Evaluation of the Heart Observation app – A mixed method study

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Scientific Environment

This thesis originated from the Department of Neonatal Intensive Care and the Department of Paediatric Cardiology at Oslo University Hospital. The project is affiliated with the research group PRECISE at the Faculty of Medicine at the University of Oslo. The supervision was undertaken by Professor Henrik Holmstrøm (HH), senior researcher/Associate professor Elin Børøsund (EB) and Professor Anne Moen (AM). Master student Ingeborg Martinsen Østen (IMØ) contributed as facilitator in focus group interviews, transcription and analysis.

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Anne Moen is a professor at the Faculty of Medicine and Institute of Health and Society at the University of Oslo and do also has extensive expertise in research in digital health care research. She has been my supervisor in both master thesis and a co-supervisor in this PhD project. I am very thankful for your great support in writing applications and your competent and good support in the qualitative parts of the research.

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Sammendrag

Bakgrunn

Å føde et barn med hjertesykdom forårsaker stress og engstelse hos foreldre. Barselperioden kan bli fylt av usikkerhet, avansert behandling og bekymringer for fremtiden. Foreldrene kan oppleve at spedbarnet får symptomer som anstrengt pust, spiseproblemer, avvikende søvnmønster eller at barnet er mye utilpass og misfornøyd som følge av hjertesykdommen. Mange barn med alvorlig medfødt hjertefeil reiser hjem i påvente av kirurgi og videre behandling. Dette gjør at foreldre til spedbarn med hjertesykdom ofte får et ekstra omsorgsansvar, og studier har vist at de har høyere forekomst av angst, depresjon og stress enn foreldre til andre syke barn. Det økte stressnivået blant foreldrene skyldes både barnets økte omsorgsbehov og en usikkerhet om hjertefeilens konsekvenser. Mange foreldre synes det er vanskelig å gjenkjenne symptomer på en forverring av barnets tilstand, beskrive det de opplever og å beslutte hva de skal gjøre. Tiltak for å støtte foreldre i vurderingen av barnet sitt er derfor etterspurt. Barnekardiologisk og Nyfødt intensiv avdeling ved Oslo Universitetssykehus har med bakgrunn i dette utviklet en Hjerteobservasjons-app (HOBS) som har til hensikt å kvalitetssikre utskrivelsen fra sykehus, gi foreldrene relevant og individualisert informasjon samt gi dem beslutningsstøtte hjemme.

Mål

Hensikten med dette doktorgradsprosjektet har vært å beskrive utviklingen og å evaluere gjennomførbarhet, nytte og foreldrestress ved bruk av HOBS. Tre artikler presenterer de ulike trinnene i denne utforskningen:

Artikkel I: Beskriver konseptet, utviklingsprosessen og foreldres og sykepleieres tilfredshet med funksjonene i første versjon av HOBS. Beskriver også forbedringer og tilpasninger av funksjonene i en ny versjon av appen.

Artikkel II: Presenterer en evaluering om bruk av HOBS var gjennomførbar i helsetjenestene rundt familiene og beskriver deretter etableringen av en implementeringsstrategi til en kontrollert studie.

Artikkel III: Evaluerte om standard praksis med skriftlig informasjon i en fysisk perm eller den digitalisere løsningen med HOBS opplevdes som mest nyttig for foreldrene, samt i hvilken grad de ulike intervensjonene påvirket foreldrenes stress.

Metode

HOBS ble utviklet med bakgrunn i et konsept om utskrivningsklarhet basert på overgangsteori. I tillegg til funksjoner i appen innebar HOBS intervensjonen en introduksjon av funksjoner i appen ved inkludering, samt hjelp av barnets sykepleier til å observere barnets baseline og allmenntilstand med

støtte i appen. HOBS ble først evaluert i en gjennomførbarhetsstudie med kvalitative intervjuer. Familiene ble inkludert i studiene mens de var innlagt på nyfødt intensiv på OUS. Barnas alder var under 3 måneder. I *studie I* svarte 9 familier på et spørreskjema om brukertilfredshet og ble intervjuet ved utskrivelse og 1 måned etter hjemreise. I tillegg ble brukertilfredsheten evaluert ut fra 2 gruppeintervjuer med 8 sykepleiere som hadde forskjellige funksjoner i oppfølging og pleie av barna. Intervjuene ble analysert med rammeverksanalyse. *Studie II* evaluerte om intervensjonen var akseptert og gjennomførbar basert på tematisk innholdsanalyse av samme datamateriale. I denne studien ble også helsepersonell som fulgte opp familiene ved lokalsykehus intervjuet (9 sykepleiere, 7 kardiologer og 8 helsesykepleiere). HOBS ble deretter testet i *studie III* av foreldre til 80 barn med alvorlig medfødt hjertefeil. Vi brukte et pragmatisk kontrollert design. Halvparten fikk utskrevet informasjon i en perm og ble inkludert først. Deretter inkluderte vi familiene som fikk HOBS. Foreldrene svarte på spørreskjemaer om opplevd nytte etter 1 måned og om sykdomsrelatert stress under sykehusoppholdet, og etter 1 og 4 måneder etter hjemreise.

Resultater

Artikkel I: Alle barna i familiene (n=9) som fikk opplæring og brukte HOBS hadde alvorlig medfødt hjertefeil ved fødsel. Foreldrene vurderte HOBS til å ha svært god systembrukbarhet både ved utreise og etter en måned hjemme. Funksjonene i HOBS ble tatt godt imot av foreldre og sykepleiere, men noen endringer var ønsket. Ut fra dette valgte vi å legge til en interaktiv sjekkliste for hjemreise og ytterligere individualisere informasjon og innstillinger til barnet.

Artikkel II: Erfaringer fra foreldrene (i studie I) og helsepersonell ble slått sammen og organisert i 4 hovedtemaer: (1) «Individualisering av støtte i starten»; innebar å tilpasse tidspunkt for introduksjon og veiledningsmengde ut fra behov, (2) «Utvikling av trygghet og mestring»; innebar at foreldre opplevde kontroll over situasjonen samt trygghet i å vite hva de skulle se etter, (3) «Normalisere når det er mulig»; innebar et ønske fra både foreldre og helsepersonell om å tilpasse bruken av HOBS etter barnets tilstand, samt (4) «Innføring i en kompleks helsetjeneste»; innebar at helsepersonell var positive til å implementere HOBS og at uerfarne ønsket å bruke appen for egen kompetanseheving. Disse 4 hovedtemaene ble lagt til grunn for gjennomføringen av studie III.

Artikkel III: Vi inkluderte totalt 40 familier i gruppen som fikk skriftlig informasjon i perm og 40 i gruppen som fikk HOBS. Frafall i svar på spørreskjema fra fedre på opp til 74% underveis gjorde at bare svar fra mødre ble analysert. Mødre som benyttet HOBS-appen opplevde intervensjonen som signifikant mer nyttig både ved utskrivelse og hjemme sammenlignet med de som mottok informasjon i perm. På grunn av signifikant forskjell mellom sykelighet i gruppene valgte vi å stratifisere utvalget i to grupper, til de som var ferdigbehandlet og de som fortsatt hadde utfordringer med hjertesykdommen. Etter stratifisering var mødrenes stress-skår i HOBS gruppen kontinuerlig noe lavere, med en liten til moderat effektstørrelse som ikke var statistisk signifikant. Begge gruppene hadde redusert stress 1 måned etter at de kom hjem fra sykehuset, og det var ingen forskjell mellom gruppene i endring av stress fra første måling.

Konklusjon

Dette doktorgradsarbeidet er det første i verden som har evaluert en individualisert mobil-app til spedbarn med et bredt spekter av alvorlig medfødt hjertefeil med funksjoner som hjelper foreldre selv å vurdere forverring basert på barnets egen helsetilstand ved utskrivelse. Prosjektet omfatter hele den komplekse prosessen med utvikling av innhold og utforming av en helt ny app basert på teori om utskrivelsesklarhet. Et grunnleggende prinsipp har vært å hjelpe foreldrene til å bli kjent med barnets fysiologiske reaksjoner og væremåte før utskrivelsen. HOBS har i de tre studiene vist god brukertilfredshet og gjennomførbarhet, og vist seg nyttig for foreldre i overgangsfasen fra sykehus til hjemmet. I tillegg har helsepersonell sett nytten med appen ved utskrivning og oppfølging og ønsker å implementere verktøyet i sine tjenester. Viktige funn som gjentas i de ulike delstudiene er at introduksjon bør tilpasses foreldrenes mottagelighet og at appen bør individualiseres etter barnets helsetilstand. Å muliggjøre deling med partner og å kommunisere direkte med helsepersonell kan øke nytteverdien av HOBS. I tillegg viser studien at økt fokus på forverring før utskrivelse og muligheten til å vurdere barnet hjemme ikke skaper mer sykdomsrelatert stress enn standardoppfølging.

Summary

Background

Giving birth to a child with heart disease causes stress and anxiety in parents. The postnatal period may be filled with uncertainty, advanced treatment and concerns for the future. They may experience symptoms in their infant such as labored breathing, feeding difficulties and general discomfort due to the heart disease. Many children with severe congenital heart defects are sent home while awaiting surgery and further treatment. Previous studies of mental health show that parents of infants with heart disease have higher rates of anxiety, depression, and stress compared to parents of other sick children. The increased stress level is linked to a combination of the child's increased care needs and a sense of uncertainty of the future consequences of the heart defect. Many parents find it difficult to recognize symptoms of deterioration, to describe what they observe and to decide necessary actions. The Pediatric Cardiology and Neonatal Intensive Care Unit at Oslo University Hospital has therefore developed a heart observation app (HOBS) which aims to ensure the quality of the discharge process, to provide information and to offer decision support at home.

Objective

The purpose of this PhD project has been to explore the development of HOBS and to evaluate its feasibility, usability, and effect on stress levels among parents. Three papers address the different parts of this exploration:

Paper I: Describes the development of HOBS and its theoretical foundation. It also explored the usability of the initial features and thereby refined the content and features to fit parents` and nurses' experiences and needs.

Paper II: Presents an evaluation of the feasibility of HOBS in the healthcare services to establish an implementation strategy for the controlled study.

Paper III: Presents the evaluation of whether standard routines with printed discharge information in a binder or the digital solution provided by HOBS was perceived as most useful by parents, and to what extent the different interventions affected parental stress.

Methods

Development of HOBS was based on a concept of discharge readiness grounded on transition theory. In addition to features in the app, the HOBS intervention involved an introduction at inclusion, and assistance from the infant's nurse to observe the infant's general condition using the app. First, HOBS was evaluated in a feasibility study with qualitative interviews. We recruited families while they were admitted to the neonatal intensive care unit at the National Hospital. The age of the infants was below 3 months. In *Study I*, 9 families completed a questionnaire about usability and participated in

an interview at discharge and one month after discharge. Nurses (n=8) with various roles in the follow up and care also participated in 2 focus group interviews. The interviews were analyzed using framework analysis to evaluate usability. In *Study II*, the same interviews of parents and focus group interviews of healthcare professionals were further analyzed using thematic content analysis to evaluate whether the intervention was accepted and feasible. This study also included interviews with health care professionals who followed up the families (9 nurses, 7 cardiologists and 8 community nurses). Finally, HOBS was tested in *Study III* by 80 parents of children with severe CHD. We used a pragmatic controlled design with subsequent groups. All families who received printed discharge information in a binder were enrolled before we started enrollment of families who received HOBS. The parents answered questionnaires about perceived benefit after 1 month and about illness-related stress during the hospital stay, and 1 and 4 months after discharge. We examined differences between the groups and changes in stress over time using statistical analyses.

Results

Paper I: All children in the families (n=9) who received training and used HOBS had severe congenital heart disease at birth. Parents rated HOBS as having very good system usability at both discharge and one month after coming home. The features of HOBS were well received by both parents and nurses, but some changes were required. An interactive checklist for discharge and further individualization of information and settings for each child were among the additions made.

Paper II: We compiled and organized experiences from parents (in Paper I) and healthcare professionals into four main themes: 1) "*Individualizing Initial Support* "; addresses the importance of timing of introduction and the amount of guidance based on individual needs. 2) "*Developing confidence and coping*"; addresses that parents experiences control over the situation and confidence in knowing what to look for. 3) *"Normalize when appropriate*"; addresses that use of HOBS should be adapted based on the child's condition, and 4) "*Implementation in a Complex Service Pathway*"; addresses that healthcare professionals were positive about implementing HOBS and that those with sparse inexperience of CHD wanted to use it to increase their knowledge. These four main themes were used as a foundation for the implementation in study III.

Paper III: We included 40 families in the group that received written information in a binder and 40 in the group that received HOBS. The dropout in questionnaires among fathers was about 74% throughout the study. Hence, only responses from mothers were analyzed. Due to significant differences in morbidity between the groups, we chose to stratify the sample into two groups; those who had completed treatment and those who had sustained challenges with their heart disease. Mothers who used the HOBS app found the intervention significantly more useful both at discharge and at home compared to those who received information in a binder. In the HOBS group, stress scores were consistently somewhat lower with a small to moderate effect size not reaching statistical significance. Both groups had reduced stress one month after returning home from the hospital, and there was no difference between the groups in the change in stress from the first measurement.

Conclusion

This doctoral thesis is the first in the world to evaluate an individualized mobile app for infants with different kinds of severe congenital heart disease with features that help parents assess deterioration by themselves based on the child's own health status at discharge. The project encompasses the complex process of development and design of a completely new app, based on discharge readiness theory. A fundamental principle has been to help parents become familiar with the child's physiological reactions and behavior before discharge. Basing HOBS on the concept of discharge readiness has been useful for designing key features of the app and providing guidance to support its use. In the three studies, HOBS has shown good system usability, been accepted, and proven useful for parents in the transition phase. Additionally, healthcare professionals have seen the benefit of the app's systematic impact on discharge and follow up and are interested in implementing the tool in their services. Key findings across the sub-studies emphasize that the introduction should be adapted to parents' receptiveness, the app should be customized to the child's individual needs, and that features for sharing and communicating may improve the usefulness of HOBS. Increased focus on detecting deterioration and enabling parents to assess their child at home did not increase the illness-related stress compared to standard follow-up routines.

Abbreviations, Terms and Definitions

Abbreviations

CHD	Congenital Heart Disease
HOBS	Heart OBServation App
SUS	System Usability Scale
PIP	Pediatric Inventory for Parents
EPDS	Edinburgh Postnatal Depression Scale
TSD	Services for Sensitive Data
EHR	Electronic health records
HCP	Health care professionals
GA	Gestational age
OUH	Oslo University Hospital

Terms and definitions as used in this thesis

E-health: application of information and communication technology in healthcare. Represents a wide concept and encompasses telemedicine, telecare, mobile health (mHealth), and electronic health records (EHR), and artificial intelligence (AI).

Telemedicine: use of technology to provide medical care remotely. For example, remote consultations, follow-up visits, and monitoring of CHD infants

mHealth: (mobile health) refers to the utilization of mobile devices, such as smartphones and tablets, for healthcare applications. In pediatric cardiology, mHealth has been employed for educating parents and patients, managing diseases, facilitating communication, and remotely monitoring vital signs

Home monitoring: Parents are provided devices that daily measures vital signs, such as saturation, heart rate and weight, and then transmit these data to clinicians on a regular basis. In addition, other devices are used for messaging, video conference and dialog.

Palliative surgery: Refers to surgical procedures that aim to alleviate symptoms and improve the quality of life for patients, without completely correcting the underlying heart defect.

Cardiac impairment: Were defined as reduced cardiac functionality such as significant residual defects, planned or expected cardiac surgery and infants who required medication due to cardiac impairment.

Comorbidities: includes non-cardiac conditions that significantly impact the child's health and development, such as genetic disorders, multiple malformations, and organ failure

Transition: A passage from one life phase, physical condition, or social role to another, resulting in a temporary disconnectedness of the normal way of living, which demands an adjustment of the person and the environment (1)

Feasibility: The possibility, capability, or likelihood of something being done or accomplished. Feasibility is about determining whether a plan or project can be successfully carried out.

Usability: A quality attribute that measures how easy and efficient a product or user interface is to use. It evaluates how effectively, efficiently, and satisfactorily specific users can achieve their goals within a particular context

Acceptability: A multi-faceted construct that reflects the extent to which people delivering or receiving a healthcare intervention consider it to be appropriate, based on anticipated or experienced cognitive and emotional responses to the intervention (2).

Adoption: Refers to the process of accepting, implementing, or starting to use something new. It implies a transition from not using the tool to incorporating it into regular use or practice.

Capability-enhancing decision support tool: Refers to a system or software designed to aid parents (the user) in making informed decisions. Such tools enhance the decision-making process by providing information and insights, effectively increasing the user's capability to make better, more informed decisions.

List of publications

Paper I

Hjorth-Johansen, E., Børøsund, E., Moen, A., Harmens, A., Martinsen, I., Wik, G., Fredriksen, B. E., Eger, S. H. W., & Holmstrøm, H. (2022). Heart OBServation app: development of a decision support tool for parents of infants with severe cardiac disease. Cardiol Young, 1-9. https://doi.org/10.1017/s1047951122002438

Paper II

Hjorth-Johansen E, Børøsund E, Martinsen Østen I, Holmstrøm H, Moen A. Acceptability and Initial Adoption of the Heart Observation App for Infants with Congenital Heart Disease: Qualitative Study. JMIR Form Res 2023; 7:e45920. URL: https://formative.jmir.org/2023/1/e45920 DOI: 10.2196/45920

Paper III

Hjorth-Johansen E, Børøsund E, Moen A, Østen IM, Wik G, Solevåg AL, Eger SHW, Holmstrøm H. An individualised mobile app was beneficial for the mothers of infants with severe congenital heart defects. Acta Paediatr. 2024 Dec 21. https://doi.org/10.1111/apa.17556.. PMID: 39707745.

1. Background

Congenital heart disease (CHD) is one of the most common malformations in newborns. It is still a major cause of infant death worldwide and particularly close follow up is recommended for the most fragile infants. At the same time, deaths often occur in less complex diagnosis and some happen after gradual deterioration at home. To meet this challenge, it is advised to structure discharge preparations and to ensure knowledge about what to look out for. Hence, Oslo University hospital (OUH) has developed a mobile app called the Heart observation app (HOBS) to increase awareness of symptoms of deterioration. This PhD project evaluates if HOBS is feasible and useful without increasing the psychosocial burden in parents.

1.1 Congenital heart disease

Congenital heart disease (CHD) is one of the most common malformations in newborns and the global prevalence of CHD at birth was 1.8 % in 2017(3). In Norway, the reported prevalence is 1.2 % (4), which implies that between 500 and 600 children are born with CHD annually.

CHD contains about one hundred different diagnoses, classified in the International Pediatric and Congenital Cardiac Code (IPCCC) system (5). Combinations may cause complex defects in innumerable variants. Examples of common defects are holes in the walls of the heart, narrow or interrupted blood vessels, defective valves and abnormal connections. CHDs are also classified from mild to severe depending on the expected outcome. Around 20% of all infants born with a CHD have severe CHDs corresponding to 100-120 infants annually in Norway (6). The present dissertation relates to infants with severe CHDs. These infants often exhibit significant symptoms such as low oxygen saturation of the blood resulting in bluish color of the skin (cyanosis), and/or cardiac impairment (heart failure). Interventions, such as surgery or cardiac catheterization may be necessary after birth as well as intensive care and drug treatment. Even after successful initial treatment most of these children need lifelong follow up and some of the most fragile children need repeated surgery during early childhood.

1.1.1 Monitoring symptoms of deterioration

CHD is still a major cause of infant death worldwide, and one of the main causes in countries with high socio-demographic index (3). In Norway, about 10% of children with severe CHD die within the first 2 years of life (7). Recent research shows that 29% of these deaths occur unexpectedly, of whom 60 % (2-3 children per year in Norway) die after a gradual deterioration at home (7). Close follow up is recommended for the most vulnerable infants with certain defects such as single ventricle (SV), particularly hypoplastic left heart syndrome (HLHS). At the same time, most of the unexpected deaths occurred in children with less severe defects. This may be due to lacking knowledge about sudden deterioration among parents, or subtle signs of deterioration in this population (8) . It underscores that adverse outcomes are not confined to specific diagnostic groups and extend beyond those who currently receives home monitoring of vital signs to day (7, 9). Hence, closer follow up has been suggested also for infants with other risk factors, such as persistently low oxygen saturation, staged surgery or cardiac impairment (7). However, home monitoring of an extended group of infants may not be cost efficient (10). The most important response to these findings and recommendations may be careful discharge preparations to ensure that parents know what to look for and what to do in case of worsening (11).

1.2 Psychological adaptation in parents

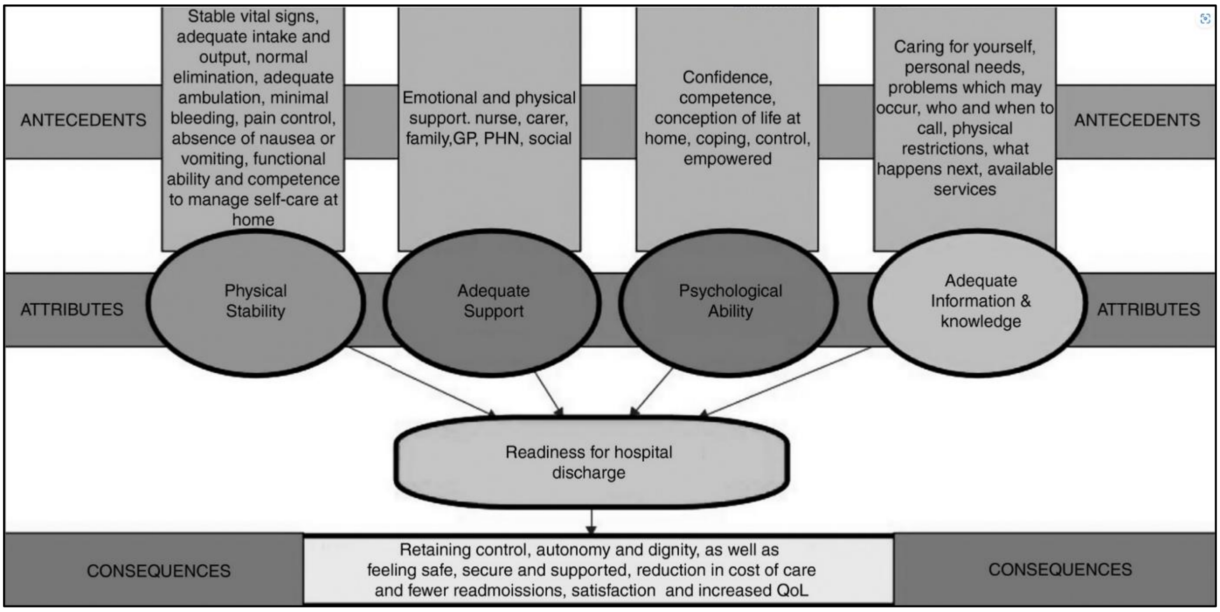
Diagnosis of CHD is very frightening and usually anxiety level, depression symptoms, and stress perception increase in both parents (12). To give birth to a child with cardiac disease replaces the maternity period with heart surgery, intensive care and concerns for the future. Several studies have found that mothers who receive a diagnosis of their infant's condition after birth experience more stress during the maternity period compared to those who receive a diagnosis before birth. However, mothers diagnosed before birth typically exhibit higher depressive scores (13-15). Additionally, mothers of infants with severe CHD have more symptoms of depression that persist over time compared to those with a mild or moderate CHD (16, 17). The differences in stress and depression levels likely reflect the stages of processing the initial shock of the diagnosis (12).

In addition to psychological challenges in the maternity period, parents of infants with CHD are at the risk of prolonged psychological difficulties because of the inevitable added burden of caring for a fragile infant/child (18). Chronic psychological reactions are common and reflected in parental mental health studies, which shows that up to 30% have symptoms of post-traumatic stress syndrome, 25-50% have symptoms of depression and /or anxiety, and 30-80% report stress-related psychological disorders (17). Other research also suggests that maternal, factors such as, worry, mental health, subjective perceptions of severity, and family functioning may be more important than illness severity or surgical factors in determining outcomes regarding behavioral outcomes in children (19), and that parental stress may be of particular concern when the child is <1 year of age (20). As stated by Lisanti: “The link between parental stress and child emotional, behavioral, and neurodevelopmental outcomes should become a priority for research in the next decade”(20). So far, studies of how interventions to families of infants with severe CHD such as home monitoring affect psychological adaptation is scarce (21, 22). At the same time, there is a risk that unnecessary vigilance regarding deterioration using home monitoring may increase the burden of the long-term stress in the family (23, 24). Hence, focus on interventions who may support parents` psychological adjustment both in discharge preparations and post discharge may offer a positive contribution of family adaptation(25). An intervention that helps parents to recognize symptoms of deterioration should therefore balance vigilance and stress to avoid exaggerated vigilance, so that normalization and psychological adaptation can be promoted (23).

1.3 Readiness for Discharge

Readiness is both a state and a process that takes place from admission to post hospitalization. To be ready for hospital discharge is found to be critical for coping after discharge (26). The concept of readiness for hospital discharge are based on Meleis` Transition theory (1), and transition theory is used as a theoretical reference in different kinds of interventions in transitions supporting the CHD population (27-29). Weiss and colleagues (26, 30) has studied the concept related to parents. According to them, readiness is a central component of the discharge planning process and nurses, and other health care professionals has an important role in facilitating this process (30).
In a concept analysis by Galvin et al (31), readiness for hospital discharge is characterized by four core attributes: 1) physical stability and competence to manage self-care at home; 2) adequate support to cope after leaving the hospital; 3) psychological ability to manage the process; and 4) adequate information and knowledge to respond to common problems (Figure 1). She states that if these attributes are fulfilled, the family will retain control and be empowered, as well as feeling safe and supported (31).

Figure 1. Concept of discharge readiness by Galvin (2017)



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1.3.1 The concept of readiness for discharge related to infants with CHD

1) Physical stability and competence to manage self-care at home

Physical stability in infants with CHD may include infants that go home to wait for slow progress of deterioration before pending surgery. In this period some infants are especially fragile and may experience acute admissions from sudden episodes of circulatory collapse or deterioration (7, 9). Awareness of such progress and physical instability is psychological challenging for most parents and are reflected in higher anxiety score in parents of more severe CHD (17). Nevertheless, when the infant and the family are discharged, they need to be prepared and have the competence to manage self-care at home adapted to the present needs and stability of their infant.

The concept of guided participation before discharge is central to support families in developing competencies for care of their infant after hospitalization (32). It includes incorporating parents in all aspects of care so that they know the infant as a person, gives care to the infant, communicate and engage with others about needs, and engage in problem-solving, decision-making and learning. In CHD such participation is described to be used in a home monitoring program to prepare parents to go home and take care of medical administration, monitoring vital signs, nutrition management and wound care (33). Such competence may be facilitated by engagement and participation in care at the hospital trough family centered care (24, 34). Using a family centered strategy and guided participation may ensure that parents and health care providers agree on readiness of discharge, because the perception of this may differ between parents and health care professionals (30).

2) Adequate support to cope after leaving the hospital

Support to cope includes both physical and psychological support and may come from both private, organizational and health care sources. Just knowing about an available support and where to make contact is important and is a facilitator to readiness in general (31)

Specific recommendations to improve support to families in health care services has been included in overarching recommendations to the CHD population from a British expert group (11). To ensure adequate support they recommend structured discharge and transfer of care including a named pediatrician and specialist (liaison) nurse, standard structured discharge document distributed to follow up care teams to enhance comprehension about the infants CHD, and step-down care in all severity groups. To the most vulnerable infants with HLHS and single ventricle they also recommend home monitoring supported by a team (ibid). In addition, information about the importance of support from family and friends may increase the feeling of control and should be communicated to parents (35).

3) Psychological ability to cope in the discharge process

The third attribute is psychological ability to cope in the discharge process. Such ability depends on a sufficient level of energy in patients/care givers, a desire to involve themselves, and an awareness of the benefits of preparations for discharge so they can start to prepare (31, 36).

Psychological ability is especially important to consider in parents of infants with CHD because these parents experience more intense stress than parents of other pediatric populations (20, 37). In addition, mothers in maternity are in an especially vulnerable situation after giving birth and need to recover before they get ready to change from coping at hospital to start planning and managing hospital discharge and care of the infant at home (20, 38). When parents experience a high degree of readiness to change to discharge focus, they may report less depression and may view the infants` condition in a more positive light. If patients experience a low degree of readiness to change, studies find that patients feels depressed, anxious and vulnerable in the face of change (36). According to this, preparation for discharge should be individualized and parent led at their own pace and level of understanding, because too much too soon can overwhelm and destabilize and disrupt readiness(36).

4) Adequate information and knowledge to respond to common problems

The fourth attribute is having adequate information and knowledge and includes information needed to respond to common concerns and problems during the post hospitalization period (31). This includes the possession of knowledge in relation to caring for the infant, medical needs; problems that might occur; who and when to call, what happens next and available services (30).

Regarding CHD parents, a study from 1972 showed that knowledge in parents of children with CHD was poor and that psychological reactions and worries to the consequences of the disease did not correlate with the severity of the diagnosis due to this (39). Later studies continued to document that parents' understanding of their child's cardiac disease was inadequate (40-44). Because of lack of knowledge and the consequences it has for surveillance of infants and parents' psychological well-being, studies have been conducted to explore parents` and health care professionals' views of needs of knowledge before discharge from hospital. Most topics of necessary knowledge was found to be weighted higher by parents than clinicians in one study (45). But, in general, knowledge about the underlying cardiac defect, the goals of the surgical repair, care of the incision, nutritional support, how to administer medications, potential complications and when to call health care provider is deemed important. (45-49). In addition, information about infant development, challenges specific to their infant, and pragmatic strategies to support normal development have been found to be important (48). The importance of recognition of, and response to, clinical deterioration is reflected in a British study (8). In this study, 20 families of infants who had undergone cardiac surgery during the neonatal period were interviewed after acute readmission or death at home. According to the study, many parents found it difficult to recognize symptoms implying that their child's health and wellbeing deteriorated early enough. Moreover, in situations where symptoms were detected, they had difficulty describing them or decide what action to take (ibid).

1.3.2 Readiness for Discharge as a concept to support development of HOBS

A former theoretical description of the concept of readiness for hospital discharge by Weiss (30) has been useful in supporting the development of the "My Heart Binder" which is used in standard care at OUH. Consequently, during the initial phase of developing a mobile application to parents of infants with CHD, Galvin`s refined Concept of Readiness for Discharge was useful to understand identify features and actions that was necessary to achieve our goals.

1.4 Existing digital health in support of parents of infants with CHD

1.4.1 Home monitoring

The most vulnerable infants who are born with hypoplastic left heart syndrome (HLHS) require staged surgical procedures, and between the first and the second surgical procedure these infants have had the highest mortality of all CHD groups. Before 2000, inter-stage mortality ranged between 15-20 %, but after starting with home monitoring with parental daily records of weight and oxygen saturation, followed up weekly by health professionals, the mortality rate was reduced to between 2-20 % (50). This vulnerable group of CHD infants was therefore the first group to utilize digital follow up (in 2014) with digital transfer of patient data within a program called The Cardiac High Acuity Monitoring Program (CHAMP)(50). Later, providers of digital home monitoring systems have expanded home monitoring to other vulnerable infants with single ventricle in the inter-stage period between first and second surgery (51, 52). In 2018 a home monitoring program called REACH was offered to families with post cardiac surgery, but no improvement in mortality, morbidity or psychological adaptation was found (10, 53). In Norway, approximately 2-3 infants with HLHS is given birth each year. Home monitoring with digital transfer of data to be evaluated consecutively by a team, is therefore deemed as too comprehensive to establish due to few patients in Norway. Hence, home monitoring is done manually by a HLHS coordinator. Due to this, developing a new tool in the present project, targeted a broader spectrum of diagnosis and a less comprehensive solution increasing vigilance of deterioration and decision support at home using mobile Health (mHealth).

1.4.2 mHealth in pediatric CHD

Mobile apps present opportunities to facilitate the discharge process and be a source of support at home(54). Such solutions may include parent teaching and decision support with individualized, contextual information at the point of need. A systematic review of available applications for parents of infants in neonatal care prior to developing the HOBS in 2019, revealed that peer-reviewed literature or empirical studies related to such apps was nearly non-existent (55). Applications developed for parents of healthy infants generally took the user to a web site or online articles. Functionality of these apps were limited, with none of them providing customized functionalities (56). Apart from applications used to digital transfer of data within home monitoring programs, we did not identify any mobile applications that covered parents' need of information, decision support and assessment of symptoms of heart disease in infants before starting our development project. Nevertheless, during this PhD project some health care providers have started to develop and evaluate mHealth applications with varying degrees of customization and interactive features to support CHD parents (Table 1).

Table 1. mHealth solutions to support parents with infants with severe congenital heart disease

Name of mHealth (Origin and Reference)	**Evaluation**	**Features**
WeChat (China) **(57-60)**	**Method:** Feasibility study and randomized controlled trials **Results:** Positive attitude to WeChat and positive impact on Knowledge, Quality of life and anxiety post corrective surgery	Training program at hospital. Educational text, pictures and videos and chat with nurses between 18.00-22.00. Not individualized Communication with HCP through various formats (picture, text and video)
Home Care for Heart Health app. (USA) **(61)**	**Method:** Description of development and the program Web site: Home Care for Heart Health — Blake Lane (jblakelane.com)	Evidenced-based intervention with a quick reference guide (binder) for parents of children with CHD, an accompanying app, family-friendly pathways, and clinician education. Not individualized No communicative features
The Healing Hearts at Home Application (HHH) (USA) **(62)**	**Method:** Pilot study of usefulness, stress and coping **Results:** No change Web site: Healing Hearts Home Care - Personalised Home care Services	Includes spiritual care, educational tutorials, tracking of clinical parameters, emotional and psychological support, and follow-up care. Not individualized No communicative features
CHAT2App (United Kingdom) (Christopher Bowers et al., 2024)	**Method:** Feasibility study of proto type and program description CHAT2App	Based on CHAT (paper-based support for monitoring infants with single ventricle) Individualized Video, picture and text communication with an available team
Preparing Heart and Mind (PHM™) (USA) **(63, 64)**	**Method:** Feasibility study, program description and RCT **Results:** No significnat reduction of anxiety, traumatic stress or depressive symptoms after birth. Compared to standard care. Web site: Preparing Heart and Mind	Nurse-guided mHealth care intervention. 2 sessions with a nurse combined with 9 available topics during pregnancy and 1 session with nurse and 6 allocated topics after birth. Aim: Reduce emotional distress and support caregiving for parents with a fetal CHD diagnosis. Not individualized/but specific topics to 17 conditions. Communicative features: text messages

Simultaneously during development of HOBS, digital follow up such as Dignio (65) and Checkware (66), has been adapted to support home care with care plans, video consultations and digital transfer of data in early discharged premature infants at hospitals in Norway (67). So far, these programs do not have a constantly available team for home monitoring and do not support parents with individualized information and specific decision support to the CHD population.

1.5 Addressing the Challenges Identified in transition of Infants with severe CHD from hospital to home

Transition theory, and particularly the conceptualization of readiness for discharge, have as mentioned been used as a framework to guide discharge preparations to parents of infants with CHD at OUH since 2011. Based on this, standard care has been to hand over individualized information leaflets in a binder (The My Heart Binder) in combination with interdisciplinary guidance and care (68) (Appendix 13). Taking into account that infants with severe CHD still died unexpectedly after gradual deterioration at home in Norway (69), and that parents have considerable psychosocial challenges and need for knowledge, it was a clear need to improve quality in our discharge preparations to parents about signs of deterioration in a pedagogical and comprehensive way. When we started the HOBS project it was natural to embed content from the My Heart binder in features in the HOBS app (70). Our hypothesis was that using the concept of readiness for discharge as an underpinning theory to define features in the HOBS intervention could cover most aspects of discharge preparations. In addition, we hypothesized that such a digital solution would be more useful than printed information in a binder and ensure both the safety of the child and not increase the psychological burden in parents if successful.

2. Primary objective and specific aims

2.1 Primary objective

The primary objective of this PhD project was two-fold. First, we wanted to explore feasibility through usability, accept and initial adoption of HOBS in a qualitative study. Second, we aimed to evaluate usefulness and impact on parental stress compared to standard care because increased focus on symptoms of worsening is seen as potentially stressful.

2.2 Specific aims

Specific aims regarding feasibility of HOBS:

Study I - Usability

- To describe the development of HOBS and it`s theoretical foundation in discharge readiness
- To explore the usability of the initial features
- To adapt the contents and features to parents` and nurses' experiences and needs

Study II - Accept and adoption

- To explore parents` and health care professionals` experience of using HOBS during discharge and through health care services
- To prepare a feasible intervention for both parents and health care professionals

Specific aims regarding impact of HOBS:

Study III – Usefulness and stress

- To compare the usefulness of HOBS versus printed information for parents
- To compare parents` disease-related stress when using HOBS versus printed information

3. Method

3.1 Developing and evaluating complex intervention

Complex interventions are defined as interventions containing multiple interacting components (71). Complexity might be inherent in the intervention itself, such as the number of components involved; the range of behaviors targeted; expertise and skills required by those delivering the intervention, flexibility of the intervention; and number of settings it is implemented into(ibid). The HOBS intervention has several components such as flexibility, several users, settings, and components inherent in the intervention and can be seen as a complex intervention.

According to The United Kingdom Medical Research Council`s (MRC) framework for developing and evaluating complex interventions, developing and evaluating such interventions can be considered in terms of phases (71). These phases are not necessarily sequential but should include: 1) Identification and development of the intervention; 2) Assessment of feasibility of the intervention and feasibility of the evaluation design; 3) Evaluation of the intervention and; 4) efficient implementation (71).

The MRC framework also recommend that each phase should include considerations about six core elements:

1. The intervention`s interaction with context
2. Underpinning program theory
3. Diverse stakeholders' perspectives
4. Key uncertainties
5. Refinement of the intervention
6. Comparative resources and outcome

This thesis describes the three first phases of development and evaluation, and in table 2 there is an overview of core considerations and how we have addressed these in each phase.

Table 2. Core considerations in the three phases of evaluation of HOBS

	Phases		
Core considerations	**1.Development**	**2.Feasibility (study I + II)**	**3.Evaluation (Study III)**
Interaction with context	* Define interaction with standard care * Nurses as facilitator	* Implementing actions at OUH, local hospitals, outpatient clinic and community health centers	* Measure adoption and implementation success

	* Physicians as facilitator in outpatient clinic	* Interview guide exploring use at hospital and in follow up	
Underpinning program theory	* Concept of discharge readiness	* The Theoretical Framework of Acceptability * The Consolidated Framework for Adoption of mHealth	*Concept of discharge readiness
Diverse stakeholders perspectives	* Parents, Nurses, physicians, community nurses and liaison nurses	* Interviews of parents, nurses, physicians, community nurses and liaison nurses	*Stress and usefulness measured in parents
Key uncertainties	* Level of decision support	* Feasibility regarding usefulness and usability in healthcare services *Impact on psychological adaption	Verify impact on: *psychological adaption *Usefulness compared to standard care
Refinement of the intervention after completed phase	* Iterative methods during development	* Individualized and interactive discharge checklist *Timing of introduction *Individualize level of assessments *Guideline of introduction to nurses *Tip-leaflet about HOBS to parents	*Add information on how and why to do observations in "Normal to my child" *Guideline to outpatient clinic.
Comparative resources and outcome	* Replace the My Heart Binder with HOBS	Evaluate stakeholders view about replacing binder	Compare usefulness and psychological impact in a controlled trial

HOBS = Heart Observation app, OUH = Oslo University Hospital

3.2 Mixed methods in evaluation of complex interventions

Usually, evaluative designs uses experimental quantitative methods (71, 72.p 49). When the intervention is complex, such as the HOBS intervention, there will often be necessary to understand mechanisms behind the results and why the intervention work or not (71, 73.p 323). The goal with mixed methods is not to use one of the methods to confirm the truth, but to develop knowledge that says more than only one method (72.p 203). In our study of HOBS, we used an exploratory mixed methods design starting with qualitative data collection in a feasibility study with semi structured interviews to explore usability, accept and feasibility of the intervention by parents and health care professionals (study I+II). Thereafter, we continued with a subsequent quantitative phase and conducted a controlled trial to assess usefulness of HOBS and impact on users' psychological adaptation compared to standard care (study III). Using such multiphase design to support the process through development, implementation and evaluation, helped us to include multiple perspectives (74). Table 3 gives an overview of the three studies and their characteristics, design and methods.

Table 3. Study characteristics

	Study design	Participants	Data collection	Analysis
Study I	A qualitative study to explore usability and adapt features to user needs	Families with infants with severe congenital heart disease (n=9)	Semi structured interviews of parents Self-reported outcome measures	Framework method analysis (75)
		Nurses at OUH (n=8)	System use (i.e., log-data) 2 focus group interviews of nurses	
Study II	A qualitative study to explore usefulness and accept of the intervention through the discharge process and after discharge	Families with infants with severe congenital heart disease (n=9) participating in study I Healthcare Professionals in follow up: Nurses (n=9), Cardiologists (n=7), Community Nurses (n=8)	Semi structured interviews of parents and health care professionals Focus group interviews System use (i.e., log-data)	Thematic content analysis guided by Braun and Clark (76)
Study III	A Pragmatic controlled trial with subsequent groups	Mothers (n=73) of infants with severe CHD	Self-reported outcome measures	Statistical analysis using Stata 18.0
			System use (log-data)	Descriptive statistics, bivariate analysis, Linear Mixed models analysis

OUH = Oslo University Hospital

3.2 The heart observation app (HOBS)

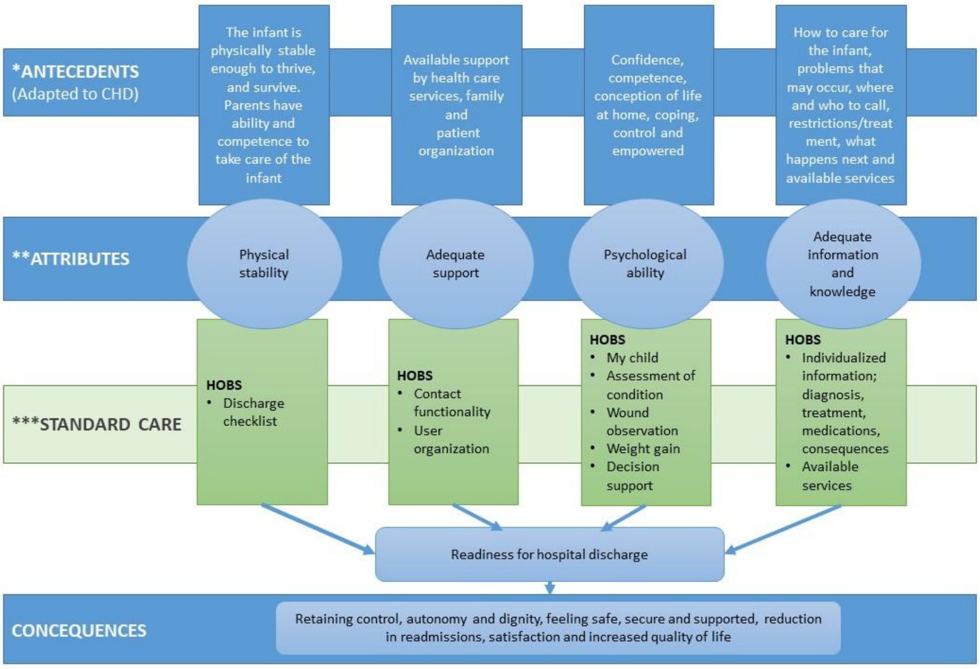
An intervention to parents of infants with CHD aiming to support discharge preparations and decision support at home must include several interacting components. Hence, the HOBS intervention is a complex intervention that includes individualization of content and observations, knowledge of CHD required from nurses, national implementation in follow up, and several aims inherent in the concept of readiness for discharge.

3.2.1 Development of the HOBS Intervention

In the first phase of our project an interdisciplinary group from (OUH)developed the Heart Observation app (HOBS) using an iterative systematic design and evaluation process in conjunction with the considerations in the MRC guidelines (71, 77). To include diversity of stakeholder perspectives we established a multidisciplinary and user-centered project group to guide the development of content and features in the application. In addition, parents of children with CHD, parents of hospitalized infants, nurses and neonatologists at NICU installed a prototype of HOBS and completed assigned tasks. Feedback about the features gave ideas to revision before the usability and feasibility study was initiated.

The application was initially intended as a decision support tool. Due to a key uncertainty, that the algorithms might not catch deterioration without parents` additional interpretation, we decided to design the application to be a capability-enhancing decision support tool. This increased the importance of features to support preparation for discharge readiness (31). The attributes from the concept that seemed possible to address within the scope of the application was to; promote competence to manage the infant's care, make adequate support available, and present adequate knowledge. Hence, features supporting these attributes were intertwined in HOBS (Figure 2). Based on the readiness for discharge concept, expected outcomes were retaining control, feeling safe, secure and supported and a reduction in acute admissions and thereby increased awareness of deterioration without increased stress (Figure 2). As described, standard care includes individualized printed information in a binder. The individualized information is exactly the same in information leaflets as in HOBS and follows the same rules for allocation (68). The My Heart binder was therefore considered as a comparative intervention.

Figure 2. The concept of Discharge readiness and how HOBS features aimed to support its attributes



** Antecedents are adapted to congenital heart disease ** Attributes kept as in the original concept. *** Standard care is an important foundation and includes bedside guidance in infant care, oral information from cardiologist/surgeons and consultations with psychologist and/or CHD liaison nurse. HOBS was expected to structure guidance. Supportive features in HOBS in green boxes.*

3.3.2 HOBS features

After the initial development (phase1), we decided to keep the features described in table 4 and evaluate their usability and acceptability in study I+II.

Table.4. Overview of HOBS features and content (before study I and II)

Feature	Icon
My Child Health care professionals help parents to register diagnosis, treatment, consequences and needs after discharge. These settings individualize a set of observations in 'Normal for my child', questions in the 'Assessment function', and to adapt personalized 'Information.	👶
Normal for My Child Parents select their infant's normal condition and behavior from predetermined alternative descriptions of respiration, circulation, elimination, nutrition, sleeping, and satisfaction. Six to ten categories are individualized depending on expected consequences from the CHD.	👶
Information Based on the settings from 'My child' individualized information is allocated to a reading list. The list contains links to nationally approved information for parents about diagnosis, consequences, medication, treatment, and follow up.	ℹ

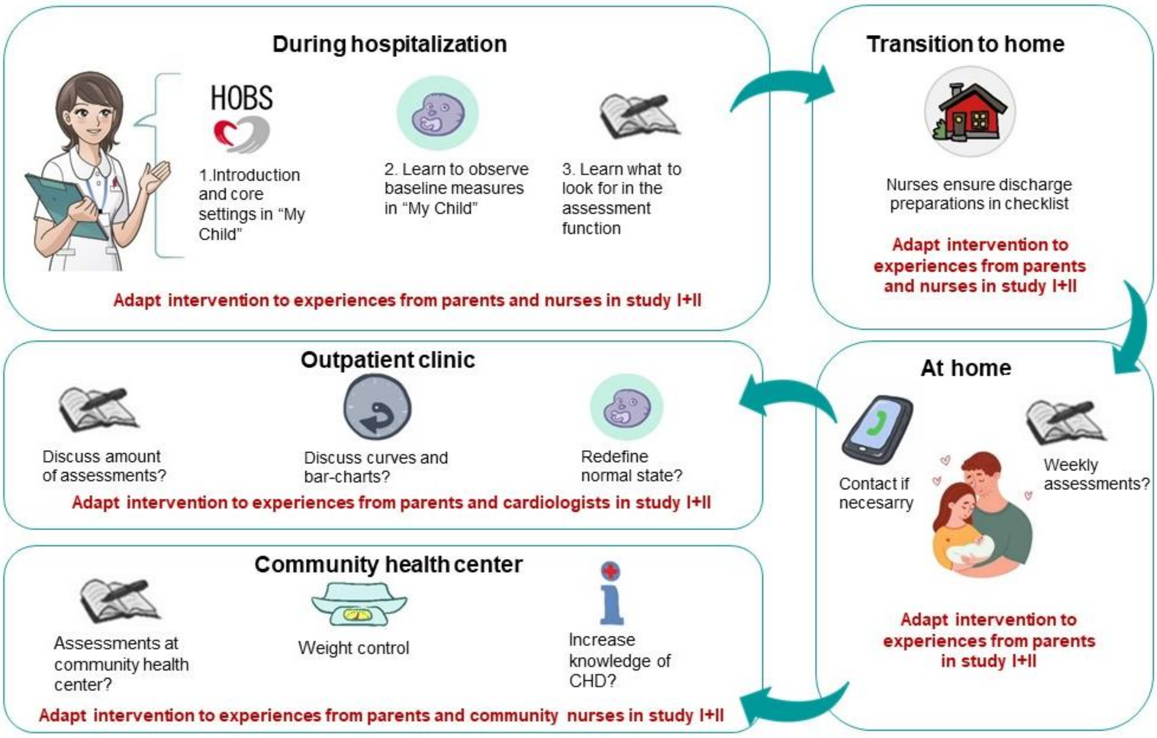
Contact Contains telephone numbers to the specialist center at Oslo University Hospital (OUH), liaison nurses and emergency care. Information about who and when to call on different occasions is explained. At discharge, parents register local telephone numbers to health services. Parents may call directly from the application.	
Assessment function *Assessment of the child after discharge is* based on the infant`s normal condition. Parents receive between 8–14 questions. 1. Parents assess respiration, circulation, elimination, eating, sleeping, satisfaction, and well-being by answering 'yes' or 'no' to questions about deterioration. A tip-button may instruct them on how to do an assessment, how to interpret results, and what to do. In the end of the assessment, they receive a list of symptoms of worsening and a general advice to contact healthcare professionals if they are uncertain. 2. *Wound assessment:* picture tool to observe and compare development of wounds or other visual objects of interest. The tip button provides advice about signs of infection. 3. *Registration of weight and other measurements:* Weight gain is calculated as sufficient or not	  
Summary Provides an overview of completed assessments in bar charts and curves. This feature may support communication about the infant`s condition with health professionals during follow up	
Automatic discharge list to complete settings Disappeared automatically when settings were imputed.	

Source of illustrations: Shutterstock and Flu Hartberg

3.3.3 HOBS in the health care setting

A core element in MRC framework is to consider how the intervention interacts with the context such as standard care and the health care system it was developed for (71). In Norway, Health care services to infants with severe CHD usually starts with an initial hospitalization at the specialist center at OUH. This is the only specialist center that performs heart surgery in children. At OUH, standard care for families of infants with CHD includes bedside guidance from nurses in infant care, conversations with cardiologist/surgeons, and consultations with psychologist and/or CHD liaison nurses. We decided that bedside nurses were the most appropriate health care professionals to guide parents using HOBS. This included an essential, educational part to promote parents' understanding of their child's normal appearance and physiological responses. If necessary, nurses could confer with a physician or the project manager (me). After initial diagnosis, stabilization and initial discharge preparations, OUH transfer infants to their local hospital (19 in total). Here, final recovery after surgery, adjustment in medical treatment and final discharge preparations are completed. Regular follow up after discharge is done at local outpatient clinics. If necessary, local cardiologists refer infants back to the specialist center or receive advice about further treatment. All Norwegian infants also follow scheduled visits at community Health centers for assessment of growth and development. The local cardiologist is the core resource to evaluate the CHD condition while community health center nurses evaluate and support normal development of the infant. It was important to explore the adoption of HOBS in these settings (Figure 3).

Figure 3. Implementation of HOBS to parents and core uncertainties of best practice through the health care pathway in study I and II



HOBS = Heart Observation App, CHD = Congenital heart disease, Source of illustrations: Shutterstock and Flu Hartberg

3.4 Participants in the studies

In all the three studies, families were recruited at OUH after diagnosis, after initial surgery or start of other treatment (figure 4). We included parents of all infants with severe CHD under three months of age and gestational age more than 33 completed weeks at birth. Comorbidity could be present. The exclusion criteria were a primary arrhythmic disease, parents' inability to read, write, or speak Norwegian, and lack of access to a smartphone.

In study I and II, we also included health care professionals to shed light on their experiences and views. This included 2 focus group interviews with nurses at the specialist center and individual semi structured interviews via phone of local healthcare professionals who had followed the families through health care services, such as local nurses, cardiologists and community nurses.

3.5 Implementation of Interventions in the studies

3.5.1 HOBS

Actions to support health care professionals

Implementation to health care professionals was organized by EHJ and supported by the project leader Henrik Holmstrøm (HH) in all phases. In the feasibility study (paper I and II) the implementation strategy was tentative, and we were attentive to responses from healthcare professionals and parents during the study period (table 6). Table 5 shows implementation actions to health care professionals and changes conducted before study III.

Table 5. Actions completed to ensure familiarity of HOBS and supportive all health care professionals

Implementation measures in study I+II	Implementation measures in study III
To everyone	
➢ Website about the project (www.hobs.no)	➢ Continued with updated progression
➢ E-learning about features and tentative tips to guidance available at Læringsportalen (an E-Learning portal used by Norwegian hospitals) and at www.hobs.no	➢ Updated e-learning based on study I+II
	➢ Possibility to upload HOBS on their own phone
At OUH	
➢ Nurses and neonatologists received a 20-30 minute introduction	➢ Updated information at morning meetings with health care professionals
➢ Bedside guidance when needed	➢ Bedside guidance when needed
➢ Bedside checklist	➢ Updated bedside checklist
➢ Phone with HOBS available at the Neonatal intensive care unit	➢ Removed
To local health care services	
➢ Email to local nurses, cardiologist and community nurses that followed up the infants	➢ Email sent to leaders of units responsible for follow up (to local hospital, community health centers and outpatient clinics)
➢ Customized PowerPoint presentation with guidance printed and attached with documents sent to local hospital	➢ Updated: Customized PowerPoint presentation with guidance printed and attached with documents sent to local hospital
➢ A note about settings and completed guidance to parents in electronic health records (EHR)	➢ Continued with notes about settings and completed guidance to parents in EHR
	➢ Possibility to attend digital lectures

OUH = Oslo University Hospital, HOBS = Heart observation App

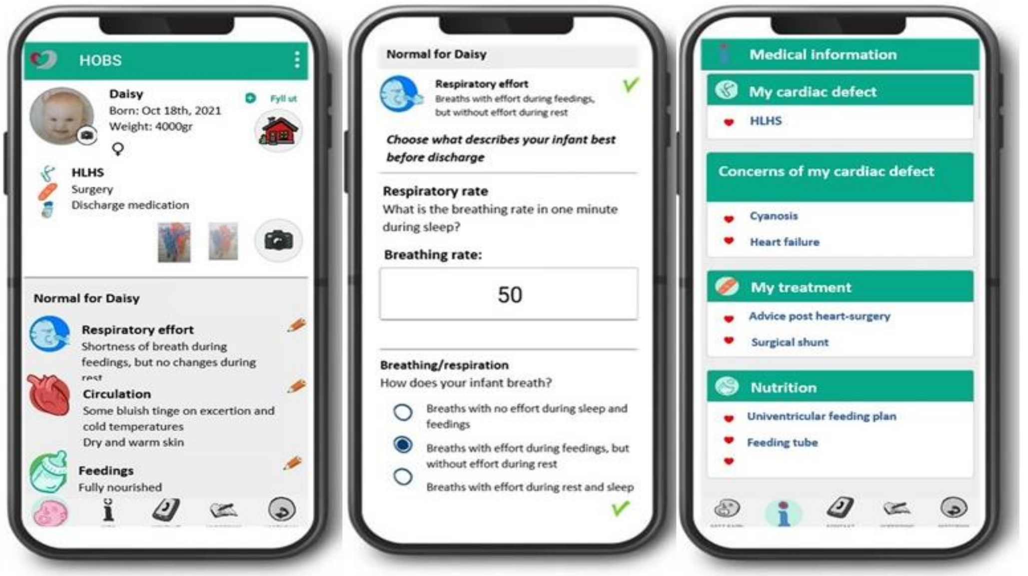
Features and actions to support parents (study III)

The features and the initial implementation strategy to parents was tested in the feasibility study (paper I and II, Table 3 and Figure 3). According to the response in the feasibility study, we made some changes in the application and the instructions for support from health care professionals in the controlled trial. Specific changes in the application prior to Study III were:

- Refinement of categories in the section for normal to my child (image 2)
- Individualized interactive discharge checklist (image 4)
- More specific advice in the assessment function (image 5)
- Embedded list with overview of possible tasks for parents in different stages (Appendix 14)

The final features are shown in figure 4 and supportive actions in figure 5. HOBS was introduced to parents by EHJ before they answered the baseline questionnaires (se figure 4).

Figure 4. Features in the HOBS app in the controlled trial



Daisy
Born: Oct 18th, 2021
Weight: 4000gr
♀

HLHS
Surgery
Discharge medication

Normal for Daisy

Respiratory effort
Shortness of breath during feedings, but no changes during rest

Circulation
Some bluish tinge on excertion and cold temperatures
Dry and warm skin

Feedings
Fully nourished

Normal for Daisy

Respiratory effort ✓
Breaths with effort during feedings, but without effort during rest

Choose what describes your infant best before discharge

Respiratory rate
What is the breathing rate in one minute during sleep?

Breathing rate:
50

Breathing/respiration
How does your infant breath?

○ Breaths with no effort during sleep and feedings
● Breaths with effort during feedings, but without effort during rest
○ Breaths with effort during rest and sleep

✓

Medical information

My cardiac defect
- HLHS

Concerns of my cardiac defect
- Cyanosis
- Heart failure

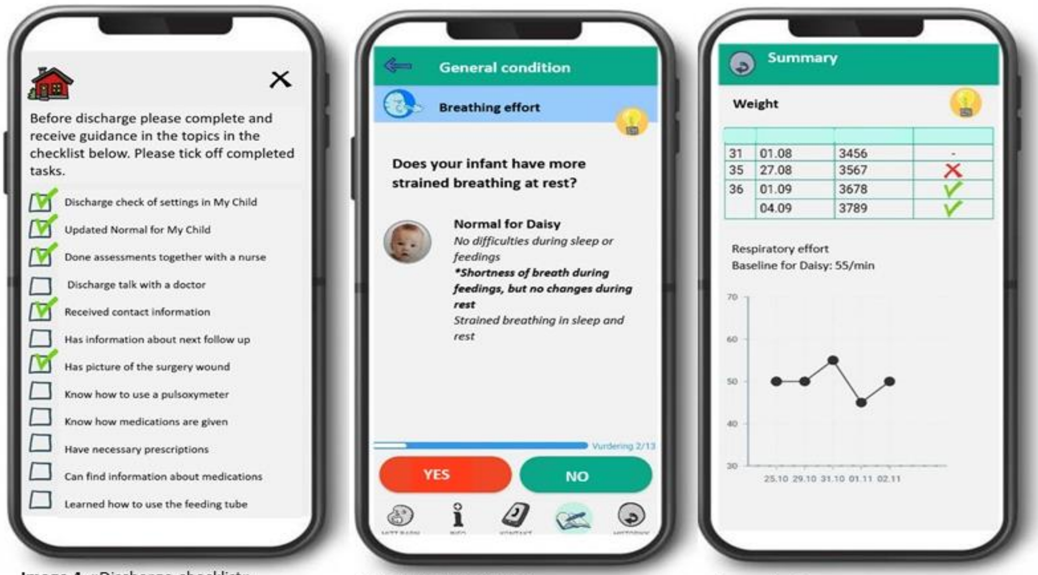
My treatment
- Advice post heart-surgery
- Surgical shunt

Nutrition
- Univentricular feeding plan
- Feeding tube

Image 1. «My Child»

Image 2. «Normal for my child»

Image 3. «Information»



Before discharge please complete and receive guidance in the topics in the checklist below. Please tick off completed tasks.

☑ Discharge check of settings in My Child
☑ Updated Normal for My Child
☑ Done assessments together with a nurse
☐ Discharge talk with a doctor
☑ Received contact information
☐ Has information about next follow up
☑ Has picture of the surgery wound
☐ Know how to use a pulsoxymeter
☐ Know how medications are given
☐ Have necessary prescriptions
☐ Can find information about medications
☐ Learned how to use the feeding tube

General condition

Breathing effort

Does your infant have more strained breathing at rest?

Normal for Daisy
No difficulties during sleep or feedings
****Shortness of breath during feedings, but no changes during rest***
Strained breathing in sleep and rest

Summary

Weight

31	01.08	3456	-
35	27.08	3567	✗
36	01.09	3678	✓
	04.09	3789	✓

Respiratory effort
Baseline for Daisy: 55/min

Image 4. «Discharge checklist»

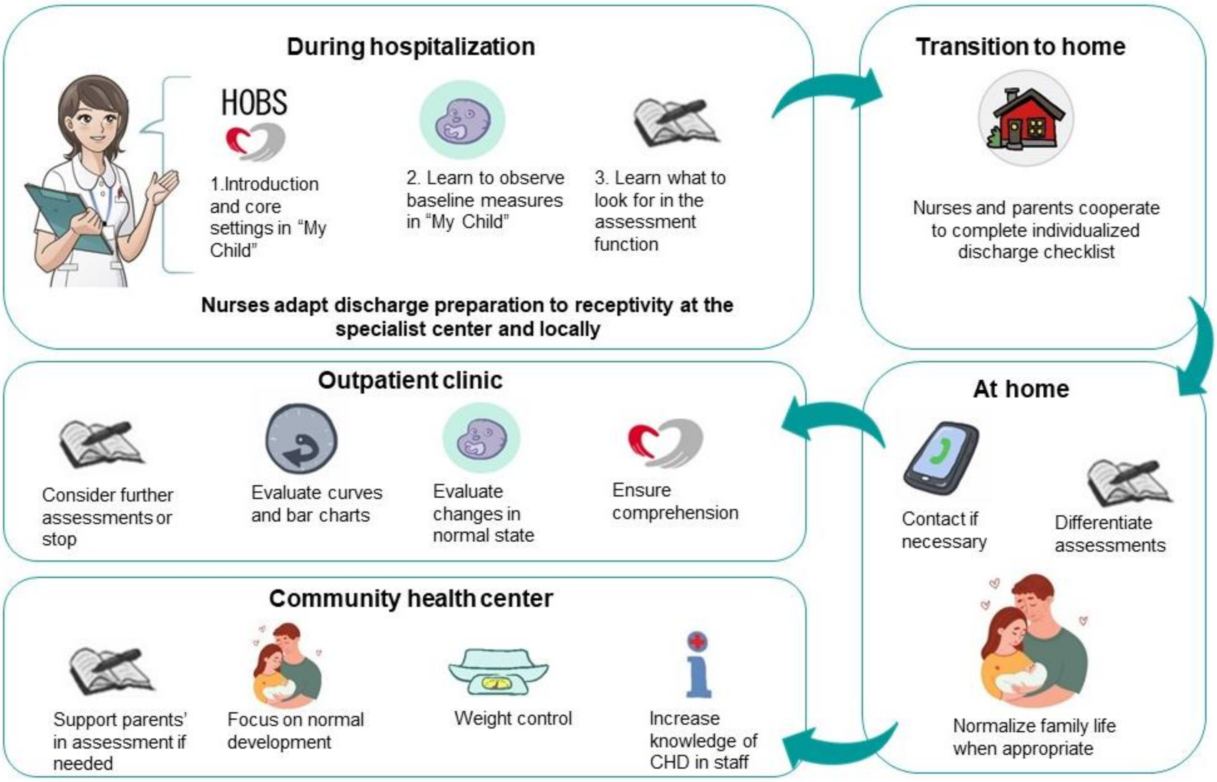
Image 5. «Assessment»

Image 6. «Summary»

Specific changes of support from health care professionals were:

- Adjusting the time of introduction according to parents' receptivity
- List with overview of possible tasks in different stages given to parents (Appendix 14)
- Parents complete individualized interactive discharge checklist in HOBS together with nurses
- Updated bedside checklist for nurses to support parents (Appendix 15)
- Flexible number of assessments at home based on advice from cardiologist
- No regular assessments in community health centers

Figure 5 Implementation of HOBS to parents through the health care services in study III

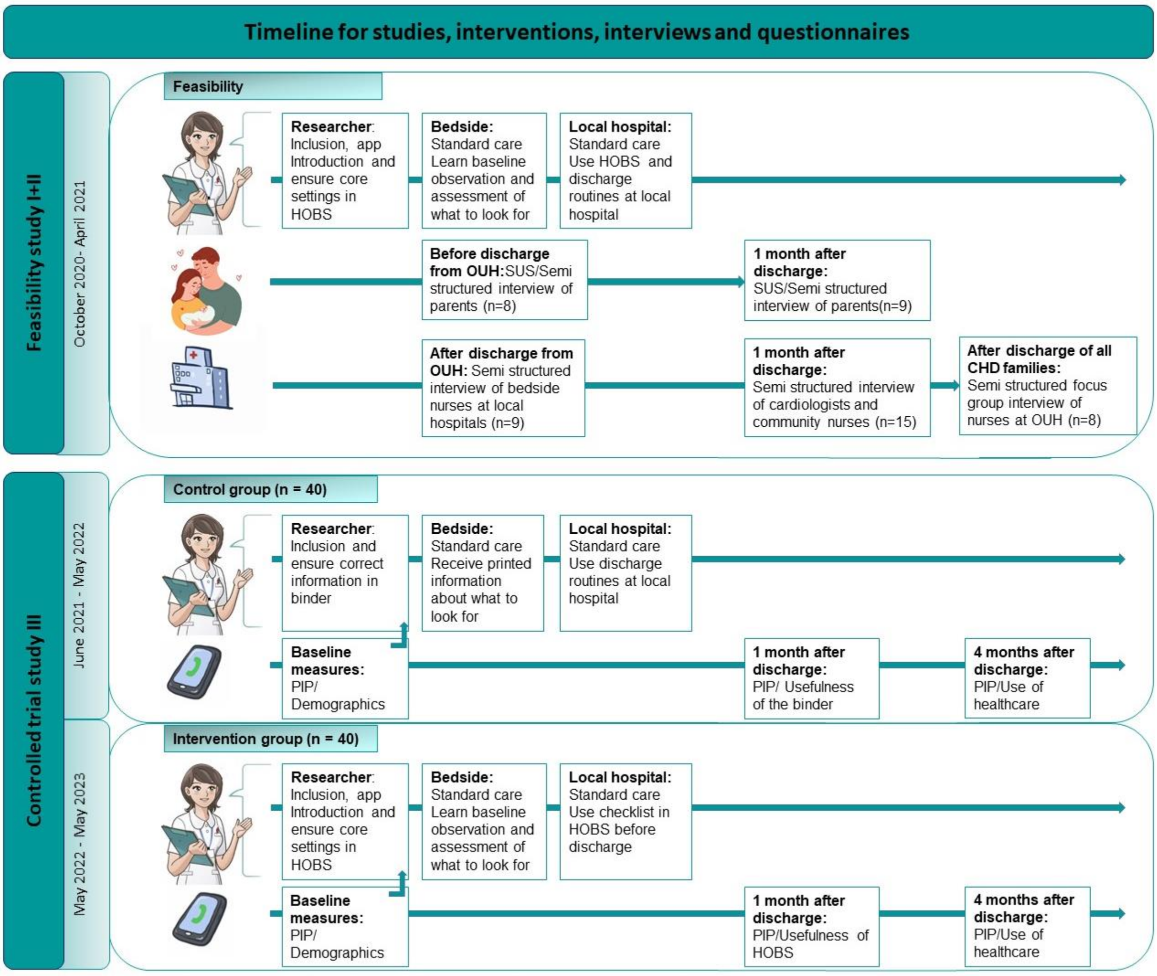


HOBS = Heart Observation App, CHD = Congenital heart disease, Source of illustrations: Shutterstock and Flu Hartberg

3.5.2 The My Heart Binder

In the controlled trial (paper III) the My Heart Binder was given to parents by nurses before they answered the baseline questionnaires (Figure 6). It contained paper-based information about their child's diagnosis, medication, the possible consequences, post-operative care, what to look for, and where and when to call if necessary. As in HOBS, it was individualized to each patient by EHJ. The nurses also provided standard care and guided parents bedside by following a discharge checklist (Appendix 13).

Figure 6. Timeline for interventions and questionnaires in study I, II and III.



OUH = Oslo University Hospital, SUS = System Usability Score, PI = Pediatric Inventor for Parents, HOBS = Heart Observation App, Source of illustrations: Shutterstock and Flu Hartberg

3.6 Data collection in the feasibility study (paper I and II)

In the feasibility study (paper I and II), parents were interviewed by EHJ at discharge, about their initial experiences of using HOBS and about the guidance from health care providers. One month after discharge from local hospitals, EHJ conducted another telephone interview about further experiences (see interview guides in Appendix 5). After both interviews a link to answer the System Usability Scale (SUS) (Appendix 9) was sent by SMS. The instrument consists of 10 items and gives a general score of system usability (78). It has five response options from strongly disagree to strongly agree and total scores with a range from 0 to 100, with 100 indicating the most positive response.

In addition, EHJ and IMØ conducted 2 focus group interviews at OUH, and EHJ conducted telephone interviews of health care professionals following the families at local hospitals and at the community health services (See interview guides in Appendix 6, 7 and 8). An overview of timeline in the studies is found in figure 6.

3.6 Data collection and outcome measures in the controlled trial (paper III)

After all parents had completed their study period in the feasibility study, we started to include parents in the controlled trial. We used a pragmatic controlled trial with consecutive groups due to risk of contamination in guidance from health care professionals and between parents at the common parent room. Hence, we returned to standard care in combination with the My heart Binder and started to include parents in the control group. Simultaneously we analyzed data from the feasibility study to finish refinements in the HOBS intervention in accordance with the MRC guidelines (table 2) (71).

3.6.1 Outcome measures

Parents completed outcome measures related to psychosocial adaptation, and usefulness of interventions in the controlled trial. The following outcome measures were used in Paper III.

Perceived usefulness of interventions

The questionnaire about perceived usefulness of interventions contains seven questions about usefulness of the interventions during discharge and at home (Appendix 10). We developed the questions for the study based on the aims of the interventions. Wording was thoroughly evaluated in the research group. Answers were given on a 5-point Likert scale ranging from one for not at all to five for a very high degree. A total score for usefulness was calculated (range 7–35). If appropriate, parents could choose “not applicable” to ensure validity of the questions (79). Cronbach’s alpha showed high internal consistency (α = 0.88), and factor analysis showed good item correlation (KMO = 0.80).

The Pediatric Inventory for parents (PIP)

The PIP measures parental stress related to children with chronic disease (80). It contains 42 items that are answered on a 5-point Likert scale within four domains: 1) communication, 2) emotional distance, 3) medical care and 4) role function. All items are answered twice, one for frequency and one for difficulty. These 2 subscales make up the PIP total stress score ranging from 84-420. A higher score reflects more disease related stress. The instrument has shown good reliability and content validity (80). The instrument can provide answers about the causes and degree of stress and has shown to correlate significantly with anxiety, stress and depression (80, 81). The instrument was available in English and was translated by EHJ into Norwegian through six recommended steps for cultural adaption of questionnaires (82). Cronbach’s alpha in our study showed high internal consistency for the total frequency and difficulty subscales at baseline, one month and four months after discharge with a α =.95/.95/.96 in PIP-D total, and α =.91/.93/.94 in PIP-F total respectively. In PIP-D sub domains, α ranged between 0.70-0.93 at all time-points and in PIP-F sub domains α was between 0.70-0.84 at all time-points except during admission where the communication domain was $\alpha = 0.56$ and medical care was $\alpha = 0.63$.

3.6.2 User log, received interventions and report on utility of health care services

Details about features used were extracted from user log in the Intervention group. In the control group, parents verified which parts of the intervention they had received. In addition, parents reported use of health care services between discharge and four months after discharge.

3.4 Analysis

This is a mixed methods study, and we used different methods for analysis in each sub-study adapted to the aim of each investigation (table 5).

3.4.1 Framework analysis in study I: Usability of the HOBS application

Framework Analysis Method (FAM), first described by Ritchie and Spencer in 1994 (75), is particularly useful for studies with predefined themes, such as our investigation into the usability of features in HOBS. Essentially, FAM is a content analysis method that involves summarizing and classifying data within a thematic framework. This approach keeps data close to its original form, making it a good choice for descriptive and exploratory studies (83). The six steps of analysis using FAM and how we included this in our study is described in table 7.

Table 7. Framework analysis in study I

	Steps in Framework analysis	*Specific actions in study I: Usability of the HOBS application*
1	Familiarization/transcription	Interview and transcription (EHJ+IMØ)
2	Develop a coding scheme	Predefined themes based on features in HOBS: 1) My child, 2) Normal for my child, 3) measure of condition, 4) wound observation, 5) weight, 6) information, 7) Summary, 8) contact, 9) overall impression and 10) missing features or content
3	Applying codes to the dataset-> indexing	Comments about each feature were interpreted, discussed, and condensed into a meaningful unit as close as possible to its or original form (code) (EHJ/IMØ)
4	Comparison within and between cases	First, data from parents and nurses were analyzed separately. Next, we merged the data sets from parents and nurses and combined them
5	Charting	First we analyzed cases and second by theme to see data across cases under themes
6	Mapping and interpretation	Compare and contrast across cases (EHJ/IMØ). Explore ideas for new features and changes to the existing design. See table 2 in paper 1 for details (The HOBS development group).

EHJ =Elin Hjorth Johansen, IMØ = Ingeborg Martinsen Østen

3.4.2 Thematic content analysis in paper II: Accept and initial adoption

Data from interviews of parents and focus group interviews of nurses were used in both paper I and II, but in paper II data were analyzed inductively. In addition, we analyzed interviews of health care professionals from local follow up. Thematic content analysis, as described by Braun and Clark, (76, 84) was used to analyze the whole data set as described in table 8.

Table 8. Thematic Content analysis in study II

	Steps in Thematic Content Analysis	Specific actions in study II: Accept and initial adoption
1	Familiarizing yourself with your data	Interviewed, transcribed data consecutively, and wrote summary and initial ideas regarding follow up in each case (EHJ).
2	Generating initial codes	Systematically coding interesting parts of the data across data set from both health care professionals and parents, collating data relevant to each code (EHJ+IMØ)
3	Searching for themes	Collated codes into potential themes, gathering all data relevant to each potential theme using word comments (EHJ+IMØ). Transferred interviews and codes into NVivo (EHJ).
4	Reviewing themes	Checking if the themes work in relation to the coded extracts for parents and health care professionals by generating a thematic map (EHJ).
5	Defining and naming themes:	Refined each theme, and generated clear definitions and names for each theme (EHJ, IMØ, EB, AM)
6	Producing the report	Final analysis and selection of quotes, final analysis of selected extracts, evaluating own results in comparison to other literature, The Theoretical Framework of Acceptability and The Consolidated Framework for Adoption of mHealth (EHJ, IMØ, EB, AM, HH). See details in paper II.

EHJ =Elin Hjorth Johansen, IMØ = Ingeborg Martinsen Østen, EB = Elin Børøsund, AM = Anne Moen, HH = Henrik Holmstrøm

3.4.3 Statistical analysis in paper III: Controlled trial

Statistical analysis was performed using Stata Standard Edition (Stata Corp LLC), version 18. Data for demographics, health information, usefulness questions, and the PIP were normally distributed, hence we analyzed those using independent t-tests. For binary variables, we utilized Chi-squared and Fisher’s exact tests. To examine the mean between-group changes in mothers of infants with sustained cardiac impairment in PIP, we employed a linear mixed-effects model. In instances where less than 5% of items were missing for a subscale, we imputed the mean value of the remaining items for that specific subscale (Schulz & Grimes, 2002). To ensure the validity and reliability of the PIP, we conducted a thorough validation process using Cronbach’s alpha for scale reliability, correlations to evaluate discriminant and concurrent validity. To evaluate the construct validity and scale reliability of the questionnaire for perceived usefulness of interventions we applied factor analysis and Cronbach’s Alpha.

4. Ethical considerations

4.1 Consents and ethical approval

The Regional Committee for Medical and Health Research Ethics, Southeast, Norway (2019/1271) and the Privacy Protection and Data security committee at OUH (19/23041) approved the studies. The studies were in accordance with the Declaration of Helsinki (85), and the controlled trial was registered on ClinicalTrials.gov (NCT04315610).

Both parents and all health care professionals provided written informed consent (Appendix 1-4).

4.2 Data protection

All parents in the feasibility study and the intervention group in the controlled trial had to download and log on to HOBS. Before adapting the application to their infant, they were ask to read user terms and accept how we secured data about the infant in the phone and about transmission of user clicks. Usage data were encrypted and sent to an information secured project area at Services for Sensitive Data (TSD) at University of Oslo (UiO). Questionnaires were sent to participants in a link by SMS. Responses were automatically stored in TSD with access for approved members of the project team. Data extracted from EHR, and interviews were stored on a protected area at OUH for sensitive data. Written consents and patient identification numbers were stored in a locked drawer separated from other data.

4.3 Developer as evaluator and conflict of interest

In the HOBS project, I and the main supervisor (HH) were responsible for both development and the evaluation of the intervention. Conflict of interests are often focusing on financial interests but it is also possible that other benefits from developing a successful intervention may have an impact on career and other societal benefits and thereby influence a biased judgement (86, 87). Hence, such desires could increase the risk of bias or poor judgment in the evaluation of HOBS (86). At the same time, it is impossible to eliminate the role of the researcher, and his/her knowledge may increase insight and comprehension in analysis (Malterud, 2021.p 20). In other studies developers as evaluators has been found to increase the likeliness of good results in both qualitative and quantitative research of educational interventions (88). This might be due to enthusiasm and close follow up of implementation by the researcher but at the same time measures to reduce bias and ensure validity and trustworthiness should be considered in the study design (See discussion chapter 6.6.1).

Participants, being aware that the developer is evaluating the intervention, may be more skeptical about giving an honest response. Parents may in addition be skeptical about telling the truth due to further follow up at the hospital developing the application. Hence, the interviewer (EHJ) did not reveal her own role as developer to parents to reduce such an impact. To health care professionals it was impossible to separate these roles due to the needs of guidance and follow up in practice. An important measure was therefore to ask for both positive and negative feedback in interviews of health care participants (Appendix 6).

4.4 Vulnerable study participants

Principle 20 of the Declaration of Helsinki claims that: *"Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research"(85).* Due to this, the HOBS app is specifically aimed at CHD. Hence, it has not been possible to evaluate it by others than parents of infants with CHD. In addition, the intervention is aimed to improve outcomes described in studies that shows unexpected deaths in Norwegian infants with CHD (7, 89) and psychological distress in parents (16). Finally, the results from this study have the potential to improve detection of unexpected deterioration and can be useful for the families and thereby ethically justifiable according to this principle.

Due to high medical vulnerability in the infants we assessed predictable risks and burdens to the infants and their parents (85). Measures to minimize the risks were implemented inherent in HOBS and in follow-up care. To continuously monitor risks and to be able to act on adverse events, we established a link to our project area at TSD. Next, we embedded the link into HOBS, at the website and in distributed project information. All participants and others could report events regarding HOBS and EHJ and HH could immediately receive mail from TSD with a link to such reports. A safety board was established to evaluate events together with EHJ and HH to reduce an eventual bias due to the conflict of interests in events that could occur. Nevertheless, no adverse events were reported.

5. Results

In mixed methods research, meaningful, transparent and clear demonstration of how results from qualitative and quantitative data form a coherent whole might be challenging. To facilitate this integration, it may be useful to use visual joint displays (74, 90). I have used such displays to present results from our specific aims of feasibility and impact, and to bring data together to demonstrate and reveal meta-inferences and to explain how the qualitative and quantitative findings confirm, diverge or complement each other.

5.1 Feasibility

Our first aim was to assess the feasibility of HOBS, and to do this we evaluated its usability and acceptability.

5.1.1 Usability

To engage both parents and the healthcare professionals, it was essential that the system was user-friendly and effective (54, 91). Hence, usability was the focus and aim in paper I. The SUS score was 82.3 at discharge, and 1 month after discharge, it was 81.7. This represents good and sustained usability. The qualitative findings from the framework analysis showed in overall, that HOBS was easy and intuitive to use, the information content experienced as relevant, available and easy to understand, and that existing features was in overall appreciated by parents although some improvements were required. Details of results and refinements regarding each feature are found in Table 2 in Paper I. Joint display of usability data in this thesis is found in table 9.

5.1.2 Acceptability and initial adoption

Our second aim regarding feasibility was to evaluate acceptability and initial adoption (paper II). Parents` and health care professionals` adoption rate and their willingness to integrate HOBS into their daily routines may reflect acceptability and, subsequently, the overall feasibility of the intervention. Qualitative findings in paper II demonstrated a positive attitude to the intervention from both parents and health care professionals. Nevertheless, some adaptations due to experiences such as timing of introduction and individual amount of HOBS assessments was implemented into the intervention supporting HOBS in the controlled trial (Figure 5). Although health care professionals had none or sparse experience with HOBS before the controlled trial, most parents` in the controlled trial reported that health care professionals had given some kind of support before discharge (83-97%) (Table 10). In addition, quantitative results from parents` user log shows higher user rates during discharge and until 1 month, but reduced use after 1 month.

In study III, mothers of infants with sustained cardiac impairment that used HOBS had significantly fewer planned consultations with a cardiologist. In the HOBS group, 12 out of 20 (60%) had ≤ 4 consultations, and 8 out of 20 (40%) had ≥ 5 consultations. In contrast, in the control group, 2 out of 11 (18%) had ≤ 4 consultations, and 9 out of 11 (82%) had ≥ 5 consultations (p = 0.025).

5.2 Impact

After the feasibility study and refinements of HOBS our next aim was to evaluate the impact of HOBS on usefulness and disease related stress in parents.

5.2.1 Usefulness

All three studies focused in some way on the usefulness of HOBS. Qualitative findings from both the usability study in paper I and acceptability and adoption in paper II may therefore enlighten the quantitative findings of usefulness score in the controlled trial (paper III) (Table 11). The mean total score of perceived usefulness in mothers was significantly higher in the intervention group (23.90) compared to the control group (17.0) (Mean difference 6.9, p = 0.001). Cohen`s d was 0.99, which reflects a large effect and thereby shows large improvement (92). At the same time, the usefulness scale ranges from 1 (not at all) to 5 (in a very high degree) and the mean usefulness score of HOBS was 3.4. This indicates that HOBS have good usefulness but not to a very high degree and further improvement could be an advantage.

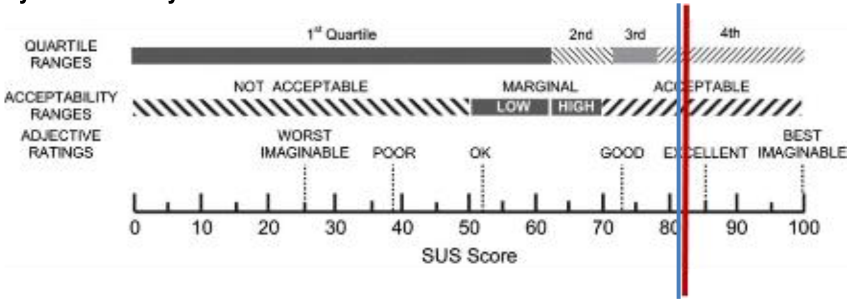
5.2.2 Disease related stress

Both semi structured interviews and questionnaires focused on stress, either related to use of HOBS (paper I and II), or stress related to the infants' disease assessed with PIP in Paper III (Appendix 11). In the analysis of PIP, the groups were stratified on sustained cardiac impairment or not because of the inherent increased stress in taking care of infants with sustained cardiac impairment. In the controlled trial (paper III), there were no significant differences in PIP score between the intervention and control group. The linear mixed effect models showed consistent, but not statistically significant lower PIP scores in the intervention group with a difference in mean of 22.7, 13.6 and 18.9 at baseline, 1 month and 4 months, respectively, with a Cohen's d of 0.45, 0.57 and 0.45 respectively. This is a small to moderate effect size. There was no change in the mean scores between the groups over time. For further details see table 12 in this thesis. In the controlled trial, we observed more unplanned hospital admissions in the HOBS group compared to the control group (p = 0.016) (Table 1, Paper III). However, after adjusting for severity of CHD, this difference was no longer significant (p = 0.25).

5.3 Mixed methods integration

The four joint displays (Table 9-12) show quantitative results alongside qualitative themes and quotes related to our aims of usability, acceptability, usefulness and stress. Mixed methods meta-inferences are displayed in the table and interpretation of these meta-inferences are discussed in section 6.1.

Table 9. Joint display of Usability scores and parents` experiences in paper I

Quantitative results	Qualitative result	Meta-inferences
System Usability Score  **System Usability Score (SUS): At discharge (red line): 82,3 - At 1 month after discharge (blue line): 81.7 (Interpretation: Very good and sustained usability)*	**Overall impression:** * Easy and intuitive to fill out and use. * Helpful and available checklist if needed * Appreciated weight and wound functionality * Information was relevant, available and easy to understand. **Requirements:** * Sharing settings and input with a partner * Nuance some categories in *Normal for my child* * Clearer description of interpretation of what to do about negative measures of increased vomiting and crying	In general, the SUS scores and the qualitative results in paper I confirms each other, that HOBS is an overall easy and intuitive app Some improvements were required in some features which may reflect why scores did not reach excellent

**Paper I = The usability study. For more details about results (77)*

Table 10. Joint display of user log, accept and adoption in study III and parents' experience in study I and II

<table>
<tr><th>Quantitative results</th><th colspan="2">Qualitative result</th><th>Meta inferences</th></tr>
<tr><th></th><th>Themes Paper (II)</th><th>Quotes</th><th></th></tr>
<tr>
<td>Adoption in Health Care professionals (HCP) N=36
<table>
<tr><th>Received HOBS guidance/support</th><th>n (%)</th></tr>
<tr><td>Guided how to observe and assess the infant</td><td>35 (97)</td></tr>
<tr><td>Guided in assessment function</td><td>34 (94)</td></tr>
<tr><td>Supported use of checklist at discharge</td><td>30 (83)</td></tr>
</table>
</td>
<td>Positive attitude in health care professionals
HCP thought HOBS would be reassuring to parents and helpful in their own work.

Systemizes guidance and transfer
Nurses said using HOBS systemized their guidance

Differentiate according to severity
Cardiologists said HOBS could contribute positively in communication about the infant's condition</td>
<td><i>...Before the parents leave the hospital, you may have to go through the app several times, and nurses should have assessed the child together with the parents, really. [N1]</i>

<i>...And well, they do not know the app very well, but they are very positive when they have used it a bit and I have just let them have my phone and check it out. [M6]</i>

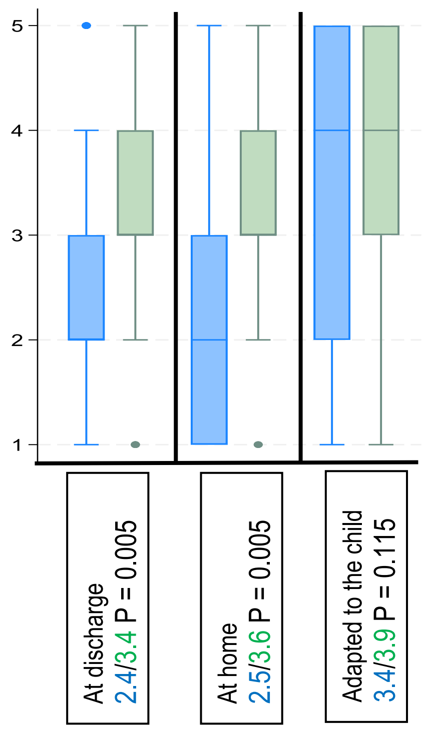
<i>...So, in a way, for those infants who are developing heart failure or have an oxygen saturation of 75%, it is more relevant perhaps, but this baby is doing so very well. (C3)</i></td>
<td>Quantitative reports on support from health care professionals confirm the qualitative findings. HCP are positive and try to adopt the intervention into their usual care to parents, have sparse familiarity</td>
</tr>
<tr>
<td>Adoption and acceptability in parents
<table>
<tr><th>User log from features in HOBS in study III</th><th>Intention-to-treat</th><th>Used, n (%)</th></tr>
<tr><td>Used discharge checklist</td><td>36</td><td>34 (94)</td></tr>
<tr><td>Used contact functionality in HOBS</td><td>36</td><td>27 (75)</td></tr>
<tr><td>Used information links about cardiac impairment</td><td>30</td><td>23 (78)</td></tr>
<tr><td>Completing HOBS assessments first month</td><td>36 (if needed)</td><td>24 (67)</td></tr>
<tr><td>Completing HOBS assessments between 1and 4 months</td><td>36 (if needed)</td><td>15 (42)</td></tr>
<tr><td>Viewing video of respiratory distress</td><td>36</td><td>28 (78)</td></tr>
</table>
</td>
<td>Normalize when appropriate
When the infant's situation was stabilized and parents felt confident in what to look for, many chose to skip assessments using HOBS to normalize the family situation

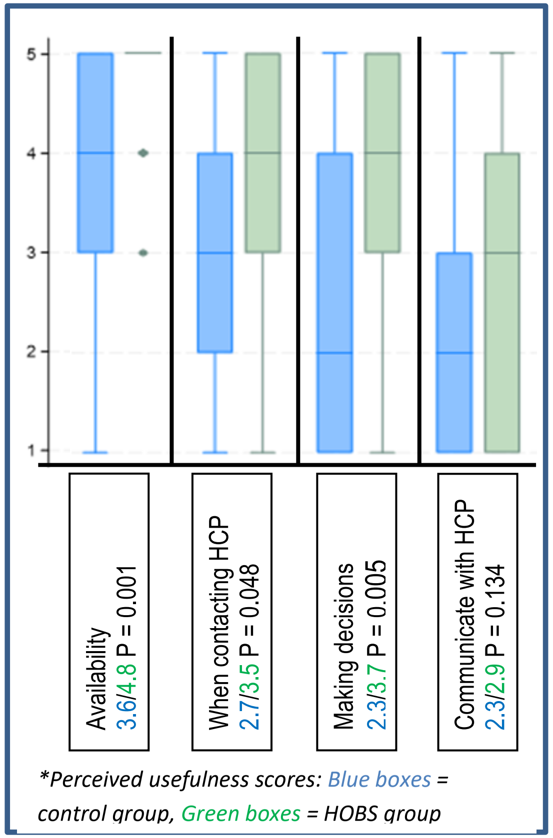
Not an everyday app
Parents chose to put HOBS away, and only use it if something required necessary attention.</td>
<td><i>The app is really quite brilliant when you need it, but when he [the infant] is stable and fine, we don't need it in the same way, but in times when it has been a bit uncertainty and we have something we wonder about, it has been very nice to have as a source of information. [F 10]</i>

<i>"It is not such an everyday app, so therefore I used it when I was a little unsure of something, and to read something" M1</i></td>
<td>In general, the user log assessments and the qualitative results in paper II confirm each other regarding adoption in parents. Both show a reduction in use over time due to a wish to individualize assessments to normalize family life when appropriate.</td>
</tr>
</table>

- *Quotes taken from Paper I and II. M = Mother, N = nurse, C = Cardiologist.*

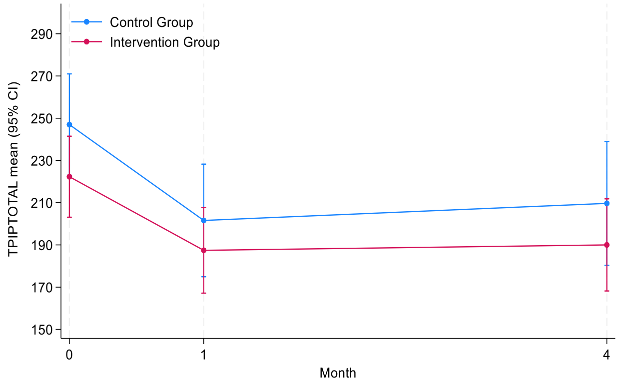
Table 11. Joint display of Usefulness scores in study III and parents ‘experience in study I and II

Quantitative results (Paper III)	**Qualitative results from the Paper I+II** **Themes (paper)**	**Meta inferences**
 *Perceived usefulness scores: Blue boxes = control group. Green boxes = HOBS group.*	**At discharge** **New Functions (I)** Analysis in paper I revealed a need for a discharge checklist. **Systemizes guidance and transfer (II)** Nurses reported that utilizing HOBS in conjunction with parents during discharge preparations provided structure and helped them determine what to include. Parents experienced that HCP were not familiar with HOBS.	Usefulness scores may confirm the qualitative findings that HCP had sparse experience with HOBS, which entailed moderate support to fulfill HOBS actions at discharge. User log (Table 10) confirmed a high degree of utilization of discharge checklist.
	At home **Developing confidence and coping (II)** Parents experienced confidence and coping by gaining control over observations of wound healing, weight gain, whom to contact if necessary, and to find information if unsure. **Checklist supports self- efficacy (II)** Used HOBS as a checklist in the back of their mind for awareness of the infant's condition **Not an everyday app (II)** When the infants had stabilized many chose to skip assessments.	Significantly increased usefulness score at home confirms parents` experiences in qualitative findings, that HOBS increased control over the situation. User log confirmed a relatively high degree of adoption initially and reduced utilization after 1 month (Table 10).
	Adapted to the child **Information (I)** Parents found the information relevant, available and easy to understand. **My child (I)** The “Normal for my child” feature was evaluated to just partly reflect the specificity of their infant.	We expected both interventions to be well adapted to the infant due to similar allocation and good response in qualitative findings. Individualization in my child did not increase experience of adaptation significantly as we expected

 *Perceived usefulness scores: Blue boxes = control group, Green boxes = HOBS group	**Availability** **Overall impression (I)** An available tool that is with parents at all times.	Usefulness score was higher in the HOBS group confirming the qualitative finding that a binder is less available.
	When contacting HCP **Contact (I)** Important to have and to impute contact numbers. Information about contacts at one place. Used in many different ways.	Usefulness score confirmed parents' experience of HOBS as useful when contacting HCP. Log (table 10) showed that most parents used the contact functionality
	Making decisions **Checklist supports self-efficacy (II)** Most parents found that the checklist in HOBS helped them to assess the infant, and for some, it contributed to act on symptoms.	Quantitative results confirmed the qualitative findings that the assessment functionality was useful in decision making.
	Communicating with HCP **Positive attitude in health care providers (II)** Positive attitude in HCP but sparse experience using HOBS **Shared understanding (II)** Cardiologists said that HOBS seemed to contribute in consultations about the infant's condition. Parents were experienced as more informed.	The Usefulness score is discordant with the qualitative findings of expected usefulness in communication. Increased shared understanding may happen based on structured learning even if HOBS is not used as a communication tool. No improvement in communication may imply that utilization and support from HCP is not fully integrated and that implementation in local hospitals probably wasn't good enough (Table 10)
Correlation between total usefulness score and cardiac impairment or not: **r. 0.34 (p = 0.035)**	**Normalize When Appropriate (II)** Parents and HPC focused on the importance to normalize daily living **Differentiate According to Severity (II)** Parents and HCP expressed that use should be individualized according to severity after discharge.	Quantitative results confirmed the qualitative findings that parents of infants with sustained cardiac impairment benefitted more from HOBS than parents with infants with corrected CHD

** Range: 1 = Not at all, 5 = In a very high degree. Range total usefulness score: 7-35. NA= Not applicable. M= mother, F= father, N= Nurse, C= cardiologist. HCP = Health Care Professionals. Quotes copied from paper I and II.*

Table 12. Joint display of disease related stress in study III and parents` experience in study I and II

Quantitative results (Study III)	Qualitative result (study I + II)		Meta inferences
	Theme	**Quotes**	
Graph 1. Trajectory of PIP total score from linear mixed models analysis  *Pip total range: 84-420. Mean difference at hospital admission, one and four months after discharge: 22.7, 13.6 and 18.9 respectively. Cohen`s d = 0.45 during admission, 0.57 after 1 month and 0.42 after 4 months.* *Mean between group change from baseline to 4 months after discharge: 4.2 (-28.9 to 37.2) p=.804*	**Developing confidence and coping (II)** Parents developed confidence and coping by control over observations of wound healing, weight gain, whom to contact, and where to find information using HOBS. Knowing their infants' normal baseline gave confidence in assessments at home.	…It has been my biggest worry to go home when everyday life comes and I am all alone with him. Well, it is very much like that security whether I use it (HOBS) or not somehow, so now that I have it, I keep it in mind as an extra bit of security then (M6).	Quantitative results confirmed the qualitative findings that parents coped better and felt less stressed after a while at home. Quantitative results showed that the same trajectory of stress is found in parents in both groups.
	1. At hospital **Timing according to receptivity (II)** Nurses experienced variance in stress and receptivity among parents. Important to avoid increased burden in an already stressful situation. **2. After discharge** **Developing confidence and coping (II)** To increase awareness of symptoms of deterioration may increase stress and anxiety. Most parents indicated that HOBS increased their sense of safety at home. **Normalize when appropriate (II)** Parents as well as health care professionals focused on the importance of normalizing daily living and individualize use of HOBS according to severity after discharge.	***1. At hospital*** *… Yes, I think it was a bit close to having a sick child. I think it was a bit overwhelming for me. (…) I think in a way you should probably take it (the training) when you get home. When you're kind of ready (M4)* ***2.After discharge*** *…There is a bit of stress in this, but, I think it would possibly have been more stressful if I didn't know what to look for (M2)* *...Absolutely no stress connected to the app at all. Very nice tool. And if there had been problems, or if he [the infant] had had any challenges in relation to an assessment, then it would have been used even more, I am absolutely sure of that. (M3)*	**1. At hospital** High PIP score at hospital confirms that parents struggle with psychological distress during hospitalization. Qualitative findings expanded the importance of timing the discharge preparations. **2. After discharge** PIP scores were lower but not significant, confirming the qualitative finding that most parents felt safe and had control. Qualitative results increase the probability that PIP score might be significantly lower if not underpowered

** PIP = Pediatric inventory for Parents. TPIP total = Total score for PIP. M =mother. Quotes copied from Paper 1 and 2*

6. Discussion

This thesis aims to explore and evaluate if a mobile app based on a theoretical concept of readiness for discharge can be usable (paper I), accepted (paper II) and useful without increasing stress in parents of infants with severe congenital heart disease (paper III). The quantitative and qualitative findings from the three studies are combined in a mixed methods meta-analysis. The results mostly correspond and reinforce each study's conclusions on the feasibility and impact of HOBS. Both system usability scores and qualitative findings documented good and sustained usability, HOBS was accepted and initially adopted by parents in the discharge process, and healthcare professionals were positive and wanted to adopt HOBS in clinical practice. As expected, the user logs in the controlled trial showed more use around discharge, gradually declining over time. This probably illustrates parents' wish and need to normalize family life.

The controlled trial showed better usefulness scores for HOBS compared to printed information, which was confirmed and elaborated by qualitative findings in the feasibility study. HOBS was more useful in discharge preparations, at home, in decision making and when contacting health care professionals. However, the parents did not experience improved communication in contrast to health care professionals' experience of improved and shared understanding in the feasibility study.

Disease related stress was continuously lower in the intervention group, although not significant. Despite uncertainty in quantitative results, the qualitative finding confirmed that most parents felt safe and experienced control which may reflect less stress. Qualitative results increase the probability that PIP score might be significantly lower with a properly powered sample.

6.1 Discussion of main findings

In the following section I will discuss the usefulness of HOBS` and its impact on parental stress, and how this may relate to usability, accept and adoption. The HOBS application is something in between a home monitoring program with data transfer to EHR and digital educational information. I have not found other solutions in the research literature that have the same combination of features as HOBS. Hence, a direct comparison of usability to other solutions is difficult. Therefore, this discussion will connect our findings with features in other solutions evaluated in the research literature and to concept of readiness for discharge. Finally, I will demonstrate how HOBS may have supported parents based on this framework and propose ways to improve HOBS or similar digital tools based on our findings (7.1).

6.1.1 Usefulness

Our hypothesis in the controlled trial was that an interactive mobile application aiming at increasing discharge readiness and decision support such as HOBS would be more useful than printed information in a binder. Usefulness scores from the controlled trial of HOBS showed an overall improvement and confirmed this hypothesis (paper III). In addition, qualitative findings supported and complimented these results (table 11). Important aspects to discuss regarding usefulness are the importance of individualization, the usefulness in discharge preparations, decision making, communication and support.

The importance of individualization

The HOBS app offers a high degree of individualization in all features, such as in the information, observations, assessments and the discharge checklist. This individualization was clearly appreciated and accepted by parents in our feasibility study. In other studies individualization has been required from parents to enhance usefulness (54, 62). It is also in line with the patient-centered approach to mHealth, which emphasize individualization and integration of mHealth into the patients' treatment plan (54), and the fourth attribute in the concept of readiness for discharge which emphasize personalized information and knowledge (31). In addition, individualization may improve acceptance in users (2).

An important and novel aspect of individualization in HOBS is helping parents to understand what is normal for their child (11). The solution for registration of a baseline and the possibility to assess changes from it, was the most challenging to develop due to the diversity in human appearance and the inflexible digital format. This challenging adaptation was reflected in parents' wish for more categories in normal for my child (Paper I), and in one mother who felt that her infant's shifting appearance was stressful to define and assess (Paper II). Although appreciated as good support for assessing the child, this did not increase the experience of individualization in our quantitative results (table 11). Nevertheless, parents appreciated the possibility to set a baseline for their child as a feature that gave them control over the infant's normal condition. It increased their awareness of what to observe in their child, thereby providing them with adequate knowledge, which is identified as important in the concept of readiness for discharge (31). At the other hand, choosing between categories may have reduced parents` experience of a true description of their infant and thereby reduced experience of usability of the individualization (paper I). Recently, video recording of infants during sleep is proposed as an alternative to individualize the infants` baseline, which may increase comprehension of changes even more (93).

Usefulness in discharge preparation

In our feasibility study, the final inductive analysis of feature usability resulted in making the existing discharge checklist more individualized and interactive, which aimed to enhance parents' sense of empowerment. This was done to complement the first attribute in the concept of discharge readiness which emphasize parents ability and competence to take care of the infant (31). The assumption was, that if parents became involved and had to agree that they had fulfilled tasks and were ready for discharge, they would be more aware of discharge requirements and feel more prepared (34). The discharge checklist was not evaluated in the feasibility study, but as shown in user-log data, it was adopted and used by most parents (94%). The usefulness score significantly increased in the HOBS group compared to the Binder, but if this feature had impact on usefulness is uncertain. We found no other studies testing digital discharge checklists in the literature, but a printed solution used to prepare parents prior to home monitoring of infants. It contains of several steps ("Stepping Stones to Home") where parents confirm knowledge and ability through teach back at each step (33).

Results in our study verified that most parents received help from health care professionals. At the same time, the quality of this support is uncertain because health care professionals were unfamiliar with using HOBS (paper II). Although nurses expressed that HOBS structured their guidance, lack of knowledge about CHD may reduce the ability to support parents properly (paper II). Nevertheless, other studies of discharge readiness have shown that quality of discharge teaching have significant impact on readiness, which again leads to reduced coping difficulty after discharge (94). As described in the MRC framework further thorough implementation of HOBS after the last refinement have finished is important (71). Based on study findings, a final refinement in HOBS has been to embed tutorials about how to observe and set the normal baseline for the infant. In addition, a resource group is established at OUH to provide most of the guidance and to support nurses with sparse experience of CHD and HOBS.

Usefulness in making decisions

An important aspect of caring for vulnerable infants is having the knowledge and ability to detect signs of deterioration (69). In our mixed-methods study, most parents found HOBS to be useful in making these decisions. In most home monitoring programs for the most vulnerable infants, healthcare professionals make these decisions together with parents based on received data (50), and some of these programs use a deterioration score to support decisions (95). Because home monitoring wasn't feasible in Norway, we developed a capability-enhancing tool. This may have resulted in a lower usability score, as receiving calculated results with recommended actions at the end of an assessment could be less complicated to comprehend. However, automatic response could simultaneously increase the risk of receiving invalid recommendations.

In the CHD population different levels of vulnerability is present, and as shown in meta-inferences in table 10, parents did not need the application daily. They wanted to normalize family life without focusing on symptoms of deterioration if possible. Hence, the number of assessments and follow up from health care services should be differentiated (paper II). These results support the recommendations from a British expert group, stating that all parents should have access to a tool that helps them to decide if their infants need health care assistance, because death occurs unexpectedly and not necessarily in conjunction with the most severe CHD (11). Therefore, parents of infants with surgically corrected defects could benefit from receiving individualized educational information. In addition they should learn how to observe their infants based on a normal baseline if necessary (11). In the other end of the scale, especially vulnerable infants such as those with HLHS should be offered additional support with home monitoring with a possibility to transfer data, but not to solely expect timely response from a health care team (11, 93).

Communication and support from others

In our qualitative findings in the feasibility study, both health care professionals and parents expressed shared understanding due to content in written information and more structured and objective assessments. Nevertheless, an improvement in communication with health care providers was not verified in the controlled trial. This may relate to a complex implementation of a complex intervention in a pragmatic designed study (71). Most health care professionals had sparse or no experience using HOBS in their communication, and because of this they may have forgotten or refrained to ask for HOBS assessments. Lack of such follow up by health care professionals may reduce both use and experience of mHealth as useful (54, 91). Our qualitative findings of improved communication seen from the cardiologists' view, may therefore stem from more structured knowledge at discharge of what to look for, even if HOBS was not used as a tool in consultations at the outpatient clinic.

At the same time, lack of a possibility to share data to the EHR could also be one of the reasons for the lack of improvement in communication and only a borderline significance of improvement when contacting health care services (table 12). Although this was not mentioned in our interviews, other studies have found that transmission of results, pictures and video consultations are requested and may clarify communication in follow up (59, 93). In a country like Norway, were especially fragile infants with CHD are sparse and receive follow up from 19 different hospitals a continuous available team is not applicable, but features supporting video communication, chat and picture transmission could probably improve communication (59). At the same time, such features may increase the experience of being supported as mentioned as important in the concept of readiness for discharge (31).

Additionally, the concept of discharge readiness, emphasize that support from their partner is very important and enhances coping after discharge (31, 96). Hence, in addition to features that improve communication with and support from health care professionals, parents should be given the opportunity to share app content and assessments to support each other, and to be able to present all data together at the outpatient clinic even if only one parent are present. The total usefulness score of 3.4 may partly reflect that the ability to share input and settings with a partner were required from parents but not implemented. This functionality has been highlighted in other studies (93), and incorporating it would likely have significantly improved the parents' experience of feeling supported, which is a key aspect of the concept of discharge readiness (Figure 2)(31).

6.1.2 Disease related stress

In our qualitative findings most parents expressed that they felt safe and confident using HOBS. At the same time, doing an assessment was a bit stressful, although knowing what to look for was reassuring (paper II). These findings were confirmed in our controlled trial, which showed that disease related stress did not increase in parents with cardiac impairment despite increased focus on symptoms of deterioration in HOBS (paper III). It also showed that both the control and intervention group reduced their stress levels significantly from admission to one month after discharge.

In other studies of disease related stress, mothers of infants with more severe CHD have significantly higher PIP score than mothers of infants with corrected heart effects (17, 97). Hence, significant differences in severity between the groups in our study made it necessary to stratify our sample, which reduced the statistical power. When stratified, mothers of infants with sustained cardiac impairment in the HOBS group showed a constantly lower, but non-significant, PIP score from the first assessment until four months (Table 12). Considering the current modest sample size, moderate effect size between 0.42-0.57 increase the probability that PIP score could be lower in the HOBS group with a properly powered sample (98). In addition, the qualitative findings that parents felt confident may support this assumption. Another limitation in this result is that parents received interventions before answering the baseline questionnaire (99). Hence, HOBS may have had an impact on parents` expectation for managing observations already from baseline, or possibly, groups may have differed already in advance.

Nevertheless, an overarching goal of the HOBS project was to reduce acute admissions and death and the intervention group had significantly more unplanned admissions (paper III). Such outcomes are shown to occur in infants with sustained cardiac impairment (69), but at the same time, unplanned hospital admissions may also reflect hyper vigilance in parents. Due to the uncertainty of the origin of the increased unplanned admissions, we examined it closer in this thesis with further statistical analysis, and as described in 5.2.2, unplanned admission where not different between the groups in infants with cardiac impairment. At the same time, visits at the outpatient clinic were significantly lower in the HOBS group. This may reflect that the cardiologists expected parents to be more aware when using HOBS and changed to a less intense consultation-schedule. This change of practice is further reflected in initiatives from cardiologists to start parent-controlled consultations with support from HOBS after the present study.

In general there are few studies regarding the impact of home monitoring and mHealth interventions on stress among parents of children with CHD (96). So far comprehensive interventions with close follow up and monitoring do not necessarily reduce the stress levels (100). For example, a home monitoring program with daily assessments and follow up from a team twice a week, did not reduce stress in mothers of infants after cardiac surgery compared to regular assessments without follow up from a team (10). At the same time, another study concluded that stress and anxiety correlated with perception of how well the child is doing physically (100), and perception of the infant`s stability may be affected by demands of doing regular assessments. In contrast, studies of the WeChat in China, of parents with infants with less severe CHD, have shown reduction in depression, anxiety and stress compared to written information in a leaflet (57, 58). Parents in these studies had no assessment schedule to follow but could chat with a nurse every evening if they needed. Another program from USA, called “Preparing Heart and mind”, reduced psychosocial distress in parents before birth, but did not after birth although their focus was to reduce such distress (63, 64). Our own results are uncertain when it comes to reducing stress. However, our findings in the feasibility study is in line with other studies that parents wants to stop doing assessments if possible, because doing it was found to be stressful and a constant reminder of the infants vulnerability (93, 101). This may partly explain that adherence of daily assessments has been an important challenge in home monitoring of infants with single ventricle and HLHS (102). Such parenting has been described as parenting under pressure and increased/hyper vigilance is seen as an inevitable burden that parents have to live with (18). To balance the need of assessments to ensure the child’s safety and to reduce parents stress by reduce assessments is a difficult balance, but a recent study found no association between adherence to assessment in home monitoring and interstage mortality (103). This may support the assumption that if parents are competent and know what to look for, they may find good support in a decision support tool such as HOBS. Such a tool can help them detect changes in their infant’s condition and contact healthcare professionals when needed (11).

Access to healthcare support when needed can potentially reduce stress (31, 57, 58). However, regular assessments may inadvertently increase stress by highlighting the infant's vulnerability regardless of the availability of healthcare professionals (10, 23, 54). Therefore, an individualized approach should be implemented tailored to the severity of the CHD. This could reduce unnecessary number of assessments and may balance the safety of the child and the impact on parents stress.

6.2 Methodological considerations

As shown in my presentation of this study, it`s methods and results, there are several methodological limitations and uncertainties to discuss which have an impact on our certainty in conclusions and possibility to generalize findings to other settings.

6.2.1 Validity and trustworthiness when using the developer as evaluator

In qualitative research, it is essential to account for the researcher's position and role by writing a reflexive analytical text that explains how inferences are drawn from the data (73). When reporting results, evaluators must clarify their own position, methodological choices, and theoretical approaches to justify their data interpretations (104, 105). My position in the HOBS project was that I joined the project due to the findings of unexpected deaths in CHD infants and the interesting possibility to support parents in a more interactive and modern way through mHealth. At the same time, I was concerned that more focus on doing assessment could increase worries in parents of infants with CHD. Hence, I insisted on doing a thorough evaluation of the outcomes of the project through a doctoral thesis. The fear of increasing the burden to parents has therefore been an important preunderstanding to many of the choices in both development and evaluation of HOBS (72.p 44). Additionally, my theoretical starting point in the concept of readiness for discharge used in standard care(31), the binder and HOBS affects both the study design and data interpretation (72.p 44, 73.p 276).

In both qualitative and quantitative evaluations the researcher's may introduce bias, but at the same time, it is impossible to completely eliminate the role of the researcher from a study in general (88). A disadvantage if using the developer as the evaluator could be a desire to interpret results in favor of the intervention, but an advantage of using the developer as evaluator is that the researcher’s knowledge of the field may increase insight and comprehension in analysis (72.p 20). Nevertheless, in a complex intervention like HOBS, the evaluator's goal should not be solely to approve or reject the intervention. Instead, the focus should be on assessing the various outcomes and findings that may emerge and presenting the results as part of an intervention-theory along with key outcome variables (71).

Many researchers argue that bias is particularly crucial to consider in qualitative research due to the presence of multiple interpretations (72.p 193, 105). However, qualitative research shares the same scientific principles, such as systematic and reflective knowledge development, with processes open for discussions and opposition (105). Hence, to increase the trustworthiness of interpretations and results transparency in data analysis is important (105). To increase transparency we have analyzed data descriptively which may be more close to raw data and reduce the disturbance of my own preunderstanding (72.p 48). In addition striving for openness and transparency by explicitly documenting choices, steps, and decisions enhances trustworthiness and allows other researchers to examine the process (106). This includes accounting for deviant cases and disconfirming data in the interpretation. When writing up results, researchers should provide evidence or quotes to support their interpretations and inferences (73.p 274). In the present study, all these actions are strived for in paper I and II (70, 77).

Another core strategy to perform rigorous research is to use triangulation to enhance validity. In this thesis, I have applied different types of triangulations, such as method triangulation by including both framework analysis and thematic content analysis in interpretation of qualitative data. Additionally, I employed a mixed methods design, combining qualitative and quantitative results in joint tables, and "source triangulation" by interviewing both parents and health care professionals from various disciplines. This approach was taken to thoroughly explore the experiences of using the new intervention in a preliminary study and to objectively measure its usefulness and impact in order to generalize its effectiveness in a controlled trial and elaborate the findings with qualitative data (106). As Malterud (72.p 203) states, the aim of mixed methods is not to use one method to confirm the truth, but to develop knowledge that provides a deeper and more comprehensive understanding.

To sum up, evaluative designs typically use experimental quantitative methods, but for complex interventions like HOBS, it is often necessary to understand the mechanisms behind the results and why the intervention works or not *(71, 73.p 323)*. Using a multiphase design to support the development, implementation, and evaluation process helps challenge the bias that can arise from relying on a single perspective *(73.p 322, 107).* While each method used alone may have limited generalizability or transferability, combining them can improve generalizability and enhance the transferability of the intervention to other settings and increase trustworthiness *(73. p 329, 107).* By using all these strategies to increase trustworthiness of results from the present study, I hope that other researchers and stakeholders interpret conclusions as valid and reliable despite my role as both a developer and evaluator.

6.2.2 Uncertainties of results in evaluation of complex interventions

The controlled trial in this PhD project includes a complex intervention, in a complex environment, using a pragmatic design. A pragmatic controlled trial takes place in real-world settings with usual care, aimed at informing decisions on implementing an intervention. In contrast, an explanatory randomized controlled trial takes place in idealized conditions to maximize the opportunity for detecting beneficial effects. There are pitfalls and advantages with both, and most trials are on a continuum between these two extremes, and do not fit into one category (108). In table 12, I present the degree of pragmatism in our controlled trial using the PRECIS-2 tool (Ibid). The tool asks the researcher to score their study on a Likert scale from 1 = Very explanatory (ideal conditions) to 5 = very pragmatic (usual conditions). As shown in table 12, scores in our trial are reflecting a very pragmatic approach where the aim is to inform decisions of implementing HOBS.

Table 12. PRECIS-2 score for trial domains

	Domain	Rationale	score
1	**Eligibility**	Participants in the trial are mostly similar to those who will receive the intervention if it was part of usual care (exclusion criteria; language, prematurity < GA 33, home care).	4
2	**Recruitment**	No extra effort was made to recruit participants other than ask those hospitalized at OUH until three months after birth with severe CHD.	5
3	**Setting**	The setting of the trial is similar to standard care where infants are treated at OUH and sent to follow up at local hospitals and community care.	5
4	**Organization**	Resources, provider expertise and the organization of care delivery are not changed, but the researcher introduced HOBS and ensured delivery of both interventions. The HOBS intervention was included in existing routines with minimal training.	4
5	**Flexibility (delivery)**	The flexibility in the intervention is high to adapt intervention to the infant and parents` needs. Nurses and cardiologists guide parents based on advice from guideline tools.	5
6	**Flexibility (adherence)**	The flexibility in adherence is high, due to the concept of individualization and based on results from qualitative findings. The cardiologist recommend frequency and which assessments to do.	5
7	**Follow up**	Intensity of measurement are individualized, and user controlled but moderately increased. Follow up of participants (consultations) are the same as in usual care.	4
8	**Primary outcome**	The trial's primary outcome (usefulness and stress) is very relevant to participants and have an impact on further adoption and implementation.	5
9	**Primary analysis**	All data from mothers of the primary outcome are included in the analysis.	5

Scores from 1-5 on a Likert scale; 1 = Very explanatory (ideal conditions) to 5 = very pragmatic (usual conditions), OUH = Oslo University Hospital, GA = Gestational age, CHD = Congenital heart disease, HOBS = Heart Observation app

Results from such a pragmatic study may contain many uncertainties due to the inherent complexity of the real-world setting, and the reasons behind the observed outcomes can be difficult to pinpoint

(109). So, when it comes to studying complex interventions, it is advised to engage pragmatically and use a flexible approach to explore uncertainties. Researchers should therefore develop a theory explaining the rationale of expected outcomes to clarify uncertainties. These uncertainties should inform the research questions (71). As mentioned, during our development process we had theoretical assumptions based on the concept of discharge readiness about which attributes to include to reach our aims(31).

Uncertainty of results may be increased by flexibility of the intervention and adherence to the intervention given to participants. When it is implemented in several health care services that follow up the participants, the adherence may differ even more. Hence, it is important to evaluate adoption of the intervention in services and by participants (Skivington 2021) (Table 11). In our study, nurses performed bedside care and had tasks to complete (appendix 13 and 15), but flexibility in how to conduct the guidance. Although having a high rate of conducted guidance in the HOBS group (table 10), it may not reflect quality in support. The level of experience and knowledge about infants with CHD differed, and unfortunately families preparing for discharge were not allocated to experienced nurses due to other patients` needs. In accordance to focus group interviews with nurses, some expressed that they did not have the competency to perform guidance (paper II). This competency was compensated for by nurses from the HOBS resource group, but unfortunately not possible on all occasions. Such feasibility issues must be considered when interpreting results and in further implementation strategy.

Ignorance of unexpected outcomes is an issue in a complex intervention study, but being attentive and observant to unexpected outcomes may reduce such ignorance (109). Hence, such studies should go through several phases, exploring feasibility and effect using both quantitative and qualitative methods (71). An example from this dissertation is the lack of improvement in communication where qualitative findings expanded the understanding of why it did not improve as expected (Table 10).

In science a primary goal is to increase knowledge in order to explain, understand and intervene, and this may be difficult to achieve if there is a lot of uncertainty (109). When advising other stakeholders to implement a complex intervention where conclusions could be uncertain or complex, it is recommended to not simplify advice but keep it complex (110). The MRC framework for evaluating complex interventions supports this approach, emphasizing that developing a refined program theory is a key outcome of the evaluation process (71). When results and their uncertainties are properly described, the burden to judge if an intervention is transferable to another setting is placed on the reader (76.p 282). Due to this we have refined our framework of how a mHealth intervention such as HOBS may add knowledge to the concept of discharge readiness. We suggest how existing and future refinements in similar solutions may support parents with CHD in the discharge process (Figure 7).

6.2.3 Recruitment and stratification

All recruited families in the controlled trial had children that were diagnosed with a severe CHD. Because we asked all parents admitted to the neonatal intensive care unit to participate in the study, we expected a natural randomization of CHD severity through prevalence in annual births, despite using consecutive groups (4). As shown in paper III this expectation failed and we ended up having significantly different groups with a higher amount of complex CHD in the intervention group.

During the admission period, parents experienced high levels of psychological distress. As emphasized in the literature (36, 38) and shown in paper II, readiness to focus on discharge preparation were unlikely to occur before the infants` condition stabilized. This was typically close to the time of discharge to home or transfer to local hospitals. To reduce the exposure of additional burden of research instruments on parents, we combined study inclusion and introduction of HOBS in the same session followed by sending baseline questionnaires in a link. Receiving the intervention before answering questionnaires at baseline may therefore increase the uncertainty of our results. In retrospect, questionnaires should have been administrated before introduction to interventions to be more certain about the initial impact of HOBS on stress in mothers. This would have increased the strength of the study. At the same time, no procedures can compensate for the inherent uncontrolled pre-existing differences between groups in a pragmatic or quasi- experimental designed study (99).

Due to the significantly different groups and the expected variation in stress based on severity, it became necessary to stratify the infants into 2 categories: those who had completed treatment and those who had sustained cardiac impairment. In addition, the increased attrition rate during the study resulted in too few respondents compared to our initial power calculations (Paper III). Nevertheless, our hypothesis and aim were that HOBS should not increase stress in parents. In relation to this, quantitative results indicate somewhat less stress than the control group, and our conclusion to continue to use HOBS is therefore within safe limits. In addition, qualitative findings of parents feeling safe and having control support this conclusion (paper II).

6.2.4 Outcome measures

As a rule of thumb, instruments should be validated for the population you study (111, 112), but in general, Norwegian instruments to measure parents’ experiences are limited and search for instruments that focused on the specific aims in our evaluation of HOBS was not possible to find. Due to this, we chose to develop a questionnaire aiming at testing usefulness (Appendix 10), and to translate a questionnaire with focus on parental disease related stress (PIP) (Appendix 11).

6.2.4.1 Researcher developed questionnaire

Validity and reliability of data collected using a researcher developed questionnaire depend on how it is designed, used, and validated, and there are several pitfalls (79). First, it is recommended to base the instrument on a conceptual framework to ensure concept validity (113). In our study both interventions and the content in the information was based on the concept of discharge readiness(31) (Figure 2). Hence, chosen items in the questionnaire were based on aims of the interventions. Second, questions needed to be carefully formulated, and the research group discussed the wording to avoid ambiguity and misinterpretation. We replaced the word "Binder" with "App" in the intervention group to ensure that parents knew what they responded to. We chose a 5-point Likert scale to be able to generate data suitable for parametric analysis (114). A box to tick if not appropriate gave parents a possibility to avoid items about situations they had not experienced, to reduce ambiguity (112). In addition, the questions were used in a mixed methods study and results from the questionnaire aimed to quantify, confirm and elucidate findings from the explorative phase (Table 10). Thereby ignored aspects could be considered from the qualitative data. Explorative factor analysis was conducted after the study to check the reliability of the developed questionnaire. This showed that all seven questions made a substantial contribution to the concept of usefulness. The items correlated to a high degree with the total scale, representing that they had a common factor influencing them. They also correlated moderately to each other (r = 0.30-0.80), reflecting that items were not measuring the exact same issue (115).

Due to measures taken to ensure concept validity, good psychometric results and the fact that the results verify findings in the exploratory phase we consider our questionnaire to be appropriate in the present study.

6.1.4.2 Translation and cultural adaption of PIP

In our controlled trial of HOBS, we wanted to find out if increased focus on symptoms of deterioration using HOBS increased parents stress levels. We found no Norwegian instruments that measured parental stress after discharge and connected it to disease related events. Hence, we decided to translate the Pediatric Inventory for Parents (PIP) (80). The PIP was designed for parents of children with chronic disease and initially tested in parents of children with diabetes and other diseases (80). The instrument showed good reliability and content validity in the original version (80). It is one of the most used instruments assessing parenting stress and caregiver burden in children with CHD (97, 100, 116-121). In validity studies, PIP have demonstrated a significant correlation to state anxiety, stress (80), and depression (81).

Translation was done by following the six steps presented in established guidelines by Beaton and colleges and supported by the COSMIN study Design checklist for patient reported outcome measurement instruments (82, 122). Researchers, parents, and healthcare professionals cooperated to establish the best translation from English to Norwegian and the developer finally approved the back translated version. We interviewed 5 parents of infants with CHD who approved the 42 events (items) in PIP as relevant in their situation and a comprehensive measure to measure their stress. In addition to translation, we adapted the questionnaire from a paper version that presents items with frequency response and difficulty response at the same row to a digital version with a possibility to use both vertical and horizontal response with downward scrolling (Appendix 11). Parents confirmed to comprehend instructions and the format, but we have not compared the solutions and their impact on responses in our study.

Due to number of participants and other limitations in our study the evaluated properties were; 1) Reliability; including internal consistency and test-retest, 2) Concurrent validity; including interscale correlations and construct validity, and 3) Discriminant validity between severity groups (Appendix 11) (122). The PIP showed in general good reliability and validity in our study population except from a moderate scale reliability in two subscales during admission (Appendix 11). Due to the small sample size, some of these results might be uncertain (122). Nevertheless, our results of validity and reliability were in general good and repeated through the whole study period. In addition our results of stress of the impact of severity are in line with other results from the CHD population in parents of older children where more complex CHD gives higher PIP scores (17, 97, 100, 116).

Based on this, the Norwegian version of the PIP seems to be a valid instrument for mother of infants with CHD. At the same time, the PIP measures a broad specter of events. Not all these events may be affected by receiving a mobile app and this might be a pitfall when using it to evaluate the impact from HOBS on stress. In retrospect, it might have been an advantage to include a short instrument measuring state anxiety. Both to measure unspecific anxiety and to evaluate the construct validity of PIP against state anxiety as done in the original version (80).

7. Implication for clinical practice

To ensure economic sustainability, the Association for Children with Heart Disease (FFHB) has taken ownership of HOBS and launched a website to support both parents and healthcare professionals (HOBS - Foreningen for hjertesyke barn). They have initiated a comprehensive implementation strategy, which involves visiting all hospitals in Norway, either digitally or in person, to raise awareness about HOBS and educate healthcare professionals on how they can assist parents. Additionally, all local hospitals are invited to join a national network within FFHB that gathers HOBS resources.

During this project, the readiness for discharge concept has been useful to support development and evaluation of the HOBS intervention. The same framework could be used to develop interventions for the discharge process of various patient categories. In the present project, we have refined the intervention and expanded features in HOBS to better meet requirements in attributes in the concept of discharge readiness.

In figure 7 our results from meta-inferences in the present mixed methods study are included in colors related to the process of refinement and implication for practice.

Added measures after the feasibility study (in red)

Based on our work in the feasibility study we added interactivity and individualized the discharge checklist to ensure knowledge and empowerment in the discharge process. We also adapted the level of assessments to each individual to be able to normalize when possible, to avoid additional stress. All other features were mainly kept as before the feasibility study, due to good usability scores and acceptance from users.

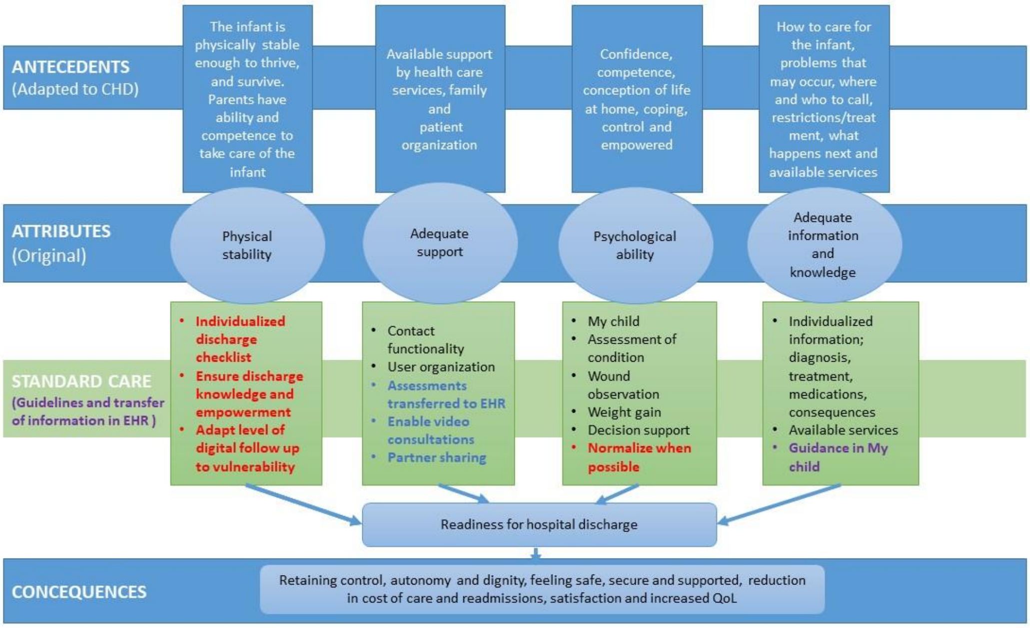
Added measures after this mixed methods study (in purple)

After the controlled trial guidelines for hospital units and outpatient clinics has been developed to give parents better support from health care professionals locally. In addition, new possibilities in EHR at OUH made it possible to include predefined actions for guidance of HOBS for nurses in the patients care plan. This care plan is distributed to local hospitals after initial treatment. At OUH a resource group is responsible for guiding parents in daily work. To always ensure adequate knowledge, we also embedded guidance in HOBS by including information about how to observe and set an infant’s normal baseline in Normal for my child.

Recommended features in future updates of HOBS (in blue)

In future solutions we would recommend adding partner sharing, a possibility to transfer assessments and pictures to EHR and enable video consultations to ensure adequate support. The level of assessment and digital support could in this way be adapted to the level of vulnerability by the cardiologist together with parents. Such features need to be adapted to health care services and their EHR.

Figure 7 Concept of readiness for discharge adapted to HOBS after this mixed methods study



Bold red = Added functionality or supportive actions in the controlled trial. Purple = Added functionality and supportive actions after the mixed methods study. Blue = Recommended features in future solutions

7.1 Future research

The fields of mHealth and digitally mediated interventions are rapidly evolving, and different solutions develop in parallel. Our concept of digital follow-up assessments of infants' baseline condition has now been integrated into the MyDignio app (65) and CheckWare`s digital follow up solution (66). These developments primarily focus on digital follow up in home care from the hospital and parent-managed outpatient clinics. Assessment questions used in HOBS have been adopted and may be applied individually into the infant’s care plan. However, these solutions do not include continuous home monitoring with an always-available team to respond to assessments. Compared to HOBS, they also lack individualized information to CHD population and guidance to interpret results alongside assessments. Therefore, health care professionals should use HOBS to inform and help parents to interpret their infants` condition prior to discharge regardless of such follow up. The feasibility, usability, and overall impact of these combined solutions should undergo further investigation once they are established.

In the present study, we excluded parents not speaking Norwegian, although these parents represent a large proportion of the CHD families in Norway. In addition to language barriers, foreign-born parents more commonly have low education, low socio-economic status and limited social capital.

Such disadvantages may increase parental stress and affect the infants' safety and navigation through health care services (20). FFHB has planned to translate the HOBS app using artificial intelligence (AI) which would provide support also to these families. To measure if such a tool could increase health literacy and collaboration with healthcare professionals would be a very important research project. Regarding this, a parent version of the HLQ has recently been developed and validated into Norwegian (123). This version is at the moment translated into several languages in a PhD project and may open up for opportunities to evaluate if HOBS affects foreign-born parents' health literacy. In addition, stress will be important to evaluate due to these parents additional challenges (20).

8. Conclusion

This thesis aimed to explore and evaluate whether a mobile app, based on the theoretical concept of readiness for discharge, could be usable (paper I), accepted (paper II), and beneficial without increasing stress for parents of infants with severe congenital heart disease (paper III). Quantitative and qualitative findings from the three studies were combined in a mixed-methods meta-analysis. The results were largely consistent and reinforced each study's conclusions regarding the feasibility and impact of HOBS. Both system usability scores and qualitative findings indicated good and sustained usability. HOBS was accepted and initially adopted by parents during the discharge process, and healthcare professionals were positive to incorporate HOBS into clinical practice. As expected, user logs from the controlled trial showed more frequent use of the app around the time of discharge, with usage gradually declining over time. This likely reflects parents' desire and need to normalize family life.

8. References

1. Meleis AI. Transistion Theory: Middle-Range and Situation-Specific Theories in Nursing Research and practice. New York: Springer Publishing Company; 2010.
2. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res. 2017;17(1):88.
3. Collaborators GBDCHD. Global, regional, and national burden of congenital heart disease, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet Child Adolesc Health. 2020;4(3):185-200.
4. Leirgul E, Fomina T, Brodwall K, Greve G, Holmstrom H, Vollset SE, et al. Birth prevalence of congenital heart defects in Norway 1994-2009--a nationwide study. Am Heart J. 2014;168(6):956-64.
5. International pediatric and Congenital Cardiac code [Internet]. 2005 [cited 20.02.2024]. Available from: http://ipccc.net/.
6. Wik G, Jortveit J, Sitras V, Perminow KV, Pripp AH, Dohlen G, et al. Detection of severe congenital heart defects in live-born infants in Norway 2017-2020. Acta Paediatr. 2024;113(1):135-42.
7. Wik G, Jortveit J, Sitras V, Døhlen G, Rønnestad AE, Holmstrøm H. Unexpected death in children with severe congenital heart defects in Norway 2004-2016. Arch Dis Child. 2021. 106(10):961-966
8. Tregay J, Brown KL, Crowe S, Bull C, Knowles RL, Smith L, et al. Signs of deterioration in infants discharged home following congenital heart surgery in the first year of life: a qualitative study. Arch Dis Child. 2016;101(10):902-8.
9. Crowe S, Ridout DA, Knowles R, Tregay J, Wray J, Barron DJ, et al. Death and Emergency Readmission of Infants Discharged After Interventions for Congenital Heart Disease: A National Study of 7643 Infants to Inform Service Improvement. J Am Heart Assoc.. 2016;5(5):e003369.
10. Medoff Cooper B, Marino BS, Fleck DA, Lisanti AJ, Golfenshtein N, Ravishankar C, et al. Telehealth Home Monitoring and Postcardiac Surgery for Congenital Heart Disease. Pediatrics. 2020;146(3):e20200531.
11. Crowe S, Knowles R, Wray J, Tregay J, Ridout DA, Utley M, et al. Identifying improvements to complex pathways: evidence synthesis and stakeholder engagement in infant congenital heart disease. BMJ Open. 2016;6(6):e010363.
12. Mutti G, Ait Ali L, Marotta M, Nunno S, Consigli V, Baratta S, et al. Psychological Impact of a Prenatal Diagnosis of Congenital Heart Disease on Parents: Is It Time for Tailored Psychological Support? J Cardiovasc Dev Dis. 2024;11(1):31.
13. Solberg O, Dale MT, Holmstrom H, Eskedal LT, Landolt MA, Vollrath ME. Long-term symptoms of depression and anxiety in mothers of infants with congenital heart defects. J Pediatr Psychol. 2011;36(2):179-87.
14. Bevilacqua F, Palatta S, Mirante N, Cuttini M, Seganti G, Dotta A, et al. Birth of a child with congenital heart disease: emotional reactions of mothers and fathers according to time of diagnosis. J Matern Fetal Neonatal Med. 2013;26(12):1249-53.
15. Davey BT, Lee JH, Manchester A, Gunnlaugsson S, Ohannessian CM, Rodrigues R, et al. Maternal Reaction and Psychological Coping After Diagnosis of Congenital Heart Disease. Matern Child Health J. 2023;27(4):671-9.
16. Solberg O, Gronning Dale MT, Holmstrom H, Eskedal LT, Landolt MA, Vollrath ME. Trajectories of maternal mental health: a prospective study of mothers of infants with congenital heart defects from pregnancy to 36 months postpartum. J Pediatr Psychol. 2012;37(6):687-96.
17. Woolf-King SE, Anger A, Arnold EA, Weiss SJ, Teitel D. Mental Health Among Parents of Children With Critical Congenital Heart Defects: A Systematic Review. J Am Heart Assoc. 2017;6(2):e004862.

18. Rempel GR, Ravindran V, Rogers LG, Magill-Evans J. Parenting under pressure: a grounded theory of parenting young children with life-threatening congenital heart disease. J Adv Nurs. 2013;69(3):619-30.

19. McCusker CG, Doherty NN, Molloy B, Casey F, Rooney N, Mulholland C, et al. Determinants of neuropsychological and behavioural outcomes in early childhood survivors of congenital heart disease. Arch Dis Child. 2007;92(2):137-41.

20. Lisanti AJ. Parental stress and resilience in CHD: a new frontier for health disparities research. Cardiol Young. 2018;28(9):1142-50.

21. Rudd NA, Ghanayem NS, Hill GD, Lambert LM, Mussatto KA, Nieves JA, et al. Interstage Home Monitoring for Infants With Single Ventricle Heart Disease: Education and Management: A Scientific Statement From the American Heart Association. J Am Heart Assoc. 2020;9(16):e014548.

22. Stoffel G, Spirig R, Stiasny B, Bernet V, Dave H, Knirsch W. Psychosocial impact on families with an infant with a hypoplastic left heart syndrome during and after the interstage monitoring period - a prospective mixed-method study. J Clin Nurs. 2017;26(21-22):3363-70.

23. Meakins L, Ray L, Hegadoren K, Rogers LG, Rempel GR. Parental Vigilance in Caring for Their Children with Hypoplastic Left Heart Syndrome. Pediatr Nurs. 2015;41(1):31-50.

24. Lisanti AJ, Vittner DJ, Peterson J, Van Bergen AH, Miller TA, Gordon EE, et al. Developmental care pathway for hospitalised infants with CHD: on behalf of the Cardiac Newborn Neuroprotective Network, a Special Interest Group of the Cardiac Neurodevelopmental Outcome Collaborative. Cardiol Young. 2023;33(12):2521-38.

25. McCusker CG, Doherty NN, Molloy B, Rooney N, Mulholland C, Sands A, et al. A controlled trial of early interventions to promote maternal adjustment and development in infants born with severe congenital heart disease. Child Care Health Dev. 2010;36(1):110-7.

26. Weiss ME, Piacentine LB. Psychometric properties of the Readiness for Hospital Discharge Scale. J Nurs Meas. 2006;14(3):163-80.

27. Moons P, Bratt EL, De Backer J, Goossens E, Hornung T, Tutarel O, et al. Transition to adulthood and transfer to adult care of adolescents with congenital heart disease: a global consensus statement of the ESC Association of Cardiovascular Nursing and Allied Professions (ACNAP), the ESC Working Group on Adult Congenital Heart Disease (WG ACHD), the Association for European Paediatric and Congenital Cardiology (AEPC), the Pan-African Society of Cardiology (PASCAR), the Asia-Pacific Pediatric Cardiac Society (APPCS), the Inter-American Society of Cardiology (IASC), the Cardiac Society of Australia and New Zealand (CSANZ), the International Society for Adult Congenital Heart Disease (ISACHD), the World Heart Federation (WHF), the European Congenital Heart Disease Organisation (ECHDO), and the Global Alliance for Rheumatic and Congenital Hearts (Global ARCH). Eur Heart J. 2021;42(41):4213-23.

28. Bratt EL, Burstrom A, Hanseus K, Rydberg A, Berghammer M, On behalf on the S-CHDc. Do not forget the parents-Parents' concerns during transition to adult care for adolescents with congenital heart disease. Child Care Health Dev. 2018;44(2):278-84.

29. Gaskin KL. Patterns of Transition Experience for Parents Going Home from Hospital with their Infant after First Stage Surgery for Complex Congenital Heart Disease. J Pediatr Nurs. 2018;41:e23-e32.

30. Weiss M, Johnson NL, Malin S, Jerofke T, Lang C, Sherburne E. Readiness for discharge in parents of hospitalized children. J Pediatr Nurs. 2008;23(4):282-95.

31. Galvin E, Wills T, Coffey A. Readiness for Hospital Discharge: A Concept Analysis. J Adv Nurs. 2017;73(11):2547-2557.

32. Pridham KF. Guided participation and development of care-giving competencies for families of low birth-weight infants. J Adv Nurs. 1998;28(5):948-58.

33. Tanem J MA. Amobile Application as a Tool for Guided Participation. In: Pridham K LR, Schroeder M, editor. Relationship-Based Guided Participation in Pediatric Nursing Practice; New York: Springer Publishing Company; 2018. p. 341-54.

34. Anthony MK, Hudson-Barr D. A patient-centered model of care for hospital discharge. Clin Nurs Res. 2004;13(2):117-36.

35. Gramszlo C, Karpyn A, Christofferson J, McWhorter LG, Demianczyk AC, Neely T, et al. Meeting Parents' Needs for Education and Preparation following Congenital Heart Disease Diagnosis: Recommendations from a Crowdsourced Study. Am J Perinatol. 2024;41(S 01):e446-e455.
36. Dalton CC, Gottlieb LN. The concept of readiness to change. J Adv Nurs. 2003;42(2):108-17.
37. Lawoko S. Factors influencing satisfaction and well-being among parents of congenital heart disease children: development of a conceptual model based on the literature review. Scand J Caring Sci. 2007;21(1):106-17.
38. Rogan F, Shmied V, Barclay L, Everitt L, Wyllie A. "Becoming a mother'--developing a new theory of early motherhood. J Adv Nurs. 1997;25(5):877-85.
39. Offord DR, Cross LA, Andrews EJ, Aponte JF. Perceived and actual severity of congenital heart disease and effect on family life. Psychosomatics. 1972;13(6):390-6.
40. Williams IA, Shaw R, Kleinman CS, Gersony WM, Prakash A, Levasseur SM, et al. Parental understanding of neonatal congenital heart disease. Pediatr Cardiol. 2008;29(6):1059-65.
41. Chessa M, De Rosa G, Pardeo M, Negura DG, Butera G, Giamberti A, et al. What do parents know about the malformations afflicting the hearts of their children? Cardiol Young. 2005;15(2):125-9.
42. Cheuk DK, Wong SM, Choi YP, Chau AK, Cheung YF. Parents' understanding of their child's congenital heart disease. Heart. 2004;90(4):435-9.
43. Lobel A, Geyer S, Grosser U, Wessel A. Knowledge of congenital heart disease of mothers: presentation of a standardized questionnaire and first results. Congenit Heart Dis. 2012;7(1):31-40.
44. Beeri M, Haramati Z, Rein JJ, Nir A. Parental knowledge and views of pediatric congenital heart disease. Isr Med Assoc J. 2001;3(3):194-7.
45. Arya B, Glickstein JS, Levasseur SM, Williams IA. Parents of children with congenital heart disease prefer more information than cardiologists provide. Congenit Heart Dis. 2013;8(1):78-85.
46. Daily J, FitzGerald M, Downing K, King E, del Rey JG, Ittenbach R, et al. Important knowledge for parents of children with heart disease: parent, nurse, and physician views. Cardiol Young. 2016;26(1):61-9.
47. Mannarino CN, Michelson K, Jackson L, Paquette E, McBride ME. Post-operative discharge education for parent caregivers of children with congenital heart disease: a needs assessment. Cardiol Young. 2020;30(12):1788-96.
48. Pye S, Green A. Parent education after newborn congenital heart surgery. Adv Neonatal Care. 2003;3(3):147-56.
49. Stinson J, McKeever P. Mothers' information needs related to caring for infants at home following cardiac surgery. J Pediatr Nurs. 1995;10(1):48-57.
50. Shirali G, Erickson L, Apperson J, Goggin K, Williams D, Reid K, et al. Harnessing Teams and Technology to Improve Outcomes in Infants With Single Ventricle. Circ Cardiovasc Qual Outcomes. 2016;9(3):303-11.
51. Blair L, Vergales J, Peregoy L, Seegal H, Keim-Malpass J. Acceptability of an interstage home monitoring mobile application for caregivers of children with single ventricle physiology: Toward technology-integrated family management. J Spec Pediatr Nurs. 2022 Jul;27(3):e12372.
52. Castro D, Pérez-Rivero P, Quintero-Lesmes DC, Castro J. Design of a mobile application for home monitoring of babies with complex congenital heart disease. Revista Cuidarte. 2022;13.
53. Fleck DA, Marino BS, Costello JM, Ravishankar C, Torowicz D, Alden C, et al. The REACH protocol: an innovative strategy for home management of infants with complex CHD. Cardiol Young. 2018;28(7):961-7.
54. Jacob C, Sezgin E, Sanchez-Vazquez A, Ivory C. Sociotechnical Factors Affecting Patients' Adoption of Mobile Health Tools: Systematic Literature Review and Narrative Synthesis. JMIR Mhealth Uhealth. 2022;10(5):e36284.
55. Richardson B, Dol J, Rutledge K, Monaghan J, Orovec A, Howie K, et al. Evaluation of Mobile Apps Targeted to Parents of Infants in the Neonatal Intensive Care Unit: Systematic App Review. JMIR Mhealth Uhealth. 2019;7(4):e11620.

56. Davis DW, Logsdon MC, Vogt K, Rushton J, Myers J, Lauf A, et al. Parent Education is Changing: A Review of Smartphone Apps. MCN Am J Matern Child Nurs. 2017;42(5):248-56.
57. Xie WP, Liu JF, Lei YQ, Cao H, Chen Q. Effects of WeChat follow-up management of infants who underwent ventricular septal defect repair on parents' disease knowledge and quality of life: A prospective randomized controlled study. J Card Surg. 2021;36(10):3690-7.
58. Zhang QL, Lei YQ, Liu JF, Cao H, Chen Q. Using telemedicine to improve the quality of life of parents of infants with CHD surgery after discharge. Int J Qual Health Care. 2021; 25;33(3):mzab133.
59. Lin WH, Chen YK, Lin SH, Cao H, Chen Q. Parents' understanding and attitudes toward the use of the WeChat platform for postoperative follow-up management of children with congenital heart disease. J Cardiothorac Surg. 2023;18(1):66.
60. Zhang QL, Lin SH, Lin WH, Chen Q, Cao H. The effect of applying telehealth education to home care of infants after congenital heart disease surgery. Int J Qual Health Care. 2023; 14;35(1):mzac102.
61. Lane B, Hanke SP, Giambra B, Madsen NL, Staveski SL. Development of a clinician–parent home care education intervention. Cardiol Young. 2019;29(10):1230-5.
62. Miller VA, Newcombe J, Radovich P, Johnston F, Medina E, Nelson A. The Healing Hearts at Home© Mobile Application Usability and Influence on Parental Perceived Stress: A Pilot Study. Int J E-Health Med C. 2021;12(3):90-105.
63. McKechnie AC, Elgersma KM, Iwaszko Wagner T, Trebilcock A, Damico J, Sosa A, et al. An mHealth, patient engagement approach to understand and address parents' mental health and caregiving needs after prenatal diagnosis of critical congenital heart disease. PEC Innov. 2023;9;3:100213.
64. McKechnie AC, Elgersma KM, Ambrose MB, Sanchez Mejia AA, Shah KM, Iwaszko Wagner T, et al. Nurse-guided Mobile Health Care Program to Reduce Emotional Distress Experienced by Parents of Infants Prenatally Diagnosed with Critical Congenital Heart Disease: A Pilot Study. Prog Pediatr Cardiol. 2024;72:101687.
65. Dignio. 2024 [Internett] [Updated 28.Aug 2024; cited 20.dec 2024] Available from: https://dignio.com/no/mydignio/.
66. CheckWare. EG CheckWare 2007 [Internett] [Updated 17.dec 2024; cited 20.dec 2024] Available from: https://www.checkware.no/digital-hjemmeoppfolging.
67. Gustavsen LJ, Le Marechal F, Tandberg BS. Observational study showed that using video consultations was a viable way of delivering an early discharge programme for preterm infants. Acta Paediatr. 2024;113(7):1524-1530.
68. Hjorth-Johansen E. Hjem etter hjerteoperasjon i nyfødtperioden: Kan skriftlig informasjon basert på overgangsteori møte foreldres behov for informasjon og øke deres kunnskap og mestring ved utskrivelse fra sykehus? [Master thesis]. Oslo: Universitetet i Oslo; 2013.
69. Wik G, Jortveit J, Sitras V, Dohlen G, Ronnestad AE, Holmstrom H. Unexpected death in children with severe congenital heart defects in Norway 2004-2016. Arch Dis Child. 2021;106(10):961-6.
70. Hjorth-Johansen E, Børøsund E, Martinsen Østen I, Holmstrøm H, Moen A. Acceptability and Initial Adoption of the Heart Observation App for Infants With Congenital Heart Disease: Qualitative Study. JMIR Form Res. 2023;7:e45920.
71. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021; 30;374:n2061.
72. Malterud K. Kvalitative forskningsmetoder for medisin og helsfag. 4 ed. Oslo: Universitetsforlaget AS; 2021.
73. Green J, Thorogood N. Qualitative Methods for Health Research. 4th edition ed. London: SAGE Publications Ltd; 2018. 254 p.
74. Guetterman TC, Fetters MD, Creswell JW. Integrating Quantitative and Qualitative Results in Health Science Mixed Methods Research Through Joint Displays. Ann Fam Med. 2015;13(6):554-61.

75. Ritchie J, Spencer L. Qualitative Data Analysis for Applied Policy Research. In: Huberman AM & Miles MB, editor. The Qualitative Researcher's Companion. Thousand Oaks, California: SAGE Publications, inc; 2002. p. 305-329.
76. Braun V, Clarke V. Successful qualitative research: A Practical Guide for Beginners. London: SAGE Publications Ltd; 2013. 400 p.
77. Hjorth-Johansen E, Børøsund E, Moen A, Harmens A, Martinsen I, Wik G, et al. Heart OBServation app: development of a decision support tool for parents of infants with severe cardiac disease. Cardiol Young. 2022: 33(8):1350-1358.
78. Bangor A, Kortum P, Miller J. Determining What Individual SUS Scores Mean: Adding an Adjective Rating Scale. J Usability Stud. 2009;4:114-23.
79. Ranganathan P, Caduff C. Designing and validating a research questionnaire - Part 1. Perspect Clin Res. 2023;14(3):152-5.
80. Braniecki S, Kazak AE, Tercyak KP, Streisand R. Childhood Illness-Related Parenting Stress: The Pediatric Inventory for Parents. J Pediatr Psychol. 2001;26(3):155-62.
81. Casaña-Granell S, Lacomba-Trejo L, Valero-Moreno S, Prado-Gasco V, Montoya-Castilla I, Pérez-Marín M. A brief version of the Pediatric Inventory for Parents (PIP) in Spanish population: Stress of main family carers of chronic paediatric patients. PLoS One. 2018;13(7):e0201390.
82. Beaton DE, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine (Phila Pa 1976). 2000;25(24):3186-91.
83. Klingberg S, Stalmeijer RE, Varpio L. Using framework analysis methods for qualitative research: AMEE Guide No. 164. Med Teach. 2024;46(5):603-10.
84. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.
85. World Medical Association. WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects 2022 [Internett] [Updated 13. Dec 2024; cited 10.Oct 2024]Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/.
86. Office of Research integrity. Conflict of Interest [Internet] [updated 2021; cited 2021 09.12]. Available from: https://uaf.edu/ori/responsible-conduct/conflict-of-interest/index.php.
87. Lødrup Carlsen K, Staff A. Forskningshåndboken Fra idè til publikasjon [Internet]. Oslo: Oslo Universitetssykehus; 2017 [updated 08.12.21; cited 2021 08.12.]. 2017:Available from: https://oslo-universitetssykehus.no/avdelinger/documents/forskningshandboken.pdf.
88. Olson CA. Conflict of interest and evaluation research: should we do effectiveness studies of our own educational programs? J Contin Educ Health Prof. 2013;33(4):203-5.
89. Wik G, Jortveit J, Sitras V, Dohlen G, Ronnestad AE, Holmstrom H. Severe congenital heart defects: incidence, causes and time trends of preoperative mortality in Norway. Arch Dis Child. 2020;105(8):738-43.
90. Guetterman TC, Fàbregues S, Sakakibara R. Visuals in joint displays to represent integration in mixed methods research: A methodological review. Methods in Psychology. 2021;5:100080.
91. Jacob C, Sanchez-Vazquez A, Ivory C. Social, Organizational, and Technological Factors Impacting Clinicians' Adoption of Mobile Health Tools: Systematic Literature Review. JMIR Mhealth Uhealth. 2020;8(2):e15935.
92. Sullivan GM, Feinn R. Using Effect Size-or Why the P Value Is Not Enough. J Grad Med Educ. 2012;4(3):279-82.
93. Bowers C, Tomlinson A, Gaskin KL, Wray J. CHAT2App: Supporting Caregivers of Infants with Congenital Heart Disease. Extended Abstracts of the 2024 CHI Conference on Human Factors in Computing Systems: Association for Computing Machinery; 2024. Article 508. p.1-9. Available from: https://dl.acm.org/doi/10.1145/3613905.3637450
94. Weiss ME, Sawin KJ, Gralton K, Johnson N, Klingbeil C, Lerret S, et al. Discharge Teaching, Readiness for Discharge, and Post-discharge Outcomes in Parents of Hospitalized Children. J Pediatr Nurs. 2017;34:58-64.

95. Aly DM, Erickson LA, Hancock H, Apperson JW, Gaddis M, Shirali G, et al. Ability of Video Telemetry to Predict Unplanned Hospital Admissions for Single Ventricle Infants. J Am Heart Assoc. 2021;10(16):e020851.
96. Lumsden MR, Smith DM, Wittkowski A. Coping in Parents of Children with Congenital Heart Disease: A Systematic Review and Meta-synthesis. J. Child Fam. Stud. 2019;28(7):1736-53.
97. Kaugars A, Shields C, Brosig C. Stress and quality of life among parents of children with congenital heart disease referred for psychological services. Congenit Heart Dis. 2018;13(1):72-8.
98. Cohen J. A power primer. Psychol Bull. 1992;112(1):155-9.
99. Streiner DL, Norman GR, Cairney J, Streiner DL, Norman GR, Cairney J. 11 Measuring change. Health Measurement Scales: A practical guide to their development and use: Oxford University Press; 2015. p. 254-272. [cited Oct 2024]. Available from: Measuring change | Health Measurement Scales: A practical guide to their development and use | Oxford Academic
100. Caris EC, Dempster N, Wernovsky G, Butz C, Neely T, Allen R, et al. Anxiety Scores in Caregivers of Children with Hypoplastic Left Heart Syndrome. Congenit Heart Dis. 2016;11(6):727-32.
101. Gaskin KL, Wray J, Barron DJ. Acceptability of a parental early warning tool for parents of infants with complex congenital heart disease: a qualitative feasibility study. Arch Dis Child. 2018;103(9):880-6.
102. Erickson LA, Emerson A, Russell CL. Parental mobile health adherence to symptom home monitoring for infants with congenital heart disease during the single ventricle interstage period: A concept analysis. J Spec Pediatr Nurs. 2020;25(4):e12303.
103. Jackson SR, Chowdhury SM, Woodard FK, Zyblewski SC. Factors associated with caregiver adherence to mobile health interstage home monitoring in infants with single ventricle or biventricular shunt-dependent heart disease. Cardiol Young. 2023;33(6):893-8.
104. Gezelius SS, Mittenzwei K. Forskerens frihet når interesser vil styre,. In: Ingierd H, Bay-Larsen I, Hiis Hauge K, editors. Interessekonflikter i forskning,. Oslo Norway: Cappelen Damm Akademisk; 2019. p. 45-68.
105. De nasjonaleforskningsetiske komiteene. Veiledning for forskningsetiske og vitenskapelig vurdering av kvalitative forskningsprosjekt innen medisin og helsfag Oslo 2019 [updated 23.05.2019; cited 2021 08.12.]. Available from: https://www.forskningsetikk.no/retningslinjer/med-helse/vurdering-av-kvalitative-forskningsprosjekt-innen-medisin-og-helsefag/.
106. Moen K, Middelthon A-L. Qualitative Research Methods. In: Laake P, Benestad HB, Olsen BR, editors. Research in Medical and Biological Sciences. Amsterdam: Academic Press; 2015. p. 321-78.
107. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Int J Nurs Stud. 2013;50(5):587-92.
108. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. BMJ. 2015;350:h2147.
109. Hofmann B, Holm S. Philosophy of Science. In: Laake P, Benestad HB, Olsen BR, editors. Research in Medical and Biological Sciences. Amsterdam: Academic Press; 2015. p. 1-41.
110. Stirling A. Keep it complex. Nature. 2010;468(7327):1029-31.
111. Streiner DL, Norman GR, Cairney J. Health Measurement Scales: A practical guide to their development and use [internett]. 5 edn: Oxford University Press; 2014 [cited Oct 2024]. Available from:Health Measurement Scales: A practical guide to their development and use | Oxford Academic
112. Boynton PM, Greenhalgh T. Selecting, designing, and developing your questionnaire. BMJ. 2004;328(7451):1312-5.
113. Streiner DL, Norman GR, Cairney J, Streiner DL, Norman GR, Cairney J. 3 Devising the items. Health Measurement Scales: A practical guide to their development and use: Oxford University Press; 2014. p. 19-37. [cited Oct 2024]. Available from: Devising the items | Health Measurement Scales: A practical guide to their development and use | Oxford Academic
114. Streiner DL, Norman GR, Cairney J, Streiner DL, Norman GR, Cairney J. 4 Scaling responses. Health Measurement Scales: A practical guide to their development and use: Oxford University Press;

2014. p. 38-73. [cited Oct 2024]. Available from: Scaling responses | Health Measurement Scales: A practical guide to their development and use | Oxford Academic

115. Streiner DL, Norman GR, Cairney J, Streiner DL, Norman GR, Cairney J. 5 Selecting the items. Health Measurement Scales: A practical guide to their development and use: Oxford University Press; 2014. p. 74-99. [cited Oct 2024].Available from: Selecting the items | Health Measurement Scales: A practical guide to their development and use | Oxford Academic

116. Choi Y, Lee S. Coping self-efficacy and parenting stress in mothers of children with congenital heart disease. Heart Lung. 2021;50(2):352-6.

117. Jackson AC, Frydenberg E, Koey XM, Fernandez A, Higgins RO, Stanley T, et al. Enhancing Parental Coping with a Child's Heart Condition: A Co-production Pilot Study. Compr Child Adolesc Nurs. 2020;43(4):314-33.

118. Poh PF, Lee JH, Loh YJ, Tan TH, Cheng KKF. Readiness for Hospital Discharge, Stress, and Coping in Mothers of Children Undergoing Cardiac Surgeries: A Single-Center Prospective Study. Pediatr Crit Care Med. 2020;21(5):e301-e10.

119. Grootenhuis MA, Jantien Vrijmoet-Wiersma CM, Koopman HM, Ottenkamp J, van Roozendaal M. A multicentric study of disease-related stress, and perceived vulnerability, in parents of children with congenital cardiac disease. Cardiol Young. 2009;19(6):608-14.

120. Bishop MN, Gise JE, Donati MR, Shneider CE, Aylward BS, Cohen LL. Parenting Stress, Sleep, and Psychological Adjustment in Parents of Infants and Toddlers With Congenital Heart Disease. J Pediatr Psychol. 2019;44(8):980-987.

121. Eagleson KJ, McCombs D, Gerlich TM, Justo RN, Kasparian NA, Bora S. Systematic Review of Instruments Assessing Psychosocial Adaptation and Outcomes Among Families of Children With Congenital Heart Disease. J Pediatr Psychol. 2023;48(6):537-52.

122. Mokkink LB, Prinsen C, Patrick DL, Alonso J, Bouter LM, De Vet H, et al. COSMIN Study Design checklist for Patient-reported outcome measurement instruments. Amsterdam, The Netherlands. 2019:1-32. [updated: july 2019, cited sept. 2024]. Available from: COSMIN checklist with 4-point scale

123. Wahl AK, Hermansen Å, Tschamper MB, Osborne RH, Helseth S, Jacobsen R, et al. The Parent Health Literacy Questionnaire (HLQ-Parent). Adaptation and validity testing with parents of children with epilepsy. Scand J Public Health. 2024;52(1):39-47.

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Heart OBServation app: development of a decision support tool for parents of infants with severe cardiac disease

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Abstract

Background and objectives: Many parents of infants with CHD find it difficult to recognise symptoms of deterioration in their children. Therefore, a personalised decision support application for parents has been developed. This application aims to increase parents' awareness of their infant's normal condition, help them assess signs of deterioration, decide who and when to contact health services, and what to report. The aim of this paper is to describe the concept and report results from a usability study. *Methods:* An interprofessional group developed a mobile application called the Heart OBServation app in close collaboration with parents using an iterative process. We performed a usability study consisting of semi-structured interviews of 10 families at discharge and after one month and arranged two focus group interviews with nurses caring for these families. A thematic framework analysis of the interviews explored the usability of features in the application. Usability was assessed twice using the System Usability Scale, and a user log was registered throughout the study. *Results:* The overall system usability score, 82.3 after discharge and 81.7 after one month, indicates good system usability. The features of Heart OBServation were perceived as useful to provide tailored information, increase awareness of the child's normal condition, and to guide parents in what to look for. To empower parents, an interactive discharge checklist was added. *Conclusions:* The Heart OBServation demonstrated good usability and was well received by parents and nurses. Feasibility and benefits of this application in clinical practice will be investigated in further studies

An estimated 500–600 children are born with CHD in Norway each year. Approximately 25% of them have severe defects and require early diagnosis and treatment.[1] CHD is still a major cause of infant death, and approximately 10% of Norwegian children with severe heart disease die during the first two years of life.[2] Recent research shows that 29% of these deaths occurred unexpectedly outside of/unrelated to surgery, 60% of which after gradual deterioration at home.[3] Many parents find it difficult to recognise worsening symptoms in their children. They also struggle to describe the physiological and behavioural changes that occur and decide what action to take.[4]

In Britain, an expert group suggested actions to improve services and reduce adverse events after discharge. They recommended education and training of parents before discharge, clear guidance to families and health professionals on “what is normal” for that child as well as signs and symptoms to look for and how to respond to them, and the distribution of important contact numbers. They also recommend early warning tools that should be nationally standardised to improve navigation of the complex services pathway.[5]

To support parents' ability to perform their new caregiving responsibilities and detect deterioration after discharge, comprehensive interstage home monitoring programmes have been developed for parents of infants with single ventricle.[6,7] Such programmes use combinations of written material, films, and digital solutions that aims to educate parents, support the health professionals teaching them, and offer tools for detecting deterioration. Some of these programmes exchange data digitally with healthcare teams. In Norway today, the population of infants with single ventricle is small, but recent data show that other infants with CHD also are in need of supportive initiatives.[3] In addition, strategies to support parents at home must be compatible with existing health services.

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Based on these challenges for parents, one of our project group members suggested the concept of a digital tool for decision support in 2018. A multidisciplinary team further developed this concept. Hence, this article aims to describe the development and usability of a personalised application for mobile phones that seeks to interactively increase parents' awareness of their infant's normal (habitual) condition, help them recognise signs of deterioration, and help decide who and when to contact for help.

Materials and methods

An interdisciplinary group from Oslo University Hospital developed the Heart OBServation app to support parents of infants with severe CHD. This group of infants includes a large clinical spectrum. Some infants require extensive monitoring at home, whereas others can be managed through parental care.

Development of intervention

The Heart OBServation app was developed using an iterative systematic evaluation process (Fig 1). It included a combination of: 1) exploration and stakeholder involvement; 2) literature review and theoretical conceptualisation; 3) development of features and content; 4) study of features' usability; and 5) revision of HOBS, incorporating this study's findings.

Exploration and stakeholder involvement

The initial goal was to reduce stress and mortality by providing parents with a decision support tool. This idea was presented using paper prototypes to the Norwegian Association for Children with Congenital Heart Disease, health professionals at the Department of Pediatric Cardiology, and Neonatal Intensive Care Unit at Oslo University Hospital. Users and medical professionals endorsed this concept and the clinic formally approved it. We established a multidisciplinary and user-centred project group to guide the development of content and features in the application. To ensure that the user perspective was captured, the mother of a child with CHD participated in the development process throughout the project. The chief adviser in the Norwegian Association for Children with CHD provided additional contact with parents for feedback during the development process. To ensure a flexible and intuitive system of features, we included a user experience designer. Through an iterative process of exploration and stakeholder involvement, one test group included six parents of children with CHD and four test groups consisted of 28 nurses and two neonatologists from the neonatal ICU. The patients installed a prototype of the mobile application, completed tasks using a questionnaire, and provided written and oral feedback about the features. Following revision based on this feedback, four parents of infants with CHD hospitalised in the neonatal ICU used a test phone for one day, which also gave us valuable feedback

Literature review and theoretical conceptualisation

During the iterative development process, we explored two main theoretical perspectives on how to build supportive features in the application. The application was initially intended as a decision support tool. Such tools usually include a combination of general and individual health information to support decisions regarding patients' health. They can advise users if something is normal, show information relevant to the problem, and recommend actions based on an algorithm.[8] Infants with CHD are vulnerable, and their symptoms may be subtle and similar to normal physiological and developmental variations. Hence, we acknowledge the risk of providing clear recommendations of actions based on an algorithm. With the educational goals in mind and to prevent incorrect decisions, we designed the application as an educational tool. HOBS suggests which signs to look for, how parents could assess them, and when to contact health professionals based on their own interpretations.[9] Since no automated recommendations are made, the HOBS app does not qualify as a medical software device.[10]

Developing the application as a capability-enhancing decision support tool raised the importance of including features to support discharge preparation and readiness. Parents in the target group for HOBS were in transition from hospital to home care for infants with CHD. Readiness for discharge includes competence managing self-care at home, receiving adequate support to cope with life after leaving the hospital, the psychological ability to manage the process, and adequate information and knowledge to respond to common problems.[11] To promote competence managing the infant's care, available support and adequate knowledge were within the scope of the application and intertwined in the features.

Development of features and content

After the initial development phase, we decided to include the following six features:

My Child. In this feature, parents in collaboration with health professionals register information about their child's birth (weight and date), diagnosis, treatment, and needs after discharge, including surgery, pathophysiology, nutritional demands, medications, and need for health-related equipment. The application uses this information to individualise observations in "Normal for my child", questions in the "Assessment function", and to adapt personalised "Information" (Fig 2, Image 1, upper square). A list of tasks to be completed before discharge is included in this section to ensure the completion of settings and guidance of use.

Normal for my child. This feature is built upon the concept that awareness of the infant's normal condition enhances the recognition of signs of deterioration.[5] The consequences of CHD vary, and the "normal" status must be personalised.[12] Hence, in this feature, parents select their infant's condition and behaviour from predetermined alternative descriptions of respiration, circulation, elimination, nutrition, sleeping, and satisfaction. There are 6–10 categories depending on the surgical procedures and monitoring equipment. In each category, parents choose from a list of options that best matches their child. The healthiest choice is at the top of the list, making symptoms of deterioration comprehensible (Fig 2, Images 1 and 2). Parents add concrete numbers for oxygen saturation, respiratory rate, and heart rate.

Information. Individualised information based on the settings from "My child" is allocated to a reading list. The list contains links to nationally approved information for parents, developed by cardiologists and other healthcare professionals working with infants with CHD. This feature aims to support parents in managing self-care at home and responding to common problems[11] (Fig 2, Image 3).

Contact. Telephone numbers to the national centre at Oslo University Hospital are listed in this feature. Information about who and when to call on different occasions is explained, and parents can call directly from the application (Fig 2, Image 4).

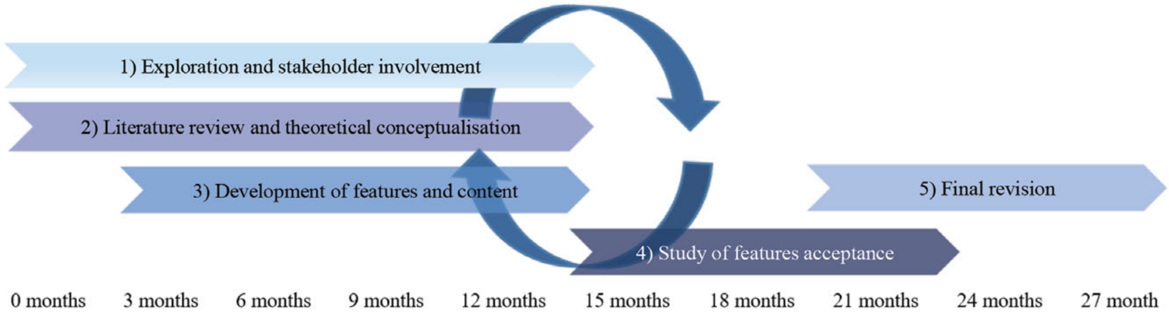
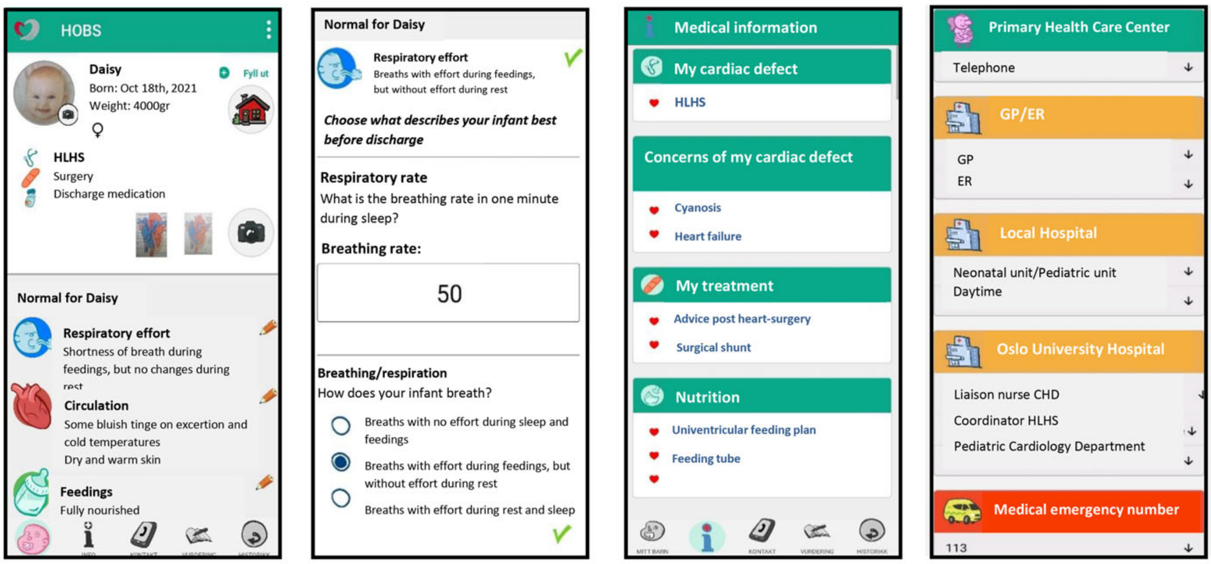


Figure 1. Iterative stages in the development of the Heart OBServation (HOBS) app.



Daisy
Born: Oct 18th, 2021
Weight: 4000gr

HLHS
Surgery
Discharge medication

Normal for Daisy

Respiratory effort
Shortness of breath during feedings, but no changes during rest

Circulation
Some bluish tinge on excertion and cold temperatures
Dry and warm skin

Feedings
Fully nourished

Image 1. «My Child»

Normal for Daisy

Respiratory effort
Breaths with effort during feedings, but without effort during rest

Choose what describes your infant best before discharge

Respiratory rate
What is the breathing rate in one minute during sleep?

Breathing rate:

50

Breathing/respiration
How does your infant breath?

○ Breaths with no effort during sleep and feedings
● Breaths with effort during feedings, but without effort during rest
○ Breaths with effort during rest and sleep

Image 2. «Normal for my child»

Medical information
My cardiac defect
- HLHS

Concerns of my cardiac defect
- Cyanosis
- Heart failure

My treatment
- Advice post heart-surgery
- Surgical shunt

Nutrition
- Univentricular feeding plan
- Feeding tube

Image 3. «Information»

Primary Health Care Center
Telephone

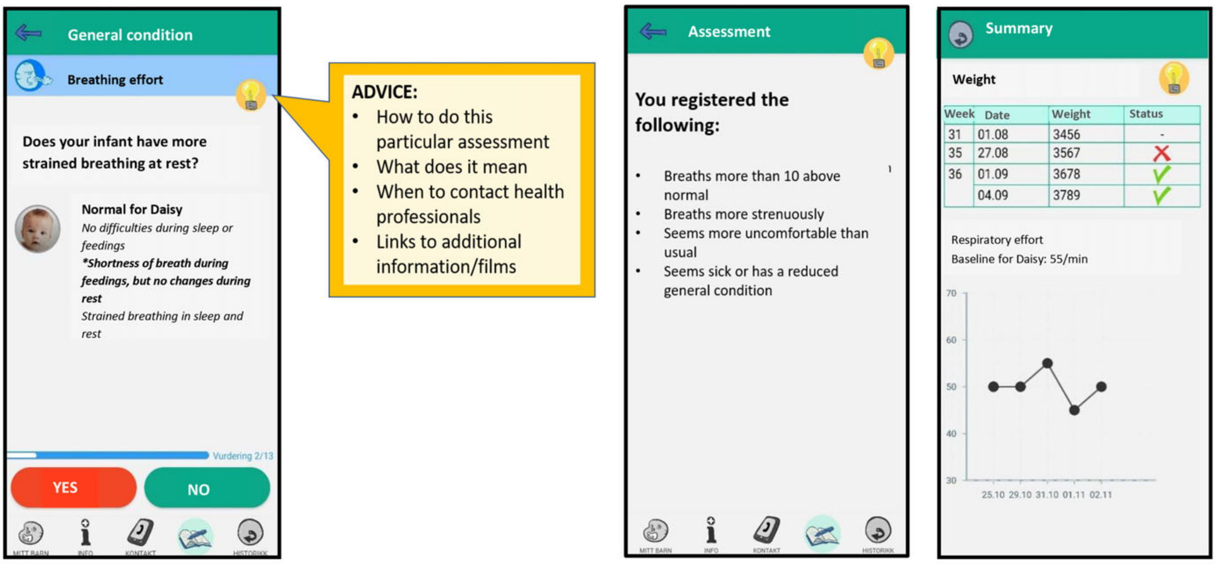
GP/ER
GP
ER

Local Hospital
Neonatal unit/Pediatric unit
Daytime

Oslo University Hospital
Liaison nurse CHD
Coordinator HLHS
Pediatric Cardiology Department

Medical emergency number
113

Image 4. «Contact»



General condition
Breathing effort

Does your infant have more strained breathing at rest?

Normal for Daisy
No difficulties during sleep or feedings
****Shortness of breath during feedings, but no changes during rest***
Strained breathing in sleep and rest

Image 5a. «Assessment»

ADVICE:
- How to do this particular assessment
- What does it mean
- When to contact health professionals
- Links to additional information/films

Assessment

You registered the following:

- Breaths more than 10 above normal
- Breaths more strenuously
- Seems more uncomfortable than usual
- Seems sick or has a reduced general condition

Image 5b. «Assessment respons»

Summary

Weight

Week	Date	Weight	Status
31	01.08	3456	-
35	27.08	3567	✗
36	01.09	3678	✓
	04.09	3789	✓

Respiratory effort
Baseline for Daisy: 55/min

Image 6. «Summary»

Figure 2. Features in Heart OBServation app (HOBS).

When the infant is ready for discharge, parents should register the allocated telephone numbers to local health services before leaving the hospital.[11]

Assessment of my child. The assessment feature covers knowledge to support what to look for.[5] It consists of three areas.

1) *The general condition* was based on the normal condition of the infant. Based on the settings, parents receive 7–14 questions. The selection of questions includes measures from the paediatric early warning score and more specific symptoms of deterioration in infants with CHD.[4,13] Parents assess respiration, circulation, elimination, eating, sleeping, satisfaction, and well-being. They answer “yes” or “no” to questions about deterioration, and a tip-button (light bulb) may instruct them on how to do it, how to interpret the result, and what to do (Fig 2, Image 5a). At the end of the assessment, they receive a summary of worsening symptoms and a general advice to contact healthcare professionals if they are still uncertain or uncomfortable (Fig 2, Image 5b).
2) *Wound assessment:* Parents may take and save pictures of wounds or other visual objects of interest they want to follow. The tip button provides advice about signs of infection.
3) *Weight registration and other measurements:* Weight may be plotted, and weight gain is calculated as sufficient or not visualised by a red cross or a green tick in the summary function.

Summary. The Summary feature provides an overview of completed assessments. Previous assessments of the infants’ conditions are presented as bar charts, and other measurements are presented as curves (Fig 2, Image 6). This function provides an overview and may support communication with health professionals during consultation and follow-up.

Legal aspects

The Information Security Department at the Oslo University Hospital approved the data protection impact assessment and risk analysis of the application for privacy considerations and information security.

Study of features’ usability

After the initial development, we examined the experiences of HOBS features among parents and nurses in a usability study

Study intervention procedure. The eligibility criteria for participation among the parents were that they owned a smartphone, were parenting an infant hospitalised with severe CHD at Oslo University Hospital, gestational age above 34 weeks, and had appropriate Norwegian communication skills. We recruited families after the infant’s cardiac surgery or the final diagnosis if no intervention was conducted before discharge. They signed a written consent. Parents got the Heart OBServation app on their own phones and received a 10–15-min introduction of its main features. Because infants with CHD varies in severity and need of monitoring, each family was advised to make assessments until they were confident in what to look for, before consultations and if they felt unsure of the infant’s condition. An electronic reminder in the hospital’s electronic system for monitoring and ordinations popped up twice a day for the nurses to ensure continuation of guidance before discharge. A checklist of nursing tasks to prepare parents for discharge was attached to the patient’s binder.

Nurses who engaged in family guidance and patient care received a 20-min lecture on the purpose and use of Heart OBServation, its features, and the tasks to complete together with the families. They were encouraged to consult the e-learning course on how to guide the parents and other resources available on the Heart OBServation website, established to support health professionals nationwide (www.hobs.no). A test phone with the application was also available in the unit to make nurses confident with the Heart OBServation app features and content.

Semi-Structured parent interviews. Parents participated in two semi-structured interviews via phone: at the time of discharge from OUH and one month later. The researcher followed a semi-structured interview protocol. The topics in the interviews at discharge were questions about app features and functionality or any other comments. The second interview focused on the usability of the Heart OBServation app features and change requests.

System usability and system use. After both interviews, the System Usability Scale was sent electronically to the parents to measure system usability of the Heart OBServation app.[14] The instrument gives a general score of system usability and consists of 10 items, with five response options from *strongly disagree* to *strongly agree*. Total scores range from 0 to 100, with 100 indicating the most positive response.

In addition, we collected system user logs to capture the use of the assessment function and information links.

Focus group interviews with nurses. Eight nurses from three departments that followed the families in the study were recruited to two focus group interviews after the last family had completed their participation. Their work experience was 1–35 years. The moderator followed a semi-structured interview guide and used a PowerPoint presentation of the Heart OBServation app features to refresh memories and avoid misconceptions. Each feature was discussed, and requests for additions and changes were encouraged. An observer noted the ambiguity and wrapped up the discussion to clarify the interpretations.

Deductive framework analysis. A deductive framework analysis was used to evaluate the features of the application.[15] Comments were sorted as they related to the Heart OBServation app features: 1) my child, 2) normal for my child, 3) measure of condition, 4) wound observation, 5) weight, 6) information, 7) summary, 8) contact, and 9) overall impression. Comments about each feature were interpreted, discussed, and condensed into a meaningful unit representing the patients’ views. Initially, we analysed data from parents and nurses separately. Next, we merged the data sets and compared them to determine the necessary revisions to the Heart OBServation app. Finally, all data in the framework was analysed to explore ideas for new features and changes to the existing design.

Results

Patients of the usability study

Eleven families were consecutively included over a period of three months. One infant recovered before discharge, and one family did not respond to phone calls or questionnaires and did not use the application after hospital discharge (Table 1). The diagnoses represented among the infants were “tetralogy of Fallot”, “Ebstein anomaly”, “aortic stenosis”, “coarctation of the aorta”, “interrupted aortic arch”, and “truncus arteriosus”. For more demographic information regarding the parents and infants, see Table 1. All infants attended follow-up after discharge, and no adverse events occurred during the study.

Results regarding system usability and system use

The overall system usability scores after discharge were 82.3 and 81.7 after one month, indicating good system usability (70–100).[16]

Five parents used the assessment function to evaluate whether they should contact health professionals or not. Only one parent made contact and that was related to observation of increased respiratory distress. The amount of assessment varied depending on CHD severity and cardiologist recommendations. Each parent entered 2–9 different information links (median, 6), but many of the links were entered several times, with a peak at the beginning of the study (Table 1). The most frequently used link was about the infant's diagnosis, postoperative care, and consequences of the infant's condition. Users overlooked the possibility of reading extended information in additional tabs within the allocated information.

Semi-Structured interviews and focus groups

Both parents were invited to participate in semi-structured interviews, but only three fathers joined after discharge from Oslo University Hospital and two after one month at home. The first interview lasted for a mean 12 min (range, 7–14 min). Five of these interviews occurred when the child was still at a local hospital and four when they were at home. The second interview lasted for a mean 18 min (range, 10–26 min). The focus group interviews with nurses lasted for 75 and 90 minutes.

The Heart OBServation features were considered as intuitive and easy to use. Users found the contents and features valid and the information relevant, available, and easy to understand. They requested only minor revisions to the features and content. Table 2 presents an overview of the results after the framework analysis, illustrating quotes regarding each feature

Final revision of the Heart OBServation app

Overall, the results from the qualitative analysis, System Usability Scale, and log data provided useful information for the revision of Heart OBServation. The project group held digital workshops to review, select, and decide on revisions. The final revisions included nuance some categories in "normal to my child", more explicit advice in some areas of "the assessment feature", add an interactive discharge preparation list, and redesign "the information feature" to be more personalised. See Table 2 for details of the requested and fulfilled revisions.

Discussion

In this paper, we report on the process of development, usability testing, and revision of a smartphone application to support the parents of infants with severe CHD as an alternative to traditional paper-based information. The results of this usability study are promising, as the usability scores were high, and the parents and nurses evaluated Heart OBServation baby as easy to use. Users considered the content and features valid and requested only minor revisions. Interviews with parents and nurses provided useful information about their use of the application and necessary revisions.

An important aim of the Heart OBServation application was to help parents know what was normal for their child and use it as a baseline for assessments.[5] Parents and nurses expressed that the use of Heart OBServation drew attention to and provided control over something parents would normally have been less aware of. Choosing between defined categories does not precisely describe the infant's condition, but the added nuances may refine the parents' apprehension about their child. The parents did not express any problems when assessing changes from their registered normal condition. Our interpretation is that the personalised design facilitated the parents' awareness of "what is normal" versus not.[5]

Support for discharge preparation is an important aim of the Heart OBServation app. The existing discharge checklist for the application was neither interactive nor personalised, and nurses were unsure about parents' ability to execute the right initial settings by themselves. To agree on completion of learning tasks is important for the empowerment of parents and discharge preparations.[11] Such empowerment has been facilitated in programmes to support parents of infants with single ventricle in home monitoring programmes.[17] Hence, an interactive discharge feature for parents based on personalised settings in "My child" to confirm readiness for discharge was included and advanced underneath the home icon.

Parents evaluated the information function as relevant, available, and easy to understand. Further investigations revealed that some information headings were general, and user logs revealed that tabs used to explore additional electronic information were overlooked. Hence, we revised the information feature to use a more personalised design and removed the tabs to obtain hidden information.

Requests for new functionality, such as sharing information and settings between parents, were not included because of financial limitations and data privacy matters. We also rejected the request of a calendar in Heart OBServation to track events and consultations because this function is available on all mobile phones.

For unknown reasons, one family did not use the application after discharge. As mentioned by a nurse in one of the focus groups, this could relate to the fact that parents not necessarily appreciate mobile applications, or it might be overwhelming to capture in a chaotic situation.[18] We do not know whether paper information and contact with health professionals would have been preferred in this case. However, the availability of information in a mobile app may be beneficial to all parents as experienced by parents and nurses in this study. An ongoing study will compare whether Heart OBServation or written information is preferred in discharge preparation and follow-up.

Fathers participated in only five of the 17 interviews. Nevertheless, these fathers were positive about the features of the application. Reasons for limited participation may have been that mothers are still primary caregivers on paid leave, hospitals' coronavirus disease 2019 precautions and visit restrictions disfavoured fathers, and fathers had started working by the time of the second interview. In this situation, the possibility of sharing content could have been favourable to utilise Heart OBServation for both parents.

There are limitations to the present work related to the short trial period and small number of patients. One of the aims of the application is to empower parents to recognise deterioration in their children. Although many parents acknowledged the benefit of having a checklist of symptoms to look for, only one family experienced deterioration during the trial period, which is not enough

Table 1. Parent and infant demographics, clinical characteristics, and user logs (n = 9)

Characteristics	n (%)	Median	Max	Min
Main caregiver first month				
Mother	9 (100)			
Main caregiver age		31	38	27
Years of education after mandatory school		7	9	3
Families with siblings	6 (67)	1	4	1
Single parents	1 (11)			
Infant birth and medical information				
Gestational age		39.3	40.6	37.2
Female	2 (22)			
Male	7 (78)			
Antenatal diagnosis	2 (22)			
Postnatal diagnosis	6 (67)			
Post-discharge diagnosis	1 (11)			
Surgery	6 (67)			
Catheterisation	2 (22)			
Waiting for surgery	4 (44)			
Medical treatment after discharge	4 (44)			
Hospital stay				
Total days of admission at specialist centre		12	21	7
Days with HOBS before discharge from specialist centre		6	9	2
Days at local hospital before discharge	5 (56)	1	7	0
Consultations with liaison nurse	8 (89)	2	3	0
Consultations psychologist	7 (78)	2	3	0
Follow-up after discharge				
Days of follow-up from local hospital after discharge	4 (44)	0	21	0
Consultations with cardiologist after discharge	9 (100)	2	4	2
Consultations with community nurse	9 (100)	3	4	2
Days from discharge to second interview		38	44	30
Type of smartphone				
Apple	7 (78)			
Android	2 (22)			
Log from app				
Number of assessments to practice at hospital	8 (89)	1	2	0
Number of assessments at home	9 (100)	2	7	1
Entered information links	9 (100)	6	9	2

to claim that Heart OBServation increases their capability to recognise and act on possible deteriorations. On the other hand, half of the included families used the assessment function when managing uncertainty of symptoms like crying and vomiting and felt reassured and did not contact healthcare professionals. This reassurance could be a potential benefit.

Conclusion

This study is the first to evaluate usability of features in a mobile application, to support parents to infants with a broad spectrum of severe CHD diagnosis. The Heart OBServation app combines new and already established strategies to prepare and support parents with severe CHD in one interactive application. This application

Table 2. Results from deductive analysis of parents‘ and nurses‘ experiences of the functionality of the heart OBServation (HOBS) app

Feature and description	Extract from parental evaluation of the features	Illustrating quotes from parents	Extract from nurses’ evaluation of features	Illustrating quotes from nurses	Changes
My child: Individualise HOBS to the infant regarding diagnosis, treatment, needs, and birth information. Controls settings in normal for my child, sssessment of condition, and information.	**Experiences:** Easy and intuitive to fill out. Wants introduction and support to secure correctly filled out. **Requests:** None.	“We (with a nurse) kind of went through it again and adapted it completely, so I think it was very easy” Mother (M)3	**Experiences:** Clear, simple, and comprehensive. Entail guidance to choose the right topics. **Requests:** None.	“I think it is quick and specific on what is important” Nurse (N)4 “I would not trust parents to do it (settings) on their own” N3	Include completion of app settings in discharge function.
Normal for my child: Infant’s appearance is selected by parents regarding, respiration, circulation, elimination, eating, sleeping, and satisfaction.	**Experiences:** Easy and intuitive to fill out. Raises awareness of child’s normal appearance. **Requests:** Nuance some categories (vomiting, eating habits, and clammy skin).	“It was very easy to fill in, but I might wish it was a little more options” M6 “It varies during the day . . . He gets hot and humid sometimes, but other times he is dry and hot” M3 “ . . . I feel confident about her normal condition” . . . ”I might not have such control without it (HOBS)” M9	**Experiences:** Gives systematic, specific overview to required observations. Focuses on respirations and circulation, which parents usually do not pay attention to. Enables a retrospective view of what was normal for the child. **Requests:** Video of respiratory distress should be included. More nuanced categories in eating, skin appearance, and vomiting.	“It is much more systematic” . . . “It was not presented in such a way before and to be able to go back” N3 “But I think it’s the two on top (respiration and circulation) that we care about a lot, and the next two that parents would like to talk about. Because it is nutrition they are very concerned about” N2 “I think that with video, parents can more easily assess normal respiration for their child” N1	Video of respiratory distress is included as a link. Nuance three categories.
Assessment of condition: Parents record respirations, circulation, elimination, eating, sleeping, and satisfaction due to an algorithm. They answer yes or no to questions about deterioration and a tip button may advise them how to do it, how to interpret the result, and what to do.	**Experiences:** Nice to have as a checklist if needed. Gives awareness of what to look for and what it means. Not necessary to use it every time because they remember. It might be stressful to know that normal changes like increase of crying and vomiting may imply deterioration. **Requests:** Clear description of interpretation of what to do about negative measures of increased vomiting and crying.	“I am thinking . . . it’s just an extra reminder of what I should follow and be aware of” M8 “ . . . I think they (the advice) are great. Very simple and informative. Very soothing really because it’s kind of eerie” M6 “The assessment part I think is quite despairing at times because it is a question of whether the child cries more than usual. . . . I then think that it is something with the heart right away” M4	**Experiences:** Clarifies what to look for in a list. Useful as a tool to learn what to look for and how to do it. **Requests:** None.	“It becomes very clear when you are going to assess your child” – “You should look after these things!” N5 “And it’s easier to assess the baby with the app, and the parents might think so too” N1	Include completion of teaching about interpretation of measure in a discharge function.
Wound observation: Parents may take pictures of wounds or other visual things they want to follow. A tip button gives advice about signs of infection.	**Experiences:** Appreciate the possibility to compare wound pictures. One mother had technical issues. **Request:** To use phone gallery.	It was very nice that there was a nurse who remembered that it was wise to have a picture for comparison from the hospital” M2	**Experiences:** Value the opportunity to compare wounds. Explains what to look for in a sufficient way. **Requested:** None.	“I think it is a very nice tool if used. You may see improvement or possibly a deterioration” N5	Add completion in discharge function.
Weight: Weight may be plotted and weight gain is calculated to be sufficient or not and visualised by a red cross or green checkmark.	**Experiences:** Used by all caregivers. Appreciates the confirmation of good weight gain.	“ . . . I think that it was pretty good when you got such a green checkmark. It was kind of a relief, to see that things worked as they should” M7	**Experiences:** No specific comments		None.

(*Continued*)

Table 2. (*Continued*)

Feature and description	Extract from parental evaluation of the features	Illustrating quotes from parents	Extract from nurses' evaluation of features	Illustrating quotes from nurses	Changes
Information: Parents receive individualised information based on an algorithm from "My child" in a reading list.	**Experiences:** Relevant, available, and easy to understand. **Requested:** Parents missed information about: Sick siblings, exercise after operation.	"Both her great-grandmother, who has worked forty years in the hospital, and the young lady at eight, got the same information and thought the information was fair" M8	**Experiences:** More available in HOBS than in handouts. Possibility to gather written information is absent. **Requested:** None.	"I'm very happy that, it's now on the app, not in those binders" N3 " . . . the binder comes in handy when they are more than three months, because when they come to surgery number three, the binder follows the kid" N2	Personalise headlines in information categories. Add information as requested.
Summary: Measures of condition are presented as bar chart and other measurements in curves.	**Experiences:** Not interested in curves, but numbers from normal appearance. **Request:** Possible to delete results.	"I only did it once, the week he was restless and unhappy. I counted how much he was breathing. He had same number as before - it was good" M1	**Experiences:** No experience of use.		Possible to delete results in curves and diagram.
Contact: Parents may gather telephone number to local contact during hospitalisation. Information about who to call when is added to each service level.	**Experience:** Used in many different ways, but most important to gather number and information at one place. **Request:** None.	"I have used it every time I needed numbers for all those we are going to call. I have entered all those numbers we put in the app before we left" F11 "It is okay to have everything in one place really" M2	**Experiences:** Important information to receive. Traffic light makes it visual as more or less acute. Adds valuable information about who to call when. **Requested:** Add tip on important information in emergency calls.	"It is very nice that there is both contact information but also about when they should contact the different units" N7 "I think, they can be quite stressed if the child gets pretty bad at home in a way. It is very nice that things are easily accessible if they are entered" N5	Include important information in emergency calls. Add completion in discharge function.
Overall impression	**Experience:** Easy, helpful, and available tool. Not an everyday app.	"It is a practical tool, instead of the binder. Everything is gathered at one place and the telephone is with us at all times" M11 "It was written inside the app, use if you are unsure of something. It is not such an everyday app, so therefore I used it when I was a little unsure of something, and to read something" M1	**Experiences:** More available and forward-looking. Specific heart disease focus makes it to something else than an "everyday app," which is good. Not all parents and health care workers are fond of apps.	"I think that by having it on the phone, it might be used more, and you never forget to take your phone with you when you go to hospital" N6 "It's very good with the app . . . honestly, I've been sceptical all the way, thinking back on how overwhelming it would have been to have one sick child and then learn this as well. Instinctively, I could only wish to just be a mom and call if there was something I was wondering" N8	Maintain written information as a possibility. Let parents choose what features to use.
New functions	**Requests:** A notebook for recording events and questions. A timeline/calendar to record consultations. Automatic sharing adaptation and measurements with a partner.		**Requested:** An interactive checklist for discharge teaching may systemise and clarify tasks to learn.		Interactive discharge function based on My child.

aims to increase parents' awareness of their infant's normal (habitual) condition, help them assess signs of deterioration, decide who and when to contact for health services if necessary, and what to report. Heart OBServation was well received by parents and nurses in this usability study. The feasibility and benefits of this application in clinical practice will be investigated in further studies.

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Conflicts of interest. None.

Ethical standards. Ethical approval for this study was obtained from the Regional Committee for Medical and Health Research Ethics, South East, Norway (2019/1271). All patients received written information about the study before giving their written consent to participate and were informed that they could withdraw from the study at any time.

References

1. Leirgul E, Fomina T, Brodwall K, et al. Birth prevalence of congenital heart defects in Norway 1994–2009—a nationwide study. Am Heart J 2014; 168: 956–964.
2. Wik G, Jortveit J, Sitras V, Døhlen G, Rønnestad AE, Holmstrøm H. Severe congenital heart defects: incidence, causes and time trends of preoperative mortality in Norway. Arch Dis Child 2020; 105: 738–743.
3. Wik G, Jortveit J, Sitras V, Døhlen G, Rønnestad AE, Holmstrøm H. Unexpected death in children with severe congenital heart defects in Norway 2004–2016. Arch Dis Child 2021; 106: 961–966.
4. Tregay J, Brown KL, Crowe S, et al. Signs of deterioration in infants discharged home following congenital heart surgery in the first year of life: a qualitative study. Arch Dis Child 2016; 101: 902–908.
5. Crowe S, Knowles R, Wray J, et al. Identifying improvements to complex pathways: evidence synthesis and stakeholder engagement in infant congenital heart disease. BMJ Open 2016; 6: e010363.
6. Gaskin KL, Wray J, Barron DJ. Acceptability of a parental early warning tool for parents of infants with complex congenital heart disease: a qualitative feasibility study. Arch Dis Child 2018; 103: 880–886.
7. Rudd NA, Ghanayem NS, Hill GD, Lambert LM, Mussatto KA, Nieves JA, et al. Interstage home monitoring for infants with single ventricle heart disease: education and management. J Am Heart Assoc 2020; 9: e014548.
8. Makhlysheva A, Kristian N, Ruiz LM, Bakkevoll PA, Pedersen R. Klinisk beslutningsstøtte - Vurdering av standard og arkitektur. Tromsø: Nasjonalt senter for e-helseforskning; 2017. Contract No.: 978–82-.
9. Nystrom D. How should risks posed by decision support be managed? AMA J Ethics 2020; 22: E952–E955.
10. Statens legemiddelverk. Klassifisering av medisinsk utstyr [Guideline]. Oslo: Statens legemiddelverk; 2021 [updated 17.06.2021; cited 2021 19.01]. Available from: https://legemiddelverket.no/medisinsk-utstyr/hvordan-sette-medisinsk-utstyr-pa-markedet/klassifisering.
11. Galvin EC, Wills T, Coffey A. Readiness for hospital discharge: a concept analysis. J Adv Nurs 2017;73(11):2547–2557.
12. Daily J, FitzGerald M, Downing K, King E, del Rey JG, Ittenbach R, et al. Important knowledge for parents of children with heart disease: parent, nurse, and physician views. Cardiol Young 2015; 26: 61–69.
13. Lambert V, Matthews A, MacDonell R, Fitzsimons J. Paediatric early warning systems for detecting and responding to clinical deterioration in children: a systematic review. BMJ Open 2017; 7: e014497.
14. Bangor A, Kortum PT, Miller JT. An empirical evaluation of the system usability scale. INT J HUM-COMPUT INT 2008; 24: 574–594.
15. Green J, Thorogood N. Qualitative Methods for Health Research. 4th edn. London: SAGE Publications Ltd, 2018.
16. Bangor A, Kortum P, Miller J. Determining what individual sus scores mean: adding an adjective rating scale. J Usability Stud 2009; 4: 114–123.
17. Tanem JMA. Amobile Application as a Tool for Guided Participation. In: Pridham KLR, Schroeder M (eds). Guided Participation in Pediatric Nursing Practice: Relationship-Based. New York: Springer Publishing Company; 2018. 341–354.
18. Woolf-King SE, Anger A, Arnold EA, Weiss SJ, Teitel D. Mental health among parents of children with critical congenital heart defects: a systematic review. J Am Heart Assoc 2017; 6: e004862.

II

Original Paper

Acceptability and Initial Adoption of the Heart Observation App for Infants With Congenital Heart Disease: Qualitative Study

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Abstract

Background: Approximately 1% of all infants are born with a congenital heart disease (CHD). Internationally CHD remains a major cause of infant death, some of which occur unexpectedly after a gradual deterioration at home. Many parents find it difficult to recognize worsening of symptoms.

Objective: This study aims to report the acceptability and initial adoption of a mobile app, the Heart Observation app (HOBS), aiming to support parents' understanding and management of their child's condition and to increase quality in follow-up from health care professionals in complex health care services in Norway.

Methods: A total of 9 families were interviewed on discharge from the neonatal intensive care unit and after 1 month at home. The infant's primary nurse, community nurse, and cardiologist were also interviewed regarding their experiences about collaboration with the family. The interviews were analyzed inductively with thematic content analysis.

Results: The analysis generated 4 main themes related to acceptability and adoption: (1) Individualize Initial Support, (2) Developing Confidence and Coping, (3) Normalize When Appropriate, and (4) Implementation in a Complex Service Pathway. The receptivity of parents to learn and attend in the intervention differs according to their present situation. Health care professionals emphasized the importance of adapting the introduction and guidance to parents' receptivity to ensure comprehension, self-efficacy, and thereby acceptance before discharge (Individualize Initial Support). Parents perceived that HOBS served them well and nurtured confidence by teaching them what to be aware of. Health care professionals reported most parents as confident and informed. This potential effect increased the possibility of adoption (Developing Confidence and Coping). Parents expressed that HOBS was not an "everyday app" and wanted to normalize everyday life when appropriate. Health care professionals suggested differentiating use according to severity and reducing assessments after recovery to adapt the burden of assessments when appropriate (Normalize When Appropriate). Health care professionals' attitude to implement HOBS in their services was positive. They perceived HOBS as useful to systemize guidance, to enhance communication regarding an infant's condition, and to increase understanding of heart defects in health care professionals with sparse experience (Implementation in a Complex Service Pathway).

Conclusions: This feasibility study shows that both parents and health care professionals found HOBS as a positive addition to the health care system and follow-up. HOBS was accepted and potentially useful, but health care professionals should guide parents initially to ensure comprehension and adapt timing to parents' receptivity. By doing so, parents may be confident to know what to look for regarding their child's health and cope at home. Differentiating between various diagnoses and severity is important to support normalization when appropriate. Further controlled studies are needed to assess adoption, usefulness, and benefits in the health care system.

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KEYWORDS

congenital heart disease; readiness for discharge; mobile app; follow-up, health services; mHealth

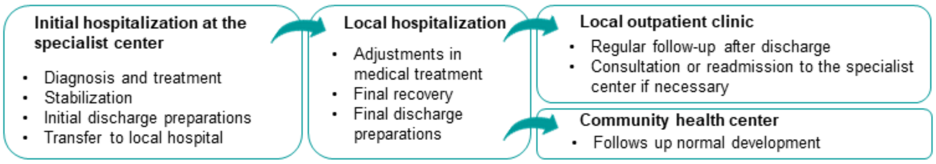
Introduction

Congenital heart disease (CHDs) are a birth defect affecting approximately 1% of newborns [1]. Approximately 25% of these infants have a severe CHD, and in Norway approximately 125 infants are born with a severe CHD each year [2]. Internationally, CHD is still a major cause of infant death [3], and around 10% of Norwegian children with severe heart disease die during the first 2 years of life [4]. Recent research shows that 29% of these deaths occurred unexpectedly unrelated to surgery, of which 60% after a gradual deterioration at home [5].

Many parents express difficulties in recognizing deterioration, and in situations where symptoms are detected, it may be difficult to describe them or decide what to do [6]. Comprehensive interstage home-monitoring programs using digitally transmitted assessments to a follow-up team support parents of the most vulnerable infants with single ventricle [7,8]. In Norway today, the population of this subgroup of infants with CHD remains small, but recent data show that other infants with CHD are also in need of supportive initiatives [5]. In Britain, an expert group recommended to develop an early warning tool to all infants with a severe CHD, which should be standardized nationally to improve discharge preparation and follow-up [3].

Solutions adapted to mobile apps present novel opportunities to meet recommendations in follow-up for a more diverse group of infants with CHD. In recent years some initiatives have been started. In China, an app called "WeChat follow-up" supports parents with educational videos and information, telephone consultation, and chat with other parents using the app. This has shown to reduce worries and depression, improve quality of life, and increase knowledge about simple CHD [9,10]. An educational program including a mobile app with information to parents about infants with CHD was also developed in the United States. This app is informative but is not adapted to each child and not yet scientifically assessed [11]. Although these initiatives are promising, new strategies have to be compatible with the existing health services and personal, social, cultural, and organizational factors must be addressed [12-14]. In Norway, the Oslo University Hospital (OUH) is the only specialist center that performs surgery for children with CHD. In addition, they follow-up families in difficult cases and give advice and cooperate with local hospitals when needed (Figure 1). This gives the specialist center an opportunity to standardize an early warning tool and distribute it during their follow-up of 19 local hospitals. Hence, a project group at the specialist center developed the Heart Observation app (HOBS) in close collaboration with parents of infants with CHD and health professionals at local health care services [15].

Figure 1. Health care services to infants with CHD initially treated at the specialist center in Norway. CHD: congenital heart disease.



HOBS is a complex intervention and The Medical Research Council recommends evaluating the feasibility of such interventions to ensure implementation [12]. A feasibility study should be designed to assess areas such as optimal content and delivery, acceptability, and adoption of the intervention among both recipients and deliverers of the intervention [12,14,16].

According to the Theoretical Framework of Acceptability, the concept of acceptability includes users' attitude toward the intervention, burden of attendance, the extent to which the intervention fits with users' value system, comprehension of the intervention, the effort to engage in the intervention, perceived effectiveness, and self-confidence to participate in the intervention [17]. Acceptability focuses on individual aspects, but when evaluating mobile health (mHealth) used by multidisciplinary teams in clinical care, it is important to have an additional focus on the interplay between technical, social, and organizational aspects. To do so, we have consulted a consolidated framework for adoption of mHealth [16]. Usability and optimization of HOBS content were reported previously [15]. The aim of this paper is therefore to present the feasibility study in which we report the results of assessment of acceptability and initial adoption among intervention deliverers and recipients to optimize implementation in an ongoing controlled trial.

Methods

The HOBS Intervention

Overview and Features

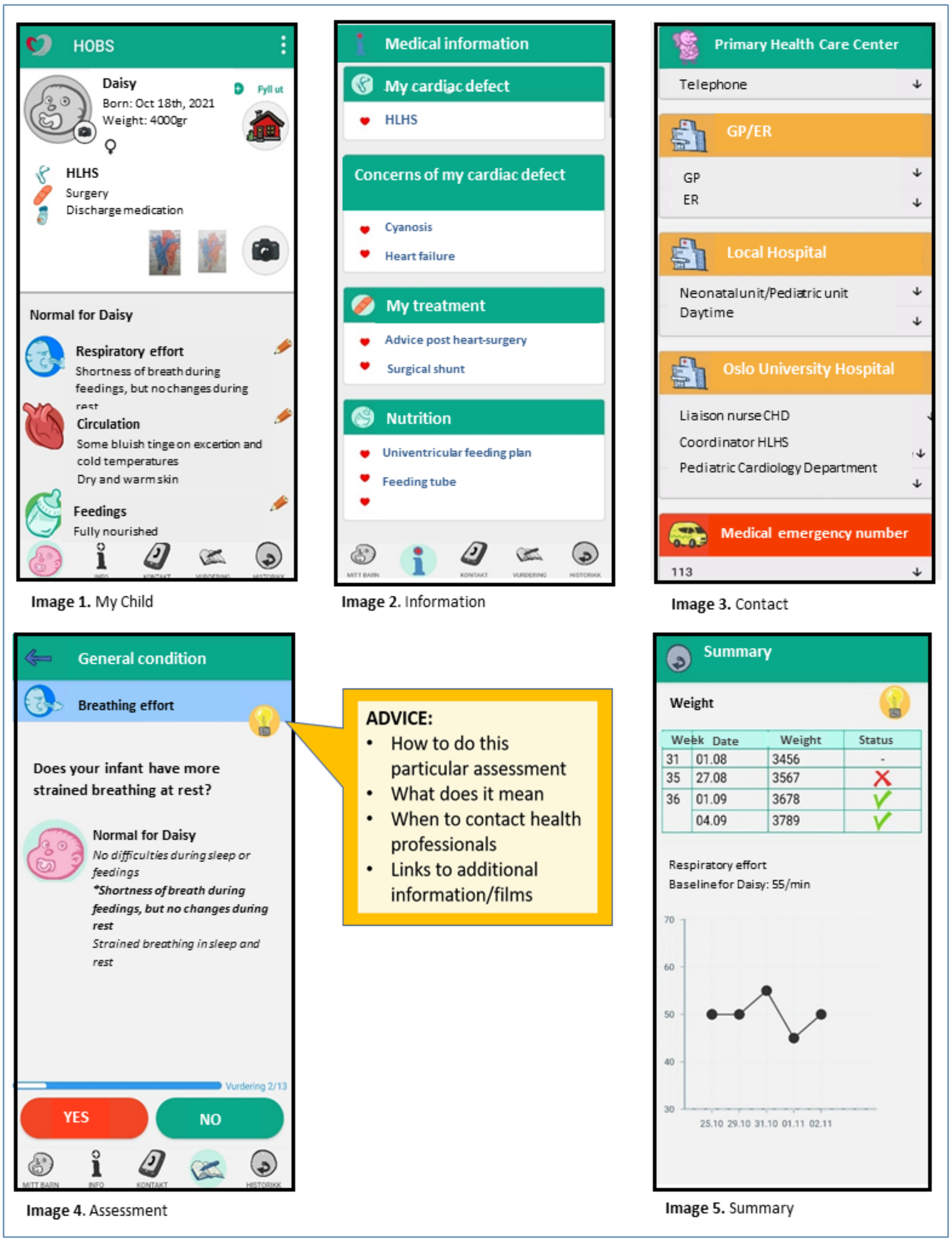
HOBS is developed as a capability-enhancing decision support tool and to support discharge preparations and follow-up at outpatient clinics [15].

HOBS has 5 main features: (1) My Child, (2) Information, (3) Contact, (4) Assessment, and (5) Summary (Figure 1).

My Child

To personalize HOBS, the diagnosis, treatments, and need for monitoring and equipment are registered in "My Child" (image 1 in Figure 2). This provides parents with a personalized set of observations, information, and assessment questions. At discharge, parents do a final observation of their infant and store this information in the app as the normal baseline for the infant.

Figure 2. Features in The Heart Observation app (HOBS).



HOBS

Daisy
Born: Oct 18th, 2021
Weight: 4000gr

HLHS
Surgery
Discharge medication

Normal for Daisy

Respiratory effort
Shortness of breath during feedings, but no changes during rest

Circulation
Some bluish tinge on excertion and cold temperatures
Dry and warm skin

Feedings
Fully nourished

Image 1. My Child

Medical information

My cardiac defect
- HLHS

Concerns of my cardiac defect
- Cyanosis
- Heart failure

My treatment
- Advice post heart-surgery
- Surgical shunt

Nutrition
- Univentricular feeding plan
- Feeding tube

Image 2. Information

Primary Health Care Center
Telephone

GP/ER
GP
ER

Local Hospital
Neonatalunit/Pediatric unit
Daytime

Oslo University Hospital
Liaison nurse CHD
Coordinator HLHS
Pediatric Cardiology Department

Medical emergency number
113

Image 3. Contact

General condition

Breathing effort

Does your infant have more strained breathing at rest?

Normal for Daisy
No difficulties during sleep or feedings
Shortness of breath during feedings, but no changes during rest
Strained breathing in sleep and rest

ADVICE:
- How to do this particular assessment
- What does it mean
- When to contact health professionals
- Links to additional information/films

Image 4. Assessment

Summary

Weight

Week	Date	Weight	Status
31	01.08	3456	-
35	27.08	3567	✗
36	01.09	3678	✓
	04.09	3789	✓

Respiratory effort
Baseline for Daisy: 55/min

Image 5. Summary

Information

This feature contains personalized information about the child's diagnosis and its consequences, treatments, and use of equipment for monitoring, postoperative care, and nutrition (image 2 in Figure 2).

Contact

This feature contains explanations on where and when to contact health care professionals at the specialist center, locally and in emergency (image 3 in Figure 2). Parents add numbers to local services.

Assessment

This focuses on general condition, wound assessment, and weight gain. It presents personalized questions about changes from baseline regarding the child's circulation, breathing, eating habits, and well-being (image 4 in Figure 2). An advice functionality guides parents on how to interpret signs.

Summary

This collects results from measurements and presents them in bar graphs and curves, and gives advice for the interpretation of weight gain (image 5 in Figure 2).

In this study, the HOBS intervention also included some support from health care professionals. These were (1) an overall introduction of features when uploading data to the app, (2) support to perform and choose the correct settings in "My Child" and to add observations in "Normal for my child" by bedside nurses, and (3) support to encourage parents to ask questions if they were uncertain about certain areas during hospital stay and before discharge.

Study Design

HOBS is a complex intervention and therefore evaluated in several phases using a mixed methods design [12]. We have completed a usability study to adapt the app to the needs of parents and health care professionals [15]. This qualitative study aims to explore its feasibility, acceptability, and adoption to address further implementation in health services.

Ethical Considerations

This study was approved by the Privacy Protection and Data security committee at Oslo University Hospital (project number 19/23041), and the Regional Committee for Medical and Health Research Ethics, South East, Norway (2019/1271). All parents signed an informed consent before taking part in the study and were informed that they had the opportunity to withdraw from the study at any time. Empirical findings from the study were presented as deidentified statements, according to Norwegian legislation.

Inclusion and Introduction of HOBS to Parents

The eligibility criteria for participation among the parents were parenting an infant hospitalized with a severe CHD at the specialist center, gestational age above 34 weeks, having a smartphone, and able to read and write Norwegian. Bedside nurses invited families to learn about the project after the infant's cardiac surgery or after the final diagnosis if no intervention was conducted before discharge. Those interested in participating received more information from the first author (EH-J). Parents agreeing to participate in the study signed a written consent form, before installing HOBS on their own phones. They received a 10–15-minute introduction of the main features of HOBS from the first author, and bedside nurses responsible for the patient helped parents with further personalization of the app to the infant. Because of COVID-19 precautions, mothers and fathers could only visit the unit 1 at the time, so most guidance to parents was given separately. As the severity of CHD varies among infants, and therefore the need for monitoring, each parent was advised to use HOBS (1) for assessments until they were confident in what to look for, (2) before consultations, and (3) if/when they felt unsure of the infant's condition. They were encouraged to cooperate with nurses, cardiologists, and community nurses regarding their infant's health using the app.

Inclusion and Introduction of HOBS to Health Care Professionals

Nurses who were engaged in the guidance of parents and patient care at the specialist center received a 20-minute lecture about the purpose and use of HOBS, its features, and the tasks to complete together with the families. A test phone with the app was also available at the unit to make nurses confident with the features and content of HOBS. They were also encouraged to consult an e-learning course about the various features of HOBS and other resources available on the HOBS website, which was established to support health care professionals nationwide [18]. A checklist of nursing tasks to help parents prepare for discharge was available at the bedside. An electronic reminder in the hospital's electronic system for monitoring and ordinations popped up 2 times a day for the nurses to ensure continuation of guidance before discharge. In local hospitals, nurses received a list of tasks to complete, but no lecture or test phone to practice. To support implementation of local follow-up, the first author called the local hospitals, providing information to the head nurse about the e-learning course on HOBS features, and asked for it to be shared among nurses in their hospitals. She also asked for identification of a nurse responsible for following up with the family that we interviewed after discharge from the local hospital.

On the day the infant was discharged from the specialist center, the first author contacted local cardiologists and community nurses following up with the family to share information about HOBS and asked for an opportunity to interview them 1 month after discharge. All health care professionals received the HOBS e-learning course in a link or as a Microsoft PowerPoint presentation, and were encouraged to include HOBS in their further cooperation with the parents.

Data Collection

Interviews With Parents

Parents participated in 2 semistructured interviews via phone at the time of discharge from the specialist center and 1 month later (Table 2). The first author used a tape recorder and followed a semistructured interview protocol. The topics in the interviews during discharge were questions related to their experience with the introduction of and initial guidance with

HOBS at the specialist center. For 5 families, the interviews were conducted when the child was still at a local hospital and for 4 while they were at home. The second interview focused on acceptability and adoption of HOBS during the follow-up of the child, and whether it affected their psychological adaption at home.

Individual Interviews and Focus Group Interviews With Health Professionals

Nurses and cardiologists at 6 local hospitals and community nurses at 8 different community centers were individually interviewed via phone by the first author (Table 1). She used semistructured interview protocols about their experience of cooperating with the family and views about implementing HOBS in their services.

In addition, we conducted 2 focus group interviews with nurses at the specialist center that followed the families in the study after the last family had completed the HOBS intervention. The moderator (EH-J) followed a semistructured interview guide and used a Microsoft PowerPoint presentation of HOBS features to refresh memories and avoid misconceptions. Experiences in using the app for guidance were discussed. One of the co-authors (IMØ) observed the interviews, noted ambiguity, and wrapped up the discussion to clarify the interpretations.

Table 1. Overview of interviews of parents and health care professionals.

Role/participation	Invited	Withdrew	Interviewed	Total minutes	Mean minutes	Range
Families first interview[a]	10	2[b,c]	8	96	12	7-14
Families second interview[d]	10	1[c]	9	162	18	10-26
Nurses	9	0	9	215	13	11-26
Cardiologists	9	2[c]	7	107	13	8-19
Community nurses	9	1[c]	8	122	16	9-22
Focus group	10	2[e]	8	165	N/A[f]	75-90

[a] 8 mothers and 3 fathers.

[b] One family withdrew due to time constraints.

[c] Did not reply.

[d] 9 mothers and 2 fathers.

[e] Time conflict.

[f] N/A: not applicable.

Analysis

We used inductive thematic analysis as described by Braun and Clarke [19] for data analysis. EH-J and IMØ transcribed interviews and controlled the transcription consecutively during the study period. They wrote a summary of the 9 cases, consisting of interviews of parents and their health care professionals, to become familiar with the data (step 1). They interpreted, discussed ambiguity, and coded all interviews (step 2). EH-J organized interviews from parents and groups of health professionals separately into subthemes using NVivo (QSR International). IMØ generated themes from focus group interviews using Microsoft Word (step 3). After initial coding, both reviewed subthemes by condensing paragraphs from stakeholders' experiences into meaningful units and restructured subthemes and themes (step 4). Finally, they merged themes from stakeholder groups to determine overarching themes (step 5). To clarify thoughts and inferences, they explained each theme and subtheme, and used quotes from participants to illustrate the subtheme of interest in a table. To validate interpretation, this final document was discussed with 2 other study authors (AM and EB) who were not involved in the initial development of HOBS. One mother of a child with CHD from the development group acknowledged the themes and interpretations as reasonable based on her own experience of HOBS and quotes from parents in this study. The Theoretical Framework of Acceptability and The Consolidated Framework for Adoption of mHealth supported further analysis of acceptability and adoption among parents and health care professionals to support further implementation of HOBS. The first author translated the quotes used in this article from Norwegian to English, and displayed them together in this paper to ensure agreement about translation and interpretation. We followed the "Consolidated criteria for reporting qualitative research" (COREQ) for writing this paper [20].

Results

Demographics and Clinical Characteristics of Parents and Infants

A total of 11 families were invited to participate from October 2020 to January 2021. All invited families agreed to participate; 1 family was not reachable after discharge and 1 infant had a quick recovery before discharge and thus were not eligible due to the scope of the study. For further details about the characteristics of parents and infants in the participating 9 families, see Table 2.

Table 2. Demographics and clinical characteristics of parents and infants (N=9).

Characteristics	Values
Main caregiver in the first month	
Mother, n (%)	9 (100)
Main caregiver age, median (range)	31 (27-38)
Years of education after mandatory school, median (range)	7 (3-9)
Families with siblings, n (%)	6 (67)
Single parents, n (%)	1 (11)
Infant diagnosis, n (%)	
Antenatal diagnosis	2 (22)
Postnatal diagnosis	6 (67)
Diagnosis after discharge from the maternity ward	1 (11)
Infant treatment[a], n (%)	
Surgery	6 (67)
Catheterization	2 (22)
Waiting for surgery	4 (44)
Treatment with drugs after discharge	4 (44)
Hospital stay, median (range)	
Total days of admission at the specialist center	12 (7-21)
Age of infants at the introduction of HOBS[b] (days)	8 (2-51)
Days with HOBS before discharge from the specialist center	6 (2-9)
Days at a local hospital before discharge	1 (0-7)
Consultations with a liaison nurse	2 (0-3)
Consultations with a psychologist	2 (0-3)
Follow-up after discharge, median (range)	
Days of follow-up from the local hospital after discharge	0 (0-21)
Consultations with a cardiologist after discharge	2 (2-4)
Consultations with a community nurse	3 (2-4)
Days from discharge to the second interview	38 (30-44)

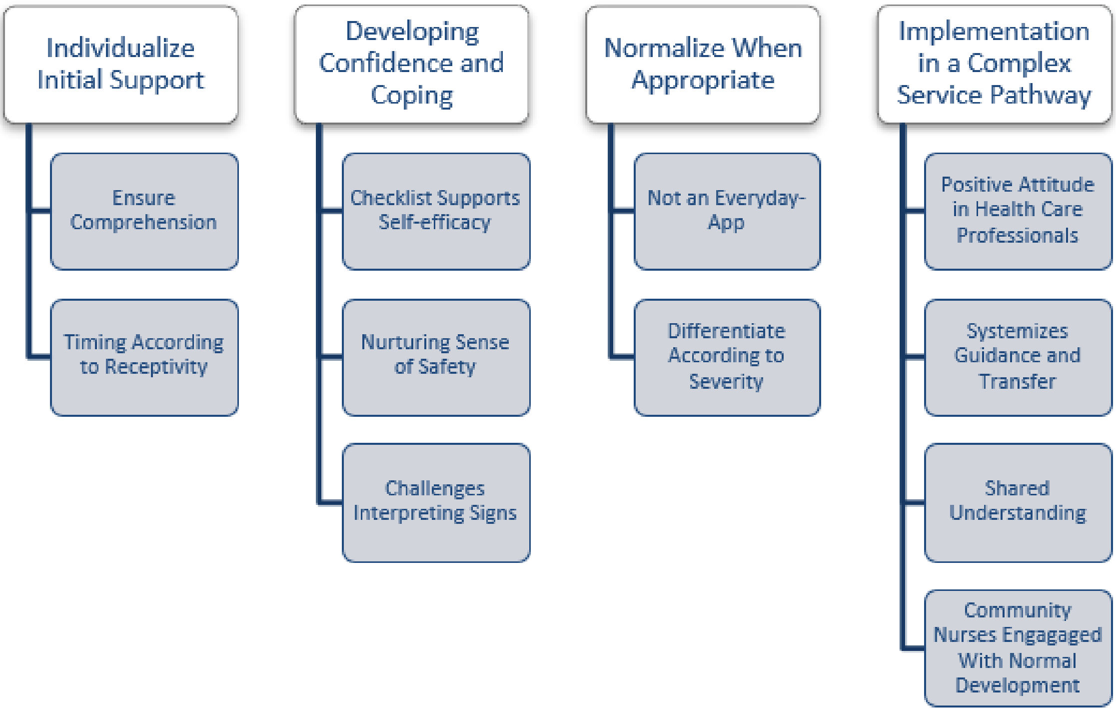
[a] Infants could receive several treatments.

[b] HOBS: Heart Observation app.

Results From Qualitative Interviews

The results represent analysis drawn from the data from families and their health care professionals. A total of 4 themes were identified: (1) Individualize Initial Support, (2) Developing Confidence and Coping, (3) Normalize When Appropriate, and (4) Implementation in a Complex Service Pathway. An overview of subthemes from parents and health professionals and their connection to themes are shown in Figure 3.

Figure 3. Themes and subthemes generated from parents' and health care professionals' experiences related to use of The Heart Observation app (HOBS).



Individualize Initial Support

Overview

In this study, infants had a broad spectrum of CHDs that led to various treatments, concerns, times of diagnosis, length of hospital stay, and days from birth to introduction of HOBS (Table 2). This variety demonstrated the heterogeneity of considerations, including specific concerns to be aware of, parents' psychological state, initial receptivity of information, and interaction with health care professionals at the specialist center. Hence, individualizing the initial support was important to facilitate parents' acceptability and experience of usefulness of HOBS. Topics regarding "Individualize Initial Support" were sorted into 2 subthemes: Ensure Comprehension and Timing According to Receptivity.

Ensure Comprehension

HOBS was seen as intuitive and easy to use by all parents, and most parents thought that the introduction and guidance to use the app were sufficient. Nevertheless, 2 parents of children with additional concerns, such as expected development of heart failure and cyanosis, mentioned a need for reassurance of comprehension and specific training in assessments. They asked for repetition of and focus on assessments before discharge:

> *...I think it was very nice that we went through it thoroughly first, and did a review with the nurses afterwards. (...) It would certainly have been nice to go through that (the assessments), maybe twice, when I was at the specialist center, to become even more confident about that part.* [Mother 9]

Based on experiences of parents' comprehension, nurses suggested individualizing guidance to parental receptivity, providing parts of information and guidance over several occasions as well as a checkup before discharge to ensure comprehension. Preferably, experienced nurses who have both knowledge of concerns regarding CHD and pedagogical skills to adjust training to parents' readiness should give the guidance. Although information is available in the app, they suggest ensuring parents have the correct settings in "My Child" and parents' comprehension of assessment with health care professionals before discharge to optimize utilization and correct use.

> *...Before the parents leave the hospital, you may have to go through the app several times, and nurses should have assessed the child together with the parents, really.* [Focus group 1, nurse 1]

Timing According to Receptivity

Parents were introduced to HOBS after surgery or after treatment plan was clarified if no surgery was necessary before discharge. Most parents mentioned the time of introduction and initial guidance regarding HOBS as appropriate. One mother who unexpectedly gave birth to a child with a severe CHD was introduced to HOBS after 2 days. She was overwhelmed and declined to receive guidance regarding app settings and observations before discharge. She had installed HOBS and entered the settings in "My Child" and baseline without help at home. At the second interview, she said:

> *... Yes, I think it was a bit close to having a sick child. I think it was a bit overwhelming for me. (...) I think*

> *in a way you should probably take it (the training) when you get home. When you're kind of ready.* [Mother 4]

Nurses at the specialist center also experienced variance in stress and receptivity among parents and noted that it was important to consider this to avoid increased burden in an already stressful situation. They had experienced that inappropriate timing could affect parents self-efficacy and attitude to relate to guidance:

> *...It's nice to go through the app when things have calmed down a bit. Because I notice a big difference in what the parents are able to deal with.* [Focus group 1, nurse 3]

Developing Confidence and Coping

Overview

Parents appreciated the information in HOBS as relevant, comprehensive, and available when needed. Most parents expressed that they developed confidence and coping skills by gaining control over observations of wound healing, weight gain, whom to contact if necessary, and where to find information if unsure of something using HOBS. Knowing their infants' normal baseline was important and gave confidence to detect changes. Nurses at local hospitals and cardiologists in follow-up described parents as informed, answering questions confidently at the outpatient clinic. This potential positive impact on confidence and coping seemed to enhance accept and adoption. Aspects regarding this theme were divided into 3 subthemes: Checklist Supports Self-efficacy, Nurturing Sense of Safety, and Challenges Interpreting Signs.

Checklist Supports Self-efficacy

HOBS intends to teach parents what to look for and helps them to decide whether they should contact their providers if they are uncertain about their infant's condition. Most parents found that the checklist in HOBS helped them to assess the infant; they kept it as a guide in the back of their mind, and for some, it contributed to act on symptoms. A mother described how the HOBS assessment function supported her decision making in times of uncertainty:

> *...Because he cried a lot for a while, and I was not sure if it was normal baby needs or something with the heart. (...) I did the checklist inside the app and read that description about what to do. So it felt better, and I was not that worried.* [Mother 1]

Only 1 infant needed treatment for deterioration during the study period. On this occasion, HOBS supported decision making. The infant's father said that he and his wife suspected a developing heart failure, and because their suspicion was supported/confirmed by features in HOBS, they contacted health professionals:

> *...It was actually, because they reduced his medication. So then, we saw clear symptoms of heart failure. (...) We did not have to wonder what it was.* [Father 10]

Nurturing Sense of Safety

To add focus on symptoms of deterioration in discharge preparation, instead of just telling parents to treat the infant as normal, may increase stress and anxiety, and thereby the burden of using the app. However, most parents indicated that HOBS increased their sense of safety when they were asked how using HOBS affected them. As one mother said:

> *...Absolutely no stress connected to the app at all. Very nice tool. And if there had been problems, or if he [the infant] had had any challenges in relation to an assessment, then it would have been used even more, I am absolutely sure of that.* [Mother 3]

Nevertheless, 1 mother mentioned that actually doing the assessment was a bit stressful, but knowing how to do it increased her self-confidence:

> *...There is a bit of stress in this, (...) But, I think it would possibly have been more stressful if I didn't know what to look for.* [Mother 2]

Challenges Interpreting Signs

Although 8 out of 9 parents coped well and felt confident about interpreting signs, the mother who did not receive guidance at the hospital expressed that the assessment of the infants' crying and amount of vomiting turned normal changes into disease-related changes. The community nurse following this family also reflected on this as a challenge because most infants normally go through some weeks of increased restlessness after delivery. Hence, it could be difficult to relate to such symptoms. This perceived incoherence increased the burden of using HOBS to this mother and made her anxious:

> *...The assessment part seems to me to be challenging at times, because one question is whether the child cries more than usual. And hey, it's him, and I think there's something wrong with the heart right away.* [Mother 4]

Normalize When Appropriate

Overview

After the initial use of HOBS at the local hospital, further use was influenced by parents' aspiration to be a normal family. Parents as well as health care professionals focused on the importance to normalize daily living and individualize use of HOBS according to severity after discharge. This theme was divided into 2 subthemes: Not an Everyday App and Differentiate According to Severity.

Not an Everyday App

Many parents reflected on their initial anxiety to go home, of being alone with a newborn child with CHD following diagnosis, and were positive about using HOBS after the initial introduction to meet their needs. However, when the infant's situation was stabilized and parents felt confident in what to look for, many chose to skip assessments due to time constraints or said they forgot to do it.

> *…It has been my biggest worry to go home when everyday life comes and I am all alone with him. Well,*

> *it is very much like that security whether I use it or not somehow, so know that I have it, I keep it in mind as an extra bit of security then.* [Mother 6]

Several parents expressed that they wanted to leave the illness behind when they left the hospitals, and return to normal everyday life after discharge. All parents expressed in some way that HOBS is not an "everyday app" and they had chosen to put HOBS away, and only use it if something came up that required necessary attention.

> *...It has not scared us. I actually feel quite safe. It is the app. The app is really quite brilliant when you need it, but when he [the infant] is stable and fine, we don't need it in the same way, but in times when it has been a bit uncertainty and we have something we wonder about, it has been very nice to have as a source of information.* [Father 10]

Differentiate According to Severity

Most cardiologists and community nurses emphasized the need to normalize the situation regarding stabilized infants. The cardiologists requested that the amount and type of assessments should be based on the infants need and on how severe the cardiac disease was:

> *...So in a way, for those infants who are developing heart failure or have an oxygen saturation of 75%, it is more relevant perhaps, but this baby is doing so very well.* [Cardiologist 3]

Implementation in a Complex Service Pathway

Overview

Parents and their infants must relate to several health care providers in a complex pathway through different services. Time to learn to use the app varied, and after discharge, parents had 2-4 consultations with the outpatient clinic and 2-4 consultations at the community health care center during the study period of 1 month (Table 2). Topics regarding implementation in the service pathway were sorted into 4 subthemes: Positive Attitude in Health Care Professionals, Systemizing Guidance and Transfer, Shared Understanding, and Community Nurses Engaged With Normal Development.

Positive Attitude in Health Care Professionals

Nurses at the specialist center and locally were enthusiastic toward the content and focus of the app. They thought HOBS would reassure parents and be helpful in their own work. Health care professionals outside the specialist center only had information about HOBS through e-learning and Microsoft PowerPoint presentations, and they asked for access to the actual app prior to further implementation. Parents mentioned that they had to show local health care professionals how they used HOBS and most parents found it positive to share and had a positive attitude about the app:

> *...And well, they do not know the app very well, but they are very positive when they have used it a bit and I have just let them have my phone and check it out.* [Mother 6]

Systemizing Guidance and Transfer

Many cardiologists mentioned that they had time constraints during consultations and appreciated that competent nurses introduced HOBS to parents. Two of the cardiologists saw a potential that HOBS could enhance cooperation between services. Nurses, both at the specialist center and locally, shared that using HOBS together with parents in discharge preparation systemized guidance and helped them to know what to include in their discharge preparations. Hence, they thought it would improve the quality of discharge preparation.

> *...I guess I have guided them in a way in the past, but now I get a tool that I can use systematically which means that I do not leave anything out.* [Nurse 7]

In addition, nurses and community nurses pointed out that HOBS gave knowledge and opportunities to understand the complexity of CHD in an individual child, and the infants' follow-up, if they knew the settings in HOBS for a particular infant.

> *...Because I am not that familiar with these heart children, and because there are different diagnoses, and different symptoms and different prospects for the future, I think it was very clear to see; -oh yes you have done that, then we can expect this.* [Nurse 6]

Shared Understanding

After discharge, cardiologists at the outpatient clinic focused on hemodynamics through echocardiographic ultrasound. In addition, it was important for them to receive information about how parents perceived the infant's general condition. Most cardiologists noted that HOBS could contribute positively to the conversation about the infant's condition:

> *...It is important how they (parents) perceive their child. (...) So, in that sense, this (HOBS) can help me with the assessment through the conversation with the parents.* [Cardiologist 6]

Parents also emphasized such shared understanding and a positive contribution to conversation:

> *...I have read the fine articles that were in the app, and I think they were very explanatory and very easy to understand for someone who is not a doctor. (...) Which means, that I understand the medical language a little better."* [Mother 6]

Cardiologists emphasized that HOBS provides more specific observations, and that several parents using HOBS gave relevant answers to questions that concerned the cardiologist. One of the cardiologists mentioned that such joint attention could improve their dialog:

> *...It is good that they can use it to assess, so they have more objective assessments to give to us, and not just a feeling that things are going poorly.* [Cardiologist 2]

Community Nurses Engaged With Normal Development

Most community nurses have limited clinical experience in caring for infants with CHD and appreciated the individualized information they could receive using HOBS. They anticipated that vulnerable infants, postsurgical infants, or infants waiting for surgery might benefit from HOBS. At the same time, they expressed that the community health services should follow-up normal development not the cardiac disease.

> *...At the health center, we must have follow-up on the healthy part of the child to what is normal development and growth. So, I think this will be, in a way, between parents and the specialist health service and possibly a general practitioner.* [Community nurse 9]

This view reflects community nurses seeking to limit responsibility and support, and in some community nurses, it reflects low self-efficacy regarding interpretation of assessment. As one community nurse puts it:

> *...It is a bit difficult for us as community nurses. When to normalize and when to say, yes, this could be the heart defect.* [Community nurse 4]

Discussion

Principal Findings

The major finding of this feasibility study was that both parents and health care professionals regarded the content and functionality of HOBS as a positive addition to the health care system and follow-up. HOBS was considered feasible, acceptable, and potentially useful, especially when guidance was timed to individual needs and comprehension was ensured. Parents may then become confident, knowing what to look for, and be vigilant at home. Differentiated use according to the child's condition supports appropriate normalization in less severe cases.

Individualize Initial Support

Despite different viewpoints, parents and nurses shared the understanding that appropriate timing and guidance in individualized sessions were important. To give birth to a child with cardiac disease causes stress and anxiety in parents [21]. Discharge preparations are often challenging and may suffer from reduced ability to handle a new situation because of overwhelming feelings after delivery and during hospitalization [22-25]. Hence, an unfortunate timing and lack of training may reduce comprehension and utilization and eventually confidence to perform assessments in HOBS. Adapting the introduction and training to parents' perceptivity to ensure comprehension and reduce the burden of attendance might optimize utilization in follow-up [17]. However, overdoing reminders and guidance in this situation may be unfortunate and reduce acceptability [14]. In general, visits to the outpatient clinic are frequent the first month, which makes it possible to ensure comprehension after discharge if necessary. In addition, health care professionals that offer coaching and use data presented by parents may enhance the adoption of services such as HOBS [14].

Developing Confidence and Coping

Parents in this study considered the information content of HOBS relevant, comprehensive, and easily available. Such information serves as health education and if complemented with assessment functionality, it facilitates the adoption of mHealth in many studies, especially if personalized and received after initial diagnoses, such as HOBS [14]. Caring for a recently discharged infant with CHD requires an understanding and awareness about what to look for [3]. To be constantly aware and assess signs of deterioration might however be stressful, irrespective of apps used [26]. In this study, parents appreciated the sense of safety that the checklist of assessments provided. Hence, the intention to support confidence and coping seems to be achieved. At the same time, a single episode of deterioration in this study cannot verify whether HOBS will be effective to detect deterioration. However, when parents are confident in what to look for may give them an opportunity to normalize daily living and at the same time feel relaxed and secure because they have easy access to available and relevant information and a checklist to confer with [27]. The opposite may occur if parents are overwhelmed and this results in deficient introduction and guidance and hinders comprehension and self-efficacy [23].

Normalize When Appropriate

A finding in this study was that parents said they reduced the number of assessments performed very soon, and user log reported in the previous usability study confirmed that parents had a median of 2 assessments at home during the first month [15]. Frequent consultations with health care professionals have reduced adoption in other studies [14]. Therefore, few assessments in this study may be explained by frequent consultations with cardiologists and community nurses during the study period. At the same time, parents expressed a wish to end assessments and focus on normal daily living when confident. This corresponds with studies of an early warning tool for parents of infants with CHD [27]. Nevertheless, an educational mHealth intervention for parents of a diverse group of infants with CHD showed that biweekly monitoring of vital signs over time did not reduce stress, anxiety, and adverse events [26]. To be constantly reminded of disease and symptoms may maintain anxiety [14]. Hence, a reduction in routine assessments might reduce the burden. Yet, well-educated and informed parents may cope well under such pressure [28]. Consequently, discontinued use of HOBS may not correlate with acceptability, considering that parents perceived HOBS as effective and intended to do assessments if necessary [29,30]. Our results indicate that parents were able to find the balance between awareness of symptoms and coping with their new situation. This supports the feasibility of HOBS as a tool for discharge preparation and decision support in times of uncertainty.

Implementation in a Complex Service Pathway

One of the principal findings of this study was that health care professionals viewed parents who used HOBS as well informed and confident in assessing their child. Despite the knowledge about possible deterioration, most parents were able to normalize family life after discharge. HOBS was developed as an early warning tool to support parents to detect deterioration based on recommendations from an expert group [3]. A well-known concern among health care professionals is that parents may become more anxious if they have to assess and be aware of symptoms of worsening instead of treating their child as normal

[31]. Such contextual factors might influence adoption and acceptability by health care professionals and thereby effectiveness of the intervention [12]. In this study, health care professionals emphasized a possibility to differentiate use according to the condition of the child. The flexibility to adapt the assessments to the parents' total burden may facilitate acceptability by making the intervention compatible with their own ethical view [17]. This may promote successful integration into existing services and thereby the adoption among health care professionals [13]. For parents of the most vulnerable infants, awareness of symptoms might not be enough and the infant's cardiologist should recommend extending assessments over time [32]. Whether parents maintain the ability to detect deterioration even if they do not use the app regularly is currently uncertain. The adoption, use, and effects of HOBS among both parents and health care professionals need further evaluation over time.

As recommended for patient-centered approaches to mHealth adoption, we initially focused on integrating the intervention into the patient families' journey all through health services [14]. This integration may explain acceptance and adoption reported in this study. In addition, our results show that different health care professionals have different and additive experiences and views of how the app may contribute.

Nurses were most enthusiastic and wanted to use the app to systemize and ensure quality in their guidance of parents. Such an expectation of improved parent education may encourage their adoption and further adherence to HOBS. However, nurses in the focus groups were concerned with general nurses' ability to guide parents as intended. They suggested establishing an expert group to give the guidance, which is in line with recommendations to enhance adoption [13,14].

mHealth solutions such as HOBS are more likely to be adopted by clinicians if it empowers their patients [13]. In this study, cardiologists had little experience using HOBS but agreed to including HOBS into their services. This was supported by the experience of confident parents and enhanced communication regarding their infant's general condition. At the same time, they also emphasized differentiation according to the child's condition, which might reflect a conditional acceptance based on expected usefulness and management by parents in different cases.

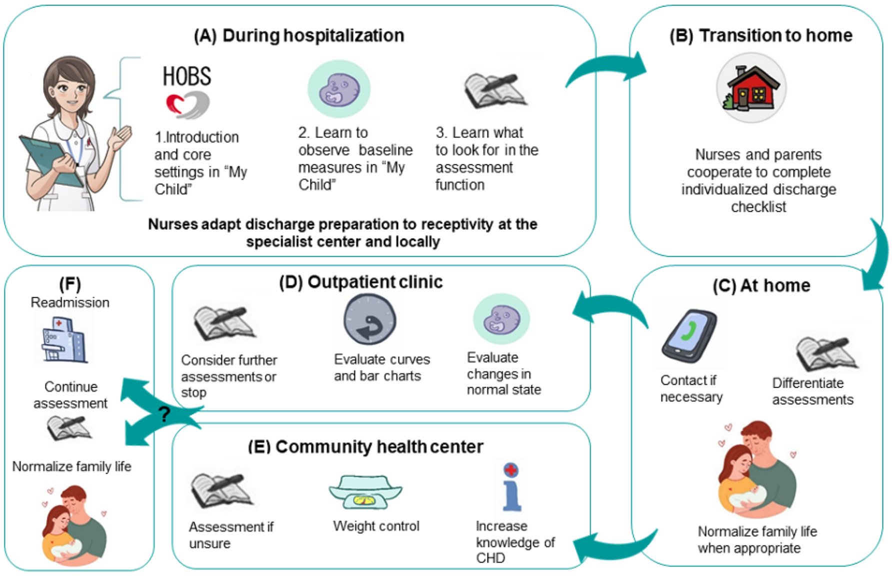
However, community health nurses were more hesitant to adopt HOBS as a tool in daily consultations. One explanation may be that condition-specific solutions do not fit with their existing workflow and responsibility. Another explanation may be a lack of competence in CHD with fear of exposing knowledge gaps [13]. At the same time, they expressed positive attitude toward HOBS and were eager to learn and use it to increase their competency.

The positive attitude and perceived effectiveness of the app among health care professionals are beneficial regarding future implementation and adoption of the intervention [13,17]. In the ongoing controlled trial, adoption of the HOBS intervention will be assessed among both parents and health care professionals [33].

Implications for Practice

This feasibility study has explored acceptability and initial adoption of an app (HOBS) to identify factors that might influence its implementation in health care services. Based on these experiences, we have adjusted the strategy for implementation. As shown in Figure 4, parents are introduced on time to HOBS through 3 main areas during hospitalization (Figure 4A): (1) Introduction and core settings, (2) Observations in "Normal for my child," and (3) Assessments of deterioration. Next, completion of discharge formalities is performed with the embedded checklist (Figure 4B). After discharge parents perform assessments according to severity (Figure 4C) and collaborate with the outpatient clinic regarding comprehension and results, and consider further assessments (Figure 4D). The community health center receives HOBS as a knowledge base and supports parents in assessments if they are unsure of their infant's condition (Figure 4E). Further use is adapted according to the infant's condition (Figure 4F). To support health care professionals, we offer a health care version of HOBS and an e-learning course with advice on how to guide parents. In addition, information in the patient journal about settings and guiding tasks to fulfill is sent from the specialist center to local hospitals. All these parts of the intervention program aim to ensure readiness for discharge; to improve parents' confidence and coping; and to optimize comprehension, usefulness, and decision making. An ongoing controlled trial of the presented HOBS intervention assesses parents' readiness for discharge, psychological adaptation, health literacy, and contact with health care services and compares them with standard care.

Figure 4. Implementation strategy for The Heart Observation app intervention in the upcoming controlled trial based on this feasibility study. Source of illustrations: Shutterstock and FluHartberg.



Limitations

In this study, several limitations have to be addressed. First, our results of acceptability and adoption are promising but not conclusive. HOBS is a complex intervention with many components, and the context differs between health care centers, and parents may have different ability to use the app. This challenges any evaluation because the path to success might vary [12,34]. Our study sought to capture a broad spectrum of CHD diagnoses, concerns, and levels of health care. This resulted in interviews of local health care professionals with limited experience using HOBS. The results may therefore reflect anticipated rather than experienced effects. However, infants presenting with CHD are in general rare at most local hospitals and the unfamiliarity may reflect the situation in clinical practice. Second, the first author was deeply involved as content expert in the development of HOBS and in charge of the main part of data collection in the interviews, transcription, and analysis, which could increase the risk of researcher bias in the qualitative analysis. To reduce any potential bias, the coauthors contributed actively in the analysis. Third, it is possible that awareness about an upcoming interview may have affected motivation to use the app and it has been difficult to address negative experiences because the perceived providers (OUH) of the app are responsible for their infant's further treatment. Fourth, we have followed parents and their health care professionals for a short period to evaluate acceptability and adoption and to address further implementation strategies.

Conclusions

In general, parents and health care professionals felt HOBS as a feasible and positive addition to the health care system and follow-up. Our study shows that HOBS is accepted and useful when health care professionals guide parents and adapt the introduction and training to parents' receptivity. Parents may then become more confident and know what to look for when caring for their infant with CHD at home. It will be important to differentiate use according to the child's condition, and to support normalization through follow-up. Accounting for personal, social, and organizational factors will support feasibility and adoption of HOBS and its benefits. Further studies are needed to assess benefits and adoption in parents and health care professionals.

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Data Availability

The data sets generated during or analyzed during this study are not publicly available due to the Norwegian legislation and concerns of participants' confidentiality.

Conflicts of Interest

None declared.

References

1. Hoffman JIE, Kaplan S. The incidence of congenital heart disease. Journal of the American College of Cardiology 2002;39(12):1890-1900. [doi: 10.1016/S0735-1097(02)01886-7] [Medline: 25458661]
2. Leirgul E, Fomina T, Brodwall K, Greve G, Holmstrøm H, Vollset SE, et al. Birth prevalence of congenital heart defects in Norway 1994-2009--a nationwide study. Am Heart J 2014 Dec;168(6):956-964 [FREE Full text] [doi: 10.1016/j.ahj.2014.07.030] [Medline: 25458661]
3. Crowe S, Knowles R, Wray J, Tregay J, Ridout DA, Utley M, et al. Identifying improvements to complex pathways: evidence synthesis and stakeholder engagement in infant congenital heart disease. BMJ Open 2016 Jun 06;6(6):e010363 [FREE Full text] [doi: 10.1136/bmjopen-2015-010363] [Medline: 27266768]
4. Wik G, Jortveit J, Sitras V, Døhlen G, Rønnestad AE, Holmstrøm H. Severe congenital heart defects: incidence, causes and time trends of preoperative mortality in Norway. Arch Dis Child 2020 Aug;105(8):738-743 [FREE Full text] [doi: 10.1136/archdischild-2019-317581] [Medline: 32051128]
5. Wik G, Jortveit J, Sitras V, Døhlen G, Rønnestad AE, Holmstrøm H. Unexpected death in children with severe congenital heart defects in Norway 2004-2016. Arch Dis Child 2021 Oct;106(10):961-966 [FREE Full text] [doi: 10.1136/archdischild-2020-319936] [Medline: 33597179]
6. Tregay J, Brown KL, Crowe S, Bull C, Knowles RL, Smith L, et al. Signs of deterioration in infants discharged home following congenital heart surgery in the first year of life: a qualitative study. Arch Dis Child 2016 Oct;101(10):902-908 [FREE Full text] [doi: 10.1136/archdischild-2014-308092] [Medline: 26823534]
7. Rudd NA, Ghanayem NS, Hill GD, Lambert LM, Mussatto KA, Nieves JA, American Heart Association Council on CardiovascularStroke Nursing; Council on Lifelong Congenital Heart DiseaseHeart Health in the Young; Council on Arteriosclerosis, ThrombosisVascular Biology; Council on Clinical Cardiology;Council on LifestyleCardiometabolic Health. Interstage Home Monitoring for Infants With Single Ventricle Heart Disease: Education and Management: A Scientific Statement From the American Heart Association. J Am Heart Assoc 2020 Aug 18;9(16):e014548 [FREE Full text] [doi: 10.1161/JAHA.119.014548] [Medline: 32777961]
8. Tanem JM. A mobile application as a tool for guided participation. In: Pridham KF, Limbo R, Schroeder MM, editors. Guided Participation in Pediatric Nursing Practice: Relationship-Based Teaching and Learning With Parents, Children, and Adolescents. New York, NY: Springer Publishing Company; May 2018:341-354.
9. Xie W, Liu J, Lei Y, Cao H, Chen Q. Effects of WeChat follow-up management of infants who underwent ventricular septal defect repair on parents' disease knowledge and quality of life: A prospective randomized controlled study. J Card Surg 2021 Oct;36(10):3690-3697. [doi: 10.1111/jocs.15848] [Medline: 34318543]
10. Zhang Q, Lei Y, Liu J, Cao H, Chen Q. Using telemedicine to improve the quality of life of parents of infants with CHD surgery after discharge. Int J Qual Health Care 2021 Sep 25;33(3):mzab133. [doi: 10.1093/intqhc/mzab133] [Medline: 34490460]
11. Lane B, Hanke SP, Giambra B, Madsen NL, Staveski SL. Development of a clinician-parent home care education intervention. Cardiol Young 2019 Oct;29(10):1230-1235. [doi: 10.1017/S1047951119001318] [Medline: 31469062]
12. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ 2021 Sep 30;374:n2061 [FREE Full text] [doi: 10.1136/bmj.n2061] [Medline: 34593508]
13. Jacob C, Sanchez-Vazquez A, Ivory C. Social, Organizational, and Technological Factors Impacting Clinicians' Adoption of Mobile Health Tools: Systematic Literature Review. JMIR Mhealth Uhealth 2020 Feb 20;8(2):e15935 [FREE Full text] [doi: 10.2196/15935] [Medline: 32130167]
14. Jacob C, Sezgin E, Sanchez-Vazquez A, Ivory C. Sociotechnical Factors Affecting Patients' Adoption of Mobile Health Tools: Systematic Literature Review and Narrative Synthesis. JMIR Mhealth Uhealth 2022 May 05;10(5):e36284 [FREE Full text] [doi: 10.2196/36284] [Medline: 35318189]
15. Hjorth-Johansen E, Børøsund E, Moen A, Harmens A, Martinsen I, Wik G, et al. Heart OBServation app: development of a decision support tool for parents of infants with severe cardiac disease. Cardiol Young 2022 Aug 08:1-9. [doi: 10.1017/S1047951122002438] [Medline: 35938297]
16. Jacob C, Sanchez-Vazquez A, Ivory C. Understanding Clinicians' Adoption of Mobile Health Tools: A Qualitative Review of the Most Used Frameworks. JMIR Mhealth Uhealth 2020 Jul 06;8(7):e18072 [FREE Full text] [doi: 10.2196/18072] [Medline: 32442132]
17. Sekhon M, Cartwright M, Francis JJ. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. BMC Health Serv Res 2017 Jan 26;17(1):88 [FREE Full text] [doi: 10.1186/s12913-017-2031-8] [Medline: 28126032]
18. Hjorth-Johansen E. HOBS - en app for foreldre med nyfødte hjertebarn. HOBS. 2020. URL: https://www.hobs.no [accessed 2023-03-09]

19. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology 2006 Jan;3(2):77-101. [doi: 10.1191/1478088706qp063oa]
20. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-357. [doi: 10.1093/intqhc/mzm042] [Medline: 17872937]
21. Woolf-King SE, Anger A, Arnold EA, Weiss SJ, Teitel D. Mental Health Among Parents of Children With Critical Congenital Heart Defects: A Systematic Review. J Am Heart Assoc 2017 Feb 01;6(2):e004862 [FREE Full text] [doi: 10.1161/JAHA.116.004862] [Medline: 28151402]
22. Rogan F, Shmied V, Barclay L, Everitt L, Wyllie A. "Becoming a mother'--developing a new theory of early motherhood. J Adv Nurs 1997 May;25(5):877-885. [doi: 10.1046/j.1365-2648.1997.1997025877.x] [Medline: 9147193]
23. Dalton CC, Gottlieb LN. The concept of readiness to change. J Adv Nurs 2003 Apr;42(2):108-117. [doi: 10.1046/j.1365-2648.2003.02593.x] [Medline: 12670379]
24. Galvin EC, Wills T, Coffey A. Readiness for hospital discharge: A concept analysis. J Adv Nurs 2017 Nov;73(11):2547-2557. [doi: 10.1111/jan.13324] [Medline: 28440958]
25. Lumsden MR, Smith DM, Wittkowski A. Coping in Parents of Children with Congenital Heart Disease: A Systematic Review and Meta-synthesis. J Child Fam Stud 2019 Apr 17;28(7):1736-1753. [doi: 10.1007/s10826-019-01406-8]
26. Medoff Cooper B, Marino BS, Fleck DA, Lisanti AJ, Golfenshtein N, Ravishankar C, et al. Telehealth Home Monitoring and Postcardiac Surgery for Congenital Heart Disease. Pediatrics 2020 Sep;146(3):e20200531 [FREE Full text] [doi: 10.1542/peds.2020-0531] [Medline: 32817266]
27. Gaskin KL, Wray J, Barron DJ. Acceptability of a parental early warning tool for parents of infants with complex congenital heart disease: a qualitative feasibility study. Arch Dis Child 2018 Sep;103(9):880-886. [doi: 10.1136/archdischild-2017-313227] [Medline: 29567664]
28. Rempel GR, Ravindran V, Rogers LG, Magill-Evans J. Parenting under pressure: a grounded theory of parenting young children with life-threatening congenital heart disease. J Adv Nurs 2013 Mar;69(3):619-630. [doi: 10.1111/j.1365-2648.2012.06044.x] [Medline: 22616855]
29. Bowen DJ, Kreuter M, Spring B, Cofta-Woerpel L, Linnan L, Weiner D, et al. How we design feasibility studies. Am J Prev Med 2009 May;36(5):452-457 [FREE Full text] [doi: 10.1016/j.amepre.2009.02.002] [Medline: 19362699]
30. Siebenhüner AR, Mikolasek M, Witt CM, Barth J. Improvements in Health Might Contradict Adherence to Mobile Health Interventions: Findings from a Self-Care Cancer App Study. J Altern Complement Med 2021 Mar;27(S1):S115-S123. [doi: 10.1089/acm.2020.0111] [Medline: 33788602]
31. Rempel GR, Harrison MJ, Williamson DL. Is "treat your child normally" helpful advice for parents of survivors of treatment of hypoplastic left heart syndrome? Cardiol Young 2009 Apr;19(2):135-144. [doi: 10.1017/S1047951109003485] [Medline: 19272201]
32. Erickson LA, Emerson A, Russell CL. Parental mobile health adherence to symptom home monitoring for infants with congenital heart disease during the single ventricle interstage period: A concept analysis. J Spec Pediatr Nurs 2020 Oct;25(4):e12303. [doi: 10.1111/jspn.12303] [Medline: 32662243]
33. Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. Implement Sci 2007 Nov 30;2:40 [FREE Full text] [doi: 10.1186/1748-5908-2-40] [Medline: 18053122]
34. Rogers PJ. Using Programme Theory to Evaluate Complicated and Complex Aspects of Interventions. Evaluation 2008 Jan 01;14(1):29-48. [doi: 10.1177/1356389007084674]

Abbreviations

CHD: congenital heart disease
COREQ: Consolidated criteria for reporting qualitative research
HOBS: Heart Observation app
mHealth: mobile health
OUH: Oslo University Hospital

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ORIGINAL ARTICLE

An individualised mobile app was beneficial for the mothers of infants with severe congenital heart defects

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Abstract

Aim: This national study focused on the individualised Heart Observation (HOBS) mobile phone app, which helps the parents of infants with severe congenital heart disease (CHD) with discharge preparations and decision making at home.

Methods: We enrolled two groups of parents from 2021 to 2023, during their child's initial hospitalisation at Oslo University Hospital, Norway. Measurements were carried out at baseline and one and four months after discharge. The study examined 73 mothers, who assessed the usefulness and stress-related impact of either printed materials or the HOBS app, as the fathers' responses were insufficient.

Results: The HOBS app was significantly more useful than the printed information, with regard to discharge preparations, follow up at home and ongoing decision making, particularly if the infants had sustained cardiac impairment. The average total usefulness scores were 23.9/35 (95% CI 21.6–26.1) versus 17.0/35 (95% CI 14.1–20.0), respectively. Initial stress significantly decreased from baseline in both groups and elevated awareness of deterioration did not increase stress in the HOBS group.

Conclusion: Mothers who used the HOBS app found it significantly more useful than the controls who received printed information, particularly if their infant had sustained cardiac impairment. Elevated awareness of deterioration did not increase stress.

KEYWORDS
cardiac impairment, decision support tool, maternal stress, mobile app, severe congenital heart disease

1 | INTRODUCTION

Congenital heart disease (CHD) affects approximately 1% of all infants and about 25% of cases are severe. In Norway, 125 infants are born with severe CHD each year.[1] Severe CHD is still a major cause of infant deaths worldwide and one of the main causes of mortality in countries with high socio-demographic indexes.[2] Particularly close follow up is recommended for infants with persistently low oxygen saturation, staged surgery or residual cardiac impairment.[3] In Norway, about 10% of infants with severe CHD die within the first 2 years of life.[3] Research has shown that 29% of these deaths occurred unexpectedly and that 60% happened after gradual

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Abbreviations: CHD, congenital heart disease; CI, confidence interval; HOBS app, heart observation app; PIP, paediatric Inventory for Parents.

deterioration at home.[3] Adverse outcomes have not been confined to specific diagnostic groups and have extended beyond those currently receiving home monitoring.[3]

Giving birth to a child with CHD causes stress and anxiety for their parents.[4] The anticipated maternity period is replaced with uncertainty, heart surgery, intensive care and concerns about the future. Parents have been reported to have higher levels of anxiety, depression and stress than other parents.[5] These increased stress levels relate to a combination of the child's increased care requirements and the need for increased vigilance. Studies have stated that monitoring symptoms should be balanced and not excessive, so that family life can be as normal as possible.[6,7]

Discharge preparations and tools that provide support by balancing vigilance and normalisation may increase safety for vulnerable infants and keep parental stress at a manageable level. Studies have shown that, despite good results for morbidity and mortality, home monitoring of infants with a single ventricle or post cardiac surgery did not reduce parental stress.[8,9] Mobile phone apps have the potential to ensure good-quality discharge preparations and support the decisions made by the parents of a diverse group of infants with CHD.[10] However, mixed results regarding stress reduction have been reported by the parents of infants with less severe CHD.[11–13]

Oslo University Hospital is a national specialist centre for all paediatric cardiac surgery in Norway. A project group from the specialist centre developed the Heart Observation (HOBS) mobile phone app with parents and local healthcare professionals.[14] We hypothesised that using the HOBS app would be more useful than the existing printed information and would not increase parental stress. A feasibility study showed that parents found that HOBS was a useful tool that made them feel confident.[15] The aim of this controlled trial was to compare how useful HOBS was when it was compared with standard care using printed information and to assess the effects that the app had on parental stress.

2 | METHODS

This national study was conducted from 7 June 2021 to 6 May 2023 with two different groups of parents and measurements at three time points (Figure 1). We identified the parents of all infants with severe CHD who were treated at Oslo University Hospital before being transferred to one of the 19 local hospitals for follow up. They were recruited if their infants were under 3 months of age, had severe CHD and had been born at more than 33 completed weeks of gestation. Other anomalies or genetic or chromosomal conditions could be present.[16] The exclusion criteria were primary arrhythmic diseases, the parents' inability to read, write or speak Norwegian and no access to a smartphone.

Parents knew which study group they were assigned to before agreeing to participate. Both of the child's parents provided written, informed consent and both received links to the questionnaires via text messages. These were sent at baseline, which was after their child's diagnosis or surgery, and then one and four months after discharge (Figure 1).

Key Notes

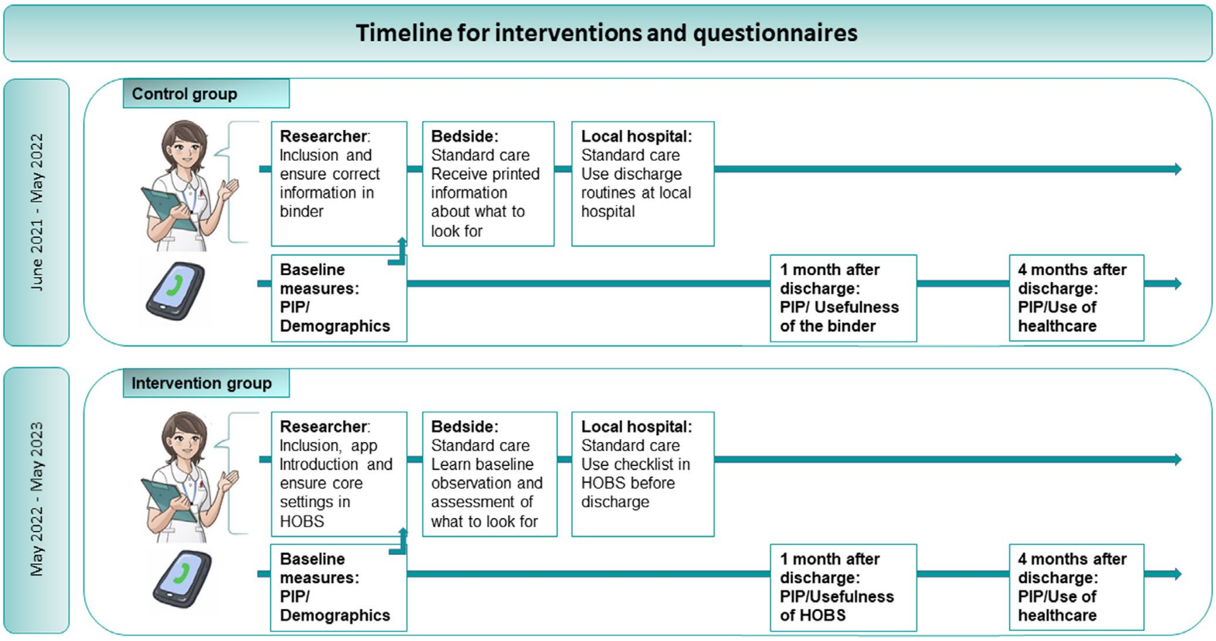
- We compared how useful mothers found traditional printed information or the Heart Observation (HOBS) mobile phone app when their children had severe congenital heart disease.
- Mothers found the HOBS app significantly more useful for discharge preparations, follow up at home and ongoing decisions than those who received printed information, particularly if their infant had sustained cardiac impairment.
- Elevated awareness of deterioration did not increase stress levels in the HOBS group.

2.1 | Group allocation and implementation

Randomisation was not possible due to the complex nature of the intervention and the need for follow up at local hospitals. There was a high probability of the intervention becoming contaminated in the hospital setting, if the parents in the control and interventional groups discussed the study or healthcare professionals adapted new routines for discharge preparations. That is why we chose to include the participants in two subsequent groups in a pragmatic controlled trial.

The control group were recruited first, from 7 June 2021 to 10 May 2022, and they received the My Heart Binder, which has been part of the department's standard care since 2011 (Appendix S1).[17] This was given to them by the nurses before they answered the baseline questionnaires (Figure 1).[17] The binder contained paper-based information about their child's diagnosis, medication and post-operative care. It also covered the possible consequences of their condition, what to look for and where and when to call if necessary. The material was individualised to each patient by the first author. The nurses also provided standard care and guided the parents at their child's bedside by following a discharge checklist.

The intervention group were recruited from 16 May 2022 to 6 May 2023. They downloaded the HOBS app and received a brief introduction from the lead author (EHJ), who is a specialist nurse, on how it could be used. She also helped them to personalise the app by guiding the settings about their child's diagnosis, treatment and any monitoring and equipment they needed. This happened before they answered the baseline questionnaires (Figure 1). This provided the parents with a personalised set of observations to define the child's baseline information. The app also provided information adapted to their child's care needs, questions to help the parents assess the infants' condition at home and a personalised discharge checklist (Appendix S1). The intervention included support from healthcare



PIP = Pediatric Inventory for Parents. HOBS = Heart Observation App
Source of illustrations: Shutterstock and FluHartberg

FIGURE 1 Timeline for the interventions and questionnaires.

professionals. The nurses also provided bedside support and explained to the parents how they could observe and assess their child using the app. They were also encouraged to request any guidance they needed.

The app has six main interactive features: my child, information, contacts, discharge checklist, assessment and a summary function displaying former assessments (Appendix S1). A previous study has described the HOBS features and the results of a feasibility analysis.[14]

2.2 | Outcomes

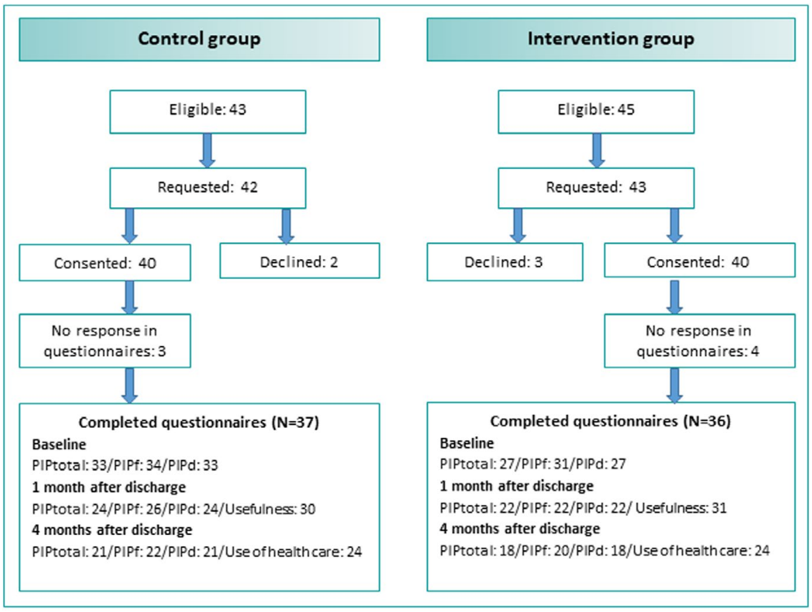
2.2.1 | Demographics and health information

The family's demographic information were registered at inclusion. This included the parents' age, marital status and education and how many siblings their child had. The specialist nurse (EHJ) collected the child's detailed medical information from the electronic patient records. Then she, and a cardiologist (HH) who was blinded to the group allocation, categorised all the infants in the control and intervention groups into two subgroups, based on their present and future medical needs. The first group comprised those who had completed their treatment. They included those with surgically corrected lesions, such as coarctation of the aorta, transposition of the great arteries and anomalous pulmonary venous connection. This group had all shown satisfactory postoperative development. The second group comprised infants with sustained cardiac impairment, such as significant residual defects, complex anomalies with planned or expected cardiac surgery and those who required medication after 1 month. The parents of the infants in the second group received extra information about symptoms and how to interpret and act on the signs of heart failure or cyanosis.[3] This information was incorporated into the written material or the HOBS app, as appropriate.

2.2.2 | Usefulness and use of interventions

The parents were asked to answer seven questions about the perceived usefulness of the interventions during their child's discharge and at home (Table 2). The questions were developed for the study, based on the aims of the interventions, and the wording was thoroughly evaluated by the research group.[18] The answers were provided by using a five-point Likert scale, ranging from one for not at all to five for a very high degree. The total usefulness score ranged from 7 to 35. Parents could choose not applicable, if appropriate, to ensure the validity of the questions.[18] Cronbach's alpha was 0.88, which showed high internal consistency.

When they were discharged by the local hospitals, the parents in the control group verified which leaflets they had been given. We used electronic user logs for the different features used in the HOBS apps. These registered the parents' assessments, what information links they had received and tapped on, calls made to healthcare services from the application and the use of the discharge checklist.



*PIPtotal = Pediatric Inventory for Parents total score; PIPf = Pediatric Inventory for Parents frequency subscale; PIPd = Pediatric Inventory for Parents difficulty subscale

FIGURE 2 Trial flow chart of mothers, with adjusted response rates for each questionnaire.

2.2.3 | Paediatric inventory for parents (PIP)

We used the PIP to measure disease-related parental stress.[19] The PIP comprises 42 items within four domains: communication, emotional functioning, medical care and role function. Parents indicate how often an illness-related event had occurred in the past 7 days, using the frequency subscale and a five-point Likert scale, ranging from one for never to five for very often. They also report how difficult that event was in the difficulty subscale, which uses a five-point Likert scale ranging from one for not at all, to five for extremely. Each subscale ranges from 42 to 210 and the sum of both subscales provides the total PIP stress score of 84–420. This instrument has shown good reliability and content validity and has correlated highly with state anxiety. However, no clinical cut-offs have been established.[19]

We translated the PIP from English to Norwegian for the present study, using acknowledged methods,[20,21] and conducted extended validity analyses. Cronbach's alpha showed high internal consistency for the total PIP measurements: 0.96 at baseline and 0.97 for both 1 month and 4 months after discharge. The values for the total frequency scale were 0.91, 0.93 and 0.94, respectively, and they were 0.95, 0.95, and 0.96 for the total difficulty scale.

The parents also answered questions about the planned and unplanned use of healthcare services 4 months after discharge.

2.3 | Statistical methods

The required sample size, based on the primary outcome of the PIP scores, was calculated for 1 month after discharge. Based on a statistical power of 0.80, a significance level of 5%, and a difference of 20 in the total PIP difficulty scores, we needed to analyse data from 52 families. We included 80 families, to allow for a 40% dropout rate during the study. An independent *t*-test was used to compare the differences between the groups, because the demographics, health information, usefulness responses and PIP scores were normally distributed. The chi-square test and Fisher's exact test were used for binary variables, as appropriate. A linear mixed-effects model was used to analyse the mean between group changes in the PIP. There were eight questionnaires, where less than 5% of the items were missing for a subscale. In these cases, we imputed the mean value for the remaining items in that specific subscale.[22]

2.4 | Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics, South East, Norway (2019/1271), and the Hospital's Privacy Protection and Data security committee (19/23041) and it was registered at ClinicalTrials.gov (NCT04315610). Both parents provided written, informed consent.

3 | RESULTS

3.1 | Participants

There were 40 families recruited to the standard care group and 40 to the HOBS group (Figure 2). The mothers and fathers were both invited to take part, but there was a high dropout rate among the fathers and the final analysis only comprised data from the mothers.

Figure 2 shows the dropout rates for each questionnaire. Four families in the HOBS group and three in the control group did not respond to any of the questionnaires and were excluded from the demographic and health information analyses (Table 1). This meant that the analyses were based on 36 mothers using the HOBS and 37 mothers using the standard printed information.

3.2 | Demographics and health information

All the infants who were included had severe CHD, according to the International Paediatric and Congenital Cardiac Code.[23] The HOBS intervention group had more complex CHD diagnoses and significantly more cardiac impairment, due to their CHD after discharge, than the control group. In addition, the HOBS group received more cardiac medication, underwent more palliative surgery, had longer local hospital stays and used feeding tubes more frequently after 1 month (Table 1). The HOBS group also had more unplanned hospital admissions and more planned visits with community nurses than the control group. There were no registered deaths. There were two unplanned admissions in the control group, one due to COVID-19 and the other due to the respiratory syncytial virus. There were 10 unplanned admissions in the HOBS group, including three for urgent cardiac catheterisation, three for nutrition issues, one for COVID-19 and one for the respiratory syncytial virus. The last two had other respiratory problems, such as bronchomalacia. The HOBS and control groups were similar when it came to all the other parameters, including parental age, marital status, education and siblings (Table 1).

3.3 | Implementation and use of interventions

After initial treatment at Oslo University Hospital, both groups were followed by a total of 19 local hospitals. Infants in the control group were discharged to 14 different local hospitals and the HOBS group to 16 different local hospitals. Both groups received their interventions based on an intention to treat basis and the percentage that completed these ranged from 83–100% (Appendix S3). The HOBS logs showed that the overall use of the core features ranged from 75% to 94%. Just over three-quarters (76%) of the 36 mothers completed the HOBS' assessments during the study period a median of four times. These decreased to 42% of users and a median of two times between one and four months after discharge.

3.4 | Usefulness

The response rate for questions related to usefulness was 81% (30/37) in the control group and 86% (31/36) in the HOBS group (Table 2). The average total scores for usefulness were17.0 points, with a 95% confidence interval (CI) of 14.1–20.0 for the printed information, and 23.9 points (95% CI 21.6–26.1) for the HOBS app, which was significantly higher ($p < 0.001$). The high usefulness scores correlated with the total number of assessments ($p = 0.006$) and the links that were used ($p = 0.029$) in the HOBS group. Usefulness correlated with cardiac impairments after discharge in both groups ($p = 0.028$) and the mothers of infants with cardiac impairment found the HOBS app significantly more useful than the mothers who used the standard care binder ($p = 0.035$).

3.5 | Disease-related parental stress

The univariate analysis of the PIP scores showed no differences in stress between the groups at any time point (Table 3). High PIP scores at 4 months correlated significantly with sustained cardiac impairment after discharge ($r = 0.65$, $p < 0.001$). The increased disease-related stress burden on the mothers of infants with cardiac impairment, along with the significantly skewed distribution of these infants between the intervention and control groups, required stratification. Linear mixed models were then used to compare mothers in each severity group over time. The linear mixed effect models showed consistent, but not significantly lower, PIP scores in the HOBS group, but no significant change in the mean scores between the groups over time (Figure 3).

4 | DISCUSSION

This study showed that the mothers of infants with severe CHD found the HOBS mobile phone app significantly more useful than the mothers who used the standard care binder of information. This applied to the discharge preparations, support at home, situations where mothers were uncertain about deterioration and when to contact healthcare professionals. Sustained findings also indicated that using HOBS did not increase maternal stress, despite its increased and structured focus on symptoms that indicated deterioration.

4.1 | Improved discharge support

It is important for parents to be prepared when an infant with severe CHD is discharged from hospital after initial treatment. Using the HOBS app significantly improved the outcomes of discharge support that were measured in the mothers. This improvement may stem from the integrated features in HOBS that educate parents and improve their understanding and assessment of their child's condition. A specialist nurse helped the parents to set up the child's baseline data on the HOBS app and this provided them with a reference point for new, structured assessments after discharge. This is important, because it probably made the parents more aware of what was normal for their child.

The embedded checklist in the HOBS app may have initiated more conversations about the child's discharge and improved the mothers' confidence. Parents in the control group, who just received

TABLE 1 Characteristics of the families and infants and their use of healthcare services.

Characteristics of respondents	Control group		Intervention group		*p* value
Parents and family situation					
Age (years), mean (SD)					
Mother ($n=35/n=33$)	31.2 (5.4)		31.1 (5.1)		0.914
Father ($n=33/n=33$)	32.3 (5.1)		33.8 (5.2)		0.247
Education after primary school in years, mean (SD)					
Mother ($n=35/n=33$)	6.5 (3.3)		5.4 (2.6)		0.123
Father ($n=33/n=33$)	4.8 (2.5)		5.0 (3.3)		0.706
Married or cohabitating, *n* (%)	37 (100)		36 (100)		
Having siblings in the family, *n* (%)	17 (49)		19 (58)		0.457
Child status	$n=37$		$n=36$		
Boy, *n* (%)	19 (54)		18 (50)		0.510
Birth weight in kg, mean (SD)	3.4 (0.7)		3.2 (0.6)		0.162
Gestational age in weeks, mean (SD)	38.3 (1.9)		38.3 (2.0)		0.144
Intrauterine diagnosis, *n* (%)	18 (48)		21 (58)		0.407
Diagnosis, *n*					
Transposition of the great arterias	9		0		
Coarctation of aorta	7		9		
Tetralogy of fallot	4		3		
Anomalous pulmonary venous connection	4		0		
Complex transposition of the great arterias	3		4		
Univentricular heart	0		4		
Atrioventricular canal defect	0		4		
Pulmonary atresia with ventricular septal defect	0		3		
Double outlet of the right ventricle	0		3		
Miscellaneous diagnoses	10		6		
Treatment, *n* (%)					
Surgery	28 (76)		29 (81)		0.614
Catheterization	4 (11)		4 (11)		0.967
Corrective surgery	24 (65)		17 (47)		0.129
Palliative surgery*	4 (11)		12 (33)		0.025
Waits for timing of surgery*	10 (27)		18 (50)		0.044
Receives cardiac medication*	13 (35)		22 (61)		0.026
Challenges after discharge, *n* (%)					
Cardiac impairment after discharge	19 (51)		30 (83)		0.004
Need of gavage feeding at home	5 (14)		11 (31)		0.080
Comorbidity**	5 (14)		9 (25)		0.213
Hospital stay (days), median, (range)					
At specialist centre	13 (2–59)		14.5 (3–77)		0.437
At local hospital	4 (1–26)		7 (0–144)		0.013
Use of healthcare services after discharge	$n=24$		$n=24$		
Unplanned admissions to hospital after discharge, *n* (%)	2 (8.3)		9 (37.5)		0.016
Planned consultations	High (≥5)	Low (≤4)	High (≥5)	Low (≤4)	
Cardiologist	13 (54)	11 (46)	9 (38)	15 (63)	0.385
Liaison nurse	1 (4)	23 (96)	1 (4)	23 (96)	0.755
General Practitioner	1 (4)	23 (96)	1 (4)	23 (96)	0.755

TABLE 1 (Continued)

Characteristics of respondents	Control group		Intervention group		*p* value
Community nurse	9 (38)	15 (63)	17 (71)	7 (29)	0.041
Unplanned consultations					
Cardiologist	4 (17)	20 (83)	5 (20)	19 (79)	1.0
Liaison nurse	1 (4)	23 (96)	2 (8)	22 (92)	1.0
General practitioner	0	24 (100)	0	24 (100)	1.0
Community nurse	2 (8)	22 (92)	2 (8)	22 (92)	1.0

*Included in the group with infants with cardiac impairment. **Comorbidity includes prematurity, other congenital anomalies, such as airway, pulmonary, gastrointestinal, and genitourinary anomalies, and genetic syndromes.[16]

TABLE 2 Perceived usefulness of interventions.

	Control group (*n* = 30)		Intervention group (*n* = 31)		
Possible score: 1–5 range 5–35	**Mean**	**(95% CI)**	**Mean**	**(95% CI)**	***p***
1. To what degree do you experience that the information in the binder/app is adapted to your child?	3.4	(2.9–4.0)	3.9	(3.5–4.3)	0.115
2. To what degree has the binder/app been useful to you during discharge from the hospital?	2.4	(1.7–2.9)	3.4	(3.0–3.8)	0.005
3. To what degree has the binder/app been useful after you came home?	2.5	(1.9–3.1)	3.6	(3.2–3.9)	0.005
4. To what degree, has the binder/app helped you making decisions in times of uncertainty or deterioration?	2.3	(1.6–3.0)	3.7	(3.0–4.3)	0.004
5. To what degree has advice in the binder/app been helpful about contacting healthcare professionals?	2.7	(2.2–3.3)	3.5	(3.0–4.0)	0.048
6. To what degree do you experience that the binder/app is available when you need it?	3.6	(3.0–4.2)	4.8	(4.6–5.0)	<0.001
7. To what degree has the binder/app been useful in communication with healthcare professionals?	2.3	(1.6–2.9)	2.9	(2.3–3.5)	0.134
Total sum of usefulness	17.0	(14.1–20.0)	23.9	(21.6–26.1)	<0.001

the printed information, did not have their own checklist and the nurses were responsible for completing the discharge preparations. The shift of responsibility, and the use of a structured tool in the HOBS group, may have increased maternal empowerment.[10,15]

4.2 | Usefulness of interactive features

Going home with an infant who could deteriorate emphasises the importance of understanding what signs to look for and how to recognise them. The higher usefulness scores for the HOBS app at home, compared to the standard printed information, might be explained by the interactive features. These provided clear stepwise directions on how to observe and assess the infant's condition. The individualised list of signs to look out for were similar in both groups. However, when the parents used the printed information they had to search for more information themselves, whereas the recommended resources were integrated into HOBS. Other studies have stated that a video demonstrating respiratory distress would be useful for parents and it was appreciated by many of the parents who used the HOBS app.[15,24]

Providing pictures may have made it easier to assess wounds using the HOBS app rather than the printed information.[14] Obviously, parents who received the printed information lacked direct access to quality-assured educational videos and pictures. The easily available, interactive information and support that HOBS provided may have contributed to the improved use of information and decision support at home.[14]

In general, personalisation leads to better adoption of mobile health apps.[25] One study, of the Healing Hearts at Home app, reported that the parents of infants with CHD requested individually adapted information.[11] In the present study, the parents in both groups received individualised information and the mothers found that it was adapted well to their child.

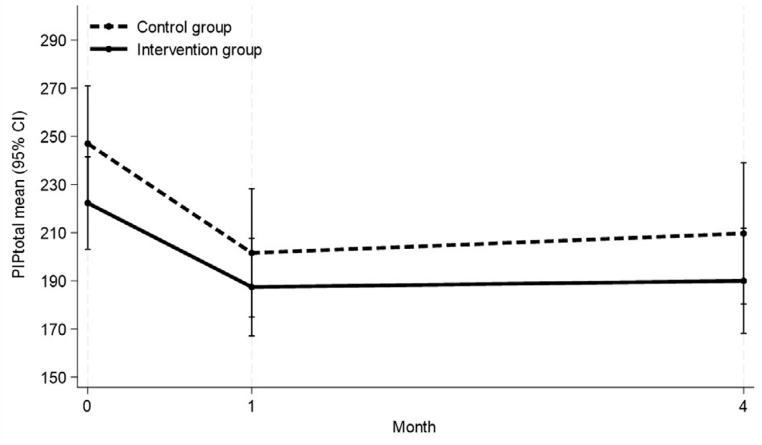
The mothers of infants with sustained cardiac impairment needed more information after discharge, more preparations before discharge and more information about symptoms to be aware of and observe. This was reflected in the higher usefulness scores from the mothers in both groups and the fact that they used HOBS more than the mothers of those whose child had completed treatment. That finding supports another study that reported that the use of the HOBS app differed according to disease severity.[15] Nevertheless, the mothers of infants with cardiac impairment who used the HOBS app reported significantly higher scores for usefulness than the mothers who used the printed information.

TABLE 3 Results of the Paediatric Inventory for Parents (PIP) questionnaire from mothers of all infants.

	Control group			Intervention group			
	(*n*)	mean	SD	(*n*)	mean	SD	*p*
At specialist centre (baseline)							
PIPtotal	(33)	225.2	49.3	(27)	220.0	48.3	0.678
PIPftotal	(34)	119.4	22.7	(31)	117.0	22.0	0.661
PIPdtotal	(33)	105.8	27.3	(27)	103.1	27.1	0.705
One month after discharge							
PIPtotal	(24)	177.3	58.2	(22)	178.1	41.6	0.922
PIPftotal	(26)	94.6	27.7	(22)	97.8	19.5	0.669
PIPdtotal	(24)	83.0	30.7	(22)	80.3	22.7	0.573
Four months after discharge							
PIPtotal	(21)	162.8	56.2	(18)	188.4	52.6	0.093
PIPftotal	(22)	86.6	26.1	(20)	102.0	25.4	0.050
PIPdtotal	(21)	75.9	30.0	(18)	88.9	29.0	0.113

Abbreviations: PIPtotal, paediatric inventory for parents total score; PIPftotal, paediatric inventory for parents frequency subscale; PIPdtotal, paediatric inventory for parents difficulty subscale.

FIGURE 3 Linear graphs showing the mean between-group changes in the PIP total over time, among the mothers of infants with cardiac impairment.



PIPtotalmean = Pediatric Inventory for Parents totalscore. Range 84 – 420

	Mean value at baseline (CI)	**Mean value at 1 month (CI)**	**Mean value at 4 months (CI)**	**Mean change (CI)**	**Mean betweeen group change**
Control group	245.6 (221.8-269.5)	200.7 (174.0-227.3)	208.7 (179.4-238.1)	-36.9 (-63.0 to -10.8)	
Intervention group	222.6 (203.3-241.8)	187.6 (167.2-207.9)	189.8 (167.9-211.7)	-32.7 (-52.9 to -12.5)	4.2 (-28.9 to 37.2) p=.804

4.3 | Communication with healthcare professionals

Many mothers added contact numbers and made direct calls from the HOBS app. The same page provided advice on who they should contact and in what circumstances. This may explain the high score for being able to contact healthcare professionals. However, the mothers did not say that HOBS was more useful when communicating with healthcare professionals. This potential benefit may have been limited by the fact that the medical staff were unfamiliar with the application. Many local hospitals used HOBS for the first time during the study, which may have reduced its effect on communication.[26]

One potential advantage of digital solutions is the ability to share results from assessments, together with pictures and videos, with healthcare professionals.[27] However, HOBS could not be used as a third-party app for digital communication with healthcare services, due to information and security restrictions in Norway. In addition, features like this require well-organised and more or less continuous contact with healthcare professionals, which may not be cost-effective in this population.[9] Users of other digital support apps, such as WeChat, appreciated the direct communication with a CHD nurse, as well as the educational material.[12] Despite this, the parents who used WeChat wanted to be able to digitally transfer pictures, videos and video communication as well as send text messages.[24] The method that is chosen is a question of resources and local conditions and our study showed good maternal responses to an easily available solution.

4.4 | Use and normalisation

The user logs showed that HOBS was mainly used for the first month after discharge and less frequently between one and four months. Assessments and information links were only used when needed, which corresponded to the findings of our previous feasibility study. Parents want a normal family life when possible[15] and other studies have found similar priorities in populations with CHD.[7,28] However, our concerns about the excessive use of the app, because of the increased availability, did not materialise. Other studies have confirmed that the frequent use of home assessments is not desirable, because they constantly remind users of their child's vulnerability and disease.[25] Parental education before discharge may increase vigilance and give them the self-confidence they need so that they don't keep doing regular assessments. It may also ensure that they use the app when needed.[28]

4.5 | Disease related stress and vigilance

Digital supportive apps have been shown to reduce stress and anxiety in cases of mild CHD.[12] However, home monitoring has not been associated with less stress and anxiety among the parents of infants with more complex malformations.[9,28] Parenting infants with severe CHD and sustained cardiac impairment almost inevitably increases disease-related stress.[7,29] When that was measured with the PIP in our study, it showed a borderline higher frequency of stress-related events in the HOBS group at 4 months. This was probably because infants in the HOBS group had significantly more cardiac impairment, were waiting for surgery, had higher care demands and had more unplanned admissions. When we compared the mothers of infants with sustained cardiac impairment, there was no significant difference in maternal stress between the HOBS and control groups (Figure 3).

More of the frequent admissions among the HOBS group could be explained by exaggerated vigilance when using the application.[6] However, all the admissions were related to a specific illness that needed treatment and surveillance, reflecting higher morbidity in the intervention group. In summary, our study indicates that HOBS enabled mothers to monitor their infants at home without causing them extra stress.

4.6 | Limitations

This study had several limitations. It was a non-randomised pragmatic controlled trial that provided a complex intervention in a complex setting. The intervention was implemented at a specialist centre and the infants were then discharged to local hospitals for further follow up. Variations in care and support at the different hospitals may have had an impact on the results and how well the intervention was used.[25] However, both groups received the intended information and most of the questions about usefulness were independent of local healthcare professionals. Complex studies like this may have the best internal validity if they are solely used in the environment that the application was designed for. Consequently, the findings are not automatically transferrable to other settings without adaptations.[30]

Furthermore, the questions about usefulness were developed for this specific study. Questionnaires that have been devised by researchers may suffer from ambiguity and misinterpretation.[18] In this study, the questions were based on a well-grounded concept and the aims of the interventions and the wording were thoroughly discussed in the research group. Nevertheless, we are not aware of any established alternative and the results agree with our earlier feasibility study.[14]

To decrease the burden on the respondents during their child's admission to the neonatal intensive care unit, the first PIP measurement was carried out on the same day that the parents started to use the intervention. This may have had an impact on the mothers' responses. The results should be interpreted in light of the small sample size, the high attrition at 4 months and the uneven distribution of infants with cardiac impairment in the groups. We have no reasonable explanation about why the infants in the HOBS group had more complex CHD and consider this unfortunate distribution as incidental. This uneven distribution resulted in an underpowered analysis of stress and may have decreased the probability of discovering a true effect. Finally, we were only able to assess the mothers who used the HOBS app or the standard printed information, due to the high dropout rate among the fathers.

5 | CONCLUSION

Mothers who used the HOBS app found it significantly more useful for discharge preparations, follow up at home, ongoing decision making and contacting healthcare professionals than the controls who received printed information. This was particularly the case if their infant had sustained cardiac impairment. The structured parental education embedded in HOBS app, and its interactive features, may explain these benefits. This study indicated that most mothers who used HOBS managed to balance normalisation and vigilance without excessive stress.

ACKNOWLEDGEMENTS

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

Data are available upon reasonable request.

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REFERENCES

1. Wik G, Jortveit J, Sitras V, Dohlen G, Ronnestad AE, Holmstrom H. Severe congenital heart defects: incidence, causes and time trends of preoperative mortality in Norway. Arch Dis Child. 2020;105(8):738-43.
2. GBD 2017 Congenital Heart Disease Collaborators. Global, regional, and national burden of congenital heart disease, 1990–2017: a systematic analysis for the global burden of disease study 2017. Lancet Child Adolesc Health. 2020;4(3):185-200.
3. Wik G, Jortveit J, Sitras V, Dohlen G, Ronnestad AE, Holmstrom H. Unexpected death in children with severe congenital heart defects in Norway 2004-2016. Arch Dis Child. 2021;106(10):961-6.
4. Woolf-King SE, Anger A, Arnold EA, Weiss SJ, Teitel D. Mental health among parents of children with critical congenital heart defects: a systematic review. J Am Heart Assoc. 2017;6(2):e004862.
5. Lawoko S. Factors influencing satisfaction and well-being among parents of congenital heart disease children: development of a conceptual model based on the literature review. Scand J Caring Sci. 2007;21(1):106-17.
6. Meakins L, Ray L, Hegadoren K, Rogers LG, Rempel GR. Parental vigilance in caring for their children with hypoplastic left heart syndrome. Pediatr Nurs. 2015;41(1):31-50.
7. Lumsden MR, Smith DM, Wittkowski A. Coping in parents of children with congenital heart disease: a systematic review and meta-synthesis. J Child Fam Stud. 2019;28(7):1736-53.
8. Abernathy BR. Home monitoring in patients with Hypoplastic left heart syndrome: a literature review. Pediatr Nurs, vol. 44, no. 2, 2018.
9. Medoff Cooper B, Marino BS, Fleck DA, et al. Telehealth home monitoring and Postcardiac surgery for congenital heart disease. Pediatrics. 2020;146(3).
10. Tanem JMA. A mobile application as a tool for guided participation. In: Pridham KLR, Schroeder M, eds. Guided Participation in Pediatric Nursing Practice: Relationship-Based Teaching and Learning with Parents, Children, and Adolescents. Springer Publishing Company; 2018:341-54.
11. Miller VA, Newcombe J, Radovich P, Johnston F, Medina E Jr, Nelson A. The healing hearts at home© Mobile application usability and influence on parental perceived stress: a pilot study. International Journal of E-Health and Medical Communications (IJEHMC). 2021;12(3):90-105.
12. Xie W-P, Liu J-F, Lei Y-Q, Cao H, Chen Q. Effects of WeChat follow-up management of infants who underwent ventricular septal defect repair on parents' disease knowledge and quality of life: a prospective randomized controlled study. J Card Surg. 2021;36(10):3690-7.
13. Zhang QL, Lei YQ, Liu JF, Cao H, Chen Q. Using telemedicine to improve the quality of life of parents of infants with CHD surgery after discharge. Int J Qual Health Care. 2021;33(3).
14. Hjorth-Johansen E, Børøsund E, Moen A, et al. Heart OBServation app: development of a decision support tool for parents of infants with severe cardiac disease. Cardiol Young. 2022;33:1-9.
15. Hjorth-Johansen E, Børøsund E, Martinsen Østen I, Holmstrøm H, Moen A. Acceptability and initial adoption of the heart observation app for infants with congenital heart disease: qualitative study. JMIR Form Res. 2023;7:e45920.
16. Chowdhury D, Toms R, Brumbaugh JE, et al. Evaluation and management of noncardiac comorbidities in children with congenital heart disease. Pediatrics. 2022;150(2):e2022056415E.
17. Hjorth-Johansen E. Home After Heart Surgery In The Neonatal Period: Does Written Information Based On Tranistion Theory Meet Parents Needs For Information And Improve Their Knowledge And Coping After Discharge? . University of Oslo; 2013.
18. Ranganathan P, Caduff C. Designing and validating a research questionnaire—part 1. Perspect Clin Res. 2023;14(3):152-5.
19. Braniecki S, Kazak AE, Tercyak KP, Streisand R. Childhood illness-related parenting stress: the pediatric inventory for parents. J Pediatr Psychol. 2001;26(3):155-62.
20. Beaton D, Bombardier C, Guillemin F, Ferraz MB. Guidelines for the process of cross-cultural adaptation of self-report measures. Spine. 2000;25(24):3186-91.
21. Mokkink LB, Prinsen C, Patrick DL, et al. COSMIN Study Design Checklist for Patient-Reported Outcome Measurement Instruments. Amsterdam Public Health research institute; 2019:1-32.
22. Schulz KF, Grimes DA. Sample size slippages in randomised trials: exclusions and the lost and wayward. Lancet. 2002;359(9308):781-5.
23. The International Society for nomenclature of paediatric and congenital heart disease. International pediatric and Congenital Cardiac code; 2005. Available from: http://ipccc.net/
24. Lin W-H, Chen Y-K, Lin S-H, Cao H, Chen Q. Parents' understanding and attitudes toward the use of the WeChat platform for postoperative follow-up management of children with congenital heart disease. J Cardiothorac Surg. 2023;18(1):66.
25. Jacob C, Sezgin E, Sanchez-Vazquez A, Ivory C. Sociotechnical factors affecting patients' adoption of mobile health tools: systematic literature review and narrative synthesis. JMIR Mhealth Uhealth. 2022;10(5):e36284.
26. Jacob C, Sanchez-Vazquez A, Ivory C. Understanding clinicians' adoption of mobile health tools: a qualitative review of the Most used frameworks. JMIR Mhealth Uhealth. 2020;8(7):e18072.
27. Rempel GR, Ravindran V, Rogers LG, Magill-Evans J. Parenting under pressure: a grounded theory of parenting young children with life-threatening congenital heart disease. J Adv Nurs. 2013;69(3):619-30.
28. Gaskin KL, Smith L, Wray J. Evaluating the congenital heart assessment tool: a quality improvement project. Cardiol Young. 2023;33(6):878-85.
29. Rudd NA, Ghanayem NS, Hill GD, et al. Interstage home monitoring for infants with single ventricle heart disease: education and management. J Am Heart Assoc. 2020;9(16):e014548.

30. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Int J Nurs Stud. 2013;50(5):587-92.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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Dissertation Appendix Documents

Consents and ethical approvals:

1) Consent form parents Study I and II (in Norwegian)
2) Consent form health care professionals at OUS Study I and II (in Norwegian)
3) Consent form to local health care professionals Study II (in Norwegian)
4) Consent form parents Study III (in Norwegian)

Interview guides:

5) Interview guide parents (first and second interview) Study I and II
6) Interview guide focus group interview nurses Study I and II
7) Interview guide local nurses Study II
8) Interview guide cardiologists and community nurses: Study II

Questionnaires:

9) System usability Scale Study I (in Norwegian)
10) Usefulness of interventions Study III (In Norwegian)
11) Pediatric Inventory for Parents (PIP) (in Norwegian)
12) Edinburgh Postnatal Depression Score (EPDS)

Tools for implementation:

13) The My Heart Binder and bedside checklist for nurses in standard care
14) Advice for parents of possible features in HOBS
15) Bedside checklist for nurses in HOBS

APPENDIX 1

Forespørsel om deltakelse i forskningsprosjektet

"Mobilapplikasjon for foreldre til barn med hjertesykdom"

Bakgrunn

Dette er et spørsmål til deg om å delta i en forskningsstudie for å evaluere nytten av en mobilapplikasjon for foreldre til nyfødte barn med hjertefeil/sykdom som skal reise hjem. Dere forespørres fordi dere har et barn som har hjertefeil/sykdom og er utredet her ved Rikshospitalet.

Formålet med studien er å evaluere om applikasjonens funksjoner er nyttig for dere når dere skal vurdere endring i barnets helse, for å hjelpe dere å ta beslutninger, gi dere støtte ved kommunikasjon med helsepersonell og for å gjøre informasjon tilgjengelig etter utskrivelse.
Barnekardiologisk avdeling og Nyfødt intensiv avdeling ved Oslo Universitetssykehus er ansvarlig for prosjektet og behandling av data i studien gjøres via Tjenester for sensitive data (TSD) ved Universitetet i Oslo.

Hva innebærer studien?

I studien vil dere få tilbud om å laste ned en mobilapplikasjon på egen mobiltelefon. Appen har kode for pålogging slik at informasjonen som ligger der ikke kan sees av andre. Dere får opplæring og oppfølging av helsepersonell ved nyfødt intensiv i hvordan appen kan brukes. For øvrig vil dere få muntlig informasjon og veiledning slik som andre foreldre. Begge foreldre eller den som har vært mest sammen med barnet intervjues før utreise og på telefon etter 1 måned. Spørsmålene skal handle om hvordan appen har bidratt når dere har vurdert barnets helse, deres opplevelse av valg om å kontakte og kommunisere med helsevesenet og om den informasjonen dere trenger er tilgjengelig og nyttig.

I tillegg til spørsmålene i intervjuene ber vi om opplysninger om barnets diagnose, behandling og kontakt med helsetjenester etter hjemreise, samt lov til å snakke med lokalt helsepersonell dere har samarbeidet med om bruk av appen. Vi innhenter også data fra appen om hvilke funksjoner som blir brukt. Intervjuene blir tatt opp på bånd og siden lagret på TSD.

Mulige fordeler og ulemper

Dere vil ikke ha noen spesielle fordeler av studien, men erfaringer fra studien vil senere kunne hjelpe andre med samme diagnose. Ved å delta får dere mulighet til å påvirke og foreslå endringer som må til for at appen skal være nyttig for andre foreldre i samme situasjon.

Hva skjer med informasjonen om deg og barnet ditt?

Informasjonen som registreres skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer/direkte gjenkjennende opplysninger. En kode knytter deg og barnet til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til dere. Det vil ikke være mulig å identifisere dere i resultatene av studien når disse publiseres. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert og dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir uansett slettet senest 31.12 2029. Etter ny personopplysningslov har behandlingsansvarlig (Oslo Universitetsykehus) og prosjektleder Elin Hjorth-Johansen et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag.

Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet. Slike henvendelser rettes til Personvernombudet ved institusjonen (personvern@ous-hf.no)

Frivillig deltakelse
Det er frivillig å delta i studien. Dersom du ikke ønsker å delta, trenger du ikke å oppgi noen grunn, og det får ingen konsekvenser for den videre behandlingen du får ved sykehuset.

Dersom du ønsker å delta, undertegner du samtykkeerklæringen på neste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling på sykehuset. Dersom du senere ønsker å trekke deg, kan du kontakte prosjektleder Elin Hjorth-Johansen telefon 986 76 884.

Samtykke for deltakelse i studien

Vi er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

(Signert av prosjektdeltaker, dato)

Bekreftelse på at informasjon er gitt deltakeren i studien

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

APPENDIX 2

Forespørsel om deltakelse i forskningsprosjektet

"Mobilapplikasjon for foreldre til barn med hjertesykdom"

Bakgrunn

Dette er et spørsmål til deg om å delta i en forskningsstudie for å evaluere nytten av en mobilapplikasjon som hjelpemiddel for foreldre til barn med alvorlig hjertesykdom etter utreise. Du forespørres fordi du har hatt en rolle og bidratt i behandlingen der foreldrene har samtykket til å delta i en studie i bruken av appen i ca1 måned.

Formålet med studien er å vurdere om mobilapplikasjonen er en gjennomførbar og nyttig intervensjon i helsetjenestene foreldrene bruker. I tillegg skal det evalueres om applikasjonens funksjoner er nyttig for vurdering av endring i barnets tilstand, for beslutnings- og kommunikasjonsstøtte, og tilgjengelighet av informasjon etter utskrivelse. Oslo Universitetssykehus ved Barnekardiologisk avdeling er forsknings- og databehandlingsansvarlig.

Hva innebærer studien?

Deltakelse innebærer å være med på et fokusgruppeintervju med sykepleiere og leger ved Barnekardiologisk avdeling og Nyfødtintensiv-avdelingen som har hatt kontakt med foreldrene under sykehusoppholdet ved Rikshospitalet. Temaene i intervjuet vil være samarbeid med og veiledning av foreldrene rundt applikasjonen. Det antas at fokusgruppe intervju vil ta ca en time, men tidsrammen tilpasses etter behov. Samtalene tas opp med diktafon, transkriberes og behandles med innholdsanalyse.

Mulige fordeler og ulemper

Du vil ikke ha noen spesielle fordeler av studien, men erfaringer fra studien vil senere kunne hjelpe andre. Ved å delta får du mulighet til å påvirke og foreslå endringer som må til for at appen eller den skriftlige informasjonen skal være nyttig for andre foreldre i samme situasjon.

Taushetsplikten gjelder fortsatt

Deltakelse i studien fritar deg ikke fra taushetsplikten. Dersom du blir bedt om å gi opplysninger som kan identifisere pasienter, har du plikt til å forsikre deg om at forsker har lov til å innhente de taushetsbelagte opplysningene. I alle andre tilfeller må ingen opplysninger som kan identifisere pasienter fremkomme under studien. Dersom du ved et uhell avgir slik informasjon må du gjøre forskeren oppmerksom på dette og kreve at de taushetsbelagte opplysningene slettes. Forskeren skal etterkomme et slikt krav umiddelbart.

Hva skjer med informasjonen om deg?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer/direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Avdelingsledelsen eller ledelsen ved sykehuset vil ikke gis tilgang til navnelisten. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir uansett slettet senest i 2029. Etter ny personopplysningslov har behandlingsansvarlig (Oslo Universitetsykehus) og prosjektleder Elin Hjorth-Johansen et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet. Personvernombud ved institusjonen er personvern@ous-hf.no

Frivillig deltakelse

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Formålet med studien er å vurdere gjennomførbarhet av mobilapplikasjonen i helsetjenestene foreldrene bruker. I tillegg skal det evalueres om applikasjonens funksjoner er nyttig for vurdering av endring i barnets tilstand, for beslutnings- og kommunikasjonsstøtte, og tilgjengelighet av informasjon etter utskrivelse. Oslo Universitetssykehus ved Barnekardiologisk avdeling og Nyfødt intensiv avdeling er forsknings og databehandlingsansvarlig.

Hva innebærer studien?

Studien innebærer deltagelse i et semistrukturert intervju (eventuelt på telefon) for helsepersonell som har hatt kontakt med foreldrene lokalt. Temaene i intervjuet vil være samarbeid med og veiledning av foreldrene rundt applikasjonen. Det antas at telefonintervjuet kan ta ca 10-15 minutter. Tidsrammen tilpasses etter behov. Samtalene tas opp med diktafon, transkriberes og behandles med innholdsanalyse.

Mulige fordeler og ulemper

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Samtykke for deltakelse i studien

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Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

APPENDIX 4

Forespørsel om deltakelse i forskningsprosjektet

"Mobilapplikasjon for foreldre til barn med hjertefeil"

Bakgrunn

Dette er et spørsmål til deg om å delta i en forskningsstudie for å evaluere nytten av en mobilapplikasjon for foreldre til nyfødte barn med hjertesykdom som skal reise hjem. Dere blir forespurt fordi dere har et barn som har hjertesykdom og er utredet og behandlet her ved Rikshospitalet. Formålet med studien er å undersøke hvordan foreldre mestrer situasjonen etter utskrivelse og om informasjon via mobilapp er bedre enn tradisjonell skriftlig informasjon. Barnekardiologisk avdeling ved Oslo Universitetssykehus er ansvarlig for prosjektet. Behandling av data i studien gjøres via Tjenester for sensitive data (TSD) ved Universitetet i Oslo.

Hva innebærer studien?

Dersom dere samtykker i deltagelse i studien vil du/dere enten få mobilapp med informasjon eller skriftlig informasjon på papir. Muntlig informasjon og veiledning gis til alle foreldre. Om dere får app eller skriftlig informasjon avhenger av tidspunktet dere er i avdelingen.

I perioden når app tildeles får dere tilbud om å laste ned appen på egen telefon eller nettbrett. Appen har kode for pålogging slik at informasjonen som ligger der ikke kan sees av andre. Dere får opplæring og oppfølging av helsepersonell ved nyfødt intensiv i hvordan appen brukes. I perioden der skriftlig informasjon utdeles får deltagende foreldre en perm med tilpasset informasjon til sitt barn.

Vi vil be dere om å besvare spørreskjema om hvor forberedt dere er på utskrivelsen, stress, engstelse og mestring samt registrere kontakt dere har hatt med helsetjenester i studieperioden. Dette vil bli sendt elektronisk så dere kan svare på mobil eller PC. Dere skal svare på spørreskjemaer fire ganger. Dette er ved inkludering på Rikshospitalet, før utreise fra lokalsykehus, samt 1 og 4 måneder etter hjemreise. Det er ønskelig at begge foreldre svarer på hver sine spørreskjema, men det er ikke nødvendig for å delta i studien. I tillegg til spørreskjemaene ber vi om opplysninger som barnets diagnose og behandling samt deres alder og utdanning.

Mulige fordeler og ulemper

Dere vil ikke ha noen spesielle fordeler av studien, men erfaringer fra studien vil senere kunne hjelpe andre med samme diagnose. Ved å delta får dere mulighet til å påvirke og foreslå endringer som må til for at appen eller den skriftlige informasjonen skal være nyttig for andre foreldre i samme situasjon.

Hva skjer med informasjonen om deg og barnet ditt?

Informasjonen som registreres skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer/direkte gjenkjennende opplysninger. En kode knytter deg og barnet til dine opplysninger gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere dere i resultatene av studien når disse publiseres. Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert og dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede opplysninger. Opplysningene blir uansett slettet senest 31.12 2031. Etter ny personopplysningslov har behandlingsansvarlig (Oslo Universitetsykehus) og prosjektleder Elin Hjorth-Johansen et selvstendig ansvar for å sikre at behandlingen av dine opplysninger har et lovlig grunnlag. Dette prosjektet har rettslig grunnlag i EUs personvernforordning artikkel 6 nr. 1a og artikkel 9 nr. 2a og ditt samtykke. Du har rett til å klage på behandlingen av dine opplysninger til Datatilsynet. Slike henvendelser rettes til Personvernombudet ved institusjonen (personvern@ous-hf.no).

Frivillig deltakelse
Det er frivillig å delta i studien. Dersom du ikke ønsker å delta, trenger du ikke å oppgi noen grunn, og det får ingen konsekvenser for den videre behandlingen du får ved sykehuset.

Dersom du ønsker å delta, undertegner du samtykkeerklæringen på neste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling på sykehuset. Dersom du senere ønsker å trekke deg, kan du kontakte prosjektleder Elin Hjorth-Johansen på telefon 986 76 884.

Samtykke for deltakelse i studien

Vi er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

(Signert av prosjektdeltaker, dato)

Bekreftelse på at informasjon er gitt deltakeren i studien

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

APPENDIX 5

Intervjuguide: foreldre

Intervjuguide til foreldre ved utskrivelse

Foreldrene intervjues ved utreise og hoved omsorgsgiver (evt med partner) intervjues på telefon 1 måned etter hjemreise om applikasjonens funksjonalitet og hvordan den har bidratt til å; a) vurdere barnets tilstand ved usikkerhet om forverring, b) beslutte tiltak, c) kommunisere med helsevesenet samt d) individualisere informasjon.

Hensikt: Gjøre appen best mulig for foreldre til barn med hjertefeil/sykdom. Men også å få til en best mulig introduksjon på Rikshospitalet. Intervjue 1 handler om introduksjonen og veiledningen på Riksen.

Informasjon til deltager før oppstart av intervju: Alt som sies tas opp, og det er mulig å be om at det slettes! Ny samtale om ca 1 mnd.

Tema	Spørsmål	Evt oppfølgingsstikkord
Introduksjon i appens funksjoner	Hvordan opplevde du/dere **oppstartinformasjonen** og introduksjonen av mobilapplikasjonen	Hvor **lett å forstå**? Mengde informasjon? **Tidspunkt** for informasjon? Etter op./diagnose **Sted** for første introduksjon? Var det nødvendig med introduksjon?
Tilpasning til barnet	Hvordan var det å **tilpasse appen** til barnet?	Diagnose? Konsekvenser? Utstyr? «Normalt for mitt barn»
		Ingenting passer, Stressende, Betryggende, Vanskelig?
	Har dere **vurdert barnets tilstand** med vurderingsfunksjonen? På hvilken måte har det i så fall påvirket dere?	Pusting, spising, etc Engstelse, forståelse, trygghet, forvirrende?
Tilpasset og tilgjengelig informasjon	Har du/dere **lest noe av informasjonen** som ligger i appen? Hvordan oppleves i så fall informasjonen dere har fått?	Tips funksjonen? Informasjon om kontakter? Konsekvenser, hjertefeil, annet? Pålitelig kilde, tilpasset deres barn, lett eller vanskelig å lese?
	Har det hatt noen påvirkning på forståelsen av det leger og sykepleiere sier?	
Kommunisere med helsevesenet	Har du blitt veiledet av sykepleier eller leger ifht appen? Hvordan har det vært?	Mange forskjellige svar? Variasjon i kompetanse? Hierarki? Forståelse av det som sies?
Avslutning	Hvordan har du opplevd å bruke/få appen som veilednings- og informasjonsstøtte her på sykehuset?	

	Er det noe som bør endres eller tilrettelegges bedre?	Introduksjon, oppfølging av sykepleier, lege sosionom og kontaktsykepleier
Sluttkommentar	Er det noe som bør tas opp som ikke er nevnt?	
Utsjekksfunksjon	Har du fått hjelp til å se over innstillingene?	Evt bidra ved behov
	Navn på helsestasjon og fastlege	Be om tillatelse til å ringe for å spørre om hvordan oppfølgende helsepersonell opplever appen samt sende dem informasjon om appen.

Intervju guide til foreldre ved 1 mnd (etter 6 ukers kontroll)

Hensikt:

- Finne ut hvordan funksjonen er brukt til å:
    - vurdere barnet helsetilstand,
    - beslutte tiltak,
    - få kunnskap,
    - kommunisere med helsepersonell
- Hvordan de har opplevd å bruke appen totalt sett
- Og hvordan det har påvirket dem (trygg/usikker/stress)

Tema	Spørsmål	Evt oppfølgingsstikkord
TILPASNING I MITT BARN	Hvordan har du OPPLEVD å tilpasse appen til barnet ditt/fylle ut Mitt barn evt gjøre endringer? Hvordan har du/dere brukt funksjonen? Har du gjort noen endringer i mitt barn etter at dere dro fra RH? Har det vært noe usikkerhet hos deg eller helsepersonell som har hjulpet deg lokalt?	Er det gjort tilpasninger etter utskrivelser fra riksen? Kontaktinformasjon til lokal helsehjelp? «Normalt for mitt barn» før utreise? Bilder av hjertefeilen? Støtte hos lokalt helsepersonell?
INFORMASJONSFUNKSJONEN	Hvordan har dere opplevd å bruke informasjonsfunksjonen? Hvordan har dere brukt INFORMASJONSFUNKSJONEN?	Pålitelighet, tilpasset deres barn, lett eller vanskelig å finne riktig informasjon? Savner dere noe informasjon eller støttefunksjoner? Var språket forståelig? Var det noe som var vanskelig?
VURDERINGSFUNKSJONEN	Hvordan har dere brukt VURDERINGSFUNKSJONEN? Sår funksjonen? Vekt?	Nyttig? Hyppighet? Endring i behov for å gjøre det? Kjennskap til tegnene? Brukt som rutine eller ved bekymring om sykdom?
	Hvordan har dere opplevd å bruke vurderingsfunksjonen? Er den brukt sammen med helsepersonell?	Engstelse, forståelse, trygghet? Økt mobilbruk?
BESLUTTE TILTAK	Hvordan har dere bestemt hva dere skal gjøre i ulike situasjoner med tanke på barnets helse?	Gjort vurdering i app. (generell tilstand eller sår)? Ved forverringer i resultatlisten? Brukt informasjonsskriv?

		Ringt helsepersonell uavhengig av app og tildelt informasjon? Brukt tipsknapp i vurderingen?
HISTORIKKFUNKSJONEN	Hvordan har dere brukt historikk funksjonen?	Listen/stolpediagrammet over forverringer? Vekt tabell? Kurver for respirasjon/metning?
KONTAKTFUNKSJONEN	Har du brukt kontaktfunksjonen? Hvordan?	I hvilke sammenhenger? Brukt registrerte nummer i kontaktfunksjonen?
Kommunisere med helsevesenet	Har appen blitt brukt i forbindelse med samtaler med kardiolog, lege eller helsesykepleier.	Telefonsamtaler, konsultasjoner? Vanskelig/lett å svare på spørsmål om barnets tilstand? Tryggere? De hører ikke på det som blir sagt? Vet de hva HOBS er? Sett i historikk delen for å forklare?
	Hvor mange ganger har dere vært i kontakt med ulike helsetjenester siden utskrivelse?	Planlagt og uplanlagt Hvilke problemer? Akutt eller ikke? KARDIOLOG: HELSESØSTER: FASTLEGE:
Funksjonalitet	• Tekniske problemer? • Navigere i appen? • lett/vanskelig å finne det du ønsker? • Var språket forståelig? Var det noe som var vanskelig? • bildene/ikonene i appen? • skriftstørrelsen?	Beskrive evt Sender ny funksjonalitets test
Avslutning	Hva er den totale opplevelsen av å bruke appen hjemme?	Vil dere bruke den fremover? I så fall på hvilken måte?
	Hvordan har det påvirket dere å få en app som HOBS?	
	Er det noe som savnes, bør endres eller tilrettelegges bedre i appen eller oppfølgingen?	
Sluttkommentar	Er det noe som bør tas opp som ikke er nevnt?	

APPENDIX 6

Intervjuguide: fokusgrupper

Introduksjon:

- Velkommen
- Kort om prosjektet:
  - Ide Anna Harmens som ble formidlet som et ønske fra FFHB til Barnekardiologisk avdeling.
  - Førte til et samarbeid mellom Barnekardiologisk avdeling og Nyfødt
  - Dette intervjuet er en del av studien av gjennomførbarhet og kartlegging av oppfølgende helsepersonell sine synspunkter om appen
  - For øvrig gjort 45 intervjuer (sykepleier (9), kardiologer (8), helsesykepleiere (9) foreldre 2x10) totalt 7 ulike lokalsykehus.
- Vi skal snakke om
  - Erfaringer dere har gjort med veiledning rundt appen,
  - foreldres responser,
  - behov for endring av funksjoner i appen
  - behov for støtte/veiledning til foreldre under sykehusoppholdet og før og etter utskrivelse
  - Opplæring av helsepersonell (evt)
- Vi gjør dette for å revidere appen til et best mulig verktøy:
  - for foreldre i overgangen til hjemmesituasjonen
  - til veiledning i helsetjenesten rundt familiene
  - mer strømlinjeformet helsetjeneste evt økt kunnskap

Det er derfor viktig at vi både snakker om det som har gått bra og det som ikke har gått så bra! Jeg ønsker ærlige tilbakemeldinger slik at appen blir best mulig!

Dere er spurt fordi dere har erfaring med appen i sammen med foreldre de siste månedene. Dere har ulik erfaring med pasientgruppen fra tidligere, men dette er bra for diskusjonen fordi erfaringen til helsepersonell som følger opp barna også er varierende. Alles innfallsvinkel er derfor viktig og ingen svar eller spørsmål er feil.

Ingeborg vil gjøre notater og avrunder diskusjonen til slutt dersom hun opplever at noe var uklart. Min rolle er å holde oss innenfor tiden og jeg vil dermed kanskje avbryte for å sørge for at vi kommer videre. Jeg har noen spørsmål om temaene som er nevnt, men ønsker også at dere diskuterer dere imellom rundt temaene vi er inne i. Jeg har tatt frem en presentasjon der jeg kan vise dere funksjonene vi snakker om så hvis dere trenger den som støtte til noe dere vil forklare underveis så bare spør.

Tema	Spørsmål	Eventuelt stikkord
Introduksjon	Runde rundt bordet: • navn, stilling/profesjon, • kjennskap/erfaring med HOBS	• HOBS.no? • «Øveapp»?
Mitt barn (intro: fylles delvis ut ved introduksjon og ber foreldre sluttføre med sykepleier/lege)	Hvilke tanker har dere om denne funksjonen? Relevant? Nok kategorier? Responser fra foreldre? Er det noen som har veiledet i denne funksjonen?	Tvil i valg? hjertefeil, konsekvenser, utstyr med hjem (med, sonde, metningsmåler, ernæring) Noe som mangler?
Normalt for mitt barn (Intro: fylles delvis ut ved introduksjon og ber foreldre sluttføre med sykepleier/lege)	Hvilke tanker har dere om denne funksjonen? Relevant? Nok kategorier? Hvordan har dere opplevd å veilede foreldrene? Endringer underveis i forløpet? Responser fra foreldre?	Funksjonsområder som respirasjon, sirkulasjon, ernæring, diurese, søvn og tilfredshet.
Vurdering av tilstand (Intro: ber foreldre gjøre dette sammen med sykepleier)	Hvilke tanker har dere om denne funksjonen? Hvilke erfaringer har dere med å veilede foreldrene i tegn på forverring? Responser fra foreldre?	Hvordan har dere gjort det med appen? Sammenlignet med før? Har funksjonen noe påvirkning på innhold og struktur i veiledningen?
	Har dere brukt tips funksjonen i veiledningen?	Som forklaring eller som bakgrunn? Filmene?
	Hvilke erfaringer har dere med å veilede foreldrene i observasjoner av sår?	Sammenlignet med før?
Informasjonsfunksjonen (intro: jeg viser og peker, men går ikke inn på informasjon)	Hvilke tanker har dere om denne funksjonen? Hvordan fungerer det at foreldre får informasjonen elektronisk?	Behov for noe skriftlig? Veiledningsmateriale? legemiddel opplæring Sammenlignet med skriftlig/perm
Kontaktfunksjonen (ber foreldre legge inn sine kontakter lokalt)	Hvilke tanker har dere om denne funksjonen? Har dere veiledet noe i forhold til hvor og når de skal ta kontakt etter hjemreise?	Forskjell på perm/skriv eller app (kontakt lege)
Historikk funksjonen	Hvilke tanker har dere om denne funksjonen?	Noe mer som burde være mulig/tilgjengelig under denne funksjonen?

	Har noen erfaring med denne funksjonen i veiledningen?	
Funksjoner TOTALT SETT	Hvordan oppleves utformingen/ strukturen? Flere funksjoner? Noe som bør bort?	Hvordan er utformingen for veiledning?
Veiledningen med foreldre rundt appen:	Introduksjon av app til foreldre?	Betydning for egen veiledning?
	Hvordan har dere gjennomført det? Har dere gjort det annerledes enn tidligere? Har appen påvirket innholdet i veiledningen? Har appen påvirket struktur? Hvordan har dere opplevd å veilede foreldrene?	Beskriv en veiledning! Behov for hjelpemidler? For eksempel forklare hemodynamikk? (Hjertetegning) Vite hva man bør si/ikke si? Opplevelse av egen kompetanse Sammenlignet med før?
	Hvordan har veiledningssituasjoner oppstått?	Hvem tar initiativ? Meta vision oppgave, spørsmål fra foreldre? Like mye som før?
	Hvilke responser har foreldrene hatt?	På appen og på veiledningen Optimisme, stress, engstelse mm Virker de mer opplyst
Utreise	Hvilke erfaringer har dere gjort ved utreisesjekk og samtale før utreise?	Sammenlignet med før?! Hjem, til annet sykehus? Logisk? Verktøy i utreisesamtalen?
Optimal appbruk krever introduksjon og veiledning/støtte fra helsepersonell	Har dere noen tanker om hvordan dette kan løses på RH?	Plan for veiledning til foreldre. Introduksjonssamtalen? Veiledning underveis? Utskrivningssamtale? Hjelpemidler i veiledningen?
	Samarbeid mellom helsepersonell	Ved RH
	Hvordan kan vi samarbeide med lokalt helsepersonell?	Utskrivning Normalt for barnet
Sluttkommentar i fht erfaringer	Er det noe som bør tas opp som ikke er nevnt?	Endringer? noe du savner? Ideer til videre utvikling?

APPENDIX 7

Intervjuguide: lokale sykepleiere

Tema	Spørsmål	Eventuelt stikkord
Introduksjon	Hvilken rolle har du hatt i forhold til behandling og veiledning av familiene?	Runde rundt bordet, profesjon, rolle i app-veiledning og/eller annen behandling/veiledning.
Egen kompetanse i bruk av appen og støtte til bruk av appen	Hvordan har du satt deg inn i og lært å bruke appen?	Kjennskap til HOBS.no? E-læring på hobs.no?
	Hvilke erfaringer har du gjort i veiledningen når foreldrene har all informasjon på sin telefon?	For eksempel forklare hemodynamikk? (Hjertetegning) Behov for hjelpemidler? Sammenligning med tidligere…
Samarbeid	Hvordan har den tverrfaglige kommunikasjonen rundt valg foreldrene skal gjøre i appen foregått?	Avklaringer rundt rett hjertesvikt,cyanose, metningsmåler eller ikke, diagnose, illustrasjon av hjerte?
	Hvilke erfaringer har dere gjort med samarbeid med andre i barnets helseteam rundt appen?	Informasjonsutveksling? kommunikasjon med lokalt helsepersonell? Interesse?
Veiledning og samarbeid om ulike funksjoner.	Hvordan har veiledningssituasjoner oppstått rundt appen?	Hvem tar initiativ?
	Hvordan har dere opplevd å veilede foreldrene i valg under funksjonen «Mitt barn»?	Ubesvarte felter, operasjonstype, Skal barnet ha hjertesviktskriv? Hvordan løses usikkerhet?
	Hvordan har dere opplevd å veilede foreldrene i valg for «normalt for mitt barn»	Ikke nødvendig? Evt Funksjonsområder som respirasjon, sirkulasjon, ernæring, diurese, søvn og tilfredshet
	Hvilke erfaringer har dere med å veilede foreldrene i tegn på forverring?	Sammenlignet med før? Gjøres det? Utrygg eller mer trygg på hva som er rett?
	Hvilke erfaringer har dere med å veilede foreldrene i observasjoner av sår?	Sammenlignet med før?
	Hvilke erfaringer har du med tipsfunksjonen for å forstå hva foreldrene skal se etter ifht forverring?	Eks inndragninger, hudtemperatur
	Hvilke erfaringer har du gjort med bruk av utreisefunksjonen?	Hjem, til annet sykehus? Logisk?
	Hvilke reaksjoner har dere opplevd hos foreldrene under oppholdet/i veiledning/eller ved bruk av appen?	Engasjement, ønsker om å forstå og vite, tekniske spørsmål, usikkerhet, engstelse irritasjon, oppgitthet, tar initiativ? Holder på hele tiden? Uinteressert?
Sluttkommentar	Er det noe som bør tas opp som ikke er nevnt?	Egen oppfatning av bruk av HOBS i oppfølgingen generelt?!
	Er det noe som bør endres eller tilrettelegges bedre?	Brukerstøtte? I HOBS? Samarbeid her og lokalt? Ideer til videre utvikling?

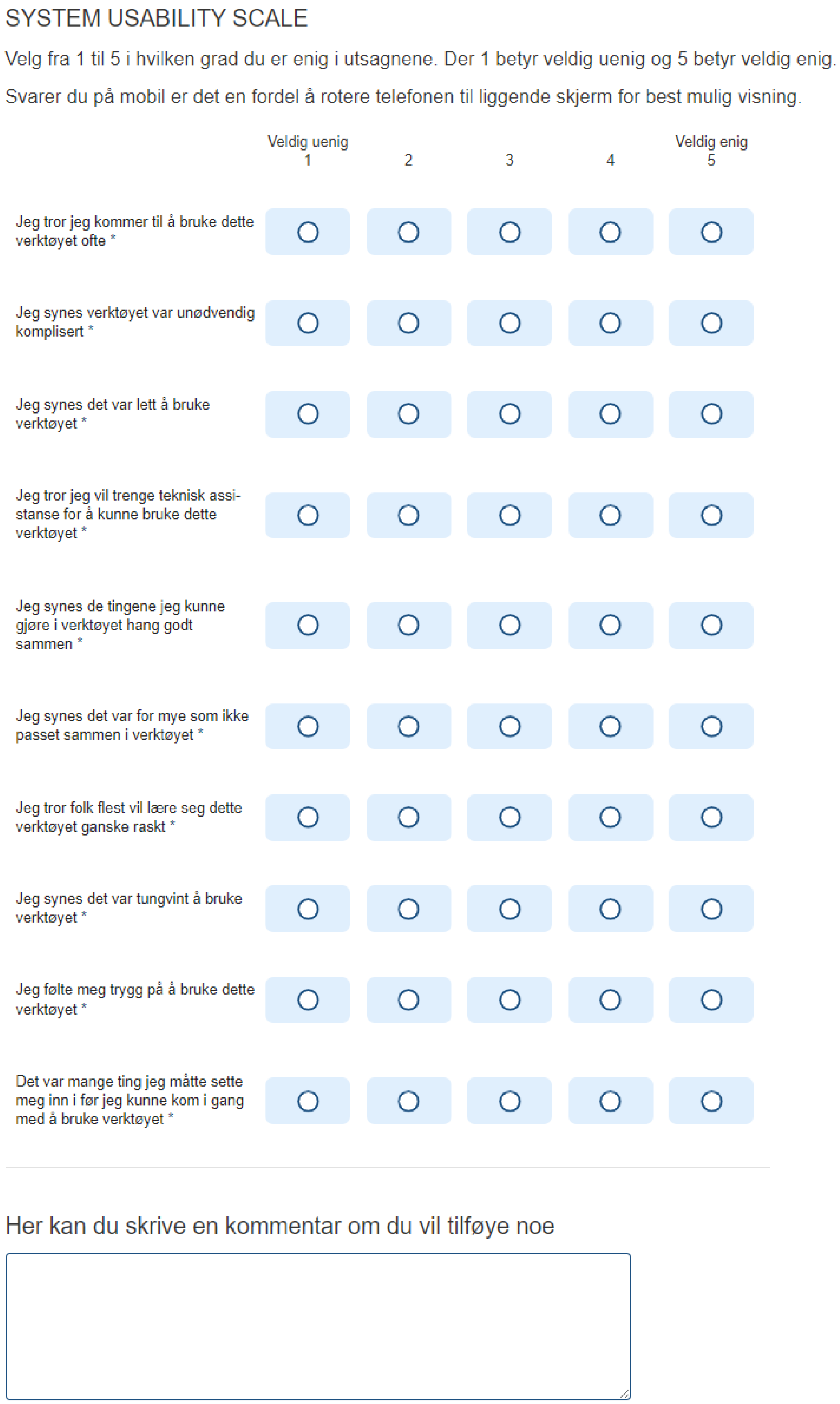
APPENDIX 8

HOBS forskningsprosjekt

Intervjuguide: kardiolog, helsesøster

Tema	Spørsmål	Eventuelle oppfølgingsstikkord
Kartlegging av funksjon og kunnskap om appen	Din stilling/funksjon i fht barnet	
	Hvor mange ganger har du vært i kontakt med foreldrene til (barnet)?	Planlagt og uplanlagt
	Har du kjennskap til/brukt nettsiden om HOBS appen? Gjennomført e-læring?	Hvis ikke→ Har du ideer om hvordan siden kan formidles til lokal helsetjeneste? Hvis ja → tilbakemeldinger på nytte og ønske om mer/annen type informasjon
Veiledning og samarbeid med foreldre i ulike funksjoner i appen	Har foreldrene vist til appen når de har tatt kontakt /ved samtaler under konsultasjoner?	Hvis ja→ Kan du beskrive dette?
	Har du samarbeidet med foreldrene rundt innstillinger og valg i appen?	Hvis ja → Hvilke erfaringer? Vurderinger av barnets tilstand, kontaktinformasjon, valg på medikamentliste, annet?
Signaler på forverring	Har du erfaringer der foreldrene tok kontakt utenfor planen på grunn av forverring eller andre spørsmål?	Hvis ja→ Kan du beskrive dette? Hvordan hadde foreldrene oppdaget at barnets tilstand var forverret? Var appen tatt i bruk?
	Hvis ja→Hvordan var kommunikasjonen rundt forverringen?	Tydelighet, vag eller fokusert, misforståelser, overbeskyttende/engstelse relatert til alvorlighet
Avslutning	Har det vært annerledes å jobbe med familien når de har app?	Hvordan? Sammenlignet med standard care?
	Hva er den totale opplevelsen av å jobbe med foreldre med app som veiledings- og informasjonsstøtte?	
	(Hvordan) tenker du at appen kan brukes fremover i din sammenheng?	
	Er det noe som bør endres eller tilrettelegges bedre?	Eks: Informasjon/veiledning til din arbeidsplass
Sluttkommentar	Er det noe som bør tas opp som ikke er nevnt?	

APPENDIX 9



SYSTEM USABILITY SCALE

Velg fra 1 til 5 i hvilken grad du er enig i utsagnene. Der 1 betyr veldig uenig og 5 betyr veldig enig.

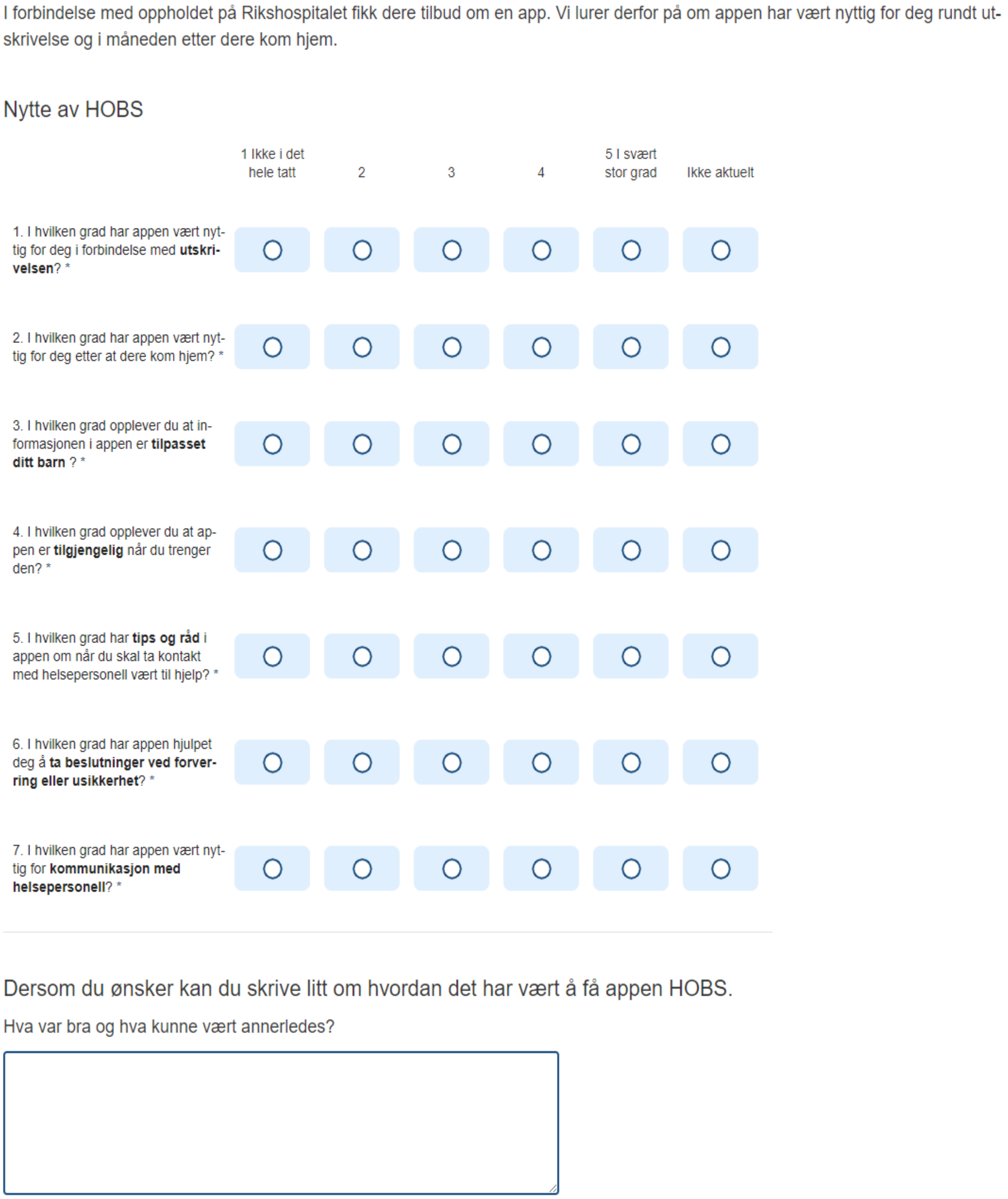
Svarer du på mobil er det en fordel å rotere telefonen til liggende skjerm for best mulig visning.

	Veldig uenig 1	2	3	4	Veldig enig 5
Jeg tror jeg kommer til å bruke dette verktøyet ofte *	○	○	○	○	○
Jeg synes verktøyet var unødvendig komplisert *	○	○	○	○	○
Jeg synes det var lett å bruke verktøyet *	○	○	○	○	○
Jeg tror jeg vil trenge teknisk assistanse for å kunne bruke dette verktøyet *	○	○	○	○	○
Jeg synes de tingene jeg kunne gjøre i verktøyet hang godt sammen *	○	○	○	○	○
Jeg synes det var for mye som ikke passet sammen i verktøyet *	○	○	○	○	○
Jeg tror folk flest vil lære seg dette verktøyet ganske raskt *	○	○	○	○	○
Jeg synes det var tungvint å bruke verktøyet *	○	○	○	○	○
Jeg følte meg trygg på å bruke dette verktøyet *	○	○	○	○	○
Det var mange ting jeg måtte sette meg inn i før jeg kunne kom i gang med å bruke verktøyet *	○	○	○	○	○

Her kan du skrive en kommentar om du vil tilføye noe

APPENDIX 10

Questionnaire about usefulness of interventions



I forbindelse med oppholdet på Rikshospitalet fikk dere tilbud om en app. Vi lurer derfor på om appen har vært nyttig for deg rundt utskrivelse og i måneden etter dere kom hjem.

Nytte av HOBS

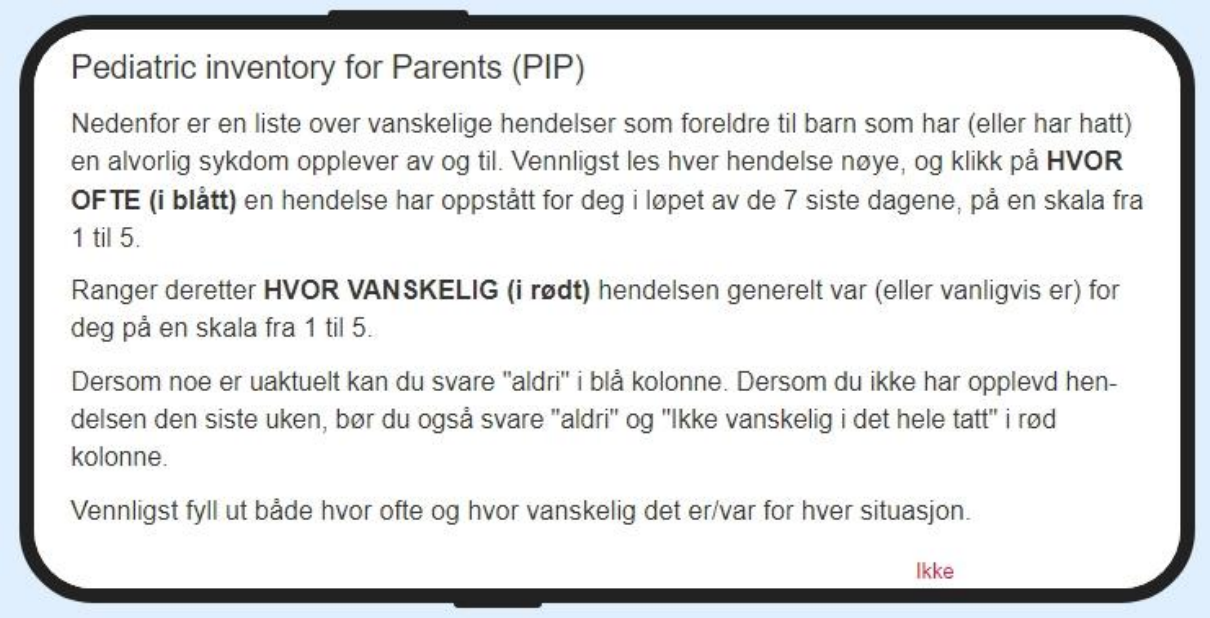
	1 Ikke i det hele tatt	2	3	4	5 I svært stor grad	Ikke aktuelt
1. I hvilken grad har appen vært nyttig for deg i forbindelse med **utskrivelsen**? *	○	○	○	○	○	○
2. I hvilken grad har appen vært nyttig for deg etter at dere kom hjem? *	○	○	○	○	○	○
3. I hvilken grad opplever du at informasjonen i appen er **tilpasset ditt barn** ? *	○	○	○	○	○	○
4. I hvilken grad opplever du at appen er **tilgjengelig** når du trenger den? *	○	○	○	○	○	○
5. I hvilken grad har **tips og råd** i appen om når du skal ta kontakt med helsepersonell vært til hjelp? *	○	○	○	○	○	○
6. I hvilken grad har appen hjulpet deg å **ta beslutninger ved forverring eller usikkerhet**? *	○	○	○	○	○	○
7. I hvilken grad har appen vært nyttig for **kommunikasjon med helsepersonell**? *	○	○	○	○	○	○

Dersom du ønsker kan du skrive litt om hvordan det har vært å få appen HOBS.

Hva var bra og hva kunne vært annerledes?

APPENDIX 11

Introduction in Nettskjema to PIP due to mobile phone layout



Pediatric inventory for Parents (PIP)

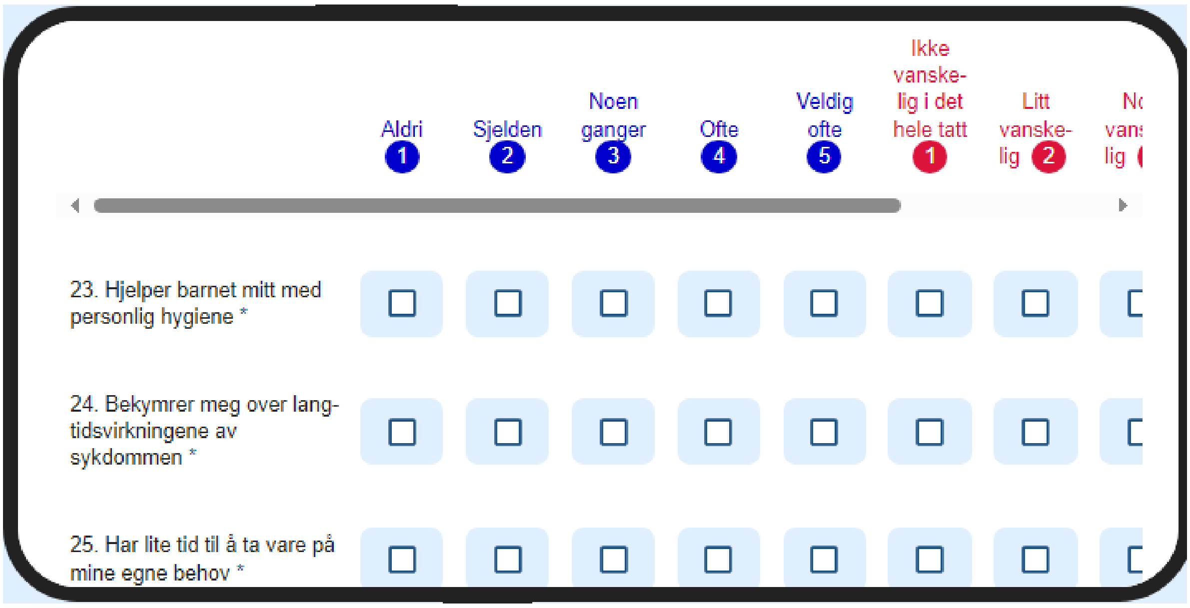
Nedenfor er en liste over vanskelige hendelser som foreldre til barn som har (eller har hatt) en alvorlig sykdom opplever av og til. Vennligst les hver hendelse nøye, og klikk på **HVOR OFTE (i blått)** en hendelse har oppstått for deg i løpet av de 7 siste dagene, på en skala fra 1 til 5.

Ranger deretter **HVOR VANSKELIG (i rødt)** hendelsen generelt var (eller vanligvis er) for deg på en skala fra 1 til 5.

Dersom noe er uaktuelt kan du svare "aldri" i blå kolonne. Dersom du ikke har opplevd hendelsen den siste uken, bør du også svare "aldri" og "Ikke vanskelig i det hele tatt" i rød kolonne.

Vennligst fyll ut både hvor ofte og hvor vanskelig det er/var for hver situasjon.

Layout of PIP at mobile phone screens



	Aldri 1	Sjelden 2	Noen ganger 3	Ofte 4	Veldig ofte 5	Ikke vanskelig i det hele tatt 1	Litt vanskelig 2	N vans lig
23. Hjelper barnet mitt med personlig hygiene *	☐	☐	☐	☐	☐	☐	☐	☐
24. Bekymrer meg over langtidsvirkningene av sykdommen *	☐	☐	☐	☐	☐	☐	☐	☐
25. Har lite tid til å ta vare på mine egne behov *	☐	☐	☐	☐	☐	☐	☐	☐

Blue color=frequency subscale, Red color = difficulty sub scale, Slide bar in grey enables scrolling across the form.

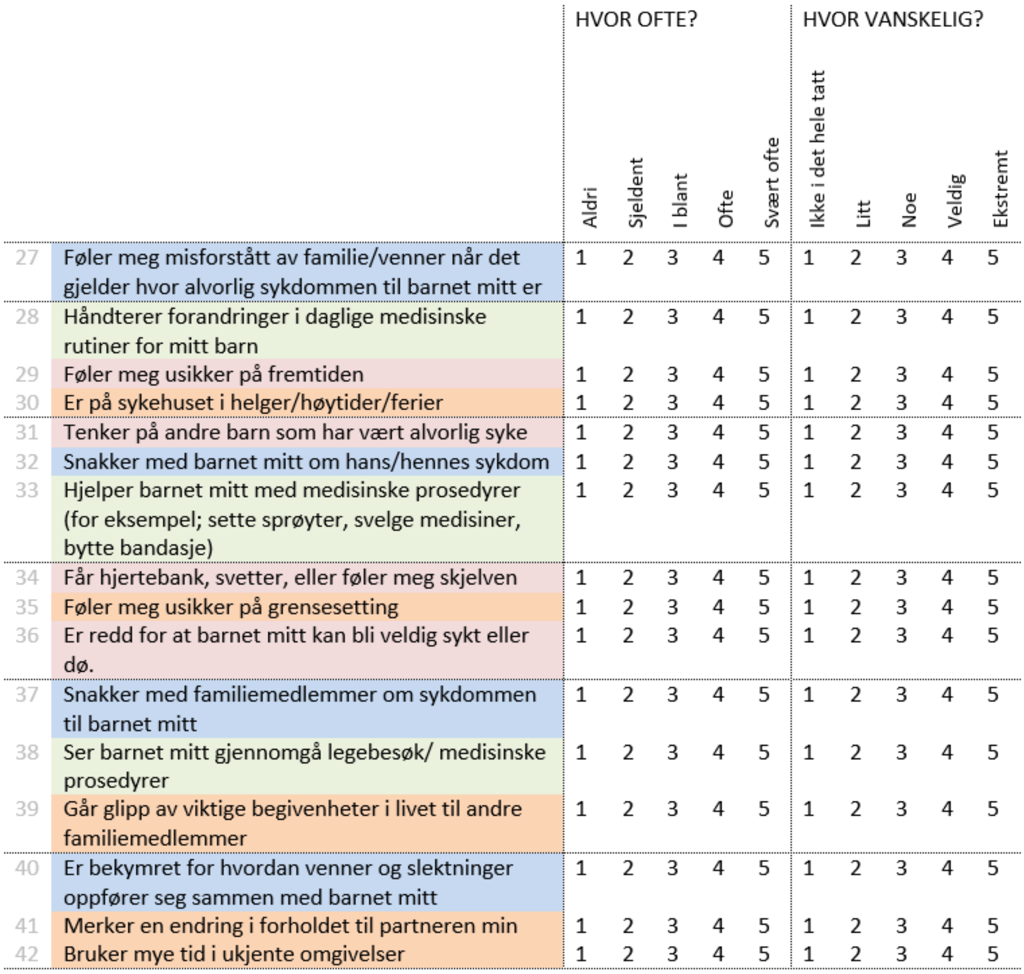
The Pediatric inventory for Parents original layout and overview of the 42 items

The Pediatric Inventory for parents (PIP)

Opprinnelig utviklet av Dr Randi Streisand, RSTREIS@childrensnational.org Streisand, R., Braniecki, S., Tercyak, K. P., & Kazak, A. E. (2001). Childhood illness-related parenting stress: The pediatric inventory for parents. *Journal of Pediatric Psychology*, 26(3), 155-162.
Norsk oversettelse av Elin Hjorth-Johansen i samarbeid med en prosjektgruppe.

Nedenfor er en liste over vanskelige hendelser som foreldre til barn som har (eller har hatt) en alvorlig sykdom opplever av og til. Vennligst les hver hendelse nøye, og sett ring rundt **HVOR OFTE** en hendelse har oppstått for deg i løpet av de 7 siste dagene, på en skala fra 1 til 5.
Ranger deretter **HVOR VANSKELIG** hendelsen generelt var, eller vanligvis er for deg på en skala fra 1 til 5.
Dersom noe er uaktuelt kan du svare «aldri» i første kolonne. Dersom du ikke har opplevd hendelsen den siste uken, bør du svare «aldri» og «ikke vanskelig i det hele tatt» i kolonne to.
Vennligst fyll ut både hvor ofte og hvor vanskelig det er/var for hver situasjon.

		HVOR OFTE?					*HVOR VANSKELIG?*				
		Aldri	Sjeldent	I blant	Ofte	Svært ofte	Ikke i det hele tatt	Litt	Noe	Veldig	Ekstremt
1	Har problemer med å sove	1	2	3	4	5	1	2	3	4	5
2	Krangler med familiemedlemmer	1	2	3	4	5	1	2	3	4	5
3	Tar med barnet mitt til lege eller sykehus	1	2	3	4	5	1	2	3	4	5
4	Mottar informasjon som opprører meg	1	2	3	4	5	1	2	3	4	5
5	Kan ikke gå på jobb/jobbe	1	2	3	4	5	1	2	3	4	5
6	Ser humøret til barnet mitt endre seg raskt	1	2	3	4	5	1	2	3	4	5
7	Har samtale med lege	1	2	3	4	5	1	2	3	4	5
8	Ser at barnet mitt har problemer med å spise	1	2	3	4	5	1	2	3	4	5
9	Venter på prøvesvar til barnet mitt	1	2	3	4	5	1	2	3	4	5
10	Har økonomiske problemer	1	2	3	4	5	1	2	3	4	5
11	Prøver å ikke tenke på min families vanskeligheter	1	2	3	4	5	1	2	3	4	5
12	Føler meg forvirret av medisinsk informasjon	1	2	3	4	5	1	2	3	4	5
13	Er sammen med barnet mitt under medisinsk behandling/undersøkelser	1	2	3	4	5	1	2	3	4	5
14	Vet at barnet mitt har vondt eller smerter	1	2	3	4	5	1	2	3	4	5
15	Prøver å ta hånd om andre familiemedlemmers behov	1	2	3	4	5	1	2	3	4	5
16	Ser at barnet mitt er trist eller redd	1	2	3	4	5	1	2	3	4	5
17	Snakker med sykepleieren	1	2	3	4	5	1	2	3	4	5
18	Tar beslutninger om medisinsk behandling eller medisiner	1	2	3	4	5	1	2	3	4	5
19	Tenker på at barnet mitt er isolert fra andre	1	2	3	4	5	1	2	3	4	5
20	Er langt unna familie og/eller venner	1	2	3	4	5	1	2	3	4	5
21	Føler meg nummen innvendig	1	2	3	4	5	1	2	3	4	5
22	Er uenig med helsepersonell som har ansvar for barnet mitt	1	2	3	4	5	1	2	3	4	5
23	Hjelper barnet mitt med personlig hygiene	1	2	3	4	5	1	2	3	4	5
24	Bekymrer meg over langtidsvirkningene av sykdommen	1	2	3	4	5	1	2	3	4	5
25	Har lite tid til å ta vare på mine egne behov	1	2	3	4	5	1	2	3	4	5
26	Føler meg hjelpeløs når det gjelder tilstanden til barnet mitt	1	2	3	4	5	1	2	3	4	5



		HVOR OFTE?					HVOR VANSKELIG?				
		Aldri	Sjeldent	I blant	Ofte	Svært ofte	Ikke i det hele tatt	Litt	Noe	Veldig	Ekstremt
27	Føler meg misforstått av familie/venner når det gjelder hvor alvorlig sykdommen til barnet mitt er	1	2	3	4	5	1	2	3	4	5
28	Håndterer forandringer i daglige medisinske rutiner for mitt barn	1	2	3	4	5	1	2	3	4	5
29	Føler meg usikker på fremtiden	1	2	3	4	5	1	2	3	4	5
30	Er på sykehuset i helger/høytider/ferier	1	2	3	4	5	1	2	3	4	5
31	Tenker på andre barn som har vært alvorlig syke	1	2	3	4	5	1	2	3	4	5
32	Snakker med barnet mitt om hans/hennes sykdom	1	2	3	4	5	1	2	3	4	5
33	Hjelper barnet mitt med medisinske prosedyrer (for eksempel; sette sprøyter, svelge medisiner, bytte bandasje)	1	2	3	4	5	1	2	3	4	5
34	Får hjertebank, svetter, eller føler meg skjelven	1	2	3	4	5	1	2	3	4	5
35	Føler meg usikker på grensesetting	1	2	3	4	5	1	2	3	4	5
36	Er redd for at barnet mitt kan bli veldig sykt eller dø.	1	2	3	4	5	1	2	3	4	5
37	Snakker med familiemedlemmer om sykdommen til barnet mitt	1	2	3	4	5	1	2	3	4	5
38	Ser barnet mitt gjennomgå legebesøk/ medisinske prosedyrer	1	2	3	4	5	1	2	3	4	5
39	Går glipp av viktige begivenheter i livet til andre familiemedlemmer	1	2	3	4	5	1	2	3	4	5
40	Er bekymret for hvordan venner og slektninger oppfører seg sammen med barnet mitt	1	2	3	4	5	1	2	3	4	5
41	Merker en endring i forholdet til partneren min	1	2	3	4	5	1	2	3	4	5
42	Bruker mye tid i ukjente omgivelser	1	2	3	4	5	1	2	3	4	5

Color codes: Blue = Communication, Pink = Emotional function, Green = Medical Care, Orange= Role function

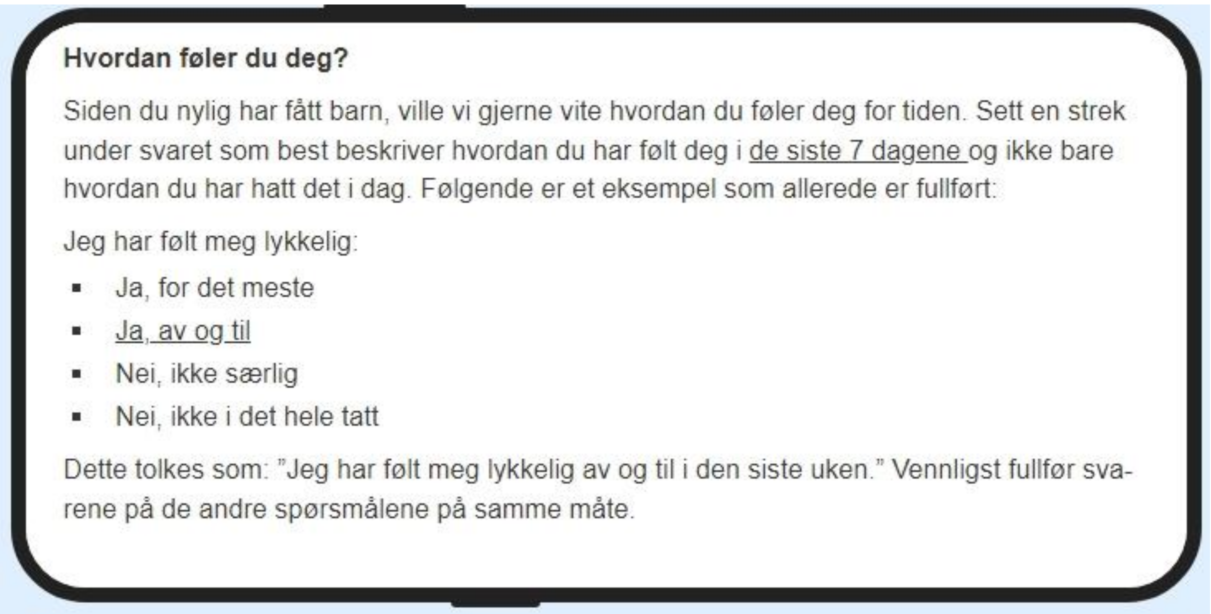
Measurement properties of the Pediatric inventory for Parents in the HOBS study

Measurement properties	Statistical analysis	Statistical results	conclusion
Reliability (internal consistency)	Cronbach's alpha (α)	PIP-D total: α =.95/.95/.96. In PIP-D sub domains α was between 0.70-0.93 at all time-points PIP-F total: α =.91/.93/.94. In PIP-F sub domains α between 0.70-0.84 except during admission (communication α = 0.56 and medical care α= 0.63)	Good scale reliability in PIP-D and PIP-F, but moderate scale reliability in PIP-F during hospitalization.
	Test-retest with paired t-test between PIP-F and PIP-D at one and four months	PIP-F total: 1 month: P = .357 mean difference = 2.9 points PIP-D total: p =.879. Mean difference 0.5	Good reliability
Concurrent validity	Interscale correlations: Pearsons` correlation between PIP-F and PIP-D	r =.88, p <.001	Good concurrent validity
	Construct validity: Pearsons` correlation between PIP-D and EPDS	Differences between PIP at 1 and 4 months correlated highly with differences between EPDS at 1 and 4 months: r. =81, p.<001	Good construct validity
Discriminant validity	T-test between CT and sustained CI during admission, one month and four month after discharge.	PIP-D total: Mean in CT and CI: during admission 94.6/109.9 (P = .034), after 1 month; 67.2/89.9 (p=.006) and after 4 months; 63.3/94.8 (p<.001)	Good discriminant validity

PIP-F total= pediatric Inventory for Parents frequency scale, PIP-D total= pediatric Inventory for Parents difficulty scale, EPDS = Edinburgh Postnatal Depression Score, CT = completed treatment, CI = Cardiac impairment

APPENDIX 12

Overview of layout and questions in EPDS (Norwegian version by…)



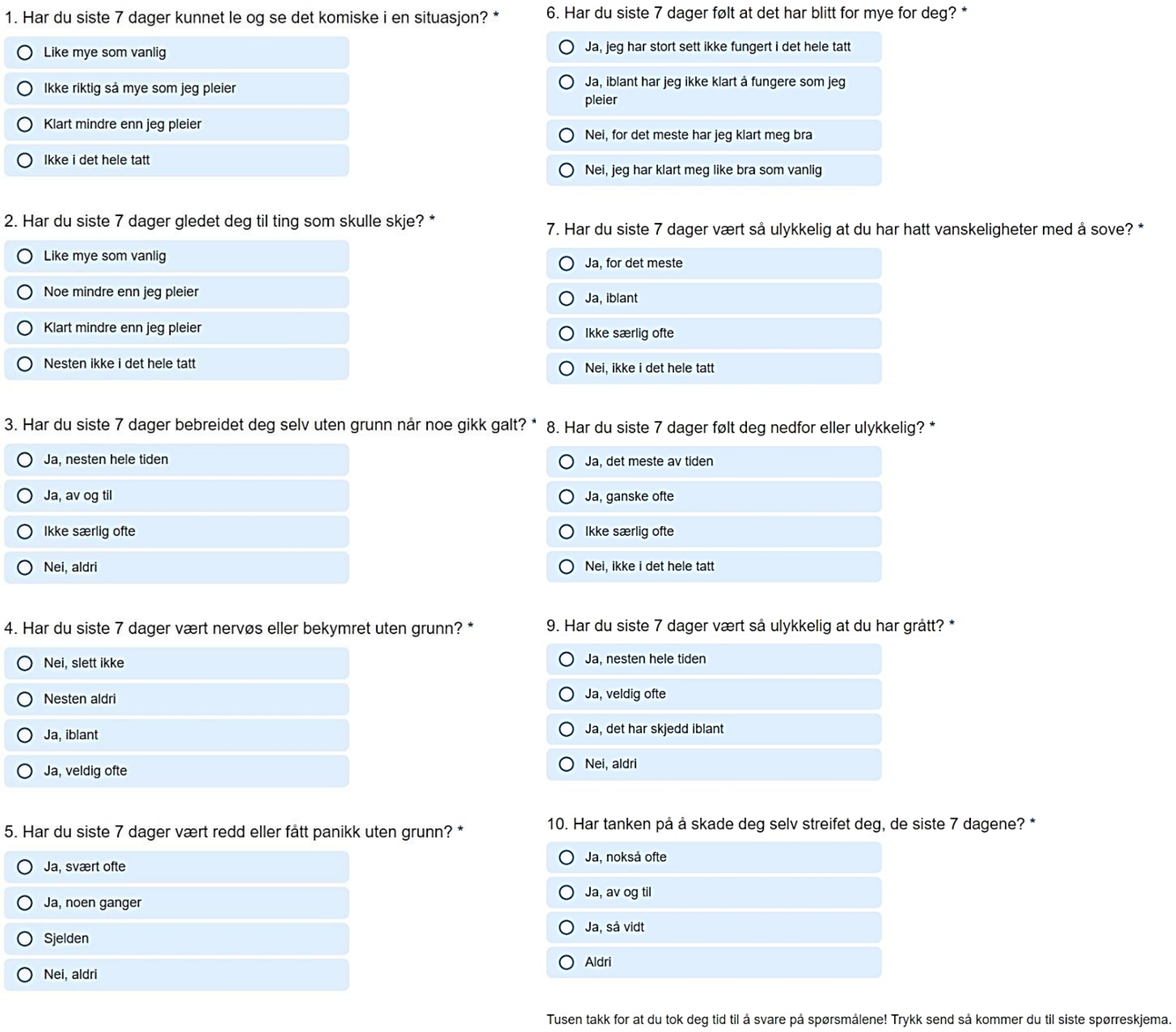
Hvordan føler du deg?

Siden du nylig har fått barn, ville vi gjerne vite hvordan du føler deg for tiden. Sett en strek under svaret som best beskriver hvordan du har følt deg i de siste 7 dagene og ikke bare hvordan du har hatt det i dag. Følgende er et eksempel som allerede er fullført:

Jeg har følt meg lykkelig:

- Ja, for det meste
- [✓ Ja, av og til]
- Nei, ikke særlig
- Nei, ikke i det hele tatt

Dette tolkes som: ”Jeg har følt meg lykkelig av og til i den siste uken.” Vennligst fullfør svarene på de andre spørsmålene på samme måte.



1. Har du siste 7 dager kunnet le og se det komiske i en situasjon? *

○ Like mye som vanlig
○ Ikke riktig så mye som jeg pleier
○ Klart mindre enn jeg pleier
○ Ikke i det hele tatt

2. Har du siste 7 dager gledet deg til ting som skulle skje? *

○ Like mye som vanlig
○ Noe mindre enn jeg pleier
○ Klart mindre enn jeg pleier
○ Nesten ikke i det hele tatt

3. Har du siste 7 dager bebreidet deg selv uten grunn når noe gikk galt? *

○ Ja, nesten hele tiden
○ Ja, av og til
○ Ikke særlig ofte
○ Nei, aldri

4. Har du siste 7 dager vært nervøs eller bekymret uten grunn? *

○ Nei, slett ikke
○ Nesten aldri
○ Ja, iblant
○ Ja, veldig ofte

5. Har du siste 7 dager vært redd eller fått panikk uten grunn? *

○ Ja, svært ofte
○ Ja, noen ganger
○ Sjelden
○ Nei, aldri

6. Har du siste 7 dager følt at det har blitt for mye for deg? *

○ Ja, jeg har stort sett ikke fungert i det hele tatt
○ Ja, iblant har jeg ikke klart å fungere som jeg pleier
○ Nei, for det meste har jeg klart meg bra
○ Nei, jeg har klart meg like bra som vanlig

7. Har du siste 7 dager vært så ulykkelig at du har hatt vanskeligheter med å sove? *

○ Ja, for det meste
○ Ja, iblant
○ Ikke særlig ofte
○ Nei, ikke i det hele tatt

8. Har du siste 7 dager følt deg nedfor eller ulykkelig? *

○ Ja, det meste av tiden
○ Ja, ganske ofte
○ Ikke særlig ofte
○ Nei, ikke i det hele tatt

9. Har du siste 7 dager vært så ulykkelig at du har grått? *

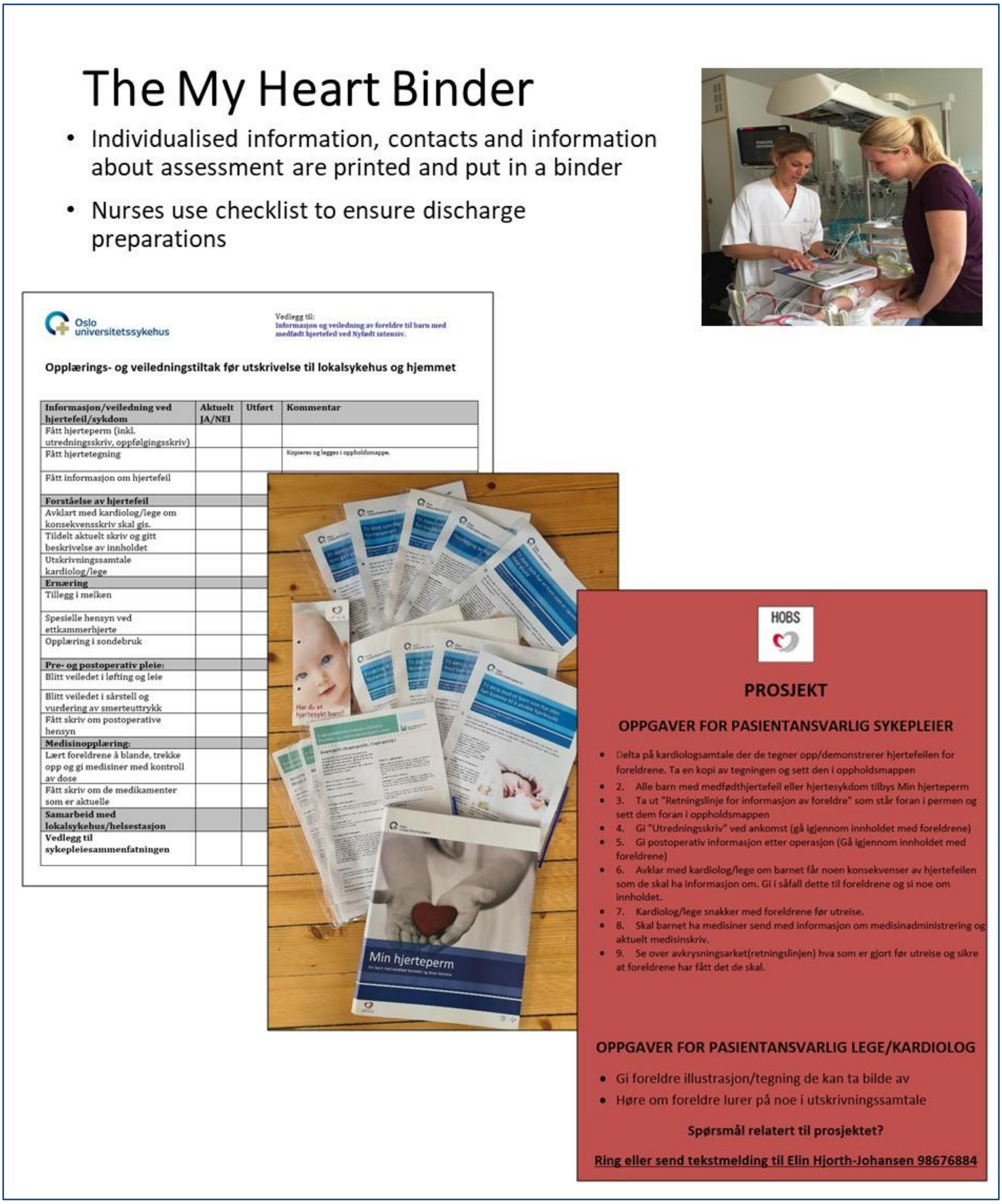
○ Ja, nesten hele tiden
○ Ja, veldig ofte
○ Ja, det har skjedd iblant
○ Nei, aldri

10. Har tanken på å skade deg selv streifet deg, de siste 7 dagene? *

○ Ja, nokså ofte
○ Ja, av og til
○ Ja, så vidt
○ Aldri

Tusen takk for at du tok deg tid til å svare på spørsmålene! Trykk send så kommer du til siste spørreskjema.

APPENDIX 13



The My Heart Binder

- Individualised information, contacts and information about assessment are printed and put in a binder
- Nurses use checklist to ensure discharge preparations

Oslo universitetssykehus

Vedlegg til:
Informasjon og veiledning av foreldre til barn med medfødt hjertefeil ved Nyfødt intensiv.

Opplærings- og veiledningstiltak før utskrivelse til lokalsykehus og hjemmet

Informasjon/veiledning ved hjertefeil/sykdom	**Aktuelt JA/NEI**	**Utført**	**Kommentar**
Fått hjerteperm (inkl. utredningsskriv, oppfølgingsskriv)			
Fått hjertetegning			Kopieres og legges i oppholdsmappe.
Fått informasjon om hjertefeil			
Forståelse av hjertefeil			
Avklart med kardiolog/lege om konsekvensskriv skal gis.			
Tildelt aktuelt skriv og gitt beskrivelse av innholdet			
Utskrivningssamtale kardiolog/lege			
Ernæring			
Tillegg i melken			
Spesielle hensyn ved ettkammerhjerte			
Opplæring i sondebruk			
Pre- og postoperativ pleie:			
Blitt veiledet i løfting og leie			
Blitt veiledet i sårstell og vurdering av smerteuttrykk			
Fått skriv om postoperative hensyn			
Medisinopplæring:			
Lært foreldrene å blande, trekke opp og gi medisiner med kontroll av dose			
Fått skriv om de medikamenter som er aktuelle			
Samarbeid med lokalsykehus/helsestasjon			
Vedlegg til sykepleiesammenfatningen			

HOBS

PROSJEKT

OPPGAVER FOR PASIENTANSVARLIG SYKEPLEIER

- Delta på kardiologsamtale der de tegner opp/demonstrerer hjertefeilen for foreldrene. Ta en kopi av tegningen og sett den i oppholdsmappen
- 2. Alle barn med medfødthjertefeil eller hjertesykdom tilbys Min hjerteperm
- 3. Ta ut "Retningslinje for informasjon av foreldre" som står foran i permen og sett dem foran i oppholdsmappen
- 4. Gi "Utredningsskriv" ved ankomst (gå igjennom innholdet med foreldrene)
- 5. Gi postoperativ informasjon etter operasjon (Gå igjennom innholdet med foreldrene)
- 6. Avklar med kardiolog/lege om barnet får noen konsekvenser av hjertefeilen som de skal ha informasjon om. Gi i såfall dette til foreldrene og si noe om innholdet.
- 7. Kardiolog/lege snakker med foreldrene før utreise.
- 8. Skal barnet ha medisiner send med informasjon om medisinadministrering og aktuelt medisinskriv.
- 9. Se over avkrysningsarket(retningslinjen) hva som er gjort før utreise og sikre at foreldrene har fått det de skal.

OPPGAVER FOR PASIENTANSVARLIG LEGE/KARDIOLOG

- Gi foreldre illustrasjon/tegning de kan ta bilde av
- Høre om foreldre lurer på noe i utskrivningssamtale

Spørsmål relatert til prosjektet?

Ring eller send tekstmelding til Elin Hjorth-Johansen 98676884

APPENDIX 14

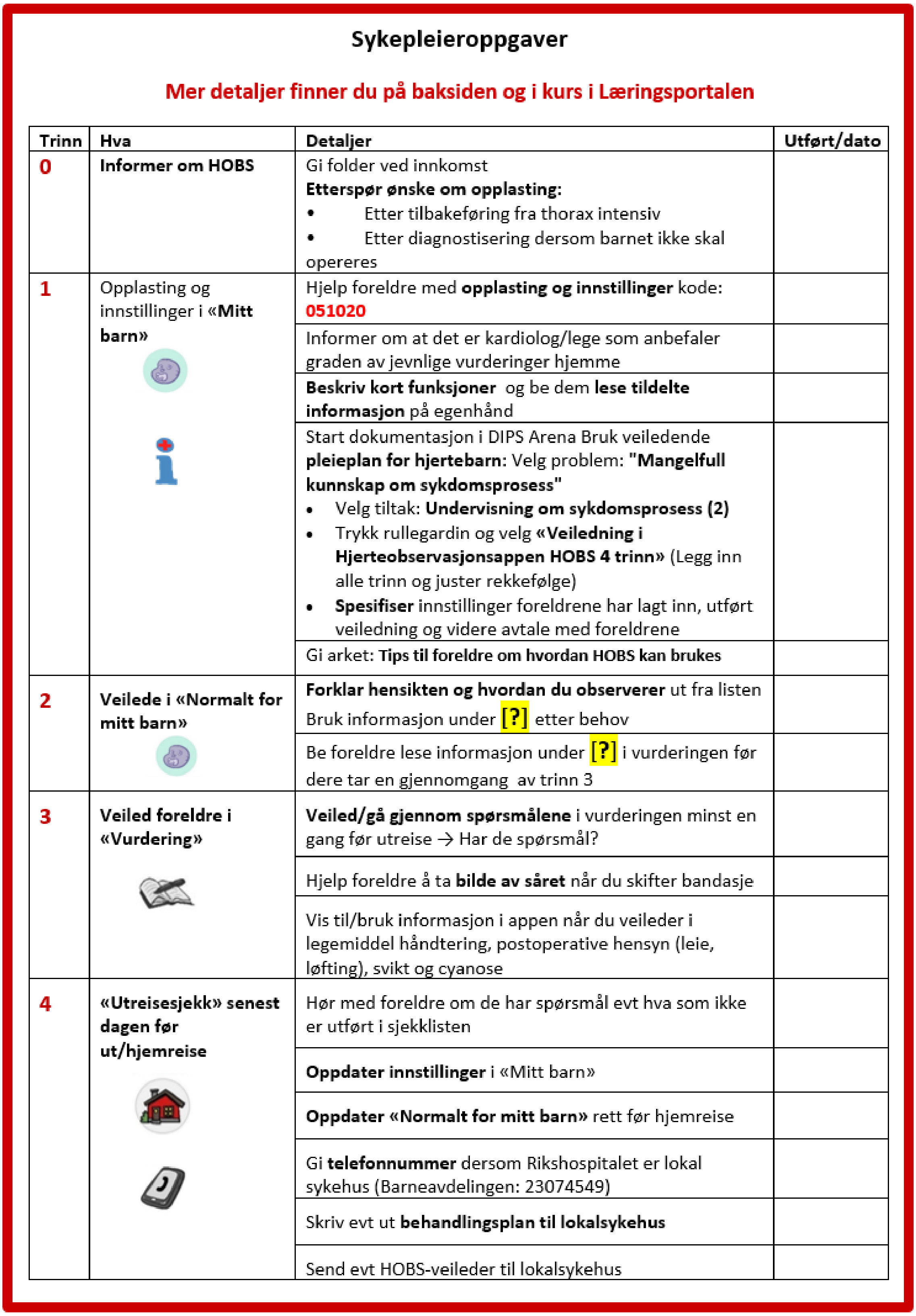
Tips til foreldre om hvordan HOBS kan brukes (Aktiveringskode til HOBS: 051020)

Når:	**Hva:**	**Detaljer**	**Hvor finner jeg dette?**
På syke-hus	Gjør innstillinger i **«Mitt barn»**	o Få hjelp av helsepersonell til riktige innstillinger o Sjekk før utreise fra Rikshospitalet og lokalsykehus	👶
	Gjør innstillinger i **«Normalt for mitt barn»** på Rikshospitalet	o Få veiledning av helsepersonell hvordan du kan observere barnet ditt og velg den normalsettingen som passer best o Rediger eventuelt siste gang rett før hjemreise o Eks: skal dere bruke utstyr/medisiner hjemme?	👶
	Gjør en **vurdering** («Generell tilstand») sammen med sykepleier minst en gang før utreise fra Rikshospitalet	o Les informasjonen under **spørsmålstegnene** o Spør om ting du ikke forstår o Ta gjerne bilde av **såret** før utreise o Noter **målinger** (f.eks. vekt og pustefrekvens) dersom du skal følge med på dette.	? 📖
	Les tildelt **informasjon** i Informasjonsdelen	o Bruk eventuelt link til pasientjournal	ℹ
	Legg inn **telefonnummer** som du får av lokalt sykehus/helsestasjon etc.	o Gjør at du vet hvem du skal kontakte om hva o Gjør at du kan ringe rett fra appen!	📱
	Gjør **utreisesjekk** sammen med helsepersonell	o Før utreise fra Rikshospitalet o Før hjemreise	🏠

Hjemme	Vurderinger:
	o Det kan være en fordel å bli godt kjent med appen, men det er vanligvis ikke nødvendig å gjøre jevnlige vurderinger hjemme. Avtal derfor med kardiolog/koordinator om dere bør fortsette med dette (for eksempel ukentlig)
	o For øvrig er det en fordel å gjøre vurdering:
	  o Ved usikkerhet
	  o Før polikliniske kontroller eller innleggelser
	o **Les tips for tolkning under spørsmålstegnene** i vurderingsdelen, men ikke vær redd for å ta kontakt med helsepersonell når du er usikker!
			📖
			?

Ved kontroller	o Diskuter eventuelt resultat av vurderinger med helsepersonell/ kardiolog o Vis eventuelt kurver og målinger ved polikliniske besøk o Juster eventuelt hva som er normalt for barnet		↩
Spørsmål?	o **Ta kontakt med Foreningen for hjertesyke barn** ffhb@ffhb.no o **Ta kontakt med behandler om barnets helse!**		Mer info på nettsiden: www.hobs.no

APPENDIX 15



Sykepleieroppgaver

Mer detaljer finner du på baksiden og i kurs i Læringsportalen

Trinn	Hva	Detaljer	Utført/dato
0	**Informer om HOBS**	Gi folder ved innkomst **Etterspør ønske om opplasting:** • Etter tilbakeføring fra thorax intensiv • Etter diagnostisering dersom barnet ikke skal opereres	
1	Opplasting og innstillinger i «**Mitt barn»**	Hjelp foreldre med **opplasting og innstillinger** kode: **051020**	
		Informer om at det er kardiolog/lege som anbefaler graden av jevnlige vurderinger hjemme	
		Beskriv kort funksjoner og be dem **lese tildelte informasjon** på egenhånd	
		Start dokumentasjon i DIPS Arena Bruk veiledende **pleieplan for hjertebarn**: Velg problem: **"Mangelfull kunnskap om sykdomsprosess"** • Velg tiltak: **Undervisning om sykdomsprosess (2)** • Trykk rullegardin og velg **«Veiledning i Hjerteobservasjonsappen HOBS 4 trinn»** (Legg inn alle trinn og juster rekkefølge) • **Spesifiser** innstillinger foreldrene har lagt inn, utført veiledning og videre avtale med foreldrene	
		Gi arket: **Tips til foreldre om hvordan HOBS kan brukes**	
2	**Veilede i «Normalt for mitt barn»**	**Forklar hensikten og hvordan du observerer** ut fra listen Bruk informasjon under **[?]** etter behov	
		Be foreldre lese informasjon under **[?]** i vurderingen før dere tar en gjennomgang av trinn 3	
3	**Veiled foreldre i «Vurdering»**	**Veiled/gå gjennom spørsmålene** i vurderingen minst en gang før utreise → Har de spørsmål?	
		Hjelp foreldre å ta **bilde av såret** når du skifter bandasje	
		Vis til/bruk informasjon i appen når du veileder i legemiddel håndtering, postoperative hensyn (leie, løfting), svikt og cyanose	
4	**«Utreisesjekk» senest dagen før ut/hjemreise**	Hør med foreldre om de har spørsmål evt hva som ikke er utført i sjekklisten	
		Oppdater innstillinger i «Mitt barn»	
		Oppdater «Normalt for mitt barn» rett før hjemreise	
		Gi **telefonnummer** dersom Rikshospitalet er lokal sykehus (Barneavdelingen: 23074549)	
		Skriv evt ut **behandlingsplan til lokalsykehus**	
		Send evt HOBS-veileder til lokalsykehus	