

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 21/06/2010	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 13/07/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/09/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

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

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/10/2010

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

Age group

Adult

Sex

Both

Target number of participants

150 families (75 in each group)

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)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.neonatal.rh.dk>

ROR

<https://ror.org/05bpbnx46>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Copenhagen University Hospital (Denmark) - Department of Neonatology

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration