Guided Family-Centred Care - relieving parental stress related to preterm birth and hospital admission through guided communication between parents and health care professionals

Submission date	Recruitment status	[X] Prospectively registered
21/06/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
13/07/2010	Completed	Results
Last Edited	Condition category	Individual participant data
07/09/2011	Mental and Behavioural Disorders	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mrs Janne Weis

Contact details

Department of Neonatology, 5024 Blegdamsvej 9 Copenhagen Denmark DK-2100 +45 35458614 janne.weis@rh.regionh.dk

Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

A randomised controlled intervention study of patient-centred communication with neonatal nurses in parents of preterm children and their levels of parental stress

Acronym

GFC

Study objectives

Parental stress is reduced when communication with healthcare professionals is focused on individualised support. Using the method Guided Family-Centred Care communication will be based on the perspectives of the individual family-members resulting in individualised support. By relieving parental stress during hospital admission the transition to home is made easier as the parents confidence in parental skills are increased and managing the parental role in everyday life with the baby is strengthened.

Ethics approval required

Old ethics approval format

Ethics approval(s)

According to the Ethics Board of The Capital Region of Denmark there is no obligation to obtain approval of this kind of project.

Study design

Single centre interventional controlled study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Parental stress

Interventions

Intervention group:

Guided Family-Centred Care based on frequent conversations between the parents and healthcare professionals. Parents use semi-structured reflection sheets for some conversations.

Reflection sheets:

Three sheets have been developed:

- 1. Admission conversation used when preparing for a conversation held in the initial critical phase. Consists of questions focused on parents experiences and needs emotional as well as practical.
- 2. Follow-up conversation used when preparing for a conversation held in a more steady phase: Consists of unfinished sentences focused at values clarification.
- 3. Discharge conversation: Consists of questions focused on identification of the parents' worries and delights of going home. Weekly follow-up conversations without using reflection sheets are held throughout hospital stay. Conversations are registered in a Case Report Form.

Control group:

No special actions - must not at any time use reflection sheets.

The total duration of the intervention is the total admission period which normally lasts until the expected date of birth - corresponding to 6 - 17 weeks or longer.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Difference between the groups in reduction of stress level during admission. The Parental Stress Scale:NICU (PSS:NICU) will be administered at admission and at discharge. PSS:NICU is developed to measure parents experiences of stressors from the physical and the psycho-social environment in the NICU. Stress is measured on a 5-point Likert Scale rating from 1 = Not at all stressful to 5 = Extremely stressful. Measured within the first 72 hours of admission and within the last 24 hours of admission.

Key secondary outcome(s))

- 1. Differences in parental stress score within the three subscales of the PSS:NICU
- 2. Difference in parents scoring experiences of collaboration with neonatal nurses using the Nurse Parent Support Tool (NPST). NPST measures parents experiences of support and collaboration using a 5-point Likert scale rating from 1 = Almost never to 5 = Almost always.

Measured within the last 24 hours of admission.

Completion date

31/10/2012

Eligibility

Key inclusion criteria

- 1. Both parents (if possible) of premature babies born before 34 weeks of gestation admitted to the neonatal intensive care unit, Copenhagen University Hospital
- 2. Inclusion within the first 24 hours of hospital admission (when the condition of the baby is very critical inclusion can be postponed)
- 3. Must be able to speak, read and write in Danish

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Key exclusion criteria

Parents of babies where the survival of the child is most doubtful

Date of first enrolment

01/10/2010

Date of final enrolment

31/10/2012

Locations

Countries of recruitment

Denmark

Study participating centre Department of Neonatology, 5024

Copenhagen Denmark DK-2100

Sponsor information

Organisation

Copenhagen University Hospital (Denmark)

ROR

https://ror.org/05bpbnx46

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Copenhagen University Hospital (Denmark) - Department of Neonatology

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes