A Parent Dashboard in the Pediatric Intensive Care Unit: Does it reduce Parental Stress?

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Ethical review	Approved WMO
Status	Pending
Health condition type	Psychiatric disorders NEC
Study type	Interventional

Summary

ID

NL-OMON57034

Source
ToetsingOnline

Brief title
PICU-DASH

Condition

- Psychiatric disorders NEC

Synonym
Parental stress, posttraumatic stress disorder

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: Dashboard, Parental stress, Pediatric Intensive Care Unit, PTSD

Outcome measures

Primary outcome

Parental stress during PICU admission of their child, measured at PICU

discharge.

Secondary outcome

1) Overall acute stress in parents during PICU admission of their child,

measured at PICU discharge.

2) Parental satisfaction with information during their child's PICU stay,

measured at PICU discharge.

3) PTSD symptoms of parents, measured at 3 months post-discharge from the PICU.

Study description

Background summary

The admission of a child to the PICU is an extremely stressful event for both the child and the parents. Parents often experience extreme stress due to uncertainty about the condition of their child, as well as changes in their parental role. This stress can lead to PTSD symptoms in parents after their child is discharged from the PICU. This may have negative consequences for the recovery and development of the child, as well as the parent-child relationship. Additionally, PTSD in parents can have a negative societal impact due to participation implications and reduced life opportunities after their child is discharged from the PICU.

Study objective

The overall research aim is to reduce stress in parents during PICU admission of their critically ill child by informing parents with a parent dashboard, to eventually reduce PTSD symptoms. This study seeks to reduce the negative impact of stress on parents after their child is discharged from the PICU, which could

otherwise limit their participation in society and opportunities in life. Maintaining parental health also ensures a healthier environment for the child, and as such contributes to the growth and development of the child after discharge.

Study design

A randomized controlled trial to compare the use of a parent dashboard providing real-time information about the medical status of the critically ill child during PICU admission with standard care without a parent dashboard.

Intervention

The intervention group will have access to the parent dashboard, while the control group will receive standard care without the parent dashboard.

Study burden and risks

Both the intervention and control group will benefit from the scheduled follow-up contact moment at 3 months post-discharge from the PICU. Additionally, parents in the intervention group may potentially experience additional benefits through the use of the parent dashboard. During the informed consent process, it will be clearly communicated that the decision not to participate in the research will not affect the care provided to their child.

Both groups are expected to complete questionnaires at discharge and at 3 months post-discharge. Completing the questionnaires at discharge will take approximately 27 minutes, while completing the questionnaires 3 months post-discharge will take about 10 minutes in total. Before the start of the study, participants should have a clear understanding of the time commitment required for the research procedures, enabling them to make informed decisions based on realistic information. The research addresses significant clinical, scientific, and societal needs and ultimately aims to improve the well-being of parents during and after the admission of their critically ill child to the PICU.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

All parents of critically ill children (term neonates (gestational age >37 weeks) up to 18 years old), who are admitted to the PICU during the inclusion period, and who are expected to stay in the PICU for more than 48 hours, are eligible for inclusion.

Exclusion criteria

Child exclusion criteria are 1) *do not resuscitate* code at PICU admission, 2) expected death within 24 hours, 3) readmission to the PICU or transfer from another PICU or neonatal NICU, and 4) expected length of stay in the PICU < 24 hours.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2025
Enrollment:	280
Type:	Anticipated

Ethics review

Approved WMO

Date:	03-10-2024
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	NL86633.078.24