Study protocol: peer delivered early intervention (Learning through Everyday Activities with Parents for Infants at risk of Cerebral Palsy: LEAP-CP) for First Nation Australian infants at high risk of cerebral palsy – an RCT study

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INTRODUCTION
Cerebral palsy (CP) is the most common childhood physical disability with rates approximately 50% higher in First Nations Australian children. This study aims to evaluate a culturally-adapted parent-delivered early intervention programme for First Nations Australian infants at high risk of CP (Learning through Everyday Activities with Parents for infants with CP; LEAP-CP).

METHODS AND ANALYSIS
This study is a randomised assessor masked controlled trial. Infants with birth/postnatal risk factors will be eligible for screening. Infants at high risk of CP (‘absent fidgety’ on General Movements Assessment, and/or ‘suboptimal score’ on the Hammersmith Infant Neurological Examination) aged 12–52 weeks corrected age will be recruited. Infants and their caregivers will be randomised to receive LEAP-CP (intervention) or health advice (comparator). LEAP-CP is a culturally-adapted programme of 30 home visits delivered by a peer trainer (First Nations Community Health Worker); and includes goal-directed active motor/cognitive strategies, CP learning games and caregiver educational modules. The control arm receives a monthly health advice visit, based on the Key Family Practices, WHO. All infants continue to receive standard (mainstream) Care as Usual. Dual child primary outcomes are Peabody Developmental Motor Scales-2 (PDMS-2) and Bayley Scales of Infant Development-III. The primary caregiver outcome is the Depression, Anxiety and Stress Scale. Secondary outcomes include function, goal attainment, vision, nutritional status and emotional availability. Sample size: total of 86 children (43/group) will enable an effect size of 0.65 on the PDMS-2 to be detected (80% power, \(\alpha=0.05; 10\%\) attrition).

Ethics and dissemination Ethics approval through Queensland ethics committees and Aboriginal Controlled Community Health Organisation Research Governance Groups, with families providing written informed consent. Findings will be disseminated with guidance from the Participatory Action Research, in collaboration with First Nations communities; peer-reviewed journal publications and national/international conference presentations. Trial registration number ACTRN12619000969167p.

STRENGTHS AND LIMITATIONS OF THIS STUDY
⇒ This study is an appropriately powered randomised assessor masked controlled trial of a novel culturally-adapted peer-delivered early intervention for First Nations Australian infants at risk of cerebral palsy and alike conditions.
⇒ Co-design of the LEAP-CP intervention content and service delivery with First Nations community partners to ensure a culturally relevant and safe programme.
⇒ Outcomes are evaluated with standardised measures, using culturally appropriate tools where available, to evaluate a range of infant and family domains, including functional motor, cognitive and communication developmental outcomes; infant growth; and maternal mental health.
⇒ This is a pragmatic randomised controlled trial; as such ‘care as usual’ interventions and other ‘real world’ factors may influence the data and its interpretation.
common childhood physical disability (2.72/1000 in 1996–2005 and 1.4/1000 2010–2012), with rates approximately 50% higher in First Nations children (4.01/1000 in 1996–2005). First Nations communities in Australia have undergone colonisation including the sequelae of dispossession of their land, displacement of family and community structures and intergenerational trauma including forcible removal of children for assimilation. These sociocultural human rights violations have negatively influenced the social determinants of health in many communities, and resulted in a greater exposure to infant risk factors for CP, as well as gaps in obstetrical and neonatal care; including increased rates of central nervous system injury and infection, chronic illness and psychosocial deprivation. Conversely, spiritual and cultural connectedness and positive kinship relationships have been shown to facilitate improved family function, providing important protective factors to promote child physical, social and emotional well-being.

The first 1000 days of a baby’s life are now well understood to lay a critical foundation for the individual’s lifelong trajectory. It is essential that infants who are likely to have CP and other similar motor conditions of presumed central origin (herein ‘CP and alike conditions’) are identified early to enable proactive targeted motor and cognitive training to stimulate the postnatal brain and musculoskeletal development, as well as fostering protective factors to enhance family functioning. Our international clinical practice guideline (CPG) has recommended that reliable detection of infants at risk of CP should occur from 12 weeks corrected age (C.A.), using the General Movements Assessment (GMA) and Hammersmith Infant Neurological Examination (HINE). Earlier identification enables targeted infant interventions to occur earlier, as well as facilitating improved early family support. First Nations Australian families, both living in remote and metropolitan communities, often do not receive a diagnosis or intervention until after the child’s second birthday; missing a significant window to optimise neuroplasticity and support. To identify infants likely to have CP in First Nations communities, we need to implement culturally safe, simple, affordable community surveillance models, and establish pathways to link those requiring ongoing support to local, accessible, evidence-based interventions. The lay health worker model has been highly effective in First Nations communities, cross-cultural and hard to reach contexts, providing a viable service delivery model to improve access, acceptability, community empowerment and sustainability.

Several key ingredients have been shown to enhance outcomes in First Nations family programmes. Parenting programmes which provide home-based support for First Nations parents have been reported to promote more positive parent–child interactions, improve the enriched home environment, support caregiver mental health and facilitate more positive perceptions of the parenting role. Reviews of the parenting intervention literature further recommend that programmes are co-designed by First Nations communities thereby promoting self-determination and ownership; delivered by (or with) cultural practitioners using culturally embedded approaches; are holistic, focusing on child and family and promoting linkages within the community; are strength-based and relational; and use structured content which is delivered flexibly and responsively to families. Telehealth has also been shown as an effective modality to successfully facilitate the delivery of such culturally appropriate health services. Little is known about the effectiveness or components influencing outcomes in parenting programmes specifically designed for First Nations families of an infant with CP. The Learning through Everyday Activities for Parents programme for infants at risk of Cerebral Palsy (LEAP-CP) aims to address this knowledge gap, representing a paradigm shift for the provision of evidence-based screening, detection and intervention for infants at high risk of CP and alike conditions in First Nations communities in Australia. This novel approach is delivered through First Nations Community Health Workers (FNCHW) supported through telehealth by allied health professionals, providing a viable and scalable solution co-designed for this context. LEAP-CP is delivered early; it is a proactive culturally adapted approach using the latest evidence for early surveillance, enabling support before challenges arise. LEAP-CP is delivered flexibly by members of the local community (FNCHWs) for their own community; providing holistic developmental and family support, allowing all Australian children to reach their potential. LEAP-CP supports the caregiver within their family and community context; it emphasises and builds on the strengths of the child, family and community, and promotes partnership with existing community services.

METHODS AND ANALYSIS

Study design

The overarching study consists of two component studies: (1) Early intervention study, testing the effectiveness of a novel peer-delivered multidomain intervention (LEAP-CP) a randomised assessor masked controlled multisite trial; and (2) Detection study, exploring the validity of an early detection programme for identifying First Nations Australian infants at high risk of CP and/or neurodevelopmental disability (NDD). The intervention study, informed by the Consolidated Standards of Reporting Trials guidelines, will be described in detail in this protocol (see figure 1). Recruitment commenced in July 2021. To date, the project has screened n=143 infants for randomised controlled trial (RCT) eligibility, with n=8 infants at ‘high risk of CP’ recruited to the RCT.

AIMS AND HYPOTHESES

 Aim 1

To determine the efficacy of a peer-delivered multidomain early intervention (LEAP-CP) on motor and...
**Figure 1** Consolidated Standards of Reporting Trials flowchart for infants in the Learning through Everyday Activities with Parents-Cerebral Palsy (LEAP-CP) study. ATOMIC, Australian Therapy Outcome Measure for Indigenous Clients; Ax, Assessment; BSID-III, Bayley Scales of Infant Development, 3rd edition; CA, corrected age; COPM, Canadian Occupational Performance Measure; CP, cerebral palsy; DASS, Depression Anxiety and Stress Scale; EAS, Emotional Availability Scales; EA-SR, Emotional Availability-Self Report; FNCHW, First Nations Community Health Worker; GMA, General Movements Assessment; HA, Health Advice (programme); HINE, Hammersmith Infant Neurological Examination; HOME, Home Observation for Measurement of the Environment; NICU, neonatal intensive care unit; PDMS-2, Peabody Developmental Motor Scales, 2nd edition; PEDI-CAT, Paediatric Evaluation of Disability Inventory-Computer Adaptive Test; Pre-ViAS, Preverbal Vision Assessment; RCT, randomised controlled trial; SCN, special care nursery; TSI, Torres Strait Islander.
cognitive outcomes in First Nations Australian infants at high risk of CP and alike conditions.

**H1:** First Nations Australian infants with CP who receive the LEAP-CP intervention will have better motor development on the Peabody Developmental Motor Scales compared with infants in the control group.

**H2:** First Nations Australian infants with CP who receive the LEAP-CP intervention will have better cognitive development on the Bayley Scales of Infant Development compared with infants in the control group.

**Aim 2**
To determine the efficacy of a peer-delivered multidomain culturally adapted early intervention (LEAP-CP) on a caregiver’s mental health outcomes.

**H3:** Caregivers who receive the LEAP-CP intervention will have reduced depression and anxiety scores on the Depression, Anxiety and Stress Scale compared with those in the control group.

**Aim 3**
To determine the efficacy of a peer-delivered multidomain early intervention (LEAP-CP) on developmental outcomes and nutritional status in First Nations Australian infants at high risk of CP and alike conditions.

**H4:** First Nations Australian infants with CP who receive the LEAP-CP intervention will have better communication, vision, nutritional status and emotional availability compared with infants in the control group.

**Recruitment**
Participants: Infants with one or both parents identifying as Aboriginal and/or Torres Strait Islander (First Nations), with a confirmed diagnosis or at high risk of CP or alike conditions, aged 12–52 weeks CA will be recruited. Recruitment for the LEAP-CP intervention study is state-wide in Queensland in partnership with existing Aboriginal Controlled and mainstream health organisations, and may be expanded into other Australian states. Infants and/or their biological mother must have one or more risk factors to be screened for potential inclusion, including: pregnancy complications (eg, antenatal maternal infection, pre-eclampsia, intrauterine growth restriction, placental abnormalities, antenatal substance abuse), infants born preterm (born <37 weeks’ gestation), term-born with neonatal encephalopathy, 5-min Apgar <6, neurological risk factors (eg, congenital disabilities, small for gestational age, seizures, low birth weight <2500 g) or postnatal complications (eg, head injury, stroke, infection, non-accidental injury). First Nations Australian infants identified with these risk factors and/or admitted to the neonatal intensive care unit/special care nursery will be screened for eligibility and invited to participate in the LEAP-CP intervention study if they meet the following criteria.

**Exclusion criteria**
Infants with known or suspected chromosomal or neurodegenerative conditions will not be eligible to participate. Infants with complex medical conditions requiring acute medical care (ongoing hospital admission for medical management of the infant’s digestive or respiratory system at the time of study entry at ≤12 months CA) will also be excluded. The intervention requires infants to be able to engage in play-based activities with their family in the home. Infants who are medically unstable at the time of identification are still eligible to join once their medical status is stable (if within the study age range).

**Randomisation and blinding**
After completion of baseline assessments, families will be block randomised (group n=6–8), stratified by neurodevelopmental severity HINE (<40 and ≥40) using central concealed random allocation to receive either LEAP-CP or health advice (1:1 ratio). Randomisation will be based on computer-generated sequences by a centralised coordinator using Research Electronic Data Capture tools (REDCap) hosted at The University of Queensland. Eligibility and baseline assessments will be completed prior to randomisation by field staff. Study participants, including caregivers, FNCHWs administering the intervention and Care as Usual (CAU) teams will be naive to intervention status. Researchers assessing the outcomes and analysing the data will be blinded to intervention status.

**Interventions**
Infants from both study arms are able to continue to access the standard (mainstream) CAU including routine
primary medical and allied health programmes (occupational, physio and speech therapies as required), as per their family’s preference (see table 1 for comparison of intervention arms). All CAU service-use (frequency and duration) will be documented at each follow-up assessment (baseline, post-intervention, 24 months CA) on the Health Resource Use Form,19 and included in the analysis.

Intervention Arm: Learning through Everyday Activities with Parents (LEAP): Culturally-Adapted Peer-Delivered Intervention plus CAU

The LEAP-CP intervention is a multidomain best practice intervention consisting of infant goal-directed active motor, communication training, learning games and caregiver educational modules, based on recommendations of the International CPG,16 effectiveness shown in systematic reviews20–23 and early intervention trials.24 25 The components shown necessary for effective interventions for infants with CP include (1) goal-directed activities, (2) child active motor learning, (3) home-based delivery,20 (4) responsive caregiving and (5) enriched environments.21 LEAP-CP is based on a caregiver coaching model which promotes caregiver problem solving and self-determination. The theoretical underpinnings of LEAP-CP are to (1) optimise neuroplasticity through goal-directed cognitive, active motor and communication training and environmental enrichment; and (2) promote the responsiveness of the caregiver–infant dyad; with caregivers supported relationally to enact the intervention components by a peer trainer (FNCHW) using a coaching model. Family-lead goal setting will be facilitated by an allied health professional in conjunction with the FNCHW, which is reviewed throughout the intervention duration. At least three initial goals will be set based on caregiver priorities and the child’s level of ability using the Australian Therapy Outcomes for Indigenous Children (ATOMIC) and Canadian Occupational Performance Measure (COPM). Goals will be reviewed every 3 months and updated as required.

Specifically, LEAP-CP includes:

- **Goal-directed, child active, relevant, task specific training** which includes motivating infant-generated activities based on caregiver-identified goals (upright skills, mobility, upper limb skills, cognitive, communication, vision skills). Goals are practiced to optimise learning, to perform the new goal behaviours independently; using principles of motor learning, including appropriate incrementation, repetition

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**Figure 2** Eligibility flowchart for determining ‘high risk’ of cerebral palsy. AbF, abnormal fidgety; CA, corrected age; CP, cerebral palsy; F+, fidgety present; F–, absent fidgety; GMA, General Movements Assessment; HINE, Hammersmith Infant Neurological Examination; RCT, randomised controlled trial.
Table 1  Template for Intervention Description and Replication (TIDieR)

<table>
<thead>
<tr>
<th>Intervention: LEAP-CP+CAU</th>
<th>Control: Health advice+CAU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Essential elements</td>
<td></td>
</tr>
<tr>
<td>Caregiver-identified goals.</td>
<td>Caregiver health advice (feeding/nutrition/health).</td>
</tr>
<tr>
<td>CP learning games</td>
<td></td>
</tr>
<tr>
<td>Caregiver education (learning principles, caregiver mental health, feeding/nutrition/health).</td>
<td></td>
</tr>
<tr>
<td>Rationale/theory</td>
<td>Based on global recommendations by the WHO</td>
</tr>
<tr>
<td>(i) Optimise neuroplasticity through goal-directed cognitive, motor, communication training and environmental enrichment; and (ii) promote the responsiveness of the caregiver-infant dyad; with caregivers supported to enact the intervention components by a peer trainer (FNCHW). Based on recommendations of the International Clinical Practice Guideline,16 efficacy shown in systematic reviews20–23 and early intervention trials.12–22 The components shown necessary for effective interventions for infants with CP include (i) goal-directed tasks; (ii) home-based delivery using a coaching model, (iii) responsive caregiving; and include (iv) active motor learning and (iv) enriched environments.</td>
<td>Integrated Management of Childhood Illness Key Family Practices, Queensland Personal Health Record and Child Health Information Booklet.18–21 This includes counselling on breast feeding and introduction of complementary nutrition, hygiene practices, safety in the home/community, vaccinations and management of the sick child.</td>
</tr>
<tr>
<td>Materials</td>
<td></td>
</tr>
<tr>
<td>LEAP-CP manual (goals, games, caregiver education)—sample available on request from authors.</td>
<td>Health advice manual—sample available on request from authors.</td>
</tr>
<tr>
<td>Supportive chair with tray (if indicated). Toy kit (including simple infant toys linked to goal target). Story book.</td>
<td></td>
</tr>
<tr>
<td>Procedures</td>
<td></td>
</tr>
<tr>
<td>FNCHW coaches caregivers in how to perform to two to three tasks addressing family-set goals each week with their infant (for practice between sessions) and takes short videos for review with the coordinator. Motivating toys/games (introducing two new CP Learning Games) are incorporated into the goal training, and families supported to locate/make the resources required. Caregiver education is conducted in a discussion-based format (one module from Learn, Love and Grow each fortnight) using the 5 As approach (Ask, Affirm, Add, Answers to questions, Action). Alternate fortnights there were reviews of goal progress and recap of education/actions.</td>
<td>FNCHW provides caregiver education in a discussion-based format (two topics per month).</td>
</tr>
<tr>
<td>Intervention provider</td>
<td></td>
</tr>
<tr>
<td>Caregiver/s who regularly spend time with infant. FNCHW (completion of certificate in Indigenous Community Health/nursing or equivalent; online training for 5 days plus monthly support (3 hours/month); programme overseen by experienced paediatric Allied Health Professional (Bachelor or Masters in OT/PT/SLP; additional training in LEAP programme by programme developers).</td>
<td>Caregiver. FNCHW (completion of certificate in Indigenous Community Health/nursing or equivalent; online training for 1 day plus monthly support (1 hour/month)).</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
</tr>
<tr>
<td>Face-to-face visit by FNCHW. Allied health support predominately via telehealth.</td>
<td>Face-to-face visit by FNCHW.</td>
</tr>
<tr>
<td>Location</td>
<td></td>
</tr>
<tr>
<td>Home or other preferred community space. Preferably naturalistic learning environment.</td>
<td>Home or other preferred community space.</td>
</tr>
<tr>
<td>Number of sessions, frequency, duration, intensity, dose</td>
<td></td>
</tr>
<tr>
<td>30 sessions delivered weekly across 8–10 months. 60 min/session. Daily practice (5 days per week) for 20–40 min (depending on child's age). Mean dose to infant=105 hours.</td>
<td>Seven sessions delivered monthly across 8–10 months. 60 min/session. Mean dose to infant=60 hours.</td>
</tr>
<tr>
<td>Tailoring</td>
<td></td>
</tr>
<tr>
<td>Goals identified by family. Content individualised based on child/family preferences and strengths.</td>
<td>No individualisation.</td>
</tr>
<tr>
<td>Modifications</td>
<td></td>
</tr>
<tr>
<td>Will be reviewed and modified if applicable following 10 sessions for first n=10 families.</td>
<td>No modification.</td>
</tr>
</tbody>
</table>

CAU, Care as Usual; CP, cerebral palsy; FNCHW, First Nations Community Health Worker; LEAP-CP, Learning through Everyday Activities with Parents for infants with Cerebral Palsy; OT, Occupational Therapist; PT, Physiotherapist; SLP, Speech Language Pathologist; WHO, World Health Organisation.

(frequency and duration) and variation.26 Goals are coached by the FNCHW, and caregivers are given visual supports (LEAP graded goal sheets, plus individualised photo/video) for ongoing community/home-based practice through the week guided by the allied health professional coordinator.

- **CP Learning Games and environmental enrichment** are based primarily on the Abecedarian curriculum modified for CP.21–27 The Abecedarian approach has strong empirical evidence from >16 RCTs in at-risk children, including a trial in CP.27–28 This includes early play-based learning (cognitive, motor, sensory, early literacy).

- **Caregiver educational modules**: These evidence-based discussion topics cover three broad areas: (1) ‘learn’—enabling active play with cognitive challenge for babies with CP;29 (2) ‘grow’—feeding, nutrition (breast feeding, complementary feeding, balanced diet) and health;30 (3) ‘love’ caregiver mental health and responsive caregiving. The ‘love’ modules developed by our coauthor (KW)31 are grounded in Acceptance and Commitment Therapy, with a focus on responsive caregiving. They emphasise values, willingness/acceptance and relationships with others and caregiver emotional availability.

The LEAP-CP intervention was originally developed for use in low-middle income countries,32 and will undergo a co-design cultural adaptation for use with First Nations Australian families, using participatory design methods (led by authors LM-R and YR), an experienced Aboriginal public health/health promotion practitioner, as part of her doctoral programme. This cultural framework
substudy is described in detail elsewhere (manuscript under preparation). The cultural adaptation process will interface with the LEAP-CP developers and steering group to ensure programme fidelity parallel to cultural acceptability, safety and sustainability. An Indigenous steering group with representation from key communities will provide input at each stage of the study implementation to ensure valuing the local stakeholders (Families as Partners); knowledge transfer/reciprocity; partnered bicultural language/knowledge exchange; culturally relevant resources enabling policy/planning change. Respecting the diversity of First Nations communities in the project, community-level differences in the delivery of the programme will be incorporated whenever possible (based on a decision by the Chief Investigator team of elements that do not alter the key programme components).

The LEAP-CP programme will integrate the diversity of Indigenous knowledge with existing scientific knowledge to develop an adapted programme with the necessary cultural wisdom. It emphasises the strengths of each family and community’s unique child-rearing preferences and practices to ensure these are respected, protected and celebrated. FNCHWs are supported to provide further adaptation and individualisation of the programme for specific families and communities using a Knowledge Creation framework.

**Dose**

Infants in the LEAP-CP intervention will receive a direct dose (delivered by the FNCHW while coaching the caregiver) of approximately 30 hours across the duration of the programme. An indirect dose, delivered by the caregiver/s in the home will be incrementally from 3 to 12 months C.A. (20 min per day for 5 days per week (1.7 hours) up to 6 months C.A.; 30 min per day for 5 days per week (2.5 hours per week) from 6 to 9 months C.A.; 40 min per day for 5 days per week (3.3 hours per week) from 9 months C.A. onwards. The overall average dose will be approximately 105 hours for the entire intervention up to 24 months CA (based on a mean daily dose of 30 min, 5 days/week for 30 weeks, plus 30 hours delivered during home visits).

**Peer-to-peer service delivery**

An experienced centralised paediatric trained allied health coordinator (with a primary degree in Allied Health) will collaborate with the local FNCHW and regional team leaders on the programme content/progress on a monthly schedule using telehealth facilities (first four visits will have weekly support, with additional frequency offered as needed). Additional bicultural support for these sessions will be provided by LM-R and/or First Nations Team Leaders to ensure cultural competence and relevance. A 5–10 min video of the caregiver demonstrating each goal with their infant will be reviewed in these sessions, with specific feedback provided by the coordinator and other FNCHWs (to ensure the goal remains at the just right level, and strategies are used appropriately). FNCHWs will facilitate the programme with the caregiver (or other significant people in the infant’s life) weekly in the home. Caregivers are the primary change agent, encouraged to do the intervention with their infant daily during the week (incremental dose from 20 to 40 min). Use of a peer-delivered service delivery model ensures cultural relevance, long-term sustainability and empowerment of caregivers. The specific tasks assigned to each role (table 2) and coaching model (figure 3) are elaborated visually.

FNCHWs will be initially trained using a self-directed Small Private Online Course, with follow-up discussion facilitated by the allied health coordinator (5 days duration). Topics include: Introduction to the programme and key components; Overview of disability and child development; Orientation to training and support model; Conducting community visits; Steps and stages (goals and learning principles); Coaching and observing child movement/behaviour; Engaging families (counselling, knowledge creation); Caregiver mental health; Complex scenarios; Practical sessions (with child from local community) applying skills in observing play and conducting a home visit.

The FNCHWs will also have ongoing access to a virtual peer support network (other FNCHWs) and the coordinator for ongoing questions and review of challenges. A video library of the education modules, goals and games will be available for review of specific content. These strategies are intended to optimise the FNCHWs’ confidence, and programme fidelity.

First Nations Health Workers from partnering organisations will provide initial input into the training model and support needs, and feedback during the first 10 visits of the first 10 participants (in line with the overall programme modification). This will inform further adaptations to the training package to ensure its relevance and the competence/confidence of the FNCHWs.

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Tasks assigned to interventionists roles in the LEAP-CP intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caregiver</td>
<td>First nations community health worker</td>
</tr>
<tr>
<td>Who is supported</td>
<td>Provides practice of LEAP-CP intervention with infant</td>
</tr>
<tr>
<td>Frequency</td>
<td>Daily</td>
</tr>
<tr>
<td>Modality of support</td>
<td>Face-to-face in home</td>
</tr>
</tbody>
</table>

FNCHW, First Nations Community Health Workers; LEAP-CP, Learning through Everyday Activities with Parents for infants with Cerebral Palsy.
Control arm: health advice plus CAU

Infants in the control arm will continue to access CAU including mainstream routine primary and allied health programmes (Occupational Therapy/Physiotherapy/Speech Language Pathology as required), in addition to specific postnatal health advice programmes (eg, first 1000 days programmes, such as the Baby One Program at the Apunipima Cape York Health Council). In addition to the mainstream services, families randomised to the control arm will receive a monthly health advice visit (seven visits) by a different FNCHW (who is not administering the LEAP-CP intervention arm), based on the WHO’s Integrated Management of Childhood Illness Key Family Practices, Queensland Personal Health Record and Child Health Information Booklet.35–37 This includes counselling on breast feeding and introduction of complementary nutrition, hygiene practices, safety in the home/community, vaccinations and management of the sick child. FNCHWs providing the control intervention will have a 1-day orientation to the topics, and a monthly check-in with the allied health coordinator.

Adverse events

The LEAP-CP and Control interventions are considered to be safe, with no additional risks for participants beyond CAU. Any potential conflicts associated with kinship or relationships within the community will be monitored by the FNCHW/regional team leader at monthly supervision sessions and discussed with the research team as indicated. Any serious adverse events such as injury, prolonged hospitalisation or mortality occurring during programme delivery will be monitored by the Data Safety Monitoring Committee led by a non-treating senior medical professional. They will review study retention, compliance/quality of treatment and monitor any adverse or unintended effects on a 12 monthly basis and advise the Chief Investigators regarding whether the adverse events are likely related to the intervention provided in the trial.

Procedure for LEAP-CP goal-setting

During/prior to the baseline assessment/initial two appointments, caregiver-identified goals will be established using the ATOMIC and COPM forms, facilitated by the allied health professional in conjunction with the FNCHW using the ‘yarning approach’ outlined below.38 Following initial goal setting based on the ATOMIC procedures (with goals articulated by the caregiver), families are encouraged to consider any additional goals from various developmental and family domains, including motor, communication, vision, play and growth (with caregivers supported to specify functional, specific goals at the ‘just right level’ of challenge using the COPM goal setting, achievable within 3 months). Caregivers will be asked to score goals on both the ATOMIC and COPM forms using their respective scales, and identify three priorities from across the tools to target in the LEAP-CP programme.

In the LEAP-CP intervention arm, caregiver delivery of the goal-directed task training will be reviewed at each home visit and goal targets reviewed iteratively using the ATOMIC, and formally reviewed every 3 months based on the COPM (Allied Health Coordinator with FNCHW using telehealth as required). Caregiver enactment of the goals with their child will be video recorded during the home visit by the FNCHW to enable monitoring and review with the central allied health coordinator. The FNCHW will meet monthly with the central allied health coordinator to review progress, monitor goals and receive training on the next modules in the LEAP-CP programme.
Table 3  Fidelity evaluation plan for the LEAP-CP trial

<table>
<thead>
<tr>
<th>Data source</th>
<th>Monitoring frequency</th>
<th>Components of fidelity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coordinator to FNCHW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FNCHW training: 8–12 times per cycle, 2–3 hours</td>
<td>Monthly</td>
<td>Study design: X</td>
</tr>
<tr>
<td>FNCHW training checklist and video checks: written record of content delivered at each FNCHW training session</td>
<td>Monthly</td>
<td>Training providers: X</td>
</tr>
<tr>
<td>FNCHW training log: all training is video-recorded and a random selection rated</td>
<td>Twice per year</td>
<td>Delivery of treatment: X</td>
</tr>
<tr>
<td>FNCHW to caregiver</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home visit: 30 visits per child, 1 hour</td>
<td>Weekly</td>
<td>Receipt of treatment: X</td>
</tr>
<tr>
<td>Progress notes: written record of content delivered at each home visit</td>
<td>Weekly</td>
<td>Patient enactment: X</td>
</tr>
<tr>
<td>Videoed home visit observation*</td>
<td>Three/programme</td>
<td></td>
</tr>
<tr>
<td>Caregiver to infant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intervention dose (calendar with mark representing 10 min of intervention)</td>
<td>Three/programme</td>
<td></td>
</tr>
<tr>
<td>Video-recorded 10 min activity observation (caregiver–infant)</td>
<td>Three/programme</td>
<td></td>
</tr>
</tbody>
</table>

*Checklist based on fidelity tool developed by Boyd et al for the REACH trial, adapted for this project.

FNCHW, First Nations Community Health Workers; LEAP-CP, Learning through Everyday Activities with Parents for infants with Cerebral Palsy.

Fidelity
Intervention fidelity will be monitored at each level of programme delivery, including its delivery by the allied health coordinator to the FNCHW, the FNCHW delivery to the caregiver and finally enactment of the intervention by the caregiver with the infant (table 3). These levels of fidelity will be monitored to ensure consistency within and across intervention sites for (1) study design (active ingredients of LEAP-CP vs Control); (2) training providers; (3) delivery of treatment; (4) receipt of treatment; (5) caregiver–child enactment.

Outcome measurement
Outcomes will be scored from video by a researcher masked to birth history and intervention arm. Assessments will be conducted by a trained practitioner/researcher (medical/allied health/community health worker) in conjunction with an Aboriginal Health Worker/liaison officer at baseline (T0), post-intervention (T1) and at 2 years CA (T2). If any of the assessment points are within 1 month of another assessment point (including those in the LEAP-CP detection study), the two assessments will be combined. All questionnaires will be translated into Aboriginal English (as approved by test authors) and introduced using a culturally-adapted script.

Dual primary child outcomes
A dual primary child outcome was indicated due to the multidomain nature of the intervention, as well as the equal importance of the outcomes, and expected impact of the intervention.

- The child’s motor outcomes will be assessed using the Peabody Developmental Motor Scales – 2nd edition (PDMS-2) (T0–T2) a commonly used standardised measure of gross and fine motor skills in infants and children aged birth to 6 years (comprised of reflexes, stationary, locomotion, object manipulation, grasping and visual–motor integration subtests). Total motor, gross motor, fine motor and subtest raw scores will be used to indicate motor outcomes. The PDMS-2 has demonstrated concurrent validity with the Bayley Scales of Infant Development-III (BSID-III) and Gross Motor Function Measure and responsiveness to change demonstrated in infants and toddlers with CP.

- The child’s cognitive and communicative (receptive and expressive language) outcomes will be assessed using the BSID-III (T0–T2) a gold-standard norm referenced assessment for infants and children aged 1–42 months. Cognitive and language raw scores will be used to indicate cognitive outcomes. These subscales (cognitive and language) have demonstrated concurrent validity compared with the Wechsler Preschool and Primary Scale of Intelligence—III (r=0.71–0.83), and strong reliability (internal consistency, and test–retest intraclass correlation coefficient (ICC) 0.91–0.93) for the composite scores (cognitive and language) across all ages. Despite the availability of the BSID-IV, the BSID-III will be used in this study to allow the use of the low motor/low vision version to improve validity when assessing children with mild-to-moderate motor and/or vision impairment.

Primary caregiver outcome
- The Depression, Anxiety, Stress Scale—Short Form (DASS) (T0–T2) is a 21-item self-report questionnaire reflecting the frequency and severity of the caregiver’s experiences with depression, anxiety and stress over the past week. It has high internal consistency.
The family strengths, what matters to families and what they value: the test-retest reliability (ICC=0.76), DASS anxiety scale and the Beck Anxiety Scale (r=0.74) and DASS stress scale and the Positive and Negative Affect Schedule (r=0.74). The DASS has been used in Australian Aboriginal people. A modified picture-based Likert scale response and ‘yarning’ prompts will be adopted for the DASS based on the Kimberly Mum’s Mood Scale (Indigenous adaptation of the Edinburgh Depression Scale).

Secondary child outcome measures—goals

Family goals will be identified by the family with the support of trained therapists in conjunction with an FNCHW/Indigenous Liaison Officer. Clinicians will use a relational ‘yarning’ approach with families in an informal play-based session to identify child and family strengths, what matters to families and what they would like to see their child learn next. Goal targets are reviewed throughout the intervention with the FNCHW face-to-face supported by the therapist using a telehealth appointment. The two goal tools (ATOMIC and COPM) will be used simultaneously to determine concurrent validity between the measures:

- The ATOMIC is a culturally responsive paediatric goal-setting tool for interdisciplinary practice developed in partnership with an urban First Australian health service and its users. The ATOMIC will be used iteratively throughout the intervention duration to measure caregiver-perceived gains in their child’s performance of the goal. Caregivers will be asked to identify ‘what is important for them/their baby?’ / ‘what they are hoping their baby will be able to do next?’. The ATOMIC has been validated in urban Aboriginal and/or Torres Strait Islander children aged >2 years, with strong inter-rater reliability (ICC=0.982–0.995; n=16) and responsiveness to measure change (38% improvement, mean difference=1.89 on a 5-point scale; n=80).

- The COPM will be used at T0, T1 and 3-monthly intervals to measure caregiver-perceived change in their child’s performance of the goal and their own satisfaction with progress. Caregivers will be asked to identify ‘what they think their baby will learn next’ / ‘what they feel is an important next skill’, and will be supported by the FNCHW/allied health professional to formulate a measurable goal which should be achievable in a 3-month period. Caregivers rate the goal on a 1–10 point scale. The COPM has established content validity, and strong construct validity, predominately tested in adult populations. It has adequate to high test–retest reliability (ICC=0.76–0.89), and good responsiveness to detect clinically meaningful change (minimal clinically important difference=2 points; n=5 studies).

Secondary child outcome measures

- The child’s functional gross motor capacity will be assessed using the Gross Motor Function Measure (GMFM-66, T0, T2), a criterion-referenced tool for gross motor assessment in children with CP. The test is valid, reliable and responsive to change in children with CP. Five dimensions measure rolling, sitting, crawling, standing and walking/running/jumping.

- The child’s functional outcomes in self-care, mobility and social function will be assessed using parent-report on the Paediatric Evaluation of Disability Inventory – Computer Adaptive Test (PEDI-CAT full version) (T0, T1). The PEDI-CAT has been developed for children with disabilities aged birth to 21 years, and Rasch-analysed in children with disabilities and typical development. Raw scores will be converted to standardised scores (0–100). The PEDI-CAT is administered online and uses an item bank which adjusts the test items dependent on how the child is scoring. Items are scored on a 4-point difficulty scale with responses ranging from unable to easy. The PEDI-CAT has good discriminant validity in children with CP, and concurrent validity with the Functional Independence Measure for Children (Wee-FIM) in children with brain injury and developmental disabilites. The PEDI-CAT is frequently used as an assessment to determine entry and allocation of resources for children entering the Australian National Disability Insurance Scheme, including in First Nations communities.

- Children’s development will be screened based on caregiver interview/direct observation using the Ages and Stages Questionnaire, Aboriginal adaptation (ASQ- TRAK) (T2), the only developmental assessment adapted and validated specifically in the target population (adaptation of the ASQ:3). There are seven interview-based questionnaires specific to the child’s age (ranging from 2 to 36 months), which assess outcomes across the domains of communication, gross motor, fine motor, problem-solving personal-social. The test yields a total domain score (out of 60) with specific domain cut-scores to indicate children requiring follow-up.

- The Preverbal Visual Assessment (PreViAs) Questionnaire is a caregiver reported evaluation of visual cognitive integrative functions through behavioural assessment for children aged <2 years. It consists of 30 questions related to one or more visual domains, including visual attention, visual communication, visual-motor coordination and visual processing. It has concurrent validity with ophthalmologist assessment with >80% specificity and 64–79% sensitivity.

- Nutritional status (T0-T2) will be determined using length (in cm to the nearest mm) and weight (kg to the nearest 100 g) which will be converted to Z scores using the WHO age and gender referenced data. Head circumference will also be collected.
The emotional availability of the primary caregiver–infant relationship will be observed and rated on the Emotional Availability Scale (EAS, T0, T1) and based on parent-report Emotional Availability-Self Report (EA-SR, T0–T2). A naturalistic caregiver-infant observation (EAS) will be videoed in the family’s own home as possible, assisted by the FNCHW, and scored by certified raters. The EAS measures the quality of the relationship across six scales: parental sensitivity, parental structuring, parental non-intrusiveness, parental non-hostility, child responsiveness and child involvement. It has high inter-rater reliability, with ICCs ranging from 0.76 to 0.96 and produces five subscales with acceptable-good internal consistency for mutual attunement ($\alpha=0.79$), capacity to involve the parent ($\alpha=0.88$) and hostility ($\alpha=0.89$) and poor for affect quality ($\alpha=0.45$) and intrusiveness ($\alpha=0.53$).

Home Observation for Measurement of the Environment (HOME) Inventory: Infant and Toddler Version (T0, T1) is a measure of the quality and quantity of parent and home stimulation, covering six domains of parent responsiveness, acceptance and involvement; and the home physical environment including availability of learning materials, and variety of stimulation. The HOME has been used extensively in cross-cultural contexts, and has demonstrated predictive validity to identify infants with developmental delay.

Social and emotional development will be reported by parents using the Brief Infant Toddler Social Emotional Assessment (BITSEA) (T1, T2). The BITSEA is a 42-item checklist which yields problem and competence scores. The tool has strong test–retest reliability (0.85–0.87), and concurrent validity with the Infant Toddler Social Emotional Assessment. It has demonstrated responsiveness to measure intervention effect, as shown following a brief home-based intervention for infants with potential behavioural problems from low socioeconomic families.

The Infant Toddler Quality of Life Questionnaire (ITQOL-SF47) (T2). The ITQOL was developed for use in infants and toddlers aged 2 months to 5 years. The ITQOL short-form measures quality of life across physical, mental and social well-being. The test has 47 items in the short-form and is completed by parent report. For each of the 47 concepts, item responses are scored, summed and transformed to a scale from 0 (worst health) to 100 (best health).

Co-variables, classifications and descriptive measures: These variables will be used to describe the groups and used as covariates in the analysis:

Medical checklist (T0, T2): This checklist gathers socio-demographic, birth and developmental history from the caregiver, and was developed by our team for a large population-based study in Australia. Questions include infant preterm status, birth complications, presence of seizures and use of medications. Questions will also assess maternal risk factors including socioeconomic risks (contributing with the perinatal data to scoring of the Social Risk Index on a 12-point scale) and maternal alcohol use via the Alcohol Use Disorders Identification Test (AUDIT-C) questionnaire.

Perinatal data (T0): The following data will be collected from the infant’s medical records (for full detail see Luke, et al):
- Perinatal/demographic data: birth weight, GA, sex, postcode, multiple birth status.
- Perinatal events that reflect complications during labour and delivery.
- Neonatal medical complications

HINE (eligibility and T0–T2) will be used to determine changes to the child’s neurological status.

In order to determine a diagnosis of CP or another NDD (autism spectrum disorder (ASD), fetal alcohol spectrum disorder (FASD) or developmental delay) (confirmed or suspected) the Medical Assessment for Differential Diagnosis will be completed by a qualified paediatrician according to published guidelines, (1) blinded; and (2) based on clinical history (on the Medical Checklist), brain imaging as available, and videoed HINE and Gross Motor Function Classification System semi-structured play session at 24 months C.A. Differential diagnosis will be based on the following guidelines:
- CP based on Surveillance of CP in Europe guidelines and International Early Detection of CP guidelines.
- FASD based on standard frontal and oblique photographs, as appropriate (analysed with the FASD Facial Photographic Analysis Software for facial dysmorphism assessment).
- ASD based on the Social Attention and Communication Surveillance-Refined (SACS-R).
- The SACS identifies children at ‘high likelihood’ of ASD between 12 and 24 months, and has high positive predictive value (>70%) at 12 months for later ASD diagnosis.

Children’s gross motor function will be classified on the Gross Motor Function Classification System extended and revised version ‘before second birthday’ descriptors (GMFCS, T2), an internationally recognised five-level classification of children’s gross motor function. The GMFCS has validity, reliability and stability for the classification and prediction of motor function of children with CP aged 2–12 years.

Children’s upper limb function will be classified on the Manual Abilities Classification System for Infants (mini-MACS, T2) the gold standard for classifying infant’s ability to handle objects in daily activities in children aged 0–4 years.

Children’s communication function will be classified on the Communication Function Classification System (CFCS, T2) the gold standard for classifying communication abilities in children aged 2–18 years.
analysing costs and outcomes of the LEAP-CPEITQOL. Economic models will be developed to appropriately reflect uncertainty in the results, as has been completed in previous RCTs by our group.49 The primary outcome for the economic evaluation will be the ITQOL. Economic models will be developed to analyse costs and outcomes of the LEAP-CP intervention (led by TC). Incremental Cost Effectiveness Ratios will be estimated and sensitivity analyses undertaken to appropriately reflect uncertainty in the results, as has been completed in previous RCTs by our group.49

Additional outcome analyses
Health economics
A within trial cost-effectiveness analysis19 will be conducted to synthesise the costs and benefits of the LEAP-CP training programme. Resource use (staff time, equipment and facility use) associated with the programme will be collected alongside the RCT using the Health Resource Use Form76 adapted for this project (T0–T2). The primary outcome for the economic evaluation will be the ITQOL. Economic models will be developed to analyse costs and outcomes of the LEAP-CP intervention (led by TC). Incremental Cost Effectiveness Ratios will be estimated and sensitivity analyses undertaken to appropriately reflect uncertainty in the results, as has been completed in previous RCTs by our group.49

Community-based participatory action research
In order to understand the effectiveness of the LEAP-CP intervention within the diverse and complex organisational and cultural contexts, a participatory analysis of the programme will also be undertaken, led by coauthors (LM-R, YR, RF and RNB).79 This analysis aims to partner with community stakeholders to develop ‘hybrid knowledge’ at the junction between First Nations and Western knowledge.79 The specific methods will be co-designed, and may include stakeholder interviews/focus group discussions and storytelling to document changes to practice and programming including greater sustainability, equity, capacity and empowerment.

Sample size
Based on pilot data from the Goals-Activity-Motor Enrichment (GAME) RCT,24 there was an effect size of 0.5 on the PDMS-2. The GAME trial tested a goal-directed active motor enrichment intervention in a sample of infants with CP aged 3–4 months CA (final outcomes at 12 and 24 months). The present study recruits children with limited access to treatment, and as such the intervention is expected to result in greater improvement than the GAME trial. A total of 39 children in each group will enable an effect size of 0.65 on the PDMS-2 to be detected with 80% power (α=0.05). Accounting for 10% attrition, this equates to a total of 86 infants (n=43/group).

Statistical analysis
Analyses will adhere with the standard principles for an RCT, focusing on differences in outcome between intervention and control arms. Intention-to-treat analysis will be undertaken, with significance set at p<0.05. The primary infant outcomes, PDMS-2 total raw score and BSID-III cognitive/communication raw score at 24 months CA will be compared between the intervention and control groups using generalised linear models. The distributional family will be Gaussian and the identity link will be used. The primary caregiver outcome, DASS score at infant’s final outcome, will also be compared between caregivers of the intervention and control groups using generalised linear models. The main effect will be treatment group (LEAP-CP/control). A modified intention to treat analysis excluding children without a confirmed CP diagnosis at 24 months will also be undertaken. Secondary analyses will use similar methods to compare outcomes at 24 months, considering differences in function (PEDI-CAT), goal attainment (COPM, ATOMIC), growth (anthropometry), emotional availability and health economics. Skewed continuous data will be transformed, and when assumptions of regression models are not met non-parametric tests will be used.

Validity of results will be determined using baseline and descriptive data, including systematic differences between those completing the intervention and dropouts. Multiple imputation techniques will be used to adjust for differential drop-out, as appropriate. RSW, lead biostatistician, will provide expert input for the analysis.

Patient and public involvement
A Steering Group with representation from key First Nations communities will provide input to the research team at each stage of the study implementation to ensure valuing the local stakeholders (Families as Partners); knowledge transfer/reciprocity; partnered bicultural language/knowledge exchange; and culturally relevant resources enabling policy/planning change. Representation of voices from within partnering organisations will also be sought, using the existing community engagement mechanisms of the organisation (eg, the Research Governance Committee of Apunipima Cape York Health Council; the Aboriginal and Torres Strait Islander Health Leadership Advisory Committee of Townsville Hospital and Health Service) or advisory groups established specifically for the study (eg, advisory panel of Aboriginal leaders and health workers in the Central Queensland Hospital and Health Service district). Each site/community will have autonomy for their level of participation and how services are established, with their unique preferences valued, and engagement led by our coauthor (LM-R) using bicultural community engagement frameworks.

The co-design of the programme will partner with individuals with a lived experience, families of a child with CP and FNCHW from partnering organisations, as outlined in the LEAP-CP Cultural Framework publication (under preparation). Furthermore, the programme is entirely embedded within existing Aboriginal and Torres Strait Islander Health Services which already provide care in the target communities and will be delivered by FNCHWs. These individuals and services will be actively involved in the everyday recruitment and conduct of the study, and further represent the user’s voice through a cultural lens.
Strengths and limitations
This study is an adequately powered randomised single-blind controlled trial of a novel peer-delivered early intervention for First Nations infants likely to have CP or alike conditions. The study is powered on the primary outcome only, and as such some secondary outcomes may have limited power. As this is a multidomain intervention, and to our knowledge the first trial of this type of intervention in this population internationally, evaluation of these secondary outcomes is considered important. Study eligibility will be determined with gold standard tools (the GMA and HINE), according to an International CPG,11 to ensure intervention is targeted to infants likely to have a later diagnosis of CP. Outcomes are evaluated with standardised measures and evaluate a range of infant and family domains, including functional motor, cognitive, visual and communication developmental outcomes; infant growth; and maternal mental health.

As far as possible, this study adheres to guidelines for the conduct of an RCT and is expected to provide valid results to test the stated hypotheses. As this is a pragmatic RCT performed in a complex population, certain confounders are present which should be considered when interpreting the findings. All children, regardless of study arm, are able to access care as usual in their community, which may dilute or influence the findings.

To control for this, infant’s access to concurrent therapies is documented monthly. Furthermore, as children in remote settings may have limited access to care as usual, it was considered valuable to provide a supplementary ‘health advice’ intervention to families in the control arm of the study. This additional service provided to the control arm beyond ‘care as usual’ may reduce the magnitude (or presence) of an effect between groups.

Being a novel multidomain study, it is expected that the LEAP-CP intervention may impact on a range of infant and caregiver outcomes. While the PDMS-2 and BSID-III were selected as the most meaningful primary infant outcomes, gains on the many secondary outcomes will be considered valid in demonstrating the effectiveness of the intervention. At the conclusion of this study, it is expected that the effectiveness of the LEAP-CP programme will be determined, and as such, provide clinicians, policymakers and health service planners working within First Nations Australian communities with the necessary information to inform the optimal management of First Nations Australian infants with CP.

Outcomes and significance
By intervening in the first year of life with the caregiver–infant dyad situated within the broader family and community context, the programme is expected to improve infant developmental outcomes while simultaneously building the confidence, capacity and support of the caregiver and family. With the current roll-out of the National Disability Insurance Scheme, the Australian healthcare system requires new models of early detection and intervention for CP. By providing early, contextualised interventions in the home it is expected a model will be developed that is feasible, sustainable and culturally appropriate. LEAP-CP has the potential to deliver important outcomes spanning several tiers of society, including infant, caregiver/family; and health systems.

LEAP-CP is anticipated to overcome barriers of getting effective interventions to the right children at the right time. Improvements to children’s developmental trajectories are expected to enable better participation in their family and community. By nature of working through local First Nations cultural brokers and training caregivers in the programme content, resilience and self-determination of First Nations peoples will be facilitated. Caregivers are expected to be more connected to their child, having a greater awareness of their child’s unique strengths and challenges and helpful ways to respond. This caregiving capability will have lasting effects on caregivers feeling equipped as their child’s first and best teacher, which will continue into the child’s schooling years. By empowering local community members as disability resource champions in their own communities and embedding the programme within existing health/community services, this intervention will have a lasting and far-reaching benefit, beyond the duration of the study. It will provide important opportunities for skill development and training of local Aboriginal and/or Torres Strait Islander workforce (including the potential to gain formal qualifications parallel to the study). It will also result in cultural protocols and policy recommendations for best-practice family support of First Nations infants with CP. Building on the peer-delivered model which has been successfully implemented in First Nations communities, as well as resource-poor contexts, this project is likely to result in a cost-effective and translatable model of care for infants with CP that is highly scalable and transposable to other disability populations.

Ethics and dissemination
This study is approved through the Children’s Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC/20/QCHQ/63906), The Far North Queensland Human Research Ethics Committee (HREC/2019/QCH/50533), The Townsville Hospital and Health Service Human Research Ethics Committee (HREC/QTHS/56008), The University of Queensland Human Ethics Research Committee (202000185) and registered with the Australia and New Zealand Clinical Trials Register. It has also been tabled at the Apunipima Cape York Health Council Research Governance Committee, Gidgee Healing Research Review Group, Gurriny Yealamucka Health Service Senior Management Team and the Townsville Aboriginal and Torres Strait Islander Health Leadership Advisory Council. Any important protocol modifications will be communicated to ethics and governance committees and recorded within the trial registration.

A two-stage consent process will be adopted for this study; caregivers will first provide informed consent for
the eligibility assessment (GMA or HINE), and subsequently, those who are eligible for the intervention (‘high risk of CP’) will be invited to provide informed consent for the clinical trial (see online supplemental information). There are no known risks associated with the interventions, and both interventions (LEAP-CP and health advice) are anticipated to provide benefit to the infant and their family.

Participant data will be stored and managed according to universal privacy and confidentiality standards in the secure online REDCap database.

Findings from this trial will be disseminated through peer-reviewed publications and at national and international conference presentations. Meaningful dissemination of results within First Nations communities will be guided by the members of the Steering Group in conjunction with the Participatory Action Research component of the project.

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Acknowledgements The authors would like to acknowledge the invaluable contributions of the implementing partner organisations for the LEAP-CP trial. Specifically, the teams at Apunipima Cape York Health Council, Gurriny Yealamucka Health Service, Gidgee Healing, Kaurareg Aboriginal Land Trust, Cairns and Hinterland Hospital and Health Service, Townsville Hospital and Health Service, Central Queensland Hospital and Health Service, North West Hospital and Health Service, Mackay Hospital and Health Service, Queensland Children’s Hospital and other partners yet to connect. We would also like to acknowledge the Born ToGetThere Consortium for their collaboration on the project (EU Horizon grant H2020-410574989, NHMRC 1194128). We acknowledge the contribution of Professor Paul Colditz in his role as Data Safety Monitor. Finally, we would like to acknowledge the support of the Queensland Cerebral Palsy and Rehabilitation Research Centre clinical research team (Ms Sarah Gibson, Ms Bernadette Shannon, Ms Kym Morris, Ms Christine Finn, Ms Ellenia Oakes) for their clinical inputs and role as advanced General Movements raters.

Contributors KB conceptualised the study, secured funding for the study, drafted the manuscript and approved the final manuscript as submitted. CF conceptualised the detection substudy (in conjunction with her PhD project). She provided critical review of the manuscript and approved the final manuscript as submitted. LL provided cultural leadership into the protocol, including the cultural frameworks, engagement and programme adaptation (in conjunction with her PhD project). She provided critical review of the manuscript and approved the final manuscript as submitted. KL conceptualised the parenting components of the study, provided critical review of the manuscript and approved the final manuscript as submitted. IN conceptualised the study, provided critical review of the manuscript and approved the final manuscript as submitted. MB provided localised input into the study protocol, input into the design of the differential diagnosis, provided critical review of the manuscript and approved the final manuscript as submitted. LR provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. MC provided critical review of the manuscript and approved the final manuscript as submitted. MB provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. MR provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. PZ-J provided cultural leadership into the protocol, provided critical review of the manuscript and approved the final manuscript as submitted. AR contributed to the conceptualisation of the Indigenous programme design, assisted in securing funding, provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. TC provided specialist input into the economic analysis, provided critical review of the manuscript and approved the final manuscript as submitted. AS provided specialist input into the telehealth components of the programme, provided critical review of the manuscript and approved the final manuscript as submitted. RSW advised on statistical design of the study, provided critical review of the manuscript and approved the final manuscript as submitted.

Funding This work was supported by a National Health and Medical Research Council-European Union Collaborative Research Grant (APP1194128); Cerebral Palsy Alliance Project Grants (PG14017 and PG055318); Children’s Hospital Foundation Project Grant (50276_2018); Perpetual Impact Grant (IPAP20200808); Tropical Australian Academic Health Centre Seed Funding (2020); NHMRC Early Career Fellowship (KB, APP1145212), NHMRC Fellowship (RB, NHMRC115038); NHMRC Centre for Research Excellence (Australasian Cerebral Palsy Clinical Trials Network NHMRC1116442).

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. See the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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REFERENCES


PARENT/GUARDIAN INFORMATION SHEET

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

What is an Information Sheet?
This 4 page Information Sheet tells you about the research project. It explains the steps, and how they will happen. This is to help you decide if you and your baby want to join the research project. Please read this Information Sheet carefully. You can ask us anything you want to know about it. You might also want to go through it with your family, friends, or health care worker.

It’s ok to say ‘no’. If you don’t want your baby to take part, you don’t have to. You can stop at any time, and you don’t have to explain ‘why’. Saying ‘no’ will not change any of your baby’s medical care or services they get.

If you want to join the research project, we will give you a consent form to sign.

What is this research project about?
We can check for certain movement and learning difficulties (cerebral palsy and adverse neurodevelopmental outcomes – see factsheet) in babies from as young as 3 months. We want to know how correctly we can identify babies with different types of movement and learning difficulties. We also want to know if a home-based program provided by Aboriginal and/ or Torres Strait Islander Health Workers is helpful for you and your family.

How will this study support me and my baby?
If we find out about movement/ learning difficulties early (including cerebral palsy and adverse neurodevelopmental outcomes), we can start play-based support straight away. We think this will give your child the best chance of developing well. This might be better movement, learning, talking, growth, and other health outcomes. We can also link you to other support, including NDIS if you qualify.

How will this study help other people in the future?
If this program is helpful for your baby, you, and your family, we can share the program with other Aboriginal and/ or Torres Strait Islander communities, particularly those in rural and remote communities.

Is the LEAP-CP project safe for my baby? The tests and home-based support are considered to be safe; they are all play-based and not invasive. There are no extra risks for you or your baby. Your baby might not like doing some of the assessments because they feel unfamiliar for them. Your baby should keep seeing their usual doctors and using other helpful services.

What are the possible inconveniences?
We are testing your baby to see if they have movement/ learning difficulties (like cerebral palsy or adverse neurodevelopmental concerns). This might make you feel worried or anxious and you might not want to know about this. By finding out about difficulties early, your baby has the best chance of developing well.

We want this program to support you and your baby. Your visits will be conducted at home (or another place which is good for you and your baby). You can make a time that suits you and your Aboriginal and/ or Torres Strait Islander Allied Health/ Community Worker or Aboriginal and/or Torres Strait Islander Health Liaison officer. If you would like to be in the LEAP-CP study you will have to give enough time to do the tests (at the beginning, middle and end), see your Allied Health Worker each week, and regularly practice the games that are shared.

FNQ PICF LGIS 9/9/2021 Version 2.2
What happens if I decide to join this research project?
There are 2 steps: the first is checking if your baby has any movement or learning difficulties. If they do, you can decide whether you want to receive the home support.

**STEP 1: Checking for movement and learning difficulties**

When your baby is newborn & 3 months old
(or later if your baby was born preterm)
Someone from our research team will video 5 minutes of your baby’s movement while your baby is still in hospital. You can then do this same video at home at 3 months (twice) on your smart phone. Your local healthcare worker can help if you like. This video will be checked by a doctor or therapist (see factsheet).

When your baby is 6 months old
Someone from our research team will check your baby’s movements which will take about 30 minutes. This will be videoed for checking by a doctor or therapist.

Getting information from you (the caregiver):
- About the pregnancy and birth
- About who is in the household and who cares for the baby
- What your baby can do
- What medical appointments your baby has
- Your mental health

Getting information from your baby’s medical file:
- Brain images (if they have any)
- Doctor’s and other medical reports

**Good result on the tests**
- Probably not a movement or learning difficulty
- Don’t qualify for home support

**Some things to worry about**
We want to have more of a look at your baby’s movement and learning

**Follow up when your baby is 1 year old**
To see how they are moving and learning, including diagnosis

**STEP 2: Giving support to both baby and you at home through the LEAP-CP study**

OK to say ‘No’
STEP 2: Giving you support at home

If you decide you want us to give you support at home, an Aboriginal and Torres Strait Islander Health Worker may continue to see you each week for about 8 months. You and your baby will have up to 4 visits from a health professional (physiotherapist/occupational therapist). Each will take about 2 hours. One check will be at the beginning, then at 12 months, then when you finish the home support program, and finally when your baby is 2 years old. Each time your baby has a longer check, we will do these things:

Checking your baby (videoed):
- Movement, like reaching, sitting, standing
- Learning and talking
- Vision/eyes
- How well they are growing

Gathering information from you (the caregiver):
- What your baby can do
- What things your baby has to learn from at home
- What family and social support you have
- Your mental health

We will ask you for the contact details for other family members (grandparent, aunty, uncle, mum, dad, or carers) to help us keep in touch. You only need to give us ones you are happy to share. We will only use these if we have trouble getting in touch with you. Other family members are welcome to join in the appointments if you would like them to.

Once you and your baby have completed the first test, you will be put in one of 2 groups (by chance), the play program or health advice. We don’t know which of these groups is best.

**Play Program:** weekly home visit (1 hr) by Aboriginal or Torres Strait Islander Health Worker
- Education (how your baby learns, interacting with your baby, helping you cope, feeding & nutrition, health)
- Specific exercises based on goals you choose (communication, play, reaching, sitting)
- Play ideas using materials from your home
- Continued access to existing services in the community

**Health Advice:** monthly home visit by Allied Health Worker
- Infant health advice about feeding, nutrition & general health
- Continued access to existing services in the community
Who is involved in this project?
The Queensland Cerebral Palsy and Rehabilitation Research Centre at The University of Queensland is partnering with local agencies, including Townsville University Hospital, Queensland Children’s Hospital, and your local health care centre to conduct this project. Ms Carly Luke and Ms Leeann Mick-Ramsamy are completing higher degrees (PhD) as part of this project. We have funding to do this project from the National Health and Medical Research Council (Australian Government), Cerebral Palsy Alliance and Children’s Hospital Foundation.

What will we do to make sure your personal information is kept safe?
Information from your tests and videos will be kept on the computer without your or your baby’s name (we can find their name again by looking at a different file). These files are protected by passwords. The paper files will be kept in a locked filing cabinet in an office at the University, without your or your baby’s name. Only the researchers and the centre management team will have access to this information.

Any information we get while you’re doing this project will remain confidential. It will only be shared with others with your permission, except as required by law or for purposes of mandatory reporting.

We will keep your and your baby’s information and videos until they are 33 years old (15 years after they turn 18). This is based on laws and government directions, including the Public Records Act 2002 and the Queensland State Archives’ State Archivist [https://www.qld.gov.au/dsiti/qsa](https://www.qld.gov.au/dsiti/qsa).

If you agree, your information will be used to answer other questions too. We want to understand how the Queensland Early Detection and Intervention Network (QEDIN) has helped to change early screening for babies who might have later difficulties with learning and moving. The knowledge Translation of Early Cerebral Palsy study (KITE-CP) also looks at early screening for babies who might have a later diagnosis of cerebral palsy. If you choose to share your information with these studies, the only extra requirement for you is a short phone call when your baby is 2 years old to see what your baby is learning and doing at that time. Your information and videos may also be kept (if you agree) and used to answer other questions in future research projects at the Child Health Research Centre.

If we give talks or write about the results of this project, we will not use any names. The whole database without any names or identifying details could be made available to other researchers if they provide an appropriate request.

Will I be told about the research results at the end?
If you want more information about your baby’s results, you can ask your doctor, Allied Health Worker or someone from the research team. You can also ask us if you want copies of publications made from this project.

- You can decide if you want you and your baby to join this research project.
- You can stop doing the research project any time you want. You don’t have to explain why.
- If you decide to stop doing the research project, it won’t change anything. Your medical care and other services will stay the same. Your relationship with the doctors and health workers will stay the same.
- You might like to chat with your family or your doctor about joining this research project.
- You can ask for more information before you decide whether to join.
If you have any questions, please contact:

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<th>Name</th>
<th>Title</th>
<th>Email</th>
<th>Telephone</th>
<th>Mobile</th>
</tr>
</thead>
<tbody>
<tr>
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Complaints or ethical issues:
This study has been given ethical approval by the Far North Queensland Human Research Ethics Committee and The University of Queensland Human Research Ethics Committee. It has also been approved by Apunipima Cape York Health Council Research Governance Committee.

Here are some people you can call if you’d like to discuss the study with someone not directly involved. You might have questions about how the study is being run. You might have concerns about your rights as a participant. You might want to make a confidential complaint:
- Far North Queensland Human Research Ethics Committee: Level 7, William McCormack Place 2, 5B Sheridan Street Cairns; 07 4226 5513
- The University of Queensland Human Research Ethics Committee: 07336 53571
- Apunipima Cape York Health Council Research Governance Committee: 07 4037 7213
STEP 1: PARENT/ GUARDIAN CONSENT FORM FOR SCREENING

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

By signing this consent form, I declare that I accept my baby and I participating and that I have understood the following:

- If my baby is demonstrating strong movements (green) on the screening assessment that this means they probably don’t have a movement/ learning difficulty (adverse neurodevelopmental outcome). This means they do not qualify for the parent/caregiver home support program.
- The reason for doing the study, benefits, and negatives of the study as described in the information sheet.
- That my baby and I may not personally directly benefit from joining the study.
- I can freely choose whether to join the research project. I can stop doing it at any time.
- I have been given information and the opportunity to ask questions.
- The information in this sheet may be stored in a research database for the purpose of this study.
- That any publication of the results will not include any names or identifying details.
- I have been given a copy of the participant information sheet and consent form to keep.

☐ I consent for the research team to access relevant information from my child’s treating clinician and/ or medical records (including brain MRI, cranial ultrasound, birth history, discharge summary).
☐ I consent for LEAP-CP to share information with any medical teams or clinical services my child is involved with or has been referred to, and for them to be involved in communicating the results to me.
☐ I consent to the referring clinician being informed of my infant’s screening assessment outcome, and for them to be involved in communicating the results to me.
☐ I consent for LEAP-CP to add information and results from my child’s assessments to be added to my child’s medical records
☐ I consent to my information being shared with two other studies – the Queensland Early Detection and Intervention Network (QEDIN); and Knowledge Translation of Early Cerebral Palsy (KITE-CP). This involves an additional phone call at two years of age.
☐ I consent to provide the name and contact details for a second designated contact in order to assist in maintaining contact for the 12 month and 2 year follow up.
☐ I consent my child’s information and videos to be used to answer other questions at the Child Health Research Centre.
☐ I consent for my child’s information/videos being used for teaching and training purposes including medical conferences, seminars, lectures for teaching health professionals.
☐ I consent for my child’s images and videos to be used in publications such as reports, brochures, medical journals and medical conference posters.
☐ I consent to being contacted by the research team to request my participation in the future for follow-up studies.

FNQ PICF LGIS 9/9/2021 Version 2.2
Participant name (print): 

Parent/caregiver name 
(print): 

SIGNATURE  Date  

I have explained the study to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their infant’s involvement in this study.

Researcher’s name (print) 

SIGNATURE  Date  

Note: All parties signing the Consent Form must date their own signature.

Verbal consent provided  Date  

Researcher’s name & 
signature 

Date  

OK to say ‘No’
OK to say ‘No’

STEP 2: PARENT/GUARDIAN CONSENT FORM FOR INTERVENTION

Early Screening and Allied Health Therapy Program for Aboriginal or Torres Strait Islander Infants at High Risk of Cerebral Palsy or Adverse Neurodevelopmental Outcomes

By signing this consent form, I declare that I accept my baby and I participating in the LEAP Allied Health Therapy Program and that I have understood the following:

- The purpose, methods, risks, and inconveniences of the study as described in the information sheet.
- That I may not personally directly benefit from joining the study.
- I can freely choose whether to join the research project. I can stop doing it at any time.
- I have been given information and the opportunity to ask questions.
- The information in this sheet may be stored in a research database for the purpose of this study.
- That any publication of the results will not include any names or identifying details.
- I have been given a copy of the participant information sheet and consent form to keep.

Participant name (print):

Parent/caregiver name (print):

SIGNATURE Date

I have explained the study to the parent/guardian who has signed above, and believe that they understand the purpose, extent and possible effects of their infant’s involvement in this study.

Researcher’s name (print)

SIGNATURE Date

Note: All parties signing the Consent Form must date their own signature.

Verbal consent provided Date

Researcher’s name & signature Date