in order to meet their individual needs. By choosing individualized developmental goals for each phase of the intervention, the therapist guides the therapy process, enables the child to gradually expand his/her abilities in targeted areas of development, and is also able to evaluate progress and outcomes of therapy.

By assessing the child's competences, emerging abilities, and needs, individual goals can be derived and related intervention strategies and techniques can be tailored to the need assessed in a specific area. These goals are set with the child's caregivers/family in mind and discussed when appropriate. *Example:* The child is aware of his/her own and the therapist's

(musical) actions; therefore, the ability to participate in reciprocal interaction is defined as one of the individual treatment goals for that child.

- **Facilitate enjoyment**

Incorporating the child's interests and meeting his/her preferences and initiatives with an attitude of positive affect, acceptance, and affection facilitates opportunities for mutual joy; this in turn enables the child to experience affect sharing as well as to experience interactions as pleasurable, rewarding, and intrinsically motivating. Strategies useful in facilitating enjoyment include incorporating the child's interests and creating a pleasant and playful atmosphere within therapy sessions that allows for shared positive affect in musical interaction. *Example:* Developing a playful musical game involving hands and feet based on a child's sensory interests.

Compatible principle within IMT for children with ASD:

- **Adjust the setting according to children's or families' needs, clinical judgment, and practical possibilities**

In order to facilitate generalization of skills to everyday settings, and to support families in building and maintaining safe relationships and reciprocal interaction between the child receiving IMT, family members, and/or caregivers, it is a useful strategy to adjust the therapy setting according to children's and families' needs, clinical judgment, and practical possibilities. This may include the implementation of caregiver-/parent- or family member-mediated intervention strategies (e.g., how to employ musical experiences in everyday interactions with the child), or the participation of parents or other family members in IMT sessions in the therapy room or at the family's home. Another example of adjusting the setting according to clinical judgment is using toys or media that are not primarily musical (e.g., role play, puppet play, movement, ball games, dancing, free play, games, and other creative media).

Usability of the treatment guide and the tool to assess treatment fidelity

First-year students, Master students, and qualified music therapists experienced in ASD were able to use the tool for rating video sequences of IMT. All response categories (i.e., codings from 0 to 5) were used, with mean ratings of items ranging between 3 and 4 (indicating the therapist's sufficient adherence to IMT). Items 3 and 7 ("tap into shared musical history" and "set treatment goals") were more difficult to assess because they might require knowledge of contextual events outside the observed sequence. This resulted in some missing data for these items (11% and 19%, respectively). The tool's internal consistency, measured by Cronbach's alpha for each of two raters, was at 0.95 and 0.96, respectively. Overall, these results supported the feasibility of the tool.

Discussion

Findings

Our study indicates that there is an international consensus on pivotal characteristics of IMT for children with ASD. It also shows that these can be operationalized in the form of a treatment guide that reflects the clinical practice of trained music therapists. Pilot data on its usability for assessing treatment fidelity indicate that the developed tool is feasible to use within research, clinical practice, and training. It is important to note that what is being assessed through this tool is adherence to IMT as described in this treatment guide (including competence in IMT in case of '4' or '5' codings), and not the competence as a (music) therapist in general.

Limitations

As we were only able to include a limited number of survey addressees from a certain selection of countries within our study, its findings are inevitably limited to the practices represented by those; other practices of IMT as well as new emerging trends that are not yet covered within the treatment guide will possibly necessitate some adaptation and/or refinement of some aspects.

Implications for practice

The delineation of the basic principles' purposes, rationales, therapeutic attitudes, and activities show that IMT does not use specific techniques solely aiming at circumscribed areas, but may be seen as a comprehensive and complex approach addressing various dimensions of the core characteristics of ASD simultaneously. The treatment guide supplies the field with guidelines for this intervention approach for children with ASD, enabling therapists to develop and reflect upon their clinical practice, and music therapy educators and clinical supervisors to substantiate their teaching. By using the tool to assess treatment fidelity, it is also possible for therapists to rate sessions conducted by themselves; in that case, the items "tap into shared musical history" and "set treatment goals" might be easier to assess, with the disadvantage of the ratings possibly being more prone to bias. For other areas of (music therapy) intervention, the treatment guide might serve as a model to develop similar therapy guidelines and/or categories of basic principles as well as treatment fidelity measures.

Implications for research

Treatment guidelines and fidelity measures are not often used within music therapy research as yet. The work presented in this article may therefore be considered as the first step in introducing more standardization into a complex intervention approach for children with ASD in which flexibility and child-oriented implementation are of paramount importance. The consensus model presented here and its operationalization in the form of a treatment guide may be useful for future research projects involving

multi-national collaborations. Currently, the feasibility of the treatment guide is being further evaluated within a multi-site RCT investigating the effectiveness of IMT for children with ASD aged 4 to 7 (Geretsegger et al., 2012). The consensus model might also be valuable for future directions in research including the challenge of explaining mechanisms of change through IMT more precisely, and connecting different areas of research within the field of ASD.

Conclusions

The treatment guide presented in this article contributes to developing better care for children with ASD by providing guidelines to be applied flexibly by trained music therapists according to the particular requirements and needs of the respective client. The outlined international consensus model also facilitates interdisciplinary and cross-disciplinary communication and collaboration by exemplifying how IMT works to improve communication and social interaction abilities of children with ASD.

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Table 1. Tool to assess treatment fidelity in IMT for children with ASD.

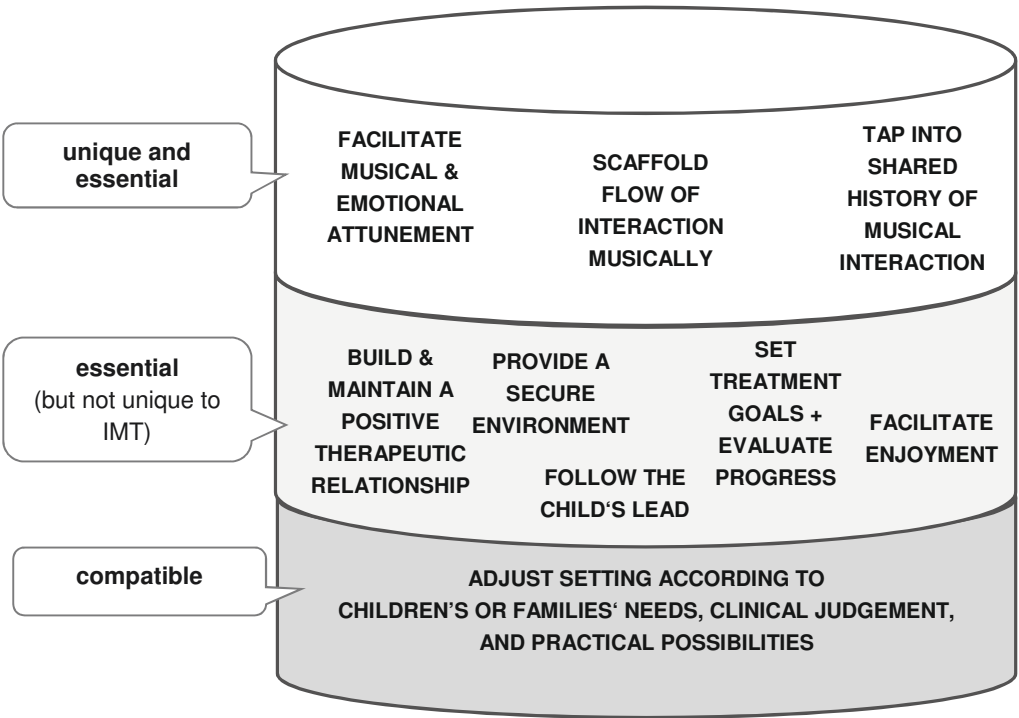
UNIQUE AND ESSENTIAL PRINCIPLES:	
	Rating (0-5):
1. <i>Musical and emotional attunement:</i> How well does the therapist use his/her behavior and expression (e.g., through music, voice, arousal level, movement, facial expression) to allow for moments of synchronization and attunement?	
2. <i>Scaffolding interaction musically:</i> How well does the therapist support the flow of interaction by using musical means and verbal, visual, or physical cues?	
3. <i>Tapping into shared musical history:</i> How well does the therapist use jointly developed forms of musical interaction to foster social communication and encourage initiations from the child?	
ESSENTIAL PRINCIPLES:	
	Rating (0-5):
4. <i>Positive therapeutic relationship:</i> How well is the therapist able to provide a supportive atmosphere for the development of a positive therapeutic relationship?	
5. <i>Secure environment:</i> Does the therapist exert strategies to convey security, reliability, and predictability?	
6. <i>Following the child's lead:</i> How well does the therapist join the child's focus of attention and interests rather than directing the child to the adult's focus of attention?	
7. <i>Treatment goals:</i> Does the therapist tailor his/her interventions to the child's developmental stages?	
8. <i>Enjoyment of interaction:</i> How well does the therapist support the child in experiencing enjoyment within the interaction (e.g., using affect in tone of voice, facial expressions, musical actions, gestures)?	
COMPATIBLE PRINCIPLE:	
The "compatible" principle of <i>setting adjustments</i> is not included in the fidelity assessment tool as it is not considered as essential to the improvisational music therapy approach by definition.	
Please describe how the setting was adjusted:	

Note. Ratings represent a combination of adherence (0-3) and competence (4-5). Response categories are: 0 = none; 1 = rarely; 2 = sometimes; 3 = frequently; 4 = full competence; 5 = mastery. See the main text for full descriptions and examples of each principle.

Table 2. Example of delineation of basic IMT principles from initial version of the treatment guide for children with ASD

<i>principle</i>	FACILITATE MUSICAL & EMOTIONAL ATTUNEMENT
<i>purpose / rationale</i>	increase opportunities for awareness of self, shared attention, social reciprocity, and relationship building
<i>attitude</i>	follow the child's focus of attention, behaviors, and interests; meet the child where s/he is musically and/or emotionally
<i>category of activities</i>	create moments of musical attunement / synchronicity that may develop into emotional attunement / emotional sharing; incorporate the child's interests and skills
<i>example / technique</i>	respond to the child's utterances and behavior using improvised music (e.g., by holding, mirroring, matching techniques)

Figure 1. Overview of principles in improvisational music therapy for children with ASD.



IV. FEASIBILITY STUDY / PILOT COHORT

Manuscript submitted for publication.

Feasibility of a trial on improvisational music therapy for children with autism spectrum disorder: An internal pilot cohort

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Funding

This study was funded through a PhD fellowship awarded to MG from Aalborg University, and through the Research Council of Norway (grant no. 213844, The Clinical Research and The Mental Health Programmes).

Acknowledgments

The authors would like to thank the families who participated in this study, and clinical psychologists Carolin Steidl and Sonja Metzler who were responsible for assessments.

Abstract

Background: Previous research suggests positive effects of music therapy for children with autism spectrum disorder (ASD), but studies were limited in either methodological accuracy or clinical relevance of their approach. To conduct more generalizable, rigorously designed, adequately powered trials investigating music therapy in ASD, it has to be ensured that study procedures are feasible and acceptable for study participants.

Objective: Addressing the scarcity of feasibility studies on trials examining complex interventions, this paper reports feasibility and acceptability data from the pilot cohort of a multi-center RCT on improvisational music therapy (IMT) for ASD.

Methods: Children with ASD aged between 4;0 and 6;11 years were randomly assigned to one of three conditions: one (low-intensity) vs. three IMT sessions per week (high-intensity) for five months vs. standard care. Generalized effects were measured using standardized scales completed by blinded assessors (Autism Diagnostic Observation Schedule, ADOS) and parents (Social Responsiveness Scale, SRS) before and 2, 5, and 12 months after randomization. Feasibility and acceptability were evaluated by examining recruitment, implementation of intervention and control conditions, assessment procedures, safety, and retention.

Results: Within this pilot cohort ($n = 15$), treatment fidelity, blinded assessment, and safety turned out as expected. Retention was 100%. Feasibility was limited regarding recruitment. Acceptability was limited related to the high-intensity condition. ADOS and SRS scores showed changes across time, demonstrating the tools' sensitivity to change.

Conclusions: Overall, the study was designed appropriately regarding the feasibility of study components. Reports on feasibility of study procedures can promote future research on complex interventions.

Keywords

feasibility, acceptability, retention, internal pilot, complex intervention

Background

Music therapy has been applied to improve difficulties of individuals with autism spectrum disorder (ASD) for many decades (M. Geretsegger, U. Holck, J. Carpentre, C. Elefant, J. Kim, & C. Gold, Unpublished Manuscript; Reschke-Hernández, 2011). Studies investigating effects of music therapy have suggested positive effects on areas at the core of the condition including social interaction, verbal communication, initiating behavior, and social-emotional reciprocity, but also suffered from methodological limitations such as small sample sizes, and experimental conditions employing interventions not normally used in clinical practice (Geretsegger, Elefant, Mössler, & Gold, 2014). When examining a complex intervention like music therapy through a rigorous and pragmatic trial, study design and implementation procedures need to be carefully chosen to ensure both scientific accuracy and clinical relevance of findings to be generalized (Thorpe et al., 2009). Pilot studies can be performed to assess the feasibility of various aspects of a trial design (Leon, Davis, & Kraemer, 2011). They can be conducted as external pilots, where pilot data are used to inform necessary changes in the main study, or as internal pilot studies (i.e., the first phase of a trial the data of which contribute to the final analysis; Arain, Campbell, Cooper, & Lancaster, 2010).

However, pilot studies providing knowledge on and specific information about the feasibility of trial procedures receive little attention in publishing (Arain et al., 2010) and scientific research training (Thabane et al., 2010), and are still rare within the music therapy literature (La Gasse, 2013; Robb, 2013). This paper's aim is to examine the feasibility and acceptability of an RCT on improvisational music therapy (IMT) for children with ASD, and to report outcomes and clinical findings from the internal pilot cohort of an ongoing randomized controlled trial called "TIME-A" (Randomised controlled Trial of Improvisational Music therapy's Effectiveness for children with Autism spectrum disorders; Geretsegger, Holck, & Gold, 2012). The full trial aims at examining whether music therapy improves social communicative skills in children with ASD, and whether a higher intensity of therapy has an impact on any changes observed. In this paper, we will focus on assessing feasibility concerning recruitment, implementation of intervention and control conditions, blinded assessment procedures, safety, and retention, and report outcomes for individual participants. It should be noted that such an internal pilot study is different from an interim analysis, where effects are analysed and special statistical methods are used to avoid alpha error inflation. The first interim analysis for the present study is planned at around 300 participants (Geretsegger et al., 2012). In contrast, the present paper does not look at effects, but at processes and other results. Our purpose is to provide investigators with useful information for designing trials on complex interventions such as music therapy, and to contribute to the knowledge on implementing studies using rigorous research methodology within clinical settings.

Methods

Participants

Study procedures used in the larger RCT are described in detail in the TIME-A study protocol (Geretsegger, Holck, & Gold, 2012). Inclusion criteria for participating in the study were ages between 4;0 and 6;11 at the time of randomization, and a diagnosis of ASD according to ICD-10 criteria as assessed by a child psychiatrist or clinical psychologist. The diagnosis of ASD needed to be reconfirmed in the baseline assessment with children fulfilling diagnostic criteria for ASD on both the Autism Diagnostic Observation Schedule (ADOS) (Lord, Rutter, DiLavore, & Risi, 2001; German version by Rühl, Bölte, Feineis-Matthews, & Poustka, 2005) and on two of three domains (A, B, C) of the Autism Diagnostic Interview-Revised (ADI-R) (Lord, Rutter, & LeCouteur, 1994; German version by Bölte, Rühl, Schmötzer, & Poustka, 2006). Participants were excluded when they were affected by any serious sensory disorders such as blindness or deafness, and when they had had music therapy sessions less than twelve months prior to study enrolment.

In this internal pilot cohort, participants were recruited in Vienna from several institutions (a major national autism help organization, children's development centers, and hospital departments). Parents in the greater area of Vienna with a child who is supposed to have some kind of developmental disorder are usually referred to one of these institutions, for example by their general practitioner or a (kindergarten) teacher, or turn to one of these institutions themselves to seek advice, counseling and/or diagnostics. The local researcher (first author) contacted these institutions individually, presenting and explaining the aims, design, and relevant procedures of the study to the respective heads and their team members. She also provided a leaflet containing introductory information about the study and the researcher's contact details that could be handed out to families potentially interested in participation. Children referred from these institutions were candidates for inclusion in the study if the eligibility criteria as defined in the study protocol were confirmed by the researcher.

Measures

Before randomization, participants were assessed using the ADOS to support the ASD diagnosis, and to establish a baseline of the respective outcome measure. The ADI-R and the Social Responsiveness Scale (SRS) (Constantino & Gruber, 2005; German version by Bölte & Poustka, 2007) were administered to parents. The Kaufman Assessment Battery for Children (K-ABC) (Kaufman & Kaufman, 1983; German version by Melchers & Preuss, 1994) was used to assess children's level of cognitive ability; in some cases where the application of the K-ABC was not feasible, a non-verbal standardized intelligence test was used if appropriate, or in exceptional cases, an estimate based on the assessor's clinical judgment.

Additionally, a simple questionnaire was given to parents asking them to assess their child's and their family's current quality of life on a scale from 0 (worst imaginable) to 100 (best imaginable). Data on amount, type, and costs of any concomitant treatment, medication, and caregiver investment within the last two months were also collected. Follow-up assessments were conducted at 2 (within-treatment) and 5 months (end of treatment in the music therapy conditions) after randomization, and also at 12 months after randomization in order to examine whether any changes are sustained after the end of therapy. The primary outcome was the ADOS Social Affect algorithm score with a modified scoring procedure ("ADOS-SA") to improve sensitivity to change, i.e. the module applied to each child was the same across assessment points (instead of adjusting the module to potentially developed expressive language skills), and the full range of scores was retained (instead of recoding 3's to 2's as in the standard diagnostic algorithm). In order to use all available information instead of just items selected for the algorithm, the total score of all items from domains A (Language and Communication) and B (Reciprocal Social Interaction), "ADOS-AB", was also used as a supplementary measure from the second year of the study period on. Secondary outcomes included the ADOS at 2 and 12 months, the SRS at 2, 5, and 12 months, and the quality of life and concomitant treatment measures. Baseline ADOS, ADI-R, SRS, and cognitive assessments as well as ADOS follow-up assessments were conducted by clinical psychologists who were blind to experimental conditions. Follow-up data from the SRS and on concomitant treatment and quality of life were collected by the first author who also acted as music therapist and parent counselor (see below).

Procedure

Following caregivers' informed consent and baseline assessments, study participants were randomly assigned to one of three conditions: 1) five months of high-intensity music therapy (three sessions of 30 minutes per week) plus three sessions of parent counseling (one session of 60 minutes immediately following randomization, and one after two and five months each); 2) five months of low-intensity music therapy (one session of 30 minutes per week) plus three sessions of parent counseling, or 3) standard care (three sessions of parent counseling, but no music therapy). Randomization was performed on an individual basis according to a computer-generated list using a ratio of 1:1:2 in blocks of 4 and 8, so that the number of children receiving music therapy was similar to the number of participants in the standard care condition. The random allocation sequence was entered into an electronic database (OpenClinica software for clinical research, version 3.3) by an independent researcher (third author). Randomisation results were only visible for the person responsible for data entering (first author). ADOS assessors were blinded to the allocation. Music therapy was conducted by a certified music therapist with several years' experience in ASD following a treatment guide for improvisational

music therapy for children with ASD that is described elsewhere (M. Geretsegger et al., Unpublished Manuscript). In this pilot cohort, parent counseling sessions were conducted by the child's music therapist and comprised supporting conversations with a focus on current concerns and challenges arising from the child's diagnosis, behavior and development; additionally, information about ASD, child development, and social communication was provided where appropriate. After the 12-month assessment, success of blinding was examined using a simple questionnaire administered to the respective assessor. Study data collected from parents, assessors, music therapist and parent counselor were stored in the OpenClinica database. To ensure data quality, all main data had to be entered twice. The study period for this internal pilot cohort was December 2011 to September 2014.

Data analysis

Descriptive data on recruitment, implementation, blinding, safety, and retention were related to additional information gained through conversations with referrers, parents, and assessors to facilitate interpretation and possible explanations. In order to evaluate whether sessions were conducted in line with the treatment guide's principles, a sample of sixteen randomly selected three-minute sequences from session video recordings were rated by two independent raters each using a newly developed tool to assess treatment fidelity (M. Geretsegger et al., Unpublished Manuscript). Due to the small sample size, no methods of inferential statistics were used for data from outcome measures. However, quantitative data from baseline and follow-up assessments were inspected on an individual basis and related to clinical observations within music therapy and parent counseling; this served to illustrate developmental trajectories and to detect potential similarities or inconsistencies between observed behavior within and outside of the treatment context. Three cases were selected purposively to reflect the variation seen in the sample.

Ethical issues

The protocol for this trial was approved by the Faculty of Humanities' Human Research Ethics Board (HREB) at Aalborg University, Denmark, "to project a low-risk research project with adequate ethical considerations taken into account" (HREB #201107, date of approval: August 8, 2011). For participant recruitment at two collaborating institutions, an additional approval of the local ethics committee was necessary; the Medical University of Vienna's ethics commission approved the study on January 12, 2012 (EK number 238/2011). Freely given, written informed consent by at least one parent/caregiver was obtained prior to any participant's enrolment in the study. Parents/caregivers gave their consent by signing an Information and Consent Form following an introductory discussion with the researcher informing them about all aspects of their and their child's participation in the study. Families were free to withdraw their consent to

participate and drop out of the study at any time, and without giving reasons.

Results

Recruitment

Twenty-five children were informally assessed for inclusion within the study period of this pilot cohort (see Figure 1). Ten children were excluded prior to baseline assessments, and therefore not enrolled, for the following reasons: six of them did not meet inclusion criteria (i.e., too young in two cases or too old in one; not fulfilling diagnostic criteria for ASD in two cases; having had music therapy less than 12 months prior to enrolment for one child), three families declined to participate after an introductory discussion, and one family was not enrolled because of other reasons (i.e., the single mother's command of German and English was not sufficient enough for her to be able to participate in parent counseling sessions and to fill in questionnaires at baseline and follow-up assessments). Other "informal" exclusion criteria that kept families from consenting to participate were complex family situations (where referring institutions found families unable to comply with study requirements in the first place), or a home address too far (e.g., more than 80 kilometers) from the locations where assessments and therapy took place; also, the requirement to attend therapy three times a week if assigned to the high-intensity condition can be considered a potential reason for the number of recruited families being lower than expected within the study period. Fifteen children were enrolled and randomized during the 22-month phase of recruitment, six of them during the first eight months and nine during the last six months.

Figure 1

The mean age at baseline was 61 months (SD = 8.1; range: 51-71) for the two music therapy conditions (n=7), and 58 months (SD = 6.1; range: 50-68) for the standard care condition (n=8). Additional participant characteristics are displayed in Table 1. Participants in the music therapy and standard care conditions did not significantly differ on any demographic factor except for one, 'first language other than German', which appeared more often in the music therapy conditions.

Table 1

Implementation of intervention and control conditions

The mean number of sessions that the four participants in the high-intensity music therapy condition (e.g., up to 60 sessions over a period of 5 months) completed was 30.8, corresponding to a percentage of 51% (individual total numbers of sessions: 33, 36, 28, and 26, see Figure 2). Reasons that

contributed to reducing the total number of sessions attended were holidays (including periods like Christmas and Easter, but also journeys abroad on the part of the families or the therapist), illness (of the child or the parent responsible for escorting the child to therapy), or general difficulty in attending therapy three times a week. This is considered not to be a financial issue, as none of the families applied for travel allowances that would have been provided in case of financial restrictions; rather, it was time or logistical restrictions (working full time, issues regarding transportation between workplace and/or kindergarten and therapy location, being a single parent, issues of care for siblings of child with ASD while the parent escorts them to therapy, etc.) that made it unfeasible for families to attend therapy three times a week. The mean number of sessions that the three participants in the low-intensity music therapy condition (e.g., up to 20 sessions) completed was 18.6 which corresponds to a percentage of 93% (individual numbers of sessions: 19, 20, and 17).

Figure 2

All three sessions of parent counseling were attended by all families (100%), although the aimed-at appointment at exactly 2 or 5 months after randomization had to be postponed in some cases due to scheduling problems or illness (or, for example, due to a participant's mother giving birth to the third child of the family at the time of the 2-month appointment). In order to address the question whether IMT was delivered as intended, treatment fidelity was assessed for a random sample of therapy excerpts using a newly developed tool as described elsewhere (M. Geretsegger et al., Unpublished Manuscript). Mean ratings on all of the tool's eight items were between 3 ("interactions appropriate to IMT are frequently observed") and 4 ("full competence: most observed interactions are appropriate to IMT"), indicating the therapist's sufficient adherence to IMT. Clinical notes from parent counseling sessions and parents' comments before/after MT sessions show that parents were supportive of their child receiving IMT; for instance, parents commented on how happily children were coming to sessions, how some of the children started to engage in singing and playing musical instruments at home, or how they seemed to interact and play more with their siblings. One single mother who struggled with logistics and child care issues to comply with the high-intensity treatment condition as best as she could showed how much she appreciated that her son received music therapy when she could hardly forgive herself an incident where she mistakenly missed an appointment. Parent counseling sessions were rather factual and simply well accepted as part of study procedures in some cases, while in others, parents commented on how meaningful it was for them to receive basic information on common difficulties related to ASD, advice on specific parenting issues, and general understanding for their concerns as parents of a child diagnosed with ASD. Several parents showed specific

interest in the research project by requesting to receive information about results and publications once the project will be finished.

Assessment procedures

For ten out of 15 children, it was not possible to apply the K-ABC due to the children's limitations in complying with the requirements of the testing situation and/or language. In five children, another standardized tool (Snijders-Oomen Nonverbal Intelligence Test, SON-R 2½-7; German version by Tellegen, Winkel, Wijnberg-Williams, & Laros, 1998) could be used, while in the remaining five children, the assessor's estimation of the child's cognitive ability based on clinical judgment served as a surrogate measure. In all 15 cases, assessors confirmed that they did not become aware of the participant's allocation until after the 12-months assessments, that is they stayed blinded in 100% of the cases. This was helped by the fact that the ADOS assessments were conducted at a different location than therapy and parent counseling sessions, thus eliminating the chance of children and parents allocated to the MT conditions showing revealing signs of familiarity with the location.

Safety

None of the participating families reported any adverse events, undesired effects, or injuries during the course of the study. Furthermore, no institutional stays related to the condition of participating children were recorded during the study period.

Retention

None of the participants dropped out during the course of the study, yielding an attrition rate of 0%. The percentage of planned measures that participants completed was 100% for the ADOS, concomitant treatment, and quality of life at all time points, and for the SRS at 0 and 12 months. Missing data for a whole measurement tool only occurred for one child at the 2- and 5-months follow-up where parents failed to return the SRS despite repeated reminders (percentage of SRS questionnaires completed at 2 and 5 months: 93%).

Concomitant treatment

At five months, nine of the fifteen participants had received additional therapy in the previous two months (five children in SC and four in the music therapy conditions). The mean amount of sessions within those two months was 12.4 (SD = 6.5) in SC and 9.5 (SD = 5.0) for children receiving music therapy. Types of concomitant treatment included occupational therapy, speech and language therapy, play therapy, behavioral interventions, social skills training, specialist services, neurofeedback, and Tomatis sound therapy. Two children were receiving nutritional supplements (zinc and various vitamins), and were following a diet (gluten-free, no carbohydrates, no milk). None of the participants was on medication.

Changes across time

The primary outcome ADOS-SA five months after randomization, coded by blinded assessors, remained the same for one child (low-intensity music therapy condition, LO); in five children (two in the high-intensity condition, HI; three in the standard care condition, SC), ADOS-SA increased from baseline to follow-up at five months; nine children (two HI, two LO, five SC) showed a decrease of ADOS-SA across this period, indicating improvement of communication and social interaction skills. Figure 3 gives a graphical overview of these results and also presents ADOS-SA outcomes for the 2- and 12-month follow-up assessments. Results pooled within SC and music therapy conditions yield a decrease of ADOS-SA from 16.5 (SD = 6.2) to 14.9 (SD = 5.2) in SC, and from 17.4 (SD = 2.6) to 16.7 (SD = 4.3) in the music therapy conditions.

Figure 3

When looking at ADOS-AB which uses all available information from ADOS domains “Language and Communication” and “Reciprocal Social Interaction”, different developmental pathways appear (see Figure 4); however, since the full range of items was not regularly scored at the beginning of the study period, data are missing for several participants, thus hindering overall comparisons.

Figure 4

Parents’ perceptions of their children’s social responsiveness also showed changes across the 5-month period of intervention (see Figure 4): for two children in the HI condition and one child in SC, the SRS total score went down, indicating that parents found their children to be more socially responsive. For one child, data at five months after randomization were not available. For the other eleven children (2 in HI, 3 in LO, 6 in SC), SRS scores increased from baseline to 5-months follow-up. When pooling results, the mean SRS score in SC decreased from 143 (SD = 32) to 135 (SD = 57), while in the music therapy conditions, it increased from 133 (SD = 29) to 142 (SD = 35) at 5-month follow-up.

Figure 5

Parents’ assessments of their child’s and their family’s quality of life improved in the majority of cases from baseline to 5-month follow-up: The participant’s quality of life increased for four children in the music therapy conditions and five children in the SC condition; for two children each in the music therapy and SC conditions, parents rated the quality of life lower at 5-month follow-up, and for one child each, the score stayed the same. Changes in family’s quality of life were similar: increase in five cases in

music therapy and four cases in SC, decrease in two cases each, and same score for two families in the SC condition. Overall means at baseline were ratings of 72.4 (SD = 16.6, range: 40-90) at baseline and 77.8 (SD = 15.7, range: 30-92) at five months for participants' quality of life, and for families' quality of life 77.9 (SD = 11.5, range: 50-90) at baseline and 81.1 (SD = 16.2, range: 30-95) at 5-month follow-up.

In two children of the music therapy conditions (1 HI, 1 LO) and 4 children of the SC condition, the direction of change was the same for ADOS and SRS scores. In the other nine children, either parents reported deterioration in social responsiveness while assessors observed increases of social communication abilities, or vice versa. These divergences might be the result of the different settings of observation (one assessment of roughly one hour vs. continuous experience in daily life; reports by blinded experts vs. by people living with the child and familiar to them, etc.) and merit detailed exploration that is beyond the scope of this article. However, in order to exemplify developmental trajectories of study participants, we want to briefly present changes over time for three individual children by linking changes in outcome measures to clinical observations from music therapy and parent counseling.

For participant #2, a girl aged 4 who had not developed verbal language yet and who was allocated to the HI condition, receiving a total of 36 music therapy sessions, both ADOS-SA and SRS scores decreased from baseline to 5-months follow-up (ADOS-SA from 17 to 14; SRS total score from 148 to 127). The girl also received one session of "Frühförderung" per week (individualized early intervention at the family's home), and started having occupational therapy once a week during the treatment period (8 sessions in total). Changes within music therapy as documented by the therapist included improved eye contact, more vocalizations, and a transition from rather rigid to more flexible interaction patterns; however, conducting sessions was often hampered by the fact that it was difficult for the girl to stay in the room for the duration of the therapy session. At five months, the child's parents reported that the girl spontaneously initiated interactions with others more often, and that she was more able to deal with changes or unexpected events in familiar routines and joint activities. Overall, the quantitative and qualitative observations regarding this child are in agreement. Two cases where they partly diverge are presented in the following.

Participant #4, a boy aged 4 and a half years who also did not use verbal language yet, was also allocated to the HI condition, but due to schedule and logistical difficulties only received a total of 26 sessions of music therapy. During the five months intervention period, he also received 10 sessions of occupational therapy and 10 sessions of play therapy. His ADOS-SA score at baseline was 19, worsened to 20 at five months (due to

a higher score in the item “quality of social overtures”), and to 21 at 12-month follow-up (due to a higher score in the item “frequency of vocalization directed to others”); at the same time, however, the participant improved at five months compared to baseline when using ADOS-AB, which was due to lower scores on three items of ADOS domains A and B that are not included in the social affect score (“use of other’s body to communicate”, “responsive social smile”, and “response to name”). Furthermore, it is noteworthy that the assessor commented on the boy’s more varied facial expression at 12-month follow-up, which could not be picked up by any of the ADOS (either SA or AB) items. The SRS score improved from an initial 147 to 140 at 5- and 12-month follow-up. Changes within music therapy included more eye contact, more incidents of shared enjoyment in musical interactions, and emerging signs of expectation within jointly developed musical play routines. The boy’s mother mentioned that he seemed more open to and interested in people, that he engaged in play with his sisters more often, that his eye contact had increased, and that both mother and boy now took pleasure in playful interactions involving strong emotional expressions (e.g., jokingly scaring each other). Here, it was especially interesting to note the divergence between changes in ADOS-SA and ADOS-AB. The latter seemed to be more in agreement with clinical observations than the former.

Participant #5, a boy aged 5 years 10 months with good verbal abilities both in his first language and in German, was allocated to the LO condition and received a total of 19 music therapy sessions. He did not receive any other type of therapy during the study period. His ADOS-SA score improved from 13 at baseline to 11 at 5-month follow-up. However, lower scores (i.e., better skills) in some items (such as “pointing”, “showing”, “overall quality of rapport”) co-occurred with higher scores on other items (e.g., “unusual eye contact”, “spontaneous initiation of joint attention”). The SRS score showed a minimal increase from 89 at baseline to 90 at five months. Developments within music therapy comprised increasing abilities to express and share a range of emotions, less agitation and restlessness, and expanding abilities to flexibly co-create joint activities and songs going beyond a simple question-response format. At five months, the child’s father also commented on less agitation at home and reported more flexibility and a changed scope of conversations, where the boy showed increasing interest in the background and context of various social situations instead of just asking “what” questions over and over again. This example illustrates that some children may experience qualitative benefits not covered by the quantitative scales.

Discussion

The findings of this pilot cohort show that the TIME-A study protocol was designed appropriately, and that the chosen procedures combining rigorous

RCT methodology with intervention conditions similar to clinical practice are feasible. This adds to reports from other small RCTs on improvisational forms of music therapy (Gattino, Riesgo, Longo, Leite, & Faccini, 2011; Kim, Wigram, & Gold, 2008; Thompson, McFerran, & Gold, 2013).

The present study also expands on previous findings by focusing and elaborating on feasibility issues. However, the examples of changes over time given in this study also serve to illustrate the complexity of individual developmental trajectories of children with ASD and their families. This complexity makes it a difficult challenge to determine appropriate outcomes and to interpret results, both on an individual and on a generalized level. There are still no agreed core outcomes for research into interventions for ASD (Wheeler, Williams, Seida, & Ospina, 2008).

Feasibility

Study procedures were suitable to ensure that assessors stayed blinded until the end of each participant's study period. Neither assessment appointments nor parent counseling sessions were missed by any of the families, and the fact that none of the participants dropped out indicates that both the music therapy and the standard care conditions proved to be sufficiently worthwhile for families to continue their study participation until the respective scheduled end. Recruitment was slower than expected, included a hiatus of eight months in the middle of the recruitment period where no prospective participants fitting inclusion criteria were identified, and eventually resulted in a lower sample size than hoped for. This might have been caused by underestimating logistical and communication difficulties that result from the fact that ASD specialist services in Vienna belong to different provider institutions and are rather scattered across the city; by the fact that the researcher at the time of the study was not working directly in any of those service institutions; and by limited work force within the local research team, resulting in sometimes limited options in scheduling appointments. Changes of ADOS and SRS scores observed across time indicate that both tools are sufficiently sensitive to change to be used as measures of effects. For ADOS, using all items instead of just those selected for the algorithm ensures that none of the information gained through assessment is lost, and provides a more detailed account of the child's abilities. SRS scores rose from baseline to 5-month follow-up for the majority of children in this sample (11 out of 15); this might be due to parents becoming increasingly aware of their children's difficulties during the course of their study participation. Thus, some observer bias might have influenced scores. However, having parents assess outcomes is desirable nonetheless in order to enhance external validity of results. The difficulties of evaluating cognitive abilities in children with ASD are highlighted by the fact that in this pilot cohort, it was not possible to use K-ABC with two thirds of the participants. For the international multi-center trial, this measure was mainly chosen because it is one of the few standardized IQ measures

available in multiple countries and languages. In other types of studies, it might be more feasible to use standardized non-verbal measures for assessing cognitive abilities of individuals with ASD.

Acceptability

Due to logistical challenges, it proved difficult for families to attend therapy sessions three times a week; this was a reason for some families to not participate in the first place, and for others to attend only a part of the full number of sessions provided. It appears that if attending therapy requires additional time for transportation (as opposed to taking place in the child's kindergarten or school), most families will not be able to attend therapy consistently for more than two times a week. Apart from this, acceptability was generally very good, as illustrated by the fact that none of the participating families dropped out during the course of the study, and that most therapy and all counseling and assessment appointments were kept.

Generalizability

More male than female individuals are affected by ASD, and it is estimated that the disorder is diagnosed between two and four times more often in boys than girls, with Asperger's syndrome being present in about 20% of people with an ASD (Fombonne, 2005; Lai, Lombardo, & Baron-Cohen 2014). The sample for this study matches these ratios and also reflects the Viennese population of children having a first language other than German (Steinmayr, 2009; in 2006, about 60% of the children born in Austria were born to parents who had previously migrated to Austria, thus often living with a family language other than German). As treatment fidelity for IMT was assessed as sufficient, the intervention applied in this study corresponds well with the usual clinical practice where therapists follow this approach. Due to the low sample size, changes of pooled scores within intervention groups may not be interpreted as indicators of effectiveness and can only be discussed within an individual context.

Limitations

The small sample size of this internal pilot cohort not only prevents any application of inferential statistics for data analysis, but also calls for caution when transferring findings to other clinical and research contexts. However, we might have facilitated making more substantiated design and implementation decisions in the planning of studies to come in similar fields by describing difficulties, successes, obstacles, and efficient strategies within this study. The fact that the researcher also conducted music therapy and parent counseling sessions herself created a specific clinical context that is not common in usual clinical practice, and might have shaped the course of therapies in a certain way. However, the objectives of IMT investigated in this trial, namely improvements in social communication skills, are prevailing goals of music therapy for children with ASD, so that the potential bias introduced is considered low, and resulting implications in

relation to interpreting results are considered negligible. Furthermore, the multiples role that the researcher combined in herself as the main contact person of the research project for referrers, families, and assessors, might have helped to retain all enrolled families within the project for the whole duration of their study participation. It remains to be examined whether attrition rates differ in similar studies with different numbers of people being directly involved with study participants.

Conclusions

There is a need for researchers in music therapy and other complex interventions to share their experiences gained conducting studies, and to report more information on feasibility of study designs. This has also been pointed out by La Gasse (2013), Leon and colleagues (2011), Robb (2013), and Thabane and colleagues (2010). Research into trial feasibility will help to build knowledge about successful strategies in examining complex interventions, will ensure that burden for study participants is minimized, and can assist researchers in designing studies that succeed in yielding robust findings which are relevant and meaningful for individuals with ASD and their families.

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Figure 1. Flow Chart of Study Participants (Dec 2011 until Sep 2014)

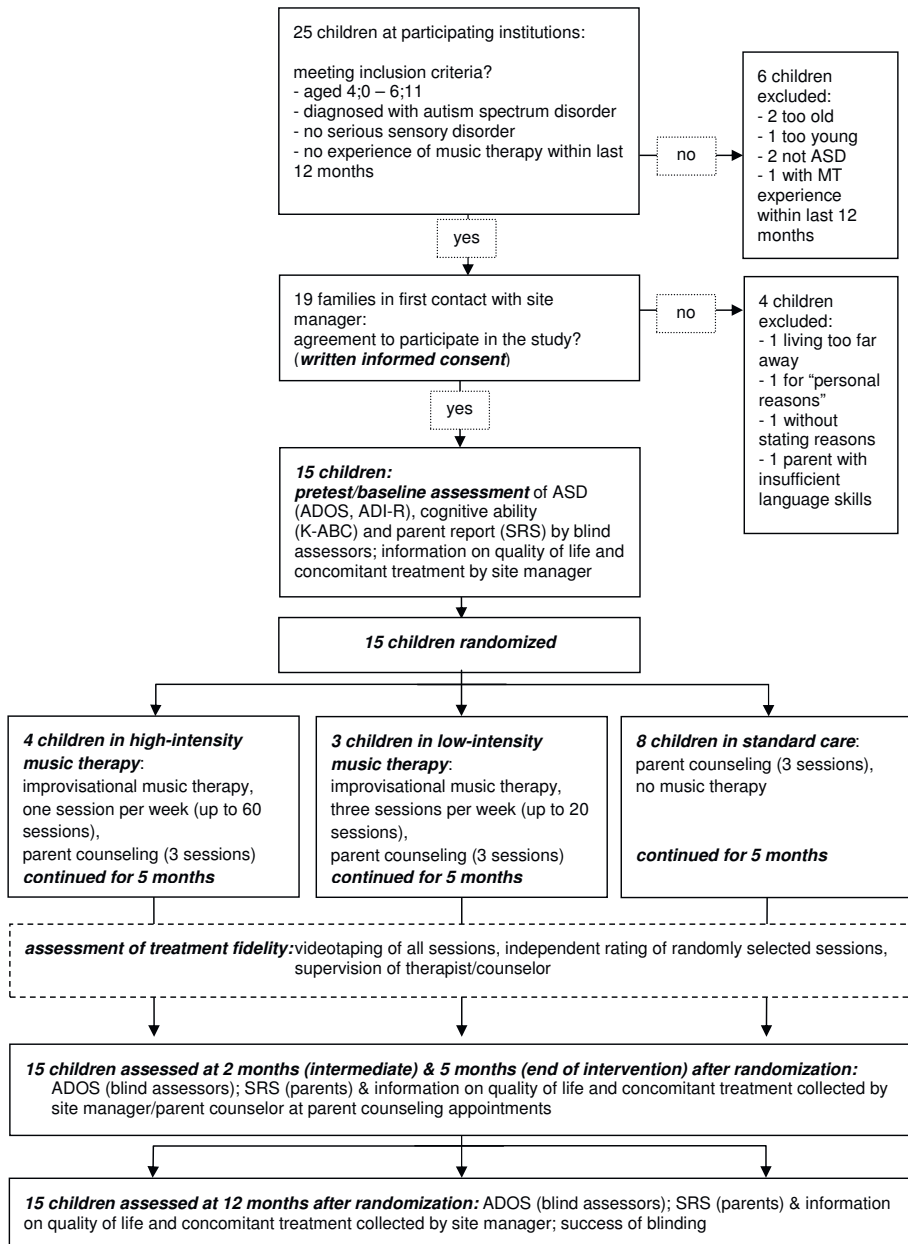
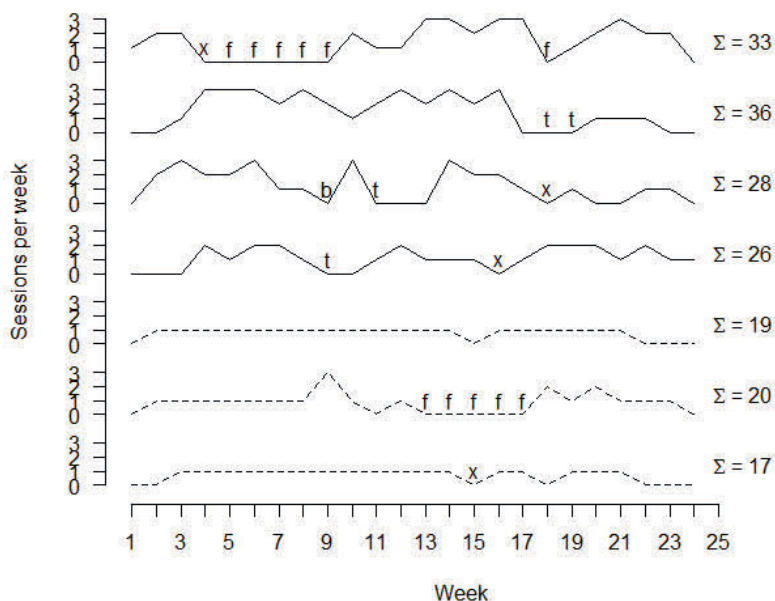
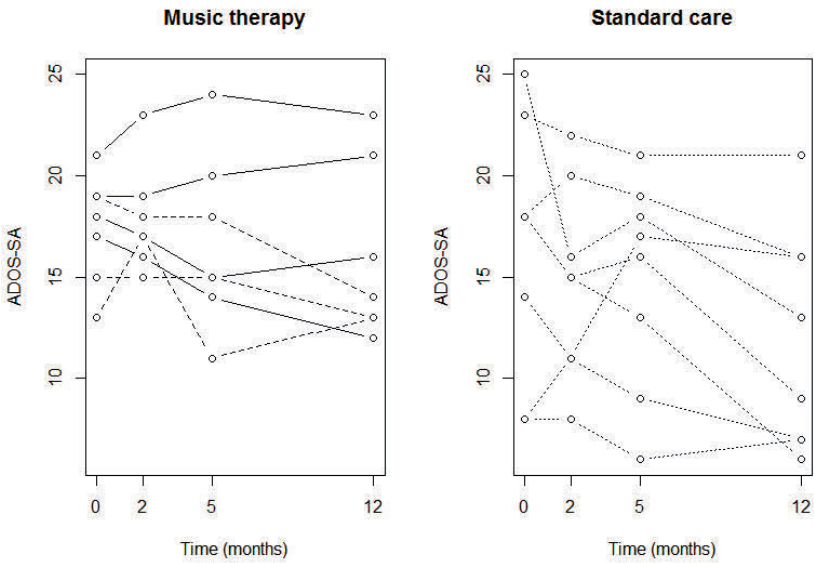


Figure 2. Distribution of MT Sessions During Treatment Period



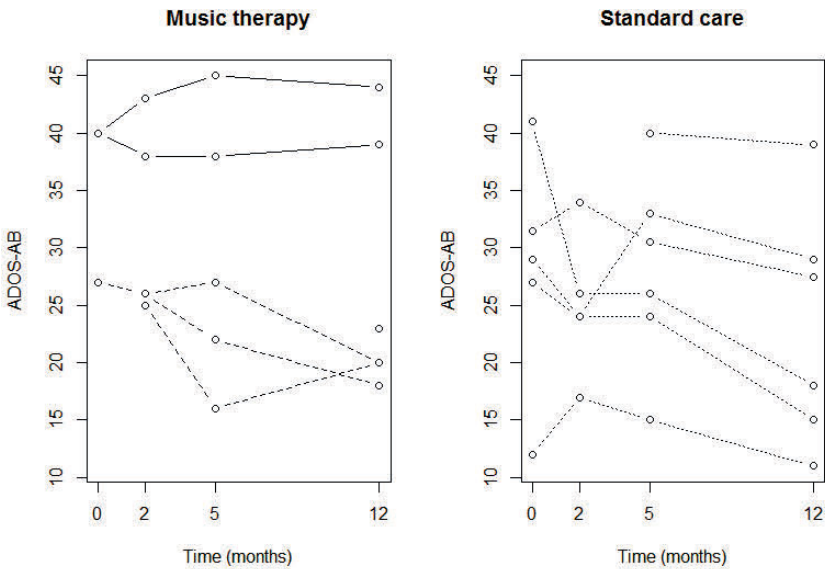
Note. Solid lines represent participants in the high-intensity condition (who were offered 3 sessions of MT per week), dashed lines represent participants in the low-intensity condition (offered 1 session of MT per week). Inserted letters indicate reasons for skipping sessions: "x = Christmas break", "f = family abroad", "t = therapist abroad", "b = mother gave birth to 3rd child".

Figure 3. Changes in Outcome Measures by Participant: ADOS-SA (primary outcome)



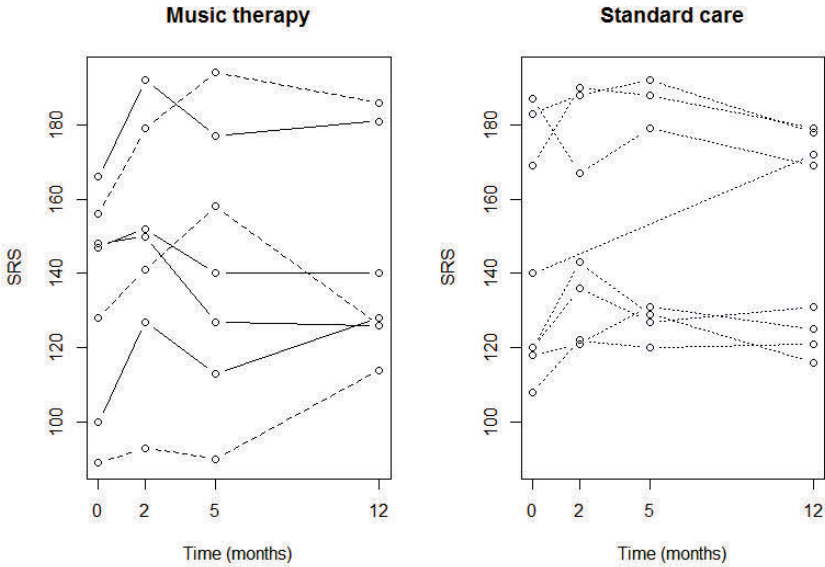
Note. ADOS-SA = ADOS Social Affect score using a modified scoring procedure to improve sensitivity to change (see main text). Solid lines represent participants who received high-intensity music therapy; dashed lines represent participants allocated to the low-intensity music therapy condition.

Figure 4. Changes in Outcome Measures by Participant: ADOS-AB



Note. ADOS-AB = total score of all items from ADOS domains A and B, using a modified scoring procedure to improve sensitivity to change (see main text). Solid lines represent participants who received high-intensity music therapy; dashed lines represent participants allocated to the low-intensity music therapy condition. Since ADOS-AB was not being regularly scored for the first 12 months of the study, data for some participants are missing.

Figure 5. Changes in Outcome Measures by Participant: SRS



Note. SRS = total SRS score. Solid lines represent participants who received high-intensity music therapy; dashed lines represent participants allocated to the low-intensity music therapy condition. For one child in the standard care condition (baseline score: 140), data were missing at 2 and 5 months, thus yielding a straight dotted line from 0 to 12 months.

SUMMARY

In this book, a PhD study is presented that investigates if and how music therapy may help to promote social communication in children with autism spectrum disorder (ASD).

The study examined several dimensions of this complex field, and includes four articles: (i) a systematic review (Cochrane review) synthesising research evidence on overall effects of music therapy for individuals with ASD; (ii) a study protocol specifying the design of TIME-A, a randomised controlled trial (RCT) examining effects of improvisational music therapy on social communication skills in children with ASD aged 4 to 7; (iii) a treatment guide that describes an international consensus model of improvisational music therapy for children with ASD; and (iv) a feasibility study summarising data from the Viennese pilot cohort of the international multi-centre project TIME-A.

In this way, this study presents feasible ways to combine clinical relevance and rigorous research methodology without compromising either, and to integrate scientific findings in the clinical application of a highly individualised approach.

Through enhancing communication and knowledge transfer between research and clinical practice in music therapy, this study contributes to collaborative efforts of providing more effective and more substantiated health care services for individuals with ASD and other conditions.

ISSN: 2246-123X
ISBN: 978-87-7112-211-4

AALBORG UNIVERSITY PRESS