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

Elin Hjorth-Johansen[1,2] | Elin Børøsund[3] | Anne Moen[4] | Ingeborg Martinsen Østen[1] | Gunnar Wik[5] | Anne Lee Solevåg[1] | Siw Helen Westby Eger[1] | Henrik Holmstrøm[2,6]

[1]Department of Neonatal Intensive Care, Oslo University Hospital, Oslo, Norway
[2]Institute of Clinical Medicine, University of Oslo, Oslo, Norway
[3]Department of Digital Health Research, Division of Medicine, Oslo University Hospital, Oslo, Norway
[4]Institute of Health and Society, Division of Medicine, University of Oslo, Oslo, Norway
[5]Department of Paediatric and Adolescent Medicine, Sorlandet Hospital, Kristiansand, Norway
[6]Department of Paediatric Cardiology, Oslo University Hospital, Oslo, Norway

Correspondence
Elin Hjorth-Johansen, Department of Neonatal Intensive Care, Oslo University Hospital and University of Oslo, Norway.
Email: ehjorth@ous-hf.no

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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

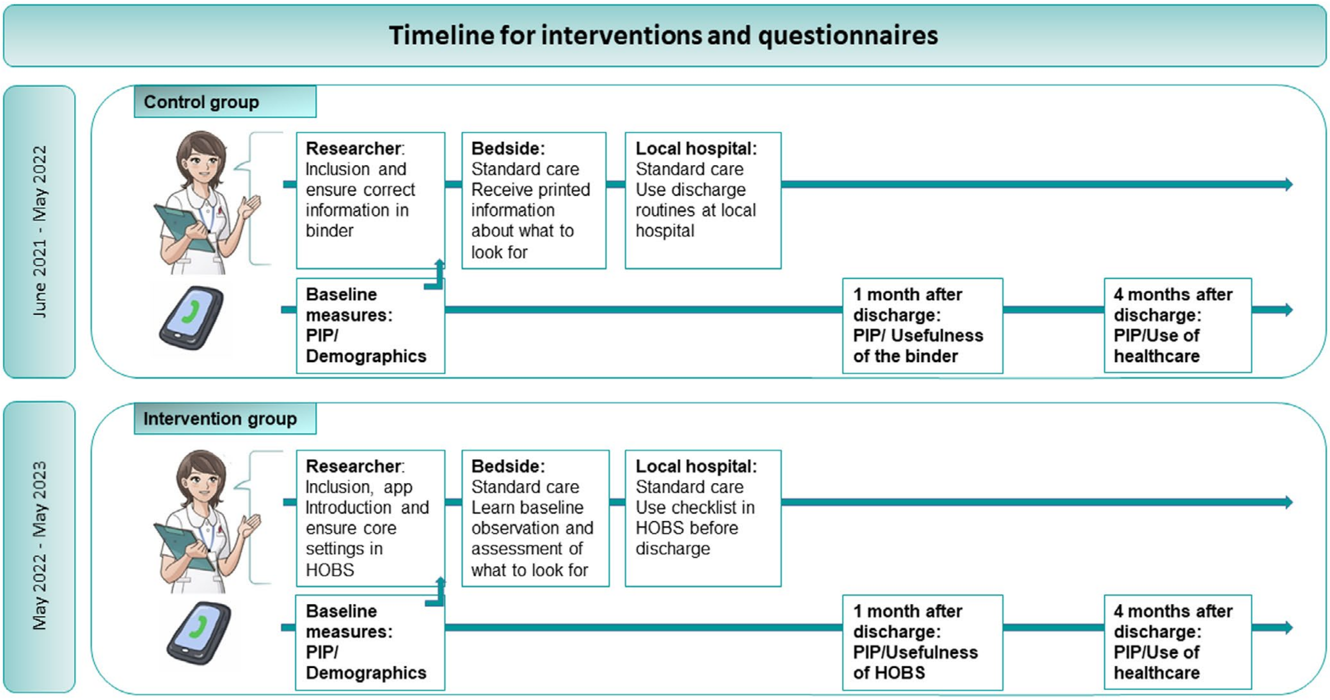
- We compared how useful mothers found traditional printed information or the Heart Observation (HOBS) mobile phone app when their children had severe congenital heart disease.
- Mothers found the HOBS app significantly more useful for discharge preparations, follow up at home and ongoing decisions than 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 postoperative 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

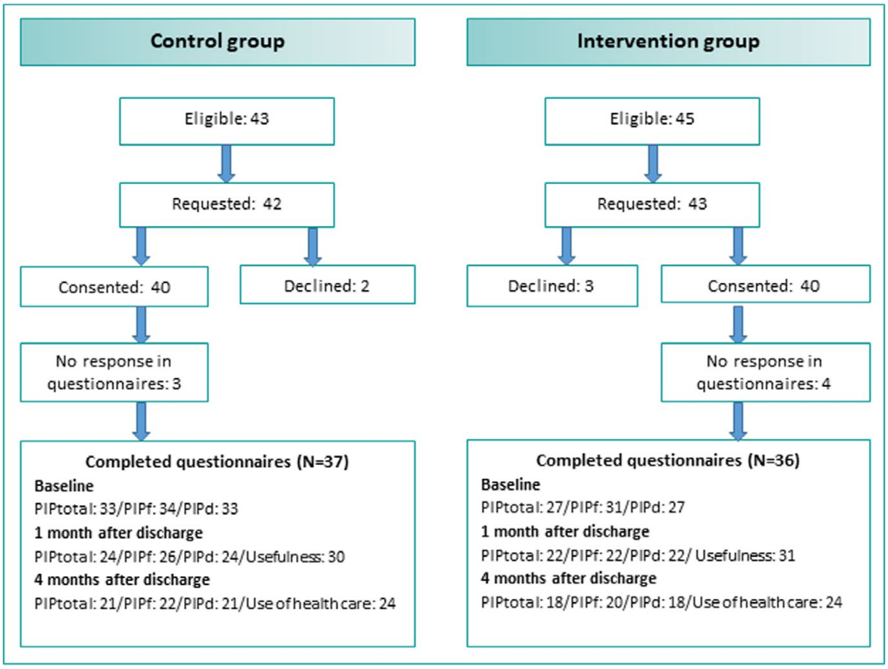
The family's demographic information were registered at inclusion. This included the parents' age, marital status and education and how many siblings their child had. The specialist nurse (EHJ) collected the child's detailed medical information from the electronic patient records. Then she, and a cardiologist (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.

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



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

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

(Continues)

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.

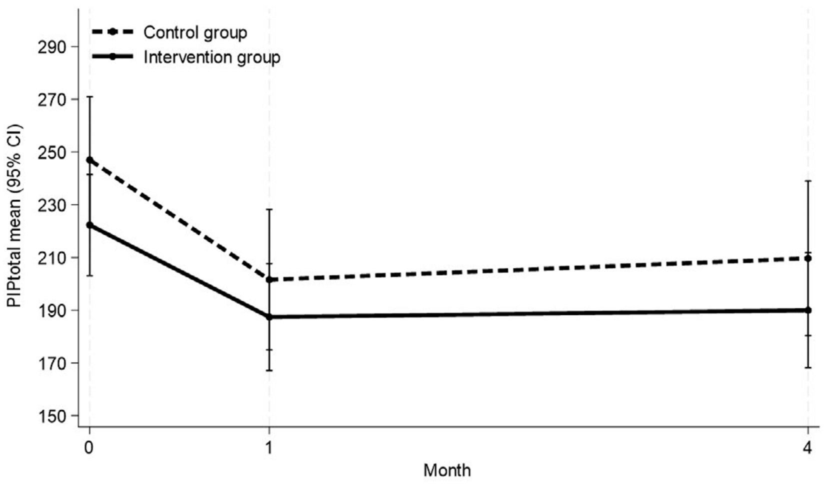
The mothers of infants with sustained cardiac impairment needed more information after discharge, more preparations before discharge and more information about symptoms to be aware of and observe. This was reflected in the higher usefulness scores from the mothers in both groups and the fact that they 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.

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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.

ORCID

Elin Hjorth-Johansen https://orcid.org/0000-0001-6808-8158
Henrik Holmstrøm https://orcid.org/0000-0003-4745-5267

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 post-operative 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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