Implementing early rehabilitation and mobilisation for children in UK paediatric intensive care units: the PERMIT feasibility study

Barnaby R Scholefield,[1,2*] Julie C Menzies,[2] Jennifer McAnuff,[3,4] Jacqueline Y Thompson,[1] Joseph C Manning,[5,6] Richard G Feltbower,[7] Michelle Geary,[8] Sophie Lockley,[9] Kevin P Morris,[2] David Moore,[10] Nazima Pathan,[11] Fenella Kirkham,[8] Robert Forsyth[12] and Tim Rapley[4]

[1]Birmingham Acute Care Research Group, Institute of Inflammation and Ageing, University of Birmingham, Birmingham, UK
[2]Paediatric Intensive Care, Birmingham Women's and Children's NHS Foundation Trust, Birmingham, UK
[3]Population Health Sciences Institute, Newcastle University, Newcastle, UK
[4]Department of Social Work, Education and Community Wellbeing, Northumbria University, Newcastle, UK
[5]Nottingham Children's Hospital, Nottingham University Hospitals NHS Trust, Nottingham, UK
[6]Children and Young People Health Research, School of Health Sciences, The University of Nottingham, Nottingham, UK
[7]Leeds Institute for Data Analytics, School of Medicine, University of Leeds, Leeds, UK
[8]Child Health, University Hospital Southampton NHS Foundation Trust, Southampton, UK
[9]PPIE Representative, Birmingham Women's and Children's NHS Foundation Trust, Birmingham, UK
[10]Institute of Applied Health, University of Birmingham, Birmingham, UK
[11]Department of Paediatrics, University of Cambridge, Cambridge, UK
[12]Translational and Clinical Research Institute, Newcastle University, Newcastle, UK

[*]Corresponding author Barney.scholefield@sickkids.ca

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Scientific summary

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Scientific summary

Background

Annually in the UK, 20,000 children (0–<18 years) require life-sustaining treatment for critical illness and injury in paediatric intensive care units (PICU). As more than 96% of admissions to PICU survive, morbidity in survivors is now a major concern. The impact of being critically ill can manifest itself in weakness, cognitive impairment, organ dysfunction and psychological problems. Unfortunately, many children and young people (CYP) experience significant and residual physical, cognitive and psychosocial morbidities following PICU that impact on their quality of life (QoL). Our focus is to minimise iatrogenic harm of critical care and maximise patient outcomes through the development, testing and implementation of novel interventions.

Early rehabilitation and mobilisation (ERM) can include individual patient-tailored interventions, or packages of care, provided by health professionals from multiple disciplines and caregivers within intensive care settings. ERM aims to promote physical (e.g. movement, functional activities, ambulation) and non-physical (e.g. speech, play, psychological, cognitive) recovery. Benefits have been demonstrated in the use of ERM in adult intensive care unit (ICU) populations in relation to patient outcomes as well as healthcare utilisation. The use of ERM in the paediatric ICU population offers significant potential to prevent morbidities associated with being critically ill, facilitate recovery and improve patient outcomes. With practical interventions appropriate to the CYP condition, age and severity of illness (referred to as 'acuity' throughout this report), there is potential to positively impact the emotional, behavioural, cognitive and functional outcomes of CYP and to benefit their caregivers' QoL across the NHS. Challenges to ERM in critically ill children include the wide age range, heterogeneous disease processes and a high proportion of children with chronic comorbidities.

While there is good evidence to support the safe and effective use of ERM in adult ICU populations, there is insufficient evidence of such an effect in children. Several international studies have demonstrated feasibility, acceptability and safety of ERM in this population using physiotherapy (PT), occupational therapy, video games and exercise equipment (e.g. in bed cycling). However, the evidence base for ERM in the paediatric ICU population in a UK context is scant. Some NHS PICUs are reported to have implemented ERM into their clinical practice, albeit that this does not always appear to have been undertaken systematically, nor has the impact on patient outcomes, service utilisation or resources been evaluated. Existing uncertainties around ERM are its current use in the UK, how best to operationalise and implement it, and its potential effectiveness. In this study, we explored current paediatric ERM practice, developed a manualised ERM intervention, then assessed feasibility of proposed ERM intervention and outcome measures in order to prepare for a definitive PICU ERM trial.

Aims

To prepare for a definitive paediatric ERM trial, we will: (1) identify current ERM practice, (2) specify the content of an ERM intervention, (3) establish the patient population for whom ERM may be appropriate, (4) determine patient-centred outcomes of ERM, and appropriate measures and (5) explore the feasibility and acceptability of an ERM future trial.

Study objectives

Understand current practice:

- to review the literature supporting current paediatric ERM practice;
- to define, identify and describe current ERM practice in UK PICs and assess capability of UK PICs to deliver ERM;
- to establish and model how many/which CYP would be appropriate for ERM in the PIC population.

Develop an ERM intervention and select patient-centred outcomes:

- to co-design manual of ERM interventions;
- to identify relevant primary and secondary patient-centred outcomes and assessment tools.

Assessment of feasibility of proposed ERM intervention and outcome measures:

- to explore feasibility and acceptability of manualised ERM intervention in a three-centre, non-randomised feasibility study.

Synthesise data and report findings:

- to combine population, intervention and standard care and outcome definitions for future trial evaluation proposal;
- to build consensus on intervention for feasible/acceptable ERM trial and explore methodological approaches and future trial design.

Methods

A mixed-methods study with three phases and five interlinked studies.

Phase 1a: scoping review of literature

Studies [randomised controlled trials (RCTs) and observational studies] of CYP (≤18 years), admitted to PICU, receiving early (within 7 days) rehabilitation and mobilisation and measuring an outcome (participants' health and well-being, health service utilisation, feasibility, acceptability or intervention implementation) were identified in electronic bibliographic databases from inception to November 2021. Study selection, data extraction and risk of bias assessment [using the Cochrane RoB tool; Risk of Bias in Non-randomised Studies – of Interventions (ROBINS-I)] were undertaken by reviewers independently. Findings were narratively synthesised.

Phase 1b: survey of current practice

An electronic web-based survey administered to healthcare professionals selected from UK PICUs to describe components of ERM, establish current ERM practice and understand barriers and facilitators to implementing ERM.

Phase 1c: observation study of current practice

All paediatric patients admitted to 14 UK PICUs and who remained in PICU at 9 a.m. on the third day were observed for up to 7 days or until PICU discharge or death (if sooner) over a 2-week observation period. Prevalence of early (day 3–day 10 post PICU admission) ERM delivery, adverse events (AEs) related to ERM delivery, clinical acuity and patient level outcomes were recorded.

Phase 2: manual development

Workshops with NHS healthcare professionals and international experts. Reviewed existing literature to identify available concepts, tools and resources and discussed ideas with healthcare professionals to develop and shape the form and specify the content of a prototype ERM intervention [the Paediatric Early Rehabilitation and Mobilisation during InTensive care (PERMIT) manual].

Phase 3: feasibility study with embedded process evaluation

This was an implementation study of a PICU-wide ERM programme, described in the PERMIT manual. The study was conducted in three PICUs. The manual describes the six steps of implementing the programme with qualitative (via debriefing weekly meetings, and HCP interviews) and quantitative (via normalisation measure development e-survey, study set-up observation) evaluation of these implementation steps and observation of feasibility and acceptability of consent model, ERM delivery and AE reporting of ERM usage in eligible PICU patients.

Phase 4: consensus study and trial design meetings

Virtual meeting with parents/family members from Phase 3 feasibility study was convened. Meeting was recorded and, with a summary leaflet of key findings, distributed to all members with accompanying questionnaire on future study design including consent model. Study management group and clinical trials methodologists developed a proposal for a future trial.

Results

Phase 1a: scoping review

We identified 36 articles that met the study eligibility criteria; 18 were full-text studies, mostly conducted in North America. There were only two RCTs; both were pilot studies confirming trial feasibility. Multicomponent 'non-mobility' and 'mobility' ERM interventions were feasible and safe. Most interventions involved physical therapy, occupational therapy and speech and language therapy.

Children under 3 years old were more likely to receive ERM interventions such as cuddles or in-bed mobilisation, whereas non-ventilated children or those aged 3 years and older were more likely to receive mobility interventions involving physical or occupational therapy. Family involvement appeared crucial when considering non-mobility ERM for children under 3 years old.

In 15/18 studies, judged to be of poor methodological quality, there was no benefit with regard to mechanical ventilation, hospital length of stay (LOS) and functional outcomes. Twelve of 18 studies provided some detail to aid replication and used qualified providers for supervision and tailored interventions. Although training and organisational strategies were sometimes applied, reporting was poor and complex intervention theories were rarely incorporated.

Phase 1b: survey of current practice

A strong multidisciplinary involvement in initiating ERM was reported. ERM was defined by participants as consisting of tailored, multidisciplinary rehabilitation packages, focused on promoting recovery. All age groups were considered for ERM. Over half of respondents favoured delivering ERM after physiological stability had been achieved (n = 69, 56%) with ERM more likely to be delivered to patients when PICU length of stay exceeded 28 days, among patients with acquired brain injury or severe developmental delay. The most commonly identified barriers were: insufficient resources and equipment (69%), limited staffing (79%), lack of recognition of patient readiness (67%), patient suitability (63%), physiological instability (81%) and sedation requirement (73%). Respondents ranked 'reduction in PICU length of stay' (74%) and 'improvement in psychological outcomes' (73%) as the most important benefits of ERM.

Phase 1c: observational study of ERM practice

We observed ERM practice in 169 patients across 15 PICUs who reached 9 a.m. on day 3 after PICU admission in our 14-day observation period. Ninety per cent of eligible patients were enrolled using an opt-out consent model. On the first study day (day 3 after PICU admission) 162/169 (96%) of patients received an ERM activity; 87% involved a mobility and 38% an out-of-bed mobility activity. The rate of ERM activities for patients remained constant across the subsequent 7 days of their PICU admission (or until PICU discharge).

Over the observation period, 3696 ERM episodes delivered 4978 ERM activities across all PICUs. Most were delivered by registered nurse or parent/family member. Positioning with and without mobility elements accounted for nearly half of all ERM activities. A wide range of ERM activities were reported but were more likely to be passive or enrichment activities rather than active ERM. 'Cuddles' by a family member/nursing staff were most frequent out-of-bed activity. We identified that family presence significantly increased out-of-bed ERM. Presence of an ERM protocol did not impact chance of out-of-bed mobility. However, some ERM was delivered to nearly all patients, including those of all ages, admission diagnoses and with the full range of organ dysfunction or organ support, including the highest level. ERM was delivered safely with a low (<3%) reported rate of AEs per ERM activity. Most AEs did not require any corrective intervention.

Phase 2: manual development

The synthesis of Phase 1 results showed that ERM is currently defined and enacted in multiple ways and that people see the potential value for the diverse patient populations within PICU and are willing to support the safe delivery of ERM but are uncertain how best to deliver it. The workshops with NHS healthcare professionals (n = 18) and with international experts (n = 3) helped generate some core guiding principles around the potential shape and content of the intervention. For example, everyone in PICU, doctors, nurses, physiotherapists and parents, are all essential for ERM delivery – everyone should take ownership. Also, ERM needs to be as inclusive as possible, with a focus on promoting movement and mobility as early as possible and with progressive increases over time. The review of existing ERM protocols and discussions with healthcare professionals enabled us to develop the prototype PERMIT manual that is focused both on the safe delivery of ERM for each patient, as well as the introduction and embedding of an ERM approach within a PICU. The PERMIT manual is informed by current evidence, experience and theory. It offers a flexible, progressive approach to the delivery of ERM, with resources including essential clinical materials – the 'bedside bundle' – that consist of an ERM daily flowchart, patient acuity levels, ERM activity levels, and pause and re-assess criteria. It also includes a step-by-step guide to putting ERM into practice – the 'implementation toolkit' – that focuses on building ERM leadership, generating staff buy-in, making ERM workable, and keeping it going over time.

Phase 3: feasibility study with embedded process evaluation

All sites implemented the PERMIT programme following the guidance in the manual. The families were positive about the study recruitment process. All sites successfully recruited the 10-patient target. All patients had an acuity level scored and these were repeated on 84% of ward rounds. The acuity level was correctly linked to ERM activity prescription and then subsequently to ERM activity delivered. The level of activity was broadly representative of the acuity level. A large number of potentially clinically relevant patient outcomes were measured through validated tools. All patients received ERM activities safely using the pause and assess criteria with only two trial reported AEs and no severe AEs. ERM was important for the physical and psychological recovery of the CYP, as well as the psychological well-being of parents/carers supporting their involvement in their child's care. Having access to research delivery support was central to support recruitment, data collection and data entry. PERMIT was seen by health professionals and parents as worthwhile, feasible and acceptable. Measuring child- and parent-reported outcomes was acceptable but follow-up at 30 days was incomplete.

Phase 4: consensus study and trial design

With input from members of the Patient and Public Involvement and Engagement (PPIE) group, parent/family members participating in PERMIT and multidisciplinary members of the study management group reviewed the findings from Phases 1, 2 and 3. We confirmed that a future PERMIT ERM clinical trial was necessary, acceptable and feasible. The most suitable trial design is a clustered stepped-wedge randomised control trial within PICUs across the NHS. The primary outcome of length of ventilation is a pragmatic compromise on measurable PICU outcome and probably accurate measure of improvement in critical illness recovery. However, further consensus work in developing the primary outcome will be required with the UK Paediatric critical care society study group and trialists prior to a definitive study proposal.

Conclusion and recommendations for future research

A definitive trial of ERM in PICU appears feasible. ERM is a complex intervention requiring institutional, departmental and multidisciplinary involvement. We have demonstrated that implementation of the PERMIT manual is acceptable, feasible and can deliver ERM safely to critically unwell and injured infants and CYP within the PICU. Further research in a definitive trial with economic assessment and demonstration of improvement in patient-related outcomes is required.

Ethics approval

- Phase 1b survey: University of Birmingham, 5 February 2019: Ref: BMS_1819_03.
- Phase 1c observational study: Regional Ethics Committee (REC) approval: 2 September 2019. East of Scotland Research Ethics Service. Health Research Association (HRA) ref: 19/ES/0102.
- Phase 2 manual development workshop: healthcare professionals: Newcastle University, 1 September 2019: Ref 14224/2018. Parents, CYP: REC approval: 28 February 2020 19/LO/1987 (substudy stopped because of coronavirus disease pandemic).
- Phase 3 feasibility study: REC approval: 26 April 2021. Berkshire Research Ethics Service. HRA ref: 21/SC/0127.

Trial oversight committee

A study oversight committee and data-monitoring ethics committee were recruited to oversee the study processes and results (see *Appendix 1*).

Study registration

The study is registered as PROSPERO CRD42019151050. The Phase 1 observational study is registered NCT04110938 (Phase 1) (registered 1 October 2019) and the Phase 3 feasibility study is registered NCT04909762 (Phase 3) (registered 2 June 2021).

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This report

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