A hybrid effectiveness-implementation study on the implementation of Telemedrics: Comfort - a clinical pain management dashboard for the NICU (TMD-COMFORT)

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This study will evaluate the effectiveness and implementation process of TMD-COMFORT, a near-real-time pain management dashboard, in the NICU of Erasmus MC-Sophia Children*s Hospital.

Ethical review	Approved WMO
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON57578

Source
ToetsingOnline

Brief title
TMD-COMFORT

Condition

- Neonatal and perinatal conditions

Synonym
Neonatal discomfort, Pain in newborns

Health condition

Pijnmanagement bij neonaten

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinical dashboard, Implementation study, Neonatal pain management, NICU

Outcome measures

Primary outcome

The primary endpoint is to assess the effectiveness of Telemedrics in improving patient comfort in the NICU, measured by the reduction in the duration of inadequately treated discomfort in neonates.

Secondary outcome

The evaluation of the implementation process will assess implementation outcomes, including acceptance, appropriateness, adherence to the protocol, and penetration.

Study description

Background summary

Vertaal dit naar het Nederlands: Neonates in the NICU are frequently exposed to pain, which can lead to significant long-term consequences such as impaired neurological development and increased pain sensitivity later in life. Managing pain in these vulnerable patients is challenging due to their rapidly changing physiology and the difficulty of assessing pain in non-verbal patients.
Although pain management protocols exist, their application often depends on individual clinical experience, leading to variability in care. Inadequate pain management or overuse of analgesics like morphine can cause short- and long-term side effects, emphasizing the need for a more structured approach. To address these challenges, Telemedrics: Comfort (TMD-COMFORT) was developed as a

clinical dashboard to assist healthcare professionals in optimizing pain management for neonates by providing real-time data and decision support. This study aims to evaluate the effectiveness of TMD-COMFORT in improving pain management and minimizing discomfort for NICU patients.

Study objective

This study will evaluate the effectiveness and implementation process of TMD-COMFORT, a near-real-time pain management dashboard, in the NICU of Erasmus MC-Sophia Children*s Hospital.

Study design

The study will employ a type 1 hybrid effectiveness-implementation design, with a primary focus on investigating effectiveness and a secondary focus on the implementation process. The study will be conducted in the NICU of Erasmus MC-Sophia Children*s Hospital and will be divided into four phases: pre-implementation (1 year), mid-implementation (4 weeks), buffer/monitoring (4 weeks), and post-implementation (1 year).

Intervention

The intervention involves the implementation of Telemedrics: Comfort, a clinical dashboard designed to support healthcare professionals in optimizing pain management for neonates in the NICU.

Study burden and risks

The implementation of TMD-COMFORT is expected to have minimal burden and risks, primarily related to technical malfunctions and data privacy. These risks are mitigated through rigorous software testing, comprehensive training, and robust data security measures. The benefits include improved pain management for neonates, enhanced workflow efficiency for healthcare professionals, and better communication with parents, outweighing the minimal risks involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Newborns
Premature newborns (<37 weeks pregnancy)

Inclusion criteria

Primary outcome (Effectiveness evaluation):
- Patients admitted to the NICU of the Erasmus MC-Sophia Children*s Hospital during the pre- and post-implementation phases of the study.

Secondary outcomes (Implementation process evaluation):
- Healthcare professional (e.g., physician, nurse, nurse-specialist) or parents of patients that has been exposed to TMD.

Exclusion criteria

Primary outcome (Effectiveness evaluation):
- Patients not admitted and discharged during the pre- or post-implementation phase.

Secondary outcomes (Implementation process evaluation):
- n/a

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-06-2025
Enrollment:	0
Type:	Anticipated

Medical products/devices used

Generic name:	Telemedrics: Comfort
Registration:	No

Ethics review

Approved WMO

Date:	27-05-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL88031.078.24