

User-Centered Development of HEARTPrep, a Digital Health Psychosocial Intervention for Prenatally Diagnosed Congenital Heart Disease

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Abstract

User-centered models for the development of digital health interventions are not consistently applied in healthcare settings. This study used a five-phase, user-centered approach to develop HEARTPrep[®], a psychosocial intervention delivered via mobile app and telehealth to mothers expecting a baby with congenital heart disease (CHD) to promote maternal, family, and child well-being. Phases of intervention development were: (I) establishing partnerships; (II) creating content; (III) developing prototype and testable intervention; (IV) conducting think-aloud testing; and (V) completing beta testing. Partnerships with parents, clinicians, and design/technology experts were integral throughout the development of HEARTPrep[®]. Parents of children with CHD also served as participants in Phases II-V, contributing to the creation of content and providing feedback to inform the iterative refinement of HEARTPrep[®]. These five phases produced a refined digital health intervention with promising feasibility, usability, and acceptability results. This user-centered approach can be used to develop digital health interventions targeting various health outcomes.

Keywords

cardiovascular disease, caregiving, pediatrics, technology, telehealth, behavioral health, mobile experience applications

Introduction

Digital healthcare, including telehealth and mobile health, can reduce barriers to healthcare access and enhance healthcare delivery.^{1,2} Digital health interventions have demonstrated efficacy in improving a variety of health outcomes, including disease management, cardiovascular health, and mental health.³⁻⁵ Development of digital health interventions should include patient and clinician engagement and user testing to ensure the resulting intervention is feasible, usable, and acceptable.⁶ User-centered models that focus on the needs of users (eg, patients) in each phase of intervention development have been published,⁶⁻¹⁰ but these methods are not consistently applied in healthcare settings.⁶ Partnerships with design and technology experts are also essential.¹¹

This study used a five-phase, user-centered approach to develop HEARTPrep[®], a psychosocial intervention delivered

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via mobile app and telehealth to mothers expecting a baby with congenital heart disease (CHD). CHD is the most common birth defect, involving one or more problems with the structure of the heart and often necessitating early cardiac surgery.¹² CHD increasingly is diagnosed prenatally and can lead to substantial psychological distress for expectant mothers.¹³ HEARTPrep[®] aims to reduce distress and social isolation and increase self-efficacy and hope for expectant mothers following prenatal diagnosis of CHD to promote maternal, family, and child well-being. Parents and clinicians from eight health systems previously contributed to the design of HEARTPrep[®] and indicated that it should be delivered via mobile app and telehealth to ensure accessibility.¹⁴ The phases used to develop HEARTPrep[®] align with those previously described,^{7,8} but were adapted for this intervention and include a phase focused on partnerships with parents, clinicians, and design/technology experts.

Method

HEARTPrep[®] Intervention

HEARTPrep[®] consists of three sequential self-paced modules and corresponding telehealth sessions delivered via mobile app to expectant mothers following prenatal CHD diagnosis.¹⁴ Module 1 (Adjusting) focuses on adjusting to and coping with the CHD diagnosis, Module 2 (Connecting) focuses on connecting with support networks and managing interpersonal difficulties, and Module 3 (Preparing) focuses on preparing for the birth and infant hospitalization. Each module includes two recorded videos of parents sharing their experiences with CHD and two articles to normalize emotions and promote adaptive coping. Information about trusted resources (eg, websites) can be accessed across all three modules. HEARTPrep[®] telehealth sessions were previously piloted, with strong feasibility and acceptability results.¹⁵

Intervention Development

Intervention development occurred between September 2021 and September 2023 at Nemours Children's Health (NCH) (Table 1). Procedures were approved by the NCH Institutional Review Board (Nos. 1768680 and 1813613) and parent participants provided written informed consent via DocuSign. All parent participants had to be fluent in English and to have previously received a prenatal diagnosis of CHD.

Phase I: establishing partnerships. Partnerships with parents, clinicians, and design/technology experts were established prior to intervention development. Partnerships developed over variable time frames, building on prior research and clinical collaborations. Weekly meetings dedicated to HEARTPrep[®] development facilitated and strengthened partnerships.

The “parent partner” had a child with CHD and experience providing peer support to other families. The “clinician partners” were two NCH fetal cardiologists and a perinatal nurse coordinator. Design and technology experts came from two centers at NCH: Center for Health Delivery Innovation (CHDI) (director, designer, editor, analyst, software engineers, and quality assurance engineers) and Research Expanding Access to Child Health Center (director of the technology and methodology core). CHDI uses design thinking to build digital health tools for patients/families,⁶ including the Nemours app, a mobile app supported by NCH for telehealth, patient education, patient-provider communication, and medical record access.¹⁶ CHDI partnered with the research team to develop HEARTPrep[®] directly in the Nemours app, allowing the team to take advantage of a well-established app platform.¹⁶ The Nemours app has been used to deliver and test digital health interventions for other conditions, including pediatric asthma, with promising initial results.¹⁷

Phase II: creating content. Written content (articles and resources) was created by the first author, reviewed by parent and clinician partners, and iteratively refined. An editor from Nemours KidsHealth,¹⁸ which specializes in delivering health information for families, further refined the language. Video content was created by filming parents of children with CHD, with the support of a videographer experienced in creating videos for healthcare interventions. Parent participants completed interviews via Skype in which they shared their experiences with CHD during the pregnancy, in the hospital, and at home. Virtual filming was chosen due to the COVID-19 pandemic, ease, and perceived benefit of filming from home. Video clips were selected by the first author for initial rough cuts, reviewed by parent and clinician partners, and edited based on feedback. The final videos were approved by parent participants.

Phase III: developing prototype and testable intervention. A designer worked with the research team to develop a prototype of HEARTPrep[®], with guidance from CHDI collaborators. The prototype was shown via Microsoft Teams to mothers who had received a prenatal CHD diagnosis. They gave feedback on content and design, and refinements were made to the prototype. HEARTPrep[®] was then built within the Nemours app by CHDI analysts, software engineers, and quality assurance engineers and was made accessible through a test environment.

Phase IV: conducting think-aloud testing. Think-aloud testing is an established tool in usability research to obtain feedback from users as they navigate independently through a task and say out loud what they are thinking and doing.^{7,19} Participants were mothers who had received a prenatal CHD diagnosis. Mothers shared their screens in Microsoft Teams as they navigated through HEARTPrep[®], and all communications were recorded, transcribed, and analyzed for

Table 1. Five-Phase, User-Centered Approach to Develop HEARTPrep[®].

Phase	Partners	Parent participants	Methods	Deliverables
Phase I: Establishing partnerships <i>Duration:</i> variable ^a	Parent: • Mother of child with CHD Clinicians: • 2 fetal cardiologists • Perinatal nurse coordinator Design and technology: • CHDI: director, designer, analyst, software engineers, quality assurance engineers, editor from Nemours KidsHealth • REACH: director of technology and methodology core	• No participants or data collection in Phase I	• Weekly meetings dedicated to HEARTPrep [®] development • Frequent communication via Microsoft Teams and email to promote collaboration	Partnerships to: • Facilitate stakeholder input on HEARTPrep [®] • Provide design and technological expertise to develop HEARTPrep [®] • Leverage existing functionality within NCH (Nemours app)
Phase II: Creating content <i>Duration:</i> 8 months	• Parent and clinician partners provided input on content (videos, articles, resources) • Medical editor refined written content to be easily understood by families	Video filming: • 7 mothers, 6 fathers whose child received prenatal CHD dx • 2 Hispanic/Latino, 5 Black, 6 NHW • Payment = \$100	• Parents participated in 1-hour recorded virtual interviews via Skype to provide content for HEARTPrep [®] videos	• HEARTPrep [®] content (videos, articles, resources) ready for prototype development
Phase III: Developing prototype and testable intervention <i>Duration:</i> 8 months	• Designer developed HEARTPrep [®] prototype • Analysts, software engineers, and quality assurance engineers developed testable HEARTPrep [®] intervention	Prototype review: • 2 mothers whose child received prenatal CHD dx in past year • 2 NHW; age: 30-34 years • Payment = \$50	• Mothers gave feedback on HEARTPrep [®] prototype • Feedback informed development of testable HEARTPrep [®] intervention	• Testable HEARTPrep [®] intervention ready for think-aloud testing
Phase IV: Conducting think-aloud testing <i>Duration:</i> 4 months	• Analyst, software engineers, and quality assurance engineers refined HEARTPrep [®] based on participant feedback	• 5 mothers whose child received prenatal CHD dx in past year • 1 pregnant, 1 in hospital with infant, 3 at home after cardiac surgery • 1 Hispanic/Latino, 2 Black, 2 NHW; age: 23-42 years • Payment = \$50	• Mothers navigated through HEARTPrep [®] and said out loud what they were thinking and doing • All communications recorded, transcribed, and analyzed for common themes • Results informed refinements to HEARTPrep [®]	• Refined HEARTPrep [®] intervention ready for beta testing
Phase V: Completing beta testing <i>Duration:</i> 4 months	• Analyst, software engineers, and quality assurance engineers refined HEARTPrep [®] based on participant feedback	• 10 mothers expecting a baby with CHD • 2 Black, 8 non-Hispanic White; Age: 21-37 years • Payment = telehealth (\$10), survey (\$25), interview (\$50)	• Expectant mothers participated in HEARTPrep [®] • Provided feedback via survey and qualitative interview • Usability data obtained from Nemours app	• Fully refined HEARTPrep [®] intervention ready for efficacy testing

Note. CHD, congenital heart disease; CHDI, Center for Health Delivery Innovation; REACH, Research Expanding Access to Child Health Center; NCH, Nemours Children's Health; Dx, diagnosis; NHW, non-Hispanic White.

^aPartnerships developed over variable time frames, building on prior research and clinical collaborations.

common themes. Results informed iterative refinements to HEARTPrep[®]. Think-aloud testing concluded once no new

issues or recommendations to improve usability or content were identified (eg, thematic saturation).

Phase V: completing beta testing. The refined intervention was beta-tested with mothers expecting a baby with CHD, providing a preliminary “real world” evaluation of HEARTPrep[®]. Expectant mothers were recruited from the NCH fetal cardiology clinic. Participants completed the HEARTPrep[®] Evaluation Survey to assess perceived acceptability¹⁵ and a qualitative interview via Microsoft Teams to assess perceived usability. Interviews were recorded, transcribed, and analyzed for common themes. Objective usability data were obtained from the Nemours app (eg, completed telehealth sessions and modules). Beta testing concluded once no new issues or recommendations to improve usability were identified.

Results

The five phases of intervention development produced a refined digital health intervention with promising feasibility,

usability, and acceptability results. Participant characteristics are in Table 1.

Phase I

Partnerships were successfully established and contributed to the results of Phases II-V, as described below and in Table 1.

Phase II

Thirteen parents (7 mothers and 6 fathers) participated in video filming. Six videos of parents sharing their experiences with CHD and 6 articles to normalize emotions and support coping (2 videos/articles per module) were created and refined with feedback from parent and clinician partners (Supplemental Material 1). Trusted resources (eg, websites and nonprofit organizations) were also compiled.

Table 2. Participant Input and Corresponding Refinements to HEARTPrep[®].

Participant Input	Refinements
<i>Phase III: Developing Prototype and Testable Intervention</i>	
Suggested additional thoughts and feelings that may be common after a CHD diagnosis	<ul style="list-style-type: none"> • Added thoughts (eg, it's in God's hands) • Added feelings (eg, regret, jealousy)
Suggested additional coping strategies: (1) focus on what you can control, (2) embrace the journey	<ul style="list-style-type: none"> • Provided tips for focusing on what you can control (eg, make a list of coping strategies to use in the hospital, create a daily routine and try to stick to it) • Provided tips for embracing the journey (eg, decorate your baby's hospital room with things from home, celebrate milestones in the hospital)
<i>Phase IV: Think-Aloud Testing</i>	
Difficulty navigating through module (can't locate home page)	<ul style="list-style-type: none"> • Removed direct links between articles so users return to module home page between each article
Link to access resources and its positioning is misleading (eg, mistaken for a message center or IT help).	<ul style="list-style-type: none"> • Changed link to access resources from “Find Help and Support” to “Resources for Your Family” • Simplified description to “Check out websites and other helpful resources” • Changed positioning of a link to increase visibility
Link to external website broken	<ul style="list-style-type: none"> • Fixed link
Missing thoughts, feelings, and actions that may be common after a CHD diagnosis	<ul style="list-style-type: none"> • Added thoughts (eg, how will this affect my other children?) • Added feelings (eg, fear of going into labor early) • Added actions (eg, preferred to be alone or not talk about it)
Missing difficulties in relationships that may be common after a CHD diagnosis	<ul style="list-style-type: none"> • Added difficulties in relationships (eg, they don't understand it's a lifelong condition, my partner is so busy that I feel like I am dealing with this alone)
Content perceived as unrealistic	<ul style="list-style-type: none"> • Removed “I am proud of myself for...” as a suggestion for coping self-talk
Unclear wording	<ul style="list-style-type: none"> • Made minor wording changes to improve clarity
<i>Phase V: Beta Testing</i>	
Difficulty remembering to complete modules; Suggested automated reminder with a direct link to an incomplete module.	<ul style="list-style-type: none"> • Plan to add automated push notification with a direct link to the module if not completed in 7 days
Difficulty making time for modules; suggested discussing module content within each telehealth session to communicate its importance and relevance; suggested personalized message (eg, email, text) to remind users that module content will be discussed.	<ul style="list-style-type: none"> • Inform users that assigned modules will be discussed during telehealth sessions • Discuss module content during each telehealth session to reinforce its importance and relevance (eg, what was helpful, what stood out, what was surprising) • Send personalized message 2-3 days before telehealth session to remind users that module content will be discussed (if not yet completed)

Phase III

Two mothers reviewed the prototype of HEARTPrep[®]. Additional thoughts (eg, It's in God's hands), feelings (eg, jealousy), and coping strategies (eg, focusing on what you can control) were added based on feedback (Table 2). HEARTPrep[®] was then built in the Nemours app (Supplemental Material 2).

Phase IV

Five mothers participated in think-aloud testing by navigating through HEARTPrep[®] in the Nemours app. Results informed changes to HEARTPrep[®] functionality to improve usability (eg, removed direct links between articles) and the addition of content (eg, difficulties in relationships) (Table 2). Changes in the wording and placement of content were also made to improve usability and clarity.

Phase V

Ten expectant mothers participated in beta testing. Eight (80%) completed three or more telehealth sessions and seven (70%) completed all three modules (Supplemental Material 3). Early delivery impacted 2 participants, preventing completion of the scheduled third session and assignment of the third module. Modules were often completed within a few days prior to a scheduled telehealth session, suggesting that scheduled sessions may serve as a deadline or reminder for module completion. Participants reported high perceived acceptability (Supplemental Material 4) and minimal to no difficulties accessing telehealth sessions or modules within the app. However, difficulties making time or remembering to complete modules between scheduled telehealth sessions were noted. Recommendations to promote module completion included automated push notifications linking directly to the incomplete module and a focus on module content within each telehealth session to communicate its importance and relevance (Table 2).

Discussion

This study applied a user-centered approach to develop HEARTPrep[®]. This approach led to important discoveries that could be addressed prior to future testing and clinical use, thereby reducing barriers to usability and adherence.

The development of digital health interventions relies on key partnerships. Each partner brought the necessary expertise based on professional or lived experiences. HEARTPrep[®] was developed within a mobile app supported by the healthcare system (Nemours app), with existing capabilities for telehealth and patient education.¹⁶ The

infrastructure to support this work through CHDI was already in place. The ease of building an intervention within an existent system was weighed against potential downsides, such as navigating competing demands on developers' time (eg, if a higher priority clinical project emerged) and ceding control over the timeline. Importantly, funding is typically required for user-centered intervention development, given the critical roles of design/technology experts and key stakeholders.

Limitations

Parents not fluent in English were excluded. A Spanish-language version will undergo user testing with Spanish-speaking mothers. This approach to intervention development was iterative, with different sample sizes for each phase, determined by the point at which no new issues or recommendations were identified. Small sample sizes are common for multiphase intervention development research.^{7,8} However, additional recommendations may have been identified with larger samples. Acceptability, feasibility, and usability will continue to be assessed as HEARTPrep[®] is tested with larger samples for efficacy.

Conclusion

Key partnerships and rigorous user testing produced a refined digital health intervention with promising feasibility, usability, and acceptability results. If determined to be efficacious through further testing, this model of intervention could be adapted for other birth defects, thereby expanding its reach and impact. This user-centered approach can be used to develop digital health interventions targeting various health outcomes.

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Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

Ethical approval to conduct this study and report the results was obtained from the Nemours Institutional Review Board (IRB Nos. 1768680 and 1813613).

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Statement of Human and Animal Rights


All procedures in this study were conducted in accordance with the Nemours Institutional Review Board's IRB Nos. 1768680 and 1813613 approved protocols.

Statement of Informed Consent

Written informed consent via DocuSign was obtained from the participating parents for their anonymized information to be published in this article. The Nemours Institutional Review Board approved the consent process.

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Supplemental Material

Supplemental material for this article is available online.

References

- Butcher CJ, Hussain W. Digital healthcare: the future. *Future Healthc J*. 2022;9(2):113-117. doi: 10.7861/fhj.2022-0046
- Doss BD, Feinberg LK, Rothman K, Roddy MK, Comer JS. Using technology to enhance and expand interventions for couples and families: conceptual and methodological considerations. *J Fam Psychol*. 2017;31(8):983-993. doi: 10.1037/fam0000349
- Siopis G, Moschonis G, Eweka E, et al. Effectiveness, reach, uptake, and feasibility of digital health interventions for adults with hypertension: a systematic review and meta-analysis of randomised controlled trials. *Lancet Digit Health*. 2023;5:e144-e159. doi: 10.1016/S2589-7500(23)00002-X
- Gentili A, Failla G, Melnyk A, et al. The cost-effectiveness of digital health interventions: a systematic review of the literature. *Front Public Health*. 2022;10:787135. doi: 10.3389/fpubh.2022.787135
- Philippe TJ, Sikder N, Jackson A, et al. Digital health interventions for delivery of mental health care: systematic and comprehensive meta-review. *JMIR Ment Health*. 2022;9:e35159. doi: 10.2196/35159
- Altman M, Huang TT, Breland JY. Design thinking in health care. *Prev Chronic Dis*. 2018;15:180128. doi: <http://dx.doi.org/10.5888/pcd15.180128>
- Canter K, Deatrick J, Hilgart M, et al. eSCCIP: a psychosocial eHealth intervention for parents of children with cancer. *Clin Pract Pediatr Psychol*. 2019;7:44-56. doi: 10.1037/cpp0000264
- Canter KS, McIntyre R, Babb R, et al. A community-based trial of a psychosocial eHealth intervention for parents of children with cancer. *Pediatr Blood Cancer*. 2022;69(1):e29352. doi: 10.1002/pbc.29352
- Teitelman AM, Gregory EF, Jayasinghe J, et al. A mobile app to promote human papillomavirus vaccine uptake among adolescents aged 11 to 14 years: development and usability study. *JMIR Nurs*. 2020;3(1):e19503. doi: 10.2196/19503
- Stephenson N, Todd K, Indelicato D, Arce S. Designing and developing a mobile application to prepare paediatric cancer patients for proton therapy. *Design for Health*. 2018;2:1-12. doi: 10.1080/24735132.2018.1448618
- U.S. Food & Drug Administration. Digital Health Research and Partnerships. November 2, 2023. <https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-research-and-partnerships>. Accessed January 5, 2024
- Oster ME, Lee KA, Honein MA, et al. Temporal trends in survival among infants with critical congenital heart defects. *Pediatrics*. 2013;131:e1502-e1508. doi: 10.1542/peds.2012-3435
- Kasparian N. Heart care before birth: a psychobiological perspective on fetal cardiac diagnosis. *Prog Pediatr Cardiol*. 2019;54:101142.
- Sood E, Gramszlo C, Perez Ramirez A, et al. Partnering with stakeholders to inform the co-design of a psychosocial intervention for prenatally diagnosed congenital heart disease. *J Patient Exp*. 2022;9:23743735221092488. doi: 10.1177/23743735221092488
- Sood E, Nees SN, Srivastava S, et al. Virtually-delivered psychosocial intervention for prenatally diagnosed congenital heart disease: feasibility and acceptability of HEARTPrep. *Pediatr Cardiol*. 2023;44(7):1479-1486. doi: 10.1007/s00246-023-03209-7
- The Nemours App. <https://www.nemours.org/patientfamily/nemours-app.html>. Accessed January 5, 2024
- Lewis K, Zettler-Greeley CM, Blake KV, Milkes A. A digital health application for managing pediatric asthma: use and benefits. *Inform Health Soc Care*. 2023;48:370-386. doi: 10.1080/17538157.2023.2250435
- Nemours KidsHealth. <https://kidshealth.org>. Accessed January 5, 2024
- Nielsen J. Thinking Aloud: The #1 Usability Tool. January 15, 2012. <https://www.nngroup.com/articles/thinking-aloud-the-1-usability-tool/>. Accessed January 5, 2024