ISRCTN13615304 https://doi.org/10.1186/ISRCTN13615304

Feasibility trial assessing the management of acute pain in children and young people attended by ambulance using the PANDA intervention

Submission date 29/05/2026	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/06/2026	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 01/06/2026	**Condition category** Signs and Symptoms	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims

Each year in England approximately 86,000 children and young people (CYP) under 18 years of age are transported by ambulance to emergency departments with acute pain. The pain may have been caused by injuries such as wounds, burns or broken bones, or by illnesses such as tummy pain. Treating pain in CYP attended by ambulance is very challenging, and research studies have shown that around 60% do not have their pain treated effectively. Without effective pain treatment, CYP may suffer adverse consequences such as post-traumatic stress disorder.

The aim of the PANDA Feasibility Trial is to assess the acceptability of the PANDA Intervention and the feasibility of conducting a future large-scale clinical trial.

Who can participate?

1. Paramedics employed by the East Midlands Ambulance Service NHS Trust, registered with the Health and Care Professions Council, working full-time in a frontline face-to-face clinical role.
2. Children and young people under 18 years of age, suffering acute pain, attended by an East Midlands Ambulance Service NHS Trust PANDA Feasibility Trial paramedic.
3. Parents and carers of enrolled children and young people aged 16+ years.

What does the study involve?

We will recruit 30 paramedics and randomise them to provide standard care, or standard care plus the PANDA Intervention. The PANDA Intervention includes: 1) a bespoke 30-minute online pain management education and training package, 2) automated feedback on their clinical practice, 3) a pocket prompt sheet, and 4) a children's distraction kit (bravery stickers and sensory toys) for use at the paramedic's discretion. We aim to enrol 45 CYP. A model of deferred consent will be used, and the parent/carer and CYP will be notified of the study at the earliest appropriate opportunity. Those enrolled will have the option to opt out or provide informed

consent for ongoing data usage, interview participation, and follow-up at 1 and 3 months. This trial is low risk – no changes to pain medication or medical devices will be made, and all distraction kit toys will be CE/UKCA marked.

What are the possible benefits and risks of participating?
This trial is low risk. The main patient facing change will be the use of a children's distraction kit in the ambulance setting, containing bravery stickers and sensory toys. Risk has been reduced by using CE/UKCA-marked toys, having an instructional insert in the kit for paramedic use, having the kit reviewed and approved by the East Midlands Ambulance Service NHS Trust Supplies and Equipment Working Group (which has representation from risk assessors, infection prevention and control, and sustainability), along with patient and public input from young people and parents/carers. We will also monitor the use of the distraction kit for patient safety incidents. Possible benefits include enhanced non-pharmacological pain relief and improved patient and parent/carer satisfaction.

Where is the study run from?
The East Midlands Ambulance Service NHS Trust (UK)

When is the study starting and how long is it expected to run for?
June 2026 to February 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Gregory Whitley, researchteam@emas.nhs.uk

Contact information

Type(s)
Public, Scientific

Contact name
None Research Team

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Additional identifiers

Integrated Research Application System (IRAS)
369084

Central Portfolio Management System (CPMS)
73641

National Institute for Health and Care Research (NIHR)
302875

Study information

Scientific Title
Improving Pain mAnagement for childreN and young people attendeD by Ambulance (PANDA): a pragmatic cluster randomised feasibility trial assessing standard care plus the PANDA Intervention versus standard care to reduce pain severity for children and young people attended by paramedics

Acronym
PANDA

Study objectives
To assess the acceptability of the PANDA intervention and the feasibility of conducting a future large scale clinical trial.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/05/2026, West Midlands – Coventry & Warwickshire Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 1048211; coventryandwarwick.rec@hra.nhs.uk), ref: 26/WM/0074

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain management

Interventions
We will recruit 30 paramedics and randomise them to provide standard care, or standard care plus the PANDA Intervention.

The PANDA Intervention aims to change the behaviour of ambulance clinicians by giving them more knowledge and confidence, making them more prepared to manage children and young people in pain. The intervention contains:
1. An education and training package
2. A system of feedback
3. A pocket prompt sheet
4. A distraction kit containing bravery stickers and sensory toys that the paramedic can use at their discretion to enhance the patient-clinician relationship and build trust

Follow up surveys:
Will ask about any ongoing pain since the ambulance attendance, sleep disturbance (completed by the parent/carer) and risk of post-traumatic stress disorder (completed by 8+ year old children and young people).
The survey will also ask about the most positive and negative memory of the event. Survey completion should take no more than 10 minutes.

Interviews:
Will be conducted online, via telephone, or face to face, as preferred, at a date/time to suit the participant. We will ask about their experience of care and how acceptable being part of the study is. For younger children we will use arts/crafts and toy ambulances when face to face to facilitate the experience-sharing process. Interviews will be audio recorded.

Data analysis:
Qualitative data will be analysed thematically. Quantitative data will be analysed descriptively. This feasibility trial will enable us to perform a sample size calculation for a future trial, including estimating the Intracluster Correlations Coefficient.

Intervention Type
Behavioural

Primary outcome(s)
1. Paramedic feasibility measured using the theoretical framework of acceptability, involving the assessment of affective attitude, burden, perceived effectiveness, ethicality, intervention coherence, opportunity costs, and self-efficacy, measured using qualitative interviews at completion of recruitment

2. The proportion of trial paramedics who attend qualitative interviews, measured using descriptive statistics at trial completion

3. The fidelity of intervention delivery, measured using qualitative interviews at completion of recruitment

4. The acceptability to children, young people, parents and carers of being attended by a trial paramedic who may or may not have received the PANDA Intervention, measured using qualitative interviews at 1 month after recruitment

5. The proportion of consented children, young people, parents and carers who attend qualitative interviews, measured using descriptive statistics at trial completion

6. The facilitators and barriers to recruitment and retention of participants, measured using qualitative interviews at 1 month after recruitment for children, young people, parents/carers, and at completion of recruitment for paramedics

7. Pain measured using either the Face, Legs, Activity, Cry, Consolability (FLACC) scale, Wong and Baker FACES® scale or Numeric Pain Rating Scale at pre- and post-pain treatment (no set assessment timepoints)

8. Development of chronic pain measured using any ongoing pain since ambulance attendance at 3 months

9. Sleep disturbance measured using the Sleep Disturbance Scale for Children at 1 and 3 months

10. Risk of post-traumatic stress disorder (PTSD) measured using the Children's Revised Impact of Event Scale (CRIES-13) scale at 1 and 3 months

Key secondary outcome(s))
There are no secondary outcomes

Completion date
28/02/2027

Eligibility

Key inclusion criteria
Paramedics (inclusion criteria to be randomised):
1. Employed by East Midlands Ambulance Service NHS Trust
2. Registered as a paramedic with the Health and Care Professions Council
3. Working full-time
4. Working entirely in a frontline face to face clinical role

Children and young people (inclusion criteria for feasibility trial enrolment):
1. Children and young people aged under 18 years of age
2. Suffering acute pain (initial pain score above zero)
3. Attended by an EMAS PANDA Feasibility Trial paramedic
4. The EMAS PANDA Feasibility Trial paramedic had active involvement in the management of the pain

Children and young people (inclusion criteria for qualitative interviews):
1. Enrolled in the PANDA Feasibility Trial
2. Aged 4–18 years

Children and young people (inclusion criteria for survey follow-up):
1. Enrolled in the PANDA Feasibility Trial
2. Aged 3–18 years

Parents/carers (inclusion criteria for qualitative interviews):
Aged 16 years and above

Healthy volunteers allowed
No

Age group
All

Lower age limit
0 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Children and young people (exclusion criteria for feasibility trial enrolment):
1. CYP in Young Offender Institutions (YOIs), Secure Training Centres, or Secure Children's Homes
2. CYP suffering major trauma (as per locally agreed definition) or critical illness, including the following conditions: cardiac arrest, sepsis, seizure, heart attack, stroke, anaphylaxis, life-threatening asthma

Date of first enrolment
01/06/2026

Date of final enrolment
30/11/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
East Midlands Ambulance Service NHS Trust
1 Horizon PLACE

Mellors Way
Nottingham Business Park
Nottingham
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NG8 6PY

Sponsor information

Organisation
East Midlands Ambulance Service NHS Trust

ROR
https://ror.org/055pdxb86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Clinical Audit & Research Unit (CARU), East Midlands Ambulance Service NHS Trust, Lincolnshire Divisional Headquarters, Cross O'Cliff Court, Bracebridge Heath, Lincoln LN4 2HL, UK, researchteam@emas.nhs.uk. Any clinical trial data shared would be fully anonymised.

Data will be shared according to our Data Access Management Plan, published on the NIHR website: https://fundingawards.nihr.ac.uk/award/NIHR302875

IPD sharing plan summary

Available on request