

Designing and Evaluating Calmer, a Device for Simulating Maternal Skin-to-Skin Holding for Premature Infants

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ABSTRACT

We describe the design and deployment of *Calmer*, a technology that simulates key aspects of *maternal skin-to-skin holding* for prematurely born infants: its inspiration, approach, physical design, and introduction into the Neonatal Intensive Care Unit. Maternal skin-to-skin holding can mitigate neonatal pain during medical procedures by as much as 50%, which can improve weight gain, sleep and later development. However, parents cannot always be present, and some infants are too fragile to be held. Interventions targeting this gap could be perceived as supplanting the mother in this intimate role, exposing her to depression and endangering her maternal bond. Over 10 years, we iteratively developed *Calmer* and demonstrated infant health benefit in a randomized clinical trial. Here, we report and reflect on pursuing this goal in a socially and technologically complex context: constraints, strategies, features, reception of the device, and surprises, such as leading to mothers feeling channeled rather than replaced.

Author Keywords

Premature infants; neonatal intensive care; NICU; pain reduction; parents; automation; Research through Design.

CSS Concepts

- Human-centered computing~Interaction design process and methods

INTRODUCTION

When a mother holds an infant on her chest, it experiences the warmth and touch of the mother's skin, the sound of her heartbeat and the breathing motion of her chest. However, when a baby is born weeks or months too soon, it struggles to survive in the Neonatal Intensive Care Unit (NICU), where it is dwarfed by complex machines dedicated to saving its life, and at the same time is deprived of crucial maternal contact. Yet, this intimate contact has major benefits for premature infants: it reduces standard pain indices in neonates by as much as 50% [9], improves infant weight gain, sleep, and blood oxygenation, and thereby reduces

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Figure 1 A prematurely born infant laying inside an incubator on *Calmer* experiencing skin-like material, breathing motion and heartbeat sound replicated from her mother.

hospital stay [14,29,43]. However, most mothers can only visit for about three hours per day, and fathers for even fewer [27]. Even when parents are present, infants may be too medically unstable to be held, and parents reluctant to disturb staff or anxious about causing harm to their fragile infant.

Our team of clinicians and researchers saw a potentially high-impact design opportunity in physically simulating key aspects of maternal skin-to-skin holding for premature infants when a parent is not present. From the perspective of the health and functioning of the family unit, however, this approach could be problematic. A mother's inability to help her infant can create feelings of alienation, role conflict, guilt, frustration and depression [24,38,64,67], exacerbating already-high stress levels and impeding emotional connection with her child [23,63,73]. A perception of maternal replacement is unhelpful here. The NICU nurses are key stakeholders, crucial allies for advancing new practices. They are protective of family relationships and deeply wary of situations that could exacerbate family stress.

In developing an intervention, we thus faced a complex balance: design a technology that simulates maternal holding while considering the NICU's technical and social context.

In this paper, we unpack the process through which we ultimately arrived at an effective design that met our objectives. *Calmer* is an actuated platform placed in an infant incubator, administering breathing motion, heartbeat sounds and skin-like tactility to an infant lying on it (Figure 1). We describe our 10-year design path, summarizing findings from testing *Calmer* in a pilot deployment and then a clinical trial

for efficacy. We also present a qualitative interview study, with parents whose infants experienced Calmer and NICU staff who treated them. As we report and reflect on designing Calmer, we extract key take-aways from our approach to designing within a complex and constrained environment like the NICU. A considerable focus in our work became the objective *of* replicating yet importantly not replacing maternal holding, an intimate human action and practice offered at time of fear, hope, life or death, and with challenges around significant maternal stress which could include consequences as serious as postpartum depression and altered mother-child bonding. As the designed outcome, Calmer serves as an exemplar for HCI that itself is emblematic of its multi-faceted design features and strategy.

RELATED WORK

Background and related work fall into two main areas: clinical background on prematurely born infants underpinning our design efforts, and works within HCI concerned with designing for a hospital context, consciously automating human actions and design-led research.

Clinical Background

Each year worldwide, over 15 million infants are born preterm (less than 37 weeks of gestation) [11]. Separated physically from their mother to ensure their survival, these infants undergo painful, repeated, but medically necessary tests and procedures. Both the early birth and this early pain exposure generate a severe mismatch between the baby and its natural environment. The Synactive Theory of Development suggests that realigning crucial aspects of the NICU experience with the in-utero environment from which the infant was separated can protect the developing brain [1]. This restoration of the in-utero environment is considered to be important by researchers, clinicians and families.

Impact of pain in neonates and pain mitigation strategies

Preterm infants can remain in the NICU for weeks to months, repeatedly undergoing essential but painful care-related procedures (e.g., heel lance for blood sampling). They may be subjected to 5-15 painful procedures a day, each procedure inducing behavioral and physiological instability [60]. Early, repeated pain exposure can induce long-term damage to many developing systems [57]. It is associated with reduced physical growth and altered stress system programming [30,36,70], damaged brain microstructure and processing [8,19,79], and long-term, altered brain development [31,55,56,58]. Moreover, neonate pain exposure can have damaging effects on mothers causing trauma and stress [71]. The bonding to their babies can be lacking and mothers often feel hopeless, helpless, useless or inadequate. Maternal depression due to these feelings can be a serious “side effect” of preterm birth on mothers [23,71].

To treat pain, pharmaceutical medications are the first line of treatment but some, for example morphine, has limited efficacy for procedure-related pain in premature infants [10,65]. Instead, mother-centered, touch-based behavioral treatments are recommended as powerful alternatives [9]. A technique called “kangaroo care” (also known as “skin-to-

skin holding”) is one of the most effective of these [40,42]. When a mother holds the infant on her chest where it experiences the touch and warmth of her skin, the sound of her heartbeat and breathing motion of her chest, as much as 50% reduction of standard pain indices can be achieved [9]. The components of skin-to-skin holding simultaneously activate multiple endogenous opioid and non-opioid pathways to reduce pain [44,47,68].

Parents and Nurses

The premature infant’s parents are significantly impacted by the slow, painful drama that plays out in millions of cases each day in NICUs across the world. Deeply engaged with their infant’s survival and well-being, they cannot always be at the bedside; they may have competing responsibilities, such as caring for other children, holding down jobs or managing their own health. In addition, some preterm infants must receive care far from home. As mentioned in the introduction, even when parents are present, there are further barriers to skin-to-skin holding.

As an alternative, facilitated tucking (FT) can be offered to neonates as a pain management approach. It is a human-touch-based holding strategy whereby a caregiver holds the infants’ limbs, head and/or trunk throughout a painful procedure while they remain in their incubator (see Figure 2a). FT is the current standard of care in some NICUs when a mother is not available at the time of a procedure, but in many others, it is considered impractical to provide because nurses may be too busy to be physically present for each procedure. They have multiple roles in a stressful work environment: educator, role model, advocate for infants and families, facilitator, and expert/authoritative caregiver [59]. Torn between obligations of technical expertise, human focus and external advocacy which often conflict [22,26,59], nurses recognize the importance and fragility of emotional aspects of the parent-infant-bond.

Simulating Prenatal and Postnatal Environments to Neonates

Early clinical research points to potential value of simulating aspects of the prenatal environment to neonates. For example, researchers have suggested playing prenatal maternal sounds in NICU incubators [20,51] and have created and tested artificial circadian environments by controlling lighting conditions through filtering mechanisms [72]. Through the design of Calmer, we simulate postnatal maternal skin-to-skin holding incorporating heartbeat sounds, breathing motion and skin texture. Importantly, our work moves into actual design and deployment.

Related Works in HCI and Design

Health-related HCI works in the Hospital and NICU

Health-related HCI has a rich history, and includes studies of hospital deployment. However, environments vary dramatically across and between hospitals, and there remains a need for design exemplars in this broad area. We describe a few selected works we see as related to our NICU context.

A project strongly related to ours is the design of *Hugsy* by Claes et al. [13], a comfort kit for neonates to facilitate and simulate maternal holding, which, like Calmer, records and

plays mothers' heartbeat sounds aiming to reduce pain of neonates. *Hugsy* was qualitatively evaluated by stakeholders in a clinical trial with positive results. Similarly, Versteegh and Chen et al. [12,69], designed *Mimo Pillow*, which plays maternal heartbeat recordings to comfort neonates. An early prototype was tested in a pilot study and in a clinical study with 19 infants showing positive results. In another example, Croes et al [15,16] propose design concepts including a child-rocking incubator mattress and the *FamilyArizing System* enabling parents to remotely send a 'hug' to their infant. Johnson et al. [39] designed aids facilitating family member support in the Intensive Care Unit (ICU) in hospitals, based on 22 interviews with both family members and hospital staff, with the particular goal of not burdening hospital staff. Similarly, we integrated practices and constraints of hospital staff in our work.

In comparison, the Calmer project (which started in 2009 before these related works from 2012-2017), is set apart through its combination of a long-term, multi-disciplinary and thorough design process, offering multiple components of skin-to-skin holding (touch, heartbeat sounds, and breathing motion) simultaneously, and its pilot-study and clinical trial with two design iterations tested in the NICU.

Designing for the NICU

Technology for the NICU, and specifically for an incubator, is a unique design space with specific considerations and we explore some of them in this paper. Others working in this space are, for example, the company Phillips, which has dedicated a significant part of their work to designing for neonatal health care [81]. Industrial design researchers at Technical University Eindhoven have examined improving parent-infant bonding in the NICU [4,5,15]. Ferris and Shepley [25] offer an overview of a human-centered design approach to neonatal incubators. For this, conforming to the needs and practices of various stake-holders of the NICU environment is common practice [7].

Consciously and Empathically Automating Human Action

Our approach also relates to works that have looked at designing technology automating human action in a meaningful or conscious way. For instance, Davidoff et al. [17] discussed automating parenting tasks in conscious ways. Ozenc et al. [50], following a RtD process, designed the *Reverse Alarm Clock* which tries to automate the parental task of keeping children in bed, also a sensitive and intimate task between parents and children.

Our work builds upon these works as another example in the space, but with a specific focus on the NICU environment. In our case, we balanced replicating maternal holding in a way where the mother partly perceived herself as virtually present in the appliance, thus did not feel entirely supplanted.

Additionally, there are related works in the area of human-robot interaction that are motivated by replacing human functionality [61,74] and by the convincing portrayal of agency, personality, intelligence, emotion or other evidence of humanity, life or self-ness. At the same time, this quest raises legitimate concerns about personal, economic, and societal impacts that machines with such capabilities exert [52,76].

Design-led Research

There is a growing interest in HCI in knowledge development through the means of design and design practice [2,28,37,66,78]. In particular, the making of artefacts has gained recent traction [e.g., 3,49,53,54], as they can give form to novel solutions that would not be arrived at otherwise [21] and help HCI researchers critically investigate emerging issues.

We want to contribute to this growing body of research where describing and reflecting on the process of arriving at a final novel design can largely be a form of research in and of itself. Our work follows an RtD approach, applying theory from neonatal development and pain research to address the needs of preterm infants as well as their parents and caregivers. In our unpacking of the Calmer project in this paper, we cover lenses proposed by Zimmerman et al. [78] in their original paper on RtD. Specifically, we describe and reflect on insights from our long-term *process* of the design of a novel *invention* in the realm of designing for neonatal pain reduction, through replicating but not supplanting maternal skin-to-skin holding—an important and intimate parental practice. The *relevance* of our design solution is demonstrated through a clinical efficacy trial. We next report in detail on specifics of the long-running, complex design process for developing our clinical device and later on, discuss several lessons we learned from this process and reflect on it as a way to *extend* this work for future research.

DESIGNING AND EVALUATING CALMER

The designing of Calmer encompassed not only the careful making of an artifact—a medical concept and technological implementation—but also, over 10 years, every aspect of its introduction to nurses, the hospital's ethics board and families. While further iteration will occur, the project has achieved critical milestones (a successful clinical efficacy trial and support from staff) needed for it to gain traction, and to support the present reporting and reflection.

In what follows, we first introduce the design team and its background and speak to the initiation of the project. Then, we detail our guiding objectives and requirements and report on Calmer's design stages along with the different ways we deployed and studied two Calmer prototypes and the encouragement and challenges we encountered.

Multidisciplinary Design Team

Our multidisciplinary team informed Calmer's design over time. The project initiator and leader (Holsti) is an occupational therapist who worked bedside in the NICU for 20 years before moving into neonatal pain research. The co-lead (MacLean) had been a haptics and human-robot interaction (HRI) researcher for 20 years prior to the project start. Other contributors included two NICU-trained nurses who were part of the project leader's NICU research program; a capstone design team of undergraduate engineering students who developed the first prototype to specification; a professional engineering team hired to build the second prototype; a senior biomedical engineer who advised on NICU requirements; and a design researcher

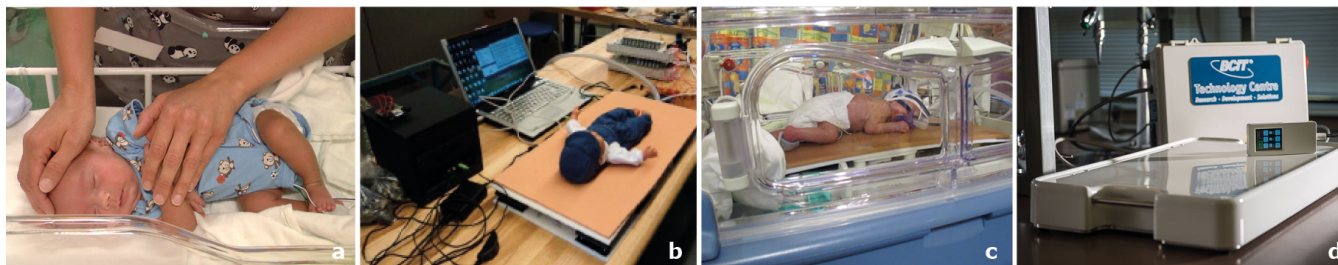


Figure 2 a) Facilitated Tucking; b) Test setup of Calmer I; c) Image from the pilot study with Calmer I; d) Calmer II.

(Hauser) who focused on documenting the project and its process. Other practitioners consulted included respiratory therapists and a group of neonatologists. Only the first two people were present for the entire time period, but every person uniquely contributed to Calmer.

Serendipitous Inspiration: Robot Breathing and Stress

Calmer was inspired by the Haptic Creature, a furry social robot mimicking a lap pet that interacts through emotive touch [77]. Created to study touch-centered emotional communication, the Creature renders emotion through crafted breathing, purring, heartbeat, and ear stiffening. When held by adult participants, this robot's breathing was found to decrease heart and respiration rates significantly and make them feel happier and more relaxed [62]. Our project leader saw the Haptic Creature demonstrated at a lab's open house. Immersed in the problem of neonatal pain and the benefit of maternal skin-to-skin holding—of which breathing and heartbeat are salient elements—she conceived the idea of turning this technology “inside out” so that an infant could lie upon it. She persuaded our haptics/HRI co-lead (who is director of the mentioned lab) to help turn this basic concept into a prototype, and the project and collaboration were born.

Design Objectives and Requirements

From the start, the primary goal of the Calmer project has been to design and build a device that reduces pain in preterm infants by simulating maternal skin-to-skin holding; and as a result, potentially alter the standard of care in neonatal pain therapy. Importantly, part of this goal has been to consider a conscious and careful integration with the technological and social complexities of the NICU environment. We now describe three core design objectives which were developed by the project team and align with the main goal.

(1) Conform to the needs and practices of multiple users and stakeholders: Although the experience of maternal holding as replicated through Calmer is targeted at infants, our prototypes and their introduction had to work for parents and NICU staff as well. Calmer could not disrupt the infant or the staff caring for it; it had to be easily operated by staff, and fit into their work practices. Imperatively, Calmer had to be accepted by parents, despite them not being direct users.

(2) A helpful adjunct to care, but not a parental replacement: We knew that it would be unacceptable for this technology to be perceived as replacing parents. Maternal skin-to-skin holding is by definition a mother's role, and replicating it is sensitive in the extreme. If Calmer were viewed as usurping this role, its use in the NICU would be rejected by parents and also staff because of the strong philosophical approach

in NICUs to promote family-centered care. The project leader was an advocate for this objective, based on a professional understanding of the clinical situation and its seriousness. The team understood that any mis-step in this area could have terminated the project. From the beginning, we were thus mindful of how the device would be perceived by parents and NICU staff. The co-leader had experience in imbuing robotic objects with life and affect via appearance and movement. In the case of Calmer, we had to defuse the appearance of such cues, yet still provide them to the infant. Beyond mammalian forms, the risk extended to movement. Breathing is a potently life- and emotion-evoking movement; it can bring even a sponge-like blob to life [18].

(3) Meet the requirements of the NICU and a clinical trial: A medical technology concept like Calmer cannot proceed without clinical validation; thus it was important for us to consider the need to work towards an eventual randomized clinical trial (RCT) by deploying Calmer in a NICU to determine its efficacy for mitigating infant pain.

In addition to supporting the planned RCT's protocol (programmable movement, start/stop, and physiological data collection), Calmer had to be robust, durable, easily moved in and out of the incubator, conform to strict hygiene protocols, electrical and acoustic standards, and allow for performance of routine and emergency procedures on the infant. It also had to be operable by research staff without supervision, allowing the principal investigator to remain at arm's length to avoid a conflict of interest in the results.

Early Considerations on Form

The preliminary idea was to create an inside-out Creature. Two considerations further narrowed our approach to the general form of our design. First, since premature infants spend much of their time in an incubator and a NICU can have significant space constraints, our design had to work within an incubator. Second, in contemplating concerns of perceived maternal replacement, the team made a commitment to avoid any sense of “selfness” in the object, through a bland, appliance-like form. This led to the form of a motion platform, engineered to be as unobtrusive in appearance, sound and function as possible.

Calmer I: Design and Implementation of a First Prototype

The purpose of *Calmer I*, our initial prototype (Figures 2b,c), was to explore and demonstrate the feasibility of our developing design with limited resources. While we did not expect it to support a clinical efficacy trial, we wanted to assess our design and engineering approach, and get a sense of how infants, parents and staff would respond to it. This

prototype needed to safely support repeated deployment, under supervision for short intervals, during medical procedures while infants were being tested for pain.

We developed Calmer I with an undergraduate engineering student team, in an 8-month iterative process. We leveraged both research and our own experience and knowledge regarding preterm infant development and needs and the NICU environment. Our approach was to simulate putative pain-mitigating components of maternal skin-to-skin holding through the modalities of breathing motion, heartbeat, and skin touch, using tactile, auditory, and kinesthetic stimuli.

With the lead and co-leads' guidance, the student team defined four technical subsystems, detailed below. As part of generating concepts for performing bodily maternal functions, they evaluated existing related technologies [e.g., 82].

Respiration

Upon reviewing federal codes [80,83–87] and codes and standards of our test hospital associated with technology use in the NICU, we chose to use pneumatic pressure (available at cribside) for actuation to avoid electrical components in the incubator which would then require isolation.

Calmer I's respiration subsystem had four pneumatically powered bellows that expanded and contracted under pressurization to produce vertical motion. The rate of airflow into the bellows was controlled by parallel solenoid valves, opened in combinations to achieve the desired motion. When stationary, the top plate rested on structural metal bars so that CPR could be performed in an emergency. To mimic breathing, the top plate raised and lowered 10 mm above this base, in a smooth trajectory; the distance was determined from sternal motion of an adult female breathing at rest obtained using motion capture technology.

Heartbeat

To simulate the sound of a human heartbeat, we used a subwoofer to produce pressure waves, located externally to the incubator. The pressure waves it created were collected and transferred by tubes to the device's interior. Inside, the waves spread within a sound box and were transmitted to the infant through holes in the top plate. In operation, the subwoofer repeated a single heartbeat sound clip. Volume was limited to 55 dBA at the infant's head, meeting international standards for NICU noise.

System Control, Operation Interface and Personalization

Calmer I's respiration and heartbeat subsystems were controlled by an Arduino microcontroller with parameters of respiration and heartbeat rates. These parameters were adjustable by researchers and nurses with a GUI displayed on a laptop. Motion could be stopped immediately (e.g. for a CPR emergency) by shutting off the airflow at the bedside.

Considering both wanting to maximally replicate maternal skin-to-skin holding and aiming to avoid parents' feelings of displacement, we explored the option of Calmer delivering customized parental physiological rates. We implemented the functionality of programming *an individual mother's breathing and heartrate* into this first prototype.

Device Body and Contact Surface

Calmer I's rectangular casing fit into an incubator as a bed. The top plate was covered with a brown silicone membrane, selected for cleanability and to replicate maternal skin tactility and stiffness. All components used were confirmed to be hygienic and cleanable to NICU standards.

The total expenditure to build Calmer I was \$650.

Initial Evaluation of Calmer I through a Pilot Study

We conducted an initial randomized pilot evaluation on 10 infants to gauge feasibility of using Calmer for pain reduction during a single, medically necessary blood test. While 10 infants is too small a sample to statistically determine efficacy, the data was encouraging. This was an important step to the project's future and to secure further funding that would support a prototype iteration and a larger clinical trial. For context, we next summarize this evaluation; the full protocol, participant inclusion/exclusion criteria and results can be found in [75].

Participants, Data Collection, Analysis and Findings

The study was executed by an independent NICU research nurse and research assistant, ensuring an arm's-length protocol for a clinical study where the inventor is also the research lead. Obtaining funding and ethics approval, study setup, recruitment, analysis, completion, and publication took about 20 months. We debriefed with the research staff post trial.

10 medically stable preterm infants were recruited by the research nurse and assigned randomly to treatments of either Calmer or facilitated tucking (FT) (see Figure 2a and Related Work). It was not ethically acceptable to use a condition with no assistance when the standard of care includes it. Mothers' resting heart and breathing rates were pre-collected and used to program Calmer for each respective infant.

To evaluate infant pain, we obtained continuous 1-minute samples of heart rate variability (HRV), a proxy measure of physiological stress and stability, analyzed it for high-frequency power (HF), representing parasympathetic (stress-reducing) activity [48], and compared changes in HF at 3 pre-defined procedural stages of *Baseline*, *Poke* (when the skin on the foot is pierced to collect a blood sample) and *Recovery*.

Infants' biological responses trended consistently with more physiological stress reduction (higher HF change) in the Calmer group. Specifically, mean (std dev) HF change from *Baseline* to *Poke* was 3.8 (3.5) vs 42.3 (34.8) Hz/ms² for the FT and Calmer groups respectively, demonstrating a positive effect on heartrate variability (more stress reduction) in infants receiving the Calmer treatment.

Within the caveats of a small sample, this was a stronger response than we expected. It encouraged us to think we were on the right path, and helped us access further resources to continue the far more expensive steps to come. Regarding infant comfort, we observed that the surface material seemed to restrict some infants in moving their limbs, due to friction, and noted it as an issue to correct. The NICU workflow was marginally affected, in the realm of what the nurses

considered acceptable but improvable. Collecting and using the mothers' individual breathing and heartrates was feasible. We viewed this as a valuable feature to be explored at little cost.

We received unsolicited positive verbal comments from two parents whose infants were randomized to Calmer treatments. One mother expressed relief in having a device help her infant during blood tests, despite knowing the nurse would be there. During NICU staff rounds, nurses and physicians referred to Calmer as an “*exciting new treatment.*”

Based on these generally positive clinical and design results, we secured funding for next steps in an application process of about one year and proceeded to build a second prototype. For this, we generated a list of desired improvements from our own perspective as well as informal staff feedback. This included replacing the laptop interface due to its intrusiveness, and minimizing cables and tubes. While effective, the pneumatic actuation was cumbersome because the bedside air supply was needed to run ventilators and other breathing devices. General robustness of Calmer I was also inadequate for a longer-term deployment.

Design Changes for Calmer II

A larger clinical efficacy trial demanded greater NICU operability, which was a main objective for *Calmer II* (Figure 2d). We needed to maintain infants on the device for a short exposure during a single painful event followed by approximately eight hours of continuous operation. This triggered many new requirements. Extended exposure would allow us to investigate Calmer's impact on infants' physiological state during both rest and periods of routine care; the latter would now include a greater variety of procedures including those which were non-painful (e.g., diaper changes), but which can induce similar stress responses [32].

This re-design was executed by a professional engineering team in consultation with our leader, co-leader and team engineer, and took 18 months. We implemented several changes while keeping with our essential objective of an “invisible” unobtrusive incubator insert. Key changes in Calmer II included changing the power source to an external electric motor for flexibility and mobility; this was a major investment that required electrical isolation and then iteration to reduce motor sounds. We had to assure materials were X-ray compatible for on-bed radiology. The skin-simulating covering was exchanged for a dual-material solution to improve infant comfort and mobility: a firm silicon pad covered by a low-friction biocompatible GORE-TEX® which better replicated the maternal sternum while meeting hygiene and infant comfort needs. For the staff interface, we replaced the laptop with a custom controller for more compact, streamlined access, consisting of a hand-sized molded plastic case with a screen, dedicated buttons and hung on a hook on the incubator's exterior. An emergency stop button (e.g., when CPR has to be performed) was added to the power box. A series of tests were devised to confirm it could meet robustness requirements.

The total expenditure to build Calmer II was about \$37,700.

Larger Clinical Efficacy Trial of Calmer II (n=49)

We ran a single-site, randomized clinical trial (RCT) with 49 infants to determine Calmer's (1) effect on acute procedural pain in preterm neonates; (2) longer-exposure impact on infant physiological stability; (3) technical performance, user experience and feasibility of eight hours of continuous use.

This RCT took 3.5 years to complete. Several factors contributed to this timeline. For example, we had to identify infants who were “relatively” stable, as we did not want to use Calmer on the sickest infants for reasons of safety; and families had to be able to cope with this on top of their other stress. Revised infection control standards triggered a mid-trial prototype modification. Finally, our collaborating NICU was moved into a new building, requiring a 4-months break in recruitment while staff became familiar with the new surroundings and procedures. Again, for context, we summarize this evaluation; the full protocol and results can be found in [33].

Participants, Data Collection, Analysis, and Findings

The study was again executed by an independent NICU research nurse and assistant, allowing the needed at arm's-length protocol for a clinical study. The nurse recruited 49 medically stable preterm infants born within 27-36 weeks gestational age.

While the RCT has greater experimental power than the pilot, we still could not use a within-subjects design (each infant with & without Calmer) because we could not rely on or dictate that the same infant would require two blood draw events during the requisite testing period. For ethical reasons, we also could not conduct a true control (no intervention) even in a between-subjects design; our baseline was once again facilitated tucking, and thus we had to look for a “no difference from the standard of care” type of result. Finally, we could not assess the impact of the individual components of Calmer (breathing, heart beat sounds, skin surface) nor personalized motion rates on pain reactivity, as this would have required a very large sample and interminably delay a more general result. Other relevant methods were the same as for the pilot evaluation.

The RCT's research protocol and a related interview evaluation (detailed in the next section) went through several steps of standard clinical review. It was approved by the Clinical Research Ethics Board of the University of British Columbia as well as BC Women's Hospital's NICU Research Committee. All types of family units were eligible as long as there was an identified primary caregiver who was legally responsible for providing consent for care and/or research. Here, this always happened to be the biological mother; they tended to be at bedside more often than fathers. NICU staff attended a 30-minute information session about the study and to get an overview of the Calmer technology.

The results of the trial showed no significant differences in pain reduction between infants on Calmer and infants receiving FT. In other words, the trial showed that Calmer was as effective as FT, the human-touch intervention and hence a viable alternative when needed. These positive

results lead to two granted patents [34,35] and our hope is that the Calmer technology will eventually be implemented in incubator designs worldwide.

With this in mind, we have estimated that in just our NICU alone, having Calmer embedded in each incubator could save almost \$500,000 per year in nursing costs [33]. Other costs to families may include reduced stress knowing there is a backup when they are not able to attend a procedure. Cost savings related to improved neonatal outcomes will be determined in future research.

Qualitative Study with Parents and Nurses on the Perception and Experience of Calmer in the NICU

In addition to studying Calmer’s efficacy, we wanted to examine its acceptability and the user experience from the perspective of both NICU staff and parents and investigate how well it catered to the social complexities and context we knew were within the NICU environment. We addressed this objective with a qualitative study conducted in parallel with the RCT. This study was central in helping us decide to move our technology development forward and provided the foundation for more in-depth qualitative research we have included in our most recent federal grant application.

Participants

To better understand and evaluate experiences with and the acceptance of Calmer, we selected a subset of infants (and parents) from the Calmer group in the RCT. We conducted interviews with their mothers and the NICU staff caring for them. The same NICU research nurse recruited these 10 mothers (referred to as M01–M10) and 10 NICU staff (referred to as S11–S20) re-affirming their consent to be interviewed. Table 1 below shows demographics for the recruited mothers and their infants. Staff participants included 8 registered NICU bedside nurses, one pediatric physician and one medical laboratory assistant. Their professional NICU experience ranged from 2 weeks to 16 years; all had completed specialty training in neonatal care.

Study ID:	M01	M02	M03	M04	M05	M06	M07	M08	M09	M10
Mother’s age (yrs)	33	33	37	41	34	42	30	36	36	30
Education (yrs)	6	6	6	5	5	5	4	7	6	4
Gest age (wks)	28.3	27.7	29.8	27.7	29.7	28.3	30.4	28.8	31.1	28.2
Birth weight (kg)	1.18	1.15	1.2	1.02	1.41	1.18	1.56	1.34	1.93	1.49
Infant age (days)	39	42	33	30	13†	25	20†	20	31	31
Resp. support‡	0	2	2	1	2	2	0	0	0	1

‡Respiratory support on Calmer study day: [0=none], [1=oxygen via nasal prongs], [2=continuous positive airway pressure]. †Indicates a twin.

Table 1 Demographics of participating mothers and their infants.

The extent of mothers’ understanding of Calmer’s purpose and function before implementation with their infant varied. All but three (M01, M06, M07) were able to personally observe their infant on Calmer.

Data Collection and Data Analysis

One author conducted all interviews (Suto) and led the thematic analysis. She was not involved in any aspect of the design of Calmer nor the larger clinical trial, maintaining an arms-length perspective. She collected qualitative data over 28 months via semi-structured, individual interviews with

the participating mothers and NICU staff (n=10/10, respectively). The interviews were conducted in either a private hospital meeting room or the NICU. Locations were determined by each participant; occasionally a family or research staff member was present with participant consent.

Although we were able to collect data, the cooperation of mothers and staff was often constrained by the environment and context with which we were dealing. Preterm infants are very fragile, often fighting for their lives going through painful yet life-saving procedures daily. Parents are desperate and can experience feelings of emotional trauma, displacement, inadequacy, and uselessness while modern specialized medical care and machines try to keep their infants alive [23,24]. Given that, mothers had to be treated sensitively. NICU staff are often stressed operating in this intense environment on a shift-work schedule. Union regulations meant they could not be interviewed or consulted with outside work hours.

We asked each group a set of questions related to their experience with and perceptions of Calmer as well as associated feelings with respect to Calmer and its mediating effects. Questions posed to staff focused on their personal relationships to technology in their workplace and their anticipation or observation of parents’ reactions to Calmer. The average interview duration was 17 (mothers) and 16 (staff) minutes. Each interview was recorded verbatim and field notes were taken on the environment, feelings expressed non-verbally by participants and other observations that might contribute to developing findings. Recordings were transcribed. Mothers’ interview data was analyzed through inductive thematic analysis [6] and using analysis software [88] to identify patterns of common experiences and perspectives. Our interviewer /analysis lead coded the data, then iteratively reviewed it to identify themes, with intervening discussions with the project team. With themes established, she iteratively cross-checked original data for possible theme overlap, missed insights and documented countering cases, and selected representative quotes (Section V-B). While staff transcripts were sparser (in part due to question focus), we confirmed that their remarks corroborated those of the mothers; none contradicted them.

Findings

Based on interviews with 10 mothers of “Calmer babies” (preterm infants who experienced Calmer in our clinical trial) and 10 NICU staff who cared for them, we looked at the fit of Calmer in the NICU environment and their perceptions and experiences of it.

Calmer’s Impact on NICU Operations:

Although a workflow analysis was beyond our scope, we did obtain staff feedback regarding the effects of Calmer in the NICU work environment. Most reported that Calmer itself was not an obstacle in their work. Three staff (S12,14,16) mentioned reduced work space, explicitly related to the research equipment (e.g., video and physiological recording gear for clinical data collection). However, this issue related only to experimental conditions related to the trial setup.

Mothers' Reactions to Calmer:

Beyond the knowledge that Calmer provided key biological parameters (breathing motion, heartbeat and touch/skin surface), mothers responded to its nondescript, innocuous, visually impersonal form and the ability to personalize this form. We describe their responses across three themes.

Theme 1 – “A back-up of me”: Mothers identified Calmer's customization as an important design feature that was both imitative and reassuring. They articulated their understanding that their heart rates and breathing rates were programmed into Calmer for their individual infant's benefit. Mothers described this physiological replication as imitating, in part, what the infants would have experienced (prenatally) had they not been born prematurely. One mother (M09) characterized the phenomenon of mimicking mothers of Calmer as “a back-up” of herself. She also expressed positive feedback on our approach of not making the technology or device humanoid yet still replicating skin-like texture, a mother's individual heartbeat and breathing rates.

Several mothers proposed that more regular use of Calmer might have reduced their stress and anxiety, some of which arose over their infrequent NICU visits due to distance and other responsibilities: “[F]or me personally, if Calmer had been in my baby's incubator from day 1, I think it would have lowered my anxiety knowing my baby was being taken care of, on that level” (M06).

Theme 2 – Strengthening the mother-infant connection: Some participants described the NICU itself as a “scary place” (e.g., M05) where parents could do little for their infants. One mother (M05) described the incubator as an isolating place for the infant and that it was hard to feel and act like a parent, given the infant's fragile health status.

Mothers described the role that Calmer played in helping to address the mother-infant connection that is interrupted through premature birth. They recognized that their babies were thrust into the “unnatural environment” (M06) of the NICU by necessity, and appreciated that Calmer offered features of the in-utero experience yet was not an exact representation. Some mothers described Calmer as an *extension* of themselves. One mother (M06) proposed that it would help mothers to know that their infant had a “*piece of them inside the incubator*” when the mothers could not be with them. Each mother expressed positive feelings about their infant on Calmer; e.g., “*if he [infant] looks comfortable [...] and his heart rate is nice, then, I'm like, ok, that's good; keeps, me calm and helps me handle the whole situation.*” (M40). Thus, the difficulty of being away from their infant was at least partially mitigated by the presence of Calmer which was viewed as helping babies “*to feel more naturally connected to their mothers*” (M06) or “*bond with its mother*” (M05) despite being taken from them prematurely.

Theme 3 – Calmer as “just a bed”: Whereas the previous themes illuminated Calmer's functions, this one captures participants' views of the device's form and preconceptions of it. Mothers' comments generally pointed to the perception of Calmer as a piece of *unobtrusive technology*.

Six mothers (M01–03,05,07,09) likened Calmer to a bed of sorts. Others described it as a *platform* (M06), *mattress* (M03,08), *air mattress* (M04), a *pad* (M09) and “*something built into the bed of the incubators*” (M07). Such benign descriptions aligned with comments such as “*it wasn't anything scary that, like there were no apprehensive thoughts about it*” (M01); and “*I wasn't worried for him or anything like that...it didn't seem invasive at all*” (M02). No comments contradicted these depictions of Calmer. This was an important affirmation for us.

One mother provided a final insight that returns to the object's form and yet captures the context: “*I mean you're full of machines and everything in the NICU anyhow so it [Calmer] was just another machine at the end of the curve [...] it wasn't, scary. It wasn't, you know, any impact on us negatively. [...] I'm happy that she's on it*” (M03).

Theme Interconnections: Comments from the mothers we interviewed convey their appreciation of Calmer's mimicking features, its potential to strengthen the infant-mother bond, and that it looks like a discreet, non-threatening bed. While these themes are important in their own right, they also relate to one another, in some cases by one illustrating an enabling mechanism of another.

For example, the customization of Calmer to each mother-infant team (Theme 1) explains how the stronger connection between the two (Theme 2) would come about. Similarly, Theme 3 (“Just a bed”) reveals Calmer's evident ability to provide a mother “back-up” (Theme 1) while at the same time strengthening her sense of connection to her infant (Theme 2)—achievements that might reasonably be predicted to be contradictory. The answer may lie in Calmer's *unobtrusive and un-robotic* look and unremarkable visual appearance, which allowed mothers, and the staff who advocated for them, to experience the technology without being distracted by it or viewing it as a replacement or competitor of themselves. This gave mothers a safe vantage from which to identify functions and feelings arising from its use, to appreciate them, and most strikingly, to personally identify with or emotionally project themselves into.

DISCUSSION

As we described in detail, the design of Calmer was propelled by several key considerations deriving from the socially and technologically complex context of the NICU. Ultimately, we arrived at a design that worked and effectively held up in a clinical trial. Patents were filed early on in the process and we continue our work towards a commercially available model, and lobbying to change neonatal care-standards. Yet, as straight-forward as this 10-year project may seem, there were various challenges and surprises that we want to reflect on; including certain things we know now because we designed Calmer.

Background and Circumstances that Mattered

The Initial Encounter and its History Mattered

There was not much of an initial ideation on what to design or what form Calmer should have. Instead, in hindsight (and that is why we described it in such detail), the initial

serendipitous encounter of a neonatal pain researcher seeing a fuzzy breathing robot and having the idea we pursued for multiple years was remarkably defining. Her leap of idea-generating creativity was driven by her history – her immersion in and passion about improving preterm infant development by reducing neonatal pain; over her career she repeatedly experienced the devastation of parents each time she had to tell them that their children’s development would not follow a typical course. The coincidence of a haptics researcher focused on breathing creatures, who was willing to join in, was another pair of rare events: researchers often do not have the capacity to jump on others’ ideas. These two people with very different experience and commitment coming together was key to this projects’ success.

Constraint Access and Iterations

Designing Calmer as a clinical device for the NICU environment was challenging in several ways. Overall, it required consistent perseverance, a bit of faith and expert knowledge. Access and iterative design based on feedback on prototypes was impractical and the context and environment had to be treated with extreme caution. As mentioned in the qualitative study’s data collection, the cooperation of users or stakeholders (infants, parents, nurses, and doctors) was often constrained. Infants are in a difficult situation and staff experience stress on a shift-work schedule and could not be interviewed or consulted with after work hours due to union regulations. Hygiene standards are also extremely demanding. Lastly, too many negative reactions to our intervention in the NICU would have easily jettisoned the project. This is due to both the importance of parent-integration, and the fact that adoption of new technology in this technology-heavy environment is viewed extremely critically, especially in the context of maternal roles.

Building a device that a premature, fragile infant with life-threatening conditions can be placed on is a challenge in and of itself. However, a main objective had to be to build a prototype that could eventually be tested in the NICU. Without testing Calmer’s efficacy, it would have no possibility of appearing in clinical practice. Here, only clinical studies are accepted for efficacy testing and it was an important objective for us to complete an RCT. Hence, we had to build prototypes that were safe, highly robust and durable, and conforming to hygiene standards, in order to evaluate them in the NICU with fragile neonates.

In a related way, evaluations of other design prototypes require them to be rather finished and durable. For example and in the context of RtD, Odom et al. [49] describe the concept of *research products*; these are designed to drive a research inquiry, have a high quality of finish so that people engage with them as they are rather than what they might become, they can fit among other things and into everyday environments, and, operate independently over time. The term “emphasizes the actuality of the design artifact helping to overcome the limitations of prototypes when investigating complex matters [...] over time” [49:2550]. We could consider Calmer I as a prototype and Calmer II closer to a research product for our RCT, yet with the significant

difference that the long-term objective remained that Calmer *will become* part of incubator designs in the future.

A Multi-Disciplinary Team with Expert & Tacit Knowledge

Our approach to trying to intervene in this complicated space and place capitalized on team members’ diverse expertise and multidisciplinary experiences (clinical backgrounds or practices, research practice, biomedical engineering, etc.). Hence, stakeholder-input was often covered by our own team members and their experiences. Several members of the design team had extensive experience working in the NICU environment. That gave us expert and tacit knowledge about the intense, demanding, dangerous (life or death) and often emotional and mentally draining environment. It also informed our requirements related to the clinical context and efficacy inquiry. In addition to our team’s expertise, the integration of consulting sessions (informal and formal) with various stakeholders and people who would or could be affected by Calmer was also key to assure interest and potential to test Calmer in the actual environment for which it was being designed.

Various ‘Users’ Experiencing Haptics: An Uncommon Challenge

Lastly, an interesting challenge emerged from designing Calmer in the context of haptics HCI. Considering the initial idea of turning a haptic robotic creature “inside out,” and trying to be considerate of not making parents feel uncomfortable or replaced, the engineering and haptics design people on the team found it a challenge to determine where the user interface was in the design. In engineering, HCI, and specifically haptics research, typically the person one is designing for would be the person who would feel and interact with the haptic features being built [46]. However, in the case of Calmer, the premature infant experiences the haptics features somewhat ‘passively’ with our design feedback being metrics on pain reduction. At the same time, others, in particular parents and staff, experience the device interface more ‘actively’ in a social or workflow sense, yet they do not actually experience its haptic features. This was a challenge unique to this project.

Responsible Mimicking of Human Behavior

Replicating Maternal Skin-to-Skin Holding through Sampling

A key part of the objectives in designing Calmer was to mimic mothers yet also consider their feelings of displacement—in other words, replicating maternal skin-to-skin holding in a conscious, empathic and integrative way.

Although it may seem like an obviously useful solution to make a device that replicates maternal skin-to-skin holding to reduce pain when parents are not available, this was also very much tied to what parents, especially mothers of pre-term infants are often feeling: displaced. We always thought we were walking a very fine line between trying to replicate, yet not replace the human practice of maternal holding.

The surprise to us was that the small *symbolic gesture* of using a mother’s *individual* heart and breathing rate, programmed into Calmer when her infant was lying on it, was so powerful and appreciated by mothers. This *act of*

sampling made them feel that Calmer was extending rather than replacing them. Paying attention to those details, we found, made individual mothers feel supported, even channeled through Calmer rather than supplanted.

No Uncanny Valley with Calmer

The *uncanny valley* describes the unsettling feeling people experience when robots or simulations are very lifelike in many ways yet are not quite convincing [45]. A humanoid object that imperfectly resembles an actual human and its behavior provokes uncanny or strangely familiar feelings of eeriness in people. Although Calmer was perceived as a welcome *back-up* of mothers rather than provoking uncanny feelings, we would not argue that deliberately mimicking pieces of a human, even if done carefully as we did in Calmer, always has a place. Furthermore, in our case the intensity and technology-heavy situation as well as the outcome of neonate pain reduction may also diffuse uncanny feelings that may arise. Parents of infants who are staying in the NICU are biased, one could say forced, towards accepting technology near their infant simply because it increases chance of survival. So, the questions remain unanswered: when is it ok to deliberately mimic aspects of a human? Particularly, in our project, where would we have gone too far? With Calmer, we created a connection without provoking uncanny feelings. Since it is so hard to ‘test’ in the NICU environment, we would not be able to explore this with other more or less mimicking forms of similar devices.

This observation brings to mind other care-giving robots that operate in related situations where technology might offer stress-reducing benefits or functionality usually offered by humans for situations when they cannot be there. Is it ethically marginal to capture an essence of a person but not more? And if so, is it acceptable to do this in a life-or-death situation, but not one less fraught, such as for instance to help a crying, but healthy, baby sleep? Without answering these questions, we want to highlight the ethical ambiguity. We believe Calmer adds an interesting example to this area.

Calmer is Emblematic of its Strategy and Features

Lastly, we want to directly point to how the Calmer project contributes a design case to the HCI community representing a unique, cautious treating and connecting of several of its parts.

Calmer is an exemplar of replicating intimate human behavior and moment that seems nearly un-replicable: a mother holding her prematurely born fragile infant—two humans being in sync. Calmer replicates intimate behavior and data at the core essence of what it means to be human: a mother’s breathing and heartbeat. Yet, if one looks at Calmer one would never assume that but instead sees a form that seems more like *just a bed* or *plastic platform*.

The long-term persistent engagement over 10 years to design Calmer resembles a design strategy that includes cautiously and well-considered contextual, social, and medical ecological needs of the various stakeholders and their situations. Our approach was particularly not to think first ‘to just replicate’ but instead consciously include actions to do it

well. However, the key may not have been the minimalist form aspects, but rather the careful treating and intertwining of all aspects in a conscious and cautious way.

Thus, Calmer serves as an interesting example leading us to think about humans, data streams, form factors, and more as it represents a unique, cautious treating and intertwining of several of its parts: form, computational behavior and actuation, data (flow), stakeholders and a hyper-sensitive and constraint context, and social and ecological considerations around those. In this way, our work contributes rewardingly to HCI research focusing on designing for the NICU and broader hospital context, conscious and empathic automation of human action, and design-led research targeting product development (in a vital context).

CONCLUSION AND FUTURE WORK

In conclusion, the Calmer project serves as an exemplar deriving from a long-term process of designing in a complicated space; it is in itself emblematic of its multi-faceted design strategy. Much was learned from designing this technology. From our reflections we can see how it can inform further work and discussions in haptics research and automating or replicating human actions, NICU design research and beyond. Our work also shows how RtD can play an important role in a vital context – and in this way, Calmer is an RtD exemplar of an innovation targeting commercialization; and we continue to work with this aspiration.

A next version of Calmer?

Ultimately, we hope that the Calmer technology becomes a standard feature of NICU incubators. We are currently working on a *Calmer III* prototype that aims for that vision. We are improving the skin-like material with material science specialists. We will this time make not one but five testable prototypes which will be implemented in a clinical study evaluating long-term stress reduction in neonates receiving Calmer treatment. For this, infants need Calmer available for use 24 hours per day. We are also working on a version of Calmer to work in low resourced countries with constraints like intermittent power and high dust.

Further Clinical Studies: Individuality of Infant Environment

Infants are sensitive and respond differently to the specific environment their mother provides; e.g., early in gestation they respond to their mother’s unique voice and smell [1,41]. It is likely that other intimate aspects of the prenatal experience, such as heartbeat and breathing, are key to the whole to which the infant responds. Although the Calmer platform supports controlled testing of each parameter’s influence, we tested them as a unit in our first RCT to screen for overall effect to avoid a very long delay. Personalized testing is a future goal dependent on expanded recruiting.

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