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ORIGINAL ARTICLE

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Short-term effectiveness of music therapy songwriting for mental health outcomes of at-risk parents in the NICU: a study protocol of an international multicenter mixed-methods trial

BACKGROUND
Preterm birth contributes to adverse mental health outcomes of parents dealing with a premature neonate. The main objective of this study is to determine whether music therapy (MT) songwriting during the infants' stay in the neonatal intensive care unit (NICU) is superior to standard care in reducing the risk of postpartum depression in high-risk parents of preterm children throughout the hospital treatment. The secondary objectives include assessment of effectiveness of MT in other aspects of mental health (anxiety level, perceived stress, mental wellbeing, coping, resilience). Furthermore, this trial will evaluate the medical and social factors that may be associated with the effects of MT songwriting.

PARTICIPANTS AND PROCEDURE
The study design is a sequential mixed method study with a dominant status QUAN to qual. The quantitative trial was designed as a parallel, multicenter, pragmatic, randomized controlled trial. The qualitative study is a descriptive phenomenological study that seeks to understand the lived experiences of participants exposed to songwriting. Participants are parents of premature infants hospitalized in NICU (106 families) in 5 hospitals, in Colombia and Poland. Intervention: 3 MT songwriting sessions per week across 3 weeks. Primary outcome: the risk of postnatal depression; secondary outcomes: anxiety level, mental wellbeing, resilience, stress, coping.

RESULTS
The results will be analyzed quantitatively and qualitatively.

CONCLUSIONS
This study will provide a report on the effectiveness of MT songwriting on mental health in at-risk parents of preterm infants.

KEY WORDS
preterm infants; postpartum depression; anxiety; MT; music therapy

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BACKGROUND

Premature birth defined as birth before 37 completed weeks of gestation (WHO, 1977) is one of the main challenges in health services worldwide, affecting approximately 13.4 million premature babies and their parents in 2020, with the greatest burden in low- and middle-income countries (Ohuma et al., 2023). The estimated global preterm birth rate is 9.9% with the national level ranging from 4 to 16% (Ohuma et al., 2023). The burden of preterm birth in Poland was 6.8% and in Colombia 7.3% in 2020 (Ohuma et al., 2023). Preterm newborns are vulnerable to mortality, morbidity and at greater risk of medical, physiological, neurophysiological, and psychological problems throughout their lives, including long-term sequelae (Perin et al., 2022; Wolke et al., 2019).

Preterm birth is one of the key contributors to adverse impacts on the family. Premature birth may be detrimental to the family system. Being a sudden and unexpected event, it causes a loss of control over the situation and is often perceived by parents as a traumatic and stressful event (Jotzo & Poets, 2005; Singer et al., 1999). Premature birth disrupts the transition to parenthood. It prevents gradual and natural preparation for the end of pregnancy and forces the mother to take up the parental role too early. Additionally, the need to hospitalize a child in the neonatal intensive care unit (NICU), separated from the family, along with the natural fear for the child's life and health, often intensifies the negative impact. Research results suggest that mothers of preterm infants are vulnerable to postpartum depression (de Paula Eduardo et al., 2019; Nguyen et al., 2023; Vigod et al., 2010), high levels of stress (Ionio et al., 2016; Singer et al., 1999), anxiety (Malouf et al., 2022; Nguyen et al., 2023), and post-traumatic stress disorder (Cook et al., 2018; Grekin & O'Hara, 2014). The father's mental health after preterm delivery is a relatively under-researched topic compared to maternal mental health in the postnatal period. Research results indicate that postpartum depression may also occur in men (Ansari et al., 2021), especially in the case of premature birth (Nguyen et al., 2023). Fathers of preterm infants might also be vulnerable to higher levels of stress and anxiety (Sandnes et al., 2024), with both being significant risk factors for depression (Vismara et al., 2016). It is important to note that the mental health of mothers and that of fathers in the NICU are linked to each other; for example, maternal depression can be a significant predictor of paternal depression, and vice versa (Edward et al., 2015; Glasser & Lerner-Geva, 2019; Musser et al., 2013; Paulson & Bazemore, 2010). This is important because high levels of anxiety and depression can lead to decreased parental sensitivity in understanding their babies' communicative signals (Zelkowitz et al., 2011), which can lead to insecure attachment patterns (Evans et al., 2012), and consequently more long-term psychosocial, behavioral, and cognitive problems for the child (Groh et al., 2017).

In addition to the above-mentioned research results, it is worth considering how at-risk parents cope with the challenging situation of having a child hospitalized in the NICU. Affleck and Tennen (1991) reported that mothers often used a combination of coping strategies, with the highest proportion seeking social support and meaningfulness in the NICU experience. Fathers most often sought meaning from the experience, followed by mobilizing support and minimizing the experience. Hughes and colleagues (Hughes et al., 1994) concluded that seeking support is the dominant parental coping strategy; however, mothers seek support from their spouses and fathers from the medical professional staff. In general, research indicates that parents more often use emotion-focused coping strategies than problem-focused strategies to deal with their experience of having a preterm infant in the NICU (Ghorbani et al., 2014; Lau & Morse, 2001; Seideman et al., 1997).

Coping is associated with resilience, which is the ability to cope with and/or modify the effects of traumatic events by developing strategies to live a full and meaningful life (Rossman et al., 2017; Southwick et al., 2015). Resilience is a dynamic process while coping refers to chosen strategies of event-associated stress management, which may not always be protective (Fletcher & Sarkar, 2013). Less resilience and more parental adversity are associated with parental coping difficulties after the hospital discharge of their child in pediatric units (Shah et al., 2018). The resilience of parents of premature babies negatively correlates with anxiety and depression and positively correlates with coping tendencies and social support (Xie et al., 2021). Mothers of infants in the NICU can develop resilience by treating their stressors and challenges as opportunities to keep moving forward and for individual growth (Bonanno, 2004; Rossman et al., 2017). Research by Rossman et al. (2017) shows that mothers were developing their strength and resilience by becoming advocates for their infants and by doing everything they could to promote their babies' health.

Family-centered care (Gómez-Cantarino et al., 2020) has been implemented in many NICU departments around the world and among other things relies on parents' involvement in the care and various therapeutic activities aimed at their children to promote their role as primary caregivers. This is particularly important in the context of prematurity, as parents often feel relegated from their role of primary caregiver because of the prominent role of medical staff in the care of their child. As it turns out, parental involvement promotes more effective coping strategies (Ochandorena-Acha et al., 2022). Engagement of parents in meaningful activities in the NICU is essential for their wellbeing (Dür et al., 2018).

Music therapy (MT) is "the clinical and evidence-based use of music interventions to accomplish individualized goals within a therapeutic relationship by a credentialed professional who has completed an approved music therapy program" (American Music Therapy Association, 2020). The effectiveness of MT in reducing anxiety, depression and stress levels has been proven in many groups of patients (Aalbers et al., 2017; Bradt et al., 2013a, b, 2016; Dogan & Senturan, 2012; Giordano et al., 2022, 2023; Kamioka et al., 2014; Nayak et al., 2000; Poćwierz-Marciniak & Bidzan, 2017; Schou, 2014). In terms of NICU context, MT has beneficial effects on both premature infants and their parents. A significant and favorable effect of MT was found in meta-analyses of randomized controlled trials in improving respiratory rate, normalizing heart rate, facilitating increased feeding volume and reducing maternal stress (Bieleninik et al., 2016; Yue et al., 2021). The latest meta-analyses only confirmed the positive effect of musical and vocal intervention on reducing infant heart rate and indicated the need for more good-quality evidence (Haslbeck et al., 2023). The latest research confirmed the promising role of MT in promoting neuroplasticity in preterm children (Haslbeck et al., 2020; Lordier et al., 2019). However, only a few clinical trials so far have actively sought to integrate parents into MT and focused on parental mental health, for example the parent-led singing approach used in LongSTEP (Gaden et al., 2022). Even data from LongSTEP (conducted in both Colombia and Poland, and also in Norway, Argentina and Israel), showing improvements in parental mental health after MT assessed at discharge, did not provide a significant effect of MT on anxiety, depression, and stress levels (Gaden et al., 2022). Several pioneering trials have been conducted in the context of family-centered MT in the NICU, targeting both mothers and fathers (Ettenberger & Ardila, 2018; Ettenberger et al., 2014, 2017; Roa & Ettenberger, 2018), but very little is known about the effectiveness of MT for at-risk parents in the NICU. Thus, more research on this topic must be undertaken to fill the gap.

The primary objective of the proposed clinical trial is to determine whether MT songwriting combined with standard care (SC) during NICU stay is superior to SC alone in reducing the risk of postpartum depression in at-risk parents of preterm children at the end of treatment.

The secondary objectives are as follows for the quantitative part of the study:

1. To assess the incidence of risk of postpartum depression and increased anxiety in parents of premature babies in the early postpartum period.
2. To determine whether MT songwriting combined with standard care (SC) during NICU stay is superior to SC alone in reducing the anxiety level in at-risk parents of preterm children at the end of treatment.
3. To determine whether MT songwriting combined with SC during NICU is superior to SC alone in reducing the risk of postpartum depression and anxiety level in at-risk parents of preterm children during the intervention period.
4. To determine whether MT songwriting combined with SC during NICU is superior to SC alone in reducing stress and improving mental wellbeing in at-risk parents of preterm born children during the intervention period and at the end of the intervention.
5. To examine medical and social factors that may be associated with effects of music therapy songwriting (factors regarding the infant: gestational age, sex of infants, birth weight, type of pregnancy: single/multiple, type of delivery: vaginal/caesarean, Apgar score at five minutes; and factors regarding the parents: age, marital status, education level, employment status, number of children, number of miscarriages and stillbirths, being a first-time mother, perception of the parents' social support network).
6. To evaluate the association between resilience and coping with the risk of postpartum depression and the level of parental anxiety at the end of the intervention.
7. The identification of mediating variables of the effect of music therapy on the risk of postpartum depression and parental anxiety level.

The trial objective for the qualitative part of the study is to understand the lived experiences of participating parents who received music therapy for their mental health.

It is predicted that MT songwriting along with SC during NICU will reduce the risk of postpartum depression and level of anxiety in high-risk parents of preterm children (Bieleninik et al., 2016; Yue et al., 2021). Moreover, MT songwriting might improve wellbeing and reduce perceived stress (De Witte et al., 2022). Following the conclusions of Xie et al. (2021), we also hypothesize that resilience and coping will be associated with less risk of postpartum depression and the level of parental anxiety. Some of the measured variables (social-demographic and medical factors) may mediate the effect of songwriting on the risk of postpartum depression and parental anxiety level (Bieleninik et al., 2021).

PARTICIPANTS AND PROCEDURE

The trial has been designed following the SPIRIT-Outcomes 2022 statement guideline (Butcher et al., 2022).

STUDY DESIGN

This project was designed as a sequential mixed method study with a dominant status (QUAN → qual) (Kroll & Neri, 2009). The quantitative trial is a par-

allel, multicenter, pragmatic randomized controlled trial (RCT) to evaluate whether music therapy songwriting combined with standard care during NICU is superior to standard care alone in improving mental health in high-risk parents of preterm children. The intervention arm will receive music therapy songwriting and standard care and the control arm will receive standard care only. The qualitative study is a descriptive phenomenological study that seeks to understand the lived experiences of participants exposed to songwriting. Ethical approval for the study has been granted by the Research Ethics Committee at the University of Gdansk, Poland (no 30/2023, date of approval: August 10th, 2023) and by the Research Ethics Committee of the University Foundation Sanitas, Bogotá, Colombia (CEIFUS 3820-23, date of approval: December 27th, 2023).

STUDY SETTINGS

The study will be conducted in the NICUs of four hospitals in Colombia: the hospitals Clínica Reina Sofía Pediátrica y Mujer, Clínica Colombia, Clínica Keralty Ibagué, and Clínica Iberoamérica, and one hospital in Poland – the Medical University of Gdansk. The number of beds in each NICU ranges from 12 to 30. All sites have staff possessing the necessary scientific and clinical expertise to conduct the study following previous clinical and research experiences.

ELIGIBILITY CRITERIA

Inclusion criteria. Parents of neonates born at ≤ 32 + $^{6}/_{7}$ weeks of gestation from both single and multiple pregnancies, with an expected hospitalization of at least three weeks from enrollment. No restrictions to gender or nationality will be applied. At least one of the parents needs to provide a signed written consent form. To meet the eligibility criteria, one or both parents should meet at least one of the following cut-offs:

- Mother having a total score of ≥ 10 and/or father having a total score of ≥ 7 on the Edinburgh Postnatal Depression Scale (EPDS);
- Mother and/or father having a total score of ≥ 8 on the Generalized Anxiety Disorder Scale (GAD-7).

Exclusion criteria. Parents of preterm infants in palliative or end-of-life care and preterm infants in social services custody. No restrictions will be placed on medical status of the infants (including auditory screening) because the treatment is targeted at the parents. Parents with known auditory problems that prevent participation in MT. Moreover, parents with a documented mental illness or cognitive impairment that prevents them from being able to complete the study intervention or outcome assessments.

The flow diagram for this study is shown in Figure 1.

TRIAL PROCEDURES

Referrals will be made by medical staff who will provide an oral and written explanation of the proposed research project. It will be emphasized that enrollment is voluntary and that it is possible to withdraw from the trial at any time. When recruiting parents, researchers will follow recommendations based on other research (Bauer et al., 2021), as well as a culturally and context-based approach to maximize target population. The first step of the project is assessing the prevalence of postpartum depression risk and/or increased anxiety among parents of neonates born before 32 + $^{6}/_{7}$ weeks of gestation. After the informed consent form is signed and parental eligibility assessment (at least one of the EPDS or GAD-7 cut-offs) are met, parents will take part in the second intervention part of the project. We aim to gather data from both parents, when possible; thus, the enrollment will take about one week. After the second informed consent form is signed and baseline assessment performed, families will be randomly assigned to receive either songwriting along with the SC or SC alone. Randomization will be made in blocks with random sequences of block sizes of 4. Randomization will be stratified by clinical sites, so a separate list for each NICU setting will be prepared. The intervention will start immediately after allocation.

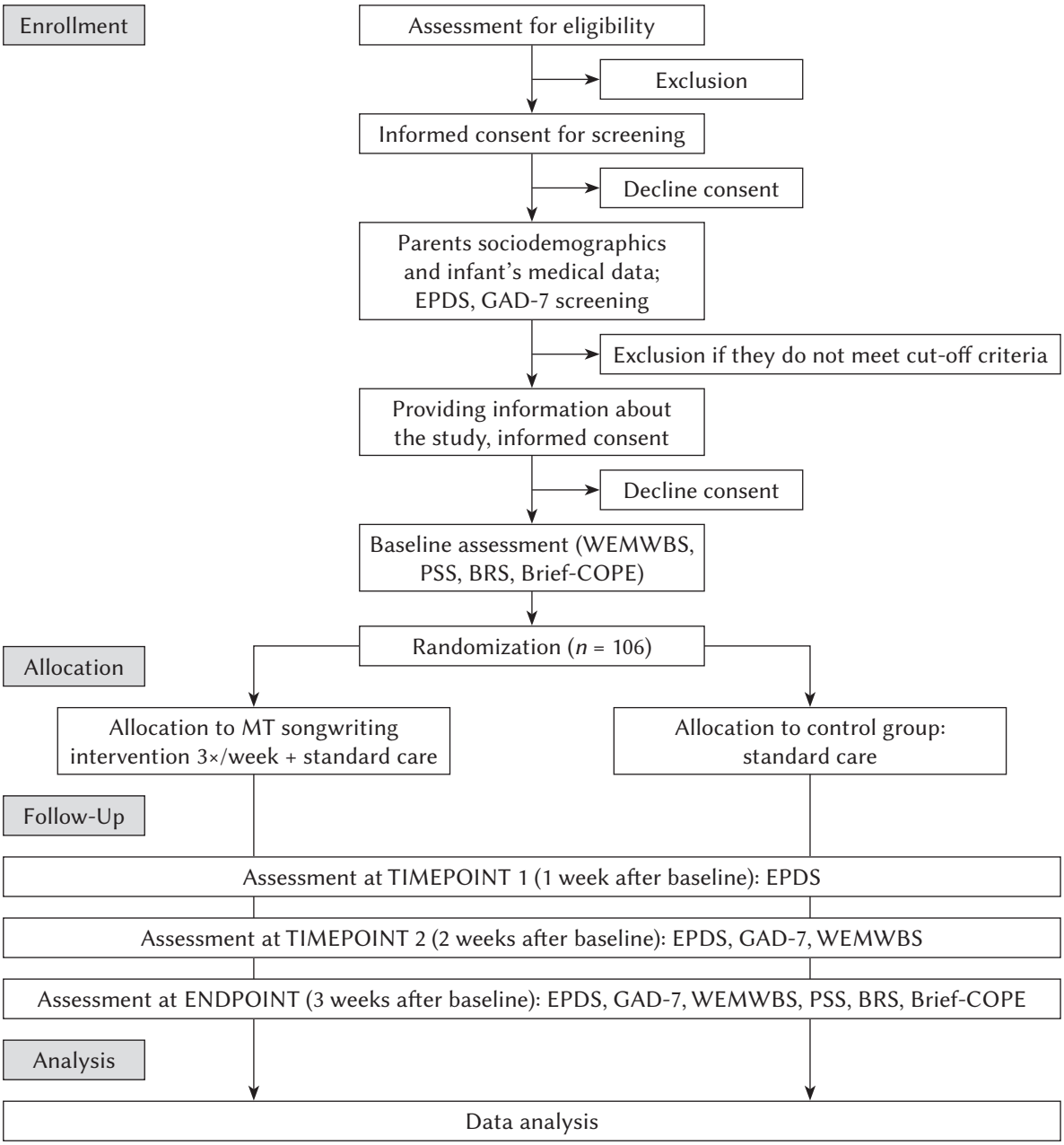
INTERVENTION

A family allocated to the intervention arm will receive 3 songwriting sessions per week across a 3-week period with a minimum of 6 and a maximum of 9 sessions. Each session will last approximately 30-45 minutes. If possible, music therapy will include both parents of premature babies; if not, then at least one. Therapists will be trained music therapists (master's level or equivalent) who have received training in the use of MT with preterm infants and their families. In the event of music therapy lasting two weeks instead of three, paper questionnaire sets will continue to be distributed at scheduled time points (following 1 week, 2 weeks, 3 weeks).

Songwriting is a frequently used method in music therapy sessions (Baker, 2016). It consists of creating the original song's lyrics and/or music together with the participants. Optionally, only the lyrics can be changed to a song already known to the participants, a technique known as 'song parody' (Baker & Wigram, 2005). Its therapeutic value in the NICU consists of promotion of the expression of emotions and ideas by parents, channeling their attention to a concrete project shared between them, giving new meaning to the hospitalization experience, and empowering parents to interact and communicate with their infant in a suitable way for its development.

Figure 1

Flow diagram for the study



Note. EPDS – Edinburgh Postnatal Depression Scale; GAD-7 – Generalized Anxiety Disorder Scale; WEMWBS – Warwick-Edinburgh Mental Wellbeing Scale; PSS – Perceived Stress Scale; BRS – Brief Resilience Scale, MT – music therapy.

MT should be conducted in accordance with the study protocol. A variation of the intervention protocol was piloted in a previous study (Ettenberger & Ardila, 2018) and consists of:

- Session 1: Initial assessment. The goal of the first music therapy session is to get to know the parents musically and provide information about the songwriting process. This is accomplished by exploring their favorite songs, for example, by singing along to the song, humming the tune together, or actively listening to it. The options to create a song (original song or song parody) are presented and the possibilities of developing the lyrics are discussed, for example, writing a letter addressed to the baby, brainstorming, and writing down current emotions and thoughts, among others. At the end of the session, information on the importance of the parents' voice and how they can get in touch with their infant musically is provided. Emotions, thoughts, and sensations that parents perceived during the session are discussed, and they are asked to express them through words, phrases, etc.

Meanwhile, the music therapist takes notes, and the parents are then given the sheet with the written words and phrases. Depending on the parents' desire, they may continue writing down further ideas for the song until the next session.

- Sessions 2-7: During the second to seventh session, the structure of the song will be created and discussed with the parents. Parents will also be invited to include written messages from other family members (e.g., siblings, grandparents, aunts, and uncles) in the lyrics if they wish. The musical elements are discussed in terms of functionality for the infant (relaxation, activation, stabilization). In each session, the developing welcome song will be sung by the parents, accompanied by the music therapist, who will use his/her voice or supporting musical instruments. The musical instruments consist of an acoustic guitar, an ocean drum, and/or a piano to play the basic chord progressions of the song. If the parents wish, the progress of the song will be recorded so that they can listen to it or sing it between the sessions.
- Sessions 8-9: The last sessions will be used to sing the song's final version for their baby with the parents. If the parents agree, a final recording of the song will also be made (outside the NICU in a quiet spot in the hallway or the parent wellness room), and a digital songbook of the song will be created in which they can put the lyrics, pictures of the infant, and decorative elements.

STANDARD CARE

Families allocated to standard care will receive necessary medical and nursing care, which might vary across countries (Poland and Colombia) and clinical settings. Standard care at the NICU may include kangaroo care and NIDCAP. Components of standard care will be collected and reported at each site.

CONTAMINATION

One potential source of contamination arises from providing MT in shared NICU rooms. Parents may observe or learn strategies from other parents in the same room (or, likely to a lesser extent, from other parents or staff on the ward). Contamination may also occur if parents participate in MT offered by sources outside of the study context but during the timeframe of the study. Due to the restrictive eligibility criteria, we do not expect that more than one family will participate in the project at the same time. Moreover, the target group of the project consists of parents of premature babies, with whom therapy will be conducted outside the shared NICU rooms if more than two families are parallel in the ongoing project.

OUTCOMES

Primary outcome

1. The risk of postnatal depression will be measured using the Edinburgh Postnatal Depression Scale (EPDS) developed by Cox et al. (1987), which is the most commonly used depression screening tool in clinical practice and research (Levis et al., 2020). It is a 10-item self-report questionnaire rated on a 4-point Likert scale – the total score ranges from 0 to 30 and higher scores indicate a greater risk for postnatal depression. Optimal cut-off points vary slightly among countries depending on sensitivity and specificity. In this trial, a cut-off of ≥ 10 for the mother and ≥ 7 for the father will be used; these have been used in previous studies in both countries (Latorre-Latorre et al., 2006; Wszołek et al., 2020). A clinically significant change of the EPDS has been defined within the frameworks of the reliable change index (RCI; 4-point differences between two measurements; Matthey, 2004) and the minimal clinically important difference (MCID) of EPDS: 4 points for improvement and 3 points for worsening (Mao et al., 2021). The EPDS was validated in Spanish by Garcia-Esteve et al. (2003) and in Polish by Kossakowska (2013) and Kaźmierczak et al. (2020). Because the time frame for evaluation is over the course of the past 7 days, the EPDS will be applied at all time points.

Secondary outcomes

1. Anxiety levels will be evaluated by the General Anxiety Disorder Scale (GAD-7), which was developed by Spitzer et al. (2006). The GAD-7 consists of 7 items rated on a 4-point Likert scale. Scores range from 0 to 21, with higher scores indicating higher anxiety levels. This trial will use a cut-off of ≥ 8 for both mothers and fathers. Using a cut-off of 8, the GAD-7 has a sensitivity of 92% and specificity of 76% for diagnosis of generalized anxiety disorder (Kroenke et al., 2007; Plummer et al., 2016). The time frame for evaluation is over the course of the past two weeks; thus, the GAD-7 will be applied at baseline, after week 2, and at the endpoint. A cultural adaptation for the Spanish language was developed by García-Campayo et al. (2010) and a recent validation in the Colombian context confirms the scales' suitable psychometric parameters with a Cronbach's α of .92 (Camargo et al., 2023) and in the Polish version with a Cronbach's α of .83 (Basińska & Kwissa-Gajewska, 2023).
2. Mental wellbeing will be measured with the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) developed by Tennant et al. (2007).

The WEMWBS consists of 14 items rated on a 5-point Likert scale ranging from 1 (*none of the time*) to 5 (*all of the time*). The global score ranges from 14 to 70; the higher the global score, the higher the level of mental wellbeing. The original version of the WEMWBS demonstrated good internal consistency with a Cronbach's α value ranging from .89 to .91 (Tennant et al., 2007) and has widely been used in intervention studies (Blodgett et al., 2022). The Spanish version was validated by López et al. (2013) and by Castellví et al. (2014) and the Polish version by Kulawska (2020). The WEMWBS will be applied at baseline, after week 2, and at the endpoint.

3. Resilience is defined as the ability to bounce back from a stressful event. It will be measured with the Brief Resilience Scale (BRS) developed in its original English version by Smith et al. (2008). The BRS contains 6 items rated on a 5-point Likert scale. The Spanish version was validated by Rodríguez-Rey et al. (2016) with a medical and non-medical population. It showed adequate internal consistency with a Cronbach's α of .80-.91 and good test and retest reliability. The Polish version was validated by Konaszewski et al. (2020). The BRS will be applied at baseline and at the endpoint.
4. Stress will be measured with the Perceived Stress Scale (PSS). The PSS is a 10-item tool developed by Cohen et al. (1983) for self-assessment of stress intensity resulting from an individual's life situation during the last month. Higher scores indicate a greater level of perceived stress. The Spanish validation was published by Sanz-Carrillo et al. (2002) and the Polish version by Juczyński and Ogińska-Bulik (2009b). The PSS will be applied at baseline and at the endpoint.
5. Coping will be assessed by the Brief COPE Inventory (Brief-COPE; Carver, 1997). Brief-COPE is a shortened 28-item version of the longer 60-item COPE Inventory and is regularly applied to assess how someone is emotionally responding to a distressing event during the last year. The items are rated on a 4-point Likert scale. The Brief-COPE is divided into three subscales assessing problem-focused coping, emotion-focused coping, and avoidant coping. The Spanish version was validated by Fernández-Martín et al. (2022) and the Polish version by Juczyński and Ogińska-Bulik as the Mini-COPE (2009a). The Brief-COPE will be applied at baseline and at the endpoint.

OTHER DATA

1. Data from parents: age (years), marital status (single/married/divorced/common-law marriage/widowed), education level (primary school/secondary school/high school/undergraduate university education/master's degree/PhD degree), work situation (employed/self-employed/unemployed), number of children in the household, number of miscarriages, number of stillbirths, being a first-time parent (yes/no), negative reproductive experience such as miscarriage (yes/no), and perceived quality of the parents' social support network (scale from 0 to 10).
2. Data from medical records: sex (male/female), gestational age at birth (weeks, days), birth weight (grams), type of pregnancy (singleton/multiple), type of delivery (vaginal/ caesarean), Apgar score at five minutes (Apgar points).

DATA COLLECTION

Data will be collected at the following time points:

- at the eligibility stage (sociodemographic data, EPDS, GAD-7 for both parents);
- at baseline (WEMWBS, PSS, BRS, Brief-COPE for both parents);
- at the end of the 1st week following randomization (EPDS);
- at the end of the 2nd week following randomization (EPDS, GAD-7, WEMWBS);
- at the end of the 3rd week following randomization (end of MT; primary endpoint; EPDS, GAD-7, PSS, BRS, Brief-COPE for both parents).

The participant timeline is presented in Table 1.

DATA MANAGEMENT

Quantitative data from parents and medical data will be collected by a research assistant (during enrollment, baseline, timepoint 1, timepoint 2 and endpoint) who will be trained in data collection procedures. Data will be stored in a licenced REDCap database, guaranteeing data anonymization and safety. Questionnaires should be completed immediately after receiving them, but if families are not able to do this, assessments will be considered valid if completed up to 1 to 2 days following each time point. Every attempt should be made to comply with target (and validity) time windows, but in rare occasions when this is not possible, sites should still gather data for assessments falling outside of the time window. All information should be stored with ID code numbers to maintain participant confidentiality. All records that contain names or other personal identifiers, such as informed consent forms, will be stored separately from study records identified by the ID code number. All study-related information on paper, including questionnaires and administrative forms, should be securely stored in locked file cabinets in areas with limited access. Data will be collected in a paper-and-pencil manner

Table 1

Participant timeline

	Study period					
	Enrollment	Baseline	Randomization	Post-allocation		Close-out
Timepoint	*Before randomization*	*0*	*During NICU stay*	t_1	t_2	*Endpoint*
Enrollment:						
Eligibility screen	×					
Informed consent	×	×				
Allocation			×			
Interventions:						
Standard care			←	—	→	
MT songwriting			←	—	→	
Assessments:						
Sociodemographic form	×					
EPDS	×			×	×	×
GAD-7	×				×	×
WEMWBS		×			×	×
PSS		×				×
BRS		×				×
Brief-COPE		×				×

Note. MT – music therapy; EPDS – Edinburgh Postnatal Depression Scale; GAD-7 – Generalized Anxiety Disorder Scale; WEMWBS – Warwick-Edinburgh Mental Wellbeing Scale; PSS – Perceived Stress Scale; BRS – Brief Resilience Scale.

and transcribed to a digital database in REDCap. To avoid biases, paper versions will be compared with electronic values for 20% of the randomly chosen participants. The entire dataset will be checked if four errors are found in a row.

BLINDING

Due to the nature of the intervention, neither participants nor staff can be blinded to allocation but are advised not to disclose the allocation status of the participant at the follow-up assessments. Data analysis will be carried out by team members blinded to the randomization outcomes.

ADVERSE EVENTS

Serious adverse events (such as resulting in death, life-threatening, requiring prolonged hospitalization, or resulting in a persistent or significant disability or incapacity) will be collected internally and reported to the core team using the adverse event form.

POWER CALCULATION AND SAMPLE SIZE

Quantitative component. To calculate the necessary sample size, the G*Power 3.1.9.7 program was used and was based on the primary outcome, postnatal depression. The assumptions used for the calculation were: effect size $f = 0.25$, an alpha error of .05, power of 85%, 2 comparison groups and 4 measurements over time, for 92 patients. Considering a 10-15% loss to follow-up, the sample will be 106 families.

Qualitative component. A theoretical sample of 25 participants is proposed and will be selected by convenience sampling of the participants assigned to the intervention group (songwriting). From each health institution, there will be 5 participants for the semi-structured interviews. This number of participants may change if data saturation is reached before the proposed sample size is complete.

STATISTICAL METHODS

All randomized patients will be analyzed according to the intention-to-treat (ITT) analysis, performed by a person unaware of the group assignment. A descrip-

tive analysis will be conducted using absolute and relative frequencies for qualitative variables and measures of central tendency and dispersion for quantitative variables, based on their distribution assessed through the Kolmogorov-Smirnov test. To compare primary sociodemographic and clinical data between the two groups to detect differences in the population, Student's *t*-test or its non-parametric equivalent will be used for quantitative variables (depending on the variables' distribution) or the chi-squared/Fisher test for qualitative variables. To assess the effects of songwriting with standard care vs. standard care alone on the depression scale score (primary outcome) and the anxiety, wellbeing, resilience, stress, and coping scales (secondary outcomes), a 2 × 2 mixed factorial ANOVA will be used. This involves one between-subjects factor (composition and standard care) and another within-subject factor (comparison before and after the intervention). The possible interaction between factors will be evaluated by combining factors and the effect size. If there is no interaction, the expected effect is the sum of the two factors. Still, if there is an interaction, the predicted effect differs from the sum. If a statistically significant interaction is identified, subgroup analysis will be conducted (sex, age, support network). Post-hoc comparisons will be performed to explore significant differences between the groups using the independent samples *t*-test. Confidence intervals will be adjusted using Bonferroni correction to control the error rate (probability of type I error). Multiple regression will be used to determine potential mediators between the intervention and the outcomes. For this model type, assumptions of multicollinearity, multivariable normal distribution, independence, and homoscedasticity must be assessed. For the construction of the multiple regression model, the following steps will be taken: 1) univariate regressions of each independent variable with the dependent variable will be performed; 2) candidate variables for the model will be selected, including those with a $p < .25$ in the univariate analysis and those with known biological significance; 3) the contribution of each variable included in the model will be assessed by examining its significance and the effect of its removal on the change in the coefficients of the remaining variables as well as the change in the adjusted R^2; 4) the multicollinearity of each quantitative independent variable will be assessed; 5) possible effect-modifying variables will be evaluated through product terms, one by one, and if any of them is not significant, it will be removed from the model, evaluating the presence of confounding; and 6) the model's residuals will be checked; they should follow a normal distribution for the model to be considered valid.

Results will be considered statistically significant when a *p*-value of less than .05 (5%) is observed. Statistical analysis will be performed using Stata V16 and R V.4.0.3.

QUALITATIVE ANALYSIS

The data from the semi-structured interviews will be analyzed according to the thematic analysis method (Braun & Clarke, 2006; Clarke & Braun, 2013). Thematic analysis identifies, analyses, and reports themes or patterns within a data set. In the first step, the data will be transcribed and organized. In the second step, a list of the general content of the data will be created, and the most striking features of the initial dataset will be highlighted in colors. In the next step, individual segments within the dataset will be coded. The codes will then be assigned and merged into potential sub-themes and themes. In the final step, a thematic map will be created to visualize the codes, sub-themes, and themes.

DISCUSSION

Previous research on MT in the NICU consistently concluded with the need for further investigation. The current study proposal aims to address current knowledge gaps through several domains: parent involvement, mixed methods design, parental with identified mental health risks and international multicenter collaboration. First, parents of premature children should be actively involved in the MT process using songwriting. Although RCTs using songwriting have been conducted so far in different areas (for example: Giordano et al., 2022, 2023), to our knowledge, there have only been two studies focusing on parents of premature children conducted with this method, one in Colombia (Ettenberger & Ardila, 2018; during the NICU stay) and another in Australia (Howden et al., 2023; outside the NICU). Still, none of these trials have included parents at risk of mental health. Second, the current study proposal employs a mixed methods design, as most studies have had either a purely quantitative or qualitative focus. Third, the current study proposal focuses on effectiveness of MT for mental health of parents targeting the risk of depression, anxiety, and stress as the outcome which has been the subject of interest in few studies so far (for example: Arnon et al., 2014; Ettenberger et al., 2024; Gaden et al., 2022; Schlez et al. 2011). Fourth, the current proposal concentrates on parents with identified mental health risks. To the best of our knowledge, this is the first time that a trial targets parents from the high-risk group of postnatal depression and/or increased anxiety as an inclusion criterion. And finally, the current proposal was established as an international multicenter study based on previous research collaborations between the sites. The protocol follows a culturally and context-based approach determined based on completed research in Polish (Bieleninik et al., 2020, 2024; Gaden et al., 2022; Ghetti et al., 2023) and Colombian neonatal settings (Ettenberger et al.,

2014, 2017; Ettenberger & Ardila, 2018). Taken together, this increases the sample size, visibility, and relevance of the results; this study will provide a broader view of the impact of MT in this population.

The findings of the proposed trial will have several practical implications. If successful, this research will indicate the prevalence of risk of postpartum depression and increased anxiety in parents of very preterm babies in the early postpartum period. These results will contribute to indicating what percentage of parents require additional psychological support due to struggling with adverse mental health outcomes during the child stay at the NICU. Second, these results might support strong recommendations to include at-risk parents as primary caregivers following a family-centered care approach (Gómez-Cantarino et al., 2020) in clinical practice. Further, this information can be used to develop targeted interventions aimed at at-risk parents whose child is hospitalized in the NICU, as not only are children born prematurely, but also their parents become parents prematurely. Ending the pregnancy before the scheduled time, lack of preparation to take on the parental role or having a child from the risk group will lead to the perception of the parental role as difficult. Taken together, ensuring appropriate holistic systems, services, investments and policies to take care of parents of very preterm children at the NICU should be a priority for decision-makers and practitioners.

CONCLUSIONS

The current randomized controlled trial protocol is designed with methodological restrictions targeting exclusively at-risk pairs of preterm infants' parents, including highly user-relevant outcomes with standardized measurement tools used in scientific research and clinical practice. A pragmatic approach is applied in several dimensions, such as flexibility of intervention delivery, flexibility of a protocol adherence, primary outcome, primary analysis, and organization (Loudon et al., 2015). Furthermore, the pragmatic approach will allow for greater generalization of the results. The procedures have been adapted to clinical practice as well as a culturally and context-based approach. This proposed trial will allow us to obtain a broad context of the impact of MT songwriting on the mental health of at-risk parents of premature neonates. The results obtained may contribute to practical implications in helping parents cope with premature babies during their NICU stay.

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Ethical approval for the study has been granted by the Research Ethics Committee at the University of Gdańsk, Poland (no. 30/2023, date of approval: August 10th, 2023) and by the Research Ethics Committee of the University Foundation Sanitas, Bogotá, Colombia (CEIFUS 3820-23, date of approval: December 27th, 2023).
The authors declare no conflict of interest.

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