






# BMJ Open 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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## ABSTRACT

**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

## 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.

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.

## INTRODUCTION

Aboriginal and Torres Strait Islander (First Nations) children in Australia have an increased risk of adverse neurodevelopmental outcomes, including cerebral palsy (CP), with poorer functional outcomes.<sup>1,2</sup> CP is the most



common childhood physical disability (2.72/1000 in 1996–2005 and 1.4/1000 2010–2012),<sup>3</sup> with rates approximately 50% higher in First Nations children (4.01/1000 in 1996–2005).<sup>2</sup> 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.<sup>4</sup> 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.<sup>5 6</sup> 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.<sup>7</sup>

The first 1000 days of a baby's life are now well understood to lay a critical foundation for the individual's life-long trajectory.<sup>8</sup> 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,<sup>9 10</sup> 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 Hamersmith Infant Neurological Examination (HINE).<sup>11</sup> 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.<sup>12</sup>

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.<sup>13</sup> 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.<sup>13 14</sup> Telehealth has also been shown as an effective modality to successfully facilitate the delivery of such culturally appropriate health services.<sup>15</sup> 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.<sup>11 16</sup> 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

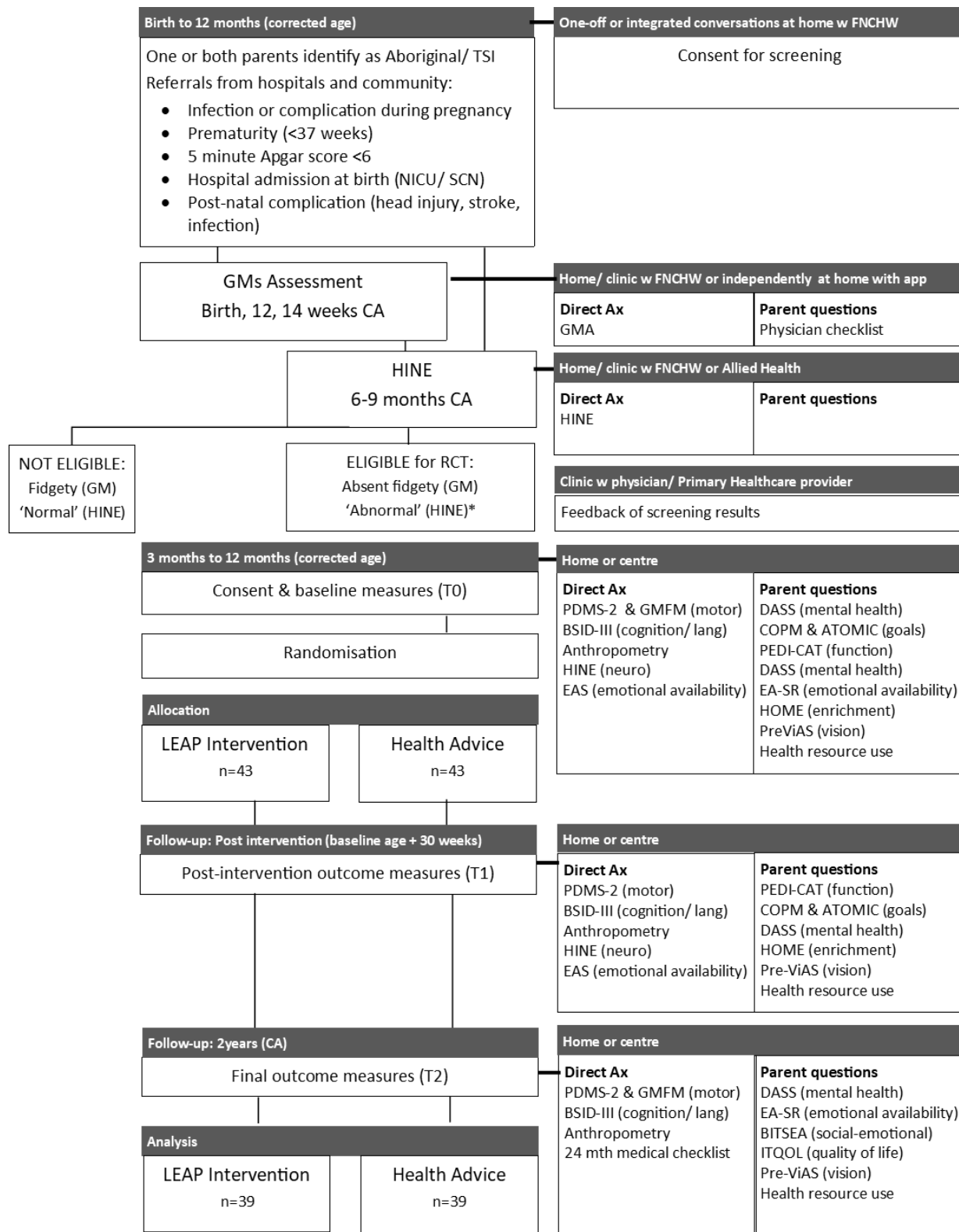
### Study design

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).<sup>17</sup> 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 multi-domain 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 multi-domain 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 C.A. 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 <2500g) 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.

### Inclusion criteria

To participate, infants must have one or more identified birth risk factors, live in one of the study geographical

areas, be aged 12–52 weeks CA, have one or both biological parents identifying as Aboriginal and/or Torres Strait Islander and be identified as high risk of CP or alike conditions (see [figure 2](#)), determined by:

- i. 'Absent' or 'abnormal' fidgety on GMs Assessment (GMA) (2× videos at 12 and 14 weeks CA) for infants aged 12–17 weeks; OR GMA 'fidgety' with segmental asymmetries; AND
- ii. 'Suboptimal HINE score' (score <57 at 3 months, <60 at 6 months, <63 at 9 months, <67 at 12 months) on the HINE (90% predictive of CP) if aged >18 weeks CA; OR 'normal' HINE score with five or more asymmetries (with confirmation from Hand Assessment of Infants with a 3-point difference between limbs).<sup>18</sup> If infants enter the study after 18 weeks CA (ie, no GMA), eligibility will be achieved by a suboptimal HINE score OR ≥5 or more asymmetries on the HINE; PLUS a clinical history congruent with a diagnosis of CP;
- iii. 'Abnormal' neuroimaging results associated with a motor disability including an abnormality in one or more of the following structures: sensorimotor cortex, basal ganglia, posterior limb of the internal capsule AND (i) OR (ii).

### 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).

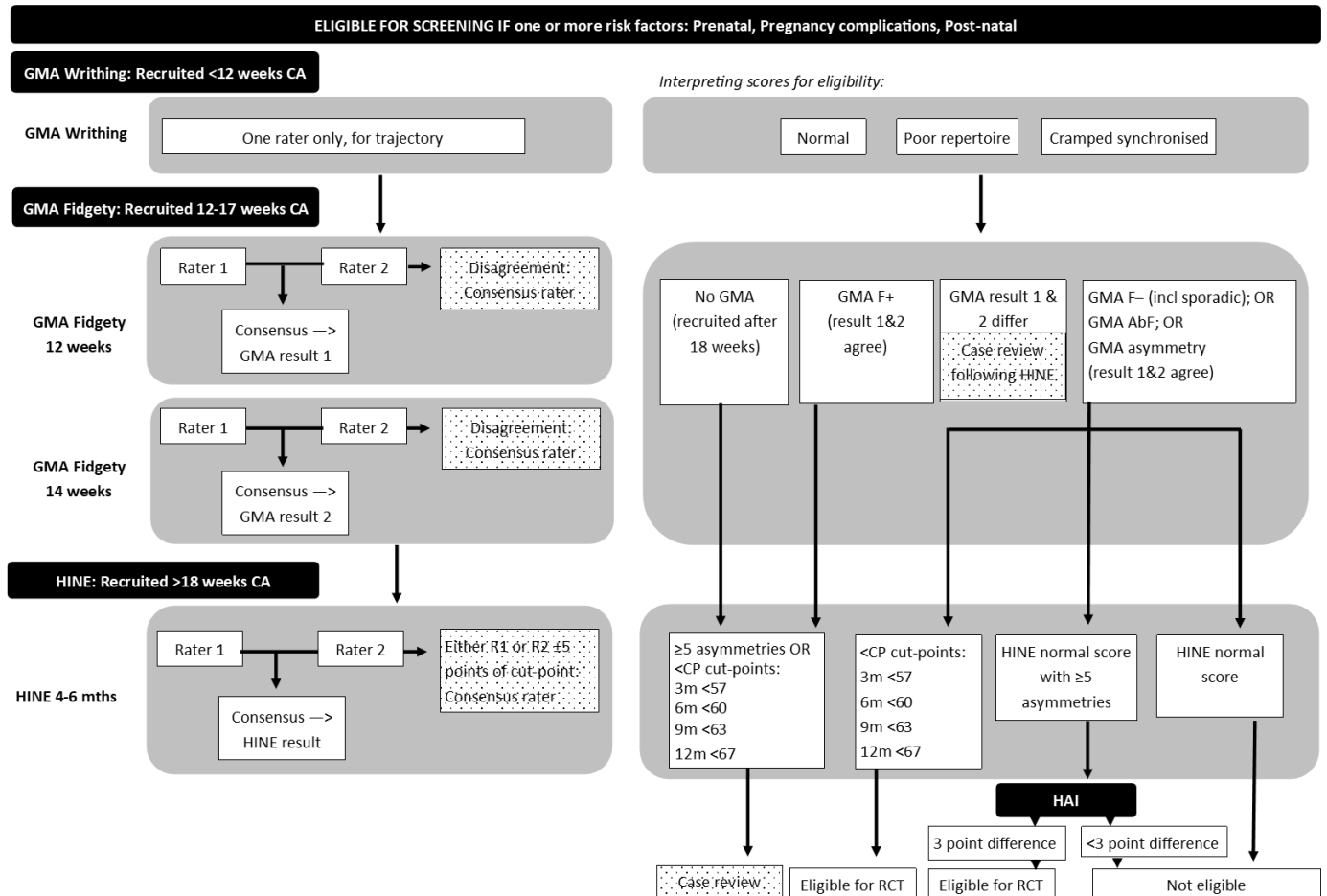
### Randomisation and blinding

After completion of baseline assessments, families will be block randomised (group n=6–8), stratified by neurological 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.<sup>18</sup> 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 naïve 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





**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.

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,<sup>19</sup> 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,<sup>16</sup> effectiveness shown in systematic reviews<sup>20–23</sup> and early intervention trials.<sup>24–25</sup> 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,<sup>20</sup> (4) responsive caregiving and (5) enriched environments.<sup>21</sup> 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

**Table 1** Template for Intervention Description and Replication (TIDieR)

	<b>Intervention: LEAP-CP+CAU</b>	<b>Control: Health advice+CAU</b>
Essential elements	Caregiver-identified goals. CP learning games. Caregiver education (learning principles, caregiver mental health, feeding/nutrition/health).	Caregiver health advice (feeding/nutrition/health).
Rationale/theory	(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, <sup>16</sup> efficacy shown in systematic reviews <sup>20–23</sup> and early intervention trials. <sup>24 25</sup> 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.	Based on global recommendations by the WHO Integrated Management of Childhood Illness Key Family Practices, Queensland Personal Health Record and Child Health Information Booklet. <sup>35–37</sup> 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.
Materials	LEAP-CP manual (goals, games, caregiver education)—sample available on request from authors. Supportive chair with tray (if indicated). Toy kit (including simple infant toys linked to goal target). Story book.	Health advice manual—sample available on request from authors.
Procedures	FNCHW coaches caregivers in how to perform 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.	FNCHW provides caregiver education in a discussion-based format (two topics per month).
Intervention provider	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).	Caregiver. FNCHW (completion of certificate in Indigenous Community Health/nursing or equivalent; online training for 1 day plus monthly support (1 hour/ month)).
Mode of delivery	Face-to-face visit by FNCHW. Allied health support predominately via telehealth.	Face-to-face visit by FNCHW.
Location	Home or other preferred community space. Preferably naturalistic learning environment.	Home or other preferred community space.
Number of sessions, frequency, duration, intensity, dose	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.	Seven sessions delivered monthly across 8–10 months. 60 min/session. Mean dose to infant=0 hours.
Tailoring	Goals identified by family. Content individualised based on child/family preferences and strengths.	No individualisation.
Modifications	Will be reviewed and modified if applicable following 10 sessions for first n=10 families.	No modification.

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.<sup>26</sup> 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.<sup>21 27</sup> The Abecedarian approach has strong empirical evidence from >16 RCTs in at-risk children, including a trial in CP.<sup>27 28</sup> 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;<sup>29</sup> (2) **'grow'**—feeding, nutrition (breast feeding, complementary feeding, balanced diet) and health;<sup>30</sup> (3) **'love'** caregiver mental health and responsive caregiving. The 'love' modules developed by our coauthor (KW)<sup>31</sup> 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,<sup>32</sup> 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.<sup>33</sup> 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.<sup>34</sup>

### 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 incremented 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.

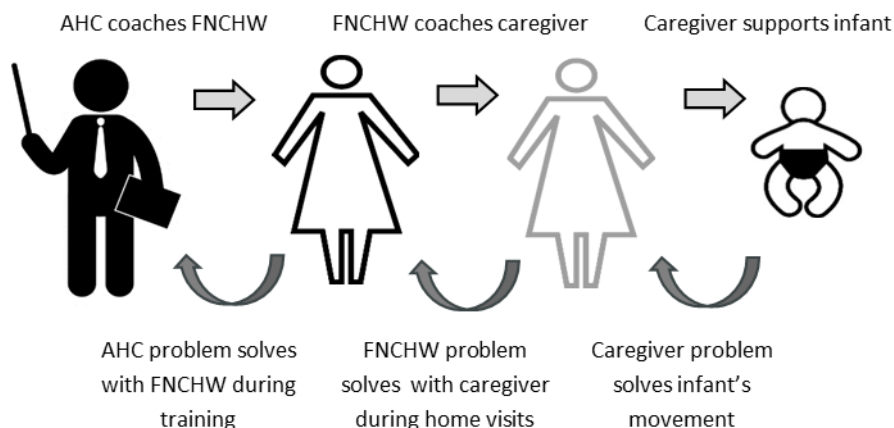
The FNCHWs will also have ongoing access to a virtual peer support network (other FNCHWs) and the coordinator for ongoing questions and review of challenges. A video library of the education modules, goals and games will be available for review of specific content. These strategies are intended to optimise 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 2** Tasks assigned to interventionist roles in the LEAP-CP intervention

	Caregiver	First nations community health worker	Allied health coordinator
<b>Who is supported</b>	Provides practice of LEAP-CP intervention with infant	Provides home visit to support caregiver to enact LEAP-CP	Provides support to FNCHW
<b>Frequency</b>	Daily	Weekly	Monthly
<b>Modality of support</b>	Face-to-face in home	Face-to-face in home	Telehealth (joint home visits as possible)

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



**Figure 3** Coaching model for Learning through Everyday Activities with Parents-Cerebral Palsy (LEAP-CP) Study. AHC, allied health coordinator; FNCHW, First Nations Community Health Worker.

#### 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.<sup>35–37</sup> 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.<sup>38</sup> 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

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

\*Checklist based on fidelity tool developed by Boyd *et al* for the REACH trial;<sup>80</sup> 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.<sup>39</sup>

## 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<sup>17</sup>), 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 – 2<sup>nd</sup> 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)<sup>40</sup> and Gross Motor Function Measure<sup>41</sup> and responsiveness to change demonstrated in infants and toddlers with CP.<sup>41 42</sup>

- ▶ 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.<sup>43</sup> 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.<sup>43</sup> 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.<sup>44</sup>

## 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

( $\alpha=0.83$ , 0.78 and 0.87 for depression, anxiety and stress, respectively).<sup>45</sup> High convergent validity has been established between the DASS and other measures of similar constructs: DASS depression scale and the Beck Depression Inventory ( $r=0.76$ ), DASS anxiety scale and the Beck Anxiety Scale ( $r=0.74$ ) and DASS stress scale and the Positive and Negative Affect Schedule ( $r=0.74$ ).<sup>46</sup> The DASS has been used in Australian Aboriginal people.<sup>47</sup> A modified picture-based Likert scale response and ‘yarning’ prompts will be adapted for the DASS based on the Kimberly Mum’s Mood Scale (Indigenous adaptation of the Edinburgh Depression Scale).<sup>48</sup>

### 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.<sup>38</sup> 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 >2years, 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.<sup>49</sup> 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.<sup>50</sup> 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).<sup>50</sup>

### 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).<sup>51</sup> The PEDI-CAT is administered online and uses an item bank which adjusts the test items dependent on how the child is scoring.<sup>51–52</sup> 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 disabilities.<sup>53–55</sup> 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.<sup>56</sup> The test yields a total domain score (out of 60) with specific domain cut-scores to indicate children requiring follow-up.<sup>57</sup>
- ▶ The **Preverbal Visual Assessment (PreViAs) Questionnaire** is a caregiver reported evaluation of visual cognitive integrative functions through behavioural assessment for children aged <2 years.<sup>58</sup> 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.<sup>59</sup>
- ▶ **Nutritional status (T0-T2)** will be determined using length (in cm to the nearest mm) and weight (kg to the nearest 100g) which will be converted to z scores using the WHO age and gender referenced data.<sup>60</sup> 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)**.<sup>61 62</sup> 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<sup>61</sup> 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 responsivity, acceptance and involvement; and the home physical environment including availability of learning materials, and variety of stimulation.<sup>63</sup> The HOME has been used extensively in cross-cultural contexts, and has demonstrated predictive validity to identify infants with developmental delay.<sup>64</sup>
- ▶ 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.<sup>65</sup>
- ▶ **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.<sup>19</sup> 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**<sup>66</sup> on a 12-point scale) and maternal alcohol use via the **Alcohol Use Disorders Identification Test (AUDIT-C)** questionnaire.<sup>17 67</sup>
- ▶ **Perinatal data (T0)**: The following data will be collected from the infant’s medical records (for full detail see Luke, *et al*<sup>17</sup>);
  - Perinatal/demographic data: birth weight, GA, sex, postcode, multiple birth status.
  - Maternal medical complications and treatment.
  - 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.<sup>68</sup>
- ▶ 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**<sup>17</sup> 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<sup>69</sup> and International Early Detection of CP guidelines.<sup>11</sup>
  - FASD based on standard frontal and oblique photographs, as appropriate (analysed with the FASD Facial Photographic Analysis Software for facial dysmorphism assessment).<sup>70</sup>
  - ASD based on the Social Attention and Communication Surveillance-Revised (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.<sup>71</sup>
- ▶ 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.<sup>72 73</sup> The GMFCS has validity, reliability and stability for the classification and prediction of motor function of children with CP aged 2–12 years.<sup>74–76</sup>
- ▶ Children’s upper limb function will be classified on the 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.<sup>77</sup>
- ▶ 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.<sup>78</sup>





- ▶ **Motor type** (spasticity, dyskinesia, hypotonia) **and distribution** (number of limbs) (T2) will be classified by a physiotherapist/physician according to the Surveillance of CP in Europe.<sup>69</sup>
- ▶ **Paediatric Rehabilitation Intervention Measure of Engagement – Service Provider (PRIME-SP)** (T1) will be completed by the FNCHW as a measure of the family's engagement with the programme.

### Additional outcome analyses

#### Health economics

A within trial cost-effectiveness analysis<sup>19</sup> 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 Form**<sup>19</sup> 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.<sup>49</sup>

#### 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, KB and RNB).<sup>79</sup> This analysis aims to partner with community stakeholders to develop 'hybrid knowledge' at the junction between First Nations and Western knowledge.<sup>79</sup> 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,<sup>24</sup> 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 ( $\alpha=0.05$ ). Accounting for 10% attrition, this equates to a total of 86 infants ( $n=43/\text{group}$ ).

#### 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 drop-outs. 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,<sup>11</sup> 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 (2020000185) 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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**Contributors** KB conceptualised the study, secured funding for the study, drafted the manuscript and approved the final manuscript as submitted. She is the Chief Investigator overseeing all aspects of the project delivery. RNB conceptualised the study, secured funding for the study, provided critical review of the manuscript and approved the final manuscript as submitted. She is the co-Chief Investigator overseeing all aspects of the project delivery. YR provided cultural leadership into the protocol, provided critical review of the manuscript and approved the

final manuscript as submitted. RF provided cultural leadership into the protocol, provided critical review of the manuscript and approved the final manuscript as submitted. CL conceptualised the detection substudy (in conjunction with her PhD project). She provided critical review of the manuscript and approved the final manuscript as submitted. LM-R 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. KW 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. LM provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. LF provided critical review of the manuscript and approved the final manuscript as submitted. GK provided localised input into the study protocol, provided critical review of the manuscript and approved the final manuscript as submitted. YC-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.

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