ISRCTN12280133 https://doi.org/10.1186/ISRCTN12280133

Do we have to restrain children forcefully and make them suffer in health care?

Submission date 19/03/2023	**Recruitment status** Recruiting	[X] Prospectively registered [ ] Protocol
Registration date 24/04/2023	**Overall study status** Ongoing	[ ] Statistical analysis plan [ ] Results
Last Edited 24/04/2023	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Too often, children are exposed to unpleasant and coercive procedures (or treatments) in healthcare. The most common of these are needle-related medical procedures, such as blood sampling, vaccination, and injections. While these procedures may be medically indicated, they can still be harmful to the child in the short- and long-term perspective. Healthcare professionals are aware of a number of evidence-based strategies that can be used to prevent, manage, and alleviate pain and distress in children in connection with needle-related procedures. However, these strategies are not being fully used in paediatric and child healthcare; consequently, children suffer unnecessarily.
Therefore, the overall aim of this study is to reduce children's pain and anxiety in connection with needle-related medical procedures. More specifically, the purpose is to evaluate an educational intervention that is designed to improve the healthcare professionals' use of pain- and anxiety-preventing strategies in caring for children during needle-related medical procedures.

Who can participate?
Children 0–17 years of age in need of needle-related medical procedures, such as blood sampling, vaccination, injections or needle in the central venous port; parents of the included children; and healthcare professionals, including physicians, nurses, paediatric nurses and ungraduated nurses.

What does the study involve?
In Study 1, children will be observed during needle-related medical procedures to explore the strategies used by professionals and parents in connection with such procedures. Together with these observations, factors such as pain and anxiety in children and parents will be measured. Likewise, information about healthcare professionals' self-reported use of strategies will be collected.
In Study 2, an intervention programme, including a revision of guidelines and an educational effort for healthcare professionals, will be developed and tested for feasibility through focus group interviews.

In Study 3, the intervention will be evaluated, possibly as an increase in the use of pain and anxiety-preventing strategies, as well as a potential decrease in pain and anxiety related to the intervention.

What are the possible benefits and risks of participating?
Every child should have access to evidence-based pain assessment and subsequent treatment using the most effective methods and means available. In practice, however, there is ample evidence that children frequently experience preventable pain. This study will contribute new and important knowledge about preventable needle-related pain among children, from newborns to young adults' experiences of pain that go unnoticed, unreported, or are not addressed. The results from this study will help healthcare professionals in choosing which strategies/interventions are effective in different situations. As this knowledge will be implemented in health care for children, it might also lead to the children experiencing health care as positively as possible. This will hopefully lead to a minimisation of fear of health care and to feelings of security for future patients in their encounters with health care. This, in turn, creates greater trust in health care, as well as reduced costs related to absent patients or examinations that need to be rescheduled.
Two ethical issues have been considered in the study. Firstly, can the questions in the survey, the observations, or the interviews harm or cause anxiety to those who participate? Questions concerning knowledge and skills may, in the case of healthcare professionals, be interpreted as controlling. Having the opportunity to contribute to research, evidence, and new ways of working can result in anxiety but can also have the opposite effect, that is, it can feel like a processing of their experiences and fears. The second issue relates to whether the observations and the interview can in any way infringe on the child's (and parents'/guardians') integrity and private sphere? In observations and interviews, there is always the risk of exceeding the limit of what the person considers as being his/her private sphere. Trust must, therefore, be established in the situation. In addition, the time allotted for the interview needs to be ample and based on the children's and families' situation. In the present study, the participants' autonomy will be at the centre of reflection, including that of the children, parents/guardians, and healthcare professionals. Research shows that children can probably understand what it means to talk about their own experiences in an interview, for example, in interviews concerning their experiences of procedures.
Participation is voluntary. Children, their parents/guardians, and healthcare professionals will be asked to provide oral and written informed consent; moreover, participants will be clearly informed about their right to withdraw at any time and for any reason without any further consequence for future care and treatment. Parents/guardians will be asked to give their consent to participate, while children will assent to participate, as minor children are not legally capable of entering into a contract and therefore unable to give legal consent.

Where is the study run from?
Uppsala University (Sweden)

When is the study starting and how long is it expected to run for?
January 2022 to December 2027

Who is funding the study?
Uppsala University (Sweden)

Who is the main contact?
Karin Enskär, karin.enskar@kbh.uu.se

Contact information

Type(s)
Scientific

Contact name
Prof Karin Enskär

ORCID ID
http://orcid.org/0000-0002-8910-1013

Contact details
Department of Women's and Children's Health
Pediatric oncological and neurological research
Uppsala University
Uppsala
Sweden
75237
+46 (0)707191545
karin.enskar@kbh.uu.se

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1

Study information

Scientific Title
Do we have to restrain children forcefully and make them suffer in health care? Evaluating an intervention for healthcare professionals to reduce anxiety and pain in children during needle-related medical procedures in healthcare

Study objectives
The overall aim of this research project is to reduce children’s pain and anxiety in connection with needle-related medical procedures. More specifically, the purpose is to evaluate an educational intervention that is designed to improve the healthcare professionals’ use of pain- and anxiety-preventing strategies in caring for children during needle-related medical procedures.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 12/04/2022, the Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02 Uppsala, Sweden; +46 (0)10 475 08 00; registrator@etikprovning.se), ref: 2022-00944-01

Study design
Non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, University/medical school/dental school

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Anxiety and pain in children during needle-related medical procedures in healthcare

Interventions
This project comprises three phases. The first phase forms the baseline, pre-intervention phase (Study 1) and is based on observations and self-reported pain- and anxiety-preventing strategies used in connection with needle-related medical procedures to which children are exposed. Thereafter, an educational intervention for healthcare professionals (HCPs) will be developed together with key stakeholders (co-creation) to provide knowledge and promote behavioural change in HCPs to increase the use of pain and anxiety-preventing strategies. The development and acceptability/feasibility testing of the educational intervention form Study 2. Finally, the researchers will assess the effectiveness of the educational intervention (Study 3).

Using a co-creational approach with children, parents, and HCPs, the intervention will be built on quality audits to ensure pain management is optimal. The theoretical underpinning of the intervention is the Capability, Opportunity, and Motivation Model (COM-B model) and Behaviour Change Wheel framework (BCW). The COM-B model will be used to identify barriers and drivers for using different strategies, which can help the researchers to find what conditions are needed for a successful change in practice. The analysis will be carried out together with key stakeholders' children, parents, and HCPs who are targeted by the intervention.

The educational intervention is structured on an educational model from the Institute of Medicine, including knowledge, skills, and attitudes through web-based lectures, process-based discussions, and reflection seminars. Such educational interventions have been proven to be effective in decreasing children's anxiety and pain during medical procedures

There are 6 months of intervention and 12 months of follow-up.

Intervention Type
Behavioural

Primary outcome measure
1. Pain in children measured using the Face, Legs, Activity, Cry, and Consolability (FLACC) scale for 0-2-year-olds, the Faces Pain Scale-Revised (FPS-R) for 4-7-year-olds and a Numeric Rating Scale (NRS) for 8-17-year-olds before, during, and immediately after the needle-related medical procedure
2. Anxiety in children aged 4-17 years old measured using the State-Trait Anxiety Inventory (STAI) short version and the Visual Analogue Scale for Anxiety (VAS-A) before and immediately after the needle-related medical procedure
3. Healthcare providers' (HCPs) use of pain and anxiety-preventing strategies measured using a questionnaire at the same time, during 2023

Secondary outcome measures
1. Level of pain and anxiety in children and parents after the intervention compared to before the intervention
2. Observed use of the strategies after the intervention compared to before the intervention
3. HCPs’ self-rated use of the strategies after the intervention compared to before the intervention
4. Parent anxiety measured using the State-Trait Anxiety Inventory (STAI) short version and the Visual Analogue Scale for Anxiety (VAS-A) before and immediately after the needle-related medical procedure
5. Injection phobia measured using the Injection Phobia Scale - Anxiety (IPSA) and the Injection Phobia Scale - Avoidance (IPSAV) before the procedure
6. Immediate reflections and perspectives related to the pain and anxiety-preventing strategies used during the procedure, measured using a short interview with the first 20 participating families in each function (in total n = 80), including children ≥4 years of age, their parents and involved HCPs, after the observation

Overall study start date
01/01/2022

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Children, parents, and HCPs from study 1 in the developmental phase
2. In the intervention phase, HCPs from the same functions as in Study 1

Participant type(s)
Other

Age group
Mixed

Sex
Both

Target number of participants
300

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/07/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
Sweden

Study participating centre
Uppsala University
Department of Women's and Children's Health
Pediatric oncological and neurological research
Uppsala
Sweden
752 37

Sponsor information

Organisation
Akademiska Barnsjukhuset

Sponsor details
Academic Children's Hospital
Uppsala
Sweden
S-751 85
+46 (0)18 617 14 90
klas.ekstrom@akademiska.se

Sponsor type
Hospital/treatment centre

Website

http://www.akademiska.se/barnsjukhuset

ROR
https://ror.org/00f378f80

Organisation
Uppsala University

Sponsor details
Department of Women's and Children's Health, Reproductive Health
MTC-huset, Dag Hammarskjölds väg 14B, 1 tr
Uppsala
Sweden
752 37
-
inger.sundstrom@kbh.uu.se

Sponsor type
University/education

Website
https://www.uu.se/en/

Funder(s)

Funder type
University/education

Funder Name
Uppsala Universitet

Alternative Name(s)
Uppsala University, UU_University, Uppsala Universitet, Sweden, UU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Results and Publications

Publication and dissemination plan
The data will be published in peer-reviewed articles as well as two doctoral theses. The data will also be presented during national and international congresses.

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
Uppsala University provides secure servers for managing and storing consent forms and data and provides administrative and data support. The research group will follow the core requirements for data management plans (DMPs) and criteria for the selection of trustworthy repositories, presented by Science Europe in 'Practical Guide to the International Alignment of Research Data Management': D/2018/13.324/4.

The name of the repository: RedCap Uppsala University
The type of data stored: Observational protocol, questionnaire and interview data
The process for requesting access: non-publicly available, data could be requested through the research group
Whether consent from participants was required and obtained: Written consent available through the research group
Comments on data anonymization: All data is confidential, no name, consent sheets or other personal characteristics will be stored together with the data

IPD sharing plan summary
Stored in non-publicly available repository