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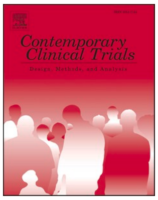

A digital Acceptance and Commitment Therapy and education intervention targeting stress of parents and caregivers with preterm babies in the neonatal intensive care unit: A randomised controlled cluster trial protocol

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ABSTRACT

Background: Parents with babies in the neonatal intensive care unit (NICU) experience high levels of stress, anxiety, and depression. The NICU experience may also lead to impaired parenting and early childhood socio-emotional problems.

Psychosocial interventions can reduce NICU parent distress. Yet many are time-intensive and costly to deliver. Acceptance and Commitment Therapy (ACT), an evidence-based psychological therapy, may address these needs. ACT has been shown to be effective in reducing distress of parents of children with chronic illnesses, particularly when combined with parent education.

Therefore, the primary aim of this study is to determine if a digital intervention that uses a brief form of ACT plus parent education will reduce the stress of primary caregivers with preterm babies in the NICU more than a digital education-only intervention or standard care control group.

Methods: In a randomised controlled cluster trial design, participants will be randomly assigned to one of three groups: ACT plus education; education-only; or standard care control. The primary outcome will be parental/caregiver stress levels, measured on the Parental Stress Scale: Neonatal Intensive Care Unit. Secondary outcomes include overall stress, anxiety, and depression. Outcome measures will be evaluated at baseline, two weeks after enrolment, discharge to home, and 3-months post-discharge.

Conclusion: This study will explore the efficacy of a digital ACT plus education intervention on parental stress levels. While position papers have advocated for the use of ACT with NICU parents, this study will be the first to test ACT as a stand-alone intervention with this population.

Trial registration: This trial was prospectively registered with the Australian New Zealand Clinical Trials Registry on 14 June 2023 (ACTRN12623000641695p).

1. Introduction

A baby's hospitalisation in the neonatal intensive care unit (NICU) can lead to significant negative effects on their parents, including elevated risks of anxiety, depression, and post-traumatic stress disorder [1–3]. These effects can last well after discharge, as NICU parents can continue to experience symptoms of these conditions for 6 months or more after birth [4,5]. Parents may also develop impaired or maladaptive parenting behaviours in the NICU, which can inhibit a baby's socioemotional development and lead to behavioural and neurodevelopmental problems in childhood [6].

Due to the significant negative impacts on parents and infants, a

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Abbreviations: **ACT**, Acceptance and Commitment Therapy; **NICU**, Neonatal Intensive Care Unit; **NPACT**, NICU Parent Acceptance and Commitment Therapy intervention.

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range of psychosocial interventions for NICU parents have been developed to improve parent and infant wellbeing. Three systematic reviews [7–9] support the efficacy of some of these interventions, including family-centred care models that focus on increasing a parent's involvement in their baby's medical care, psychotherapy-based interventions, particularly cognitive behavioural therapy, and psychoeducational interventions. Mindfulness and/or relaxation-based interventions to reduce parental distress in the NICU have also shown promise, particularly for parental anxiety [8]. Yet while these systematic reviews generally provide support for some intervention types, their efficacy findings differ across intervention approaches and parental distress conditions (i.e. anxiety, depression, acute stress). This may be in part because of the heterogeneity of “eclectic” [9] interventions used in studies with NICU parents, with many studies testing complex, multimodal, researcher and/or clinician-created interventions that have not been replicated.

This heterogeneity may also help explain why clinical implementation of effective interventions has been inconsistent across NICUs, as most of these interventions are not manualized and can be time-intensive and costly to deliver [10]. A 2023 survey of psychosocial support services for NICU parents across Aotearoa New Zealand and Australia found that NICUs have limited resources (including staff and funding) and few psychosocial support programmes available to parents [11]. A cross-sectional survey in the US reported similar findings for primary caregivers [12].

In a 2023 qualitative study designed to inform this trial [13], we interviewed NICU parents and clinicians at a Level 3 NICU in Auckland, Aotearoa New Zealand. The majority of parent participants reported that they wanted more emotional support and educational information throughout their baby's admission, as they felt “confused” and “in the dark” about many aspects of the NICU, including common medical procedures their babies were likely to experience and medical terminology used by the staff. The majority also reported that teaching parents and caregivers stress reduction strategies would be highly beneficial to reduce stress.

Acceptance and Commitment Therapy (ACT), an evidence-based form of psychological therapy that incorporates mindfulness, acceptance, and values-oriented behavioural change [14], may address some of these needs. ACT has been studied extensively across a range of populations and found to be effective in reducing distress [15,16]. While it has not yet been tested with NICU parents, ACT may be particularly well-suited to this population for a few reasons. Firstly, it is transdiagnostic [14], meaning it can be used across diagnoses (e.g. anxiety, depression), which is particularly helpful in a population that often experiences elevated rates of multiple conditions including acute stress, anxiety and depression. Second, ACT is grounded in a set of consistent core principles and skills that have been tested and replicated in more than three decades of research [15–17], and this replicability could be useful amongst the highly heterogeneous group of interventions previously developed for NICU parents. ACT can also be delivered effectively in multiple formats (online, individually, and in groups) [18,19], and delivery format is an important consideration in the often resource-constrained environment of the NICU.

Additionally, recent research with ACT and parent populations suggests ACT would likely be beneficial for NICU parents. A 2021 systematic review and meta-analysis of RCTs examining the effects of ACT with parents of children with “special health care conditions” found that the ACT-based interventions led to improvements in parent mental health, including reductions in anxiety, depression, and parental stress [20]. They also reported benefits to the child's physical and/or psychological health. The authors noted that optimal intervention components included pairing ACT with parental training and/or education about their child's health condition.

Finally, ACT has also been found to be effective in reducing distress in diverse cultures around the world [21], and its values-based approach, defined by the individual, not the therapeutic modality, may help with cultural responsivity [22]. This is important in the Aotearoa New Zealand context, where Māori families, the country's indigenous people, are more likely to experience preterm birth and maternal mortality than New Zealand Europeans. Colonisation, racism, and societal (education, housing, financial) inequities contribute to these ongoing negative health outcomes [23]. Multiple qualitative studies [24–26], including our own [13], have described some of the cultural challenges Māori families have experienced in Aotearoa New Zealand NICUs, often related to differences in cultural values.

Therefore, while position papers have advocated for the use of ACT with NICU parents [27], and one clinical trial is underway that uses an “ACT framework” as one part of a multi-modal intervention to support the transition from NICU to home [28], this study will be the first to test ACT as a stand-alone intervention with NICU parents. To do so, we will use a three-armed, randomised controlled cluster trial design that will allow us to evaluate the difference in effect on parental stress levels between an online ACT plus education intervention, an online education-only intervention, and standard care.

2. Intervention background and development

This trial and its components were designed for the Aotearoa New Zealand population in consultation with Māori and non-Māori NICU parents and caregivers, extended family members, and NICU clinicians through a previous qualitative study [13], separate consultations with Māori advisory groups, and existing research on parental stress in the NICU and ACT with parents of children with chronic health conditions (summarized in the Introduction). A digital intervention development framework focused on effective health behaviour change, which emphasizes flexible, user-informed, and potentially overlapping stages of intervention design and evaluation [29], also informed our approach.

In response to the cultural consultation described above to make this trial culturally appropriate for the Aotearoa New Zealand population, all three online courses used in this study include some well-known words of te reo Māori, one of New Zealand's official languages, and start with whakataukī, traditional Māori proverbs commonly used in meetings and educational teachings [30]. The whakataukī and te reo Māori terms were selected and reviewed by this study's two Māori co-authors, a health psychologist and a nurse/researcher.

The digital NICU Parent Acceptance and Commitment Therapy + education intervention (“NPACT”) was built on the online course provider platform Thinkific.com, which has delivered courses to more than 15 million students since its launch in 2013 [31]. The NPACT intervention was pilot-tested with clinicians and NICU parent alumni not involved in the current study. Four NICU clinicians and a health psychology researcher reviewed and tested the full NPACT intervention for accuracy and usability. Based on their feedback, minor changes were made to the intervention to improve readability, update details about the unit, and make the user experience more interactive.

In addition, three NICU parent alumni, who had participated in our previous qualitative study [13], tested the online intervention per the study protocol (i.e. completing one section per day for 7 days) to explore the acceptability and functionality of the online programme. They rated the programme very highly on a five-point Likert scale (average score of 5 = “extremely helpful”), and none reported any technical problems.

3. Aim & objectives

3.1. Primary aim

The primary aim of this study is to determine if a digital intervention that uses a brief form of ACT plus parent education will reduce the stress of primary caregivers with preterm babies in the NICU more than a digital education-only intervention or standard care control group.

3.2. Secondary aims

The secondary aims are to (1) assess the intervention's effects on other parental distress measures including overall stress, anxiety, and depression, and (2) assess any changes in these effects over time (i.e. 2-weeks after enrolment, at discharge, and 3-months post-discharge).

4. Methods

4.1. Study design

A three-armed, single-centre, randomised controlled cluster trial will be used to compare an online ACT plus education intervention (NPACT) with an online education-only intervention and standard care. The randomised controlled trial protocol was developed using the Standard Protocol Items: Recommendations for Interventional Trials guidelines and the Consolidated Standards of Reporting Trials Statement: Extension to Cluster Randomised Trials. It was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12623000641695p).

The study authors are a neonatologist and researcher with expertise in clinical trials; a health psychology researcher with expertise in digital interventions; a practicing health psychologist; a researcher who is also a registered nurse; a biostatistician; and a health psychology PhD candidate who is also a licensed mental health clinician. Only one of the study authors, the neonatologist, works at the study site, and that author will not be involved in data collection or analysis. Additionally, a research nurse, who is also a bedside nurse at the study site, is assisting with recruitment and data collection.

4.2. Study setting

This study will take place at Starship Child Health NICU, located in Auckland, Aotearoa New Zealand, which admits approximately 900 infants annually [32].

4.3. Participants

We aim to recruit 102 participants who are parents, legal guardians, and/or caregivers who are regularly (i.e. multiple days per week) in the NICU from approximately 60 family units (clusters, defined by the related baby or babies in the case of twins). Based on our previous qualitative study [13] with similar eligibility criteria at the same study site, we expect an average of 2 individuals or less per family cluster and most will likely be parent pairs (i.e. mother and father of the same baby).

4.4. Eligibility criteria

Inclusion criteria for participants will include: (1) parents and caregivers who are regularly (i.e. multiple days per week) in the NICU and are (2) 16 years or older and (3) can understand English; (4) and whose babies are born at less than 32-week gestation, (5) are less than 1 week old, and (6) have an expected admission of at least 2 weeks or more at Starship Child Health NICU.

Exclusion criteria for participants will include: (1) severe mental health disorder (e.g. psychosis) requiring in-patient care; and participants whose babies are (2) likely to die in the first week of admission or have died before randomisation, (3) have severe congenital anomalies that require surgery or impact longer-term development or health outcomes and will therefore require specialised support and/or (4) are triplets or more.

5. Procedures

5.1. Recruitment

An experienced research nurse who also works clinically in the NICU and one of the study authors (a PhD health psychology candidate and licensed mental health clinician) will screen all admitted families for eligibility by reviewing clinical data. Parents/caregivers who meet eligibility criteria will be introduced to the study by their NICU clinician. (Before recruitment began, all NICU medical staff were informed about this trial through a NICU Grand Rounds presentation and a staff email.) Interested participants will be provided with a study flyer and asked if the research team could contact them. With permission, a research team member will follow-up by phone, email, and/or in-person with each potential interested participant to assess eligibility and conduct enrolment. All participants will review the Participant Information Sheet and provide informed consent online through the research tool REDCap or through a printed consent form, which will be uploaded to REDCap.

5.2. Treatment allocation

Participants will be randomised by computer programme and stratified by twins into one of the three study arms, with the unit of randomisation as the family group. Families of the same baby (or babies in the case of twins) will be randomised into the same group to avoid sample contamination. Due to the nature of the interventions, treatment group allocation will not be concealed from participants. See Fig. 1 for the participant flow through the study.

5.3. Group timelines

After randomisation, each participant will receive a personalized email that directs them to one of three password-protected, mobile-friendly websites delivered by the online course platform Thinkific.com. These three courses are NPACT; education-only; or the standard care control course. All participants will be asked to complete one online module per day in their assigned course for one week, and they will receive a daily reminder via text or email to do so. A research team member will also contact them by text, phone or in-person to answer any questions they may have about their assigned course.

The second week of the intervention, participants will receive two text reminders throughout the week, directing them to finish or review sections from the previous week and, in the NPACT group, practise at least one of the skills taught within that programme.

All parents in this study will have access to standard care services at Starship Child Health NICU, which includes as-needed referrals to a social worker and mental health clinicians. All participants will receive a gift card at the start of the study to contribute to digital data costs of study participation; a gift card as a thank you for their time after they complete the two-week intervention; and access to the full NPACT intervention after completion of the 3-month post-discharge follow-up.

5.4. Group descriptions

5.4.1. NICU Parent ACT Plus Education Intervention (NPACT) group

The NPACT intervention (Fig. 2) has seven interactive modules designed to teach three core skills involved in ACT: (1) mindfulness for focusing the attention non-judgmentally to the present moment; (2) cognitive defusion activities to build acceptance and a new way of relating to negative thoughts and feelings; and (3) an exploration of a participant's values and the development of a values-based action plan.

Interactive components include mindfulness videos, guided question and reflection exercises, a values-based planning activity, and the options to download content and receive emailed copies of their responses. The intervention also includes short surveys for participants to provide feedback and reflect on the helpfulness of the content.

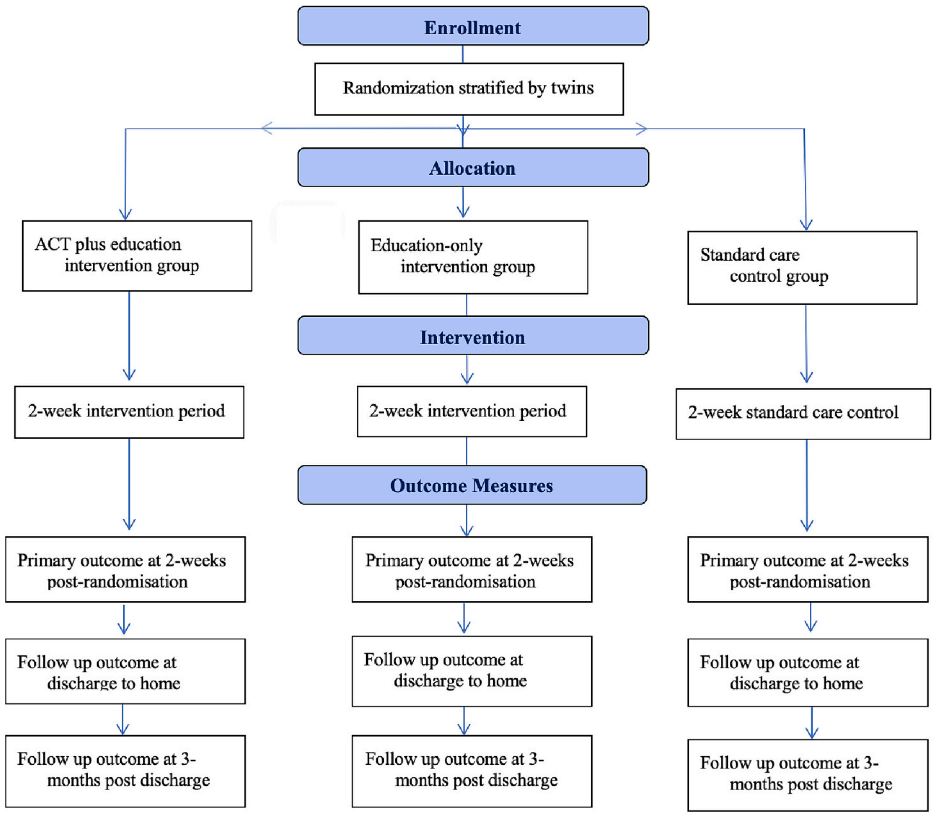

Fig. 1. Participant Study Flow.

Fig. 2. NPACT home screen.

Each section also includes educational information about the NICU and/or preterm babies, informed by the Integrated Family Delivered Neonatal Care app (created by Imperial College Healthcare in the UK) [33] and written by a Starship Child Health NICU clinician. Educational content includes common premature baby medical conditions, treatments used in the NICU, and premature baby cues and behaviours.

5.4.2. Education-only intervention group

The education-only intervention includes the education content from the NPACT intervention, described above. Seven modules cover a range of education topics including common premature baby medical conditions, treatments used in the NICU, and premature baby behaviours and development. The intervention also includes short surveys for participants to provide feedback and reflect on the helpfulness of the content.

5.4.3. Standard care control group

Participants in the standard care control group receive a personalized link to an online course with seven educational modules that use existing Starship NICU parent information web pages.

5.5. Outcomes

This study will explore NPACT's effects on parental stress in the NICU and other measures of distress, including overall stress, depression and anxiety. (See Table 1 for a timeline of outcome measures.)

Table 1
Outcome Measures & Timepoints.

	Baseline	2-weeks post-randomisation	Discharge[b]	3-months post discharge
Demographics	x			
PSS:NICU	x	x	x	
Overall stress	x	x	x	x
Anxiety	x	x	x	x
Depression	x	x	x	x
Psychological flexibility	x	x	x	x
Intervention adherence		x[a]		
Infant clinical data	x		x	

Note: [a] this measure will be collected throughout the 2-week intervention; [b]If discharge occurs more than 1 week after 2-weeks post-randomisation.

5.6. Primary outcome measure

5.6.1. PSS:NICU score at 2 weeks after enrolment

Parent/caregiver stress in the NICU will be measured with the overall stress score on the Parental Stressor Scale: Neonatal Intensive Care Unit (PSS:NICU) [34], designed to assess stressors within the NICU environment. Questions ask parents and caregivers to report their experience of a given situation on a Likert scale ranging from 1 ("not at all stressful") to 5 ("extremely stressful"). The final question asks them to rate their overall stress in the NICU on the same scale. All items will be summed and averaged to generate the overall stress score, and mean scores are classified as low (1–1.9), moderate (2–3.9) and severe (4–5) stress levels.

The PSS:NICU includes a total stress question and four sub-scales (three mandatory and one optional): sights and sounds of the NICU; appearance and behaviours of the baby; the parents' view of their role in the NICU, and the optional communication between parents and staff. The PSS:NICU used in this study does not include the optional communication sub-scale and contains 27 items. Sub-scale scores are calculated as mean scores, and they will be used as secondary outcomes in this study. PSS:NICU scores at discharge to home will also be used as secondary outcomes.

The PSS:NICU has good internal consistency for the overall stress score (Cronbach's alpha of 0.89) and for the subscales (ranging from 0.73 to 0.83). Construct validity was found to be significant between the PSS:NICU and state anxiety (current moment) score on the Spielberger State Trait Anxiety scale [35]. Additionally, each 1-point increase in the PSS:NICU overall stress score has been associated with a 2.1-point (95% CI, 1.6–2.9; $P < .001$) increase in depression scores measured on the Center for Epidemiologic Studies Depression Scale – 10 scale [36].

5.7. Secondary outcomes

5.7.1. Overall stress

The Perceived Stress Scale (PSS) [37] will be used to measure overall stress in all participants. A 14-item scale, the PSS asks participants how uncontrollable or unpredictable their lives feel on a scale of 0 ("never") to 4 ("very often) in the past month. All items on the scale are summed together, with a possible maximum score of 40. A higher score indicates higher levels of perceived stress. The PSS is a well-validated scale with a high internal reliability Cronbach's alpha of 0.88.

5.7.2. Anxiety

The 6-item Spielberger State Trait Anxiety Index (STAI-6) [38], which is the shorter version of the 20-item State Trait Anxiety Index-State (STAI-S) [35], will be used to measure anxiety. Frequently used in healthcare settings [39], the STAI-6 measures state anxiety (how one feels in the moment) using a Likert scale from 1 ("not at all") to 4 ("very much"). This scale gives a score range from 6 to 24. To create scores compatible with the original STAI-S scores, the STAI-6 scores will be divided by 6 and multiplied by 20 to give a range from 20 to 80. Scores of 38–45 indicate moderate anxiety, and severe anxiety is classified as scores of 46 or greater. The 6-item version has been found to be as valid as the long-form version, with an internal reliability Cronbach's alpha of 0.82.

5.7.3. Depression

The short version of the Center for Epidemiologic Studies Depression Scale (CESD-10) [40] will be used to measure depression. This questionnaire asks respondents how often they experience certain feelings such as "everything was an effort" on a Likert scale of 0 to 3 ranging from "rarely or not at all" to "all of the time." Two questions are reverse scored, and answers are summed, with a maximum score of 30. Totals of 10 or more indicate depression, with increasing severity as scores increase. The CESD-10 has strong internal reliability (Cronbach's alpha of 0.86) and high correlations with other depression measures.

5.7.4. Psychological flexibility

Experiential avoidance is a core component of psychological flexibility, the main behavioural process involved in ACT-based interventions [14]. Therefore, experiential avoidance will be assessed using the 9-item Acceptance and Action Questionnaire (AAQ-9) [41]. The AAQ-9 asks participants to rate their agreement with statements such as "emotions cause problems in my life" on a 7-point Likert scale, from 1 ("never true") to 7 ("always true"). Higher scores indicating greater levels of experiential avoidance and psychological inflexibility. The AAQ is a reliable and valid psychological assessment tool with good internal reliability (Cronbach's alpha of 0.7).

5.7.5. Intervention adherence

The intervention delivery platform, Thinkific.com, records participant activity data, including completion rates of modules and completion of intervention activities (such as watching a video or completing a questionnaire). This data will be used to assess participant usage of the intervention and overall adherence. Adherence to the intervention protocol will be defined as participant completion of at least 5 out of 7 modules in each of the two intervention groups.

5.7.6. Infant clinical information

A range of infant clinical data will be collected from the medical record at baseline, including: singleton or twin; Caesarean delivery; infant sex; gestational age, birthweight, and the CRIB II score. Infant clinical information will also be collected from the medical record at discharge to home, including: length of stay, weight, breastfeeding at discharge, and neonatal morbidity measures.

5.8. Ethics and data management

Ethical approval for this study was provided by the New Zealand Health and Disability Ethics Committee (#2023 EXP 17879). Privacy and confidentiality of unit-related data will be performed in accordance with the University of Auckland's ethical guidelines as well as any other local rules and regulations.

6. Statistical methods

6.1. Power calculation

We calculated the sample size with a method that takes into account the intracluster correlation coefficient, the number of participants per cluster, the expected effect, and the power of the study. We calculated to see a reduction in the individual total parental/caregiver PSS:NICU stress score from 2 to 1.8, with a SD of 0.23 at a power of 80%, alpha 0.05. This large effect size relates to between-group improvement in parental stress scores reported in a previous RCT to reduce parental stress in the NICU [42].

We predicted an average cluster size of 1.7 participants per family unit, which is based on our previous qualitative study with similar eligibility criteria at the same study site [13]. We expect most family units will be composed of parent dyads (i.e. mother and father of the same baby), and therefore used an intracluster correlation (ICC) of $\rho = 0.5$, which is the average ICC between parents of hospitalized children on emotional distress metrics reported in a previous study [43]. We added 12% to our sample size to account for potential participant drop-out rates as reported in previous studies [9] and early neonatal death.

Therefore, our total intended sample size is 102 participants from 60 family units. We aim to include approximately 15 Māori participants to match the annual average NICU admission rate of this population to Starship Child Health NICU [32].

6.2. Analyses

The main intervention effects will be evaluated on an intention-to-treat basis. Per protocol analysis will also be conducted for all standard care group participants and all participants in the intervention groups (NPACT and education-only) who complete at least 5 modules. Participants who experience protocol deviations (such as a transfer to another hospital during the intervention period) will be excluded from the per protocol analysis.

For the primary outcomes, the PSS:NICU total stress score at 2-weeks post-enrolment will be analysed using generalised linear regression with the model adjusted for scores at baseline. Secondary outcomes will be evaluated using regression models appropriate to their distributions with similar model adjustments.

6.3. Safety and risk management

REDCap will be programmed to automatically calculate participant scores on the validated scales used to collect outcome measures for anxiety and depression. If a participant's scores meet criteria for severe levels of anxiety (on the STAI-6) or depression (on the CESD-10) as noted above in the outcomes, REDCap will send an automated alert to a member of the research team. In response to this alert, the research team member will refer the participant to the hospital's mental health team (if a parent and their baby is still admitted to the NICU) or to their primary healthcare provider (if a caregiver/extended family member or if the baby is discharged) for additional support.

A data safety committee will not be used in this study as it takes place within the NICU, where parents and caregivers are monitored by medical staff as part of standard care, and is a non-blinded trial at a single site.

7. Results

The New Zealand Health and Disability Ethics Committee (HDEC) provided ethical approval on 16 August 2023 (#2023 EXP 17879). Recruitment began for this trial on Dec 14, 2023. Data collection is expected to be completed by Dec. 31, 2024.

8. Conclusions

Increased psychological distress of NICU parents is associated with a wide range of short- and long-term challenges for parents and infants, including increased risk of mental health disorders [1–3], impaired parenting, and early childhood behavioural and emotional problems [5]. Yet clinically feasible psychosocial interventions for NICU parents and caregivers in Aotearoa New Zealand are lacking [11].

Therefore, this trial will explore the efficacy of a digital ACT plus education intervention to reduce distress of NICU parents using a rigorous randomised controlled trial three-armed cluster design. While position papers have advocated for the use of ACT with NICU parents [27], this study will be the first to test ACT as a stand-alone intervention with this population. If found to improve parental outcomes, this intervention could help address the significant support needs of NICU parents in a cost-effective and clinically feasible way. Future directions can include testing the intervention in a larger clinical trial at multiple study sites and on specific mental health conditions (e.g. depression) and/or exploring longer-term effects on well-being of parents and babies. In summary, this intervention could be a culturally appropriate, cost-effective, and feasible way to improve outcomes for parents and caregivers, families, and infants in the NICU.

Ethics approval and consent to participate

The New Zealand Health and Disability Ethics Committee (HDEC) provided ethical approval of this study on 16 August 2023 (#2023 EXP 17879). All participants will complete informed written consent before participating in this trial.

Consent for publication

Not applicable.

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CRediT authorship contribution statement

Kristin H. Ginsberg: Writing – review & editing, Writing – original draft, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Jane Alsweiler:** Writing – review & editing, Supervision, Project administration, Methodology, Funding acquisition, Conceptualization. **Jen Rogers:** Conceptualization, Methodology, Writing – review & editing. **Alana Cavadino:** Conceptualization, Methodology, Writing – review & editing. **Meihana Douglas:** Conceptualization, Methodology, Writing – review & editing. **Anna Serlachius:** Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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