Aus der Klinik und Poliklinik für Kinder- und Jugendmedizin
der Universitätsmedizin der Johannes Gutenberg-Universität Mainz

# **Optimistisches vs. pessimistisches Framing bei der Übermittlung einer Prognose an Eltern sehr unreifer Frühgeborener –** Die randomisierte klinische COPE-Studie

Inauguraldissertation
zur Erlangung des Doktorgrades der
Medizin
der Universitätsmedizin
der Johannes Gutenberg-Universität Mainz

Vorgelegt von

Fiona Antonia Wocheslander geb. Forth
aus München

Mainz, 2025

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| Wissenschaftlicher Vorstand: | Univ.-Prof. Dr. Hansjörg Schild |
| Tag der Promotion: | 23. April 2025 |

**Widmung**

*„Please world, be tolerant.*
*Society, be tolerant of little flowers that are trying to grow …*
*Do not squish them because they grow too slowly …*
*Do not dig them out because they look sickly and grow weird leaves …*
*Do not stop watering them even if they are tiny and grow to be much smaller than the other bigger flowers…*
*Nurture them, find something beautiful in them even if they have lost some petals and may grow sideways."*[1]

Meine Doktorarbeit widme ich zu früh und/oder krank geborenen Kindern, deren Leben durch die Frühgeburt „anders" ist, oder die eine Komplikation erlebt haben, welche ihre Entwicklung ungewiss sein lässt oder langfristig beeinflusst. Mögen sie liebevoll umsorgt und so angenommen werden, wie sie sind.

Außerdem widme ich meine Doktorarbeit den Eltern und Familien zu früh und/oder krank geborener Kinder sowie den mit diesen Kindern und deren Eltern arbeitenden Angehörigen verschiedener Gesundheitsberufe. Mögen sie bei allen bestehenden Herausforderungen stets eine für alle Beteiligten gute Ebene der Kommunikation finden.

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[1] Janvier A. *Breathe, Baby, Breathe!: Neonatal Intensive Care, Prematurity, and Complicated Pregnancies*. Toronto: University of Toronto Press; 2020. https://doi.org/10.3138/9781487519261

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# 1 Deutschsprachige Zusammenfassung der englischsprachigen Originalpublikation mit dem Titel „Optimistic vs Pessimistic Message Framing in Communicating Prognosis to Parents of Very Preterm Infants – The COPE Randomized Clinical Trial“

## 1.1 Einleitung und Zielsetzung

Sehr unreife Frühgeborene sind besonders vulnerable pädiatrische Patient:innen und anfälliger für postnatale Komplikationen wie intraventrikuläre Hämorrhagien, die Einfluss auf ihre Mortalität und Morbidität haben. Vorhersagen im Hinblick auf das kurzfristige Überleben sowie die langfristige Entwicklung eines einzelnen betroffenen Frühgeborenen aus populationsbasierten Daten abzuleiten sowie derartige Prognosen zu kommunizieren, stellt für behandelnde Neonatolog:innen eine komplexe Aufgabe dar. Eine auf elterliche Bedürfnisse zugeschnittene Kommunikation prognostischer Daten ist bekanntermaßen wichtig, um Eltern zu befähigen, realistische Zukunftserwartungen zu entwickeln, sich in ihrer Rolle als Eltern anzupassen und Entscheidungen für ihr Kind zu treffen. Die Kontextualisierung übermittelter Informationen kann dabei Einfluss auf das elterliche Verständnis ebendieser nehmen.

Wie Eltern sehr unreifer Frühgeborener sich die Übermittlung von Prognosen vorstellen, ist trotz bestehender Studien zum Einfluss unterschiedlichen Kommunikationsverhaltens sowie der Formulierung solcher Botschaften nicht ausreichend bekannt. Im Besonderen besteht Unklarheit darüber, welche Formulierung von Prognosen präferiert wird und welche Konsequenzen die unterschiedliche Formulierung derselben Prognose haben kann. Ziel der entsprechend dem Akronym des originalen englischsprachigen Studientitels „**C**ommunicating prognosis to parents in the neonatal ICU: **O**ptimistic vs. **PE**ssimistic“ als **COPE**-Studie bezeichneten Studie war es, die Präferenz von Eltern für die optimistische oder pessimistische Formulierung einer Prognose, sowie mögliche Auswirkungen unterschiedlicher Formulierung auf die Eltern auf emotionaler und kognitiver Ebene zu untersuchen.

## 1.2 Material und Methoden

Die monozentrische, randomisiert kontrollierte Crossover-Studie wurde nach Genehmigung durch die Ethikkommission der Ärztekammer Rheinland-Pfalz zwischen Juni und Oktober 2021 in dem Schwerpunktbereich Neonatologie der Universitätsmedizin der Johannes Gutenberg-Universität Mainz durchgeführt. Vor Studienbeginn waren die Registrierung der Studie (DRKS00024466) sowie die Publikation des zugrundeliegenden Studienprotokolls (https://doi.org/10.1186/s13063-021-05796-3) erfolgt.

Die experimentelle Studie wurde als Online-Befragung durchgeführt. Teilnahmeberechtigt waren Eltern von noch lebenden, ehemaligen Frühgeborenen mit einem Geburtsgewicht unter 1500g und Behandlung an der Universitätsmedizin der Johannes Gutenberg-Universität Mainz zwischen Januar 2010 und Dezember 2019. Ausreichende Deutschkenntnisse (Selbsteinschätzung) sowie Abwesenheit einer akuten psychischen Erkrankung oder anhaltender Belastung durch die Frühgeburt des eigenen Kindes (Selbstauskunft) wurden für die Teilnahme vorausgesetzt. Teilnehmende Eltern wurden nach elektronischer Einverständniserklärung randomisiert einer von zwei Studiengruppen zugeteilt.

Als Studienintervention dienten zwei in einen für beide Studiengruppen identischen Online-Fragebogen eingebettete Video-Vignetten. Diese zeigten ein von professionellen Schauspieler:innen dargestelltes Gespräch zwischen einer Neonatologin und den Eltern eines fiktiven sehr unreifen Frühgeborenen anlässlich der Übermittlung der Diagnose einer akuten hochgradigen IVH und der damit verbundenen Prognose. Während wesentliche Aspekte der beiden Videos standardisiert und die übermittelte Prognose inhaltlich logisch gleichwertig waren, unterschieden diese sich im sogenannten Framing der Prognose. Framing wird in diesem Zusammenhang als unterschiedliche Präsentation statistisch identischer Informationen interpretiert. Die statistischen Daten für das Überleben (50%) sowie die Beeinträchtigung des Frühgeborenen im Falle des Überlebens (50%) wurden folglich entweder als Überlebenswahrscheinlichkeit und Wahrscheinlichkeit ausbleibender Beeinträchtigung (optimistisches Framing) oder als Sterberisiko und Risiko bleibender Beeinträchtigung (pessimistisches Framing) kommuniziert. Das nonverbale Auftreten der Neonatologin in beiden Videos war kohärent mit dem jeweiligen Framing der Prognose. Die beiden Video-Vignetten waren dabei in unterschiedlicher Sequenz in den Online-Fragebogen eingebettet. Die Gruppe „optimistic first“ bekam zuerst das optimistische, dann das pessimistische Framing zu sehen, die Gruppe „pessimistic first“ umgekehrt. Die Teilnehmer waren dabei für die Videosequenzen verblindet.

Der Online-Fragebogen begann mit der Erhebung soziodemografischer Daten der Eltern. Im Anschluss an jedes Video beziehungsweise nach Ansehen beider Videos wurden die primäre und verschiedene sekundäre Zielgrößen erfasst. Primäre Zielgröße war die Präferenz der Eltern für optimistisches oder pessimistisches Framing der Prognose. Sekundäre Zielgrößen umfassten die durch die Prognoseübermittlung ausgelöste elterliche Erregung, die Wahrnehmung der Neonatologin (Gesamteindruck, Mitgefühl, Professionalität), die Wahrnehmung der Prognoseübermittlung per se (Zufriedenheit mit Framing, Informationsstand über Prognose, Bereitschaft zur Entscheidungsfindung), Zukunftserwartungen der Eltern (Wahrnehmung der Prognose, Optimismus und Hoffnung für Zukunft des betroffenen Kindes) und die Erinnerung übermittelter Zahlenwerte.

## 1.3 **Studienergebnisse**

Von 906 möglichen Teilnehmer:innen wurden 256 randomisiert. Insgesamt wurden 220 Elternteile, davon 142 Mütter und 78 Väter, in die Datenanalyse eingeschlossen. Die Mütter waren bei Teilnahme im Mittel 39,1 Jahre alt, die Väter mit 42,7 Jahren im Mittel etwas älter. Der Großteil der teilnehmenden Eltern lebte in einem Zwei-Eltern-Haushalt und hatte im Mittel zwei Kinder, wobei das jeweilige Frühgeborene vor im Mittel 5,9 Jahren auf der Neugeborenen-Intensivpflegestation behandelt worden war. 114 Eltern waren der Gruppe „optimistic first“, 106 der Gruppe „pessimistic first“ randomisiert zugeteilt worden.

Insgesamt bevorzugten 196 Elternteile, das heißt 89,1% der Teilnehmer:innen, das optimistische und 24, das heißt 10,1%, das pessimistische Framing. Die Präferenz für das optimistische Framing war dabei ausgeprägter, wenn sie als zweite Variante präsentiert wurde. Teilnehmer, welche das optimistische Framing bevorzugten, zeigten insgesamt eine Präferenz für Optimismus bei Prognoseübermittlung. Die elterliche Erregung (Zustandsangst) vor Ansehen der Videos war in beiden Gruppen vergleichbar und nahm nach dem jeweils ersten Video gleichermaßen zu. Nach dem jeweils zweiten Video nahm die Erregung ab, wenn zuerst das pessimistische gefolgt von dem optimistischen Framing präsentiert wurde. Bei umgekehrter Sequenz blieb die elterliche Erregung nach dem zweiten Video vergleichbar zu der nach dem ersten Video. Bei optimistischem gegenüber pessimistischem Framing fielen der generelle Eindruck sowie die Wahrnehmung der Professionalität und des Mitgefühls der Ärztin positiver aus. Bei optimistischem gegenüber pessimistischem Framing war außerdem die Zufriedenheit mit der Prognoseübermittlung größer, die Eltern fühlten sich besser informiert und auf das Treffen einer Therapieentscheidung vorbereitet, sie empfanden die Prognose als weniger einschränkend und waren hinsichtlich der Zukunft des betroffenen Kindes optimistischer und hoffnungsvoller. Bei optimistischem Framing erinnerten Eltern die übermittelte Wahrscheinlichkeit für das Überleben des Kindes korrekter, jedoch nicht die für dessen mögliche Beeinträchtigung.

## 1.4 Diskussion

In Übereinstimmung mit vorausgehenden Studien kommt die COPE-Studie zu dem Schluss, dass Eltern unreifer Frühgeborener wie Eltern kranker Kinder eine optimistische Sicht auf die wahrscheinliche Zukunft ihres Kindes bevorzugen. Diese Erkenntnis fügt sich in das bestehende Bild ein, dass Eltern schätzen, wenn Mediziner:innen, die im Allgemeinen eine pessimistischere Sicht auf kindliche Prognosen haben, zwar ehrlich und realistisch Risiken kommunizieren, zugleich jedoch bestehende Chancen für das betroffene Kind anführen. Darüber hinaus bestätigen die Ergebnisse der COPE-Studie, dass bei Prognoseübermittlung ein geeignetes Maß an Optimismus wesentlich ist.

In der COPE-Studie zeigt sich hinsichtlich der Präferenz der Eltern sowie der elterlichen Erregung vor und nach Ansehen der Videos ein Reihenfolgeneffekt, der in experimentellen Studien mit vergleichbarem Design bereits beobachtet wurde. Als zugrundeliegend lassen sich ein Rezenzeffekt, eine veränderte Aufmerksamkeit der Eltern für bestimmte Ebenen der Kommunikation und des Inhalts bei wiederholtem Gespräch zu einem Thema sowie die emotionale Reaktion auf den Gesprächsinhalt oder die Interaktion zwischen Gesundheitspersonal und Eltern diskutieren. Anders als in vorausgehenden Studien zeigte sich eine substanzielle emotionale Reaktion in Abhängigkeit von dem Framing der Botschaft besonders nach Wiederholung des Gesprächs.

Die Ergebnisse der COPE-Studie unterstützen die Erkenntnis, dass unterschiedliches Framing von Botschaften in der Neonatologie wie in anderen Bereichen der Medizin die Wahrnehmung des Gesundheitspersonals, wesentlicher Aspekte der Kommunikation und der Nachricht selbst beeinflussen kann. Dass unterschiedliches Framing die Wahrnehmung medizinischer Fakten verändert, kann dazu Anlass geben, das richtige Verständnis dieser Fakten durch Anwenden geeigneter Strategien sicherzustellen. Wiederum sollte sich Gesundheitspersonal bewusst machen, dass Eltern kranker Kinder gewisse Fakten unabhängig vom Framing stets in positiverem Licht sehen werden als diese, weil Optimismus und Hoffnung im Angesicht von Ungewissheit für Eltern wesentlich sind. Diese schließen ein realistisches Verständnis der Situation jedoch nicht aus.

Auch wenn das Ziehen konkreter Schlüsse für die klinische Praxis auf Grundlage des experimentellen Designs und der Limitationen der Studie eingeschränkt möglich ist, stützen die Studienergebnisse die Annahme, dass optimistisches Framing für Gesundheitspersonal und Eltern positive Auswirkungen hat.

## 1.5 Schlussfolgerung und Relevanz

Die Ergebnisse der COPE-Studie legen nahe, dass ein Großteil der Eltern sehr frühgeborener Kinder optimistisches Framing bei der Prognoseübermittlung bevorzugen. Unterschiedliches Framing nimmt dabei Einfluss auf die elterliche Wahrnehmung übermittelter Inhalte. Die Ergebnisse dieser experimentellen Studie sollten Anstoß für die weitere Erforschung des Framing von Nachrichten im klinischen Umfeld der Neugeborenen-Intensivmedizin geben.

# 2 Englischsprachige Originalpublikation mit dem Titel „Optimistic vs Pessimistic Message Framing in Communicating Prognosis to Parents of Very Preterm Infants – The COPE Randomized Clinical Trial“

## 2.1 Originalpublikation

JAMA Network Open

**Original Investigation** | **Pediatrics**

# Optimistic vs Pessimistic Message Framing in Communicating Prognosis to Parents of Very Preterm Infants

## The COPE Randomized Clinical Trial

Fiona A. Forth; Florian Hammerle, Dipl-Psych; Jochem König, PhD; Michael S. Urschitz, MD, MSc; Philipp Neuweiler, MA;
Eva Mildenberger, MD; André Kidszun, MD, MA, MME

## Abstract

**IMPORTANCE** In the neonatal intensive care unit, there is a lack of understanding about how best to communicate the prognosis of a serious complication to parents.

**OBJECTIVE** To examine parental preferences and the effects of optimistic vs pessimistic message framing when providing prognostic information about a serious complication.

**DESIGN, SETTING, AND PARTICIPANTS** This crossover randomized clinical trial was conducted at a single German university medical center between June and October 2021. Eligible participants were parents of surviving preterm infants with a birth weight under 1500 g. Data were analyzed between October 2021 and August 2022.

**INTERVENTIONS** Alternating exposure to 2 scripted video vignettes showing a standardized conversation between a neonatologist and parents, portrayed by professional actors, about the prognosis of a hypothetical very preterm infant with severe intraventricular hemorrhage. The video vignettes differed in the framing of identical numerical outcome estimates as either probability of survival and probability of nonimpairment (optimistic framing) or a risk of death and impaired survival (pessimistic framing).

**MAIN OUTCOMES AND MEASURES** The primary outcome was preference odds (ratio of preference for optimistic vs pessimistic framing). Secondary outcomes included state anxiety, perceptions of communication, and recall of numerical estimates.

**RESULTS** Of 220 enrolled parents (142 [64.5%] mothers; mean [SD] age: mothers, 39.1 [5.6] years; fathers, 42.7 [6.9] years), 196 (89.1%) preferred optimistic and 24 (10.1%) preferred pessimistic framing (preference odds, 11.0; 95% CI, 6.28-19.10; $P < .001$). Preference for optimistic framing was more pronounced when presented second than when presented first (preference odds, 5.41; 95% CI, 1.77-16.48; $P = .003$). State anxiety scores were similar in both groups at baseline (mean difference, −0.34; −1.18 to 0.49; $P = .42$) and increased equally after the first video (mean difference, −0.55; 95% CI, −1.79 to 0.69; $P = .39$). After the second video, state anxiety scores decreased when optimistic framing followed pessimistic framing but remained unchanged when pessimistic framing followed optimistic framing (mean difference, 2.15; 95% CI, 0.91 to 3.39; $P < .001$). With optimistic framing, participants recalled numerical estimates more accurately for survival (odds ratio, 4.00; 95% CI, 1.64-9.79; $P = .002$) but not for impairment (odds ratio, 1.50; 95% CI, 0.85-2.63; $P = .16$).

*(continued)*

### Key Points

**Question** Do parents of very preterm infants prefer optimistic or pessimistic message framing when informed of a serious complication in their child's condition?

**Findings** This crossover randomized clinical trial using 2 scripted video vignettes depicting 2 types of message framing found that a clear majority of parents (89.1%) preferred the optimistic framing, while 10.9% preferred the pessimistic framing.

**Meaning** These results suggest that, when given prognostic information about a serious complication in their child's condition, parents of very preterm infants may prefer optimistic framing.

+ Visual Abstract

+ Invited Commentary

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

*Abstract (continued)*

**CONCLUSIONS AND RELEVANCE** When given prognostic information about a serious complication, parents of very preterm infants may prefer optimistic framing. Optimistic framing may lead to more realistic expectations for survival, but not for impairment.

**TRIAL REGISTRATION** German Clinical Trials Register (DRKS): DRKS00024466

*JAMA Network Open.* 2024;7(2):e240105. doi:10.1001/jamanetworkopen.2024.0105

## Introduction

In the neonatal intensive care unit (NICU), very preterm infants represent a particularly vulnerable patient population. They are highly susceptible to postnatal complications such as intraventricular hemorrhage (IVH), which increases their risk of mortality and is a major cause of morbidity.[1-3] Despite improved diagnostic capabilities and the increasing availability of long-term data on the outcome of very preterm infants, it remains a complex task for neonatologists to derive predictions for the short-term survival and long-term neurodevelopmental outcome of an individual infant from the results of general population-based research and to communicate these to parents.[4-10] Moreover, physicians and parents are known to have different perspectives on the importance, discussion, and understanding of outcomes.[7,11] Parents want and need prognostic information and communication tailored to their preferences.[4,11-14] These are a prerequisite for developing realistic expectations for their child, adjusting to their role as parents, and participating in shared decision-making (SDM) as surrogates for their child.[8,15-17] When communicating with parents, contextualizing the information to be conveyed can have a tremendous impact on their understanding.[18]

Although a number of studies have been conducted on the influence of different communication behaviors and message formulation, there is still insufficient knowledge about how parents of very preterm infants want to receive prognoses.[17,19-23] It remains largely unclear how prognostic information should ideally be framed to meet parents' preferences and what effects different framings of prognostic information may have in the NICU setting. The aim of this study was to examine parents' preferences for optimistic vs pessimistic message framing and how such framing possibly affects emotional and cognitive outcomes.

## Methods

This randomized clinical trial (RCT) was approved by the ethics committee of the Medical Association of Rhineland-Palatinate. All participants provided electronic informed consent. The full trial protocol[24] is available in Supplement 2. This report follows the Consolidated Standards of Reporting Trials (CONSORT) reporting guideline for RCTs.

### Trial Design, Setting, and Interventions

The COPE-Trial (Communicating prognosis to parents in the neonatal ICU: optimistic vs pessimistic) was a single-center randomized-controlled crossover trial, conducted at the Division of Neonatology of the University Medical Center Mainz (UMC Mainz) in Mainz, Germany. An experimental video vignette design[25-27] was used with 2 video vignettes, portrayed by professional actors, depicting a conversation between a neonatologist and the parents of a hypothetical very preterm infant. The content of the conversation was the diagnosis of acute severe intraventricular hemorrhage in the infant and the associated prognosis. Many aspects of the 2 videos were standardized, including the setting, actors, flow of conversation, camera work, and duration. The message in both videos was logically equivalent but differed in presentation. Statistical outcome estimates for survival (50%) and impairment (50% in case of survival) were framed as either a probability of survival and probability of nonimpairment (optimistic framing) or a risk of death and impaired survival (pessimistic framing). In both videos, the nonverbal appearance of the neonatologist was congruent with the respective framing of the message. Message framing is interpreted as a broad concept in which the presentation of statistically identical information is modulated in a variety of ways.[28] The scripts and the videos vignettes are provided as eMethods in Supplement 1.

## Participants and Procedures

Parents of surviving preterm infants with a birth weight under 1500 g treated at the UMC Mainz between January 2010 and December 2019 were eligible (906 in total) and included if they had sufficient German language skills (self-assessment). Individuals were excluded if they reported acute mental illness or persistent distress from the prematurity experience (self-report). Participants provided electronic informed consent prior to enrollment.

Participants were randomized to alternate exposure to 2 video sequences. Those randomized to the optimistic first group viewed the optimistic framing first, then the pessimistic framing, and vice versa in the pessimistic first group. Randomization was performed using computer-generated lists in blocks of variable length, stratified by participation of only the mother, only the father, and both parents. If both parents participated, they received the same allocation. Participants were assigned to study groups using sequentially numbered, sealed, opaque envelopes. Participants were masked to the sequence.[24]

## Study Outcomes

The primary outcome was the participants' preference for optimistic vs pessimistic framing. This was assessed once, after the second video, in response to the binary question of whether a participant preferred the first or the second video. Complementary to the primary outcome, participants indicated a general framing preference, ie, their preferred level of optimism in the framing of prognostic information (7-point scale: 1 [not at all optimistic] to 7 [very optimistic]).

The following secondary outcomes were assessed. At baseline and after each video, participants' state anxiety (STAI-SKD[29]), ie, anxiety as a transient response to a stimulus, was assessed as framing effect on an emotional level. A higher sum score (range, 5 to 20) indicated a higher level of state anxiety. Other secondary outcomes were only assessed after the respective first video. Participants rated the physician's overall impression (from 1 [poor] to 5 [very good]), physician professionalism (sum score range, 7-35), and physician compassion (sum score range, 5-50). Physician professionalism was assessed using a 7-item questionnaire adapted from the General Medical Council (GMC) patient questionnaire.[30] The selection of items was adapted from Tanco et al.[22,31] Physician compassion was measured with the Physician Compassion Questionnaire[32] (original scale inverted) also adapted from Tanco et al.[22,31] Higher scores indicated higher levels of professionalism and compassion. Participants' perceptions of prognostic communication (satisfaction with framing, level of information about the prognosis, preparedness for decision making) and prognostic expectations (favorability of the prognosis, optimism, and hope for the infant's future) were assessed using individually tailored questions. For each response, fully verbalized 7-point rating scales (from 1 [not at all] to 7 [very much or completely]) with a verbal equivalent for each scale point were used. Recall accuracy of the numerical estimates for survival and impairment was assessed by percentages selected by the participants. A choice of percentages between 0 and 100% in increments of 10 (for survival) or 25 (for impairment) was requested.

## Statistical Analysis

Sample size calculation aimed to detect a preference odds (ratio of preference for optimistic vs pessimistic framing) of 3:2 with 80% power by a period-adjusted analysis that accounted for 1 or 2 responding parents, respectively. This resulted in 215 single parents or 153 parent couples.[24] After a planned masked sample size reassessment based on responses from 144 parents in 90 families, we calculated a required sample size of 265 parents. End of individual recruitment was further defined as the time at which each eligible family, which had not been reached at the time of reassessment, had been contacted 5 times at 5 different times of day on 5 different days over a 5-week period. Data collection therefore ended 4 and a half months into the study when no more parents could be recruited from the eligible population.

Statistical analysis was performed using IBM SPSS Statistics 27 for Windows (IBM Corp). Analyses followed a modified intention-to treat approach. Participants who were randomized but did not start the study (ie, did not watch a single video) were excluded from the analysis. Standard descriptive statistics including means and medians, and proportions were calculated for all baseline and outcome variables. For outcome variables, appropriate effect estimates are reported along with the corresponding 95% CIs. For inferential statistics, all tests were 2-sided, and a *P* value < .05 was considered statistically significant. For all variables, the statistics have been adjusted for intrafamilial correlation (IFC), ie, the tendency of parents of the same infant to respond similarly. The IFC was quantified by the intraclass correlation coefficient (ICC) in percentage. The primary outcome was analyzed by fitting a marginal logistic regression model for correlated binary data to account for a period effect and the IFC.[24]

## Results

Of 906 individuals screened, 256 were randomized and 220 were included in the final analysis (**Figure 1**). Our sample included 142 female participants (64.5%), and 203 participants (92.3%) lived in a 2-parent household (**Table 1**). Most participants (44.1%) had 2 children, and their preterm infant had been in the NICU a mean (SD) 5.9 (2.8) years ago (range, 2.0-11.0 years). No participant discontinued study participation for elevated participation-related psychological distress or requested support by a research team member or a mental health professional.

### Primary Outcome

Participants preferred optimistic over pessimistic framing (196 of 220 [89.1%] vs 24 of 220 [10.9%]). The preference probability for optimistic framing was estimated to be 92% (95% CI, 86%-95%) after model-based adjustment for presentation order and IFC. The respective preference odds was 11.0 (95% CI, 6.28-19.10; *P* < .001).

The preference for optimistic framing was more pronounced when presented second than when presented first (adjusted preference probability: optimistic framing second, 96% [95% CI, 90%-99%] vs first, 82% [95% CI, 74%-89%]; preference odds, 5.41 [95% CI, 1.77-16.48]; *P* = .003).

**Figure 1. Participant Flow for the COPE-Trial**

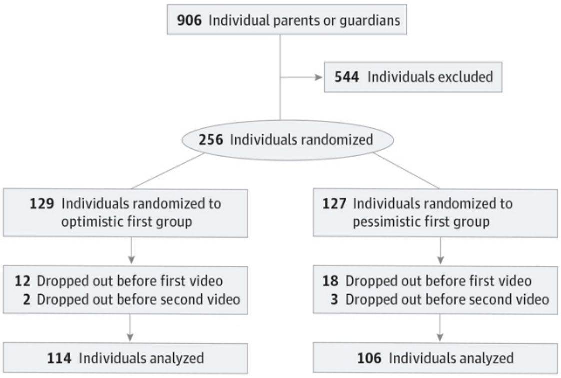


Table 1. Baseline Characteristics of Individual Participants by Intervention Groups and in Total

| Characteristics | Participants, No. (%)[a] Optimistic first (n = 114) | Pessimistic first (n = 106) | Total (n = 220) |
|---|---|---|---|
| **General characteristics** | | | |
| Constellation of participating caregivers | | | |
| Both partners | 60 (52.6) | 54 (50.9) | 114 (51.8) |
| Mothers only | 44 (38.6) | 41 (38.7) | 85 (38.6) |
| Fathers only | 10 (8.8) | 11 (10.4) | 21 (9.5) |
| Gender[b] | | | |
| Female | 74 (64.9) | 68 (64.2) | 142 (64.5) |
| Male | 40 (35.1) | 38 (35.8) | 78 (35.5) |
| Age at participation, mean (SD) [range], y | | | |
| Mothers | 39.4 (5.2) [28.0-52.0] | 38.7 (6.0) [25.0-56.0] | 39.1 (5.6) [25.0-56.0] |
| Fathers | 43.0 (7.0) [32.0-60.0] | 42.4 (7.0) [30.0-58.0] | 42.7 (6.9) [30.0-60.0] |
| **Sociocultural background** | | | |
| Migration experience | | | |
| Living in Germany since birth[c] | 92 (80.7) | 94 (88.7) | 186 (84.5) |
| Born elsewhere, immigrated to Germany | 22 (19.3) | 12 (11.3) | 34 (15.5) |
| Germany as country of identification[d] | 98 (86.0) | 91 (86.7) | 189 (86.3) |
| Multilingual | 24 (21.1) | 15 (14.2) | 39 (17.7) |
| German language acquisition | | | |
| First language | 91 (79.8) | 92 (86.8) | 183 (83.2) |
| Second language | 5 (4.4) | 5 (4.7) | 10 (4.5) |
| Foreign language | 18 (15.8) | 9 (8.5) | 27 (12.3) |
| Religiosity, mean (SD) score [range][e] | 2.2 (1.1) [1.0-5.0] | 2.7 (1.0) [1.0-5.0] | 2.5 (1.1) [1.0-5.0] |
| **Education, occupation, and medical expertise** | | | |
| Basic education | | | |
| Basic general education | 1 (0.9) | 2 (1.9) | 3 (1.4) |
| Medium general or vocational education | 29 (25.4) | 28 (26.4) | 57 (25.9) |
| General (technical) university entrance qualification | 83 (72.8) | 75 (70.7) | 158 (71.8) |
| Other | 1 (0.9) | 1 (0.9) | 2 (0.9) |
| Professional education | | | |
| No or noncompleted vocational training or studies | 4 (3.5) | 3 (2.8) | 7 (3.2) |
| Vocational training (in-company or school-based) | 47 (41.2) | 47 (44.3) | 96 (42.7) |
| University (of applied sciences) degree[f] | 62 (54.4) | 54 (50.9) | 126 (52.7) |
| Other | 1 (0.9) | 2 (1.9) | 3 (1.4) |
| Occupation | | | |
| Student | 0 | 1 (0.9) | 1 (0.5) |
| Employee | 76 (66.7) | 72 (67.9) | 148 (67.3) |
| Civil servant | 12 (10.5) | 14 (13.2) | 26 (11.8) |
| Self-employed | 16 (14.0) | 8 (7.5) | 24 (11.8) |
| Full-time at home for children, househusband or housewife | 5 (4.4) | 10 (9.4) | 15 (6.8) |
| Unemployed or job-seeking | 2 (1.8) | 0 | 2 (0.9) |
| Other | 3 (2.6) | 1 (0.9) | 4 (1.8) |
| Medical expertise (by education or profession) | 26 (22.8) | 22 (20.8) | 48 (21.8) |
| NICU experience (professional) | 3 (2.6) | 1 (0.9) | 4 (1.8) |
| Family and premature infant | | | |
| Household | | | |
| Single-parent | 4 (3.5) | 5 (4.7) | 9 (4.1) |
| 2-parent | 106 (93.0) | 97 (91.5) | 203 (92.3) |
| >2 parents, patchwork | 4 (3.5) | 4 (3.8) | 8 (3.6) |

*(continued)*

Table 1. Baseline Characteristics of Individual Participants by Intervention Groups and in Total (continued)

| Characteristics | Participants, No. (%)[a] Optimistic first (n = 114) | Pessimistic first (n = 106) | Total (n = 220) |
|---|---|---|---|
| No. of children | | | |
| 1 | 36 (31.6) | 33 (31.1) | 69 (31.4) |
| 2 | 49 (43.0) | 48 (45.3) | 97 (44.1) |
| 3 | 21 (18.4) | 15 (14.2) | 36 (16.4) |
| >3 | 8 (7.0) | 10 (9.4) | 18 (8.2) |
| Time since own NICU experience, mean (SD) [range], y | 5.9 (2.8) [2.0-11.0] | 5.8 (2.8) [2.0-11.0] | 5.9 (2.8) [2.0-11.0] |

Abbreviation: NICU, neonatal intensive care unit.

[a] Due to the rounding of the relative numbers of each expression of a characteristic to one decimal place, their sum may not always add up to exactly 100%. Characteristics of participating partners were considered separately.

[b] In the self-reported data, no one selected the third category, "diverse."

[c] Includes individuals with migration background where previous generations may have had a first-person migration experience.

[d] Data on the country of identification were missing for 1 participant in the pessimistic first group (219 total participants; 105 participants in pessimistic first group).

[e] Participants could rate themselves as religious or devout on a 5-point scale from not at all (1), a little, moderately, strongly, or very strongly (5).

[f] Summarizes participants with a bachelor's, master's, and a doctoral degree.

## Secondary Outcomes

Participants who preferred the optimistic framing video were more likely to have a general preference for optimism (adjusted mean: preference for optimistic framing, 4.72 [95% CI, 4.62-4.83] vs pessimistic framing, 3.79 [95% CI, 3.49-4.10]; adjusted mean difference, 0.93 [95% CI, 0.61-1.25]; *P* < .001).

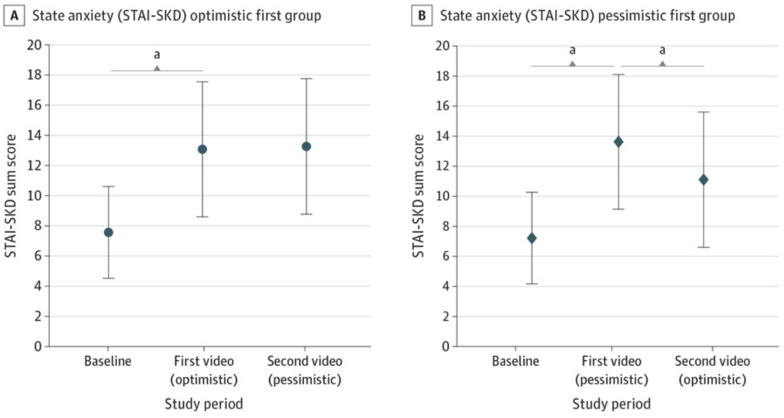
Baseline state anxiety scores were similar in both groups (adjusted mean [SD]: optimistic, 7.29 [3.04] vs pessimistic, 7.63 [3.04]; adjusted mean difference, −0.34 [−1.18 to 0.49]; *P* = .42). In response to the first video, with both optimistic and pessimistic framing, participants' state anxiety scores increased equally from baseline (adjusted mean [SD]: optimistic first, 13.13 [4.47] vs pessimistic first, 13.68 [4.47]; *P* < .001 for each). When pessimistic framing followed optimistic framing, state anxiety scores remained unchanged (adjusted mean [SD]: optimistic first, 13.13 [4.47] vs pessimistic second, 13.32 [4.49]; *P* = .54) (**Figure 2**A). In contrast, when optimistic framing followed pessimistic framing, state anxiety scores decreased (adjusted mean [SD]: pessimistic first, 13.68 [4.47] vs optimistic second, 11.17 [4.49]; *P* < .001) (Figure 2B).

When comparing optimistic vs pessimistic framing, participants rated their overall impression of the physician as more positive (adjusted mean [SD], optimistic 3.79 [0.97] vs pessimistic 2.55 [0.97]; adjusted mean difference, 1.24 [95% CI, 0.98 to 1.50]; *P* < .001) (eFigure 1 in Supplement 1). They also rated the physician as more professional (adjusted mean [SD]: optimistic, 26.57 [5.07] vs pessimistic, 19.93 [5.07]; adjusted mean difference, 6.64 [95% CI, 5.29 to 8.00]; *P* < .001) and more compassionate (adjusted mean [SD]: optimistic, 34.48 [9.36] vs pessimistic, 14.87 [9.36]; adjusted mean difference, 19.61 [95% CI, 17.06 to 22.17]; *P* < .001) (eFigure 1 in Supplement 1). The ICC was 7.3% for overall impression, 1.7% for professionalism, and 10.3% for compassion.

With optimistic framing, participants were more satisfied with the prognostic communication style (4.83 [1.48] vs 2.81 [1.48]) (**Table 2**). They felt better informed about the prognosis (4.99 [1.64] vs 3.86 [1.64]) and better prepared for SDM (3.79 [1.53] vs 2.60 [1.53]) as surrogates for their child. Participants also perceived the conveyed prognosis as more favorable (3.23 [1.15] vs 2.48 [1.15]). They were more optimistic about the infant's survival (4.42 [1.30] vs 3.64 [1.30]) and nonimpairment (3.41 [1.25] vs 2.46 [1.25]), and more hopeful for the infants' future (4.28 [1.48] vs 3.28 [1.48]).

**Figure 3**A and Figure 3B visualize the proportion of participants whose recall of conveyed outcome estimates was correct, optimistic (overestimation of survival, underestimation of impaired survival), or pessimistic (underestimation of survival, overestimation of impaired survival). With optimistic framing, the odds of correct recall of conveyed estimates were higher for survival (odds ratio, 4.00; 95% CI, 1.64-9.79; *P* = .002). A similar but nonsignificant trend was observed for

**Figure 2. State Anxiety (STAI-SKD) Scores for Before and After Video Viewings**



[a] Significant results (*P* < .05).

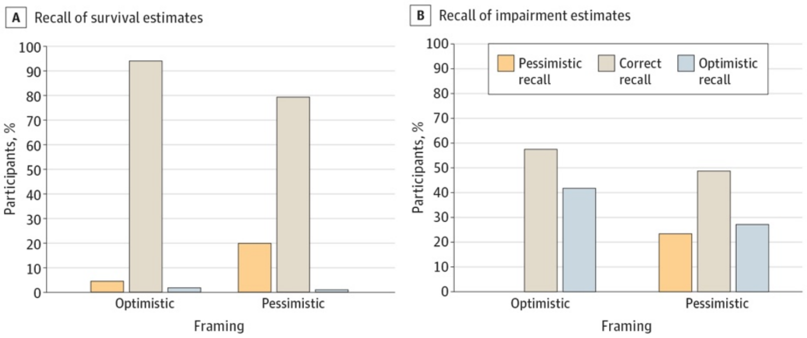
**Table 2. Effects of Optimistic vs Pessimistic Framing on Parental Perceptions Assessed After Presentation of the First Video**

| | Mean (SD) scores[a] | | Comparison of framing effects | | |
|---|---|---|---|---|---|
| Outcomes | Optimistic framing (n = 114) | Pessimistic framing (n = 106) | Mean difference (95% CI) | *P* value | ICC,% |
| Perception of prognostic communication | | | | | |
| Satisfaction with prognostic framing | 4.83 (1.48) | 2.81 (1.48) | 2.02 (1.63-2.42) | <.001 | 0 |
| Level of information about prognosis | 4.99 (1.64) | 3.86 (1.64) | 1.13 (0.70-1.57) | <.001 | 0 |
| Preparedness for decision-making | 3.79 (1.53) | 2.60 (1.53) | 1.19 (0.76-1.62) | <.001 | 23.9 |
| Prognostic expectations | | | | | |
| Favorability of prognosis | 3.23 (1.15) | 2.48 (1.15) | 0.75 (0.43-1.08) | <.001 | 22.6 |
| Optimism | | | | | |
| Concerning survival | 4.42 (1.30) | 3.64 (1.30) | 0.78 (0.41-1.15) | <.001 | 33.9 |
| Concerning nonimpairment | 3.41 (1.25) | 2.46 (1.25) | 0.94 (0.60-1.29) | <.001 | 19.1 |
| Hope | 4.28 (1.48) | 3.28 (1.48) | 1.01 (0.61-1.40) | <.001 | 2.2 |

Abbreviation: ICC, intraclass correlation coefficient.

[a] Higher scores indicate a more pronounced expression of the respective effect (range, 1-7). In the model, optimistic framing was used as reference category.

**Figure 3. Recall of Numerical Outcome Estimates**



Optimistic framing included 114 parents after presentation of the first video; pessimistic framing, 106 parents.

impairment (odds ratio, 1.50; 95% CI, 0.85-2.63; *P* = .16). With both framing variants, when deviant, recall of survival estimates was more likely to be pessimistic than optimistic (Figure 3A). With pessimistic framing, however, this trend was more pronounced (odds ratio, 8.40; 95% CI, 0.63-112.42; *P* = .11), although the result was not statistically significant. In contrast, when deviant, recall of impairment estimates was rather optimistic than pessimistic with both framing variants (Figure 3B). However, solely with pessimistic framing it was in part pessimistic. The trend for pessimistic recall of impairment estimates was more pronounced with pessimistic framing (*P* for trend < .001).

## Discussion

The COPE-Trial provides evidence that parents of very preterm infants may prefer a more optimistic view of the outcome of a serious complication. This is consistent with previous findings that parents prefer an overall optimistic view of their child's prognosis and appreciate physicians who communicate the risk of a poor outcome while acknowledging the chances of a good outcome.[33] Previous studies have shown that neonatologists often have a more pessimistic view of an infant's prognosis than parents[4,7,11,34,35] and are perceived by parents to be more pessimistic in their prognostic communication.[11,33,34,36] Parents value honest and realistic communication about their child's prognosis, but appreciate that positive aspects are also emphasized.[12,14,33,37] The level of optimism that parents consider optimal seems to be the key. Parents seem to prefer positive language, whereas what may be taken as excessive optimism or the sugarcoating of information is likely to be perceived as threatening to the parent-doctor relationship.[12,38-41] Our study results are consistent with these previous findings in that parents prefer an optimistic framing when communicating prognostic predictions.

In terms of framing preference, we found a sequence effect in favor of the respective second framing variant in both groups. This finding may be interpreted as a recency effect.[42] A similar sequence effect for preference has been observed in previous video-based communication studies in adult oncology, including one by Tanco and colleagues.[22] This effect may be due to an increased receptivity to multiple layers of communication and the critical information itself when a serious message is repeated. However, given the complexity and multidimensionality of communication, it is conceivable that this effect may also be attributable to characteristics of the parent-physician interaction, including the emotional response to the delivery of a serious message.

The latter assumption is supported by the observation of a sequence dependence not only for the framing preference but also for the emotional response to optimistic and pessimistic framing. In our study, the first communication of a serious message elicited a pronounced increase in the participants' state anxiety. This is consistent with the findings of previous video-based communication studies in adult oncology[23,43] and confirms an authentic emotional response to communication under experimental conditions for the NICU setting.[44] Consistent with Zwingmann and colleagues[43] and Porensky and Carpenter,[23] we found an effect of the physician communication style on the recipient's emotional response. But in our study, the framing-dependent difference in response was only substantial when the message was delivered a second time and with the respective opposite framing. We suspect that this may be the result of an emotional reaction. When the message was repeated with optimistic framing, state anxiety decreased substantially. However, when it was repeated with pessimistic framing, it remained almost unchanged.

Message framing has been shown to influence the perception of information and SDM in the NICU setting.[17,19,20] There is a growing body of evidence supporting the view that the process of communication, rather than the information itself, deserves most attention when counseling parents.[18] This study supports this notion, suggesting that framing influences perceptions of the attending physician and of essential components of the SDM process, including satisfaction with communication.[22,23] Our study also confirms for the NICU setting, that optimistic framing affects the parents' prognostic expectations and the physicians' and parents' shared understanding of a prognosis. Framing causes medical facts to be perceived differently. This seems to be particularly true for the parents' assessment of the risk of the very preterm infant to retain impairment. This observation can be well explained by the optimism bias. Very serious prognoses are perceived as less serious than they really are.[45,46] A potentially overly optimistic view of the infant's neurodevelopment with the preferred optimistic framing may be addressed by specific strategies. These might include the repetition of prognostic information in the course[7,12,47,48] or explicitly supplementing the potential positive outcomes conveyed with risks and potential negative outcomes in the sense of a mixed framing.[23] Additional written, visual, or audiovisual materials could be an appropriate measure to reinforce verbal information and to enhance parental understanding.[16,41,49-52] However, it should also be recognized that optimizing prognostic recall, especially of impairment estimates, may not be necessary. Impairment estimates appear to be less meaningful outcomes to NICU parents than survival estimates.[7,9,53,54] Moreover, parents generally tend to be more positive about their child's prognosis than physicians. A hopeful and optimistic view of the child's future by parents can be realistic even when the prognosis is poor. Recent studies demonstrate that hope and realism are not mutually exclusive in the context of understanding essential information in the NICU.[7,47,55] A rather positive view on the future may not be harmful in the first instance, as hopes are broad and can change in the course.[56-58]

Conclusions for practice should be drawn with caution, mainly because these results are drawn from simulated conversations outside of everyday clinical practice. In addition, it is difficult to draw conclusions from this general approach to individual communication. However, we believe that clinicians may find a more optimistic framing reassuring because it is likely to be in line with parents' preferences and may lead to more realistic expectations about prognosis while maintaining parents' hopes.

### Limitations

This study had several limitations. It is likely that the course and outcome of their own child, as well as parents' personal characteristics or emotions, may have influenced participants' responses.[4,12,19,31,59] Enrollment was lower than expected, and generalizability is limited by the single-center design and underrepresentation of parents groups whose preference may differ (parents with mental health concerns, bereaved parents, parents from racial and ethnic minority groups).[60-62] In retrospect, parents of deceased infants may have preferred pessimistic framing. Video vignettes proved to be a challenging intervention as framing a message as optimistic or pessimistic is complex and multidimensional. The intention was to keep as many aspects of the videos standardized and to vary framing as a selected aspect of prognostic communication. Congruent with the framing as a variation on the verbal level of communication, a difference occurred on the nonverbal level, such as the neonatologist's voice color, which includes vocal tone, pronunciation, resonance, and voice strength. We further recognize that the selected outcomes represent a simplification of a spectrum of possible outcomes, which may limit their meaningfulness to parents.[11]

## Conclusions

The COPE-Trial provides evidence that a large proportion of parents of very preterm infants may prefer optimistic prognostic communication. These results warrant further investigation in the clinical setting.

ARTICLE INFORMATION
**Accepted for Publication:** January 3, 2024.
**Published:** February 23, 2024. doi:10.1001/jamanetworkopen.2024.0105

**Corresponding Author:** Fiona A. Forth, Division of Neonatology, Center for Pediatric and Adolescent Medicine, University Medical Center of the Johannes Gutenberg-University Mainz, Langenbeckstrasse 1, 55131 Mainz, Germany (fionaforth@uni-mainz.de).

**Author Affiliations:** Division of Neonatology, Center for Pediatric and Adolescent Medicine, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany (Forth, Mildenberger, Kidszun); Department of Pediatric and Adolescent Psychiatry and Psychotherapy, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany (Hammerle); Division of Pediatric Epidemiology, Institute for Medical Biostatistics, Epidemiology and Informatics, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany (König, Urschitz); Journalistisches Seminar, Johannes Gutenberg-University Mainz, Mainz, Germany (Neuweiler); Division of Neonatology, Department of Pediatrics, Inselspital, Bern University Hospital, University of Bern, Bern, Switzerland (Kidszun).

**Author Contributions:** Ms Forth and Dr Kidszun had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

*Concept and design:* All authors.

*Acquisition, analysis, or interpretation of data:* Forth, Hammerle, König, Mildenberger, Kidszun.

*Drafting of the manuscript:* Forth, König, Kidszun.

*Critical review of the manuscript for important intellectual content:* All authors.

*Statistical analysis:* Forth, Hammerle, König.

*Obtained funding:* Forth.

*Administrative, technical, or material support:* Forth, Hammerle, König, Urschitz, Neuweiler, Mildenberger, Kidszun.

*Supervision:* König, Urschitz, Mildenberger, Kidszun.

**Conflict of Interest Disclosures:** None reported.

**Funding/Support:** Ms Forth received fund support from the German Research Foundation (Deutsche Forschungsgesellschaft [DFG]) and the DFG Research Training Group 2015/2, as well as by the MAInz-DOC-Promotionskolleg, Mainz Research School of Translational Biomedicine (TransMed). The DFG also settled for the costs for participant recruitment material as well as for processing costs for the ethics proposal. This project was funded in part by the DFG-Research Training Group 2015/2 as well as by a scholarship within the framework of the MAInz-DOC-Promotionskolleg.

**Role of the Funder/Sponsor:** The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

**Data Sharing Statement:** See Supplement 3.

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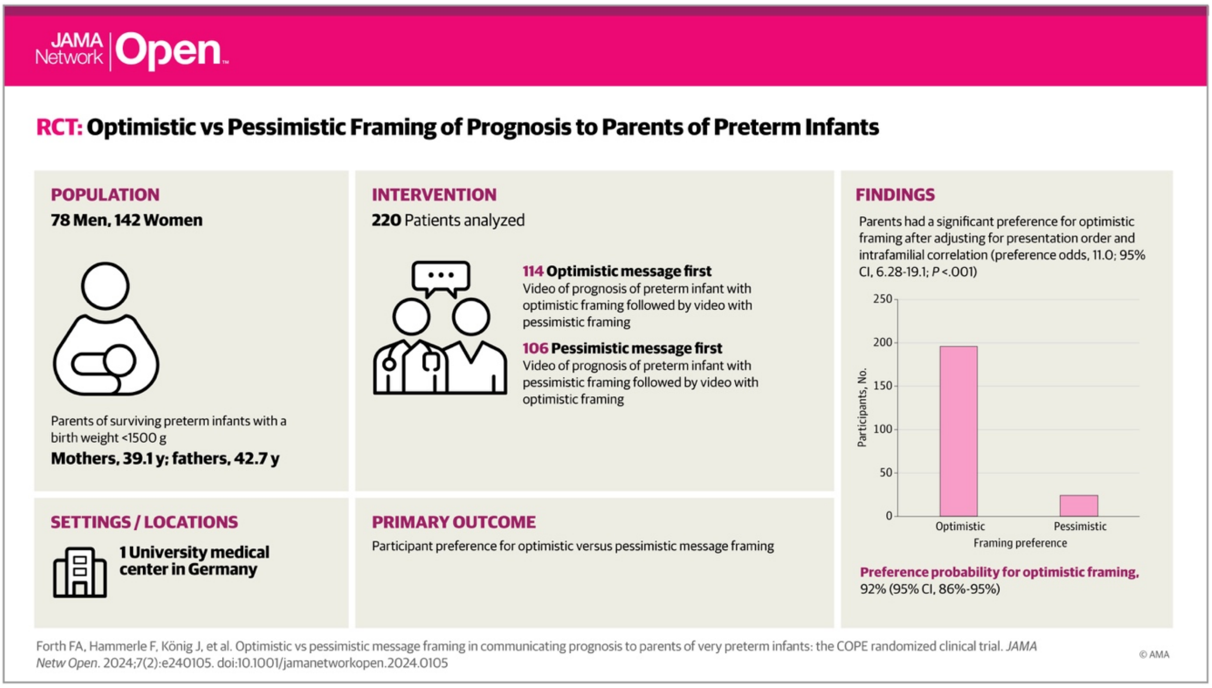
**SUPPLEMENT 1.**
**eAppendix 1.** Scripts for Video Vignettes (English Translation)
**eAppendix 2.** Scripts for Video Vignettes in German
**eFigure 1.** Perception of Physician

**SUPPLEMENT 2.**
**Trial Protocol**

**SUPPLEMENT 3.**
**Data Sharing Statement**

## 2.2 Visual abstract



JAMA Network | Open

**RCT: Optimistic vs Pessimistic Framing of Prognosis to Parents of Preterm Infants**

**POPULATION**

**78 Men, 142 Women**

Parents of surviving preterm infants with a birth weight <1500 g

**Mothers, 39.1 y; fathers, 42.7 y**

**SETTINGS / LOCATIONS**

**1 University medical center in Germany**

**INTERVENTION**

**220** Patients analyzed

**114 Optimistic message first**
Video of prognosis of preterm infant with optimistic framing followed by video with pessimistic framing

**106 Pessimistic message first**
Video of prognosis of preterm infant with pessimistic framing followed by video with optimistic framing

**PRIMARY OUTCOME**

Participant preference for optimistic versus pessimistic message framing

**FINDINGS**

Parents had a significant preference for optimistic framing after adjusting for presentation order and intrafamilial correlation (preference odds, 11.0; 95% CI, 6.28-19.1; *P* <.001)

**Preference probability for optimistic framing,** 92% (95% CI, 86%-95%)

Forth FA, Hammerle F, König J, et al. Optimistic vs pessimistic message framing in communicating prognosis to parents of very preterm infants: the COPE randomized clinical trial. *JAMA Netw Open*. 2024;7(2):e240105. doi:10.1001/jamanetworkopen.2024.0105

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## 2.3 **Supplemental content**

### 2.3.1 Supplement 1: Video-Skripte, -Links und ergänzende Grafik

# Supplemental Online Content

Forth FA, Hammerle F, König J, et al. Effects of optimistic vs pessimistic message framing in communicating prognosis to parents of very preterm infants. *JAMA Netw Open.* 2024;7(2):e240105. doi:10.1001/jamanetworkopen.2024.0105

**eAppendix 1. Scripts for Video Vignettes (English Translation)**

## a | INTRODUCTION: EXPLANATORY VIDEO

**VOICE OVER** The following scene is set at the University Medical Center Mainz. In the Neonatal Intensive Care Unit. The setting is a counselling situation: The parents of a premature infant are receiving a severe diagnosis.

After this video, we will kindly ask you to answer a few questions.

It is the third day of life of a very immature premature baby. Luisa. A girl. She was born after 23 weeks and 5 days of pregnancy. Weighing as little as 580 grams. Such an early birth carries a high risk of complications. One of those typical for premature infants is for example: a cerebral hemorrhage. Luisa's parents have already talked to the attending physicians: About premature birth and possibly arising complications thereof.

As one of these sets in, they are contacted immediately.

**Link to the video on YouTube:** https://youtu.be/ha4GuVzwAN4

## b | OPTIMISTIC VIDEO

**PHYSICIAN:** (*very calmly, without rush*) Thank you for coming on such short notice.

**MOTHER:** *(worried/anxiously)* What happened? How is Luisa?

**PHYSICIAN**: (*slowly and calmly*) She is stable at the moment. It is not life-threatening. However, ultra-sound showed a (cerebral hemorrhage) bleeding in her brain. Hence the call. As you may remember: We have talked about possible complications stemming from premature birth. Unfortunately, we've now diagnosed one with your daughter.

**FATHER:** (*pulling himself together*) A bleeding in her brain. But how?

**PHYSICIAN:** Within the brain of a premature infant there are areas especially prone to bleeding. The exact mechanisms – of how those bleedings arise – are unfortunately still widely unknown.

Here you can see the bleeding affecting much of the right cerebral hemisphere. The white area here – that's the extension of the bleeding.

**MOTHER:** *(after a while)* And what … what does that mean now for Luisa?

**PHYSICIAN:** A bleeding (cerebral hemorrhage) of this extension. That is a severe complication. We have to assume (It must be assumed): It won't be without consequences for Luisa's further treatment. And for her development (in general). There is comparable cases: Around half of the children with a bleeding of this kind survives. And of the surviving children, half again do not retain a noticeable impairment. The prognosis for affected children is therefore (very) serious. In similar cases/in cases as such, parents and physicians often decide to no longer uphold intensive medical treatment. The exact consequences for Luisa – as of now, are not easy to predict. It is however possible that the affects will be minor/she will only be minorly/mildly affected.

**FATHER**: *(grieving, sad)* But … is there no treatment? (Can it/this not be treated somehow?)

**PHYSICIAN:** I wish there were one, but no. A bleeding (cerebral hemorrhage) as such can unfortunately not be treated to date. I can only speculate at this point. There might be new possibilities for therapy in the future. There has been, for example, preliminary testing with stem cells, in order to support (enhance) recreation/regeneration. This treatment though is not yet available in the here and now.

**MOTHER***: (shivering voice)* What will happen now to Luisa? What should/shall/can we do?

**PHYSICIAN:** Nobody know what the future might hold. Lots of children do not survive situations like this. Most of them/those who do only with severe impairments/retain severe impairments.

I do, however, know children who after a severe bleeding of this kind, have developed normally.

**MOTHER / FATHER:** (*crying*)

**PHYSICIAN:** (*equally moved/saddened/empathetic*) I will give you (two) a moment, okay? I suggest we will sit down together again later. Then we can talk about our next steps.

**Link to the video on Youtube:** https://youtu.be/MpSc5T31z68

**c | PESSIMISTIC VIDEO**

**PHYSICIAN:** (*very calmly, without rush*) Thank you for coming on such short notice.

**MOTHER:** *(worried/anxiously)* What happened? How is Luisa?

**PHYSICIAN**: (*slowly and calmly*) She is stable at the moment. It is not life-threatening. However, ultra-sound showed a (cerebral hemorrhage) bleeding in her brain. Hence the call. As you may remember: We have talked about possible complications stemming from premature birth. Unfortunately, we've now diagnosed one with your daughter.

**FATHER:** (*pulling himself together*) A bleeding in her brain. But how?

**PHYSICIAN:** Within the brain of a premature infant there are areas especially prone to bleeding. The exact mechanisms – of how those bleedings arise – are unfortunately still widely unknown.

What you see here is a severe bleeding affecting much of the right cerebral hemisphere. The white area here – that's the extension of the bleeding.

**MOTHER:** *(after a while)* And what … what does that mean now for Luisa?

**PHYSICIAN:** A bleeding (cerebral hemorrhage) of this extension. That is a grievous complication. We have to assume (It must be assumed): It won't be without consequences for Luisa's further treatment. And for her development (in general). There is comparable cases: Around half of the children with a bleeding of this kind do not survive. And of the surviving children, half again retain a noticeable impairment. The prognosis for affected children is therefore (very) serious. In similar cases/in cases as such, parents and physicians often decide to stop (end) the intensive medical treatment. The exact consequences for Luisa – as of now, are hard to predict. It's probable that she will not be completely healthy or that she will not survive.

**FATHER**: *(grieving, sad)* But … is there no treatment? (Can it/this not be treated somehow?)

**PHYSICIAN:** I wish there were one, but no. The bleeding (cerebral hemorrhage) as such can unfortunately not be treated. Only the acute affects, i.e. on her (bodily) circulation. Or we can alleviate her symptoms. But we cannot influence the cause of the diagnosis itself. The process cannot be reversed. (It is impossible to reverse the process.)

**MOTHER***: (shivering voice)* What will happen now to Luisa? What should/shall/can we do?

**PHYSICIAN:** Nobody know what the future might hold. Lots of children do not survive situations like this. Most of them/those who do only with severe impairments/retain severe impairments. I wish, the prognosis were different.

**MOTHER / FATHER:** (*crying*)

**PHYSICIAN:** (*equally moved/saddened/empathetic*) I will give you (two) a moment, okay? I suggest we will sit down together again later. Then we can talk about our next steps.

**Link to the video on Youtube:** https://youtu.be/_ZjiCCoLP9c

## eAppendix 2. Scripts for Video Vignettes in German

### a | EINLEITUNG: ERKLÄRFILM

**VOICE OVER** Die nachfolgende Szene spielt in der Universitätsmedizin Mainz. Auf der Intensivstation der Neonatologie. Rahmen bildet ein Beratungsgespräch: Die Eltern eines Frühgeborenen bekommen darin eine schwerwiegende Diagnose und übermittelt.

Nach dem Video möchten wir Sie bitten, uns ein paar Fragen zu beantworten.

Es ist der 3. Lebenstag eines sehr unreifen Frühgeborenen. Luisa. Ein Mädchen. Sie wurde nach 23 Schwangerschaftswochen und 5 Tagen geboren. Mit nur 580 Gramm. Eine so frühe Geburt birgt große Risiken für Komplikationen. Für Frühgeborene sehr typisch ist zum Beispiel: Eine Hirnblutung. Luisas Eltern haben mit den behandelnden Ärztinnen bereits gesprochen: Über die Frühgeburtlichkeit und mögliche, damit einhergehende Komplikationen. Als es dazu kommt, werden sie unmittelbar kontaktiert.

**Link to the video on Youtube:** https://youtu.be/haPSDlELpew

### b | OPTIMISTISCHES VIDEO

**ÄRZTIN:** (*sehr ruhig, ohne Hektik*) Danke, dass Sie so schnell gekommen sind.

**MUTTER:** *(sorgenvoll)* Was ist denn passiert? Wie geht es Luisa?

**ÄRZTIN**: (*langsam und ruhig*) Im Moment ist sie stabil. Keine Lebensgefahr. Allerdings haben wir bei einer Ultraschall-Untersuchung eine Hirnblutung diagnostiziert. Deshalb der Anruf. Sie erinnern sich: Vorgestern haben wir ja bereits über mögliche Komplikationen bei einer Frühgeburt gesprochen. Jetzt haben wir eine solche leider bei Ihrer Tochter festgestellt.

**VATER:** (*fasst sich*) Hirnblutung? Wie ist das passiert?

**ÄRZTIN:** Im Gehirn von sehr unreifen Frühgeborenen gibt es Bereiche, die besonders anfällig für Blutungen sind. Der genaue Mechanismus – wie solche Blutungen im Gehirn entstehen – das alles ist uns leider noch nicht bekannt.

Sie sehen hier die Blutung. Sie betrifft den Großteil der rechten Hirnhälfte. Der weiße Bereich hier – das ist die ausgedehnte Blutung.

**MUTTER:** *(nach einer Weile)* „Und was … Was heißt das jetzt für Luisa?

**ÄRZTIN:** Eine Hirnblutung von diesem Ausmaß. Das ist eine ernstzunehmende Komplikation. Man muss davon ausgehen: Das ist nicht folgenlos für Luisas weitere Behandlung. Und für ihre Entwicklung. Es gibt vergleichbare Fälle: Etwa die Hälfte der Kinder mit einer solchen Blutung überlebt. Und von den Überlebenden behält wiederum die Hälfte keine deutliche Behinderung. Die Prognose ist also ernst bei derart betroffenen Kindern. In vergleichbaren Fällen entscheiden Eltern und Ärztinnen häufig nicht länger intensivmedizinisch zu behandeln.

Die genauen Folgen für Luisa – die sind zum jetzigen Zeitpunkt zwar nur schwer vorhersehbar. Es ist jedoch auch möglich, dass sie nur wenig betroffen ist.

**VATER**: *(betroffen)* Aber … Kann man das nicht irgendwie behandeln?

**ÄRZTIN:** Ich wünschte es wäre so. Nein. Eine solche Hirnblutung kann heute leider noch nicht behandelt werden. Ich kann im Moment nur spekulieren. Vielleicht gibt es zukünftig neue Therapie-Möglichkeiten. Zum Beispiel wurden schon erste Versuche mit Stammzellen gemacht. Um das Gehirn zu unterstützen bei der Regeneration. Diese Behandlung aber – die ist im Hier und Jetzt noch nicht verfügbar.

**MUTTER***: (zittrige Stimme)* Was wird denn jetzt aus Luisa? Was machen wir bloß?

**ÄRZTIN:** Niemand weiß, was die Zukunft bringt. Einige Kinder überleben solche Situationen nicht. Andere nur mit deutlichen Einschränkungen. Ich kenne aber auch Kinder, die sich nach so einer schweren Hirnblutung normal entwickelt haben.

**MUTTER / VATER:** (*weinen)*

**ÄRZTIN:** (*ebenfalls ergriffen*) Ich gebe ich Ihnen einen Moment Zeit. Ja? Mein Vorschlag: Wir setzen uns nachher nochmal zusammen. Dann besprechen wir unser weiteres Vorgehen.

**Link to the video on Youtube:** https://youtu.be/xX8DkaOCULA

## c | PESSIMISTISCHES VIDEO

**ÄRZTIN:** (*sehr ruhig, ohne Hektik*) Danke, dass Sie so schnell gekommen sind.

**MUTTER:** *(sorgenvoll)* Was ist denn passiert? Wie geht es Luisa?

**ÄRZTIN**: (*langsam und ruhig*) Im Moment ist sie stabil. Keine Lebensgefahr. Allerdings haben wir bei einer Ultraschall-Untersuchung eine Hirnblutung diagnostiziert. Deshalb der Anruf. Sie erinnern sich: Vorgestern haben wir ja bereits über mögliche Komplikationen bei einer Frühgeburt gesprochen. Jetzt haben wir eine solche leider bei Ihrer Tochter festgestellt.

**VATER:** (*fasst sich*) Hirnblutung? Wie ist das passiert?

**ÄRZTIN:** Im Gehirn von sehr unreifen Frühgeborenen gibt es Bereiche, die besonders anfällig für Blutungen sind. Der genaue Mechanismus – wie solche Blutungen im Gehirn entstehen – das alles ist uns leider noch nicht bekannt.

Sie sehen hier die schwere Blutung. Sie betrifft den Großteil der rechten Hirnhälfte. Der weiße Bereich hier – das ist die ausgedehnte Blutung.

**MUTTER:** *(nach einer Weile)* „Und was … Was heißt das jetzt für Luisa?

**ÄRZTIN:** Eine Hirnblutung von diesem Ausmaß. Das ist eine schwerwiegende Komplikation. Man muss davon ausgehen: Das ist nicht folgenlos für Luisas weitere Behandlung. Und für ihre Entwicklung. Es gibt vergleichbare Fälle: Etwa die Hälfte der Kinder mit einer solchen Blutung überlebt nicht. Und von den Überlebenden behält wiederum die Hälfte eine deutliche Behinderung. Die Prognose ist also ernst bei derart betroffenen Kindern. In vergleichbaren Fällen entscheiden Eltern und Ärztinnen häufig, die intensiv-medizinische Behandlung zu beenden. Die genauen Folgen für Luisa – die sind zum jetzigen Zeitpunkt nur schwer vorhersehbar. Wahrscheinlich ist: Sie ist später nicht ganz gesund oder überlebt nicht.

**VATER**: *(betroffen)* Aber … Kann man das nicht irgendwie behandeln?

**ÄRZTIN:** Ich wünschte es wäre so. Nein. Die Hirnblutung an sich kann leider nicht behandelt werden. Nur die akuten Auswirkungen. Zum Beispiel auf den Kreislauf. Oder die Symptome, die können wir lindern. Den Befund an sich aber, den können wir nicht ursächlich beeinflussen. Das Geschehen lässt sich nicht rückgängig machen.

**MUTTER***: (zittrige Stimme)* Was wird denn jetzt aus Luisa? Was machen wir bloß?

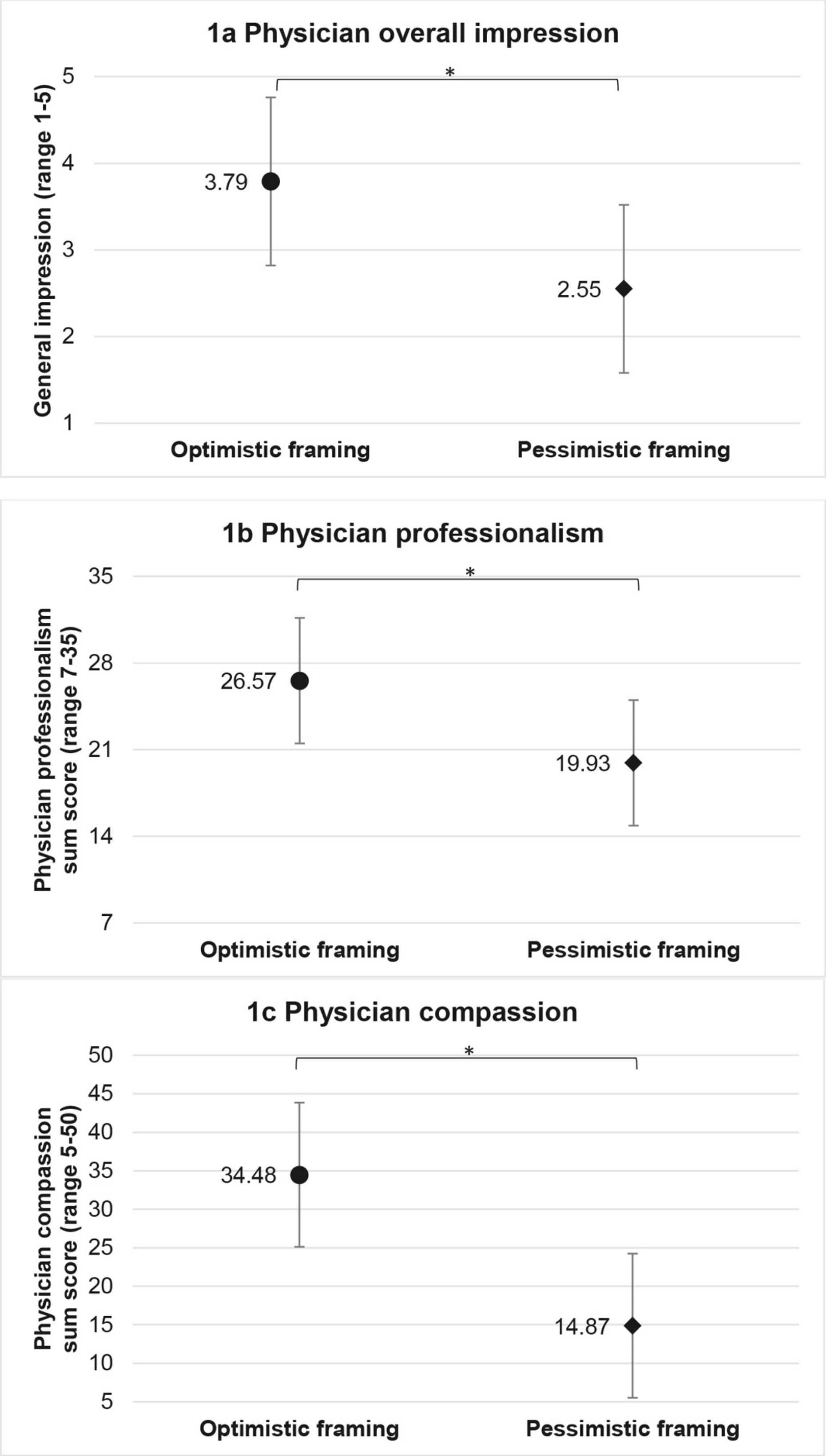
**ÄRZTIN:** Niemand weiß, was die Zukunft bringt. Viele Kinder überleben solche Situationen nicht. Die meisten nur mit deutlichen Einschränkungen. Ich wünschte, die Prognose wäre anders.

**MUTTER / VATER:** (*weinen)*

**ÄRZTIN:** (*ebenfalls ergriffen*) Ich gebe ich Ihnen einen Moment Zeit. Ja? Mein Vorschlag: Wir setzen uns nachher nochmal zusammen. Dann besprechen wir unser weiteres Vorgehen.

**Link to the video on Youtube:** https://youtu.be/K-SpGXlQawk

## eFigure 1. Perception of Physician



**eFigure 1 Perception of physician**

eFigures 1a,1b and 1c compare scores (mean±SD) for physician overall impression, professionalism and compassion with optimistic (n=114) versus pessimistic (n=106) framing. Significances are indicated with *.

### 2.3.2 Supplement 2: Englischsprachige Übersetzung des deutschsprachigen Studienprotokolls

# Scientific study protocol *(translated from German)*

## I. General information

### 1. List of abbreviations

GA - Gestational Age
BW - Birth Weight
NICU - Neonatal Intensive Care Unit

### 2. Date and version

05.02.2021, final version 3.0 as approved by the local Ethics Committee of the Medical Association of Rhineland-Palatinate (Ethik-Kommission der Landesaerztekammer Rheinland-Pfalz), Mainz, Germany, on 01.04.2021.

### 3. Title of the research project

**C**OMMUNICATING PROGNOSIS TO PARENTS IN THE NEONATAL ICU: **O**PTIMISTIC VS. **PE**SSIMISTIC

Acronym
**COPE**

### 4. Responsible study director / contact person

Dr. med. André Kidszun, M.A.
Division of Neonatology
Center for Pediatric and Adolescent Medicine
University Medical Center of the Johannes Gutenberg-University Mainz
Langenbeckstrasse 1
55131 Mainz
[redacted]

**Participating scientists**

Cand. med. Fiona Antonia Forth, Univ.-Prof. Dr. med. Eva Mildenberger
Division of Neonatology, Center for Pediatric and Adolescent Medicine,
University Medical Center of the Johannes Gutenberg-University Mainz

Dr. Jochem König, Univ.-Prof. Dr. med. et med. univ. Michael S. Urschitz, EU-M.Sc.
Division of Pediatric Epidemiology, Institute of Medical Biostatistics, Epidemiology and Informatics (IMBEI), University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany

Philipp Neuweiler, M.A. in Media Dramaturgy
Research assistant at the Journalistisches Seminar, Johannes Gutenberg-University Mainz, Mainz, Germany

Dipl.-Psych. Florian Hammerle
Department of Pediatric and Adolescent Psychiatry and Psychotherapy, University Medical Center of the Johannes Gutenberg-University Mainz, Mainz, Germany

Responsible sponsor: University Medical Center Mainz

## 5. Study type

Single-center, double-blind, randomized-controlled study in parallel-group design

## 6. Location of the research project

Center for Pediatric and Adolescent Medicine
University Medical Center of the Johannes Gutenberg-University Mainz
Langenbeckstraße 1
55131 Mainz

## 7. The research project is financially supported by the following third parties

DFG Research Training Group "Life Sciences - Life Writing"
Funding code 2015/2

## II. Justification of the research project

### 1. Background

When decisions need to be made in medicine, shared decision making is the gold standard of communication between physicians and patients. The declared aim is to enable patients or their representatives to make the best possible, jointly responsible (treatment) decision together with physicians through detailed, non-directive, non-prejudicial consultation. This type of decision-making is also sought by physicians in neonatology.[1] Beyond participatory decision-making, there is a recommendation in the context of neonatology, e.g. in antenatal consultations, to go one step further and strive for personalized decision-making in the case of impending premature birth.[2]

The birth of a very immature preterm infant is challenging even for experienced physicians due to the associated medical uncertainties, ethical controversy, and the need for timely interventions.[3] In addition, the setting of a neonatal intensive care unit (NICU) places high demands on parents.[4] Having just taken on their new role, they are expected to make vital decisions on behalf of their newborn (surrogate decision making), which have a significant impact on both their own and their child's future.
Ethically complex issues that are part of everyday life in the context of a NICU require a high level of communication. Only in this way the needs of all parties involved can be taken into account in consultation and decision-making processes. In the field of neonatal intensive care medicine, for this reason, more attention is nowadays paid to the process of decision-making than to achieving a very specific outcome.[5]

With the paradigm shift away from medical paternalism toward jointly responsible decisions in the sense of participatory decision-making, self-determination (autonomy) has gained importance as a core element of modern medicine. In this context, however, it is important to differentiate between two different forms of autonomy: absolute and relational autonomy.
Absolute autonomy allows patients (parents) to decide rationally, completely independent of the influence of their own emotions or those of others as an individual for themselves or in the best interests of the child. Physicians, as outsiders, are only allowed to (share) their factual knowledge and to inform. However, they must not take on an advisory role, so as not to color the individual's decision with their opinion.[6]

The philosophy of relational or contextual autonomy, on the other hand, postulates that every individual is in relationships with others and cannot make decisions independently of the influence of his or her environment. Rather, the individual achieves decision-making autonomy by linking his or her own rationality and emotionality with the needs of caregivers from the personal and medical, i.e., professional, environment, among others. Parents who make decisions on behalf of their children may, in the sense of relational autonomy, ask for or accept the advice of outsiders - for example, in the form of the personal interpretation of a situation or medical condition by the caring physician. Decisions are thus based on shared rational and emotional considerations.[6]

Absolute autonomy would consequently mean communicating facts in a completely neutral way. This is possible in principle, but absolute neutrality in the communication of important information is often difficult. Moreover, especially in the emotionally stressful context of the NICU, for parents, "neutral" facts require explanatory evaluation to optimize understanding of complex issues and to meet the needs of those affected. The way in which the facts are communicated inevitably influences the interpretation by those closest to them and thus their decision.[5] This makes the principle of relational autonomy a model that is feasible in practice and preferred by parents. It ultimately makes it possible to make authentic decisions with the support of professional staff.[4, 5]

In addition to preserving the autonomy of patients (parents), the application of the principles of care, beneficence, non-maleficence and justice is essential in medical consultation and decision-making processes.[7] In everyday clinical practice in general and in the context the NICU in particular, this means for medical staff to provide the best possible care for patients (here: premature infants), to be a support for their next of kin (parents) (care) and to make decisions with them in the best interests of the patients (beneficence). It is also important to provide open, honest and neutral information in order to give parents the information they need to make the most of their decision-making potential and to prevent harm (non-maleficence). In this context, harm can result, for example, from an overly vague prognosis that leads to a decision based on hoped-for outcomes rather than likely outcomes, resulting in patients receiving unnecessary therapies that are inappropriate to the real extent of the limitation of their prognosis.[8-10] Accordingly, with the patient's best interests in mind, vagueness of prognosis must be explicitly avoided. Since decisions made in the context of an inpatient stay of a very immature preterm infant are often vital ones, the communication of prognosis here particularly requires consideration of the principles just explained.

The communication of a prognosis should be an integral part of the communication between physicians and patients, as it enables them to make a realistic (treatment) decision appropriate to their situation.[11] Prognoses pose major challenges for parents and physicians alike. It is true that prognoses are based on medical experience and scientific knowledge. However, as a statement about the statistical or frequency probability of a (disease) course, they are always to a certain extent uncertain regarding the individual - including the possibility of the individual case deviating from the norm. For parents, the main challenge is to deal with the uncertainty that affects the future of their own premature baby and thus their entire environment, especially the family. For physicians, the uncertainty inherent in neonatology is a challenge for the following reasons: On the one hand, they are supposed to derive a personal prediction concerning the respective preterm infant from a frequent probability regarding the course of e.g., the diagnosis of a complication typical for preterm infants. On the other hand, it is the physician's task to communicate this outlook and the associated uncertainty to the parents. In doing so, physicians should draw a realistic picture, i.e., neither too optimistic nor too pessimistic. Prognostication therefore means making statements about a person's future that cannot be predicted with absolute certainty due to medical uncertainties and individual clinical courses.[8, 9] In this context, not only is the making of a prognosis a complex matter, but the communication of a prognosis becomes a complex undertaking due to the differing expectations of physicians and patients (and their parents). Successful doctor-parent discussions therefore require not only medical expertise on the part of the doctor, but also interpersonal competence to perceive the expectations of the parents and to behave accordingly.

Publications from specialties such as adult oncology, which are dedicated to questions in the context of communicating limiting prognoses, show that physicians initiate communication regarding prognosis and dominate it in terms of language in counseling and educational discussions.[12, 13] Prognoses are mostly formulated vaguely and supported by a focus on medical facts that are difficult for laypersons to understand.[9, 10, 12, 13] This obviously contradicts the desire of parents of critically ill children for clear communication of a concrete prognosis and explicit statements about the impact of the prognosis on the child's quality of life and the associated social environment. This type of parental desired communication succeeds mainly in delivering good news, whereas giving unfavorable prognoses is more challenging.[14] Previous studies also conclude that when communicating prognosis, care should be taken to balance concrete prognostication through honesty, as well as communicating hope in a realistic manner. Researchers postulate that this can be achieved by conveying medical empathy as well as the reassurance of non-abandonment and being available for queries.[15, 16]
The valuation of medical facts in the context of a consultation in clinical practice - whether intentional or not - is, as already mentioned, hardly avoidable. However, their influence on the consultation and decision-making process remains unclear.

The field of neonatology has some special features compared to other fields. For example, it must be considered that in a NICU, parents not only belong to the group of those (in-)directly affected, but also have to make decisions on behalf of their newborns. Decisions that are significantly influenced by the type of communication and at the same time affect the psychological well-being of the decision-makers.[8, 9, 17]

The evidence regarding the type of communication of unfavorable prognoses in the field of neonatology is still insufficient compared to other specialties, and consequently of great scientific interest. The study presented here addresses the question of which type of communication of an unfavorable prognosis is preferred by parents of very immature preterm infants, e.g., in the context of a severe complication. It is time to deal with such an important question not only theoretically but also in practice and to find out by questioning the parents of patients in which way they would like to receive such a prognosis. If the parents' preference is taken into account at the moment of diagnosis and especially at the moment of prognosis transmission, this is an important basis for future discussions, decision-making and for the best possible processing of the "history of the disease" or parental adaptation to the reality as parents of a child born immature and thus in some respects "fragile" instead of mature and healthy, which deviates from their original ideas. If parents express dissatisfaction with their child's NICU stay, this is mostly due to the fact that their children are well cared for, but their own, i.e. parental needs - often in connection with doctor-parent communication - are not sufficiently addressed.[18]

Of scientific interest in this context is whether and how communication can be geared to parental needs and preferences in the future and how this can contribute to improving the quality of care in neonatology in the long term in the sense of parent-centered, personalized communication. Parents of former preterm infants can provide valuable support thanks to their own lived experience of preterm birth, which can even be a life transformation experience for parents. There is a multitude of possibilities to give a voice to "former parents".[19-21] Especially in research projects like this one or in the scientific literature, this can be a valuable resource.

It is relevant to know that medical personnel more often give optimistic than pessimistic advice when communicating unfavorable prognoses.[9, 10, 17] Strategies of optimistic framing of unfavorable prognoses have been researched in this context.[10, 13] In this context, it is important, among other things, to define parental optimism

conceptually and to examine it more closely. This is the basis for research on the influence of a more or less optimistic framing of an unfavorable prognosis, since it must be assumed that the degree of optimism of a prognosis transmission is evaluated differently depending on the basic parental constitution (rather optimistic vs. rather pessimistic) and influences parental decision(s).
Optimism in this context is thus defined as parental expectation of the achievement of a certain goal. For example, the parents' goal could be that their child survives at all or without future impairment. The present study aims to find out whether parents with an optimistic view of life compared to those with a more pessimistic basic attitude, depending on a certain way of conveying a limiting prognosis, evaluate it differently and decide differently in the course of time. Optimistic framing of bad news is often understood as an attempt not to generate a feeling of hopelessness in patients (parents).[22, 23] There is also the assumption that in this approach the principle of hope, which is important for patients (parents), plays a decisive role in critical situations. In this context, there is a need to differentiate between the principles of hope and the aforementioned optimism.

Hope is complex and multimodal.[24] It finds expression, for example, in (general and/or specific) parental wishes for their child. While distinguishing hope from optimism in this way, it is possible to be hopeful and not optimistic at the same time. Despite an unfavorable prognosis, it is not unrealistic for parents to hope for the survival of their own child, even if they do not expect, i.e. cannot be optimistic, that it will survive.[25] Accordingly, it is possible for the consulting physician to maintain parental hope by the manner in which a prognosis is conveyed, regardless of its severity.[25] The realistic presentation of a poor prognosis in all its severity does not conflict with the communication of hope.[23, 26, 27] Rather, honesty promotes a sense of hope because it removes uncertainty and allows parents to make a decision consistent with the child's situation.[28] In this context, the question now arises whether an initial or basal high personal level of hope is reflected in a higher level of hope for one's own child even in the event of a serious complication with an unfavorable prognosis. The same applies to the opposite case of a high degree of hopelessness.

Recognizing the interindividual differences that exist between parents with regard to certain personality traits may be an important resource in choosing a way of communicating a limiting prognosis that is tailored to the parents and should therefore be investigated further. In addition to personality traits such as dispositional optimism, pessimism, and dispositional hopefulness (lack of hope), other possible factors influencing parental preference for a more or less optimistic communication style should be included. Therefore, in the context of this research project, parental coping with difficult life events (resilience), parental uncertainty (in)tolerance, and stress or dispositional anxiety will also be considered. It is of interest whether and how these factors influence the perception of the way prognosis is communicated, the physician's assessment, and a possible treatment decision. The aim is to investigate whether, according to expectation, uncertainty-intolerant parents react differently to different ways of communicating uncertainty (prognoses) than uncertainty-tolerant ones. It will also be examined whether there is a connection between anxiety or resilience in the sense of psychological resistance and parental preference for a certain type of prognosis communication.

Data from specialties other than neonatology suggest that optimistic advice is initially preferred and experienced as positive, as well as having a positive influence on the assessment of empathy and trustworthiness of medical staff. In addition, this is thought to increase trust in medical staff.[29] Current studies show that physicians often give overly optimistic advice and that the discrepancy in the assessment of the extent to which a prognosis is limited between healthcare professionals and patients or parents increases with the degree of optimism.[17] It can be assumed that physicians as well as patients (and their parents) assess the extent of the limitation of a prognosis more realistically if the prognosis is not conveyed optimistically. Excessive optimism can thus also have an unfavorable influence on the limitation of a prognosis as perceived by physicians and patients (parents), whereas less optimistic advice brings about greater agreement between both parties (concordance).[17] In particular, when the outcome resulting from the poor prognosis occurs, less optimistic counseling seems to be more favorable with respect to the relationship between physicians and patients and disease management.[23, 29] On the other hand, less optimistic counseling may also be experienced as negative, causing stress and thus complicating communication between the parties involved.[23] Thus, the extremely important question arises as to what influence the different ways of communicating an unfavorable prognosis have on the assessment of, e.g., the competence of the counselors, on the distress level of the counselees, or on the extent of perceived preparation for approaching (treatment) decisions.

In neonatology, there is a lack of empirical data with regard to the way in which unfavorable prognoses are communicated.[9, 12] At the same time, this specialty has very special demands on medical staff and patient parents in their role as surrogate decision makers. For this reason, the results of existing studies from other specialties cannot fulfill the claim that their results can be unconditionally transferred to the field of neonatology. In the context of this research project, therefore, the already elaborated, so far unanswered questions are to be taken up and decisively investigated.

## 2. Objectives of the research project, presentation of the scientific hypothesis.

Reports and recommendations published not only by medical professionals but also by professionals and at the same time experiencers, i.e., persons with lived experience of preterm birth and at the same time professional background as health care workers in the NICU (so-called POST, Parents on the Other Side of Treatment)[18, 30, 31], published reports and recommendations can be a valuable resource for improving care in neonatology. They promote an increase in knowledge regarding the parental experience of preterm birth and the challenging time in the NICU, as well as regarding the management of preterm parents in general or physician-parent communication in the context of complex situations in particular.[18, 30-33] In addition, it is known that parents want to be asked how they want information about their child to be communicated.[31] However, what type of communication, or in particular what level of optimism when communicating an unfavorable prognosis, is desired by parents in the NICU is virtually unknown and requires further research. It is also of great scientific interest what kind of communication positively influences parental perception of, for example, the degree of restriction of a prognosis or selected characteristics of the medical staff. The assessment of the medical staff can in turn influence the relationship between the medical staff and substitute decision makers and is thus an important resource in jointly finding and making the most appropriate (treatment) decision for the child in the given situation.

The following specific questions will be answered as part of the COPE-Trial:

### 2.1 Main research question - primary hypothesis

1. Parents prefer pessimistic framing of an unfavorable prognosis.

### 2.2 Secondary research questions - secondary hypotheses

1. With pessimistic framing, parental (state) anxiety is greater than with optimistic framing.
2. With pessimistic framing, parental satisfaction with communication is greater than with optimistic framing.
3. With pessimistic framing, parents estimate the conveyed outcomes more realistically than with optimistic framing.
    a. With pessimistic framing, parents show less deviation in the recall from the communicated relative probabilities (probabilistic data) regarding survival of the preterm infant (general or without impairment).
    b. With pessimistic framing, parents report a higher severity of the child's expected impairment.
    c. With pessimistic framing, parents report a higher degree of being informed regarding the prognosis.
4. With pessimistic framing, parents are less optimistic about the patient's future than with optimistic framing.
    a. With pessimistic framing, parents are less optimistic that the patient will survive the cerebral hemorrhage.
    b. With pessimistic framing, parents are less optimistic that the patient will survive without (cognitive/physical) impairment.
5. With pessimistic framing, parents express less hopefulness about the patient's future.
6. With pessimistic framing, parents indicate a higher degree of preparation to make a treatment decision together with the attending physician.
7. With pessimistic framing, the physician makes a better general impression on parents.
8. With pessimistic framing, parents rate the physician as more professional.
9. With pessimistic framing, parents rate the physician as less compassionate.
10. Physicians prefer pessimistic framing to an optimistic framing.
11. Physicians estimate the severity of prognosis more objectively when prognosis is framed pessimistically than when prognosis is framed optimistically.

## III General planning

### 1. Summary of the study procedures

Within the framework of a randomized-controlled study in a parallel group design, parents of former patients of the NICU of the University Medical Center of the Johannes Gutenberg University Mainz will be included as subjects in the study collective (for inclusion and exclusion criteria, see IV). In order to capture the perception of the parents analogous to that of the transmitters of prognoses in everyday clinical practice, (assistant) physicians will also be included in the study according to predefined criteria (see ibid.).

The present research project is generally divided into two phases.
In the first phase, study participants will be recruited through personal and electronic contact by or with the study team. Personal contact means the combination of postal and telephone initial contact with each parent. To ensure that parents are prepared for a call from a study staff member, they will receive study information by mail in advance (approximately 1-2 weeks in advance). In addition to a brief overview of the background, content and procedures of the study as well as information on data protection, this information also contains the contact details of the study team, so that they can ask questions in writing or contact the team electronically if they are interested in participating in the study. Finally, during the telephone call, the parents are given detailed verbal information about the study (background, objectives, methodological procedure, opportunities for participation, source of further information, contact details of the study team). There is room for open questions. In addition, the inclusion and exclusion criteria are discussed with the parents. As soon as one of the parents meets one of the exclusion criteria, participation in the study is discouraged or directly discontinued. The second parent of the child can decide for or against participation independently of the parent excluded from study participation.

During the acquisition process families or related parents of a preterm infant are contacted together. However, in general, the parents are not treated as an entity, but as two independent subjects. This means that fathers and mothers, or both parents of the same child, do not process the study together, but separately, in order to experience the study intervention independently. This way, on the one hand, the involvement of individual parents is also guaranteed, should one parent not be interested in participating, not be present/existent, or not be allowed to participate if predefined exclusion criteria are met. On the other hand, experience shows that parents, for example, react differently to interviews, evaluate them differently, and accordingly place different demands on these interviews. For our study, therefore, it is interesting to consider both parents separately.
Parents who are interested in participating in the study and have been informed about the study will receive the electronic invitation to participate in the COPE-Trial with parents after the initial personal contact. In addition to brief instructions regarding the practical implementation of the study (from opening the link to completing the answering of all questions), as well as the detailed versions of the study information, the data protection information, and the consent form (as a PDF in the attachment), the parents receive their personal link to the online study in this e-mail. Parents will receive their individual password separately. This is a multi-digit access code - a combination of numbers and letters. Parents who belong together receive a code that is the same in the prefix (initial character) and otherwise differs. This makes it possible to mark related parents in the data set for statistical analysis without later being able to draw conclusions about individuals. All contacted families thus receive two codes as passwords. If a parent does not participate in the study, one of the codes remains unused and consequently there is no assignment of the parents in the data set. The codes are so-called serial numbers, which fulfill several functions: they function as a password, guarantee the one-time processing of the study, i.e. prevent multiple completion of the questionnaire by one person, and allow the assignment of related parents in the data set.

By clicking on the link, the participants are taken to the password-protected survey on the SoSci Survey online platform. Each link already contains the information to which study group the respective participant is randomly assigned (see explanation of randomization on p.26). Consequently, related parents of the same preterm infant receive the same link in order to know that they are assigned to the same study group as a parent pair. The reason for this procedure is that on the one hand all parents should (be able to) participate in the study as individuals, on the other hand at the same time the assumed common response tendency (covariance) of the parents of the same preterm infant should be taken into account if both participate in the study. The password, however, is partially different for both parents, i.e. individual. The use of centrally assigned access data (link and individual password) for the password-protected survey serves to protect the test persons and their data.

After completion of the first and before the start of the second study phase, concealed randomization will take place (see VI point 3 on p. 26), i.e. the random allocation of participants to our two study groups, which will experience different interventions in the second study part. To ensure that matched parents receive the same allocation and at the same time that couples as well as single participating parents (mothers only or fathers only) are distributed in a balanced way to both study groups, randomization is performed as described in point 3 of the statistical analysis (p. 26). Parents interested in participating in the study are therefore asked during the information session (in writing and by telephone) to indicate whether one or both parents wish to participate when providing electronic feedback to the study team. If couples register with the study team using a common e-mail address, note the wish for participation of both parents in this e-mail address. If the parents register independently, please refer to the other participating parent in your feedback to allow the study team to send the same link to both parents.

The actual survey of the parents takes place online in the second phase of the study. This should enable the study participants to conduct the survey flexibly in terms of time and space. The study will be conducted using the online tool SoSci Survey (soscisurvey.de) developed in Munich, Germany. SoSci Survey allows secure surveys in terms of data protection: the program is data protection compliant according to DSGVO and BDSG and the data transmission is SSL-encrypted throughout.

The online study is divided into two parts:
The first part begins with an introduction followed by the digital version of the consent form. After reading this, the study participants must electronically agree to participate in the study via an instrument specially designed by SoSci Survey. Only with the digital signing of the consent form is it possible to process the online study. In case of non-consent, the online study is automatically terminated. If consent is given, the first study phase (baseline questionnaire) automatically begins with the recording of important characteristics of the test subjects and their preterm infants (see p.22).

Only in the second part of the study does the covert randomized assignment of the subjects to different processing areas. This is due to the fact that the parallel group design of the study provides for the two study groups to watch two videos - one the intervention (Video A), the other the control (Video B) - in immediate succession. The two study groups differ in the order in which the two videos are shown, i.e., the intervention and control (see Fig. 1). Advantages of this design are that all study participants act as their own control by watching both videos, and the question of comparability of groups with respect to confounding variables does not arise.

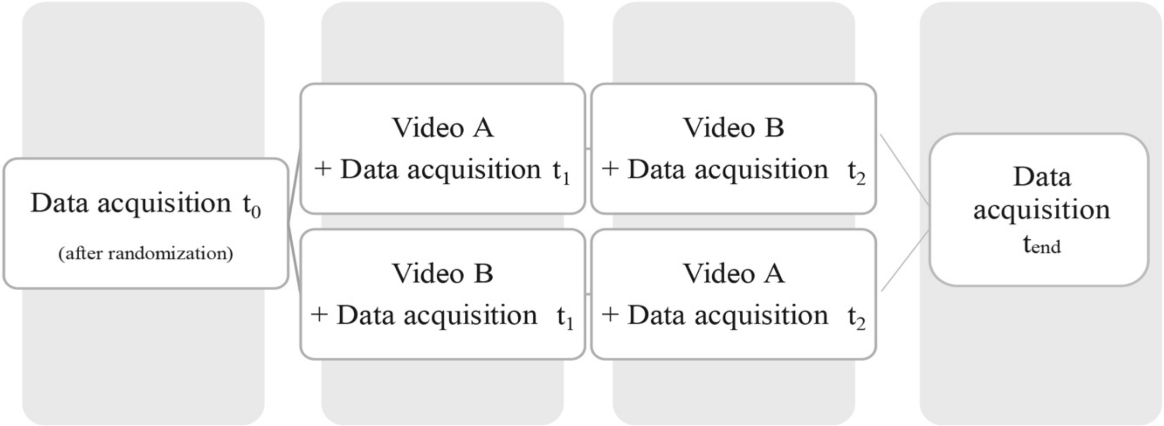


**Fig. 1: Scheme of the second study phase.**

The aim of the study is to simulate a consultation situation with transmission of an unfavorable prognosis for a very immature preterm infant. The unfavorable prognosis refers to one of the most common complications in neonatology and characteristic for very immature preterm infants - intraventricular hemorrhage with parenchymal involvement.

At the beginning of the second study section, the background is presented to the parents in an introductory video in the form of a short explanatory film (case vignette). The scenario of a premature baby with 23 5/7 weeks gestational age (GA) is described. The infant was born prematurely due to an amniotic infection syndrome. The infant subsequently experiences a complication of unilateral severe cerebral hemorrhage with parenchymal involvement on her third day of life. The participants also learn that the parents of the female preterm infant named Luisa are contacted by telephone by the attending physician for this reason. In the telephone conversation, the parents are asked to come to the ward in person for an important discussion.
Following the introductory video, the study participants watch the two videos one after the other, which correspond to the cinematic implementation of a simulated, i.e. fictitious, consultation situation with transmission of an unfavorable prognosis for a premature baby in different ways.

Video A (intervention): optimistic framing

Video B (control): pessimistic framing

Prognoses can only be predicted with great uncertainty in individual cases. For this reason, the transmission of prognostic data in both scenarios refers to outcome estimation data from scientific publications. [34, 35]

Scripted video vignettes were identified as suitable study material for the present study. Their conception, cinematic realization, and use were in accordance with the recommendations of Hillen and van Vliet.[36, 37] The development and use of video vignettes was guided by the specific research question, objectives, and particular requirements of this specific research project. The conception of the scripts was inspired by a study on the influence of more or less pessimistic communication on the perception of physician compassion from and in adult oncology.[29]

The case vignette as well as the two scripts for the two different scenarios were developed in an interdisciplinary way. The introductory video and the two videos (A and B) were shot with the support of a film team consisting of several actresses, a cameraman and camera assistance. In principle, the selected scenarios did not differ in content, but in the way the limiting prognosis was delivered (optimistic vs. pessimistic framing). The number of empathetic utterances is comparable, the different degree of optimism is achieved by variation of selected text passages. As a final thought, both scenarios contain a statement by the physician in the sense of reassurance of non-abandonment. In order to make it easier for the study participants to put themselves in the position of the parents in this consultation situation (empathization), the parents are seen from the front in the video. In the present case, a female physician communicates the prognosis. We chose a female doctor for reasons of uniformity of the videos as well as authenticity. It corresponds to the reality of most NICUs, including at the University Medical Center Mainz, that mainly women work as physicians in neonatology in this specialty.

The design of the study provides for parents included in the research project, after initial randomization, to first complete a baseline questionnaire (Data acquisition $t_0$ , see p.22) as a later basis for possible subgroup analyses. Following each of the two consecutive videos - regardless of the order in which they are presented - the subjects answer questions in the form of a post-intervention questionnaire (see Data acquisition $t_1 + t_2 + t_{end}$, p. 23ff).

## 2. Endpoints of the study

Primary endpoint

1. Parental preference for pessimistic versus optimistic message framing:
   a. Patient parents' preference for video B or A (dichotomous question with 1 = first video and 2 = second video).
   b. Rating of the desired level of optimism when an unfavorable prognosis is conveyed (unimodal, fully verbalized 7-point rating scale ranging from 1 = not at all optimistic to 7 = very optimistic).

Secondary endpoints

1. State anxiety is assessed using the German short version (5 items) of the State-Trait Anxiety Inventory (STAI-SKD) scale.[38] is used to assess state anxiety. Here, the change in parental (state) anxiety by/after viewing the first video is determined as the difference in state anxiety at time points $t_0$ and $t_1$.

2. Parental satisfaction is assessed using a fully verbalized 7-point rating scale (unimodal with 1 = not at all satisfied to 7 = very satisfied).

3. The realism of the parental assessment of the prognosis is determined by the degree of agreement between subjective assessment and objective ability to reproduce the transmitted prognostic data:
   a. Subjective assessment of the severity of the prognosis is based on a statement to be rated by the parents using a fully verbalized 7-point rating scale (1 = very bad to 7 = not bad at all).
   b. The objective ability to reproduce the transmitted information is based on the recall of the outcome data in numerical values (relative probabilities in %).
   c. The degree of parental preparedness for timely treatment decision-making is assessed using a fully verbalized 7-point rating scale (1 = not at all prepared to 7 = completely prepared).

*Note: At the end of the study, parents are also asked to provide a general assessment regarding the importance of physician-parent interviews as well as the transmission of prognoses (i.e., probabilistic data) in particular (see Data acquisition* $t_{end}$ *on p. 24).*

4. The degree of parental optimism with regard to the child's future is determined by evaluating two statements (a) on survival of the complication per se and (b) on survival without impairment via the

respective fully verbalized 7-point rating scale (unimodal with 1= not optimistic at all to 7 = very optimistic). It is taken into account in the evaluation that the degree of optimism may depend on the participants' basic attitude towards life. The basic attitude towards life is therefore initially measured using the scale Optimism-Pessimism-2 (SOP-2).[39-41] recorded.

5. The degree of perceived hopefulness is assessed using a fully verbalized 7-point rating scale (unimodal with 1= not at all hopeful to 7 = very hopeful). A possible correlation of the individual expression of parental hope recorded in the baseline using the German version of the Herth-Hope Index (HHI-D)[42, 43] with the assessment of parental hope (lack of hope) following the video.

6. Parents rate on a fully verbalized 7-point rating scale how prepared they felt by the interview to make a treatment decision with the clinician in a timely manner (1 = not at all prepared and 7 = completely prepared).

7. The general impression of the consulting physician on the parents is determined using a fully verbalized 5-point rating scale (German school grades 1 to 5)

8. To assess physician professionalism, the German translation of a subscale of the Professional Performance Questionnaire adapted from [44] (verbal anchoring with German school grades 1 to 5; sum score: range 9 - 45 points) is used. A back-translation by a native speaker was performed.

9. Physician compassion was assessed with the help of the German-translated version of the Physician Compassion Questionnaire according to [45] (5 items, polarity profiles with 10 scale points each; sum score: range 5-50). A back-translation by a native speaker was performed.

Additionally for physicians:

10. In this case, the evaluation of a colleague questionnaire is used to assess the *colleague* advising in the video. [44].
11. A fully verbalized rating scale (range 1-7) is used to self-assess the individual approach of the participating physician.

## IV. Study participants

### 1. Complete inclusion criteria

- Parents of former premature infants (birth weight < 1500 g and born after 31.12.2009)
- Postnatal treatment of a premature infant at University Medical Center of the Johannes-Gutenberg University Mainz
- Physicians with at least 6 months of work experience in a NICU.

Explanation: There will be two separate sub-projects. One study with parents as participants and one with physicians.

The study is to be carried out with the inclusion of the selected parents as well as medical personnel who are confronted with such complex scenarios in their daily work. It must be assumed that the special circumstances of the experience of a situation comparable to the scenario by parents in the past plays an important role in the influence of more or less optimistic framing of an unfavorable prognosis, for example, on the assessment of medical personnel as well as the preference of a certain type of prognosis transmission to be investigated. The expertise of the selected parental study collective is thus a prerequisite for gaining knowledge in the context of this survey. This study deliberately refrains from including parents who are actually acutely confronted with the situation of a serious complication of their preterm infant.

### 2. Complete exclusion criteria

- Lack of informed consent
- Insufficient knowledge of German language
- Self-reported acute, severe mental illness

### 3. Are subjects included who have doubts about their ability to consent or who do not have the ability to consent?

No

### 4. Will subjects lacking capacity to consent be included in the research project?

No.

### 5. How are subjects recruited and is recruitment material used?

Patient parents will be recruited in person, i.e. by mail, telephone, and electronically or in the course of a medical consultation, e.g. at discharge or in the course of the developmental neurological follow-up for former preterm infants at Mainz University Medical Center, as well as by contacting and via the parents' association of preterm infants "Frühstart e.V.". If parents are interested in participating, they successively contact the study team in person or electronically. (Assistant) Physicians with at least 6 months of work experience will be recruited in person and electronically.

## V. Study procedures

### 1. Approach to participants

The recruitment of suitable study participants is carried out by the initially listed study personnel. The associated verification of compliance with the predefined inclusion and exclusion criteria serves to ensure the recruitment of suitable parents for the study.

Following the acquisition (by post and personal telephone conversation), the information sheet, the consent form and the data protection information on the study are handed out to the test subjects electronically (e-mail). Accordingly, after receipt of the e-mail and before the start of the study, the parents can take sufficient time (at least 24 hours) to consent to or decline participation in the study. The second phase of the research project and thus participation in the study does not begin until the consent form is signed electronically. Participation can be withdrawn verbally or in writing before or at the beginning and at any time without giving reasons. Non-participation or early withdrawal from the study will not result in any disadvantages for the subjects. The same procedure for inclusion in the research project applies to female physicians.

### 2. Study process and implementation (see Fig. 2).

The study is scheduled to begin on 04/01/2021 and is planned to last for one year, but at least until the minimum number of cases (n) is reached.

After recruitment, randomization and inclusion in the study collective with electronic signing of the consent form, the study participants first complete the baseline questionnaire. After accessing the link and entering their individual password, the study participants can easily complete the study step by step from an Internet-enabled computer in the SoSci Survey online portal. When the number of cases reaches 2n, the study is terminated prematurely.

| | Registration | Data acquisition | Intervention | Data acquisition | Intervention | Data acquisition | End |
|---|---|---|---|---|---|---|---|
| Time | $t_{-1}$ | $t_0$ | $t_1$ | $t_1$ | $t_2$ | $t_2$ | $t_{end}$ |
| | | | Video | | Video | | |
| Registration | | | | | | | |
| Eligibility | x | | | | | | |
| Consent | x | x | | | | | |
| Group assignment | x | | | | | | |
| Intervention | | | | | | | |
| Video | | | A | | B | | |
| Video | | | B | | A | | |
| Evaluation | | | | | | | |
| Demographics | | x | | | | | |
| Primary endpoint | | | | | | x | |
| Secondary endpoints | | | | x | | x | x |

**Fig. 2: Study procedure and organization of data collection**

The first part of the study with a short introduction, consent to participate in the study and answering the questions of the baseline questionnaire takes about 15 to 20 minutes. The time required for the second part of the study (main part with intervention) is also around 20 minutes for the test subjects (see Fig. 3).

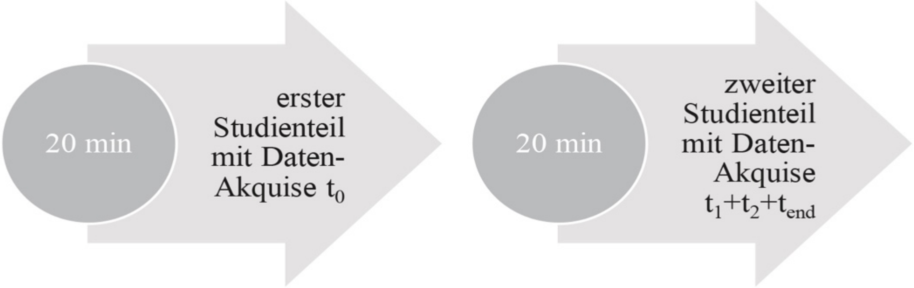


**Fig. 3: respective time required for the two study sections**

In the main part of the study, the test subjects first watch a short explanatory film before being shown the two videos one after the other in a different order, depending on their study group (see Fig. 1). After watching the first video, they are asked to comment on it by answering identical questions in each group. The questions following the two videos viewed one after the other are also identical in the two groups. After all questions have been answered, the study is considered complete. Upon completion of the survey, parents are thanked for their participation in the study and asked to close the browser window.

**The following data on the study process will be collected**:
Number of parents approached, number of parents excluded (including reasons: declined to participate, exclusion criteria, other reasons), number of parents included and randomized to the respective scenarios, number of parents discontinuing the study, number of parents finally analyzed (including reasons for non-analysis). The same applies to female physicians.

**Data acquisition $t_0$ (baseline questionnaire)**
As a basis of ensuring comparability and enabling subgroup analyses with regard to the primary and secondary endpoints of the study, sociodemographic data of the parents such as age, sex, sociocultural background (including language and religiosity/belief), highest educational attainment, employment, presence of medical expertise/knowledge, or medical background will be collected at baseline.

Since we assume that premature birth is a special life event for parents, they are asked how much they agree with the statement that the early birth of the child has changed their life, the family cohesion as well as the financial security of the family. To inquire about the influence of the premature birth on the family's instrumental resources, four items adapted from the "financial stress" subscale (F1-F4) of the Family Stress Questionnaire (FaBel questionnaire) were[46] formulated. Also, when asking about changes in family cohesion, an item of the subscale "coping problems" (F12) of the same questionnaire is used. This is followed by questions about the family (marital status, number of children in the household) and information about the premature baby (date of birth, gestational age of the premature baby at birth, birth weight, multiple birth status, fertility treatment yes/no, severe cerebral hemorrhage yes/no).

In addition, with regard to the evaluation of outcome data after study inclusion**,** the following specific (personality) characteristics of parents and medical staff will be recorded:

a. German version of the Brief Resilience Scale (BRS)[47-49]
b. The Optimism-Pessimism-2 Scale (SOP2)[39-41]
c. Herth Hope Index - German Version (HHI-D)[42, 43]
d. Uncertainty Tolerance Scale (UGTS)[50]
e. Patient Health Questionnaire (PHQ 4)[51, 52]
f. State-Trait Anxiety Inventory (STAI) Trate Scale.[53, 54]
g. German short version of the State-Trait Anxiety Inventory Scale (STAI-SKD)[38]

**Data acquisition $t_1$ after the first video (A or B)**

Parents are asked to rate the degree of optimism of prognosis communication on a 7 point rating scale (1 = not at all optimistic to 7 = very optimistic).

- Parents' (state) anxiety is assessed using the German short version (5 items) of the State-Trait Anxiety Inventory (STAI-SKD) scale.[38].
- Parental satisfaction with the way the clinician communicated the prognosis is assessed using a fully verbalized rating scale (range 1-7).
- The realism of parental assessment of prognosis is determined by the correlation between subjective assessment of the severity of prognosis (fully verbalized rating scale, range 1-7) and objective ability to reproduce the prognostic data conveyed. It will solicit a selection from percentages ranging from 0 to 100 percent in increments of ten (survival) or twenty-five (impairment).
- Parental level of optimism about the child's future (overall survival and survival without impairment) is assessed using a fully verbalized rating scale (range 1-7).
- A fully verbalized rating scale (range 1-7) is used to assess the degree of perceived hope (hopelessness).
- Using a fully verbalized rating scale (range 1-7), parents are asked whether they felt prepared to make a joint (treatment) decision with the physician in the announced follow-up interview.
- The general impression of the consulting physician on the parents is visualized by a fully verbalized rating scale (school grades 1 to 5, equal to the scale of the Professional Performance Questionnaire adapted to [44], sum score: 5-50) visualized.
- Physician professionalism is assessed using the German translation of a subscale of the Professional Performance Questionnaire (school grades 1 to 5, sum score: range 9 - 45 points) adapted from [44] determined.
- Physician compassion is assessed using the German translation of the Physician Compassion Questionnaire[45] in a slightly modified version adapted from [29]in a slightly modified version. The labels of the poles of the 5 items depicting the five dimensions of physician compassion were translated literally and back-translated by a native speaker, the scaling corresponds to a numerical rating scale with range 1-10.

**For physicians additionally:**

- In this case, the questionnaire *evaluation of a colleague is* used to evaluate the colleague according to [44].
- A fully verbalized rating scale (range 1-7) is used to self-assess the individual approach of the participating female physicians.

### Data acquisition $t_2$ after the second video (B or A)

- Parents are asked to rate the degree of optimism of prognosis communication on a 7-point rating scale (1 = not at all optimistic to 7 = very optimistic).
- Preference for video A or B (primary endpoint) is captured using a dichotomous question (1 = first video and 2 = second video).

### Data acquisition $t_{end}$ on the completion of the study

- Participants are explicitly asked about their preference for (rather) pessimistic or (rather) optimistic communication of forecasts (fully verbalized 7-point rating scale with 1 = not at all optimistic to 7 = very optimistic).
- Parents are asked to provide an assessment regarding the importance of doctor-parent discussions in general and certain discussion content (transmission of prognostic data) in particular (4 items each and a fully verbalized 5-point rating scale with 1 = strongly disagree to 5 = strongly agree).
- Parents indicate whether they feel burdened by study participation in general or by watching the videos in particular (2 items and a 5-point rating scale with 1 = not at all to 7 = very much).

- Parents are informed that the study team is planning further research projects involving parents of former preterm infants in the future. Parents are invited to express their interest in participating in future studies by contacting the study team directly by e-mail.
- Physicians have the opportunity to comment on difficulties in communicating prognoses in everyday clinical practice. A free text field is available for this purpose.

### 3. Rules for discontinuing the research project for the individual, as well as for the entire study

Only very low study-related risks are assumed for the test subjects (minimal risk). Individual subjects may discontinue the study at any time, e.g. if dealing with the subject matter is too emotionally stressful. In this case, a psychological consultation will be offered. If more than 50% of the subjects drop out of the study, the entire study will be terminated. This evaluation is carried out for every 20 subjects included.

# VI. Statistics

## 1. Sample size calculation

Simplifying, the resulting number of cases is used as the number of parent pairs to be recruited, where one or both parents may consent. Tested the null hypothesis of balanced preference, period-corrected, with a chi quadrat test for independence in the four-field table defined by sequence and 'preference for video B vs. video A'. To detect an effect corresponding to the 3:2 preference ratio with a power of 80%, in the absence of a period effect, 194 families with evaluable data from at least one parent are needed. Assuming a significant period effect, the same treatment effect in sequence AB could result in a preference for video 1 with a probability of 0.50, whereas in sequence BA it would be 0.3077. The required number of cases would then be 204. Assuming that only one parent participates per family and that the dropout rate is 5%, 215 families would have to be recruited. At least 153 families would have to be recruited if both partners always participate and the agreement in the assessment corresponds to a kappa of 0.5. After inclusion of 50 to 70 families, a reassessment of the number of cases will be scheduled.

## 2. Statistical evaluation methods

The analysis of the primary endpoint 'preference B over A' is done by fitting a marginal logistic model with the endpoint 'second video was preferred' using the method of generalized estimating equations. For this purpose, parents are considered as clusters of scope 1 or 2. The exponentiated halved coefficient of the factor 'sequence' (A then B coded as 0, B then A coded as 1) is used as the period-corrected estimate of the odds for preference of intervention A. The test of the null hypothesis is performed as a Wald chi quadrat test at the two-tailed level 0.05.

## 3. Description of the randomization method

The concealment of allocation is performed in blocks of variable length, stratified into the three strata 'participation of mother only', 'participation of father only', 'participation of both parents'. Allocation will be done after recruitment of the parents by an employee of the University Medical Center of the Johannes Gutenberg University Mainz not involved in the acquisition outside the online acquisition software and will be done in the order of consent. Both parents receive the same allocation in each case.

# VII Ethical and legal aspects

1. The study is conducted in accordance with currently valid national and international ethical and legal standards. The Declaration of Helsinki in its latest German version will be observed. The study protocol and substantial amendments will be registered with clinicaltrials.gov and the German Registry of Clinical Trials (DRKS) before the start of the study. The legal basis for the protection of personal data is the European Data Protection Regulation (DS-GVO). Personal data will only be processed after an effective declaration of consent (Art. 6 para. 1 letter c) DSGVO).
   The patient data are first collected digitally on the questionnaire. Subsequently, a code is assigned to each patient. The data is stored digitally by means of the patient code. The collection and storage of study-related data is thus exclusively in pseudonymized form.

2. **Information on the purpose and potential benefits or risks of the study.**
   The research project serves a purely scientific objective. In the long term, the study results should help to increasingly take into account individual parental needs and preferences with regard to physician-parent communication in neonatology and to strengthen parent-centered care in this special and particularly challenging specialty.
   Some parents of preterm infants describe their child's premature birth as a life-changing experience that requires them to reinvent themselves as parents and rewrite their own story.[30] Physicians should and can support parents in this process: through medical expertise and through successful communication. It is likely that the way medical information is communicated can influence parents' lived experience. The findings of this study should help to orient future communication in the context of uncertainty more towards the individual needs and preferences of parents as representatives of their children and direct experiencers and thus contribute to improving the quality of care in neonatology.
   Parents of former preterm infants can help in this process thanks to their own lived experience of preterm birth and the accompanying life transformation. This research project wants to draw attention to the importance of communication in the context of uncertainty on the one hand, and to the involvement of "former parents" in research projects on the other hand. It would be desirable in the near future to involve parents even more in neonatology or pediatric research in general and to do research with them rather than just about them. There are already concepts and scientific findings for the active involvement of "resource veteran parents" not only in research, but also in clinical care or teaching.[19-21]

   **a. What are the potential benefits to the subjects of participating in the trial?**

   Participating parents and physicians are unlikely to derive any direct individual benefits from the study. A possible group benefit may arise from improved counseling practices for future parents in a similar situation.

   **b. What are the burdens on the parents?**

   Watching the scenarios in video format and subsequently answering related questions may elicit an emotional response from parents. However, the risk of relevant exposure is estimated to be negligible.

3. **Information on the handling of the test person/patient data**

   As part of the research project, data such as age or gender are asked to describe the participants. In addition, they are asked to provide characteristic health data of their child, e.g. gestational age. All data collected are used to better assess and evaluate preferences with regard to the type of counseling in the context of transmitting a limiting prognosis. All information and statements made by the test persons in the course of the study will be treated with absolute confidentiality.

   This means that all study employees comply with the provisions of data protection law. Personal data are processed only after effective declaration of consent (Art. 6 para. 1 letter c) DSGVO). All data collected are stored on data carriers, processed exclusively on access-protected computers, and then stored safely and securely for ten years at the Center for Pediatrics and Adolescent Medicine at Mainz University Medical Center.
   To ensure that the personal data and the children's health data cannot be traced back to the subjects or their child, a code is generated (pseudonymization). The pseudonymization code is stored at an independent employee of the University Medical Center Mainz, i.e. not directly involved in the study.

Access to and evaluation of the data collected will be performed exclusively by the study director and staff directly involved in the study. The data will not be passed on to third parties. The publication of the study results takes place exclusively in anonymized form.

Participants have the right to obtain information about their personal data at any time (including the provision of a copy free of charge) and to request restriction, transfer, correction or deletion of this data. Furthermore, they may object to the processing of their data at any time (Art. 13-21 DS-GVO).

Responsible for data processing is Dr. med. André Kidszun. The responsible data protection officer is the State Data Protection Commissioner RLP (contact: poststelle@datenschutz.rlp.de).

4. **Insurance coverage is not necessary.**

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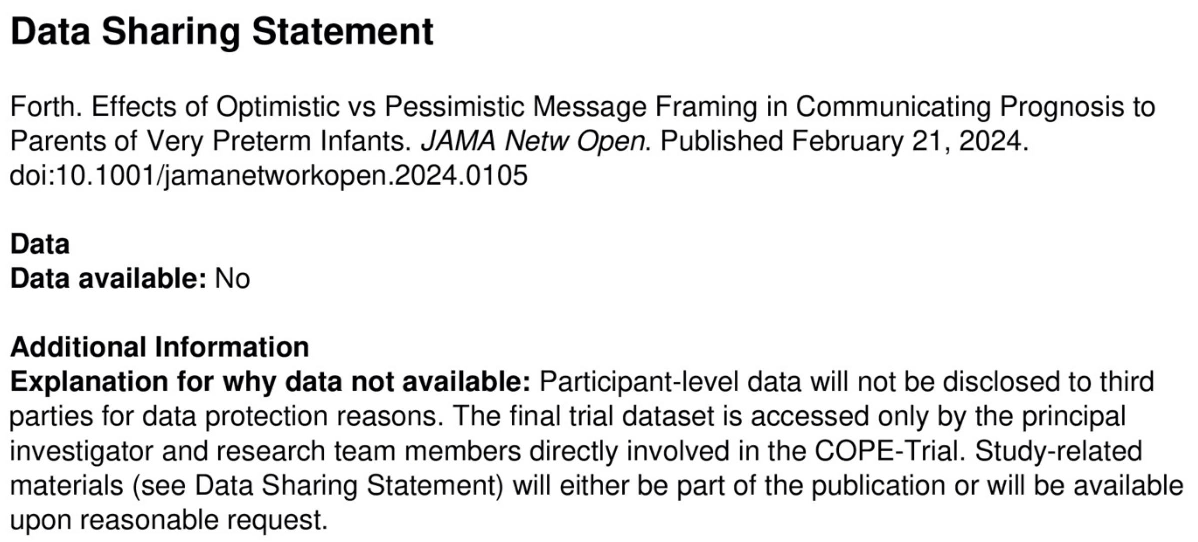
## IX. Signatures

Mainz, 05.02.2021

[redacted]

### 2.3.3 Supplement 3: Data Sharing Statement



# Data Sharing Statement

Forth. Effects of Optimistic vs Pessimistic Message Framing in Communicating Prognosis to Parents of Very Preterm Infants. *JAMA Netw Open*. Published February 21, 2024. doi:10.1001/jamanetworkopen.2024.0105

**Data**
**Data available:** No

**Additional Information**
**Explanation for why data not available:** Participant-level data will not be disclosed to third parties for data protection reasons. The final trial dataset is accessed only by the principal investigator and research team members directly involved in the COPE-Trial. Study-related materials (see Data Sharing Statement) will either be part of the publication or will be available upon reasonable request.

# 3 Danksagung

Mein besonderer Dank gilt meiner Doktormutter und Erstbetreuerin sowie meinem Zweitbetreuer für die gemeinsame Ausdifferenzierung der initialen Projektidee und die gemeinsame Konzeption des Forschungsprojekts, sowie für die fachliche Unterstützung, eingebrachte Expertise, konstruktive Kritik und Ermutigung bei der Ausarbeitung des Studienprotokolls, der Erarbeitung der Studienmaterialien, der Umsetzung des Forschungsprojekts und im Prozess der Publikation des Studienprotokolls sowie der Ergebnisse der COPE-Studie. Zudem möchte ich mich dafür bedanken, dass meine Doktormutter mir mehrfach die Möglichkeit gegeben hat, meine Arbeit vor unterschiedlichem Publikum an der Universitätsmedizin Mainz zu präsentieren, und dass sie und mein Zweitbetreuer mich ermutigt haben, die COPE-Studie auf Kongressen zu präsentieren, um wertvolle Rückmeldungen zu der Arbeit zu erhalten und unsere Perspektiven fruchtbar zu ergänzen. Meiner Doktormutter möchte ich danken, dass sie sich stets für die COPE-Studie und für mich als Doktorandin eingesetzt hat, und mich dabei unterstützt hat, herausfordernde Schritte im Promotions- und Publikationsprozess zu meistern. Bei meinem Zweitbetreuer möchte ich mich im Besonderen dafür bedanken, dass ich mit seiner Idee für ein elternzentriertes Forschungsprojekt in der Neonatologie arbeiten und auf diesem Weg mein Interesse für Forschung an sich, für Versorgungs- und „patient:innenzentrierte“ Forschung entdecken durfte. Außerdem danke ich ihm für die viele Zeit, die er sich für das Promotionsprojekt und für mich als Nachwuchswissenschaftlerin genommen hat. Vielen Dank für die Wertschätzung meiner Arbeit und Person, welche mich stets motiviert hat, weiterzumachen.

Meinem Zweitgutachter sowie der Drittgutachterin danke ich für das Interesse an der Arbeit und die wertvolle Zeit zur Begutachtung der vorliegenden Dissertationsschrift.

Darüber hinaus möchte ich den Co-Autor:innen der meiner Publikationsdissertation zugrundeliegenden Publikation „Optimistic vs Pessimistic Message Framing in Communicating Prognosis to Parents of Very Preterm Infants: The COPE Randomized Clinical Trial“ (doi:10.1001/jamanetworkopen.2024.0105) sowie der vorausgehenden Publikation des Studienprotokolls “The **COPE**-Trial—**C**ommunicating prognosis to parents in the neonatal ICU: **O**ptimistic vs. **PE**ssimistic: study protocol for a randomized controlled crossover trial using two different scripted video vignettes to explore communication preferences of parents of preterm infants.” (https://doi.org/10.1186/s13063-021-05796-3 ) herzlich für die konstruktive Zusammenarbeit und die fachliche Unterstützung in den verschiedenen Phasen des Forschungs- und Publikationsprozesses, die eingebrachte Zeit und Expertise sowie den gemeinsamen Feinschliff an Details, die den Unterschied gemacht haben, danken. Meinem medienschaffenden Co-Autoren möchte ich herzlich dafür danken, dass er durch Überarbeitung der Skripte, Rekrutierung geeigneten Kamerapersonals und geeigneter Schauspieler:innen, sowie viel Herzblut in der Postproduktion deren Umsetzung in die Video-Vignetten ermöglicht hat, welche für die Umsetzung des Forschungsprojekts wesentlich waren. Den Schauspieler:innen möchte ich für ihren großartigen schauspielerischen Einsatz für unser Forschungsprojekt danken. Den Filmenden danke ich für die Arbeit hinter den Kameras, der Illustratorin und einer Freundin für die Unterstützung am Filmset. Der Illustratorin möchte ich überdies für ihre wunderschönen Illustrationen für die Webseite zu dem Forschungsprojekt sowie die Eltern-Informationsmaterialien danken. Dem medienschaffenden Co-Autoren und dem Team einer Medienagentur danke ich für das Programmieren und Online-Schalten der Webseite.

Allen Studienteilnehmer:innen beziehungsweise allen kontaktierten Eltern danke ich von Herzen für ihre Zeit und das Teilen ihrer wertvollen Erfahrungen, welche Quelle des Erkenntnisgewinns im Rahmen des zugrundeliegenden Forschungsprojekts sind. Der Austausch mit den Eltern hat in mir den Wunsch geschürt, in der Zukunft gegebenenfalls weiter zu forschen und dabei das Kollektiv der Beforschten aktiv in den Forschungsprozess mit einzubeziehen, um die Relevanz der Forschung und Ergebnisse für die Betroffenen zu steigern.

Überdies bin ich dankbar für die beiden Förderungen, welche ich in den Jahren der Arbeit an dem der Publikation zugrundeliegenden Forschungsprojekt erhalten habe. Die Promotionsstipendien des DFG-Graduiertenkolleg 2015/2 „Life Sciences – Life Writing“, Institut für Geschichte, Theorie und Ethik der Medizin, Universitätsmedizin der Johannes Gutenberg-Universität Mainz, sowie des MAInz-DOC-Promotionskolleg, Mainz Research School of Translational Biomedicine (TransMed), Universitätsmedizin der Johannes Gutenberg-Universität Mainz, haben mir ermöglicht, mich meinem Promotionsprojekt mit ganzer Aufmerksamkeit und in Vollzeit zu widmen, Fort- und Weiterbildungen beispielweise zu Forschungsmethoden zu besuchen und an für meine Arbeit relevanten Kongressen teilzunehmen.

Meinen Eltern, meinem Lebensgefährten und unserer gemeinsamen Tochter sowie meinem Bruder möchte ich von Herzen für ihre Unterstützung auf verschiedenen Ebenen sowie in allen Gemütslagen und Phasen der Promotion danken. Danke, dass ihr mich stets motiviert habt, mein Herzensprojekt zu realisieren und abzuschließen. Meinem Schwiegervater möchte ich danken, dass er mir geholfen hat, meine Arbeit umzusetzen, indem er und sein Team in einer Medienagentur die Webseite für Eltern und Interessierte realisiert und das wunderschöne Informationsmaterial für die Eltern gedruckt und liebevoll verpackt haben. Mein Dank gilt darüber hinaus all denen Freund:innen, die in den Jahren der Promotion ein offenes Ohr für mich hatten und mir stets konstruktive Rückmeldung zu meiner Arbeit gegeben haben. An dieser Stelle möchte ich auch meinem GRK-Kollegen und guten Freund danken, mit dem ich die Höhen und Tiefen der Promotionszeit geteilt und viele Gedanken, Ideen und Expertise ausgetauscht habe.

# 4 Tabellarischer Lebenslauf