Interaction-focused music therapy with cancer-affected children and their significant others: a randomized controlled feasibility study with subsequent intervention (INMUT)

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Keywords: music therapy, paediatric oncology, assessment of parent-child interaction (APCI), feasibility randomized controlled trial, family, significant other, systemic functioning, psychological functioning, psychosocial burden

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Abstract

**Background:** Paediatric oncology/haematology patients and their families are in an existentially threatening situation for which music therapy has proven as a cross-linguistic field of action. The creative act of making music together offers the possibility to strengthen competences and makes conflicts tangible in a direct way. Besides its complementing of evidence-based biomedical care, there is little research on the feasibility and efficacy of interactive music therapy including the child and its significant other.

**Methods:** We conducted an assessor blind, prospective, multicentric feasibility randomized controlled trial (RCT) with subsequent intervention. Including 52 child-referent dyads, it investigates interaction-focused music therapy with cancer-affected children and their significant others (INMUT-KB; \( n = 21 \)) compared to music therapy only with the child (MUT-K; \( n = 21 \)), and a wait-list group (WLG; \( n = 10 \)). The measurement points include the screening for a cancer diagnosis, psychometric baseline (pre-T1), initial assessment (T1/T2), music therapy sessions (T3-T9), final assessment (T10), final psychometric evaluation (post-T10), and 3-month follow-up (T11). Feasibility and acceptability of the (1) research methodology, (2) intervention, (3) estimation of effect sizes, and (4) service use for health economic evaluation will be assessed using qualitative and quantitative data. The proposed primary outcome includes the parent-child interaction (APCI), and the proposed secondary outcomes refer to the quality of life (KINDL), symptomatology (SCL-9k), social system functioning (EXIS), the psychosocial burden (BAS), resources (WIRF) and the child's and significant other's goal attainment (GAS). We plan to investigate the efficacy of INMUT-KB and MUT-K post-intervention (T10) within the RCT design, and at 3-month follow-up (T11).

**Discussion:** This study will provide insights into the feasibility of INMUT, and the final sample needed for a confirmatory RCT. We will reflect on successfully implemented study procedures, and provide recommendations for changes considering the design, procedures, measures, and statistical analyses, if necessary. The discussion will conclude with an evaluation whether a confirmatory RCT is worth the investment of future resources, including the calculated number of child-referent dyads needed based on the efficacy trends derived from this feasibility study.

**Trial registration:** ClinicalTrials.gov: NCT05534282; date of registration: 06/23/2022.

**Background**

Music therapy has proven itself many times as an interdisciplinary discipline of psychosocial care in paediatric oncology [1]. Since 2004, it has been part of the professional profile of the Psychosocial Working Group for Paediatric Oncology and Haematology (PSAPOH) [2], and in 2008 music therapy was anchored in the S3 guidelines of the PSAPOH [3]. The inclusion of important caregivers in therapy processes is explicitly recommended in these guidelines. The supply situation however is not satisfactory. Only about half of the German-speaking clinics provide music therapy [4]. Up to now, the legal health care system in Germany covers inpatient music therapy for single patients only in an individual setting. Outpatient music therapy is not reimbursed by the health insurance companies. Although important caregivers often appear to be themselves clinically affected [5], parents and other family members, such as siblings, as well as alternative significant others, such as friends or legal reference persons, are still neglected. Consequently, there is a large gap in the psychosocial support of children with cancer and their social environment [6].

**State of research**

We conducted a systematic literature search on PubMed and Cochrane databases in German and English with the time restriction 2011 to 2023. In the PubMed database, 52 literature references were found, 30 sources were not included because they were not relevant, 22 articles were pre-selected because they matched at least three of four search categories. Of those, 15 articles were examined in more detail because they matched all search parameters. The sample included 2 scoping reviews, 7 exploratory practice reviews, 5 quantitative studies such as randomized controlled trials (RCTs) and a single case design pilot study, and 1 qualitative study (Table 1).
Table 1

*Systematic keyword-based literature search*

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**PubMed from 2010 to 2023; Searched 12.01.2023**

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Table 2
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Notes: P = patient; SO = significant other; A = assessor; T = therapist; MD = Medical Doctor; CD = Clinical diagnosis; APCI = Assessment of parent-child interaction; DEMO = Demographic data; KINDL = Children and young people quality of life; EXIS = Experience in Social Systems; BAS = Burden Assessment Scale; SCL-9k = Symptom Checklist; WIRF = Witten Resources Questionnaire; GAS = Goal Attainment Scaling, SM = Significant Moments; AC = Adherence und Competence

1) Scoping reviews. The results show that music therapy can address the needs of paediatric oncology patients and families and optimise their care [7]. Music therapy is suitable as a means of promoting self-esteem, improving physical, emotional, and cognitive aspects related to the disease and, to a lesser extent, alleviating physiological symptoms. Music therapy interventions are generally well received, not only by children and young people with cancer, but also by their families and health professionals. Nevertheless, several gaps were identified in some of the studies reviewed, including a lack of specificity in terms of the outcomes achieved or the music therapy intervention methods used [8].
2) **Exploratory practice reviews:** The importance of music in the lives of children and their parents in paediatric oncology is intensively discussed [9], as it provides an experience of competence and interactive affect regulation [10], and thus is suggested as a quality improvement measure for the future growth of the profession [11]. A multicentric survey study highlights the importance of communication and collaboration between music therapists and the multidisciplinary care team using a model of family-centred care that actively involves parents and caregivers in music interventions, treatment planning, and care delivery [12]. In a feasibility and acceptability report, patients, parents, and family members describe active music-making as a coping mechanism for pain, discomfort, stress, anxiety, and boredom. Music-making increases the children's and significant others' relaxation and sleep quality, is associated with pleasure and as a way to connect [13]. Two articles report parents' perspectives [14] and adolescents’ perspectives [15] on music-induced mechanisms of action in relation to positive coping, resilience, social support and family function in an RCT from the children's oncology group around Robb and colleagues (cf. [6]).

3) **Quantitative studies:** In their RCT, Robb and colleagues report improvement in health outcomes of courageous coping, social integration, and family environment during high-risk cancer treatment using therapeutic music video interventions [6]. Another RCT and a single case design pilot study from Robb and colleagues discuss the positive effects of active music interventions on multiple biomarkers to improve understanding of dose-response effects [16, 17], as well as treatment fidelity in music-based play interventions for young children with cancer and their parents [18]. In addition, a pilot RCT by Robb and colleagues investigated the feasibility and acceptability of parent-delivered active music engagement. This intervention was successful in providing emotional relief to children but was not well received by parents [19].

4) **Qualitative studies:** The qualitative study investigates the effects of musical training on the psychological well-being and quality of life of brain tumour survivor children, their parents, and caregivers. Although positive effects were reported, the factors that stimulated the efficacy are still unknown [20].

Though these publications strongly recommend the inclusion of parents and key caregivers in the practice and research of music therapy, there is no RCT that works with the child as well as the referent person in interactive music therapy focusing on effects in the child - significant other interaction.

**Epidemiology**

Although the probability of a child to fall ill with cancer in the first 18 years of life is only 0.3%, oncological and haematological diseases are the second most common cause of death in children and adolescents [21]. In Germany, about 2,200 young people under the age of 18 are affected every year; the Society for Paediatric Oncology and Haematology (GPOH) speaks of an incidence of around 170 new cases per 1 million children in this age group. The most common types of cancer in children and adolescents are leukaemia (about 30%), followed by tumours of the central nervous system (about 24%), lymphomas (about 14%), soft tissue sarcomas (5.7%), neuroblastomas (5.5%) and nephroblastomas (about 4.2%) [21].

**Clinical picture**

According to a definition of the PSAPOH paediatric oncology patients are centred in an existential stress situation. They oscillate with their families in a field of tension caused by extreme experiences. After the shock of the life-threatening diagnosis, everyday life breaks down and starts to be determined by hospital stays with invasive medical interventions and strict therapy plans as well as social restrictions in the household environment. In addition to physical effects, children with cancer and their relatives are confronted with emotional distress caused by worries, fears, feelings of helplessness, isolation, and the loss of control and autonomy. Within such affected social systems, mainly the family, individual and systemic coping strategies must be developed which, in conjunction with existing interaction patterns, have a great impact on how these stressful situations are dealt with [2].

**Music therapy**

Although music therapy is still far from self-evidently being a part in multi-professional paediatric clinic teams in German-speaking countries, it is recommended as an integral part of the inpatient psychosocial care for children and adolescents with cancer [22, 23]. In addition to more linguistically oriented forms of therapy and counselling, it offers the possibility to express, experience and reflect on an emotional-intuitive level through musical creation [2]. The identity-building act of self-experience and self-action creates a space in which the children and adolescents meet the inner and outer demands of their existence by improvisation in different conditions such as physiological, psychological, and social terms [24]. Individual and age-specific developmental phases as well as developmental-psychological processing strategies are considered. In its professional profile of art and music therapists the PSAPOH formulates
indications for music therapy for 1) patients with physical stress criteria, such as drastic changes in body image, severe courses of illness, painful medical interventions, recurrences, prolonged hospital stays, isolation (e.g. in bone marrow transplants), immobility due to treatment, speech impairments, motor and sensory disabilities and poor prognosis; 2) patients with psychological stress criteria, such as severe anxiety, processing problems (e.g., regression, severe withdrawal, aggressive behaviour), compliance problems, particular psychological and vegetative reactions (e.g. depressive symptoms, perceptual disorders, dissociation, decompensation); 3) patients in palliative therapy; 4) patients with existing language barriers; 5) outpatients and follow-up care in the case of permanent changes in body image or physical disabilities, reintegration difficulties, behavioural problems occurring after the end of intensive therapy, the child’s wish to continue the accompaniment, identity problems and their processing, stigmatization, and difficulties in coping with the disease and mourning [2].

Efficacy of music therapy

In the Health Technology Assessment (HTA) report on music therapy as an adjunctive measure for better treatment outcomes in cancer published in 2019, the German Institute for Quality and Efficiency in Health Care (IQWiG) describes indications and evidence for a short-term efficacy of music therapy in relation to psychological endpoints such as fatigue, mood swings, anxiety, and health-related quality of life [1]. In the studies we evaluated and selected for this purpose, evidence was found that music-based interventions have positive effects on psychological well-being [13, 20], competence, resilience, and interactive affect regulation [10]. Positive effects have been found in relation to cognitive and physiological aspects [8], as indicated by bio-markers in form of cortisol and immune function measurements [16, 17] and measurement of heart rates, respiratory rates and blood pressure [25]. Music therapy has also been proven as supporting family functioning and social integration [6, 12, 14, 15, 26].

Pilot study

RCTs are considered the most rigorous standard of evidence-based research. They are often complex, time-consuming, and expensive. Before implementing a confirmatory RCT, a feasibility RCT should be conducted that replicates all the essential elements of the planned larger trial [27]. Our study to be planned is the first feasibility RCT, and RCT at all, that focuses not only on the affected children but also on their equally important significant others. It is also the first feasibility RCT to use both the blind observer-based music therapy Assessment of Parent - Child Interaction (APCI) [28, 29] in paediatric oncology and a self-report questionnaires for the child as well as the significant other addressing quality of life, systemic and psychological functioning, psychosocial burden, resources, and goal attainment. The aim is to carefully investigate the conditions for a subsequent confirmatory RCT to save costs by carrying out the interventions more efficiently in the future, and with a carefully planned while powered study sample [30].

Aims and objectives

The main focus of this assessor-blind, prospective, multicentric feasibility RCT is on the implementation of the necessary recruitment procedures, above all the inclusion of child-referent dyads and music therapists, the implementation of a newly developed music therapy including the child-referent dyad (INMUT-KB), the music therapy as usual with only the child (MUT-K) and a wait-list group (WLG), procedures considering data analyses, and the exploration of potential effects to calculate the number of child-referent needed for the subsequently confirmatory RCT [27]. Particularly in vulnerable patient groups such as the clientele described here, on the one hand, a careful estimation of the number of cases is absolutely necessary in order to be able to soundly validate the primary and secondary effects in the confirmatory RCT, and, on the other hand, in order not to spend resources unnecessarily on samples that are calculated too large and bear risks of bias and noise [30, 31]. For that purpose, we will descriptively and exploratively investigate the following research question (RQ).

1. Feasibility and acceptability of the research methodology

Children and significant others

RQ1.1: Is it possible to recruit, include and randomize the planned number of children and significant others? RQ1.2: How many children and significant others must be recruited, will participate according to the study protocol, or show study protocol violations, and what is the retention rate? RQ1.3: How well are the outcome variables accepted by the children and significant others?

Music therapists

RQ1.4
Is it possible to recruit, train and supervise the music therapists?  

**APCI Raters**

**RQ1.5** How well succeeds the certification of music therapists with the Assessment of Parent-Child Interaction (APCI) [28, 29]? **RQ1.6**: Which circumstances contribute to a successful implementation of the APCI? **RQ1.7**: Is it possible to blind the APCI raters?  

**Children, significant others, music therapists, raters**

**RQ1.8**

How well is the research methodology accepted by the children, significant others, music therapists and APCI raters, above all considering data collection and statistical analyses?  

2. **Feasibility and acceptability of the intervention**

**RQ2.1**: How evolves the process of music therapy, and its manualization, including the children and significant others (INMUT-KB), the child only (MUT-K), and the wait-list group (WLG)? **RQ2.2**: What is the degree of the music therapists' adherence to INMUT-KB or MUT-K, i.e., the percentage of treatment components defined by the manual across each music therapy session that was implemented as planned? **RQ2.3**: How strong is the children's and the significant others' compliance with INMUT-KB, MUT-K, and WLG? **RQ2.4**: How do the children, significant others, and therapists will rate the ease and intensity of participating in the music therapy? **RQ2.5**: What are additional identified benefits and barriers of both the participation of significant others in the children's music therapy, and their participation in research study? **RQ2.6**: Will there be any adverse event reported by the children or significant others throughout the study period?  

3. **Estimation of effect sizes**

**RQ3.1**: How likely is a potential effect of INMUT-KB and MUT-K to relate to the child-referent dyad versus the child alone? **RQ3.2**: What is the estimated within-subjects effect size and 95% CI for changes in the children and significant others’ primary outcome, i.e., mutual attunement, nonverbal communication, and parental emotional response, from baseline to end of music therapy? **RQ3.3**: What are the within-subjects effect sizes and 95% CIs for changes in the children and significant others' secondary outcomes, i.e., socio-psycho-physiological distress, systemic functioning, and goal attainment, from baseline to end of music therapy? And what are the within-subjects effect sizes and 95% CIs for changes in the significant others’ psychosocial burden, psychosomatic complains, resources and subjective well-being, from baseline to end of music therapy? **RQ3.4**: What proportion of children's experiencing clinically meaningful change, i.e., remission, response, deterioration, and no change?  

4. **Assessment of service use for health economic evaluation**

**RQ4.1**

How many services are received by the children and significant others post attending the music therapy intervention?  

**Methods**

**Design**

This study is planned as an assessor blind, prospective, multicentric feasibility RCT with subsequent intervention. A total of 52 clients will be randomized to either the newly developed music therapy (INMUT-KB; n = 21), the music therapy as usual (MUT-K; n = 21) or the wait-list group (WLG, n = 10). The intervention outcome will be measured including three assessment points: baseline; post-intervention (primary endpoint), and 3-month follow-up.  

**Sample size calculation**

Assuming an estimated small between-group effect size (80% power, 5% significance level), we are in need of 344 child-referent dyads in a confirmatory RCT for direct comparison of INMUT-KB and MUT-K [30]. This calculation grounds in the suggestion of at least 9% of the subsequently powered RCT sample to be seen in the prior feasibility RCT. Consequently, we will recruit at least 32 child-referent dyads. Taking the WLG into account with an additional one third of this sample, i.e., 10 child-referent dyads, and a drop-out rate of, again, an additional 25% in each study-arm, i.e., 10 child-referent dyads in addition., the total sample size for our feasibility RCT will include 52
child-referent dyads (intention-to-treat, ITT; INMUT-KB, \(n = 21\); MUT-K, \(n = 21\); WLG, \(n = 10\)). The sample size to be expected of completing the trial encompasses 40 child-referent dyads (per-protocol, PP; INMUT-KB, \(n = 16\); MUT-K, \(n = 16\); WLG, \(n = 8\)).

**Recruitment**

**Patients and significant others.** Recruitment will start in 2023, and end when we have included 52 child-referent dyads which is expected in autumn 2024. The medical management and interprofessional team of the cooperating clinics, i.e., the Community Hospital Herdecke, Clinic Center Dortmund, and Vestic Children's Clinic Datteln, will call attention of the cancer-affected children and their significant others towards this study within the inpatient setting. Prior to that, we will have informed the medical management and the interprofessional team about the study and will have distributed flyers and study information to them. All patients will present themselves to the study team and no patients will be referred.

**Therapists.** Recruitment started in 2021, and we already included 9 music therapists with a state-recognized degree from a music therapy institution certified by the German Music Therapy Association (DMtG). The certification process for the primary outcome, i.e., the Assessment of Parent-Child Interaction (APCI) \([28, 29]\) began in November 2021. A 3-day training was followed by a trial phase with 5 non-clinical child-referent dyads for each music therapist. The implementation of the assessments, embedding the APCI survey in the statistical program and the writing of the APCI reports were accompanied and reviewed individually by the APCI trainer and concluded with a joint meeting. Certification took place after completion of all supervisions by the APCI trainer in August 2022.

**Study procedures**

**Screening.** The medical management of the cooperating clinics will provide the screening of inclusion criteria. If the inclusion criteria are met, the child and significant other will receive the recruitment information. After having obtained informed consent, the child-referent dyad will be randomly assigned to one of the three study arms and informed about their assignment. Together with the interprofessional team of the responsible clinic, it will be decided whether the music therapy will take place on an outpatient basis, i.e., the Nordoff/Robbins Music Therapy Centre, Witten, or on an inpatient basis in the clinics, either in the music therapy unit or on the hospital wards.

**Baseline (T1/T2).** The paper-pencil baseline survey will be completed by all children (approx. 10 to 15 minutes) and significant others (approx. 20 to 30 minutes) (pre-T1), i.e., up to a maximum of 3 days prior to the APCI with its two manualized entry music therapy sessions (approx. 25 minutes each) (T1/T2). The APCI music therapy sessions will be video-recorded and evaluated using the APCI online program. APCI raters are blinded and will give information about significant moments in T1/T2, if at present, and based on a self-evaluation about their adherence to the APCI manual. The child and significant other also will provide information about their significant moments, if at present.

**Therapy (T3 bis T9).** The music therapy interventions will be provided in seven sessions (T3 to T9). They will last about 20 to 45 minutes, will be video-recorded and descriptively documented by the music therapists. At the end of each music therapy session, the child, significant other and music therapist will give information about significant moments, if at present. The music therapists will self-evaluate their adherence to the INMUT-KB or MUT-K manual, respectively.

**Outcome (T10).** The final APCI session at T10 will last about 25 minutes, will be video-recorded and evaluated using the APCI online program. APCI raters are blinded and will give information about significant moments in T10, if at present, and based on a self-evaluation about their adherence to the APCI manual. The child and significant other also will provide information about their significant moments, if at present.

The paper-pencil outcome survey will be completed by all children (approx. 10 to 15 minutes) and significant others (approx. 20 to 30 minutes) (post-T10), i.e., up to a maximum of 24 hours after the final APCI.

**Follow-up (T11).** A paper-pencil follow-up survey will be completed 3 months after the last APCI by all children (approx. 10 to 15 minutes) and significant others (approx. 20 to 30 minutes) (T11). (Fig. 1).

**Inclusion and exclusion criteria**
Child-referent dyad. The study will include children with 1) an oncological/haematological disease in acute inpatient treatment with chemotherapy and/or radiotherapy; 2) age range between 5 to 13 years; and 3) adequate language skills for study-related self-reporting. Exclusion criteria encompass 1) a serious physical comorbidity with impairment of brain-organic functions; 2) auditory impairment; 3) insufficient language skills; and 4) withdrawal of informed consent for study participation. Inclusion criteria of significant others refer to 1) their role as a significant other (e.g., mother, father, aunt, caregiver) and 2) sufficient language skills for study-related self-reporting. Exclusion results in 1) withdrawal of informed consent for study participation.

Therapists. Inclusion criteria for music therapists encompass a state-recognized degree from a music therapy institution certified by the German Music Therapy Association (DMtG). For the rating of the child-referent dyads in the context of the music therapy assessment, they additionally must be certified for the APCI [28, 29].

Randomization
We will use block randomization of 10 to 12 child-referent dyads each. From the total of 52 child-referent dyads to be included, 21 dyads will be randomly assigned to the INMUT-KB, 21 dyads to MUT-K and 10 dyads to WLG. The randomization plan will be carried out by an independent research assistant at the Heidelberg University Hospital, who is not otherwise involved in the study, using the statistical software R version 4.2.1 [32, 33]. The randomized allocation of the child-referent dyads into the three study arms will be performed after finalization of the screening and in presence of the informed consent of both parts. The allocation will be carried out by means of sealed envelopes (“sealed envelope method”), which will be opened in presence of the child-referent dyads together with a study staff member.

Blinding
The APCI sessions at baseline (T1/T2) and end of therapy (T10), indicating the primary endpoint of this feasibility RCTs, will be blind conducted by APCI. The music therapists will know the assignment as they will also guide the INMUT-KB and MUT-K (T3 to T9). APCI raters will not be equal the music therapists of the child-referent dyads. The included child-referent dyads will be informed about their assignment and the general aims of the study, but not about specific hypotheses of any endpoint.

Allegiance
Researchers’ and therapists’ preference for a particular treatment can lead to bias in the outcome data [34]. To avoid such bias, we will use multiple music therapists in the role of APCI assessors and/or INMUT-KB and MUT-K music therapists. They come from different music therapy traditions and are open to use their method but must be loyal to the INMUT-KB and MUT-K music therapy manual, respectively. They all will receive equal support, and contribute an equal number of hours and child-referent dyads to the project [35].

Music therapy intervention
Manual
The process-oriented free music therapy interventions methodologically oriented towards Nordoff/Robbins, Neugebauer and Aldridge [36–38] but takes into account the different practical experiences of the respective therapists. The process-orientation serves the stimulation of creativity in the music therapy and offers space for 1) the use of melodic, harmonic and rhythmic instruments that can be played and freely chosen without prior knowledge; 2) session lengths individually adapted to the needs of the child and significant other, if at present; 3) objectives tailored to the participant(s); 4) taking up topics of the participant(s) and integrating them into the interventions; 5) situational decisions about both active and receptive offers; 6) promoting relationship work in musical improvisation; and 7) linking to individual resources of the child and significant other, if at present. The focus is the relationship work in musical improvisation. While this develops between child and music therapist in the individual sessions (MUT-K), during the multi-person setting the focus is on the musical togetherness in the child-referent dyad (INMUT-KB). For better reflection, all music therapy session will be video-recorded. The therapists offer the families to watch the recordings together for formulating significant moments. The overall process of the music therapy interventions is presented to the interprofessional team of our cooperating clinics and the research team in a descriptive final report written by the therapists.
Adherence. The therapists will self-evaluate their adherence to the music therapy manuals (INMUT-KB, MUT-K) after each session.

Measures

As the purpose of this study is to explore the feasibility of a fully powered RCT, we will use different measures, including both qualitative information and quantitative data.

Feasibility and acceptability measures

Research methodology.

RQ1.1, RQ1.2: The feasibility of the protocol implementation will include the ability to meet the total recruitment goal of child-referent dyads \((n = 52)\), as well as the INMUT-KB \((n = 21)\), MUT-K \((n = 21)\) and WLG \((n = 10)\) in particular. It takes the estimation of the total sample to be recruited into account, the total drop-out rate as well as differential drop-out rate within the study-arms at all measurement times. Data will be collected through the observation of the client flow: counting the number of interested participants in the study who will 1) be recommended for inclusion by the medical directors of our cooperating clinics; 2) be contacted by our study staff to provide information about this feasibility RCT; 3) give consent to their study participation; 4) will be included into the study; 5) drop out before the baseline survey (pre-T1); 6) complete the baseline survey (pre-T1); 7) drop out before the baseline APCI diagnostics (T1/T2); 8) complete the baseline APCI diagnostics (T1/T2); 9) drop out before the start of the music therapy interventions, or from the wait-list group (pre-T3); 10) start the INMUT-KB or MUT-K (T3); 11) drop out from INMUT-KB or MUT-K, or from the wait-list group (T3 to T9); 12) complete INMUT-KB or MUT-K (T9); 13) drop out before the final APCI diagnostics (post-T10); 14) complete the final APCI diagnostics (T10); 15) drop out before the outcome survey (post-T10); 16) complete the outcome survey (T10); 17) drop out before the 3-month follow-up survey (cat-T11); 18) complete the 3-month follow-up survey (cat-T11). We will describe the causes for withdrawing and calculate the retention rate for the three study arms separately and together. Children and their significant others will be instructed to contact the therapists, research team and/or medical management in case of any adverse events. No constraints will exist regarding additional therapeutic consultations. Inclusion criteria will, however, not allow for use of additional music therapy interventions during the study period. Success will be defined as the achievement of 100% of the planned sample and retaining 75% of the clients in the INMUT-KB and MUT-K. RQ1.3: Outcome measure appropriateness will be assessed through the observation of missing data, and the delay in answering the outcome surveys. Success will be defined by missing data below 20% of the total data set, and the answering of outcome measures to a maximum of 3 days before the initial APCI assessment (pre-T1) and to a maximum of 24 hours after the final APCI assessment (post-T10). RQ1.4: The feasibility of this RCT depends on recruiting a sufficient number of music therapists. We expect about 5 to 6 cases per music therapist, so that successful recruitment includes at least 7 to 8 music therapists. RQ1.5: Successful certification to use the APCI was started by 7 music therapists and completed by 5. The APCI raters were trained in the practical use of the APCI manual, video analysis, data collection and analysis. RQ1.6: How well music therapists implement the APCI will be assessed by their self-assessment at T1/T2 and T10, using a Percentage Scale (range: 0 to 100), in addition to blind assessments by APCI raters from our APCI-certified study group. Semi-structured, experiential interviews with APCI raters will also gather information about the circumstances that contribute to successful APCI implementation. RQ1.7: The success of the APCI blind assessments will be questioned in semi-structured, experience-based interviews.[39]

INMUT-KB and MUT-K intervention.

RQ2.1: The feasibility and acceptability of the music therapy interventions and the wait-list group will be questioned in semi-structured experience-based interviews [39] considering their appropriateness to the needs of the child-referent dyads, with a special focus on the inclusion of significant others into the music therapy process. RQ2.2: Music therapists’ adherence will be assessed on their self-evaluation. RQ2.3: Children’s and significant others’ compliance to INMUT-KB and MUT-K will be assessed by the percentage of music therapy sessions attempted and completed. Their compliance to the WLG will be assessed for enquiries considering alternative music therapy interventions during the waiting period. RQ2.4: The ease and intensity of participating in both the INMUT-KB, MUT-K and WLG, and their enjoyment will be rated on a Visual Analogue Scale (range: 0 to 100). RQ2.5: Additional identified benefits and barriers of INMUT-KB and MUT-K will be questioned in semi-structured experience-based interviews considering the delivery of music therapy interventions to children with cancer and their significant others [39]. RQ2.6: Finally, as part of good clinical practice, adverse events will be monitored throughout the study and considered in relation to intervention safety and potential adverse outcomes. For any undesirable (psychological, somatic) effects during or after the intervention, psychological psychotherapists at the Center for Mental Health and
Psychotherapy (ZPP) of UW/H, directed by Prof. Dr. Christina Hunger-Schippe, will be available. In addition, the medical management and interprofessional team of our cooperating clinics will be in regular contact with the children and significant other and can be addressed spontaneously at any time.

Estimation of effect sizes.

**RQ3.1** The potential effect of INMUT-KB and MUT-K to relate to the child-referent dyad versus the child alone will be questioned in semi-structured experience-based interviews [39]. **RQ3.2** The estimation of effect sizes and 95% CI for change will concentrate on the proposed primary outcome, i.e., mutual attunement, nonverbal communication, and parental emotional response, from baseline to end of music therapy. **RQ3.3** In addition, effect sizes and 95% CI for change in the proposed secondary outcomes will be calculated from baseline to end of music therapy: i.e., socio-psycho-physiological distress, systemic functioning, and goal attainment considering the child and significant other, and the significant others’ psychosocial burden, psychosomatic complains, resources and subjective well-being. **RQ3.4** The proportion of children experiencing clinically meaningful change, i.e., remission, response, deterioration, and no change, will be explored for their quality of life (KINDL).

Service use for health economic evaluation.

**RQ4.1**

Health service use data will be collected on the Client Sociodemographic and Service Receipt Inventory (CSSRI-EU) which can be used for the calculation of costs for health service utilization and medication [40].

Proposed primary outcome measure

The **Assessment of Parent-Child Interaction (APCI)** [28, 29] was developed for at-risk families and is being used for the first time in an RCT to evaluate music therapy interaction processes in paediatric oncology. It assesses the child-referent dyad interaction based on three dimensions: mutual attunement, nonverbal communication, and emotional parental response. The training manual [28] includes theoretical considerations and the state-of-the-art literature considering the APCI, information on how to set it up, to analyse and report the collected information. The assessment sessions follow a manualized procedure: 1) welcome and exploration of the room and instruments; 2) the sequence of four different practice sessions, which are first carried out together with the therapists and subsequently by the child-referent dyad alone; and 3) the farewell. The four sequences consist of Ex1) soft/loud/soft; Ex2) musical turns; Ex3) mutual leading; and Ex4) free playing. Video evaluation is used to assess the three APCI dimensions which are transferred to the APCI online portal for the calculation of a total APCI score, sub-scores for each dimension, and further statistical analyses. In addition, 16 unique APCI profiles are created from the data, which are composed of the following observations: 1) Mutually attuned (M) / Not Mutually attuned (N); 2) Clear nonverbal communication (C) / Unclear nonverbal communication (U); 3) Supportive parenting (S) / Lack of Parenting Support (L); 4) Independent child (I) / Dependent child (D). The APCI shows good to satisfactory inter-rater reliability and test re-test reliability both in the overall score and in its sub-scores [29]. In our feasibility RCT, the raters of the APCI diagnostics were trained and certified by Rachel Swanick (Training Lead & Senior Clinical Therapist at Chroma arts therapies, UK) to use the APCI. During the study, they will be supervised by Rachel Swanick and Stine L. Jacobsen (Associate Professor of Music Therapy, Aalborg University, Denmark).

Proposed secondary outcome measures

The quality of life will be assessed using the **KINDL Children and Adolescents Version, Oncology Module** [41, 42]. It measures psychological well-being, social relationships, physical functioning, and daily activities within the last week using 40 items. The KINDL shows very good to satisfactory internal consistency, and test re-test reliability both in the overall score and regarding its dimensions.

The short form of the **Symptom Checklist (SCL-9K)** [43] measures impairment using 9 items on somatization, obsessiveness, social insecurity, depressiveness, anxiety, aggressiveness, phobic anxiety, paranoid thinking, and psychoticism. The SCL-9K is shown to have good internal consistency, and test re-test reliability on the Global Severity Index (GSI).

The questionnaire on **Experience In Social Systems Questionnaire (EXIS)** [44] measures with 12 items basic dimensions of systems functioning, i.e., accord, belonging, autonomy, and confidence in the future within the last two weeks. The EXIS shows very good to good internal consistency, and test re-test reliability, both in the overall value and regarding its dimensions.
The Burden Assessment Scale (BAS) [45] uses 19 items to assess personal stress, feelings of guilt, the need to interrupt and postpone important matters, as well as a changed time perspective in connection with the symptoms displayed by the significant other of an ill person within the last six months. The BAS shows excellent internal consistency considering its overall score.

The Witten Resources Questionnaire (WIRF) [46] measures resources in the three domains of general coping, past difficult situations and current problems, using 12 items each. The WIRF shows good to satisfactory internal consistency in the overall score as well as regarding its dimensions. In our study, we will limit the WIRF to the domain assessing coping with current problems for economic reasons.

The Goal Attainment Scaling (GAS) asks for the subjective goals of the children and significant others in free text. These are classified using the Bern Inventory of Therapy Goals (BIT-T) [47]: (1) coping with specific problems and symptoms, (2) interpersonal goals, (3) well-being, (4) existential issues, (5) personal growth, (6) residual category. In (re-)coding an extended sample of client treatment goals, the BIT-T proved to have a good interrater reliability, identified differences between diagnostic groups, and showed meaningful relations to standardized intake measures [48].

The Development of Psychotherapist Common Core Questionnaire (DPCCQ) [49–51] characterizes therapists on several subscales [52], of which we chose sociodemographic data, interpersonal style, relational skills, quality of therapists’ personal lives and difficulties in practice to be suitable for this feasibility study. The scales have been found predictive of the therapeutic alliance and outcome.

Children and significant will complete a brief demographic measure, including age, sex, and education level, and whether they are employed.

Statistical analyses

For research methodology feasibility measures considering the child and significant other, we will calculate screening, recruitment, randomization and drop-out rates (RQ1.1, RQ1.2) as well as missing data in answering the paper-pencil surveys (RQ1.3) at baseline (T1/T2), post the music therapy intervention (T10), and at 3-month follow-up (T11). Considering the APCI music therapists, we will calculate screening, inclusion and drop-out rates. The degree of implementation will be assessed by mean scores (M), standard deviations (SD) and 95% CI of the data gathered on the Visual Analogue Scale, and by calculating Cohen’s kappa as a robust measure of interrater reliability, in addition to the percentage (%) of the agreement between the raters. The circumstances that will contribute to the successful implementation of the APCI will be interpreted based on Qualitative Content Analysis (QCA) [53] and/or Consensual Qualitative Research (CQR) [54, 55] (RQ1.4, RQ1.5, RQ1.6). The success of blind rating the APCI by music therapists who are part of the study but not the music therapists of the child and significant other they work with (RQ1.7), and the acceptance of the research methodology (RQ1.8), will also be interpreted based on the QCA [53] and/or CQR [54, 55] (RQ1.8).

For intervention feasibility measures, we will use QCA and/or CQR to inform about the appropriateness of INMUT-KB and MUT-K to the child’s needs, with a special focus to also the significant other’s needs and inclusion into the intervention process (RQ2.1). The music therapists’ self-evaluated manual adherence will be calculated by mean scores (M), standard deviations (SD) and 95% CI of the gathered data. It will also be calculated using Cohen’s kappa considering the interrater reliability, in addition to the percentage (%) of the agreement between the raters. Overall treatment integrity will be calculated as the percentage (%) of treatment components defined by the INMUT-KB or MUT-K manual across sessions that will be implemented as planned [56] (RQ2.2). Children’s and significant others' compliance will be assessed by the percentage (%) of music therapy interventions attempted and completed. In addition, mean scores (M), standard deviations (SD) and 95% CI of music therapy interventions used by the WLG will be provided (RQ2.3). The ease, intensity and enjoyment of the INMUT-KB and MUT-K will be assessed by mean scores (M), standard deviations (SD) and 95% CI of the gathered data (RQ2.4). QCA [53] and/or CQR [54, 55] will serve the identification of benefits and barriers of INMUT-KB and MUT-K (2.5). Adverse events will be monitored and reported descriptively (RQ2.6).

For estimation of effect sizes, we will use QCA and/or CQR to analyze information about the association of these effects to either the child-referent dyad or the child alone (RQ3.1). Because child-referent dyads within groups (i.e., therapists) may be more similar to each other than child-referent dyads treated by different therapists, a two-level linear regression analysis will be performed to account for potential clustering effects at higher levels (i.e., child-referent dyads nested within therapists). The intraclass correlation (ICC) coefficient from the random intercept model with child-referent dyad (Level 1) and therapist (Level 2) will be calculated for the proposed primary outcome (APCI) [57]. An ICC greater than zero will indicate a clustering effect, and any statistical analysis must be adjusted for these effects. All proposed outcomes will be analyzed as intention to-treat (ITT; n = 52) using mean scores (M), standard deviations (SD) and
95% CI. The ITT calculation will be regardless of whether the child-referent dyads will violate the inclusion criteria, whether they complete the music therapy, or whether they will withdraw from the study due to protocol deviations (e.g. concurrent music therapy during the study period [58]). Missing values of less than 20% will be replaced with the conditional mean value of the subgroups (INMUT-KB, MUT-K, WLG). This will be compared to per-protocol analyses. We will use mixed-design ANOVAs (group: INMUT-KB, MUT-K, WLG; status: child-referent dyad, child alone; time: baseline, post-intervention, 3-month follow-up), adjusting for baseline scores considering demography as well as outcome data. Because treatment outcome will be measured at three assessment points, within-group effects will be further analyzed by comparisons between baseline and posts-intervention (Contrast A), and by comparisons between post-intervention and 3-month follow-up (Contrast B). Effect sizes will be presented as partial eta-squared values ($\eta^2$) and Cohen's $d$, calculated as the difference between the means divided by the pooled standard deviation ($d = \frac{x_1 - x_2}{\sqrt{s_1^2 + s_2^2 / 2}}$). Classification of effect sizes will be as follows: $\eta^2 \geq 0.10$, small effect; $\eta^2 \geq 0.060$, medium effect; $\eta^2 \geq 0.140$, large effect; Cohen's $d$ $\geq 0.20$, small effect; $d \geq 0.50$, medium effect; $d \geq 0.80$, large effect [59] (RQ3.2, RQ3.3).

The exploration of reliably significant change, i.e., the proportion of remission, response, deterioration, and no change, will be limited to the quality of life measure (KINDL) based on the reliable change index (RCI) [60]. We will use previously established internal consistency reliabilities to calculate the RCI [61], and Jacobson and Truax’s [60] cutoff C for the categorization of the children’s (no) change [62–64] (RQ3.4).

The service use for health economic evaluation will be assessed by mean scores ($M$), standard deviations ($SD$) and 95% CI of the data gathered on the Client Sociodemographic and Service Receipt Inventory (CSSRI-EU) (RQ4.1).

**Discussion**

As far as we know, this is the first assessor-blind, prospective, multicentric feasibility RCT with subsequent intervention on interaction-based music therapy for children with cancer and their significant others. The already well-researched approaches to individual music therapy with only the child (MUT-K) will be compared to a multi-person setting including the child and his or her significant others (INMUT-KB). The study examines feasibility conditions to successfully recruit, include, and randomize the child-referent dyads, as well as recruit, train and supervise music therapist for the APCI diagnostics and the conduction of the INMUT-KB and MUT-K. It also investigates the implementation of additional study conditions such as the statistical analyses and finally the calculation of the number of child-referent dyads needed for the subsequently planned confirmatory RCT.

**Innovative aspects**

This trial will be the first feasibility RCT that directly compares a multi-person music therapy, including the child-referent dyad (INMUT-KB), with a single child music therapy (MUT-K). It also is the first German RCT that uses a manualized assessment for the child-referent interaction (APCI), in addition to RCTs from other countries like e.g. Denmark [65, 66]. This assessment is adapted for the first time from work with at-risk families into a RCT working with families in paediatric oncology. The questionnaires on psychosomatic complaints (SCL-K-9), relative’s psychosocial burden (BAS), systemic functioning (EXIS), and resources for dealing with difficult situations (WIRF) are being used for the first time with important reference person in the paediatric oncology.

**Biases and limitations**

This study is a feasibility RCT with interest in carefully planning the subsequently confirmatory RCT. All statistical analyses will be descriptive and exploratory with the aim of obtaining data that can be used to design a confirmatory RCT. Consequently, the main RCT is necessary before a confirmatory statement about the effectiveness of interaction-focused music therapy for children with cancer and their significant other can be reliably made. Though this is an assessor-blind study, children and their significant other, as well as the therapists, will be informed about which study arm they will be allocated to. This however is a naturalistic fact of “real world delivery of care” ([67] p. 6). We try to balance direct and indirect allegiance by conducting the music therapy sessions involving equally educated music therapists from the different clinics on the group level and implementing high methodological quality that appears to buffer allegiance [35]. However, due to the small sample size, we will not be able to perfectly control for allegiance effects.

**Perspectives of a confirmatory trial**
We aim to conduct a subsequent, assessor-blind, prospective, multicentric, confirmatory RCT comparing INMUT-KB with MUT-K and a WG in paediatric oncology. We will use the experience and results of our feasibility study to plan an RCT that is, again, lean in content and investigates, with a strong methodological rigor, the efficacy of interaction-based music therapy based on a powered and economically feasible number of child-referent dyads. Furthermore, with the scientific presentation of music therapy effects, we are pursuing a strengthening of professional policy regarding the fight for the approval of outpatient music therapy as a health insurance benefit in Germany. This would be a milestone for comprehensive and needs-oriented support for families with children suffering from cancer.

**Trial status**

The trial is ongoing and is currently recruiting.

**Abbreviations**

APCI
Assessment of Parent-Child Interaction
BAS
Burden Assessment Scale
BIT-T
Bern Inventory of Therapy Goals
CSSRI-EU
Client Sociodemographic and Service Receipt Inventory
DEMO
Demographic data
DGVM
German Society of Behavioral Medicine and Behavioral Modification
DMtG
German Music Therapy Association
EXIS
Experience in Social Systems
GAS
Goal Attainment Scaling
GPOH
Society for Paediatric Oncology and Haematology
GSI
Global Severity Index
HTA
Health Technology Assessment
ICC
intra-class correlations
IFF
Interne Forschungsförderung
IGIM
Interprofessional Graduate School of Integrative Medicine and Health Sciences
INMUT
Interaction-focused Music Therapy
INMUT-KB
Interaction-focused Music Therapy with child-significant other-dyad
ITT
Intention-To-Treat analyses
IQWIG
German Institute for Quality and Efficiency in Health Care
KINDL
Children and young people quality of life
Declarations

Ethics approval and consent to participate

This feasibility RCT will be conducted in accordance with the Declaration of Helsinki [68]. The research unit is located within the Department of Psychology and Psychotherapy at Witten/Herdecke University. Three cooperating clinics, i.e., the Community Hospital Herdecke, Clinic Center Dortmund and Vestic Children's Clinic Datteln, serve the recruitment of the children and their significant others. Both INMUT-KB and MUT-K will be performed at the Nordoff/Robbins Centre for Music Therapy Witten or on the wards of the respective clinics. All interventions will be video recorded. The study was reviewed and approved by the Ethics Committee of Witten/Herdecke University (No. 170/2021). Written informed consent will be obtained from each interested child - significant other dyad. Staff will send or hand out study information, informed consent, and declaration about the usage of video records and will be available to answer any questions by telephone or face-to-face, e.g., in the clinics. All interested persons will be informed that they can end their participation at any time without giving reasons and without negative consequences. Confidentiality at all levels of the study will be always maintained by diagnosticians, therapists, supervisors, researchers, and staff. They bindingly must declare that no information will be passed on to third parties. The study data will be encrypted by identification codes and stored pseudonymously on the server of Witten/Herdecke University.

Consent for publication

All authors have reviewed the manuscript and agree to publication.

Availability of data and materials

All relevant data can be obtained by the first author (CB).

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

CB, BBerg and CHS conceptualized and designed this study. CB and CHS drafted the first manuscript together. AL, DS, BBern, MP as medical directors of the cooperating clinics network fundamentally supported the selection of children with cancer and their important others who appeared to fit well the inclusion criteria. CG performed the randomization. TO will give statistical assistance. SJ an RS trained the APCI diagnostics and provided supervision. LN gave access to the Nordoff/Robbins Music Therapy Centre Witten and provided supervision for the music therapy interventions. All authors critically revised the first version. All authors read and approved the final manuscript.

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Figure 1

Design, assessments and patient flow (CONSORT chart)

Note. APCI = Assessment of parent-child interaction; DEMO = Demographic data collection; KINDL = Children and young people quality of life; EXIS = Experience in Social Systems; BAS = Burden Assessment Scale; SCL-9k = Symptom Checklist; WIRF = Witten Resources Questionnaire