BMJ Open

Mixed-methods evaluation protocol for the Nurturing Connections Programme: a new Australian perinatal and infant mental health service

Sara Cibralic ,[1,2] Tracey Fay-Stammbach,[3] Angeline Landry,[4] Lee Meredith,[5] Danielle Pretty,[6] Ashleigh Allan,[6] Nicholas Olsen,[7] Jacinta Heath,[3] Deborah Costa,[8] Valsamma Eapen [1,2]

To cite: Cibralic S, Fay-Stammbach T, Landry A, *et al*. Mixed-methods evaluation protocol for the Nurturing Connections Programme: a new Australian perinatal and infant mental health service. *BMJ Open* 2025;**15**:e108094. doi:10.1136/bmjopen-2025-108094

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2025-108094).

Received 18 July 2025
Accepted 13 November 2025

For numbered affiliations see end of article.

Correspondence to
Dr Sara Cibralic;
s.cibralic@unsw.edu.au

ABSTRACT

Introduction Forming secure attachment relationships provides children with the best possible start to life. Children from families with high psychosocial vulnerability and complex mental health needs (eg, caregivers with lived experience of trauma, experiencing mental illness or substance abuse, current or past domestic violence, and/or current or a history of child protection issues) are at the greatest risk of experiencing attachment disturbances. Nurturing Connections is a new early intervention service launched by the New South Wales State Ministry of Health targeting both caregiver adversity and the caregiver-child attachment relationships in families with high psychosocial vulnerability and complex mental health needs. This paper outlines the evaluation protocol of the Nurturing Connections Programme.

Methods and analysis A mixed-methods design will be used to undertake an implementation and outcomes evaluation. The study will draw on both qualitative and quantitative data, including routinely collected service data, surveys, participant observations, and semi-structured interview and yarning circle data. Appropriate descriptive and inferential techniques will be used to analyse quantitative data while thematic analysis will be drawn on to analyse qualitative data.

Ethics and dissemination This research was approved by the South Eastern Sydney Local Health District Research Ethics Committee (2024/ETH01715). The Mid North Coast Local Health District also received ethics approval from the Aboriginal Health and Medical Research Council of New South Wales (2380/25). Evaluation findings will be shared via published manuscripts, conference presentations, as well as a final report to funding bodies.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A significant strength of this evaluation is the use of multiple methods and multiple data sources; this will strengthen the validity of findings.
⇒ A further strength is the recruitment of participants from three different New South Wales local health districts, allowing for evaluation factors that impact change across different participant groups.
⇒ Limitations include the inability to implement a randomised control trial design and a potentially high attrition rate.

INTRODUCTION

The first 2000 days of a child's life (conception to 5 years) have been recognised as a critical period of development,[1–4] with a child's experiences during this phase significantly impacting their cognitive, emotional and physical growth.[5–7] Forming and maintaining a secure caregiver-child attachment relationship (resulting from consistent and sensitive caregiving) during this key formative stage provides children with a strong foundation for mental health and well-being.[8] Conversely, insecure and disorganised attachment relationships, resulting from inconsistent and frightened/frightening caregiving, respectively, have been linked to enduring negative life consequences.[8 9] Young children whose caregivers have moderate to severe mental ill health and other complex needs (eg, substance abuse, current or past domestic violence and/or current or a history of child protection issues) are at the greatest risk of experiencing attachment disturbances and, in turn, the associated challenges in functioning, such as greater emotional dysregulation, lower social competence and poorer mental and physical health.[8 9]

The focus on early intervention and support for children and their families for improving lifelong mental health and well-being outcomes is a key policy priority for government funding nationally and internationally.[10–13] The perinatal period is acknowledged as a critical period for providing prompt and effective care for optimising outcomes for both caregivers and children.[14 15] In Australia, Perinatal and Infant

Mental Health (PIMH) services support caregivers with mental health disorders from pre-conception until the baby is 12–24 months old.[14 16] Drawing on a prevention and early intervention framework, these services focus on addressing caregiver mental health, caregiver-child attachment relationships and child development.[16]

While PIMH services have been effective in addressing both caregiver and child outcomes during the perinatal period,[17 18] caregivers with high levels of psychosocial vulnerability and complex mental health needs often require additional wrap-around support, particularly from social care services, including non-governmental organisations (NGOs) and social workers. This recognition has led to recent calls for the integration of these services and multidisciplinary collaboration, with the expectation that service integration and multidisciplinary collaboration will simultaneously improve caregiver mental health and the quality of the caregiver-child relationship while also reducing barriers associated with psychosocial adversity and service fragmentation.[19]

The Nurturing Connections Programme

In 2024 the New South Wales (NSW) State Government launched the Nurturing Connections Programme[20]—a programme for families who are pregnant or have young children (aged 0–4 years) and have high psychosocial vulnerability and complex mental health needs. The service is overseen by the NSW Ministry of Health Mental Health Branch and delivered by PIMH Services across three local health districts—Northern Sydney, South Eastern Sydney and Mid North Coast—by a multidisciplinary team, including child and family health nurses, PIMH clinicians, social workers and perinatal peer support workers.[21] Nurturing Connections aims to supplement the needs of caregivers accessing support in the NSW Health PIMH services by delivering ongoing, comprehensive care (ie, mental health, child development and social care) to ensure the caregiver's full recovery, support for family well-being and the caregiver-child attachment relationship.

Given that Nurturing Connections is a new service, its impact and effectiveness are unknown. This protocol paper outlines the procedures that will be used to undertake an implementation and effectiveness evaluation of the Nurturing Connections Programme. The evaluation objectives are (1) To evaluate the implementation of Nurturing Connections to determine its feasibility, acceptability and coverage and (2) To evaluate the effectiveness of Nurturing Connections in improving caregiver and child outcomes as well as to identify factors that moderate change across different contexts and groups. To do so, the following research questions will be addressed:

Implementation Evaluation

RQ1. What were caregiver and stakeholder experiences with Nurturing Connections?

RQ2. How satisfied were caregivers and stakeholders with Nurturing Connections in providing caregiver and child care?

RQ3. What were the components of a successful Nurturing Connections Programme model of care?

RQ4. What are the perceptions and experiences of stakeholders in relation to the transition preparation phase, assessment administration, staff delivery of services, family (re)engagement and readiness of the Nurturing Connections Programme model of care?

RQ5. Did the programme reach the intended target group?

RQ6. What programme components were administered and what was the programme completion rate?

RQ7. What additional support services were families referred to beyond the Nurturing Connections?

Effectiveness evaluation

RQ8. Does participation in the Nurturing Connections improve the quality of the caregiver-child (dyadic) relationship?

RQ9. Does participation in Nurturing Connections improve child and caregiver strengths, skills and competencies?

RQ10. Does participation in Nurturing Connections improve caregiver capacity to manage their mental health and community or social needs?

The evaluation will take place over a 2.5-year period (January 2024–June 2026) with results being used to inform service improvement while also providing a springboard for the design and implementation of similar programmes nationally and internationally.

METHODS AND ANALYSIS

Study design

During the development of Nurturing Connections, a programme logic and corresponding outcomes were developed (figure 1). The programme development was led by NSW Health and included stakeholders from participating sites, the academic partner for the programme evaluation (University of New South Wales (UNSW) Sydney), and an Advisory Group. The evaluation methodology was guided by the programme logic and outcomes. A mixed-methods evaluation protocol was developed in accordance with the steps outlined in the Centres for Disease Control and Prevention Framework for Programme Evaluation in Public Health.[22] The evaluation includes two phases: (1) Implementation evaluation and (2) Outcomes evaluation.

The implementation evaluation will use routinely collected service data, qualitative interviews and quantitative questionnaires (ie, Patient Reported Experience and Outcome Measure[23]) to evaluate key implementation outcomes including feasibility, acceptability, adoption, appropriateness, fidelity and coverage.[24 25] The findings

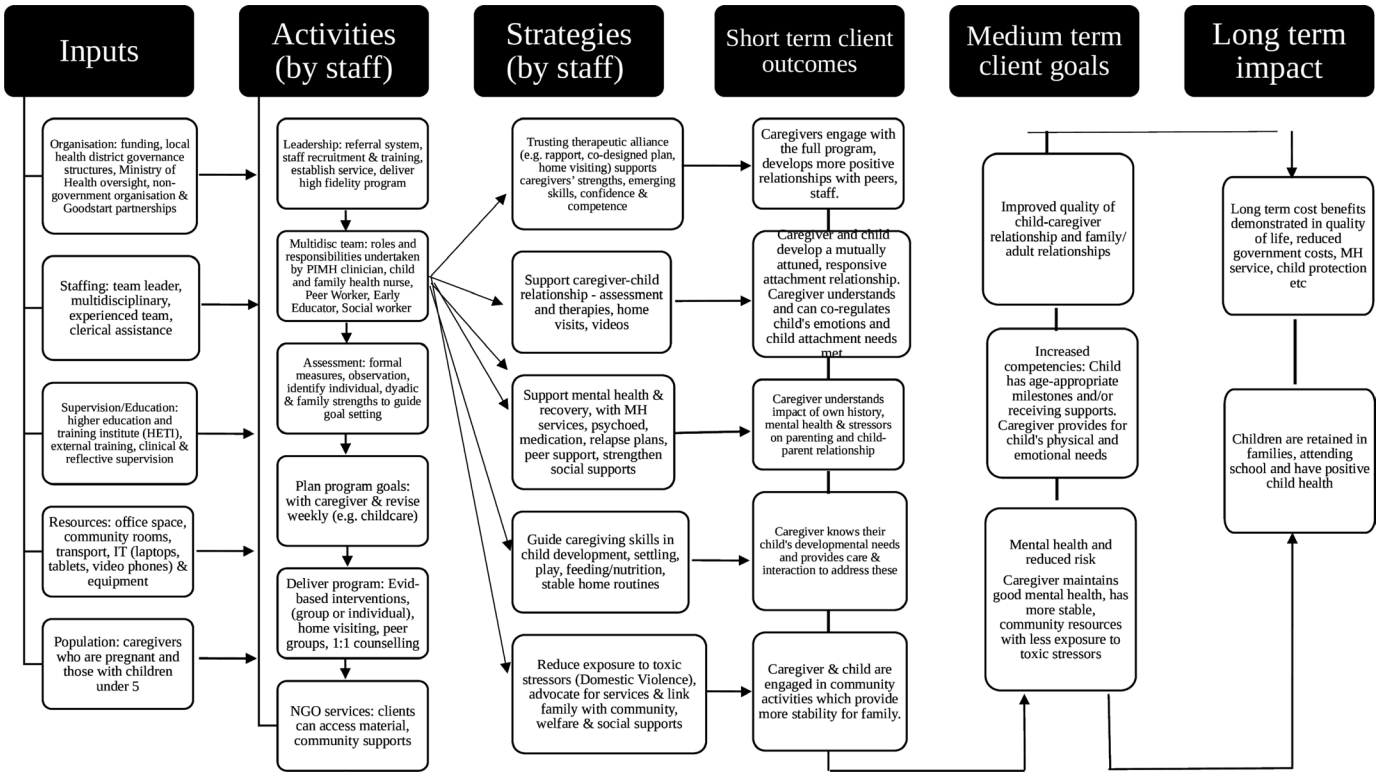

Figure 1 Programme logic and outcomes. *Note*. IT, Information and Technology; MH, Mental Health; NGO, Non-Government Organisation.

are expected to lead to a better understanding of the experiences of both the service users and the service providers' involvement in the Nurturing Connections Programme and help identify perceived barriers and facilitators to programme success.

The outcomes evaluation, also drawing on routinely collected service data, qualitative interviews, observational measures and quantitative questionnaires, will assess whether the programme is achieving its primary clinical goals, namely improvements in caregiver mental health, caregiving capacity, child socio-emotional development and the caregiver-child attachment relationship. Given the evidence that certain programmes may not work across contexts and with certain groups,[25] efforts will be made to acquire information on service users who do not complete the programme or for whom positive improvements are not observed.

Patient and public involvement

The Nurturing Connections Advisory Group comprises senior stakeholder representatives including members from Local Health Districts, policy leaders, subject matter experts, Aboriginal mental health and consumer organisations and/or peer workers. The Advisory Group provides input on programme planning, evaluation, service delivery and policy for the successful implementation and delivery of the programme. The Advisory Group is complemented by a local implementation group with input from consumers with lived experience of mental health difficulties, including Aboriginal and Torres Strait Islander representation.

Participants

Participants will include both service users and stakeholders involved in the Nurturing Connections Programme. Service user participants will include caregivers with young children and high psychosocial vulnerability and complex mental health needs accessing the Nurturing Connections Programme at either of the three NSW local health district sites. Stakeholder participants will include Nurturing Connections clinicians and managers from the three local health districts involved in the development and delivery of the programme.

Service

Nurturing Connections is an entirely new, highly specialised mental health service that offers dyadic intervention to caregivers who have children aged 0–4 years and who also experience high vulnerability and complex needs, including a diagnosed mental health illness. The service was developed following the identification of an unmet service need for families who have young children, high vulnerability and complex needs, with these families often being ineligible to receive mental health services as the acuity criteria are not met or the services are not available in the sector, for example in the case of Regional NSW where direct PIMH services do not exist. Following a competitive expression of interest process, the NSW

Ministry of Health funded three local health districts to deliver the service.

In comparison to existing services, Nurturing Connections focuses on caregivers with a diagnosed mental illness who are not in the acute phase of that mental illness. Both caregiver and child are consumers of the service (rather than the adult or child alone, which is the case for adult mental health and child mental health services 0–18 years, respectively). The service is longer in duration (6–9 months vs 3 months), is led by senior mental health clinicians (rather than a psychiatrist) and is comprised of a multidisciplinary team (detailed below). While PIMH and Child and Adolescent Mental Health services are also comprised of multidisciplinary teams, workers are hired as mental health clinicians or case managers. In Nurturing Connections, social workers, for example, are employed to carry out their professional roles in supporting families with psychosocial stressors. Distinct from available mental health services, Nurturing Connections employs a Child and Family Health Nurse, highlighting the focus on child development and the relationship between developmental delay and parent-child attachment challenges. Furthermore, the service focuses on prevention first by teaching caregivers' factors such as early infant cues to help build understanding of child development and attachment needs as well as early nutritional requirements. Conversely, existing adult and child mental health services primarily focus on intervention.

The service draws on biopsychosocial-cultural, trauma-informed and attachment models, acknowledging that multiple factors can impact caregiver and child outcomes. It provides evidence-based interventions, including attachment-focused therapies (eg, Building Early Attachment and Resilience)[26] and parent training (eg, Happiness, Understanding, Giving and Sharing)[27], home visiting, mental health perinatal peer support work, child developmental screening and support and psychiatric support. Furthermore, the service partners with non-government organisations to provide service users with integrated social and welfare supports needed to address psychosocial needs and/or social determinants of health, such as housing security, transport, Domestic and Family Violence and court advocacy services.

Setting

Northern Sydney Local Health District covers an urban area of 900 km^2 (population: 985 708).[28] The Nurturing Connections team is situated within the Macquarie Hospital campus but offers home visiting support across the entire local health district. The service is managed by one full-time PIMH coordinator and staffed by 2.5 full-time equivalent (FTE) senior mental health clinicians, one bilingual mental health clinician (0.6 FTE), one peer worker (1 FTE), social worker (1 FTE), one child and family health nurse (0.9 FTE) and one child and adolescent psychiatrist (0.2 FTE).

South Eastern Sydney Local Health District covers an urban area of 468 km^2 (population: 979 370).[29] The Nurturing Connections team is based in Hurstville and is made up of one full-time PIMH manager and three full-time treating clinicians, one perinatal peer worker (1 FTE), one child and family health nurse (1 FTE), one perinatal psychiatrist (0.2 FTE), one cross-cultural worker (0.2 FTE) and one family NGO worker (1 FTE).

Mid North Coast Local Health District covers an area of 11 335 km^2 (population: 226 422, 7.5% Aboriginal and/or Torres Strait Islander) and is considered a rural local health district within NSW.[30] The Nurturing Connections team is situated within the Kempsey Local Government Area, managed by a full-time PIMH coordinator (Clinical Psychologist), and staffed by one social worker (0.6 FTE), four full-time mental health clinicians, one full-time Aboriginal identified position, one perinatal peer support worker (0.8 FTE), one full-time child and family health nurse and one psychiatrist (0.2 FTE).

Procedure and data collection

To achieve the evaluation aims, both quantitative, observational and qualitative data will be collected during the evaluation period (December 2024–June 2026). Please refer to table 1 for an overview of planned activities to address each research question.

Quantitative data collection

Review of routinely collected service data

As part of attending a NSW Health Service, routine data relating to the attending family is collected. Within 12 to 24 months of families completing the Nurturing Connections Programme, a retrospective file review will be undertaken to determine the number of clients referred to the service, client characteristics (eg, demographics, risk factors); programme delivery metrics (eg, programme components delivered, number of programmes delivered, and the number of people attending each programme); number of families referred to additional support services beyond the core programme, insights into the extent of participants' needs and the programme's ability to address these needs comprehensively; and the number of families accessing additional services. This is expected to reflect the delivery of the core programme and the programme's effectiveness in facilitating connections to supplementary resources and support networks.

Snapshot study

During the first 12 months of the Nurturing Connections Programme, caregivers attending the service will be recruited for a 'snapshot study' to evaluate the programme's impact on additional caregiver and child outcomes. All caregivers participating in the service will be eligible to take part. Those who choose to participate will complete study measures at four time points (described in detail below).

Design

A single group, longitudinal preintervention and postintervention design will be used, with repeated measures administered at all four time points. Though caregivers

Table 1 Evaluation questions and planned activities to address questions at each evaluation phase

Evaluation question	Planned activities
Implementation evaluation	
RQ1. What were caregiver and stakeholder experiences with Nurturing Connections?	Semi-structured interviews with caregivers
RQ2. How satisfied were caregivers and stakeholders with Nurturing Connections in providing parent and child care?	Semi-structured interviews with caregivers; brief exit survey (POEM) administered to service users on discharge
RQ3. What were the components of a successful Nurturing Connections Programme model of care?	Semi-structured interviews with caregivers and stakeholders (service providers overseeing or administering Nurturing Connections
RQ4. What are the perceptions and experiences of stakeholders in relation to the transition preparation phase, assessment administration, staff delivery of services, family (re)engagement and readiness of the Nurturing Connections Programme model of care?	Semi-structured interviews with stakeholders (service providers overseeing or delivering Nurturing Connections)
RQ5: Did the programme reach the intended target group?	Analysis of routinely collected service data
RQ6: What programme components were administered, and what was the programme completion rate?	
RQ7: What additional support services were families referred to beyond the Nurturing Connections?	
Effectiveness evaluation	
RQ8. Does participation in the Nurturing Connections improve the quality of the caregiver-child (dyadic) relationship?	Analysis of snapshot study data to assess preintervention, postintervention and medium-term changes on a range of relevant variables
RQ9. Does participation in Nurturing Connections improve child and caregiver strengths, skills and competencies?	
RQ10. Does participation in Nurturing Connections improve caregiver capacity to manage their mental health and community or social needs?	

who access Nurturing Connections are not in an acute phase of illness, their often-complex presentations meant that the use of comparison or control groups was not possible for ethical reasons. Past research has, however, indicated that single group research designs are able to provide evidence of intervention effectiveness, particularly for groups that have stable illness presentations.[31]

Recruitment

After being referred to the Nurturing Connections Programme caregivers will undergo the standard intake procedure which will be undertaken by the Principal Investigator at each site. During the intake phone call, the caregiver will also be informed about the research study. For families who are suitable for the Nurturing Connections Programme, an initial assessment session will be scheduled.

Nurturing Connections Programme eligibility

Families will be eligible to attend Nurturing Connections if: (1) The caregiver is pregnant (≥24 weeks) or is a primary caregiver (including kinship or foster care) of young children (0–4 years) with whom they reside, (2) The caregiver has a primary diagnosis of a moderate-to-severe or complex mental health disorder (based on referral or triage assessment) with or without comorbidities (eg, trauma, substance misuse), (3) The caregiver's mental illness significantly impacts the caregiver-child relationship (based on the triage assessment), (4) The caregiver has two or more psychosocial vulnerabilities (eg, economic hardship, low social support, domestic violence, teenage parent, out of home care history), and (5) The caregiver resides within the catchment area. Families will not be eligible to attend the Nurturing Connections service if any of the following are evident: (1) The caregiver has an acute mental health disorder that requires active care from acute mental health services (eg, inpatient care or mother-baby units), (2) The family is already engaged in other family focused programmes (eg, Whole Family Teams[32]), (3) The caregiver has untreated, active substance dependence or problematic use and is unwilling to engage in treatment or care, (4) The caregiver is placed under a court-ordered parenting assessment or programme (eg, from the Children's Court) or (5) The child has been assumed into care and is currently not living with the caregiver.

Snapshot study eligibility

Caregivers interested in taking part in the research study will, in addition to fulfilling the Nurturing Connections Programme eligibility criteria, require spoken-and-written English proficiency (required to complete questionnaires). Eligible caregivers will be told that the study seeks to evaluate how beneficial the Nurturing Connections Programme is to families. They will then be sent the Participant Information Sheet and Consent Form documents via email by the site Principal Investigator.

Procedure

Caregivers who are willing to take part in the study will be asked to sign the study consent form and complete the Time 1 (T1, baseline) survey online administered via

REDCap[33] as well as participate in a 6 min caregiver-child interaction task during their initial face-to-face appointment. The treating Nurturing Connections clinicians will be available to support caregivers to complete the questionnaires. During this time, the treating clinicians will also complete the child emotional and social well-being questionnaire.

The caregiver online survey includes a combination of self-report and parent report measures that evaluate caregiver mental health, caregiver self-efficacy, caregiver reflective functioning and the caregiver-child attachment relationship. These measures are described in detail below. During the 6 min caregiver-child interaction task, caregivers will be instructed to 'play with (their) child as they normally would without toys' for 3 min. Researchers will then provide the caregivers with toys and instruct them to 'play with (their) child as (they) normally would with toys'. This task will either be recorded and coded at a later date or coded immediately for families who do not consent to being recorded. The data will be used to evaluate atypical caregiver communication, a factor that has been implicated in disorganised attachment.

Following the completion of T1 assessments, caregivers will commence the Nurturing Connections Programme. Time 2 (T2) assessments will be completed approximately 6 weeks after programme commencement (mid-point). On completion of the programme, Time 3 (T3) assessments will be completed. Finally, Time 4 (T4) assessments will be undertaken in 3 months post programme completion. As compensation for their time, participants will be given a $30 gift voucher after each of the four assessments. Figure 2 provides a summary of participant flow through the study. See table 2 for an overview of measures included at the various assessment time points and the variables of interest that they align with.

Measures

A combination of self-report, parent report, clinician report and observational measures will be used.

Caregiver mental health will be assessed using the Kessler Psychology Distress Scale (K10).[34] The K10 is a ten-item self-report measure, which requires respondents to indicate, on a five-point Likert scale, the frequency at which they have experienced depression, anxiety and somatic symptoms in the preceding 4 weeks. A score of 1 indicates 'none of the time' and five indicates 'all of the time'. Scores are combined to calculate the total score. Scores ranging from 20 to 24 indicate mild psychological distress,

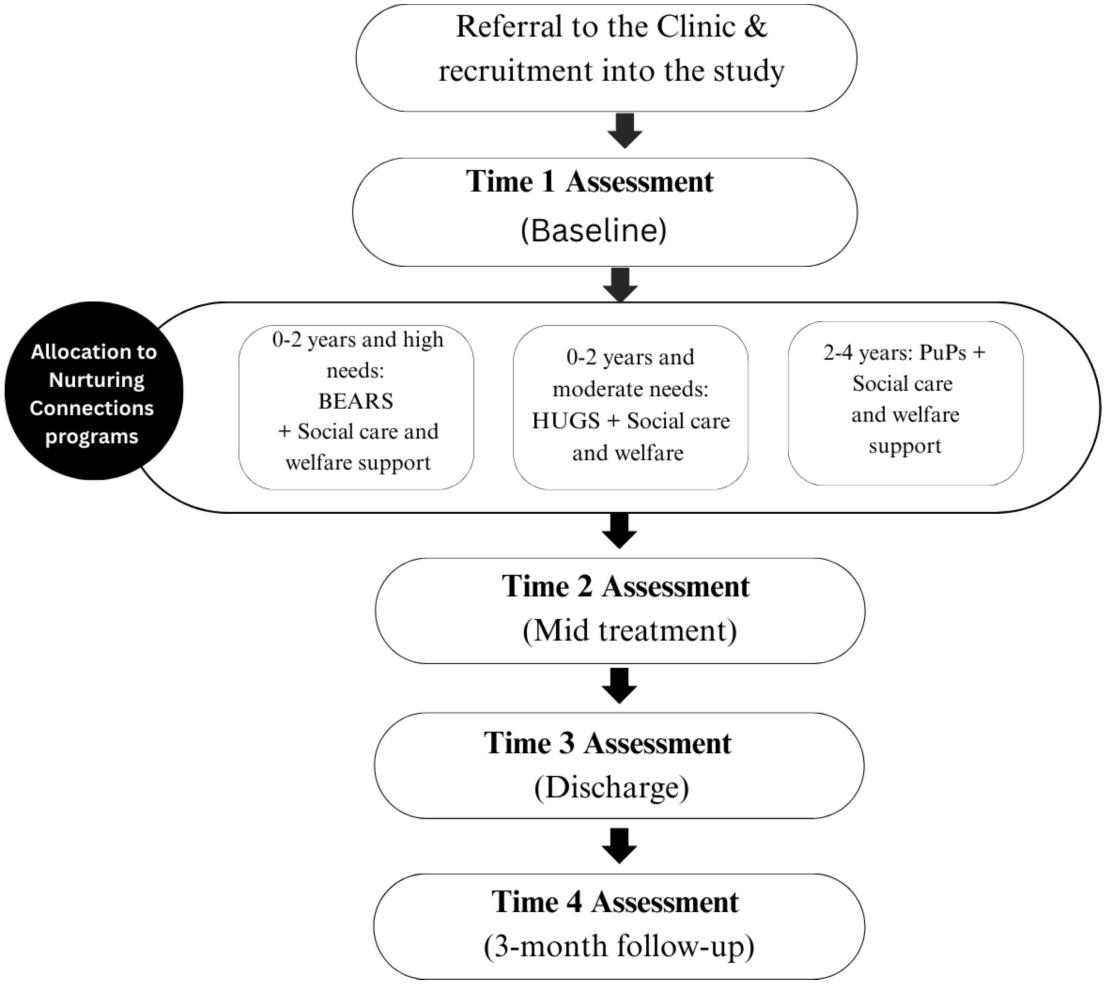

Figure 2 Participant flow through the snapshot study. *Note*. BEARS, Building Early Attachments and Resilience Support; HUGS, Happiness, Understanding, Giving and Sharing; PuPParents under Pressure.

Table 2 Snapshot study quantitative variables, measures and data collection time points

Variable	Information/measure	Completed by	T1	T2	T3	T4
Demographic information	Demographic questionnaire, clinical interview	Caregiver	x			
Child socio-emotional outcomes	Health of the nation outcome scales for infants,[37] Health of the nation outcome scales for children and adolescents[39]	Clinician	x	x	x	x
	Devereux Early Childhood Assessment for Infants/ Toddlers (DECA-I/T)[47] and Preschool Programme (DECA-P2)[39]	Caregiver	x	x	x	x
Caregiver psychological distress	Kessler Psychology Distress Scale (K10)[34]	Caregiver	x	x	x	x
Caregiver self-efficacy	Me as a parent scale short form[35]	Caregiver	x	x		x
Caregiver communication/ attunement	Atypical Maternal Behaviour Instrument for Assessment and Classification (AMBIANCE-Brief)[40]	Caregiver	x		x	
Caregiver reflective functioning	Parenting reflective functioning questionnaire[36]	Caregiver	x	x	x	x
Service experience	Patient rated outcome and experience measure[23]	Caregiver			x	

25 to 29 indicate moderate psychological distress, and 30 to 50 indicate severe psychological distress.

To evaluate *caregiver self-efficacy,* the Me as a Parent Scale[35] (MaaPS) Short form will be used. The MaaPS short form is a four-item self-report measure that requires caregivers to indicate on a five-point Likert Scale their agreement with each statement. Scores are added to calculate a total score, with higher scores indicating greater parental self-efficacy.

Caregiver reflective functioning will be measured using the Parenting Reflective Functioning Questionnaire[36] (PRFQ) (Luyten *et al*), an 18-item self-report measure. Participants respond to statements on a seven-point scale (1=strongly disagree, 7=strongly agree). The 18 questions are divided into three subscales: (1) Pre-Mentalising Modes of Mental States, (2) Certainty about Mental States and (3) Interest and Curiosity in Mental States. The Pre-Mentalising Modes of Mental States subscale assesses a caregiver's ability to understand and interpret their children's mental experiences, with higher scores indicating a greater inability to understand that children have an inner world of thoughts, feelings and emotions (ie, difficulty in mentalising). Certainty about Mental States subscale assesses caregivers' confidence in understanding their child's mental states. Greater scores on this subscale indicate overconfidence, and thus lower scores on this subscale are considered more appropriate. Interest and Curiosity in Mental States subscale evaluates a caregiver's interest in exploring and understanding a child's mental states and emotions, with higher scores indicating greater parental curiosity and interest.

Caregiver experiences of the service will be assessed using the Perinatal Patient Rated Outcome and Experience Measure[23] (POEM). The POEM is a 14-item self-report questionnaire designed to assess perinatal clients' service experience on service discharge.

Child emotional and social well-being will be evaluated using the Health of the Nation Outcome Scales. There are two age-specific versions of the scale—an infant/toddler version (HoNOSI;[37] designed for children aged 0–47 months; 15 items) and a child/adolescent version (HoNOSCA;[38] 3–18 years; 15 items). The HONOSI and HoNOSCA will be rated by clinicians. Higher scores on these scales indicate greater difficulties.

The caregiver-child attachment relationship will be assessed by the Devereux Early Childhood Assessment (DECA) attachment/relationships subscale. Three age-specific versions of the scale - an infant version (DECA-I[6]; 1–18 months; 15 items), a toddler version (DECA-T[6]; 18–36 months, 18 items) and a preschool version (DECA-P2[39]; 3–5 years; 9 items) will be used. Greater scores on this parent-reported standardised measure indicate a better caregiver-child attachment relationship.

Atypical caregiver communication will be coded using the Atypical Maternal Behaviour Instrument for Assessment and Classification[40] (AMBIANCE-Brief; 45 items) from direct observations of 6 min caregiver-child interactions. All coding will be undertaken by a primary coder with 25% of cases being double coded to ensure inter-rater reliability. Coders will be masked to assessment time point.

Qualitative data collection

Semi-Structured interviews will be conducted with service users (Nurturing Connections clients) and service providers (Nurturing Connections managers and clinicians) with a particular focus on implementation evaluation metrics[24] as detailed in table 3. Mid North Coast local health district service users from an Aboriginal and Torres Strait Islander background will have the opportunity to either attend the individual interviews or be invited to attend yarning circles, based on their preferences.

Purposive sampling will be used to recruit 10–20 service users.[41] Service users will be invited to participate in interviews when they have either (1) Completed the Nurturing Connections Programme, (2) Disengaged from the service

Table 3 Implementation evaluation metrics

Measure	Questions addressed by each implementation measure
Acceptability	Do consumers and service providers perceive the programme as agreeable?
Feasibility	Do consumers and service providers perceive the programme as feasible?
Adoption	To what extent do consumers and service providers use the programme model?
Appropriateness	Do stakeholders perceive the programme as relevant and useful?
Fidelity	Is the programme applied as intended? Are all components delivered as planned?
Coverage	How many service users of those eligible are reached?
Sustainability	What are the factors that will allow the programme to be scaled up?

due to no longer being available to attend (eg, needing to return to work) or (3) Disengaged from the service due to not seeing the benefit of continuing to attend the service (eg, no improvement in child behaviour). As saturation increases with various groups, an effort will be made to engage under-represented groups as a means to gather diverse perspectives. Those who agree to participate will take part in a 15–30 min interview via Zoom, Microsoft Teams or telephone. Yarning circles, which will be undertaken in the Mid North Coast, will be facilitated by Aboriginal staff members who have not been directly involved in the programme. Interviews and yarning circles will explore service users' reasons for accessing the service, experiences and satisfaction with the services, perceived benefits, and facilitators and barriers to access and outcomes (See online supplemental file 1 for the interview guide). As compensation for their time, participants will be offered a £30 gift voucher.

Purposive sampling will be used to recruit 10–15 service providers (approximately five from each local health district).[41] Service providers will be invited to participate in interviews during the first year of the programme. Interviews will be conducted via Zoom or Microsoft Teams and take approximately 15–30 min. During the interview, participants' perceptions of the core components of the service as well as perceived facilitators and barriers to early implementation of the service will be explored (See online supplemental file 1 for the interview guide).

Data analysis

Quantitative data analysis

Quantitative data will be collected via the REDCap platform[33] and stored securely on password protected UNSW REDCap servers. The use of REDCap's question reminder feature will minimise missing data due to missed or unanswered questions. In addition, service providers will collect data on programme components that have been administered (eg, which standardised intervention group participants received). Appropriate descriptive and inferential techniques will be used to analyse the data in IBM SPSS Statistics, V.30.[42] For each of the main snapshot study outcomes (caregiver psychological distress (K10); parenting self-efficacy (MaaPS); caregiver attunement (AMBIANCE-Brief); caregiver reflective functioning (PRFQ); child socio-emotional functioning (HoNOSI/HoNOSCA) and caregiver-child attachment relationship (DECA)) a General Linear Mixed Model (GLMM) or non-parametric equivalent tests across four time points will be used, assessing interactions within and between categories. The fixed effects will include data collection time point as categorical (T1, T2, T3 and T4), standardised intervention components (Building Early Attachments and Resilience Support,[26] Happiness, Understanding, Giving and Sharing,[27] Parents Under Pressure,[43] and the intervention x time interaction, as well as study site (Northern Sydney, South Eastern Sydney, Mid North Coast). The model will incorporate random intercepts for participants as well as random slopes for participants over intervention. The covariance structure will initially be unstructured, but if this fails to converge, diagonal (uncorrelated) random effects will be used. Cluster-robust (sandwich) variance estimators will be used due to potential clustering of observations within site.

For a sensitivity analysis, we will also allow interactions between site and timepoint, to test whether secular trends at the level of cluster affect the estimates of treatment effect. Due to the large number of df this will consume, and the corresponding decline in power, the focus will be on the stability of the effect (direction and magnitude of effect sizes) rather than formal hypothesis testing for this sensitivity analysis.

An intention-to-treat analysis will also be undertaken, with participants included in the analysis within the treatment group they were originally assigned to, regardless of the amount of treatment received.

Missing data/drop-outs

GLMMs are robust to data missing at random, given a correctly specified model and covariance structure, when the model also incorporates predictors of missingness. Baseline predictors of missingness will be obtained by mixed-effects logistic regression. Any predictors of missingness will then be included in the GLMM as covariates. As a sensitivity analysis for missing data, we will use multiple imputation, with 20 imputations and 20 iterations. Imputations will be combined using Rubin's rules. While it is possible that data may be missing not at random, addressing this will not be feasible for this study; however, we will note this as a potential limitation of the analysis.

Sample size and power calculations

As Nurturing Connections is a new service, there are no prior effect sizes that can be ascertained from the available literature. Consequently, with guidance from a statistician (author NO), the decision was made to test sample size and power under three different conditions: small (d=0.3), medium (d=0.5) and large (d=0.8) effect sizes. Assuming a drop-out rate of 20% and n=120, power under each effect size is 0.9, 0.99 and 1 respectively, using paired t-tests (pre-post intervention). Inversely, the sample size required for 80% power was 90, 34 and 15 respectively for low, medium and large effect sizes. The sample size required for 90% power was 119, 44 and 19 respectively for low, medium and large effect sizes. Given that there is a fixed pool size for recruitment of 150 (50 per local health district), there is sufficient power to detect low to large effect sizes, even with drop-out.

Qualitative data analysis

Qualitative interviews and yarning circles will be audio recorded and transcribed verbatim. The interviews will be stored securely on the UNSW OneDrive and Teams platform, which are rated by UNSW as the most appropriate platforms to store highly sensitive research data.[44] Access to raw data will be password protected and will only be accessible to key research personnel. NVivo V.12 software[45] will be used to undertake coding and analysis. The thematic analysis method will be drawn on to evaluate the data. Using the thematic analysis framework approach,[46] the evaluation will begin by coders initially familiarising themselves with the data. A coding framework based on the research questions will then be developed. Subsequently, coders will apply this framework to the data (indexing), summarise the data under headings from the framework (charting), and interpret the findings.

ETHICS AND DISSEMINATION

This study was approved by the South Eastern Sydney Local Health District Research Ethics Committee (2024/ETH01715). The Mid North Coast Local Health District also received ethics approval from the Aboriginal Health and Medical Research Council of New South Wales (2380/25). The findings from this evaluation will be shared through published manuscripts, conference presentations and reports to funding bodies, policy makers and stakeholders. A copy of the evaluation results will also be sent to participants who indicated on the consent form a desire to receive the results.

Participant safety

Potential risks will be mitigated by ensuring that participants are recruited by Nurturing Connections staff who are trained in obtaining informed consent. Furthermore, Nurturing Connections staff will be available to assist with measure completion and intervene if any distress is experienced by participants when completing self-report and/or observational measures. In addition, the qualitative interviews will be undertaken by a clinical psychologist who is equipped to address any risks that may arise. As per ethics guidelines, any adverse or unintended effects will be reported to the relevant authorities and human ethics committees.

DISCUSSION

This protocol outlines the evaluation methods that will be implemented to assess the Nurturing Connections Programme. As Nurturing Connections is a new programme, understanding its feasibility, acceptability, coverage and effectiveness will allow for an in-depth understanding of the utility of this new type of programme—a programme that targets both caregiver and child factors in families with high psychosocial vulnerability and complex mental health needs. Furthermore, the knowledge gained from this evaluation will support ongoing programme implementation as well as help inform future programme design.

A significant limitation of the evaluation is the lack of comparison or control group in the snapshot study. A randomised control trial design was not feasible due to the short evaluation time frame and the families participating in the service having high psychosocial vulnerability and complex mental health needs, making the use of a control or comparison group unethical. Given that a comparison/control group is not available, establishing causality is not possible. The snapshot study, however, tracks data over time, allowing for the examination of change in key outcome variables across time. Thus, though causality cannot be established, observed improvements may be interpreted as resulting from the intervention rather than casual effects. Furthermore, the evaluation uses a mixed methods design and draws on data from several sources including self-report measures, observational measures and routinely collected service data. Nonetheless, the utilisation of more rigorous evaluation designs may be warranted in the future. Given that the target of the programme is high risk families, a further potential limitation is the retention of families in the programme and, in turn, the research study. among other difficulties, high attrition has the potential to result in reduced statistical power resulting in a failure to detect treatment effects.

The outcomes of this evaluation will make a significant contribution to the field of PIMH. First, data from this evaluation will be used to identify the effectiveness of programmes that integrate interventions targeting both caregiver and child outcomes in families with high psychosocial vulnerability and complex mental health needs. Second, the data will allow for the identification of service enablers and barriers. Third, the evaluation of service data will provide information on service usage and gaps, including those accessed during and shortly following participation in Nurturing Connections, according to different demographic groups and location of the study sites, allowing for the identification of local gaps in services.

Author affiliations
[1]School of Clinical Medicine, University of New South Wales, Sydney, New South Wales, Australia
[2]Academic Unit of Child Psychiatry (AUCS), Sydney South West Area Health Service, Liverpool, New South Wales, Australia
[3]Mental Health Branch, New South Wales Ministry of Health, St. Leonards, New South Wales, Australia
[4]Nurturing Connections, Mid North Coast Local Health District, Port Macquarie, New South Wales, Australia
[5]Nurturing Connections, Northern Sydney Local Health District, St. Leonards, New South Wales, Australia
[6]Nurturing Connections, South Eastern Sydney Local Health District, Kogarah, New South Wales, Australia
[7]Stats Central, University of New South Wales Mark Wainwright Analytical Centre, Sydney, New South Wales, Australia
[8]MDC Associates, Sydney, New South Wales, Australia

Acknowledgements The authors would like to acknowledge Alison Barnes from Western Sydney University for her valuable consultation regarding AH&MRC ethics.

Contributors SC, TFS, AL, LM, DP, AA and VE were involved in the conception and design of the study. SC drafted the protocol paper. TFS, AL, LM, DP, AA, NO, JH and VE provided feedback and approved the final version. SC is the guarantor.

Funding This research was funded by the New South Wales Ministry of Health, funding number: Mh01.

Competing interests TFS was the state-wide policy manager of perinatal and infant mental health, Perinatal Child and Youth Team from the Mental Health Branch of the New South Wales Ministry of Health when the programme and evaluation protocol were developed. TFS was involved in the design of the study and reviewed the manuscript for publication. JH is the current state-wide policy manager of perinatal and infant mental health. JH was involved in reviewing the manuscript for publication. The publication of the manuscript was approved by the funder prior to submission for publication. The funder did not influence the study design despite author affiliations with the funder. AL, LM, DP and AA are managers/ service providers working within Nurturing Connections teams. SC, NO, DC and VE have no competing interests. SC is the guarantor.

Patient and public involvement The Nurturing Connections Advisory Group is complemented by a local implementation group with input from consumers with lived experience of mental health difficulties, including Aboriginal and Torres Strait Islander representation.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Sara Cibralic https://orcid.org/0000-0003-1888-2956
Valsamma Eapen https://orcid.org/0000-0001-6296-8306

REFERENCES

1 World Health O, Committee WHOGAbtGR. Improving early childhood development: WHO guideline. Geneva, Switzerland World Health Organization; 2020.
2 New South Wales Government. Brighter beginnings – the first 2000 days of life. 2021. Available: https://www.nsw.gov.au/initiative/brighter-beginnings#our-vision
3 House of Commons Health and Social Care Committee. First 1000 days of life. 2019. Available: https://publications.parliament.uk/pa/cm201719/cmselect/cmhealth/1496/1496.pdf
4 Fergusson DM, Horwood J, Ridder E, *et al*. Early start evaluation report. Early Start Project Limited; 2005.
5 Burke NJ, Hellman JL, Scott BG, *et al*. The impact of adverse childhood experiences on an urban pediatric population. *Child Abuse Negl* 2011;35:408–13.
6 Grasso DJ, Dierkhising CB, Branson CE, *et al*. Developmental Patterns of Adverse Childhood Experiences and Current Symptoms and Impairment in Youth Referred For Trauma-Specific Services. *J Abnorm Child Psychol* 2016;44:871–86.
7 Mendoza Diaz A, Brooker R, Cibralic S, *et al*. Adapting the "First 2000 Days maternal and child healthcare framework" in the aftermath of the COVID-19 pandemic: ensuring equity in the new world. *Aust Health Rev* 2023;47:72–6.
8 Sroufe LA, Egeland B, Carlson EA, *et al*. *The development of the person: the minnesota study of risk and adaptation from birth to adulthood*. Guilford Press, 2005.
9 Nivison MD, Labella MH, Raby KL, *et al*. Insights into child abuse and neglect: Findings from the Minnesota Longitudinal Study of Risk and Adaptation. *Dev Psychopathol* 2024;36:2499–511.
10 Australian Government. Prevention compassion care: national mental health and suicide prevention plan. 2021. Available: https://www.health.gov.au/sites/default/files/documents/2021/05/the-australian-government-s-national-mental-health-and-suicide-prevention-plan-national-mental-health-and-suicide-prevention-plan.pdf
11 NHS England. Perinatal mental health services. NHS Long Term Plan. n.d. Available: https://www.longtermplan.nhs.uk/publication/perinatal/
12 Health Canada. Government of Canada announces close to $857,000 to support maternal mental health on World Maternal Mental Health Day. 2023. Available: https://www.canada.ca/en/health-canada/news/2023/05/government-of-canada-announces-close-to-857000-to-support-maternal-mental-health-on-world-maternal-mental-health-day.html
13 Australian Government. The national children's mental health and wellbeing strategy. Available: https://www.mentalhealthcommission.gov.au/sites/default/files/2024-03/national-children-s-mental-health-and-wellbeing-strategy---full-report.pdf
14 Productivity Commission. Mental health. 2020. Available: https://www.pc.gov.au/inquiries/completed/mental-health/report
15 Austin MP, Highet N. Mental health care in the peri- natal period: Australian clinical practice guideline. 2017. Available: https://www.cope.org.au/wp-content/uploads/2018/05/COPE-Perinatal-MH-Guideline_Final-2018.pdf
16 The Royal Australian and New Zealand Collage of Psychiatrists. Perinatal mental health services. n.d. Available: https://www.ranzcp.org/clinical-guidelines-publications/clinical-guidelines-publications-library/perinatal-mental-health-services
17 Coates D, Davis E, Campbell L. The experiences of women who have accessed a perinatal and infant mental health service: a qualitative investigation. *Advances in Mental Health* 2017;15:88–100.
18 Coates D, Foureur M. The role and competence of midwives in supporting women with mental health concerns during the perinatal period: A scoping review. *Health Soc Care Community* 2019;27:e389–405.
19 Lim I, Newman-Morris V, Hill R, *et al*. You can't have one without the other: The case for integrated perinatal and infant mental health services. *Aust N Z J Psychiatry* 2022;56:586–8.
20 New South Wales Government. New therapeutic program to support vulnerable young families. 2024. Available: https://www.health.nsw.gov.au/news/Pages/20241122_02.aspx#:~:text=The%20Nurturing%20Connections%20program%20will,child%20and%20family%20health%20professionals
21 New South Wales Department of Health. Nurturing connections program. 2024. Available: https://www.health.nsw.gov.au/mentalhealth/services/parents/Pages/nurturing-connections.aspx#:~:text=How%20can%20Nurturing%20Connections%20support%20me%3F%201%20We,playgroups%20and%20activities%20for%20your%20child%27s%20emotional%20wellbeing
22 Centers for Disease Control and Prevention. A framework for program evaluation. 2024. Available: https://www.cdc.gov/evaluation/framework/index.htm
23 Royal College of Psychiatrists. Resources. 2025. Available: https://www.rcpsych.ac.uk/improving-care/ccqi/quality-networks-accreditation/perinatal-quality-network/resources
24 Proctor E, Silmere H, Raghavan R, *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38:65–76.

25 Durlak JA, DuPre EP. Implementation matters: a review of research on the influence of implementation on program outcomes and the factors affecting implementation. *Am J Community Psychol* 2008;41:327–50.
26 Bant S, Braden A, Newman L. The Building Early Attachment and Resilience (BEAR) Study–Supporting Mums and Bubs. 2023.
27 Holt C, Gentilleau C, Gemmill AW, *et al*. Improving the mother-infant relationship following postnatal depression: a randomised controlled trial of a brief intervention (HUGS). *Arch Womens Ment Health* 2021;24:913–23.
28 New South Wales Department of Health. Northern Sydney Local Health District (NSLHD). n.d. Available: https://www.health.nsw.gov.au/lhd/pages/nslhd.aspx#:~:text=Northern%20Sydney%20Local%20Health%20District%20%28NSLHD%29%20covers%20an,peoples%20are%20the%20traditional%20owners%20of%20the%20land
29 New South Wales Department of Health. South eastern sydney. n.d. Available: https://www.health.nsw.gov.au/lhd/Pages/seslhd.aspx
30 New South Wales Department of Health. Mid North Coast. n.d. Available: https://www.health.nsw.gov.au/lhd/Pages/mnclhd.aspx
31 Ip S, Paulus JK, Balk EM, *et al*. Role of single group studies in agency for healthcare research and quality comparative effectiveness reviews. 2013.
32 New South Wales Department of Health. Whole family teams. Available: https://www.health.nsw.gov.au/mentalhealth/resources/Factsheets/mh-whole-family.PDF
33 REDCap. About. n.d. Available: https://projectredcap.org/about/
34 Kessler RC, Barker PR, Colpe LJ, *et al*. Screening for serious mental illness in the general population. *Arch Gen Psychiatry* 2003;60:184–9.
35 Matthews J, Millward C, Hayes L, *et al*. Development and Validation of a Short-Form Parenting Self-Efficacy Scale: Me as a Parent Scale (MaaPs-SF). *J Child Fam Stud* 2022;31:2292–302.
36 Luyten P, Mayes LC, Nijssens L, *et al*. The parental reflective functioning questionnaire: Development and preliminary validation. *PLoS One* 2017;12:e0176218.
37 Brann P, Culjak G, Kowalenko N, *et al*. Health of the Nation Outcome Scales for Infants field trial: concurrent validity. *BJPsych Open* 2021;7:e129.
38 Gowers SG, Harrington RC, Whitton A, *et al*. Health of the Nation Outcome Scales for Children and Adolescents (HoNOSCA). *Br J Psychiatry* 1999;174:428–31.
39 LeBuffe PA, Naglieri JA. *Devereux early childhood assessment for preschoolers: user's guide and technical manual*. Kaplan Early Learning Company, 2012.
40 Madigan S, Bronfman E, Halitgan JD, *et al*. *The atypical behavior instrument for assessment and classification–brief (ambiance-brief)*. Calgary, Canada: University of Calgary, 2018.
41 Guest G, Bunce A, Johnson L. How many interviews are enough?: an experiment with data saturation and variability. *Field methods* 2006;18:59–82.
42 IMB. Downloading ibm spss statistics 30. n.d. Available: https://www.ibm.com/support/pages/downloading-ibm-spss-statistics-26
43 Dawe S, Harnett P. Reducing potential for child abuse among methadone-maintained parents: results from a randomized controlled trial. *J Subst Abuse Treat* 2007;32:381–90.
44 University of New South Wales Research. Data storage and tools. n.d. Available: https://fe.prod.unsw-anchorbuild.com/data-storage-and-tools
45 QSR International. NVivo qualitative data analysis software (version 12). n.d. Available: https://help-nv.qsrinternational.com/20/win/Content/about-nvivo/about-nvivo.htm?utm_source=chatgpt.com
46 Gale NK, Heath G, Cameron E, *et al*. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC Med Res Methodol* 2013;13:117:1–8:.
47 MacKrain M, LeBuffe P. Devereux early childhood assessment for infants and toddlers. 2007.