Nutritional Care After Hospital Discharge

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON56271

Source
ToetsingOnline

Brief title
NutriCAD

Condition

- Appetite and general nutritional disorders

Synonym
Malnutrition, Nutritonal status

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: Discharge, Feeding behaviour, Nutritional care, Parent empowerment

Outcome measures

Primary outcome

The change in growth parameters weight, length and head circumference at 6 months after discharge.

Secondary outcome

The change in: 1) Body composition (fat mass, fat free mass), 2) Duration and frequentie of nutritional support and/or dependency on nasogastric tube feeding, 3) Nutritional requirements and intake, 4) Feeding behaviour of the child, 5) Parental stress, 6) Quality of Life of children and parents, 7) Cost-effectiveness of tailored nutritional care, and 8) Barriers and Facilitators of Implementation of the multidisciplinary support team 6 months after discharge

Study description

Background summary

In the Netherlands after hospitalization 9% of children are malnourished or at (high) risk of becoming malnourished. Impaired nutritional status influences time to recovery and has a negative effect on physical, emotional, social and cognitive functioning of children, and even on the Quality of Life and stress of caregivers. After discharge from hospital the exact time span in which the nutritional status is normalized is unclear. Currently children and parents are not followed-up by a nutritional support team while care is often left to a *multitude of healthcare professionals in various care settings*.

Study objective

The aim of our study is to investigate whether a tailored nutritional care follow-up program in children who are being discharged from the hospital with nutritional support improves nutritional intake and status as well as feeding behaviour and quality of life (QoL) in children and their parents. Furthermore,

the effect on parental stress, anxiety, depression, and posttraumatic stress (PTSD) as well as QoL will be assessed with and without a tailored nutritional care follow-up program.

Study design

A randomized stepped wedged study to compare usual care with nutritional home support.

Intervention

A tailor-made nutritional plan at discharge and adjustments after follow-up encounters at 6-12 and 18 weeks after discharge. The following aspects will be evaluated: feeding difficulties and behaviors, plus the stress of the parents. The answers of the questionnaires will be displayed in a digital dashboard.

Study burden and risks

For the children enrolled in the study there might be benefits in the intervention group. No harm is expected in the usual care or intervention group. It will be made clear during the informed consent process that participation in this study might have benefit in the intervention group and no direct benefit in the usual care group and that a refusal will not have impact on their care received by the medical staff.
As well as the time investment in filling out the questionnaires. It should be clear for the participant before starting with this study how much time the study procedures cost. So, participants can make a decision based on realistic information. The project will meet an important clinical, societal, and scientific need and will ultimately lead to an improvement in the care for sick and malnourished children who are receiving nutritional support at home.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Children (Term born neonates - 18 years) admitted with newly initiated nutritional support (oral and/or enteral nutritional support) during hospitalization which is recommended to continue at home after discharge

Exclusion criteria

Children with existing nutritional support upon admission
Children in need of parenteral nutrition at discharge
Children with DSM-5 diagnosed feeding disorders such as anorexia
Absence of written informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2024
Enrollment:	260
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	22-11-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-05-2024
Application type:	Amendment
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
Other	Is in aanvraag
CCMO	NL84484.078.23