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Effectiveness–implementation hybrid-2 randomised trial of a collaborative Shared Care Model for Detecting Neurodevelopmental Impairments after Critical Illness in Young Children (DAISY): pilot study protocol

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ABSTRACT

Introduction In Australia, while paediatric intensive care unit (PICU) mortality has dropped to 2.2%, one in three survivors experience long-term neurodevelopmental impairment, limiting their life-course opportunities. Unlike other high-risk paediatric populations, standardised routine neurodevelopmental follow-up of PICU survivors is rare, and there is limited knowledge regarding the best methods. The present study intends to pilot a combined multidisciplinary, online screening platform and general practitioner (GP) shared care neurodevelopmental follow-up model to determine feasibility of a larger, future study. We will also assess the difference between neurodevelopmental vulnerability and parental stress in two intervention groups and the impact of child, parent, sociodemographic and illness/treatment risk factors on child and parent outcomes.

Methods and analysis Single-centre randomised effectiveness–implementation (hybrid-2 design) pilot trial for parents of children aged ≥2 months and <4 years discharged from PICU after critical illness or injury. One intervention group will receive 6 months of collaborative shared care follow-up with GPs (supported by online outcome monitoring), and the other will be offered self-directed screening and education about post-intensive care syndrome and child development. Participants will be followed up at 1, 3 and 6 months post-PICU discharge. The primary outcome is feasibility. Secondary outcomes include neurodevelopmental vulnerability and parental stress. An implementation evaluation will analyse barriers to and facilitators of the intervention.

Ethics and dissemination The study is expected to lead to a full trial, which will provide much-needed guidance about the clinical effectiveness and implementation of follow-up models of care for children after critical illness or injury. The Children's Health Queensland Human Research Ethics Committee approved this study. Dissemination of the outcomes of the study is expected via publication in a peer-reviewed journal, presentation at relevant conferences, and via social media, podcast presentations and open-access medical education resources.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of a hybrid effectiveness–implementation randomised control design to evaluate the DAISY model of care will help to identify important intervention–implementation interactions needed to optimise its applicability and uptake by parents and general practitioners.
⇒ The DAISY model of care is innovative as it evaluates the first post-intensive care syndrome–paediatrics follow-up intervention for children and their parents following a life-threatening illness in childhood.
⇒ Consumers, paediatric intensive care unit (PICU) clinicians and other stakeholders have co-designed the DAISY model of care intervention, ensuring the project is meaningful to consumers and has the potential to optimise the post-PICU management of children surviving critical illness.
⇒ Limitations of this pilot are that it is a two-centre study and only available to English-speaking parents, which may limit the generalisability of the findings.

Registration details The trial was prospectively registered with the Australian New Zealand Clinical Trials Registry as 'Pilot testing of a collaborative Shared Care Model for Detecting Neurodevelopmental Impairments after Critical Illness in Young Children' (the DAISY Pilot Study).
Trial registration number ACTRN12621000799853.

INTRODUCTION

Burden of critical illness on the child and family

For many years, the primary focus of critical care medicine has been to prevent mortality. Many paediatric intensive care units (PICUs) now report mortality rates as low as 2.2% in Australia.[1 2] However, these declining

mortality rates have created an emerging healthcare concern: a growing number of PICU survivors with persistent functional deficits leading to poor long-term outcomes. Young children are particularly vulnerable to the consequence of critical illness and its treatments due to a phase of rapid brain development and disrupted family processes.[3–6] Over 60% of PICU admissions occur in children under 4 years. For these children, surviving critical illness with a functional disability translates into a manifold, multiplied burden of care that extends beyond childhood. Recent literature has focused our attention towards the physical, cognitive, emotional and social impairments that are frequently experienced alone or in combination by children and families, defined as post-intensive care syndrome–paediatrics (PICS-p).[7 8]

Parents are impacted by their child's admission to PICU. Parents experience stress due to alterations in the parental role, procedures, their child's appearance,[9] anxiety,[10] depression[11] and post-traumatic stress.[12] Optimal parenting skills during this period are critical for protecting and building their child's neurodevelopment; however, increased stress can limit a parent's ability to care and advocate effectively for their child. These emotions can increase during the transition from hospital to home and are impacted by the child's functioning, and the parent's resilience, support and knowledge.[12–15] A lack of continuity of care and support after PICU discharge can contribute to increasing unmet needs, adverse patient outcomes and parent emotional well-being.[16 17] The impact and trajectory of these impairments may synergistically affect neurodevelopment, academic and work performance, and family functioning and relationships, potentially lasting a lifetime[18 19] (figure 1).

Early screening and intervention

Early recognition of young children with neurodevelopmental vulnerability is important to maximise future potential and enhance their quality of life.[20] Two broad approaches to follow-up have been used: (1) general screening, usually undertaken by primary healthcare providers and an important approach as some children do not have identifiable risk factors[21 22]; and (2) for known high-risk cohorts such as premature infants or children with congenital heart defects, targeted follow-up, to provide in-depth assessment.[23 24] Programmes of general neurodevelopmental screening have increased the number of children recognised with developmental delay and reduced the time taken to recognise developmental delay, improving referral for early intervention as recommended for all children, including those who are low risk and healthy.[20 25] Unfortunately, these programmes can be underused,[26 27] and lack of resources and training has been cited as major barriers.[28] To date, follow-up care post-intensive care unit (ICU) admission remains restricted to small, highly selected cohorts of patients and is largely hospital based and ICU led.[29–31] The gold standard of follow-up is a face-to-face assessment, but this has been considered impractical due to the number of children admitted to PICU, accessibility, time and cost. Furthermore, not all children require diagnostic assessments. It is therefore essential to explore alternate models of screening.

Parent-directed early developmental screening has the potential to supersede or supplement long-established follow-up models to improve access to early interventions and could be successful in supporting children and

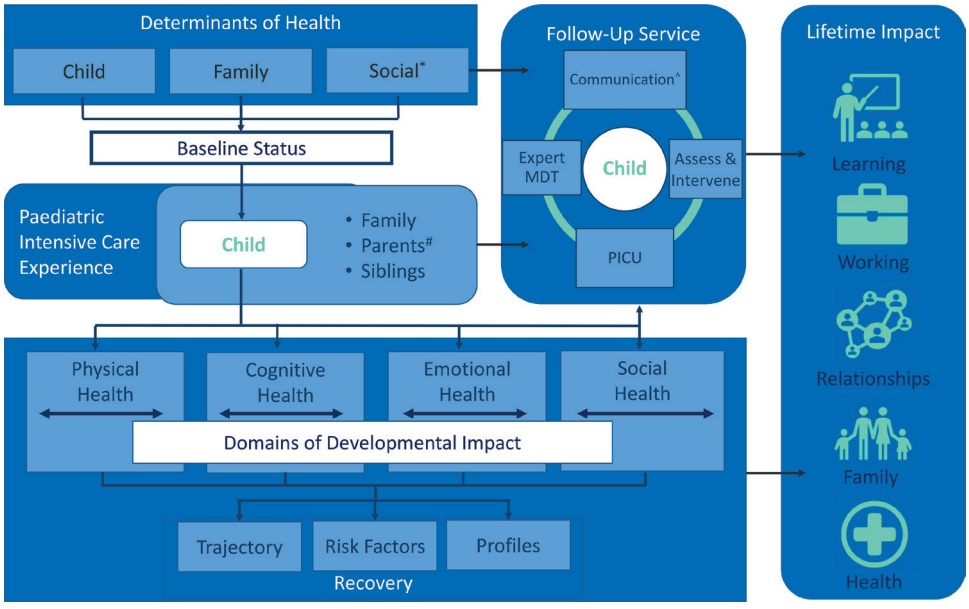

Figure 1 Adapted post-intensive care syndrome–paediatrics.[60] *Social determinants of health include concepts such as poverty, access to healthcare and community services, food security, neighbourhood and environment, housing and access to education. #Parents include guardians, caregivers and kin. ^Communication with parents, treating teams and other relevant healthcare providers, including paediatricians, general practitioners and allied health professionals currently providing care for child. MDT, multidisciplinary team; PICU, paediatric intensive care unit.

parents following PICU admission. Early screening of young children is vital for efficient and effective detection of neurodevelopmental deficits. It can assist referral for early intervention and reassure parents of typically developing children.[32] Specialists have historically administered complex, expensive and time-consuming tests, but new technologies and models of care provide contemporary opportunities for parents to monitor and learn about their child's development.[33] Parent-directed early screening interventions can either be self-directed (ie, parent independently engages with the intervention) or healthcare professional led (ie, healthcare professional provides guidance as part of the intervention). Self-directed parent programmes have greater potential for uptake as they do not require trained professionals to guide and can typically be implemented at a reduced cost. However, healthcare professional-led parent programmes have demonstrated better patient outcomes than self-directed programmes.[34]

Access to care

Currently, there is no routine, standardised follow-up care and support provided to children and their parents following all critical illnesses and injuries in Australia. Furthermore, the geographical isolation of many Australian families and recent pandemic crises have highlighted the barriers to accessing traditional treatment services. As a large country with a dispersed population, ensuring equitable access to healthcare remains challenging. Many specialist healthcare services, like PICU, are centralised to larger, populated metropolitan centres where resources and expertise are concentrated.[35] Approximately 30% of Australians live in regional or remote areas, encompassing many diverse locations and communities,[36 37] while the percentage of Indigenous populations is much higher in the more remote areas. Although only 3.3% of Australia's population are Indigenous, over half live in regional or remote areas. The 10 most disadvantaged local government areas in Australia can be found in Queensland, with 48% of Indigenous populations more likely to live in these areas.[38]

Children living in remote areas face inequities of access to healthcare and outcomes in health[39 40] that contribute to developmental delays and subsequent poorer education and health outcomes. Specifically, Indigenous children living in remote areas experience a greater burden of disease than children living in major cities.[41] While the health outcomes of people living in remote locations are poorer than those living in cities, the differences in children's developmental outcomes between proximate and remote areas are likely to be explained by geographical and demographic factors.[42]

The benefit of routine screening and outcome monitoring and general practitioner shared care

Routine screening for symptoms and quality of life using patient-reported outcome measures (PROMs) and using this information to guide patient care have been shown to lead to significant improvements in patient care and outcomes.[43–45] Professional bodies recommend the use of PROMs with systematic feedback, bringing value beyond the clinician's understanding of a patient's current well-being.[46] Use of electronic platforms to deliver PROMs (e-PROMs) can expedite and ease the practical difficulties of paper screening and reporting, including inconvenience, inflexibility, low response rates and increased data entry.[2 47] The provision of e-PROMs and feedback of results prior to clinical review minimises the barriers of limited time and resources. Recognising that hospitals may not be the best place to manage multifaceted paediatric follow-up care, together with the increasing pressures on already strained hospital services, there is a need to develop, evaluate and implement alternate models of follow-up.

In Australia, the general practitioner (GP) is the primary point of care for childhood illness and well-being; therefore, primary healthcare is ideally positioned to deal with the domains of PICS-p. GPs play a key role in the early identification of developmental issues, see young children regularly and often appreciate the family circumstances. They are ideally placed to provide support and guidance to parents and to coordinate referrals within the broader healthcare sector. However, insufficient time, knowledge gaps and lack of confidence in using validated tools have been cited as barriers to consistent delivery.[28 48 49] Care that is coordinated and shared between the hospital and primary care providers is one approach that has been explored to care for cancer survivors, including children. Evidence favours shared care, demonstrating that it is equivalent to specialist-led care across a range of PROMs, is preferred by patients and provides cost savings.[50–55] Therefore, GP shared care, supported by early screening e-PROMs and feedback of results, may help overcome barriers to post-PICU care provision and support. Routine screening and feedback of results, coupled with shared care, offer an equitable and accessible solution for children and families across our geographically diverse country, with associated benefits of time savings, remaining close to home and family, and continuity of care.

Rationale and aim of the present study

The landscape of paediatric critical illness outcomes is changing. While there will always be a priority for the traditional acute outcomes, such as length of ventilation and mortality, there is a new shift towards monitoring more long-term outcomes (LTOs),[56] which contribute to ongoing significant morbidity throughout a child's life, potentially extending into adulthood. These new morbidities can present at various stages throughout childhood and are often under-recognised. These variables of socio-emotional and behavioural vulnerability, combined with the lack of early identification and awareness, impact on high school educational achievements, professional qualifications and dependency on social welfare. They can converge, as the perfect storm, as seen in the preterm

population.[57] Hence, there is an urgency to implement and evaluate systems to measure and optimise PICU survivor LTOs. The aim of this research is to test the feasibility of a multidisciplinary, GP shared care follow-up pathway with routine outcome monitoring and referral for children and parents following paediatric critical illness. Specific objectives are to:

1. Establish the feasibility and acceptability of a 6-month developmental follow-up programme for children following critical illness and their parents using a GP shared care and an outcome monitoring pathway at 6 months after PICU discharge.
2. Measure the impact of critical illness during early childhood on neurodevelopmental vulnerability at 6 months post-discharge.
3. Assess the impact of critical illness on parental stress at 6 months post-discharge.
4. Assess the difference in neurodevelopmental vulnerability and parental stress between the GP shared care and self-directed groups at 6 months after PICU discharge.
5. Determine the impact of child, parent, sociodemographic and illness/treatment factors on child and parent outcomes.
6. Conduct an implementation analysis in line with the Consolidation Framework for Implementation Research (CFIR) and informed by the Medical Research Council guidelines for complex interventions to understand the factors influencing the implementation of the intervention and the implementation strategies.[58 59]

METHODS AND ANALYSIS

Study design

A multicentre pilot hybrid-2 randomised effectiveness–implementation trial[60] in children ≥2 months and <4 years admitted to a regional PICU will be used to simultaneously collect data on the effectiveness and implementation of the DAISY Pilot intervention. This design has been selected because: (1) there is evidence supporting the benefit of both early screening and intervention on child outcomes,[19 21 24 61] and parent-directed interventions on parental stress and confidence and child outcomes[34 62–68]; (2) there is limited evidence supporting the implementation of follow-up for PICU survivors and evidence supporting objective outcomes and long-term follow-up adoption is currently lacking[69]; and (3) with appropriate support and education, there is minimal risk in implementing parent-directed follow-up interventions.[70] The hybrid design permits important data to be collected on the transferability of evidence of effectiveness of separate elements of online screening, routine feedback and shared care in the proposed model while expediting translation of findings into clinical practice and survivor follow-up pathways.[60]

This pilot randomised controlled trial will be performed over 12 months. Follow-up will occur at 1, 3 and 6 months post-PICU discharge (figure 2). All eligible patients will be enrolled just prior to PICU discharge. The study will be reported according to the Standard Protocol Items: Recommendations for Interventional Trials, Patient Reported Outcomes (SPIRIT-PRO) checklist for inclusion of patient-reported outcomes in clinical trial protocols.[71]

Setting

Recruitment will be at the PICUs at Queensland Children's Hospital (QCH) and Sunshine Coast University Hospital (SCUH), Queensland, Australia. The QCH is Australia's largest PICU and Queensland's quaternary referral and education centre, providing advanced life support interventions to infants and children. The QCH PICU provides a service to a population of ~1.3 million children and has an average admission rate of 2000 children per year.[1 72] The SCUH PICU is a regional centre and admits approximately 500 children per year. Collectively, both units capture approximately 80% of the state's PICU admissions. The intervention will be delivered and assessed where the recruited children reside across the state of Queensland, which has a geographical area of approximately 2 million km^2 and a population of 5.2 million.[73] Although most of Queensland's population live in the southeast corner and other regional centres along the coastline, a significant number of people live in large inland centres, smaller towns and isolated communities.

Recruitment, eligibility and consent

Participants will be identified and recruited by a PICU research study coordinator at each site. Screening will commence at the time of admission to PICU and continue during admission as participant characteristics determining eligibility may evolve.

Inclusion criteria: parents of children discharged alive from PICU aged ≥2 months and <4 years at the time of PICU discharge and expected to survive to discharge to home. Sixty per cent of children admitted to the PICU are <4 years of age and adverse experiences in the first 5 years of life are known to impact on child development.

Exclusion criteria: children born at gestation <37 weeks; known high-risk cohorts already in well-established follow-up programme through neonatal ICU, cardiology or oncology services; severe intellectual disability; under palliative care; non-English-reading/speaking parent/guardian.

Consent: the parent/guardian consent forms provide information on the DAISY Pilot Study (online supplemental material 1). An informational video is also available for parents to view. Prospective, written consent will be sought from the research coordinator. The preferred approach will be face-to-face information and consent within PICU; however, as parents will be provided with sufficient time to consider the study information, consent will most likely occur in the ward environment. When a patient is discharged from PICU overnight or on the weekend, the research team may approach the parent/

	STUDY PERIOD				
Time Point	**Enrolment**	**Baseline[a]**	**1-month Post PICU[b]**	**3-month Post PICU**	**6-months Post PICU**
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Baseline ASQ-3	X				
Randomisation	X				
INTERVENTIONS:					
GP Shared Care		◆———	———	———	———◆
Active Control		X			X
ASSESSMENTS:					
Demographics		X			
Clinical treatment		X			
ASQ-3		X[c]	X	X	X
ASQ:SE-2		X	X	X	X
Pain		X	X	X	X
Feeding		X	X	X	X
PedsQL		X	X	X	X
PedsQL Fatigue		X	X	X	X
PEDS		X	X	X	X
STS		X			X
PSI-4-SF:		X	X	X	X
K6		X	X	X	X
PC-PTSD		X	X	X	X
CD-RISC-10		X			X
PSOC		X			X
Health care utilisation[#]		X	X	X	X
GP feedback					X
Parent feedback					X
Adverse events monitoring	Continuously				

Figure 2 Schedule of enrolment, interventions and assessments. [a]Assessments completed electronically while in ward environment. [b]Assessments completed electronically in home environment. [c]Assessment completed pre-randomisation. [#]Active control arm completes at all time points. ASQ-3, Ages and Stages Questionnaires, Third Edition; ASQ:SE-2, Ages and Stages Questionnaires: Social-Emotional, Second Edition; CD-RISC-10, Connor-Davidson Resilience Scale; GP, general practitioner; K6, Kessler Psychological Distress Scale; PC-PTSD, Primary Care Post-Traumatic Stress Disorder screen; PEDS, Pediatric Emotional Distress Scale; PedsQL, Pediatric Quality of Life Inventory Core and Infant; PedsQL Fatigue, Multidimensional Fatigue Scale–General Fatigue Subscale; PICU, paediatric intensive care unit; PSI-4-SF, Parenting Stress Index, Fourth Edition Short Form; PSOC, Parenting Sense of Competency Scale; STS, Short Temperament Scale.

guardian while their child is an inpatient in the ward area. In rare situations, a parent/guardian may not be present at the hospital; therefore, remote consent from parents/guardians will be sought using verbal consent via phone or written consent via email, and only if the research team has attempted to seek face-to-face contact first. Parents/guardians may revoke their consent at any point during the study without comment or penalty. In the case of withdrawal of consent, we will continue to use data collected prior to participant withdrawal unless specifically requested by the participant not to include.

Randomisation

Children who meet the eligibility criteria and whose parents consent to participate will be randomised 1:1 to either the shared care arm or the self-directed arm. A variable block randomisation schedule has been electronically generated and preloaded into the online study

database. Stratifying variables for randomisation are: age (≥1–<12 months; 12–<24 months; 24–48 months) and pre-morbid neurodevelopmental impairment (defined as Ages and Stages Questionnaire score at baseline <2 SD below mean on one or more domains). Children and parents are not blinded to the allocation.

Interventions

In developing the interventions, we employed the Knowledge to Action process framework to guide the synthesis and adaptation of evidence into a usable knowledge tool and facilitated co-design of the interventions with consumers.[74]

Collaborative shared care, supported by early, routine outcome monitoring

The intervention consists of:

1. *Parent information booklet on PICS-p:* information regarding what is PICS-p, how common it is, what to be aware of, signs to look out for and what parents can do to support their child. Booklet created by the research team and PICOLO network.[75]
2. *Collaborative shared care*: we define 'collaborative shared care' as the partnering of care between the PICU team and primary care provider (primarily a GP based in the community).[76] Both the PICU team and the primary care provider maintain ongoing involvement and support in patient care, share information, agree on common processes proactively and involve the patient throughout. Specifically, the PICU team will phone the parent at 1, 3 and 6 months post-PICU to provide 1:1 support and anticipatory education around the care of a child post-PICU.[75] In addition, the PICU team will send an email link to the parents to complete a neurodevelopmental screening assessment of their child and an emotional well-being assessment of themselves (e-PROMs). GPs were involved in the intervention development and the following steps are included in the shared care process:
   a. Family GP contact details documented in the PICU clinical information system.
   b. After child is discharged from PICU, the GP is sent a study introduction letter, an annotated example report, their patient's baseline report, the PICS-p booklet and the 'Act Now for kids 2morrow' book, developed by the Queensland Child and Youth Clinical Network.[77]
   c. At each subsequent time point (1, 3 and 6 months), the GP will be provided with the child's latest report (see 3 and 4 below).
   d. At any time point, the GP may contact the PICU team for support.
   e. Based on the report results provided, the GP will decide whether further investigations or referrals are required.
3. *e-PROMs:* parents/guardians will receive invitations for regular online screening at 1, 3 and 6 months post-PICU. The online screening module consists of a battery of well-validated PICS-p outcome measures and parents' emotional well-being surveys that take approximately 20 min to complete (online supplemental material 2). For ease, parents can complete the questionnaire on various devices, including smartphones, and over multiple sessions.
4. *Reporting of results*: the study team will develop Python scripts to automate the processes of generating a feedback report from the data collected in the purpose-built database (online supplemental material 3). The feedback report will be provided to GPs and parents at each time point. Following each screening-PROM assessment, a reminder text message or phone call will be sent by the PICU follow-up team to the parent to attend a follow-up appointment at the GP practice. The feedback is intended to flag whether a patient needs further follow-up, and to act as a stimulus to discuss ongoing management, with potential referral to allied healthcare services, such as psychology, occupational therapy, physiotherapy or speech therapy.[78 79] Any decision-making regarding ongoing management will rest with GP.

Self-directed screening, education and activities

Current standard of care in both of the participating sites is that no follow-up or support addressing the PICS-p domains is provided for general PICU patients, except in the identified excluded groups. Following several discussions with consumers, clinicians and the ethics committee, it was determined that was unethical to provide the current standard of care in the control group. Therefore, the provision of information, in the form of a self-directed intervention, was chosen to characterise the effect of the more intensive intervention in terms of relevant patient clinical outcomes. The information-based, self-directed intervention was developed in consultation with consumers and clinicians to be a minimally acceptable and effective intervention. Therefore, participants allocated to the self-directed group will receive:

1. Parent information booklet on PICS-p, as above, including suggestions for whom to contact if they are concerned.[75]
2. Routine updates on appropriate developmental milestones and activities via freely available mobile health applications: Centre for Disease Control Developmental Milestone-Tracker app[80] and Telethon Kids Institute Bright Tomorrows app.[81] Parents will be encouraged to complete developmental checks, participate in child play-based activities to develop essential child-life skills and modules to support parent-life skills.

With an increased understanding of PICS-p and appropriate developmental milestones, parents are able to follow up any concerns with GPs or other primary care providers.

Study measures and outcomes

The primary outcome is the feasibility of the study protocol; the key measure is the proportion of eligible patients who consent to participate in the study. Feasibility

will also be established using measures described by Hertzog, Thabane *et al* and Lancaster *et al*.[82–84] Secondary outcomes include child and parent-focused outcomes related to neurodevelopment and well-being. Details regarding the primary and secondary outcomes are provided in online supplemental material 2.[85–104]

Implementation

Evaluation will be informed by the UK Medical Research Council guidance on process evaluations of complex interventions and incorporate an examination of the three key trial components: context, implementation and mechanisms of impact. The CFIR will serve as the framework to understand context by examining the factors influencing the implementation of the intervention. Mixed methods will be used to collect data for the implementation outcomes listed in online supplemental material 2 and the assumptions of the programme theory.[58] Implementation outcomes will be evaluated using semistructured interviews with parents and health professionals, survey questionnaires, case report forms (CRFs), fidelity logs, study documentation and resource use data as detailed in online supplemental material 2. Selection and reporting of implementation outcomes and strategies have been guided by the taxonomy of Proctor *et al*.[105 106] The mechanisms of impact will be evaluated using interview data.

Patient and public involvement

Families and children are at the centre of this study. The study team has systematically developed and then refined the interventions using co-design principles with consumers, caregivers of children, GPs and ICU staff. This feedback has directly informed the development of interventions and will inform implementation strategies tailored to the community context. On implementation of the interventions, we will seek further input from parents through interviews to evaluate the implementation of the interventions. A parent representative is also a member of the research team and will participate in all aspects of the development, implementation, evaluation and dissemination.

Adverse events

It is acknowledged that the post-PICU population will experience several common signs and symptoms of critical illness or injury and the impact of PICU treatments. Given that the nature of this study is to investigate the long-term complications of critical illness and injury, these will therefore be reported as outcomes and will not be reported as serious adverse events. While we are not aware of any specific adverse events related to the interventions, all adverse events deemed possibly related to either intervention will be reported.

Sample size

The sample size ensures that the primary outcome (proportion of eligible patients who consent to participate) can be estimated with a high level of confidence. We will screen 233 children; assuming 80% are eligible (ie, approximately 186 participants), we expect to recruit 80% of these eligible participants (ie, 149 participants), enabling us to accurately report on the eligibility rate and recruitment rate with a 95% CI that has a maximum half-width of 6%. Recruitment is planned to be conducted over 12 months. Recruitment figures will be monitored monthly by the trial statistician (KG), and any shortfall will be reported to the project steering committee. The sites together admit approximately 2500 children per year. With 40% of children >4 years, this would leave 1500 children, making recruitment in the 12-month period feasible.

Study procedures and data management

Screening patients for eligibility will start at time of PICU admission and continue during admission as eligibility criteria may develop/change. A screening log will be maintained to document eligible and missed patients. All data will be collected by a trained research coordinator and entered into the REDCap database hosted by the Queensland University of Technology (electronic CRF).[107 108] Participants will be followed up to 6 months after randomisation. Assessments at 1, 3 and 6 months post-discharge will occur by phone unless the patient is still in hospital. Parents/guardians will be invited to complete a baseline assessment of their child's premorbid neurodevelopment status while still an inpatient in the hospital via a research iPad.

We will prospectively record identifiable patient data, including contact details, during the consent process. At 1, 3 and 6 months post-PICU, the study team will review the patient records for health status, including survival. If deemed appropriate to contact, parents will be telephoned to discuss sending the questionnaire. If ongoing consent is provided, the parent email will be confirmed, and the questionnaire sent via REDCap. Parents will be provided with three reminders prior to determining lost to follow-up status. Parents/guardians will be invited to participate in neurodevelopmental assessments via a secure, personal email link. If this method of data collection is not suitable, parents will be offered the choice to complete the assessments on paper questionnaires or via phone call. To optimise cohort retention, we will follow the protocols of Needham.[97] Source data will be entered directly onto preprinted CRFs where practical, where this cannot occur in real time, data will be retrospectively entered onto CRFs from hospital records, observation charts and resuscitation flow sheets to complete the required data set. Data will be prospectively entered into a secure web-based database and hosted by the Queensland University of Technology. All child and parent outcomes are automatically generated within the online database following parent completion of questionnaires. Hard copy data will be securely stored by the investigating site in a locked cupboard in a secured location. As required by the Queensland State Archivist, all study information and documentation will be securely stored for 15 years after the date of the child's 18th birthday. As this trial will recruit participants from 1 month of age, all records will be securely stored for a total of 33 years before being securely destroyed.

Evaluation

Implementation evaluation: feasibility and other quantitative implementation outcome data will be reported descriptively, for example, percentages, and compared against a priori determined feasibility (online supplemental material 2). Reflexive thematic analysis will be used to analyse the qualitative interview data inductively following six phases: (1) familiarising oneself with the data, (2) generating codes, (3) constructing themes, (4) reviewing potential themes, (5) defining and naming themes, and (6) producing the report.[109] The inductive analysis will be completed to generate themes that reflect the data free from any framework or theory. Deductive analysis will be completed by mapping the findings against the CFIR domains to understand barriers and facilitators of implementation.[58] Unique barriers and facilitators that do not fit within CFIR will also be explored deductively. Rigour of the qualitative research will be maintained using reflective journaling, presentation of the findings thoroughly and transparently, the involvement of experienced qualitative researchers who will oversee the interviews and coding, and the use of multiple coders to explore assumptions and interpretations of the data.

Effectiveness evaluation: descriptive statistics will be used to report baseline characteristics of the study cohort by group allocation; statistical comparison will not be undertaken. It is anticipated that there will be a degree of loss to follow-up; all available data will be analysed. Child and parent outcomes at 6 months post-PICU discharge will be presented as counts and percentages, median and IQR, or mean and SD, dependent on the distribution of the variable. Differences between groups at 6 months will be analysed using generalised estimating equations to allow for repeated time points and missing data. Stratification variables used during randomisation (age group and pre-morbid neurodevelopment) will be included in the model as fixed effects; OR along with 95% CI will be presented. Unadjusted differences and associated CIs will also be presented. The following preplanned subgroup analyses will be performed: age at enrolment (≥2–<12 months; 12–<24 months; 24–48 months), pre-morbid neurodevelopmental status (ie, stratification variables) and severity of organ dysfunction (highest Paediatric Logistic Organ Dysfunction in first 24 hours of PICU admission: no organ dysfunction (score=0), any organ dysfunction (score ≥1)).[110] The trial statistician will remain blinded to the allocation. Data will be analysed on an intention-to-treat basis, with the child or parent as the unit of analysis. As the study is not powered to detect statistical differences in effectiveness outcomes, no p values will be presented.

ETHICS AND DISSEMINATION

Ethics and safety considerations

Ethics approval for the DAISY Pilot Study was obtained from the Children's Health Services Queensland (Human Research Ethics Committee (HREC)/21/Queensland Children's Hospital Queensland (QCHQ)/73086) and Queensland University of Technology (110264). This pilot study has also been registered with the Australian and New Zealand Clinical Trials Registry (ACTRN12621000799853). This study will be conducted in compliance with the current version of the protocol. Any change to the protocol document or informed consent form that affects the scientific intent, study design, patient safety or may affect a participant's willingness to continue participation in the study is considered an amendment, and therefore will be written and filed as an amendment to this protocol and/or informed consent form. All such amendments will be submitted to the HREC for approval prior to implementation. Participant confidentiality will be strictly upheld by the participating investigators, research staff, and the sponsoring institution and their agents, and no information will be released to any unauthorised third party without prior written approval of the sponsoring institution.

Dissemination

Publication in high-impact peer-reviewed journals will be sought, and presentation at national and international conferences is anticipated. Contemporary dissemination strategies will be used, including social media, podcast presentations and Free Open Access Medical education resources to generate discussion and disseminate the outcomes of the study.

Significance

The results of this study will inform the development of a larger definitive trial. Additionally, this study will start to provide answers: best assessment strategies; child and PICU treatment risk factors to assist in stratification of care, trajectories of recovery to understand when early intervention is best provided, clusters of post-PICU behaviours using deep phenotyping, and individual and community social determinants of health. This work will also lead to the establishment of a national steering committee to establish cutting-edge standards and guidance for PICU follow-up. As the study is addressing a significant knowledge gap, this will lead to publications in high-impact journals, which will contribute to the recognition of the PICU LTOs team and the foundation in promoting ground-breaking research. Although this pilot excludes non-English-speaking parents, language bias will be addressed in subsequent iterations of the study by providing standardised assessments in additional languages and the presence of translators at consent, thus representing more linguistically and culturally diverse populations.

Positive results may have important diagnostic implications for the development of risk prediction and screening models for the early identification of individuals at risk of neurodevelopmental decline and will contribute to improved capacity and capability in systems caring for these children. When expanded to a national level, this will result in a single and cohesive follow-up approach for patients and one of the largest international PICU LTO databases with a unique wealth of clinical, and child, information. This will enable researchers to gain novel insights into treatments, risk factors and functional

outcomes for this vulnerable cohort. The research is expected to form the basis of a new, national approach to the early follow-up of children following PICU, resulting in the appropriate allocation of resources, improved patient-centred outcomes and lower costs.

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REFERENCES

1 ANZPIC Registry. Australian and New Zealand paediatric intensive care registry annual activity report 2018, 2020. Available: https://www.anzics.com.au/wp-content/uploads/2020/02/Australian-and-New-Zealand-Paediatric-Intensive-Care-Registry-Activity-Report-2018.pdf
2 Aaronson N, Choucair A, Elliott T. User's guide to implementing patient-reported outcomes assessment in clinical practice: International Society for Quality Life Research, 2011. Available: https://proms.waitematadhb.govt.nz/assets/Uploads/Implementing-PROMs-in-Clinical-Practice.pdf
3 Mustard J. Experience-Based brain development: scientific underpinnings of the importance of early child development in a global world. *Paediatr Child Health* 2006;11:571–2.
4 Lebel C, Deoni S. The development of brain white matter microstructure. *Neuroimage* 2018;182:207–18.
5 Keenan HT, Presson AP, Clark AE, *et al*. Longitudinal developmental outcomes after traumatic brain injury in young children: are infants more vulnerable than toddlers? *J Neurotrauma* 2019;36:282–92.
6 Cantwell-Bartl AM, Tibballs J. Psychosocial experiences of parents of infants with hypoplastic left heart syndrome in the PICU. *Pediatr Crit Care Med* 2013;14:869–75.
7 Aspesberro F, Mangione-Smith R, Zimmerman JJ. Health-Related quality of life following pediatric critical illness. *Intensive Care Med* 2015;41:1235–46.
8 Herrup EA, Wieczorek B, Kudchadkar SR. Characteristics of postintensive care syndrome in survivors of pediatric critical illness: a systematic review. *World J Crit Care Med* 2017;6:124.
9 Alzawad Z, Marcus Lewis F, Ngo L, *et al*. Exploratory model of parental stress during children's hospitalisation in a paediatric intensive care unit. *Intensive Crit Care Nurs* 2021;67:103109.
10 Stremler R, Haddad S, Pullenayegum E, *et al*. Psychological outcomes in parents of critically ill hospitalized children. *J Pediatr Nurs* 2017;34:36–43.
11 Rodríguez-Rey R, Alonso-Tapia J, Colville G. Prediction of parental posttraumatic stress, anxiety and depression after a child's critical hospitalization. *J Crit Care* 2018;45:149–55.
12 Yagiela LM, Carlton EF, Meert KL, *et al*. Parent medical traumatic stress and associated family outcomes after pediatric critical illness: a systematic review. *Pediatr Crit Care Med* 2019;20:759–68.
13 Melnyk BM, Alpert-Gillis L, Feinstein NF, *et al*. Creating opportunities for parent empowerment: program effects on the mental health/coping outcomes of critically ill young children and their mothers. *Pediatrics* 2004;113:e597–607.
14 Nelson LP, Lachman SE, Li SW, *et al*. The effects of family functioning on the development of posttraumatic stress in children and their parents following admission to the PICU. *Pediatr Crit Care Med* 2019;20:e208–15.
15 Rothschild CB, Rychlik KL, Goodman DM, *et al*. Association between resilience and psychological morbidity in parents of critically ill children. *Pediatr Crit Care Med* 2020;21:e177–85.
16 Jakobsen L, Kristensen KK, Laerkner E. Parents' experiences during and after their child's stay in the paediatric intensive care unit - A qualitative interview study. *Intensive Crit Care Nurs* 2021;67:103089.

17 Suleman Z, Evans C, Manning JC. Parents' and carers' experiences of transition and aftercare following a child's discharge from a paediatric intensive care unit to an in-patient ward setting: a qualitative systematic review. *Intensive Crit Care Nurs* 2019;51:35–44.
18 Als LC, Nadel S, Cooper M, *et al*. Neuropsychologic function three to six months following admission to the PICU with meningoencephalitis, sepsis, and other disorders: a prospective study of school-aged children. *Crit Care Med* 2013;41:1094–103.
19 Baker SC, Gledhill JA. Systematic review of interventions to reduce psychiatric morbidity in parents and children after PICU admissions. *Pediatr Crit Care Med* 2017;18:343–8.
20 Council on Children with Disabilities,. Section on developmental behavioral pediatrics, bright futures Steering Committee, et al. identifying infants and young children with developmental disorders in the medical home: an algorithm for developmental surveillance and screening. *Pediatrics* 2006;118:405–20.
21 Guevara JP, Gerdes M, Localio R, *et al*. Effectiveness of developmental screening in an urban setting. *Pediatrics* 2013;131:30–7.
22 Thomas RE, Spragins W, Mazloum G, *et al*. Rates of detection of developmental problems at the 18-month well-baby visit by family physicians' using four evidence-based screening tools compared to usual care: a randomized controlled trial. *Child Care Health Dev* 2016;42:382–93.
23 Doyle LW, Anderson PJ, Battin M, *et al*. Long term follow up of high risk children: who, why and how? *BMC Pediatr* 2014;14:1–15.
24 Marino BS, Lipkin PH, Newburger JW, *et al*. Neurodevelopmental outcomes in children with congenital heart disease: evaluation and management: a scientific statement from the American heart association. *Circulation* 2012;126:1143–72.
25 Heckman J. The economics of investing in children. *Policy Briefing* 2006;1.
26 Alexander KE, Mazza D. Scrapping the healthy Kids Check: a lost opportunity. *Med J Aust* 2015;203:321–2.
27 Jureidini J, Raven M. Healthy Kids Check: lack of transparency and misplaced faith in the benefits of screening. *Aust N Z J Psychiatry* 2012;46:924–7.
28 Waters EB, Haby MM, Wake M, *et al*. Public health and preventive healthcare in children: current practices of Victorian GPs and barriers to participation. *Med J Aust* 2000;173:68–71.
29 Manning JC, Scholefield BR, Popejoy E, *et al*. Paediatric intensive care follow-up provision in the United Kingdom and Republic of Ireland. *Nurs Crit Care* 2021;26:128–34.
30 Griffiths JA, Barber VS, Cuthbertson BH, *et al*. A national survey of intensive care follow-up clinics. *Anaesthesia* 2006;61:950–5.
31 Cook K, Bartholdy R, Raven M, *et al*. A national survey of intensive care follow-up clinics in Australia. *Aust Crit Care* 2020;33:533–7.
32 Lipkin PH, Macias MM, COUNCIL ON CHILDREN WITH DISABILITIES, SECTION ON DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS. Promoting optimal development: identifying infants and young children with developmental disorders through developmental surveillance and screening. *Pediatrics* 2020;145. doi:10.1542/peds.2019-3449. [Epub ahead of print: 16 12 2019].
33 Jones DJ. Future directions in the design, development, and investigation of technology as a service delivery vehicle. *J Clin Child Adolesc Psychol* 2014;43:128–42.
34 Collins DAJ, Tully LA, Piotrowska PJ, *et al*. Perspectives on ParentWorks: Learnings from the development and national roll-out of a self-directed online parenting intervention. *Internet Interv* 2019;15:52–9.
35 Moynihan KM, Alexander PMA, Schlapbach LJ, *et al*. Epidemiology of childhood death in Australian and New Zealand intensive care units. *Intensive Care Med* 2019;45:1262–71.
36 Australian Bureau of Statistics. Household income and wealth, Australia 2017-2018. Available: https://www.abs.gov.au/statistics/economy/finance/household-income-and-wealth-australia/latest-release
37 Australian Institute of Health and Welfare. Rural and remote health, 2020. Available: https://www.aihw.gov.au/reports/australias-health/rural-and-remote-health
38 Australian Bureau of Statistics. 2033.0.55.001 - Census of Population and Housing: Socio-Economic Indexes for Areas (SEIFA), Australia, 2016, 2018. Available: https://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/2033.0.55.001~2016~Media%20Release~Census%20shows%20our%20most%20advantaged%20&%20disadvantaged%20areas%20(Media%20Release)~25
39 Jones DM, Lyle D, Brunero C, *et al*. Improving health and education outcomes for children in remote communities: a cross-sector and developmental evaluation approach. *Gateways: International Journal of Community Research and Engagement* 2015;8:1–22. doi:10.5130/ijcre.v8i1.4163
40 Teitler JO, Reichman NE, Nepomnyaschy L, *et al*. A cross-national comparison of racial and ethnic disparities in low birth weight in the United States and England. *Pediatrics* 2007;120:e1182–9. doi:10.1542/peds.2006-3526
41 Dossetor P, Thorburn K, Oscar J. Health services for Indigenous children in remote Australia: a strategic literature review, 2021. Available: https://assets.researchsquare.com/files/rs-386342/v1/df4f62e1-557a-4b94-b6f8-0cb0a8cef166.pdf?c=1631880256
42 Maggi S, Irwin LJ, Siddiqi A, *et al*. The social determinants of early child development: an overview. *J Paediatr Child Health* 2010;46:627–35.
43 Ishaque S, Karnon J, Chen G, *et al*. A systematic review of randomised controlled trials evaluating the use of patient-reported outcome measures (PROMs). *Qual Life Res* 2019;28:567–92.
44 Anderson LM, Papadakis JL, Vesco AT, *et al*. Patient-Reported and parent proxy-reported outcomes in pediatric medical specialty clinical settings: a systematic review of implementation. *J Pediatr Psychol* 2020;45:247–65.
45 Bele S, Chugh A, Mohamed B, *et al*. Patient-Reported outcome measures in routine pediatric clinical care: a systematic review. *Front Pediatr* 2020;8:364.
46 Lambert MJ, Whipple JL, Kleinstäuber M. Collecting and delivering progress feedback: a meta-analysis of routine outcome monitoring. *Psychotherapy* 2018;55:520.
47 Bachman JW. The patient-computer interview: a neglected tool that can aid the clinician. *Mayo Clin Proc* 2003;78:67–78.
48 Allen SG, Berry AD, Brewster JA, *et al*. Enhancing developmentally oriented primary care: an Illinois initiative to increase developmental screening in medical homes. *Pediatrics* 2010;126 Suppl 3:S160–4.
49 Honigfeld L, McKay K. Barriers to enhancing practice-based developmental services. *J Dev Behav Pediatr* 2006;27:S30–3. doi:10.1097/00004703-200602001-00009
50 Turbitt E, Kunin M, Gafforini S, *et al*. Perspectives of Australian general practitioners on shared care for paediatric patients. *Aust J Prim Health* 2017;23:147–53. doi:10.1071/PY16002
51 Ducassou S, Chipi M, Pouyade A, *et al*. Impact of shared care program in follow-up of childhood cancer survivors: an intervention study. *Pediatr Blood Cancer* 2017;64:e26541. doi:10.1002/pbc.26541
52 Kooij L, Groen WG, van Harten WH. The effectiveness of information technology-supported shared care for patients with chronic disease: a systematic review. *J Med Internet Res* 2017;19:e221. doi:10.2196/jmir.7405
53 Zhao Y, Brettle A, Qiu L. The effectiveness of shared care in cancer survivors—a systematic review. *Int J Integr Care* 2018;18:2–17. doi:10.5334/ijic.3954
54 Singer S, Gianinazzi ME, Hohn A, *et al*. General practitioner involvement in follow-up of childhood cancer survivors: a systematic review. *Pediatr Blood Cancer* 2013;60:1565–73. doi:10.1002/pbc.24586
55 Mitchell GK, Burridge L, Zhang J, *et al*. Systematic review of integrated models of health care delivered at the primary-secondary interface: how effective is it and what determines effectiveness? *Aust J Prim Health* 2015;21:391–408. doi:10.1071/PY14172
56 Raman S, Brown G, Long D. Priorities for paediatric critical care research: a modified Delphi study by the Australian and New Zealand intensive care Society paediatric Study Group. *Critical Care and Resuscitation* 2021;23:194–201. doi:10.51893/2021.2.oa6
57 Terrien Church P, Luther M, Asztalos E. The perfect storm: the high prevalence low severity outcomes of the preterm survivors. *Current Pediatric Reviews* 2012;8:142–51. doi:10.2174/157339612800681325
58 Keith RE, Crosson JC, O'Malley AS, *et al*. Using the consolidated framework for implementation research (CFIR) to produce actionable findings: a rapid-cycle evaluation approach to improving implementation. *Implement Sci* 2017;12:15.
59 Moore GF, Audrey S, Barker M, *et al*. Process evaluation of complex interventions: medical Research Council guidance. *BMJ* 2015;350:h1258.
60 Curran GM, Bauer M, Mittman B, *et al*. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Med Care* 2012;50:217.
61 Schonwald A, Huntington N, Chan E, *et al*. Routine developmental screening implemented in urban primary care settings: more evidence of feasibility and effectiveness. *Pediatrics* 2009;123:660–8.
62 Baggett KM, Davis B, Feil EG, *et al*. Technologies for expanding the reach of evidence-based interventions: preliminary results for

promoting social-emotional development in early childhood. *Topics Early Child Spec Educ* 2010;29:226–38.
63 Morawska A, Sanders MR. Self-Administered behavioural family intervention for parents of toddlers: effectiveness and dissemination. *Behav Res Ther* 2006;44:1839–48.
64 Tarver J, Daley D, Lockwood J, *et al*. Are self-directed parenting interventions sufficient for externalising behaviour problems in childhood? A systematic review and meta-analysis. *Eur Child Adolesc Psychiatry* 2014;23:1123–37.
65 Costello AG, Nugent BD, Conover N, *et al*. Shared care of childhood cancer survivors: a telemedicine feasibility study. *J Adolesc Young Adult Oncol* 2017;6:535–41.
66 Wake M, Lycett K, Clifford SA, *et al*. Shared care obesity management in 3-10 year old children: 12 month outcomes of HopSCOTCH randomised trial. *BMJ* 2013;346:f3092.
67 Lv S, Ye X, Wang Z, *et al*. A randomized controlled trial of a mobile application-assisted nurse-led model used to improve treatment outcomes in children with asthma. *J Adv Nurs* 2019;75:3058–67.
68 Frey SM, Contento NC, Halterman JS. Nurse-Delivered outpatient asthma education for children and caregivers: a pilot study to promote shared asthma management. *J Asthma* 2021;58:413–21.
69 Long DA, Fink EL. Transitions from short to long-term outcomes in pediatric critical care: considerations for clinical practice. *Transl Pediatr* 2021;10:2858–74.
70 Van Cleave J, Kuhlthau KA, Bloom S, *et al*. Interventions to improve screening and follow-up in primary care: a systematic review of the evidence. *Acad Pediatr* 2012;12:269–82.
71 Calvert M, Kyte D, Mercieca-Bebber R, *et al*. Guidelines for inclusion of patient-reported outcomes in clinical trial protocols: the SPIRIT-PRO extension. *JAMA* 2018;319:483–94.
72 Children's Health Queensland Hospital and Health Service. Children's Health and Wellbeing Services Plan 2018-2028; 2018.
73 Queensland Government Statistician's Office. Population counter, 2021. Available: https://www.qgso.qld.gov.au/
74 Graham ID, Tetroe JM. *The knowledge to action framework. in models and frameworks for implementing evidence-based practice: linking evidence to action*. Sydney: John Wiley & Sons, 2010: 207–22.
75 PICOLO Network. Post intensive care syndrome in paediatrics; 2021. www.picolo.org
76 Shaw J, Sethi S, Vaccaro L, *et al*. Is care really shared? A systematic review of collaborative care (shared care) interventions for adult cancer patients with depression. *BMC Health Serv Res* 2019;19:120.
77 Statewide Child and Youth Clinical Network's Child Development Subnetwork. Child development in Queensland hospital and health services. 2 Act now for kids 2morrow: 2021 to 2030. Brisbane Queensland Health; 2021.
78 Ivers N, Jamtvedt G, Flottorp S, *et al*. Audit and feedback: effects on professional practice and healthcare outcomes. *Cochrane Database Syst Rev* 2012;6:CD000259 https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD000259.pub3/epdf/abstract/es
79 Ivers NM, Sales A, Colquhoun H, *et al*. No more 'business as usual' with audit and feedback interventions: towards an agenda for a reinvigorated intervention. *Implement Sci* 2014;9:14.
80 Centers for Disease Control and Prevention. CDC's Milestone Tracker App, 2021. Available: https://www.cdc.gov/ncbddd/actearly/milestones-app.html
81 Telethon Kinds Institute. Bright Tomorrows start today (parent APP), 2021. Available: https://www.telethonkids.org.au/projects/bright-tomorrows-start-today/
82 Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract* 2004;10:307–12
83 Hertzog MA. Considerations in determining sample size for pilot studies. *Res Nurs Health* 2008;31:180–91.
84 Thabane L, Ma J, Chu R, *et al*. A tutorial on pilot studies: the what, why and how. *BMC Med Res Methodol* 2010;10:1.
85 Squires J, Potter L, Bricker D. *The ASQ user's guide for the Ages & Stages Questionnaires: A parent-completed, child-monitoring system*. Baltimore, MD, US: Paul H Brookes Publishing, 1995.
86 Squires J, Bricker DD, Heo KH. Identification of social-emotional problems in young children using a parent-completed screening measure. *Early Childhood Research Quarterly* 2001;16:405–19.
87 Varni JW, Seid M, Kurtin PS. PedsQL 4.0: reliability and validity of the pediatric quality of life inventory version 4.0 generic core scales in healthy and patient populations. *Med Care* 2001;39:800–12.
88 Saylor CF, Swenson CC, Reynolds SS, *et al*. The pediatric emotional distress scale: a brief screening measure for young children exposed to traumatic events. *J Clin Child Psychol* 1999;28:70–81.
89 Benfer KA, Weir KA, Bell KL, *et al*. Longitudinal study of oropharyngeal dysphagia in preschool children with cerebral palsy. *Arch Phys Med Rehabil* 2016;97:552–60.
90 Voepel-Lewis T, Malviya S, Tait AR. Validity of parent ratings as proxy measures of pain in children with cognitive impairment. *Pain Manag Nurs* 2005;6:168–74.
91 Manworren RCB, Hynan LS. Clinical validation of FLACC: preverbal patient pain scale. *Pediatr Nurs* 2003;29:140–6.
92 Gordijn MS, Suzanne Gordijn M, Cremers EMP, *et al*. Fatigue in children: reliability and validity of the Dutch PedsQL™ multidimensional fatigue scale. *Qual Life Res* 2011;20:1103–8.
93 Haskett ME, Ahern LS, Ward CS, *et al*. Factor structure and validity of the parenting stress index-short form. *J Clin Child Adolesc Psychol* 2006;35:302–12.
94 Kessler RC, Barker PR, Colpe LJ, *et al*. Screening for serious mental illness in the general population. *Arch Gen Psychiatry* 2003;60:184–9.
95 Kessler RC, Green JG, Gruber MJ, *et al*. Screening for serious mental illness in the general population with the K6 screening scale: results from the WHO world mental health (WMH) survey initiative. *Int J Methods Psychiatr Res* 2010;19 Suppl 1:4–22.
96 Prins A, Ouimette P, Kimerling R. The primary care PTSD screen (PC-PTSD): development and operating characteristics. *International Journal of Psychiatry in Clinical Practice* 2004;9:9–14.
97 Needham D. Improving long-term outcomes research for acute respiratory failure, 2021. Available: https://www.improvelto.com/
98 Zimet GD, Dahlem NW, Zimet SG, *et al*. The multidimensional scale of perceived social support. *J Pers Assess* 1988;52:30–41.
99 Connor KM, Davidson JRT. Development of a new resilience scale: the Connor-Davidson resilience scale (CD-RISC). *Depress Anxiety* 2003;18:76–82.
100 Rogers H, Matthews J. The parenting sense of competence scale: investigation of the factor structure, reliability, and validity for an Australian sample. *Aust Psychol* 2004;39:88–96.
101 Johnston C, Mash EJ. A measure of parenting satisfaction and efficacy. *J Clin Child Psychol* 1989;18:167–75.
102 Pedlow R, Sanson A, Prior M, *et al*. Stability of maternally reported temperament from infancy to 8 years. *Dev Psychol* 1993;29:998–1007.
103 Prior MR, Sanson AV, Oberklaid F. *The Australian temperament project. temperament in childhood*. Oxford, England: John Wiley & Sons, 1989: 537–54.
104 Sanson A, Prior M, Garino E, *et al*. The structure of infant temperament: factor analysis of the revised infant temperament questionnaire. *Infant Behavior and Development* 1987;10:97–104.
105 Proctor E, Silmere H, Raghavan R, *et al*. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Adm Policy Ment Health* 2011;38:65–76.
106 Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. *Implementation Science* 2013;8:1–11.
107 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
108 Harris PA, Taylor R, Minor BL, *et al*. The REDCap Consortium: building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.
109 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
110 Schlapbach LJ, Straney L, Bellomo R, *et al*. Prognostic accuracy of age-adapted SOFA, SIRS, PELOD-2, and qSOFA for in-hospital mortality among children with suspected infection admitted to the intensive care unit. *Intensive Care Med* 2018;44:179–88.