BMJ Open

WELCOME: Digital transition of premature and newborn infants with special care needs to postdischarge care – study protocol for a randomised controlled duo-centred study

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To cite: Sehn L, Otter M, Will J, *et al*. WELCOME: Digital transition of premature and newborn infants with special care needs to postdischarge care – study protocol for a randomised controlled duo-centred study. *BMJ Open* 2025;**15**:e104346. doi:10.1136/bmjopen-2025-104346

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2025-104346).

Received 28 April 2025
Accepted 19 September 2025

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ABSTRACT

Introduction The transition from hospital to home can be challenging for parents of premature infants due to a lack of education on specific care. This may lead to both higher readmission rates and healthcare costs. Telehealth interventions can improve the quality of care specific to premature and critically ill newborns. This protocol outlines the WELCOME study and evaluates its feasibility and effectiveness of this approach.

Methods and analysis This two-centre randomised control trial (RCT) will assign 240 families with premature and critically ill newborns to an intervention or control group. The study has a parallel group design and an exploratory framework. The control group will receive standard postdischarge care. The intervention group will additionally receive scheduled video consultations, digital assessments and 24/7 access to educational resources. Primary outcomes will focus on 30-day readmission and emergency care use. Secondary outcomes will include child development and parental health. The intervention is expected to be feasible, with high acceptance and minimal drop-out. It will aim to improve parents' self-efficacy and health literacy. If successful, insights from this multimethod telehealth study will inform standard care.

Ethics and dissemination Results will be published in anonymised and summarised form in international and national journals and symposia. The study received ethical approval from the Ethics Committee of the Ludwig-Maximilians-University Munich (No. 25-0028) and was registered in the German Clinical Trials Register on 6 March 2025 (DRKS00034422).

Trial registration number DRKS00034422.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This app-based telehealth intervention in Germany supports the transition from intensive care to home care, enhancing parental health literacy and self-efficacy through a centralised platform.
⇒ An RCT is a suitable study design to assess its effectiveness.
⇒ Key advantages include interpreter support, provided technical equipment and improved access for rural and socially disadvantaged families.
⇒ Recruiting qualified staff will be challenging due to the shortage of clinical specialists.
⇒ The intervention, supplementing standard care, exposes parents to potentially redundant enquiries or discussions with postdischarge care providers.

INTRODUCTION

One in 10 newborns worldwide is born prematurely, with Germany having one of the highest rates in Europe (8%–9%).[1–4] More than 15% of preterm infants require neonatal intensive care, often for weeks, due to physiological instability, feeding difficulties and a high risk of infection.[5–7] Their long-term health depends on effective postdischarge care, which largely falls on parents.[8 9]

Medically complex term infants also need continued care. In Germany, umbilical artery catheter infections occur in 5%–6% of cases, and respiratory infections like RSV lead to frequent hospitalisations.[10–13] Parents of these infants report significantly higher stress and anxiety than those of healthy newborns.[14–16] The transition from hospital to home can be overwhelming, as parents become solely responsible for care, often without sufficient guidance.[17 18] Feeding difficulties and other complications commonly emerge only after discharge, leading to higher readmission rates and costs.[19 20]

Germany's outpatient care system struggles with bureaucracy, fragmentation and workforce shortages.[21–23] Midwifery and paediatric home care services are not universally available, particularly in rural areas, and many families do not receive adequate support.[7 24] Social factors like financial stress,

living in rural areas and language barriers reduce access to care.[25–27]

Previous studies investigating digital interventions involving video consultations have demonstrated positive outcomes and high feasibility of implementation.[28–31] A structured, digital postdischarge programme could bridge care gaps by providing accessible, expert-led support at home. The objective of the WELCOME project is to assess the effects on the primary outcomes of hospital readmissions and emergency visits within the critical first 30 days after discharge, as well as the secondary outcomes such as child development, parental well-being and stress. This protocol evaluates the WELCOME project and the effectiveness of its complementary telehealth intervention compared with standard care alone. The aim of this protocol is to clearly define the study design, methodology and ethical considerations to ensure that the study is conducted systematically and is reproducible.

METHODS AND ANALYSIS

The WELCOME project will be conducted in the metropolitan areas of Munich and Berlin, including surrounding regions up to 50 km. Eligible families will be recruited before their discharge from Ludwig-Maximilians-University Hospital Munich (LMU Hospital) and Charité—Universitätsmedizin Berlin (Charité). Eligibility criteria for both groups will include premature infants who require increased social, medical and/or nursing care between 34 and 37 weeks of gestation; families with newborns born before 34 weeks of gestation; families with newborns with an extremely low birth weight (less than 1000 g), a low birth weight (between 1000 g and 2500 g) or extreme immaturity (gestational age less than 28 weeks) and families with sick full-term infants with congenital malformations or perinatally acquired diseases requiring social, medical and/or nursing follow-up care. Children born at term without increased need for postdischarge care or infants in a palliative situation will be excluded. The eligibility criteria were chosen to include a broad spectrum of newborns. However, we exclude those who we feel would not benefit from or need the intervention. A total of 120 families will participate in the intervention group. Families in the control group will receive only the standard postdischarge care, while the intervention group will receive standard care along with the WELCOME telehealth intervention (see figure 1).

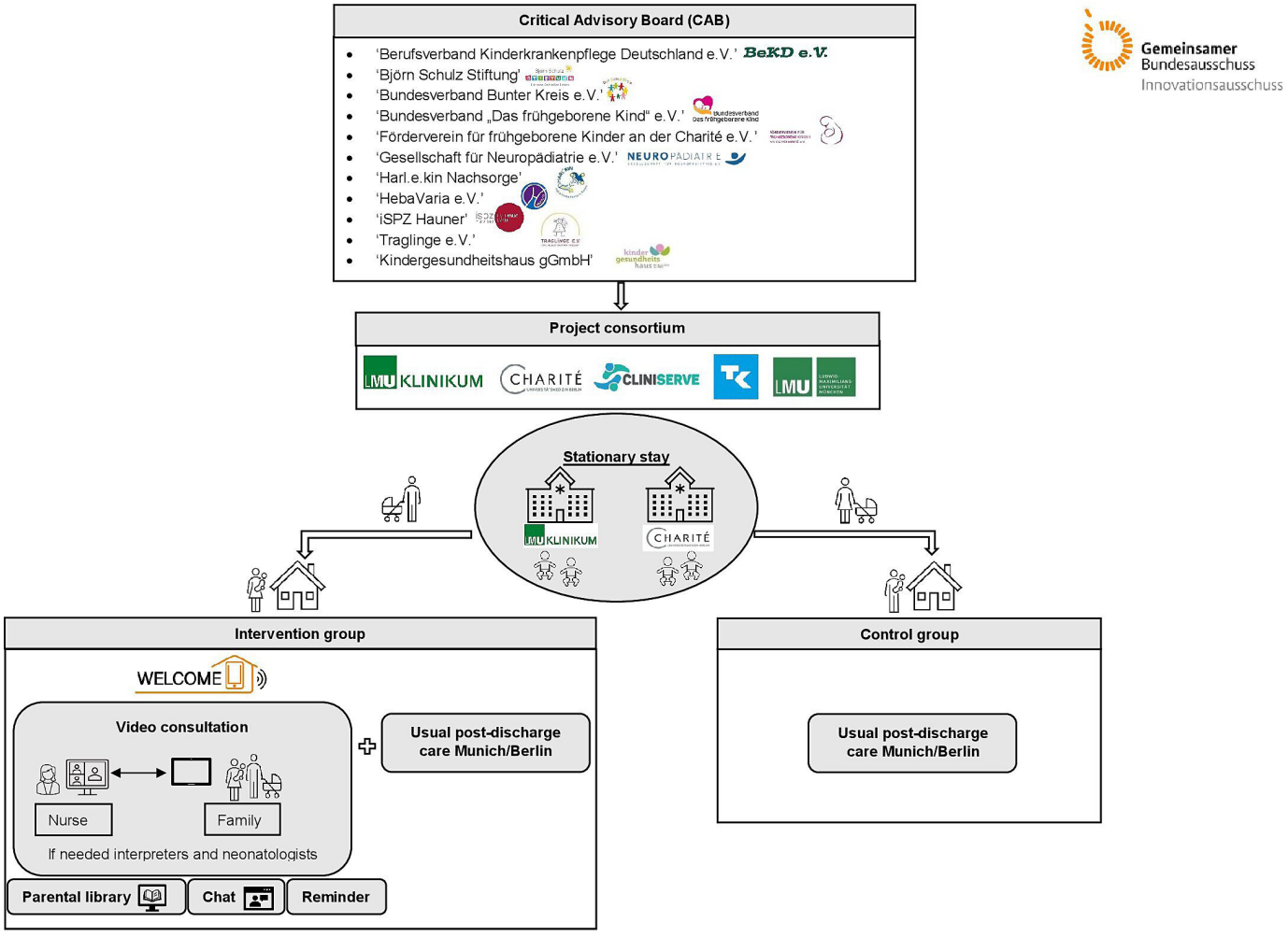

Figure 1 Structure of the study.

Figure 2 WELCOME telehealth intervention.

This intervention will consist of two main components (see figure 2). It will begin with digital assessments and homecare technology delivered through 15 scheduled multilingual video consultations over a period of 7–8 weeks. Participants will subsequently have 24/7 access to a knowledge platform containing educational materials, information on care structures and postdischarge services. This parent library contains high-quality resources, primarily webpages and flyers, as well as some videos, on the following topics: general child care, creating a safe environment, nutrition and breastfeeding, and mental health and support services. Additionally, they will be able to consult experts via chat or scheduled short-term video consultations. The individuals delivering the intervention are professional-level postgraduate nurses specialising in paediatric nursing. They have at least 3 years' clinical experience. They all complete a specifically created curriculum containing 32 units of blended learning. The principal investigator ensures that all personnel delivering the intervention have completed the curriculum.

Study design

This randomised, two-centre intervention study will use a parallel-group design with three follow-ups. Families will be randomly assigned to either the intervention or control group (see figure 3 based on Consolidated Standards of Reporting Trials recommendations[32]). The control group will receive standard postdischarge care, while the intervention group will additionally receive the WELCOME telehealth intervention. Usual postdischarge care includes discharge planning within the hospital. After discharge, families have free access to midwives, family doctors, social medical care and paediatric centres at hospitals.

Participant timeline

Participant enrolment, intervention implementation and assessments will follow a fixed timeline, as shown in figure 4 from the parental perspective. Data collection for primary and secondary outcomes will take place at four time points (t_0, t_1, t_2, t_3). Additional data for the intervention group will be collected during video consultations ($t_{intervention}$), if necessary. Participants will be able to withdraw from the study at any time.

Sample size

Since no representative data exist for Germany on 30-day readmission rates or emergency department use among families with preterm and newborn infants, success is defined as a 40% reduction in 30-day readmissions and lower emergency treatment rates in the intervention group. This estimate is based on reference studies from the USA and Sweden.[31 33] To detect these effects with a one-sided test, 104 participants per group are required, assuming a 5% significance level and 80% power. An expected dropout rate of 10% at the primary outcome measurement (30 days) has been accounted for. The control and intervention groups will have a 1:1 ratio, with outcome probabilities of 0.31 and 0.54, respectively. Power calculations using G*Power indicate a total of approximately 240 families will be needed over 18 months.[34]

Recruitment

Families will be recruited consecutively, limited to those insured by the cooperating health insurance provider. Eligible families will be invited through the neonatology departments of the study centres, with five wards at LMU Hospital and seven at Charité participating. Study coordinators at each site will receive daily updates on planned discharges and will contact families 3–4 days before discharge. If necessary, an interpreter will assist in explaining the study and confirming eligibility. Families will be randomly assigned to either the intervention or control group after obtaining signed written informed consent (participant consent form can be found in the online supplemental material). Recruitment will be carried out by the study coordinators, physicians and nursing staff at each site and continue for a duration of 18 months (August 2025–January 2027). Each centre's intervention team consists of six intervention nurses and two doctors. The number of families assigned to each

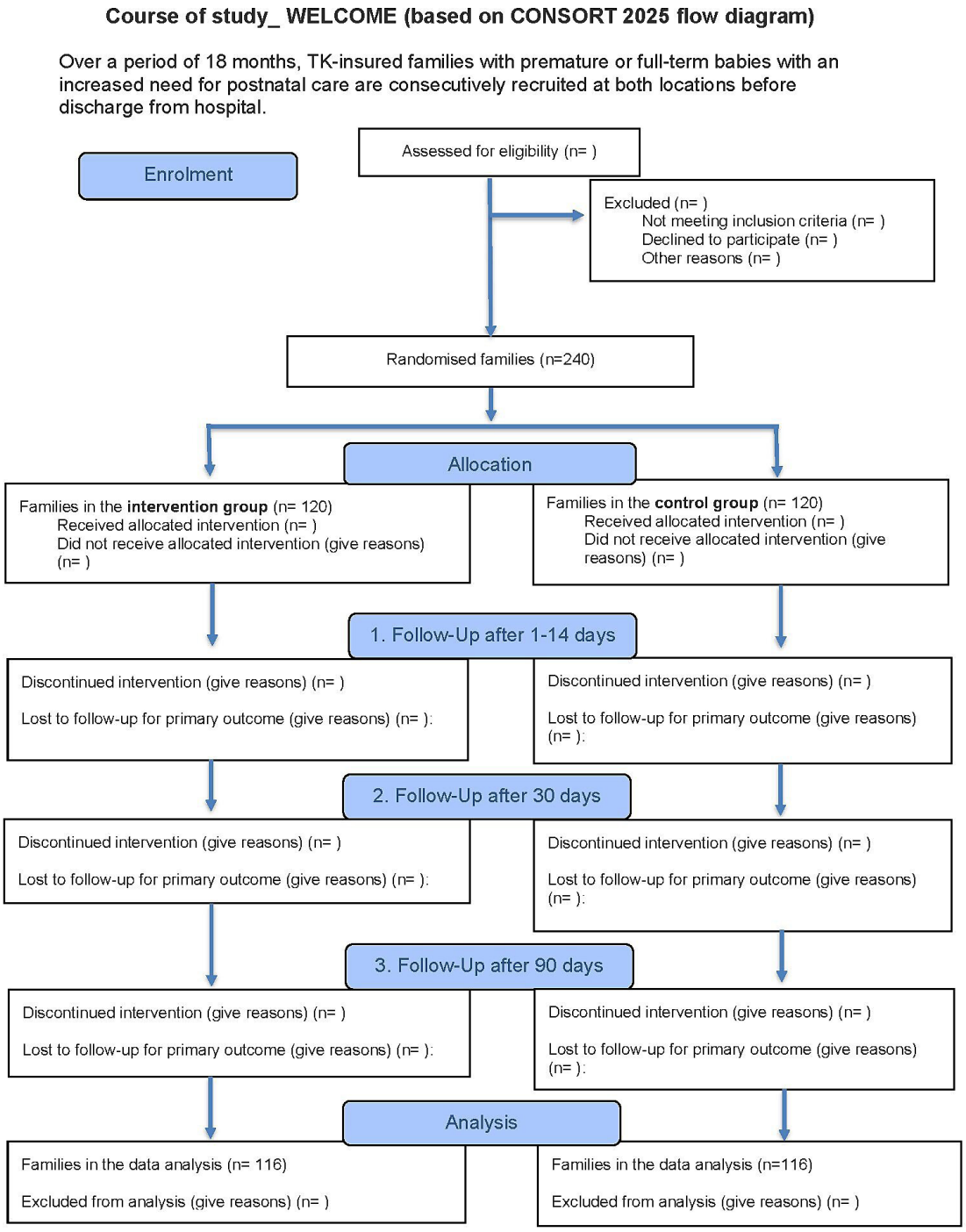

Figure 3 Study flow diagram.

intervention nurse varies greatly depending on their position percentage.

Randomisation and implementation

Randomisation will follow a computer-generated 1:1 allocation, stratified by study site and will be conducted externally by the IBE, Chair of Public Health and Health Services Research, using RStudio. The IBE will generate a randomisation table and will integrate it into the REDCap (Research Electronic Data Capture) randomisation module. REDCap will be a secure, web-based platform designed for research data management, offering an intuitive interface audit trails, automated export procedures and integration with external sources.[35 36] Study team members will not be involved in generating the randomisation list or setting up REDCap. The person enrolling participants can initiate digital randomisation to intervention or control group using the random allocation sequence.

To improve adherence, parental input was incorporated before finalising adjustments to the application. This ensured that the user interface met their needs. In order to ensure that care providers adhere to the protocol,

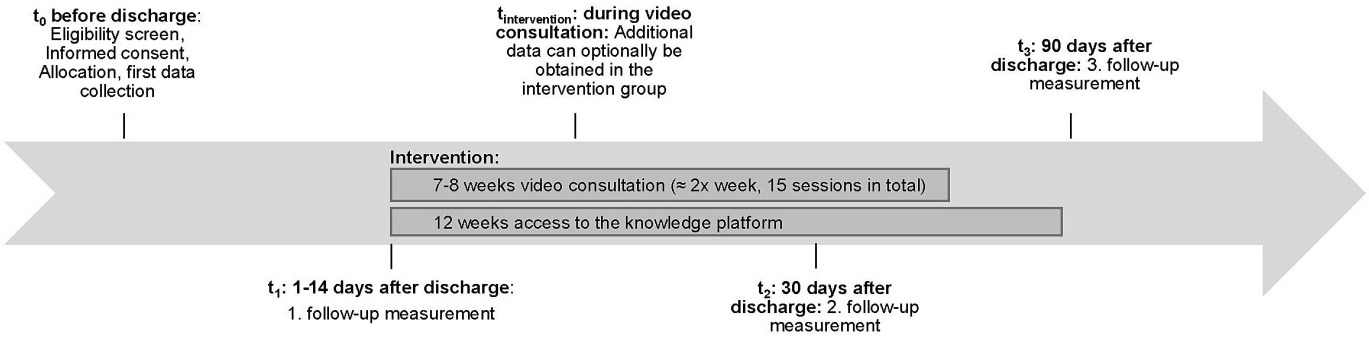

Figure 4 Participant timeline.

biweekly team meetings are scheduled to discuss ongoing cases. The number of video consultations conducted and the access rate to the parent library can be used to monitor participant adherence.

Patient and public involvement

Patient and public involvement began in 2022 during preliminary study development, with multiple meetings gathering input from various organisations. A Critical Advisory Board (CAB), meeting twice a year, provides guidance throughout the study. The CAB includes representatives from patient and public interest organisations. Research findings will be published Open Access for broad accessibility.

Blinding

Due to the open nature of the intervention, neither the participating families nor the study centre staff will be blinded before or after assignment to a group. Unblinding procedures will not be applicable.

Outcomes

Outcome data will be collected at four time points: before discharge (t_0), between days 1 and 14 after discharge (t_1), on day 30 (t_2) and on day 90 (t_3). Physicians, nurses and research assistants will collect data, with contributions from families and additional information obtained from health insurance records. For the intervention group, supplementary data may be gathered during video consultations ($t_{intervention}$).

The primary outcome measures will compare the intervention and control groups in terms of readmission rates and emergency scenarios within 30 days after discharge. Readmission will be defined as any unplanned hospital admission, while an emergency scenario will refer to any instance where parents call emergency services or visit an emergency department. Data on hospital admissions and emergency service use will be obtained from family health insurance records.

Child-centred secondary outcomes will assess developmental, behavioural, physiological parameters and complication rates. Growth indicators, including weight, height and head circumference, will be measured as follows: at baseline (according to medical records) and at three follow-up time points. Medical factors such as complications, medical devices, probes, medications, respiratory diseases and skin conditions will also be examined. Behavioural aspects, including nutrition, drinking behaviour and sleep patterns, will be assessed through standardised questionnaires. Additionally, care indicators will be extracted from medical records. To evaluate early neurological development, the Standardised Infant Neurodevelopmental Assessment will be conducted in addition to two times 30 s short pixelated video sequences with pixelated faces.[37]

Parent-centred secondary outcomes will examine the intervention's effects on parental stress, anxiety and depression, which will be measured using the Depression Anxiety and Stress Scale.[38] Bonding will be assessed with the Prenatal and Postnatal Bonding Scale (PPBS).[39] Breastfeeding self-efficacy will be measured using the Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF NICU) and a self-generated questionnaire including items of SuSue and KiGGs.[40–42] Parental well-being will be evaluated with the WHO Well-Being Index.[43] Self-efficacy and family effectiveness will be measured using the Perceived Maternal Parenting Self-Efficacy tool (PMP S-E).[44] Knowledge levels will be assessed through digital health literacy (HLS19-DIGI) and the Nursing Outcome Classification (NOC).[45 46] User acceptance of the intervention will be measured using the NASA Task Load Index and selected items from the Technology Acceptance Model.[47 48] Since the PPBS, BSES-SF, NOC and PMP S-E questionnaires have not yet been validated in German, they will undergo forward and backward translation before being piloted.

A detailed overview of the different data assessments across time points is displayed in table 1 and the online supplemental material, Assessment Overview.

Plans to promote participant retention and complete follow-up

Parents were involved in customising the intervention from the outset, ensuring it is needs-oriented and family-centred to improve retention. Interim analyses will assess whether the current participation rates will meet the required number of study participants. Daily checks for missing data or irregularities will be performed. Study information will be adjusted as needed to address parents' questions and concerns, in accordance with the ethics application.

Table 1 Study timeline

	Study period				
Time point*	t_0	t_1	$t_{intervention}$	t_2	t_3
Enrolment: eligibility screen, informed consent and allocation	X				
WELCOME (intervention arm)†		⟷	⟷	⟷	⟷
WELCOME (control arm)‡		⟷	⟷	⟷	⟷
Assessments:					
Family history§	X				
Child parameters¶	X	X	X	X	X
Stress, anxiety and depression (DASS)	X	X		X	X
Bonding (PPBS)	X	X	X	X	
Breastfeeding behaviour (BSES-SF NICU+self-generated questionnaire (with items from KiGGS and SuSe)	X	X	X	X	X
Well-being (WHO questionnaire for well-being)	X	X		X	X
Level of knowledge					
Digital health Literacy (HLS19-DIGI)	X			X	X
Level of knowledge Preterm Infant Care (NOC)	X			X	X
Family effectiveness/self-efficacy (PMP S-E)		X	X	X	
30-day readmission and emergency use**				X	
User acceptance (NASA-TLX, 2 items from TAM)				X	
Neurological development (SINDA, general movement videos)					X

*t_0=Before discharge (baseline); t_1=1–14 days after discharge; $t_{intervention}$=Optional additional data collection during each video consultation for the intervention group; t_2=30 days after discharge; t_3=90 days after discharge.
†Data collection for the intervention group is performed by the associated research team at each study location.
‡The control group's data are collected by the study team at each study centre.
§Family history: Family information: Parents' age, siblings, exposures (smoking, alcohol, drugs), infections during pregnancy, medication/caffeine use, infections/pathogens, professional qualifications, language barriers, education level, migration status, residence status, housing situation, marital status, household income, postdischarge care services. Child Information (baseline): Diagnosis, gestational age at birth and discharge, length of hospital stay, age at discharge, birth weight, weight at discharge, birth size, height at discharge, head circumference at birth and discharge, complications/additional diagnoses during stay, access/probes, drainage (drains, stoma), inflammation of puncture site, medical devices, breathing conditions at discharge (oxygen administration), skin condition, drinking behaviour, nutrition.
¶Child parameters: Weight, height, head circumference, excretions, temperature, sleeping behaviour, skin condition, nutrition, medication, drainage, tube, bandages, oxygen, monitor, complications.
**30-day readmission and emergency use: 30-day readmission rate, number of uses of first aid facilities, rescue centres or emergency doctors within 30 days after discharge.
BSES-SF, Breastfeeding Self-Efficacy Scale-Short Form; DASS, Depression Anxiety and Stress Scale; NASA-TLX, NASA Task Load Index ; NICU, Neonatal Intensive Care Unit; NOC, Nursing Outcome Classification; PMP S-E, Perceived Maternal Parenting Self-Efficacy tool; PPBS, Pre- and Postnatal Bonding Scale; SINDA, Standardised Infant Neurodevelopmental Assessment; TAM, technology acceptance model.

Data management

The project partner Institute for Medical Information Processing Biometry and Epidemiology (IBE), as the independent data owner, will be responsible for overall data management, security and storage, following national data protection regulations and Good Clinical Practice. Data will be stored in a secure IT infrastructure at the Chair of Public Health and Health Services Research. The IBE will operate a complete IT system in protected server rooms, meeting the requirements for handling sensitive patient and study data. REDCap will manage the data, which will be stored in pseudonymised form. The decoding matrix will be accessible only to authorised study personnel. Data will be deleted 10 years after study completion. Site personnel will ensure data accuracy before evaluation by the Institute of Health and Nursing Science at Charité. All parties will maintain confidentiality, ensuring no personal data will be disclosed during analysis.

Statistical methods

Primary and secondary outcomes

Data will be analysed descriptively using RStudio.[49] Parametric or non-parametric tests, along with mixed modelling, will be employed to assess differences and perform subgroup analyses. Differences in primary outcomes between groups at t2 will be assessed using appropriate statistical tests.[50] Changes over time in secondary outcomes and the effect of the 'group' variable (intervention vs control) on target parameters will be analysed using mixed models. These models will include time as a categorical variable, the group variable and their

interaction. If the intervention changes during the study, an additional category (eg, intervention-adjusted) may be added, and confirmatory power analysis will be applied. Significance will be adjusted using the Bonferroni correction, and effect sizes will be reported.[50 51] Table 2 presents a sample table of demographic and clinical characteristics.

Additional analyses

Subgroup analyses will be conducted based on clinical parameters (eg, preterm infants) and social factors (eg, socio-economic status, migration status, place of residence). These will primarily be modelled as interaction terms in the mixed models (eg, group×subgroup interactions) to evaluate differential effects of the intervention. Where appropriate, stratified analyses will be performed within subgroups using the same statistical tests as the primary analysis. In the case of small subgroup sizes, non-parametric or Bayesian approaches may be considered. Correction for multiple comparisons in subgroup analyses will be applied.

Handling non-adherence and missing data

Only questionnaire data will depend on protocol adherence, and no missing data will be expected for other regularly collected data. Missing data in patient-reported outcomes will be addressed using multiple imputation. Participants who engage in fewer than 50% of the intervention sessions (<8 sessions) will be considered drop-outs. To reflect real-world effectiveness, an intention-to-treat evaluation, considering all participants regardless of adherence, will be conducted in addition to the per-protocol approach, in which only participants who engaged in at least 8 intervention sessions will be considered, to assess efficacy under ideal conditions. The anticipated drop-out rate will be 10%. The mixed model analysis will handle missing data effectively, reducing bias by using all available data under the missing-at-random assumption.[52 53]

Oversight and monitoring

The project consortium consists of the LMU Hospital as consortium leader, as well as the consortium partners Charité, TK health insurance, Cliniserve GmbH and the Chair of Public Health and Health Services Research at the Institute for Medical Information Processing, Biometry and Epidemiology—IBE of the LMU. Additionally, there is a CAB especially built for the study that performs the supervision of the study and consists of: 'Bundesverband Das frühgeborene Kind e.V.'; 'Bundesverband Bunter Kreis e.V.'; 'HebaVaria e.V.'; 'Förderverein für frühgeborene Kinder an der Charité e.V.'; 'Berufsverband Kinderkrankenpflege Deutschland e.V.'; 'Gesellschaft für Neuropädiatrie e.V.'; 'Harl.e.kin-Nachsorge in Bayern'; 'integriertes Sozialpädiatrisches Zentrum im Dr. von Haunerschen Kinderspital—iSPZ Hauner'; 'Traglinge e.V.'; 'Bjoern Schulz Stiftung' and 'Kindergesundheitshaus gGmbH'.

Table 2 Example of demographics and clinical characteristics

	Intervention	Control	P value
Study centre 1 (n (%)) Study centre 2 (n (%))			
Basic data of included families			
Mother's age at birth in years (mean±SD, range)			
Infection during pregnancy (n (%)) ► Yes ► No ► Not known			
Mother's marital status (n (%))			
Citizenship (n (%)) ► German ► European Union ► Other			
Language of communication (n (%)) ► German ► English ► Other (with translator)			
Highest parental education level (n (%)) ► No formal education ► Primary education ► Secondary education ► Post secondary education ► Undergraduate education ► Postgraduate education			
Net monthly income of the household (n (%)) ► Below €900 ► €900–€1299 ► €1300–€1799 ► €1800–€2299 ► €2300–€2899 ► €2900–€3599 ► €3600–€4499 ► €4500–€5000 ► Above €5000 ► Not specified			
Number of children included per family (n (%)) ► 1 ► 2 ► 3 ► 4			
Basic data included children*			
Sex (n (%)) ► Female ► Male ► Divers			
Gestational age ► Born with 20–29 weeks (Z3A.2) ► Born with 30–39 weeks (Z3A.3) ► Born with >40 weeks (Z3A.4)			

Continued

Table 2 Continued

	Intervention	Control	P value
Birth weight ► Below 500 g (P07.00) ► 500–749 g (P07.01) ► 750–999 g (P07.02) ► 1000–1249 g (P07.10) ► 1250–1499 g (P07.11) ► 1500–2500 g (P07.12) ► Above 2500 g			
Top 5 side diagnoses (n (%)) ► …			
Top 5 complications (n (%)) ► …			
Aftercare services (n (%)) ► Paediatrician ► Midwife ► Social-medical aftercare			

*n between included families and included children is different as some families had twins or triplets.

No separate data monitoring commission will be established. The Institute of Clinical Nursing Science at Charité will serve as an independent evaluator, while the IBE will act as the data monitoring and quality management committee. Independence will be ensured by separating the monitoring and evaluation institution from the intervention sites. Due to its structural separation from clinical care at Charité, the Institute will monitor data collection without conflicts of interest or influence from the funding organisation.

Interim analyses will be conducted after enrolment reaches 25%, 50% and 75% of the target population. These analyses will ensure data completeness, reliability, validity and reproducibility and will allow for adjustments based on the collected data. They will be performed by the IBE, as independent data management partner. Interim analyses will not be blinded, as group allocation is recorded within the REDCap database and is an essential variable for monitoring group-specific data characteristics. Analyses will include descriptive comparisons of demographic variables between intervention and control groups (eg, via data visualisations), quantification of missing data and summaries of completed cases and dropout rates. Interim findings will be made available to all project partners through a secure R Shiny dashboard.

If high dropout rates or adverse events emerge, modifications to the intervention will be considered to improve efficacy, safety and acceptance. The authority to make decisions regarding the continuation, modification or termination of the trial based on interim results rests solely with the project lead. Any modifications to the protocol will follow ethical approval and documentation procedures.

Adverse and serious adverse events will be closely monitored and reported. Cases will be discussed with the CAB, and necessary measures will be taken. Minor adverse events will be reviewed in regular CAB meetings, while serious events will be reported immediately, prompting project adjustments as needed.

Data protection clearance and IT security will be obtained before the trial begins. The Ethics Committee will primarily operate during the approval phase and will not conduct regular oversight meetings. Any protocol deviations, adverse events or ethical concerns will be promptly reported to local ethics committees. CAB audits will occur twice a year—once online and once in person.

Any amendments will be submitted to the local Ethics Committees and updated in the clinical trial registry. Study coordinators will receive daily updates on planned discharges and will arrange for an interdisciplinary team member to inform eligible families about the study approximately 3–4 days before discharge. Interpreters will assist as needed. Families who provide informed consent will be enrolled.

All study data will be used solely for scientific purposes, stored anonymously for 10 years and will not be linked to biological specimens since no biological samples will be collected. Furthermore, data will be collected and stored pseudonymously. Only study team members will access pseudonymised participant data. After 10 years, all data will be deleted.

Risk of bias and mitigation strategies

Several measures have been taken to minimise potential sources of bias throughout recruitment, allocation and implementation. Recruitment is limited to families insured by the cooperating health insurance provider, which may limit generalisability; however, eligibility criteria are applied uniformly across both sites through standardised recruitment materials and staff training to minimise selection bias. Families with language barriers are supported by professional interpreters, and efforts are made to ensure their full participation. Language skills and migration backgrounds will be monitored during the interim analysis. If it turns out specific groups are underrepresented, measures will be taken in consultation with the CAB. Performance bias is addressed through biweekly team meetings, protocol standardisation and staff training. All study participants will be followed according to the same schedule, and adherence to intervention use (eg, platform access, video consultations) will be monitored. Dropouts and reasons for attrition are documented. Analyses will be conducted on both an intention-to-treat and per-protocol basis. Subgroup analyses will examine potential differences by key demographic and clinical characteristics.

DISCUSSION

The WELCOME project is clinically relevant because there are still gaps in healthcare provision in structurally weak areas in Germany.[7 24] Germany lags behind other countries in terms of digitalisation.[54] This is why the development, implementation and evaluation of this

form of digital healthcare are important. Previous studies investigating similar telehealth concepts have shown that implementing telehealth concepts can improve parental outcomes such as depression.[28–31]

The study is expected to provide data on the initial implementation of video consultations with parents of premature and full-term infants in Germany. Assessments will provide insights into child development and parental mental health and well-being.

The intervention is expected to be feasible, with a minimal dropout rate and a high acceptance. However, some factors that can affect the implementation of the study remain. Due to healthcare workforce shortages, filling planned positions might be difficult. Part-time staff or employees restricted from direct patient contact (eg, pregnant staff) could, however, serve as intervention nurses for video consultations. Furthermore, it is unclear whether a sufficient number of families can be recruited for the study, particularly in view of the current decline in birth rates, and whether there will be many dropouts.[55] Moreover, there is a risk that families will receive more care than they need alongside existing postdischarge care services. Different service providers may cover the same topics, which could make them seem redundant to parents. Early risk monitoring during data collection will help minimise those risks. As with any new technology implementation, there is the chance that technical issues regarding functionality and usability may arise. However, project partners have experience integrating new technologies, and potential users will test the chosen system during concept development. The trial has limitations regarding generalisability, as it involved only a specific population within two study centres. Therefore, the findings can only be generalised to settings with comparable conditions. Furthermore, given the extensive data collection, some inaccuracies may occur. However, the study team tried to minimise these to the greatest extent possible through the structured training and education of the care providers involved.

Nevertheless, the intervention offers a centralised platform to support families of newborn and premature infants. This includes video consultations and chats with specialist nurses, as well as an online library containing educational material, tips and contact details for further support. Key strengths include the option of interpreter support for families who would benefit from it, and the technical equipment provided. As this is an additional digital care option, access for rural and socially disadvantaged families can be improved. The RCT design is suitable for assessing the effectiveness of the WELCOME intervention.

Ethics and dissemination

The study protocol received ethical approval from the Ethics Committee of the Ludwig-Maximilians-University Munich (No. 25-0028). Results will be published anonymously in international peer-reviewed journals and will be presented at national and international symposia.

Data availability

The full study protocol, materials and datasets will be available from the corresponding author on reasonable request. All findings, including negative and inconclusive results, will be published in peer-reviewed journals.

Post-trial care

The WELCOME concept supplements standard postdischarge care for preterm and newborn infants with high care needs. It does not alter usual care or pose known risks, so no special follow-up provisions are required.

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Acknowledgements We thank Nicole Herzig and Julia Englisch (TK-Health Insurance) and Julian Nast-Kolb and Quirin Körner (Cliniserve) for their contributions to study development and Theresa Hahn for proofreading the English manuscript. We also acknowledge the ward managers and neonatal nursing staff at LMU Hospital and Charité, as well as CAB members, including: 'Bundesverband Das frühgeborene Kind e.V.'; 'Bundesverband Bunter Kreis e.V.'; 'HebaVaria e.V.'; 'Förderverein für frühgeborene Kinder an der Charité e.V.'; 'Berufsverband Kinderkrankenpflege Deutschland e.V.'; 'Gesellschaft für Neuropädiatrie e.V.'; 'Harl.e.kin—Nachsorge in Bayern';'integriertes Sozialpädiatrisches Zentrum im Dr. von Haunerschen Kinderspital—iSPZ Hauner''; 'Traglinge e.V.''; 'Bjoern Schulz Stiftung'' and 'Kindergesundheitshaus gGmbH'' for their valuable input in the study's development.

Contributors UF, AT, AWF and MC developed the study concept, design and proposal. LS wrote the manuscript. MO, MC, SK, RMSV, AWF, ES, JW, AT and UF critically revised it for intellectual content. All authors approved the final manuscript. The corresponding author and guarantor, LS, confirms that all of the listed authors meet the criteria for authorship.

Funding This work was supported by the Federal Joint Committee (G-BA), Gutenbergstraße 13, 10587 Berlin, Germany, funding ID: 01NVF23107.

Disclaimer The funding comes from a competitive grant of state subsidies from the German Health Fund; the funder is therefore not associated with the sponsor. The funder has no role in the study design, collection, management, analysis and interpretation of data, writing of the report and the decision to submit the report for publication. Public funding is provided indirectly, as the funds are transferred to the project sponsors via the G-BA as an intermediary.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

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