STUDY PROTOCOL

improving Pain mAnagement for childreN and young people attendeD by Ambulance (PANDA): protocol for a realist review. [version 1; peer review: 2 approved with reservations]

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Abstract

Background

Each year in England, 450,000 children and young people (CYP) under 18 years of age are transported by ambulance to emergency departments. Approximately 20% of these suffer acute pain caused by illness or injury. Pain is a highly complex sensory and emotional experience. The intersection between acute pain, unwell CYP and the unpredictable pre-hospital environment is convoluted. Studies have shown that prehospital pain management in CYP is poor, with 61% of those suffering acute pain not achieving effective pain relief (abolition or reduction of pain score by 2 or more out of 10) when attended by ambulance. Consequences of poor acute pain management include altered pain perception, post-traumatic stress disorder and the

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development of chronic pain. This realist review will aim to understand how ambulance clinicians can provide improved prehospital acute pain management for CYP.

Methods

A realist review will be conducted in accordance with the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) guidance. A five-stage approach will be adopted; 1) Developing an Initial Programme Theory (IPT) – develop an IPT with key stakeholder input and evidence from informal searching; 2) Searching and screening – conduct a thorough search of relevant research databases and grey literature sources and perform screening in duplicate; 3) Document selection – assess documents for relevance and rigour in duplicate; 4) Extracting and organising data – code relevant data into conceptual "buckets" using qualitative data analysis software; and 5) Synthesis and Programme Theory (PT) refinement – utilise a realist logic of analysis to generate context-mechanism-outcome configurations (CMOCs) within and across conceptual "buckets", test and refine the IPT into a realist PT.

Conclusion

The realist PT will enhance our understanding of what works best to improve acute prehospital pain management in CYP, which will then be tested and refined within a realist evaluation.

Registration

PROSPERO Registration: CRD42024505978

Any reports and responses or comments on the article can be found at the end of the article.

Plain Language Summary

Each year in England approximately 90,000 children and young people under 18 years of age suffer with acute pain and require transport by ambulance to emergency departments. The pain may have been caused by injuries such as wounds, burns or broken bones, or by illnesses such as tummy pain. Paramedics and other ambulance clinicians aim to reduce pain at the scene and during hospital transport. Whilst access to pain management is considered a fundamental human right, around 60% of children and young people who require an ambulance do not have their acute pain treated effectively. Without effective pain treatment, adverse consequences such as post-traumatic stress disorder may occur. We aim to understand how ambulance clinicians can provide improved prehospital acute pain management for children and young people.

We will develop a theory about what is most important when considering the improvement of acute pain management for children and young people attended by ambulance. We will use published evidence, opinions from experts in the field, such as paramedics,

paramedic educators and clinical leaders, and opinions from members of a Young Persons Advisory Group, to help us create this theory. We will then conduct a thorough search for any published documents that can help us test this theory. Such documents may include published journal articles, clinical practice guidelines, dissertations or newspaper articles for example. We will then use the information within all the relevant documents to test our theory and make refinements. This will allow us to produce a refined theory of what works best to improve acute pain suffered by children and young people who need an ambulance. We will then test and refine this theory in a future study by asking children, young people, parents, carers and ambulance clinicians about parts of the theory.

Keywords
Acute Pain, Analgesia, Child, Emergency Medical Services, Paramedics, Paediatrics

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Introduction

Ambulance services across England transport 4.7 million patients to emergency departments (ED) each year, of which 450,000 (9.5%) are children and young people (CYP) under 18 years of age[1]. Acute pain caused by injury or illness is a common symptom presented to ambulance clinicians, and is suffered by approximately 20% of transported CYP[2]. Paramedics and other ambulance clinicians aim to reduce pain at the scene and during hospital transport[3], however this can be challenging in CYP due to a variety of barriers including fear and anxiety – which can distort pain assessment[4], environmental factors, staff feeling ill prepared to manage pain due to limited education and training and low exposure rates to CYP, and difficulties in assessing and treating pain, particularly regarding limited analgesic options and difficulties of analgesic administration in CYP[5].

Access to pain management is considered a fundamental human right[6] and effective pain relief has been identified as a key quality outcome measure for ambulance services[7]. Despite this, prehospital pain management in CYP is considered poor[8,9]. Ambulances, equipment and staff uniform, are often not tailored towards children and young people, and as such, an ambulance call out can be a frightening experience[5]. A recent study found that only 39% of CYP who suffered acute pain in the prehospital setting achieved effective pain relief (defined as the abolition or reduction of pain >=2 points on a 10-point scale)[2]. The consequences of poor acute pain management may include the development of post-traumatic stress disorder[10,11], altered pain perception[12,13], and the subsequent development of chronic pain[14,15].

The limited range of analgesic options available to UK ambulance clinicians are in part due to legal restrictions[16,17] which preclude the use of key controlled drugs such as fentanyl by UK registered paramedics, which can be administered intranasally[18] or via a lozenge[19]. Nitrous oxide is widely available to UK ambulance clinicians but is challenging to administer to CYP due to its cumbersome nature[20]. Methoxyflurane offers a promising alternative due to its light weight and ease of use, but is not currently licenced for children in the UK[21], with results of a major clinical trial due soon[22]. These legal restrictions may change in the wake of the Manchester Arena Enquiry[23] and the recent call to arms to "make children's pain matter" by Eccleston *et al.*[24], however reliance for improvement should not rest on single strategies. Whilst an increased range of analgesics would be welcome, it would unlikely resolve the complex challenge of providing effective prehospital pain management for CYP[25], therefore other strategies should be explored.

This realist review will aim to understand how ambulance clinicians can provide improved prehospital acute pain management for children and young people. The review will focus on potential behaviour change intervention components that could be aimed at ambulance clinicians.

Methods

Patient and Public Involvement

A Young Persons Advisory Group (YPAG) has been set up to advise on the initial design of the PANDA Study[26]. The YPAG group will continue to provide input within this realist review. The group was recruited from a state funded secondary school and comprises 25 members in total. The age range of members spans from 12 to 18 years, 60% are female (n = 15), 64% White (n = 16), 24% Asian or Asian British (n = 6) and 13% Other or Mixed ethnicity (n = 3). Four of the YPAG members have experience of being in an ambulance with a painful condition, three have been in an ambulance for other reasons and four have witnessed friends or family members going into an ambulance. The YPAG group will meet to provide insights and suggestions to develop and refine the IPT and to assist in the interpretation of the synthesis and refinement of the realist programme theory.

An established patient and public involvement group based at the University of Lincoln (the Healthier Ageing Patient and Public Involvement group (HAPPI) Group)), was involved during the initial design of the PANDA Study. The HAPPI group will continue to be involved at key stages throughout this realist review, particularly to assist with the interpretation of findings. The HAPPI Group members will provide input from a "public" perspective and will also bring external expertise to the project from their links to other patient and public involvement groups and from experience of advising several other prehospital ambulance-based research projects.

Study design

The overall PANDA Study is a realist informed complex intervention development and feasibility study, consisting of a realist review, a realist evaluation, consensus workshops and a feasibility trial[27]. The aim of the PANDA Study is to develop and test an intervention to improve pre-hospital pain management for children and young people by exploring what interventions work, for whom, in what context and how. This paper reports the protocol for the realist review component of the PANDA Study.

The PANDA Study will be framed within a realist approach as described by Pawson[28–30], which aligns to the Medical Research Council guidelines for complex intervention development[31]. A realist approach seeks to understand why, how, to what extent, for whom and in what circumstances a programme or intervention works[32]. It assumes that interventions or programmes themselves do not *cause* outcomes, rather, it is the resources offered by the intervention that trigger a response from the participant through underlying unseen **mechanisms**, that cause **outcomes**, within a specific **context**[32]. These context-mechanism-outcome configurations (CMOCs) are the foundation on which programme theory is built and may be informed by primary (realist evaluation) or secondary (realist review) data[29,30].

A realist review will be conducted, following the Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) guidance[32]. The realist review has been registered on PROSPERO, the international prospective register of systematic reviews (CRD42024505978)[33]. There are currently no equator network publication standards for realist review protocols, therefore we used the realist review publication standards as a framework to report this protocol[34]

The objectives for this realist review are:

1. To develop an initial programme theory (IPT) to map the key processes of prehospital acute pain management in CYP.
2. To focus on specific areas of the IPT to explore potential behaviour change intervention components aimed at ambulance clinicians and determine; for whom they work; in what circumstances; how; and to what extent they work.
3. To refine the IPT into a realist programme theory supported by context, mechanism, outcome configurations (CMOCs).

We will adopt a five-stage approach to conduct this realist review, informed by the RAMSES guidance[32], Pawson[29] and a recent realist review[35]. These steps will include:

1. Locating existing theories and developing Initial Programme Theory (IPT)
2. Searching and screening
3. Document selection
4. Extracting and organising data
5. Synthesis and Programme Theory (PT) refinement

Step 1: Locating existing theories and developing initial programme theory

The first stage of this realist review will involve locating existing theories about prehospital pain management in children and young people (CYP). This will involve informal searches to identify key theories in the field, what the predictors, barriers and facilitators are for effective prehospital pain management in CYP, and which components of the process are considered most important. Whilst this process is subjective, we will offset this by involving multiple key stakeholder groups in the development of the IPT, namely an Ambulance Clinician Advisory Group (ACAG), a Young Persons Advisory Group (YPAG) and a PANDA Study Realist Review Working Group. The inclusion of these groups is important as realist reviews are driven by stakeholders, enabling the inclusion of multiple perspectives[36,37].

Informal searches will be conducted to ensure that relevant documents are identified, and key data are incorporated within the initial programme theory (IPT) development process. One member of the review team (GAW) has access to a large number of relevant documents (including journal articles, theses and book chapters), having recently completed a PhD on the topic of prehospital pain management in children. Combining these documents with stakeholder input and iterative discussion within the PANDA Study Realist Review Working Group will enable the development of our IPT.

Step 2: Searching and screening

With the assistance of an academic librarian (MO), the IPT will be used as a framework to develop a comprehensive search strategy.

Database Search: Relevant keywords, subject headings and Boolean operators will be used to search major bibliographic databases. The EBSCOHost platform will be used to search MEDLINE, Cumulative Index to Nursing & Allied Health (CINAHL) Complete, PsycINFO, Web of Science Core Collection, Education Source, and Education Resources Information Centre (ERIC).

Grey Literature Search: The Cochrane Library and the clinical trials registry ISRCTN will be searched, along with other grey literature sources such as ProQuest, including ProQuest Dissertations and Theses, and Google. Expert knowledge will also be used to identify relevant documents not found during these searches. Forward and backward citation tracking will be conducted for all included documents.

Additional searches may be required during the realist review as programme theory testing and refinement progresses.

Inclusion criteria

In-line with a realist philosophy of science[29], all sources of information may contribute to the development of realist programme theory, therefore we will include, where relevant, research articles, clinical practice guidelines, policy documents, websites of professional bodies or reputable organisations, conference abstracts, theses and dissertations, along with curricula.

In addition to the wide range of documents eligible for inclusion, only documents involving or aimed at the following populations will be included:

- Ambulance clinicians (including but not limited to paramedics, emergency medical technicians, prehospital emergency nurses) who attend children and young people (CYP) suffering acute pain.
- Children and young people suffering acute pain in the prehospital setting.
- Parents/carers of CYP suffering acute pain in the prehospital setting.

Only documents reported in English, and published from January 2000 onwards will be included.

Exclusion criteria

Documents will be excluded if they are:

- Based in the battlefield, in-hospital, primary care or helicopter emergency medical service (HEMS) setting. Documents from these settings would not be representative of standard ambulance service practice.
- Focussed on chronic pain.

Documents reporting prehospital acute pain management data for children, young people *and* adults will be excluded if the data for children and young people under 18 years of age cannot be isolated and extracted.

Identified documents from the database search will be imported to Covidence (copyright licence obtained) software and screened in duplicate. Documents will be screened first by title and abstract, followed by full text review against the inclusion and exclusion criteria. Documents identified from the grey literature search will be added to and managed within MS Excel software and screened in duplicate. All grey literature documents will be subject to an initial screen, similar in nature to the title and abstract screen, followed by a full-text screen, where the full document will be reviewed against the inclusion and exclusion criteria. Disagreements on inclusion will be resolved through discussion, or involvement of a third member of the review team.

Step 3: Document selection

Documents deemed to meet the inclusion criteria will then be assessed for relevance and rigour, as per the RAMESES guidelines[32]. Relevance relates to the ability of data within a document to contribute to the testing and refinement of programme theory, and rigour relates to whether the methods used to generate the relevant data are credible and trustworthy[32]. Whilst there is relative consensus regarding the methods to assess the relevance of documents within a realist review, there is substantial uncertainty among academics regarding how best to assess rigour[38]. Given the adoption of a realist philosophy of science[29], using a checklist approach to quality assessment, as standard within a systematic review[39], is less helpful in a realist review due to the inclusive nature of data from a wide variety of sources. We will therefore not use critical appraisal/quality checklists as part of our rigour assessment.

Relevance

The assessment of relevance will be dichotomous (yes/no) and conducted within MS Excel software. Two reviewers will assess relevance of a small sample of documents and discuss with the PANDA Study Realist Review Working Group as a benchmarking exercise. If agreement is achieved, the remaining documents will be assessed for relevance, in duplicate. Disagreements will be resolved through discussion, or involvement of a third member of the review team. A third reviewer will assess 10% of reviewed documents to ensure consistency. Documents deemed not relevant will be excluded from the review.

Rigour

Rigour will be assessed in duplicate by two reviewers and based on reviewer judgement of document trustworthiness. A rating scale will be used to determine the rigor of each document (low, moderate or high rigour). Disagreements will be settled through discussion, or the involvement of a third reviewer. A third reviewer will assess 10% of reviewed documents to ensure consistency.

Rigour will be assessed at the level of the data and at the level of the programme theory[38]. Documents deemed highly trustworthy and credible at the level of the data (for example where clear methods of data production are described and references for evidence sources are listed) and are coherent at the level of the programme theory and provide consilience and analogy (for example where the documents support the programme theory well), will be rated high.

Rigour will not be used as a reason for exclusion[40]. Instead, CMOCs that are considered conceptually weak (i.e. the documents informing the CMOCs are mostly rated as low or moderate rigour) will be tested further through additional iterative searches, or within the realist evaluation.

Step 4: Extracting and organising data

Data extraction

Data extraction will occur in two phases.

1. The characteristics of included documents will be manually extracted into a Microsoft Word document, including bibliographic information and details about document type and population. This will form the summary of included documents table.

2. Included documents will then be uploaded to NVivo version 14 (copyright licence obtained) software for data extraction (coding). Qualitative and quantitative text that is relevant to the initial programme theory will be coded; this may consist of descriptions, findings or explanations of programmes or interventions that aim to improve prehospital acute pain management for children and young people[34].

Data organising

Coding will be deductive (based on the initial programme theory), inductive (where new conceptual buckets arise) and retroductive (when inferring causal mechanisms within CMOC development). Text will be coded as “parent nodes” or “child nodes” iteratively and combined/expanded during the organising phase of analysis. Coding will be conducted by one reviewer, with 10% of coded documents checked by a second reviewer.

Codes assigned as “parent nodes” will be viewed as conceptual “buckets”[41]. Text may be coded into more than one conceptual “bucket”.

Step 5: Synthesis and programme theory refinement

Synthesis

As more sections of coded text are added to each conceptual "bucket", the review team will periodically pause to determine, as far as possible, what is functioning as context, mechanism and outcome, thereby creating CMOCs. This process will use a realist logic of analysis[29]. This interpretation will be iterative in nature and supported by key stakeholder input. Coded text from more than one conceptual "bucket" may be used to create CMOCs. For each developed CMOC, a new "parent node" will be created, with all the supporting data extracts for the CMOC added. This will ensure clean and clear traceability between source data, CMOC and programme theory.

Each developed and substantiated CMOC will contribute to the development and refinement of the realist programme theory. CMOCs that are unsubstantiated, either due to low rigour or conflicting data, may be tested further through additional iterative searches or through the realist evaluation.

Data to inform our interpretation of the relationships between contexts, mechanisms and outcomes will be sought across documents. There may be instances where data coded from documents contradict each other, or only supply part of the CMOC. We may juxtapose, reconcile, adjudicate, consolidate or situate (Pawson, 2006) findings throughout the analytic process, as necessary.

Programme theory refinement

We will test the initial programme theory with data collected and synthesised from this review and refine it into realist programme theory supported by CMOCs. As this review is not assessing a specific intervention or programme, but rather the process of prehospital acute pain management in children and young people, we anticipate the realist programme theory to be segregated into stages based on outcome, progressing from proximal outcomes (focussed on ambulance clinicians – such as confidence and knowledge) to more distal outcomes (focussed on children and young people – such as pain severity). The programme theory developed from a recent realist review will be used a framework to develop our realist programme theory[42].

Stakeholder involvement

In addition to the patient and public involvement groups, we will involve other key stakeholders including ambulance clinicians, academics, clinical and non-clinical psychologists.

Ambulance clinician involvement

An Ambulance Clinician Advisory Group (ACAG) has been established, with expertise from the fields of clinical practice, education, and senior leadership. The group will meet at several stages of the review to provide insights and their expert knowledge to help with the development and refinement of the IPT, provide advice and feedback on the PT as it develops, identify any relevant literature that will assist with the research and to facilitate the interpretation of the findings.

PANDA Study Realist Review Working Group

A bespoke PANDA Study Realist Review Working Group has been created for the realist review component of the PANDA Study, which consists of academics with expertise on realist methods, the prehospital setting and the population of children and young people, clinicians, ambulance service representatives, along with clinical and non-clinical psychologists. The group will meet monthly, or more if required, to discuss the progress of the realist review and provide expertise at all stages of the review.

Ethical considerations

Not required.

Data availability

No data are associated with this article.

Software availability

NVivo 14 is a proprietary software, free alternatives such as QualCoder (https://qualcoder.wordpress.com/) could be used. Covidence is a proprietary software, alternatives such as Rayyan (https://www.rayyan.ai/) have a free membership option.

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Open Peer Review

Current Peer Review Status: ? ?

Version 1

Reviewer Report 14 August 2024

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Heli Salmi
Helsinki University, Helsinki, Finland

The authors have decided to conduct a study on how children in pain are currently managed by their prehospital emergency care providers. Then, according to literature and the current practices and circumstances, they will identify ideas for improvement, ands strategies for improvement. Ultimately, they will provide a framework about a programme.

I am happy that the authors have decided to address such an important topic in paediatric critical care. I am not familiar with the research tools the authors describe, but they seem solid and relevant. I have a few suggestions for amendments to the protocol and to the article.

I think this study protocol presentation would benefit from a “clinical touch”, both in order to make it more feasible and easier to understand for other clinicians. To meet this end,

- please explain the EMS system/ prehospital care in your context for a reader coming outside of the UK. Who attends to severely injured children in the prehospital setting? A nurse, a paramedic, a non-specialist doctor, an emergency physician, an anaesthesiologist, a paediatric anaesthesiologist? Or does it depend on the region or the case or other facts? Does this influence the choice of medications available? How are the care providers educated for paediatric pain and do all of them attend to children?
- Please discuss all relevant analgesic measures. If fentanyl is not available, what about other opioids? intravenously administered opioids? (es-)ketamine? what about adjuvant sedation and airway management to enable sufficient pain relief?
- please explain how pain is rated in your system. If the targeted pain relief outcome is at least -2 p on the scale, what scale (I presume it to be NRS or VAS or similar – but how is it assessed in infants and toddlers?)
- Perhaps the analysis should include a measure aiming at understanding how pain in children is evaluated in prehospital care. This may be the reason why children are undermedicated (if the personnel is only trained for pain score ratings, by definition all children under school age will not be able to provide a scale and are therefore at risk of not being medicated; also, the treatment response (-2 on the scale) will be impossible to achieve. Based on the results you will have, should your project also include a training tool

for evaluating pain in children of different age?
- Your project is very important and ambitious. I congratulate you on that. When you'll go as far, why leave it to a "framework for a programme" phase and not develop a full, even preliminary, programme for better pain relief for children in the prehospital care instead? I am afraid there is a risk that without this aim, the study will miss a final clinical aspect and remain too abstract to be easily used for education in the prehospital services. If, on the other hand, you wrote this with a final clinical programme in mind, your conclusions and suggestions for future would be more easily read and adopted to practice by the busy clinicians in the field. To my understanding, the study setting would enable this kind of development.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: paediatric critical care

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 13 August 2024

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Peer-review Report:
Thank you for the opportunity to peer-review the realist review protocol titled 'improving Pain mAnagement for childreN and young people attendeD by Ambulance (PANDA): protocol for a realist review.' aiming to understand how ambulance clinicians can provide improved prehospital acute pain management for Children and Young People. The protocol proposes a five-step approach for conducting the review following the RAMESES guidance to create context-mechanism-outcome configurations and test and refine the Initial Programme Theory into a realist Programme Theory.

Overall, the protocol is well-written and structured with the methods describing the core steps required to ensure scientific soundness and reproducibility. I am confident that this review will contribute positively to the field of study, and I wish all involved the best with the overall research project. I do, however, have some comments and suggestions detailed below.

Comments:
Abstract:

Methods:
As per my comment below 'perform screening in duplicate' is captured under step 2 of the methods of the study, however, screening is part of the selection of the sources to be included which is step 3. I would suggest that the authors move it to step 3.

Introduction:
Overall, the introduction is well-written and concise providing general background information, what is known and not known about the topic in the specific population and articulating the rationale for conducting the realist review. Two minor comments for the authors to consider. Please consider reviewing the last sentence of the first paragraph of the introduction. The sentence is quite long, and it is challenging to read and understand the first time. I would suggest ending the sentence after '… variety of barriers' followed by discussing the barriers in a subsequent sentence or two. My comment relates more to readability and understanding of the contents of the sentence, the information provided is valid and relevant.

After abbreviating the term 'children and young people (CYP)', I would suggest that the abbreviation is used consistently throughout the introduction and the rest of the manuscript. I would also suggest that the authors ensure that all abbreviations are used consistently throughout the protocol manuscript once abbreviated. There are some inconsistencies in the manuscript.

Methods:
Patient and Public Involvement
In the first paragraph of the section, the abbreviation 'IPT' is used, however, the term is only abbreviated later in the methods section. In addition, the term is abbreviated a few subsequent times. Please consider correcting this.

In the first sentence of the second paragraph of the section, the word 'group' appears twice *'(the Healthier Ageing Patient and Public Involvement group (HAPPI) Group))*. Perhaps the first 'group' is unnecessary.

Step 2: Searching and Screening
I would suggest that 'The Cochrane Library' be moved to the list of bibliographic databases searched instead of grey literature. Although 'The Cochrane Library' can provide access to a broad array of source documents including protocols of ongoing trials/systematic reviews, it is predominantly a source of completed systematic reviews and RCTs. The sub-heading 'Grey Literature Search' could be changed to 'Searching Other Resources' as a more commonly used sub-heading allowing for broader inclusion.

Inclusion Criteria
For the population inclusion criteria please change the bullet point "Ambulance clinicians (including but not limited to paramedics, emergency medical technicians, prehospital emergency nurses) who attend **to CYP** suffering acute pain."

Documents published from January 2000 onwards should rather be a search restriction and documents reported in English, an inclusion criterion. For both, the authors should consider provide a justification for the decision to exclude publications before 2000 and non-English documents.

Exclusion Criteria
I would argue that the last paragraph under this section discussing the screening of the search results against the eligibility (inclusion and exclusion) criteria is part of 'Step 3: Document Selection' as it is part of the stages of selecting sources for the review. Please move to Step 3. In line with this, the headings for Step 2 should be revised. Suggested options for heading 'Step 2: Evidence Search'

Step 3: Document Selection
In evidence synthesis, the results of searches and the screening process are commonly reported using a PRISMA flow diagram. Please consider adding that the selection of included sources will be reported using a PRISMA flow diagram. The reference for a PRISMA flow diagram is already in the reference list (reference 39).

For the screening of sources and the assessment of relevance and rigour, please indicate whether the duplicate screening/assessment will be conducted independently.

Rigour
Please check the spelling of rigour in the second sentence under the sub-heading 'Rigour'.

Step 4: Extracting and organising data
Although the authors describe that coding will be done by one reviewer and 10% checked by a second reviewer, this detail is not described for the data extraction process. Please describe this (how many reviewers will be involved, how will the reviewer(s) extract the data, and how will the data be checked) for the data extraction process as well.

Programme theory refinement
Please review the sentence to read 'The programme theory developed from a recent realist review will be used **as** a framework to develop our realist programme theory.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Published several articles related to acute pain management in the prehospital setting as well as published evidence synthesis articles.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.