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Better preparing parents for difficult treatment decisions

Submission date	Recruitment status	[X] Prospectively registered
06/12/2023	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2024	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Decisions about treatment options for critically ill infants in neonatal intensive care units present emotional and ethical difficulties for parents and healthcare professionals. “What would you do if it were your child?” is a question parents often ask physicians when they are unsure about which treatment to choose for their child. This study aims to gain a better understanding of the needs of parents during the decision-making process regarding two treatment options to improve medical counseling and to support parents in making decisions about the treatment of critically ill infants. The focus is on disclosure versus non-disclosure of the physician's personal perspectives in a counseling session.

Who can participate?
Adult parents (or other legal representatives) of a preterm infant born at less than 32 weeks gestation who are 18 years of age or older. They will either be recruited at the Division of Neonatology at the Inselspital Bern or via parent support groups e.g. “Frühchen Schweiz” (https://www.fruehchenschweiz.ch).

What does the study involve?
Data will be collected via a web-based questionnaire using the SoSci Survey computer software. The study is a two-arm simulation-based, randomized controlled trial using audio-visual animations to explore attitudes and views towards disclosure of a physicians' personal perspective in a counseling session with parents of critically ill infants.

What are the possible benefits and risks of participating?
Participating parents are unlikely to receive any direct individual benefit from the study. A possible group benefit may come from improved counseling practices for future parents in a similar situation. Watching the scenarios in video format and then answering related questions may elicit an emotional response from parents. However, the risk for relevant stress is estimated to be minor. The risk to participants is minimal.

Where is the study run from?
Division of Neonatology, Inselspital Bern, University Hospital, Switzerland

When is the study starting and how long is it expected to run for?
January 2023 until April 2024

Who is funding the study?
Insel Gruppe AG, Direktion Lehre und Forschung and Division of Neonatology, Inselspital Bern, University Hospital are funding the study.

Who is the main contact?
Dr. sc. hum. Christine Arnold, christine.arnold@insel.ch

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Disclosure versus non-disclosure of physicians' personal perspective during decision-making with parents of critically ill infants

Acronym

PHILIPA

Study objectives
It is hypothesized that disclosure of the physician's personal perspective will result in better parental preparation for decision-making.

Ethics approval required
Ethics approval not required

Ethics approval(s)
The study protocol was submitted to the Berne Cantonal Ethics Committee for clarification of competence (BASEC-No.: Req-2023-00884). Opinion: 17/07/2023: the ethics committee was not responsible; that is, the project does not require approval, because the project does not fall under the Human Research Act, Article 2, Paragraph 1.

Study design
Simulation-based randomized controlled trial with two arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Internet/virtual

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Parents of preterm infants

Interventions
The study is a simulation-based, randomized controlled trial (RCT) with two arms, which, through the presentation of audio-visual animations, explores attitudes and views on the disclosure of physicians' perspectives in a counseling session with parents of critically ill infants.

Parents will be individually randomized 1:1 via SoSci Survey to either control or intervention group. To collect data on a secondary outcome (preference), the groups will each receive the intervention of the group to which they are not assigned.
The intervention group (disclosure group) will receive an animated scenario in which a physician discloses her personal perspective in a consultation about a therapeutic decision regarding the placement of a tracheostoma in a critically ill infant in response to the question "What would you do if it were your child?”

In contrast, in the control group (non-disclosure group), the physician will not disclose her personal perspective, but will answer the question "What would you do if it were your child?" with general facts.

Intervention Type
Other

Primary outcome measure
Degree of parental preparation for a medical decision is measured using the 10-item German version of the Preparation for Decision-Making Scale (PDMS-G) after animation 1.

Secondary outcome measures
Current secondary outcome measures as of 24/05/2024:
1. Parental preference concerning disclosure versus non-disclosure of physicians' personal perspectives during the shared decision-making process will be asked with a dichotomous question (t2, after animation 2).
2. Preference for or against tracheostomy will be asked with a dichotomous question (t1).
3. The physician compassion as assessed by the parents using the German translation of the Physician Compassion Questionnaire (range 5–50), t1.

Previous secondary outcome measures:
1. Parental preference concerning disclosure versus non-disclosure of physicians' personal perspectives during the shared decision-making process will be asked with a dichotomous question (t2, after animation 2).
2. Preference for or against tracheostomy will be asked with a dichotomous question (t1).
3. The physician compassion as assessed by the parents using the German translation of the Physician Compassion Questionnaire (range 5–50), t1.
4. Parental anxiety after control/intervention will be assessed using the German short version (5 items) of the state scale of the State-Trait-Anxiety-Inventory (STAI-SKD), t1.

Overall study start date
01/01/2023

Completion date
31/12/2024

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 24/05/2024:
1. Parent (or other legal representative) of a preterm infant born at less than 37 weeks gestation
2. Parents (other legal representative) ≥ 18 years

Previous participant inclusion criteria:
1. Parent (or other legal representative) of a preterm infant born at less than 32 weeks gestation
2. Parents (other legal representative) ≥ 18 years

Participant type(s)
Service user

Age group

Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
232

Total final enrolment
218

Key exclusion criteria
Insufficient knowledge of project language (German or English).

Date of first enrolment
01/02/2024

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
Switzerland

Study participating centre
Division of Neonatology, Department of Paediatrics, Inselspital, Bern University Hospital
Friedbühlstrasse 19
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Sponsor information

Organisation
Inselspital, Universitätsspital Bern

Sponsor details

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Inselspital, Universitätsspital Bern

Alternative Name(s)
Inselspital, Bern University Hospital, Inselspital, Bern University Hospital, University Hospital of Bern, Universitätsspital Bern, Inselspital, Hôpital universitaire de Berne

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Furthermore, the results will be presented at international congresses.

Intention to publish date
01/07/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr. sc. hum. Christine Arnold, christine.arnold@insel.ch. Data will be available after

the study ends (01/01/2025). No consent was required due to the anonymous nature of the survey. The data is collected anonymously. Anonymized data will be made available for secondary analysis, as well as to other researchers, upon reasonable request.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1	14/07/2023	24/05/2024	No	No
Protocol file	version 2	18/01/2024	24/05/2024	No	No