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A longitudinal, mixed-methods investigation of the physical, cognitive, emotional, social health outcomes and the support needs of children and their family members in the first year after a PICU discharge

Submission date
11/11/2019

Recruitment status
No longer recruiting

Registration date
14/02/2020

Overall study status
Completed

Last Edited
18/03/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Current plain English summary as of 18/01/2022:

Background and study aims
Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them. We want to understand the physical, functional, emotional and social consequences of being on PICU to children (aged 1 month-17 years), their parents and siblings, in the first-year after a PICU admission. We will conduct a study that will collect information from these children, their parents and siblings, who have been admitted to PICU over a year to see if there are any changes over time. In addition, some families will take part in interviews in order to explore their care and support needs.

Who can participate?
1. Child aged 1 month to 17 years at the point of PICU admission, who will be discharged alive from the PICU in next 48 hours
2. Their parents or legal guardians
3. Their siblings aged 8 or older

What does the study involve?
To do this, we want to follow up 334 children, their parents, and their siblings from 10 PICUs. Information will be collected over the first-year after they have left the PICU. Information will be

collected (over the telephone or via the internet) at 1 month, 3 months, 6 months, and 12 months after leaving PICU. At 3 and 9 months, we will invite up to 40 families to take part in a face-to-face or telephone interview to talk about their health care needs.

What are the possible benefits and risks of participating?
There may not be any specific benefits to participating in this study. However, participating in this research will help us to understand what children/young people and their families' outcomes are like in the first year after PICU and whether there are ways we can improve the support for these children and their families. All participants over the age of 5 years will receive a £15 voucher at the end of the study as a token of appreciation. Furthermore for those that participate in the interview will receive an additional £10 voucher. There are no particular risks to participating in this study. Participants will receive the same medical treatment whether they take part or not. By completing the questionnaires participants will be asked to think about a potentially difficult time and for some, this may be upsetting. If this is the case then the participant can withdraw from the study at any time without giving a reason. Furthermore, if participants would like to speak to someone about how they are feeling then the study team can help signpost the participants to support.

Where is the study run from?
Nottingham University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
April 2019 to March 2023

Who is funding the study?
NIHR Academy (UK)

Who is the main contact?
Dr Joseph Manning
Joseph.Manning@nottingham.ac.uk

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Previous plain English summary:

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Study website
https://sites.google.com/nihr.ac.uk/oceanic/home

Contact information

Type(s)
Scientific

Contact name
Dr Joseph Manning

Contact details

C3084, C-floor, South Block
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
269642

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 43559, IRAS 269642

Study information

Scientific Title
A multi-centre longitudinal mixed-methods study to explore the Outcomes of ChildrEn and fAmilies in the first year after paediatric Intensive Care: the OCEANIC study

Acronym
OCEANIC

Study objectives
Current study hypothesis as of 18/01/2022:

Each year 20,000 children become very ill or injured and need specialist care within a Paediatric Intensive Care Unit (PICU). Most children survive. However, these children and their families may experience problems after they have left the PICU. These can include physical (breathing, eating and drinking), functional (moving and concentration), and/or emotional problems (stress and fears) to themselves and their families (parents and siblings). These have the potential to affect health, place burdens on parents/carers, impact on education and social development. However, we currently do not know which children and families experience problems, when the problems occur, and what causes them.

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To improve care, we will share our results with national organisations, healthcare commissioners, policy makers and the international paediatric intensive care community.

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To improve care, we will share our results with national organisations, healthcare commissioners, policy makers and the international paediatric intensive care community.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/11/2019, West Midlands – Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS; Tel: +44 (0)207 104 8010; Email: nrescommittee.westmidlands-blackcountry@nhs.net), REC ref: 19/WM/0290

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Support needs of children and family members following discharge from the paediatric intensive care unit (PICU)

Interventions
Current interventions as of 18/01/2022:

This is a multi-centre longitudinal mixed-methods study of children and their families' outcomes and support needs in the first-year post-PICU. This will involve a mixed-methods design of two linked work-packages (WP): WP1-quantitative study; WP2 – qualitative study.

Setting and sampling:
Participants for this study include: (1) child PICU survivors; (2) parents/legal guardians; (3) siblings. Participants will be recruited from five PICUs in Children's Hospitals across England. These sites include: Nottingham University Hospitals NHS Trust; Birmingham Women and Children's Hospital NHS Foundation Trust; University Hospitals of Bristol NHS Trust; Great Ormond Street Hospital NHS Foundation Trust; Alder hey Children's NHS Foundation Trust. They have been selected as sites for this study as they vary in unit size, case mix, geographical location, and patient demographic.

Work-package 1:
A consecutive sampling strategy will be employed. Each site will screen daily over a six-month period and invite all eligible children to participate in the study. Data from screening logs, including refusal to participate and admission numbers at each site, will be collected and used to contextualise the reporting of the analysis.
Data will be collected on the PICU survivor, at least one eligible parent/legal guardian, and a sibling who are able to provide assent and complete surveys independently.
• PICU survivor: If able, all child patients' ≥8 years of age will be asked to self-report. When indicated (because of their child's age or cognitive capacity), one parent who is the child's primary care provider will be asked to consistently serve as their child's proxy. When more than one parent meets criteria and are willing, parents will self-select who will serve as their child's proxy. Children becoming cognitive capable over the course of the study will be asked to self-report when able.
• Parent: At least one parent/legal guardian living with the patient will be invited to participate

and complete the family surveys. If more than one parent agrees to participate they will be asked to complete their surveys independently of their partner.
• Siblings: A sibling, ≥8 years of age who can complete surveys independently, lives with the patient, and who have not been PICU hospitalized will be invited to participate and provide assent.

Data collection and measures
WP1. Data will be collected from each child (or proxy), their parent, and sibling (if appropriate) prospectively over the first-year post-PICU discharge. Currently there is no standardised or agreed set of outcome measures for research with the PICU patient population. Therefore, the outcome measures used in this study were selected for their validity, reliability, ease of use, availability in electronic versions and previous use with population under investigation. Furthermore, the focus and selection of these measures was informed by the PICS-p framework, contemporary literature, and consultation with patients, public, and PICU clinicians. In line with feedback from this PPI, outcomes will be collected at six time-points: Baseline status (pre-PICU discharge); at PICU discharge; 1, 3, 6 and 12 months post-PICU discharge.
(a) Baseline status and demographic data will be collected through extraction from the medical records and parent report prior to PICU discharge. This will include: Participant characteristics; past medical history; current medical history; PICU discharge diagnosis; PICU length of stay; PICU activity including number of days of mechanical ventilation; other therapies.
Completion of the Paediatric Quality of Life Inventory Version 4.0 (PedsQL™), Paediatric Overall Performance Category (POPC) and Paediatric Cerebral Performance Category (PCPC) based on the child's status two-weeks prior to PICU admission.
(b) PICU admission and activity data (PICANet Data download): The site investigator (or their designated nominee) will collect the NHS number, date of birth, and date of PICU admission for each child PICU survivor recruited into the study. This data will be stored separately from the OCEANIC outcomes data on a local password protect and encrypted database. Using this information, the site investigator (or their designated nominee) will identify the child PICU survivor who has been recruited into the study on the PICANet data collection web-based system and insert their OCEANIC unique study ID onto the system. Each site will then be able to conduct a data download of a pseudo-anonymised dataset containing the PICANet minimum dataset (admission details and activity data) of OCEANIC participants from that site. This will include: demographic and socioeconomic data (participant's date of birth, sex, ethnicity, first 4 digits of their post code); pre-PICU health status (past medical history including underlying conditions and co-morbidities); and acute illness data (PIM2/PIM3; PICU admission and discharge diagnoses; co-morbidities; operations and invasive procedures performed; type of admission; PICU and hospital LOS, duration of mechanical ventilation, high frequency oscillatory ventilation, extracorporeal membrane oxygenation, renal replacement therapy, and vasopressor/inotropic support; sedative medications and days of exposure). This dataset will be sent back to the study Chief Investigator using an encrypted and password protected file via NHS email.
(c) PICU-discharge (within 72 hours), 1, 3, 6 and 12 months: Data will be collected either face-to-face (if inpatient), via telephone interview, online survey completion, or paper mail dependent on the preference of the child, parent, and sibling. All participants will be followed for one year. Where possible each participant will self-report. However, for children that are unable to self-report (due to age or cognition), a parent will proxy-report.

Data collection tools:
Child related
1. PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales and Infant Scales – Acute Version measures health-related quality of life (HRQOL) in infants, children and adolescents aged 1 month to 17 years old. The PedsQL™ Generic Core Scales are used for children ≥2 years of age. They are 23-item child self-report and parent proxy-report scales with four domains:

physical functioning, emotional functioning, social functioning, and school functioning. The PedsQL Infant Scales are used for children <2 years of age and consist of 36-45 items, depending on age, with 5 domains: physical functioning, physical symptoms, emotional functioning, social functioning, and cognitive functioning. Like the Generic Core Scales, the Infant Scales generate a total score. Both sets of instruments have good validity and reliability, have been widely used.
2. PedsQL™ Multi-dimensional Fatigue Scale is an 18-item scale that encompasses three domains: (1) General Fatigue; (2) Sleep/Rest Fatigue and (3) Cognitive Fatigue. The instructions ask how much of a problem each item has been during the past one month. The PedsQL™ Multidimensional Fatigue Scale comprises parallel children self-report and parent proxy-report formats. Higher scores indicate better HRQOL (lower fatigue symptoms).
3. PedsQL™ Pediatric Pain Questionnaire is a generic symptom-specific instrument to measure pain in patients with acute and chronic health conditions. We will use question #2, which asks participants capable of self-reporting to identify a point on a 100 mm line that best shows the worst pain the subject experienced in the past week. Anchors include “no hurting, no discomfort, or no pain” and “hurting a whole lot, very uncomfortable, severe pain”.
4. Functional Status Scale (FSS), an assessment method developed and validated to quantify functional status. The FSS includes 6 domains: mental status, sensory, communication, motor function, feeding, and respiratory. The FSS is amenable to studies of this nature due to ease of administration, its granularity, and objectivity of assessment compared to other available methods and has been used in other outcome studies.
5. Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) quantify short-term cognitive impairments and functional morbidity.27 The POPC scale is dependent on the PCPC scale, as the PCPC status is included in POPC. Studies of patients with scores of 1–4 at PICU discharge, hospital discharge, and one- and six-month follow-up show association with the Stanford Binet Intelligence Quotient, Bayley scales, and Vineland Adaptive Behaviour Scale.
6. Strengths and Difficulties Questionnaire (SDQ) is a behavioural screening questionnaire used to evaluate emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour. The SDQ quantifies low, medium, and high risk of emotional, behavioural, hyperactivity concentration disorders, or any disorder.
7. Child Revised Impact of Events Scale (CRIES-8) is an eight-item screen for post-traumatic stress symptoms in children aged between 7 and 18 years, with established reliability and validity. It has been used with children who have experienced many types of trauma, including the PICU population. A cut-off score of 17 or greater has been found to classify correctly over 80% of children with a diagnosis of post-traumatic stress disorder.
8. Children’s Hope Scale (CHS) is a very brief, six-item self-report measure of children's perceptions that their goals can be met. It has been validated for use in children and young people aged 8-17 years consisting of both healthy populations and children with a range of physical illnesses. Scores were invariant across age groups, gender, and race/ethnicity. Scores correlated significantly and in the theorized direction with external measures of similar constructs, including observer ratings of hope, and self-ratings of self-worth and depression.

Parent related
1. PedsQL™ Family Impact Module, applies to measuring the impact of paediatric chronic health conditions on their family functioning. Dimensions include: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; family relationships; and financial issues).
2. State-Trait Anxiety Inventory 6 (STAI-6) is a self-reported questionnaire that assesses symptoms of anxiety. It is a short version of the Spielberger State Anxiety Scale (SSA), with a cut-off point at 1 SD above the mean to indicate clinically relevant symptoms.
3. Patient Health Questionnaire-4 (PHQ-4) is a 4 item inventory rated on a 4 point Likert-type scale. Its items are drawn from the first two items of the 'Generalized Anxiety Disorder–7 scale'

(GAD–7) and the 'Patient Health Questionnaire-8' (PHQ-8). Its purpose is to allow for very brief and accurate measurement of depression and anxiety. PHQ– 4 scores are strongly associated with decrements in multiple domains of functional impairment; the anxiety and depression subscales make unique overall contributions to the PHQ– 4, both in terms of factorial and criterion validity; and perhaps most importantly: the results indicate that anxiety has a substantial independent effect on functioning, and even more so when co-morbid with depression.
4. The Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) is a 20-item self-report measure that assesses the presence and severity of PTSD symptoms. Items on the PCL-5 correspond with DSM-5 criteria for PTSD. The PCL-5 can be used to quantify and monitor symptoms over time, to screen individuals for PTSD, and to assist in making a provisional or temporary diagnosis of PTSD.

Sibling related
1. PedsQL™ 4.0 (outlined above).
2. SDQ (outlined above). NB. Siblings will be expected to self-report on all measures. However, for siblings under the age of 10 the SDQ measure will be done by parent proxy report. This is because the SDQ measure is only validated via parent proxy reporting.
3. Multidimensional Assessment of Caring Activities (MACA-YC18) a self-report measure that can be used to provide an index of the total amount of caring activity undertaken by the young person, as well as six subscale scores for domestic tasks, household management, personal care, emotional care, sibling care, and financial/practical care. The MACA-YC18 was designed as a short, easy-to-use measure able to provide an index of the extent of caring activities a young person is engaged in. Higher scores indicate greater levels of caring activity.
4. Positive and Negative Outcomes of Caring (PANOC-YC20) a self-report measure that can be used to provide an index of positive and negative outcomes of caring. The PANOC-YC20 consists of two 10- item subscales: (1) positive responses, and (2) negative responses, which collectively assess the subjective cognitive and emotional impact of caring in young people with higher scores indicating greater positive and negative responses, respectively.
5. Children's Hope Scale (outlined above).

Work-package 2:
Semi-structured qualitative interviews will be conducted to explore care needs at 3 months and 9 months post-PICU discharge. As advocated in the child health literature, a pragmatic and participant-centred approach (based on choice, participation, and flexibility) to collecting qualitative data will be employed. Interviews will be conducted with children, parents/legal guardians, and siblings either collectively or separately. Interviews will take place at the participants' preferred time and method (e.g. face-to-face, telephone). Interviews based on a topic guide that will be developed using the current literature and are proposed to cover the following subjects: experienced problems and needs for support, care-giving roles and responsibilities. All interviews will be audio-recorded and transcribed verbatim.

Steering group:
A steering group will be formed of national clinical experts in the field that include: Dr Lyvonne Tume - Associate Professor in Child Health and Senior PICU Nurse, University of Salford (Chair); Dr Gillian Colville - Consultant Clinical Psychologist, St Georges NHS Trust; Dr Sarah Redsell, Associate Professor of Child Health Research, University of Nottingham; Dr Barney Scholefield, Clinician Scientist and Paediatric Intensivist, University of Birmingham; Professor Jo Wray, Health Psychologist and Professor, Great Ormond Street Hospital. They will complement the core research team providing expert clinical guidance to ensuring that the OCEANIC study will be delivered to time, target and to a high standard.

Ethics and governance:
This study will be conducted according to the NHS Research Ethics Guidelines and core principles which aim to maximise the benefit to society and minimise harm. The OCEANIC study will include participation of NHS patients, requiring approval from the HRA and NHS RES.

Once eligibility criteria are confirmed, the site investigator will approach and provide written study information to the parent/legal guardian and child for consideration of study participation. PPI undertaken as part of the development of this study identified that this can be a particularly challenging time for families and involve heightened emotional responses. Therefore, the initial approach will be undertaken by the usual care team in a sensitive manner. Children and families will be given time to consider whether they wish to participate and will have the opportunity to contact the PI to ask questions before making a decision. The site investigator will then obtain informed consent from the parent/legal guardian of all children who meet the study eligibility criteria. Children who are able to provide assent will be asked for this when they are cognitively capable. Those aged over 16 years and who have the capacity to consent will complete the informed consent autonomously. For parents and siblings informed consent/assent procedures will be undertaken.

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4. Functional Status Scale (FSS), an assessment method developed and validated to quantify functional status. The FSS includes 6 domains: mental status, sensory, communication, motor function, feeding, and respiratory. The FSS is amenable to studies of this nature due to ease of administration, its granularity, and objectivity of assessment compared to other available methods and has been used in other outcome studies.
5. Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) quantify short-term cognitive impairments and functional morbidity.27 The POPC scale is dependent on the PCPC scale, as the PCPC status is included in POPC. Studies of patients with scores of 1–4 at PICU discharge, hospital discharge, and one- and six-month follow-up show association with the Stanford Binet Intelligence Quotient, Bayley scales, and Vineland Adaptive Behaviour Scale.
6. Strengths and Difficulties Questionnaire (SDQ) is a behavioural screening questionnaire used to evaluate emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour. The SDQ quantifies low, medium, and high risk of emotional, behavioural, hyperactivity concentration disorders, or any disorder.
7. Child Revised Impact of Events Scale (CRIES-8) is an eight-item screen for post-traumatic stress symptoms in children aged between 7 and 18 years, with established reliability and validity. It has been used with children who have experienced many types of trauma, including the PICU population. A cut-off score of 17 or greater has been found to classify correctly over 80% of children with a diagnosis of post-traumatic stress disorder.
8. Children’s Hope Scale (CHS) is a very brief, six-item self-report measure of children's perceptions that their goals can be met. It has been validated for use in children and young people aged 8-17 years consisting of both healthy populations and children with a range of physical illnesses. Scores were invariant across age groups, gender, and race/ethnicity. Scores correlated significantly and in the theorized direction with external measures of similar constructs, including observer ratings of hope, and self-ratings of self-worth and depression.

Parent related
1. PedsQL™ Family Impact Module, applies to measuring the impact of paediatric chronic health conditions on their family functioning. Dimensions include: physical functioning; emotional functioning; social functioning; cognitive functioning; communication; worry; daily activities; family relationships; and financial issues).
2. State-Trait Anxiety Inventory 6 (STAI-6) is a self-reported questionnaire that assesses symptoms of anxiety. It is a short version of the Spielberger State Anxiety Scale (SSA), with a cut-off point at 1 SD above the mean to indicate clinically relevant symptoms.
3. Patient Health Questionnaire-4 (PHQ-4) is a 4 item inventory rated on a 4 point Likert-type scale. Its items are drawn from the first two items of the 'Generalized Anxiety Disorder–7 scale' (GAD–7) and the 'Patient Health Questionnaire-8' (PHQ-8). Its purpose is to allow for very brief and accurate measurement of depression and anxiety. PHQ– 4 scores are strongly associated with decrements in multiple domains of functional impairment; the anxiety and depression

subscales make unique overall contributions to the PHQ– 4, both in terms of factorial and criterion validity; and perhaps most importantly: the results indicate that anxiety has a substantial independent effect on functioning, and even more so when co-morbid with depression.
4. The Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) is a 20-item self-report measure that assesses the presence and severity of PTSD symptoms. Items on the PCL-5 correspond with DSM-5 criteria for PTSD. The PCL-5 can be used to quantify and monitor symptoms over time, to screen individuals for PTSD, and to assist in making a provisional or temporary diagnosis of PTSD.

Sibling related
1. PedsQL™ 4.0 (outlined above).
2. SDQ (outlined above). NB. Siblings will be expected to self-report on all measures. However, for siblings under the age of 10 the SDQ measure will be done by parent proxy report. This is because the SDQ measure is only validated via parent proxy reporting.
3. Multidimensional Assessment of Caring Activities (MACA-YC18) a self-report measure that can be used to provide an index of the total amount of caring activity undertaken by the young person, as well as six subscale scores for domestic tasks, household management, personal care, emotional care, sibling care, and financial/practical care. The MACA-YC18 was designed as a short, easy-to-use measure able to provide an index of the extent of caring activities a young person is engaged in. Higher scores indicate greater levels of caring activity.
4. Positive and Negative Outcomes of Caring (PANOC-YC20) a self-report measure that can be used to provide an index of positive and negative outcomes of caring. The PANOC-YC20 consists of two 10- item subscales: (1) positive responses, and (2) negative responses, which collectively assess the subjective cognitive and emotional impact of caring in young people with higher scores indicating greater positive and negative responses, respectively.
5. Children's Hope Scale (outlined above).

Work-package 2:
Semi-structured qualitative interviews will be conducted to explore care needs at 3 months and 9 months post-PICU discharge. As advocated in the child health literature, a pragmatic and participant-centred approach (based on choice, participation, and flexibility) to collecting qualitative data will be employed. Interviews will be conducted with children, parents/legal guardians, and siblings either collectively or separately. Interviews will take place at the participants' preferred time and method (e.g. face-to-face, telephone). Interviews based on a topic guide that will be developed using the current literature and are proposed to cover the following subjects: experienced problems and needs for support, care-giving roles and responsibilities. All interviews will be audio-recorded and transcribed verbatim.

Steering group:
A steering group will be formed of national clinical experts in the field that include: Dr Lyvonne Tume - Associate Professor in Child Health and Senior PICU Nurse, UWE Bristol (Chair); Dr Gillian Colville - Consultant Clinical Psychologist, St Georges NHS Trust; Professor Sarah Redsell, Professor of Public Health, Anglia Ruskin University, Dr Jo Wray, Health Psychologist and Associate Professor, Great Ormond Street Hospital. They will complement the core research team providing expert clinical guidance to ensuring that the OCEANIC study will be delivered to time, target and to a high standard.

Ethics and governance:
This study will be conducted according to the NHS Research Ethics Guidelines and core principles which aim to maximise the benefit to society and minimise harm. The OCEANIC study will include participation of NHS patients, requiring approval from the HRA and NHS RES.

Once eligibility criteria are confirmed, the site investigator will approach and provide written study information to the parent/legal guardian and child for consideration of study participation. PPI undertaken as part of the development of this study identified that this can be a particularly challenging time for families and involve heightened emotional responses. Therefore, the initial approach will be undertaken by the usual care team in a sensitive manner. Children and families will be given time to consider whether they wish to participate and will have the opportunity to contact the PI to ask questions before making a decision. The site investigator will then obtain informed consent from the parent/legal guardian of all children who meet the study eligibility criteria. Children who are able to provide assent will be asked for this when they are cognitively capable. Those aged over 16 years and who have the capacity to consent will complete the informed consent autonomously. For parents and siblings informed consent/assent procedures will be undertaken.

Intervention Type
Other

Primary outcome measure
Child PICU participants:
Quality of life measured using the PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales and Infant Scales – Acute Version at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:
Quality of life and functioning measured using PedsQL™ Family Impact Module at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Sibling participants:
Quality of life measured using the PedsQL™ 4.0 (Pediatric Quality of Life Inventory) Generic Core Scales– Acute Version at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Secondary outcome measures
Current secondary outcome measures as of 16/12/2020:
Child PICU participants:
1. Fatigue measured using the PedsQL™ Multi-dimensional Fatigue Scale at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Pain measured using PedsQL™ Pediatric Pain Questionnaire at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. Functional status that includes mental status, sensory, communication, motor function, feeding and respiratory measured using the Functional Status Scale (FSS) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Cognitive impairment and functional morbidity measured by using the Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
5. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
6. Post-traumatic stress symptoms measured using the Child Revised Impact of Events Scale (CRIES-8), Young Child PTSD Screen (YCPS) and Child and Adolescent PTSD screen at 3 months, 6 months and 12 months
7. Perceptions that the participants' goals can be met, measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:
1. Symptoms of anxiety measured using State-Trait Anxiety Inventory 6 (STAI-6) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Depression and anxiety measured using the Patient Health Questionnaire-4 (PHQ-4) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The presence and severity of post-traumatic stress disorder symptoms measured using the Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) at 3 months, 6 months, and 12 months

Sibling participants:
1. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. The total amount of caring activity undertaken measured using the Multidimensional Assessment of Caring Activities (MACA-YC18) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The subjective cognitive and emotional impact of caring measured using Positive and Negative Outcomes of Caring (PANOC-YC20) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Perceptions that the participants' goals can be met measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

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Previous secondary outcome measures:
Child PICU participants:
1. Fatigue measured using the PedsQL™ Multi-dimensional Fatigue Scale at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Pain measured using PedsQL™ Pediatric Pain Questionnaire at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. Functional status that includes mental status, sensory, communication, motor function, feeding and respiratory measured using the Functional Status Scale (FSS) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Cognitive impairment and functional morbidity measured by using the Paediatric Cerebral Performance Category (PCPC) and the Paediatric Overall Performance Category (POPC) at baseline, PICU discharge, 1 month, 3 months, 6 months, and 12 months
5. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
6. Post-traumatic stress symptoms measured using the Child Revised Impact of Events Scale (CRIES-8) at 3 months, 6 months, and 12 months
7. Perceptions that the participants' goals can be met, measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Parent/legal guardian participants:
1. Symptoms of anxiety measured using State-Trait Anxiety Inventory 6 (STAI-6) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. Depression and anxiety measured using the Patient Health Questionnaire-4 (PHQ-4) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

3. The presence and severity of post-traumatic stress disorder symptoms measured using the Post Traumatic Stress Disorder (PTSD) Checklist for DSM-5 (PCL-5) at 3 months, 6 months, and 12 months

Sibling participants:
1. Emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems, and pro-social behaviour measured using the Strengths and Difficulties Questionnaire (SDQ) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
2. The total amount of caring activity undertaken measured using the Multidimensional Assessment of Caring Activities (MACA-YC18) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
3. The subjective cognitive and emotional impact of caring measured using Positive and Negative Outcomes of Caring (PANOC-YC20) at PICU discharge, 1 month, 3 months, 6 months, and 12 months
4. Perceptions that the participants' goals can be met measured using the Children's Hope Scale (CHS) at PICU discharge, 1 month, 3 months, 6 months, and 12 months

Overall study start date
01/04/2019

Completion date
31/03/2023

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/01/2022:

Child:
1. Aged 1 month (and >=44 weeks corrected gestational age) to 17 years at the point of PICU admission
2. Will be discharged alive from the PICU in next 48 hours
3. PICU total length of stay (LOS) >=48 hours at point of discharge in which the patient received PICU therapies for organ dysfunction (including any of the following invasive mechanical ventilation, vasopressors /inotropes, acute renal replacement therapy, or other extracorporeal life support)
4. At least one parent/legal guardian (>=18 years of age or considered emancipated) living with the potential subject

Parent:
1. Parent or legal guardian
2. Cohabits with the child

Sibling:
1. Aged >=8 years
2. Is a sibling of the children PICU survivor
3. Cohabits with the child PICU survivor for at least 50% of the time
4. Can independently self-report

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Previous inclusion criteria:

Child:
1. Aged 1 month (and > = 44 weeks corrected gestational age) to 17 years at the point of PICU admission
2. Will be discharged alive from the PICU in next 48 hours
3. PICU total length of stay (LOS) > = 72 hours at point of discharge in which the patient received PICU therapies for organ dysfunction (including any of the following invasive mechanical ventilation, vasopressors /inotropes, acute renal replacement therapy, or other extracorporeal life support)
4. At least one parent/legal guardian (> = 18 years of age or considered emancipated) living with the potential subject

Parent:
1. Parent or legal guardian
2. Cohabits with the child

Sibling:
1. Aged > = 8 years
2. Is a sibling of the children PICU survivor
3. Cohabits with the child PICU survivor for at least 50% of the time
4. Can independently self-report

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
1 Months

Upper age limit
17 Years

Sex
Both

Target number of participants
Planned Sample Size: 1002; UK Sample Size: 1002

Total final enrolment
787

Key exclusion criteria
Child:
1. Previously had a Paediatric ICU/Neonatal ICU admission
2. Active do not resuscitate plan/end of life pathway
3. Child in foster care or under the power of Wardship

Any participant unwilling or unable (i.e. lacking capacity) to provide consent assent

Date of first enrolment
04/12/2019

Date of final enrolment
09/05/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nottingham University Hospitals NHS Trust
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Birmingham Women's and Children's NHS Foundation Trust
Steelhouse Lane
Birmingham
United Kingdom
B4 6NH

Study participating centre
Alder Hey Children's NHS Foundation Trust
Alder Hey Hospital
Eaton Road
Liverpool
United Kingdom
L12 2AP

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Marlborough Street

Bristol
United Kingdom
BS1 3NU

Study participating centre
Great Ormond Street Hospital For Children NHS Foundation Trust
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
Manchester Children's Hospital
Manchester University NHS Foundation Trust
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Sheffield Children's Hospital
Clarkson Street
Sheffield
United Kingdom
S10 2TH

Study participating centre
St George's University Hospital
Blackshaw Road
Tooting
London
United Kingdom
SW17 0QT

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Royal London Hospital
Whitechapel Rd
London
United Kingdom
E1 1FR

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham University Hospitals NHS Trust
Nottingham
England
United Kingdom
NG7 2UH
+44 (0)115 924 9924 ext. 80676
researchsponsor@nuh.nhs.uk

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: ICA-CL-2018-04-ST2-009

Results and Publications

Publication and dissemination plan
1. Study protocol will be available as a published manuscript in Spring 2020
2. Peer reviewed scientific journals

3. Internal report
4. Conference presentation
5. Publication on website
6. Other publication
7. Submission to regulatory authorities

Intention to publish date
31/03/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		17/05/2020	18/03/2025	Yes	No