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Hugsy: A Comforting Solution for Preterm Neonates Designed to Enhance Parent-Child Bonding

Sylvie Claes, Miguel Cabral Guerra, Jiachun Du, Lisa Malou Smits
Department of Industrial Design
Eindhoven University of Technology
Eindhoven, Netherlands
e-mail: {s.claes, m.cabral.guerra, j.du, l.m.smits.1}@student.tue.nl

Deedee Kommers, Sidarto Bambang Oetomo
Neonatal Intensive Care Unit
Maxima Medical Center
Veldhoven, Netherlands
e-mail: {Deedee.Kommers, s.bambangoetomo}@mmc.nl

Abstract— **Premature neonates frequently need to spend several weeks or months in a Neonatal Intensive Care Unit (NICU). These neonates will experience a significant amount of pain, stress and discomfort during their hospital stay due to various medical interventions they will receive ranging from feeding to surgery. Although pharmacological pain treatments are available, often they are not suited for relieving of day-to-day discomfort and pain. Evidence is accumulating in the effectiveness of non-pharmacological interventions to relieve pain and discomfort for premature neonates, for example: kangaroo care, facilitated tucking, and aromatherapy. This paper describes a new non-pharmacological comforting solution that combines various non-pharmacological interventions in a holistic way to provide comfort to neonates. The proposed solution, Hugsy, facilitates kangaroo care moments, and simulates the kangaroo care experience within the incubator by providing the neonate with a parent's unique smell, heartbeat, and feeling of support. We discuss the design and application of the solution, as well as the clinical study conducted with the first prototypes. Results indicate the Hugsy is a promising solution for comforting premature neonates and enhancing parent-child bonding.**

Preterm neonates; comforting solution; bonding; heartbeat; aromatherapy; positioning; swaddling; user-centered design

I. INTRODUCTION

Babies born before the 37th week of gestation are considered to be premature and given less time to develop in the womb. Premature babies often have complicated medical problems, especially those born very early (before 32 weeks), and are usually admitted to a neonatal intensive care unit (NICU) [1]. The NICU provides specialized care for neonates, where they are given various medical treatments and nursed in an incubator [2]. A preterm neonate born before 27 weeks is given a 90 percent chance of survival largely in part due to the advances in neonatal medicine in the last 20 years. However, in the last two decades, long term and short term outcomes for preterm neonates have not improved significantly [3]. Preterm neonates in the NICU experience an abrupt transition from the protected environment of the womb into the exposed environment of the hospital, which poses significant challenges for these infants and manifests in a remarkable amount of pain and stress [4]. In follow up studies it has been found that a large portion of surviving premature babies have developmental impairments later in life. These include cognitive disorders, concentration and behavioral problems, and are partly due to the pain and stress experienced early in life in the NICU environment (painful procedures, excessive noise, and light) [4b]. Masters-level students from the Industrial Design department of the Eindhoven University of Technology collaborated on research efforts with the Maxima Medical Center of Veldhoven in the Netherlands in order to develop a comforting solution aimed at improving long-term and short-term outcomes of preterm neonates in intensive care. This paper presents in-depth the design, application, and evaluation of a novel solution designed for use in NICU's to comfort preterm neonates.

A. Sources of Pain and Stress for Preterm Neonates

Pain will be a common experience among all preterm neonates receiving intensive care, and it is one of the major sources of stress for these infants. The necessary medical interventions that cause pain can elicit mild to severe stress responses in preterm neonates. Some of these medical interventions include: insertion of nasogastric tubing (mild), heel stick blood sampling (moderate), and lumbar puncture (severe) [5]. Furthermore, preterm neonates have extremely sensitive and thin skin, and therefore the attachment and removal of adhesive electrodes for monitoring can also be painful as well as skin touch in general [6]. Current treatment for pain is commonly analgesia with opiates, although large portions of procedures occur without any pain treatment [2]. Due to current treatments for pain being in the form of analgesia and opiates, it is interesting to explore other pain management methods that do not involve drug administration.

Preterm neonates are born at a critical point for their auditory brain development, and the exposed environment of the NICU can be especially damaging, as the child leaves the protected auditory nursery that is provided by the

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mother's womb. NICU babies are overexposed to unpredictable environmental noise that can be loud and toxic such as: human voices, telephones, pagers, alarms, ventilators, infusion pumps, etc. Simultaneously, these babies are deprived of the biologically familiar, low frequency, and patterned maternal sounds such as voice and heartbeat heard in utero. The exposure to unpredictable environmental noise of the hospital can have damaging neuropathological consequences, and can compromise auditory brain development. Appropriate acoustic stimulation is crucial early in life for proper brain development, as has been shown through various animal studies. Evidence suggests acoustic stimulation in the form of mother's voice and heartbeat can pave neural pathways in the brain for the development of hearing and language skills, and increase sensitivity in the primary auditory cortex. Furthermore, auditory enrichment can also improve auditory recognition and discrimination abilities. Therefore, it can be suggested that exposing preterm neonates to biologically familiar sounds can provide them with a sensory experience that can play an important role in negating the effects of toxic hospital environmental noise on brain development [4].

B. Preterm Neonate Response to Pain and Stress

The effects of pain and stress in preterm neonates are manifested in various different responses of a physiological, neuropathological, and behavioral nature. Acute physiological responses include: apnea and bradycardia (cardiorespiratory events - CRE's), and increased heart rate and blood pressure [7]. Neuropathological consequences include: reduction in regional brain volumes, white matter microstructural abnormalities, and poor cognitive and language outcomes [4]. Finally, behavioral responses include: vocalizations like crying and gasping, increased wakefulness, grimacing with eyes squeezed shut, a stretched open mouth, fisting and toe clenching. Facial expression are considered one of the more reliable and consistent ways of assessing pain levels as it is a result of autonomic control [8].

In terms of physiological responses, severe CRE's in particular have been found to decrease cerebral blood flow, and may contribute to less optimal brain development. Therefore attempts should be made to reduce the occurrence of CRE's during NICU hospitalization in order to improve the long-term outcomes of the neonate. A growing field of research suggests that postnatal cardiorespiratory regulation is highly affected by environmental factors, particularly noise. Recent studies have demonstrated that extremely premature infants exposed to maternal sounds after birth had improved short-term cardiorespiratory regulation. Although the research in this field is ongoing, it is becoming evident that non-invasive and non-pharmacological strategies could have a huge impact for preterm neonates alongside medical therapies [7].

Finally, separation from the mother after birth also factors in with the neonate's ability to cope with pain and stress. It is standard medical practice in the western world to separate the neonate from his mother after birth, and is even more applicable for preterm neonates who need to be cared for in an incubator. The physiological stress response of neonates is coordinated by the autonomic nervous system, and heart rate variability (HRV) as a means of measuring autonomic nervous system activity. The HRV of a neonate is influenced by level of arousal, and is most accurately quantified during sleep. For optimal early brain development of the neonate, sleep is essential. Studies have found that maternal-neonate separation has been linked to a dramatically increased HRV power, and suggests central anxious autonomic arousal. Furthermore, this separation was found to have a negative impact on duration of quiet sleep. Therefore, maternal-neonate separation has been found to have a profound impact on the neonate, and is a major physiological stressor for the infant [9].

C. Reducing Pain and Stress for Preterm Neonates

There can be dire consequences of leaving procedural pain in neonates untreated, as being exposed to pain early in life can have a long term effects on how the body biochemically responds to pain and stress later in life [8]. With the most popular form of pain management being pharmacological, there are also various effective non-pharmacological methods for providing pain relief and comfort that are interesting to explore further due to their applications in the field of product design. Non-pharmacological solutions could finally offer some improvement in long term and short come outcomes for preterm neonates. Popular non-pharmacological pain management techniques that have been proven effective are kangaroo care (also known as skin-to-skin care), positioning techniques, non-nutritive sucking, and swaddling or facilitated tucking. Other techniques showing promise are providing the preterm neonate with maternal stimuli such as audible heartbeat or voice as well as smell of the mother as a form of aromatherapy [12].

Kangaroo care (KC), has been widely accepted and researched as a beneficial practice for preterm neonates. In KC the neonate is held upright and in skin-to-skin contact with the breast of the mother. This practice is commonly done with mother and baby, but can also be practiced between father and baby. Babies who have been provided this skin-to-skin contact with their mother have been found to have significantly lower instances of severe illness (specifically CRE's). These babies breastfeed more easily, have a shorter incubator stay, are discharged earlier from the hospital, have improved growth versus their non KC counterparts, and in general have a more stable condition (regular heart rate, stable temperature, and periodic breathing) [10]. Although this technique has been widely researched and its many benefits proven, the difficulty with this technique is that a parent needs to be present to provide

this care to their baby. It is often impossible for parents to be present 24/7 in the NICU (often due to lack of time because of their work, or other children to care for), and to provide KC continuously for extended periods of time. This makes providing maternal stimuli to the neonate through audible voice, heartbeat, or aromatherapy an interesting alternative to KC in order to continue to provide the benefits of KC to the preterm neonate in the incubator.

Facilitated tucking utilizes touch and positioning in order to alleviate pain for preterm neonates. This is done by a parent or nurse holding the baby in a side lying, flexed fetal position, giving him the ability to control his own body, and thus increasing his ability to control pain. By adding skin contact and postural support, a synergistic effect on pain control happens as a result [11]. Restricting movement of the neonate through swaddling has also been proven effective in reducing stress elicited by pain by mimicking the in utero experience. The side lying position with arms and legs flexed is common in mimicking in utero positioning, and can be created by rolling a blanket for containment [12]. Positioning can also be useful in bringing a neonate's hands to his mouth for non-nutritive sucking to create a pacifying effect that can relieve pain during stressful procedures [12].

Due to the fact that NICU nurses will often have multiple patients to care for at a time, and that parents cannot always be present to perform KC, it is interesting to explore how these effective comforting remedies described above can be provided to preterm neonates in the NICU through a designed solution that does not require the continued presence of a nurse or parent. This paper presents a new solution designed to promote comfort and provide the sense of maternal presence to preterm neonates in order to help reduce pain and stress in the NICU and aid in improving long-term and short-term outcomes for these neonates. This new solution utilizes maternal stimuli from the mother delivered to the baby during KC sessions together with positioning and swaddling techniques in order to soothe and comfort preterm neonates receiving incubator care and medical procedures in the NICU. The following sections of this paper will describe the designed solution in greater detail, as well as a clinical study in order to evaluate the prototypes of the proposed solution. Finally the implications and future steps of the proposed solution are discussed based on findings from the clinical study.

II. CONCEPT

Aside from in-depth literature reviews, the proposed solution was also based on extensive user testing and studies within the NICU context. This allowed a deep understanding of key stakeholders affected by the design, as well as an understanding of how the design should fit into the NICU context.

A. Key Stakeholders

When designing for this context, understanding the users is of key importance to developing a fitting solution. What is difficult in this context is that the end-users are neonates, who cannot communicate their thoughts or feelings to be involved in the design process. However, there are many other key stakeholders who are very valuable sources of information, namely nurses, neonatologists, and parents of neonates on the unit. Therefore, interviews and observations were conducted with these stakeholders in order to gain deeper insights into the NICU context, and co-create the proposed solution together. The following paragraphs describe these stakeholder insights and their influence in the proposed solution.

B. Current Situation

The NICU ward typically has at least several incubators, which usually have a covering to shield light from entering. The incubator creates a safe and stable environment for the neonate by controlling the temperature and humidity and protecting the neonate from airborne irritants and noise. These babies need constant physiological monitoring, and are therefore attached to many sensors. Using various weighted pillows and textiles; babies are positioned in an optimal way to provide comfort to the mind and body. Plush toys are sometimes also placed within the incubator for comforting purposes, and to allow parents to bond with their baby by sharing something personal. With positioning tools and plush toys being commonplace in most incubators, this can create the opportunity for these tools to integrate with new designed comforting methods.

C. Comforting Methods

Neonates can be comforted either by providing a comforting treatment, or by eliminating sources of discomfort. With the latter, some hospitals will focus on eliminating or dampening loud noises (alarms, pagers, etc.), reducing bright lighting within the NICU, and limiting movement out of the incubator only for medical procedures. Other hospitals focus on providing comforting treatment to newborns. For example, at the Maxima Medical Center in Veldhoven, emphasis is placed on parent-child bonding as an active source of comfort. In this unit, parents are allowed to visit their child at any time, and are encouraged to take part in the care of their baby. This can be for example diaper changing, or bottle-feeding. This also creates a situation in which the parents feel empowered that they can be part of their child's care, which is often difficult when the baby needs to be in the hospital. Hospitals like the Maxima Medical Center promote kangaroo care as an important part of the baby's comfort and parent-child bonding, and believe babies are most relaxed during this type of care. These babies are then often taken out of the incubator twice a day when parents visit to be laid on the chest of their parent for several hours. However, moving the baby in and out the incubator is considered by nurses to sometimes be a difficult

task, due to needing to relocate the child together with many tubes and monitoring cables in a safe way, and also keeping the baby comfortable. When being taken from the warm environment of the incubator to the cold environment of the hospital room, babies typically suffer from cold stress, exhibiting physiological stress responses. When laid onto the parental chest, typically some adjusting takes place to get the baby in a comfortable position, and the parent and baby are usually covered by a blanket in order to stay warm and hold the baby in place.

It is apparent that parents play a crucial role in the comforting of their child, however, parents cannot always be present in the hospital to provide this comfort. In all hospitals, it is becoming clear that there are situations when alternative forms of comforting are required when parents cannot be present. Due to the proven health benefits for neonates to have skin to skin contact with their parents, an alternative comforting method which simulates this parental contact seems fitting for improving the comfort and care for neonates in the NICU.

D. Concept

Based on the literature review, user studies, and many brainstorms and iterations developed with user feedback, we came to the concept called Hugsy. Hugsy facilitates and simulates KC for babies in the NICU. Hugsy allows babies to be comfortably transferred out of the incubator to their parents and held on the parental chest, while also being able to be used within the incubator to simulate the comforting experience of being held by a parent. The reason for the dual functionality of simulation and facilitation is that the design team felt it was not possible to create a solution that could be as good as the real parent. Therefore, a combination of simulation of KC together with facilitating the real KC seemed to be a fitting solution.

Figure 1 Hugsy comfort set prototype. Hugsy swaddling blanket (in center), side-positioning pillows (left and right side), foot positioning pillow (bottom left), Hugsy heartbeat recording and playback module (bottom right).

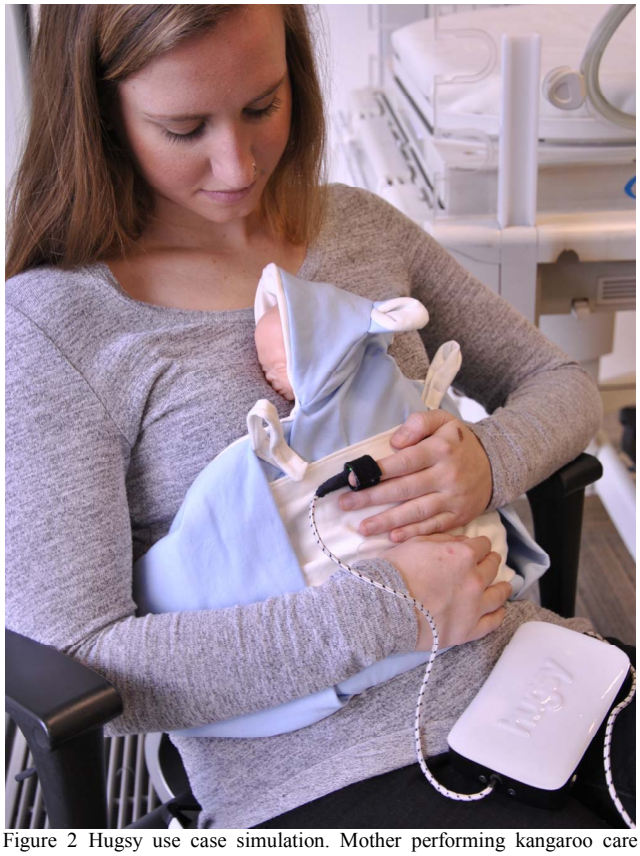

Figure 2 Hugsy use case simulation. Mother performing kangaroo care wearing Hugsy blanket, while recording heartbeat using heartbeat module.

E. Hugsy Use-Case

Hugsy aims to create a care situation within the incubator that simulates the feeling of being held closely to a parent's chest, and captures the parental stimuli by being used as a tool during KC sessions with the parent. Hugsy is therefore comprised of a set of comforting tools - a swaddling blanket, positioning pillows, and a heartbeat recording and playback module. Hugsy facilitates KC by using the swaddling blanket to swaddle the baby for comfortable transfers in and out of the incubator, thereby during these transfers the baby is kept warm and in a secure position. When on the parental chest, the swaddling blanket can be opened, and used as a carrier/wrap to hold the baby comfortably against the parental chest. By using the swaddling blanket also as a carrier/wrap, the parental scent gets absorbed into the fabric of the blanket during the KC session. During this session, the heartbeat module is used to record the unique parental heartbeat using a pulse sensor. After the KC session ends, the baby is swaddled again in the blanket to be taken back to the incubator. Within the incubator, the swaddling blanket can be manipulated in multiple ways in order to bring the baby into a womb-like position, aided by the positioning pillows, to bring comfort to the baby's mind and body. The playback speaker of the heartbeat module can then gently be placed underneath the baby, and switched on to begin playing back the recorded

parental heartbeat - the speaker has a thin oscillating membrane that provides a gentle vibration and heartbeat sound to the baby. Thereby, the baby is comforted by the parental smell captured in the blanket, the playback of the parental heartbeat, and the positioning methods that simulate the in utero experience. The design is a combination of multiple non-pharmacological modalities that have been described in literature - skin to skin contact, swaddling, facilitated tucking, providing of heartbeat vibration and/or sound, and aromatherapy.

F. Stakeholder Benefits

The solution takes into account the multiple stakeholders involved in a baby's NICU stay. Firstly, the solution takes into account the baby's comfort level and physiological stability, which is the main purpose of the design. Secondly, Hugsy aids nurses in transferring babies from the incubator to make this process feel more secure for the nurse, as transferring the baby can sometimes create a stressful situation. Thirdly, parents can feel more confident and supported holding their baby with the support of the Hugsy during KC sessions. Within the incubator, the positioning options provided by the Hugsy aids nurses in providing care moments to the child and keeping the baby in an optimal position, particularly during stressful/painful care moments. Finally, this solution takes the parents emotional well being into account. The design team discovered how difficult it can be for parents to have to leave their child in the hospital when they need to go home. With Hugsy, parents can feel that they have contributed something to the care of their child to temporarily replace them when they cannot be there. This helps parents have less stress when leaving the hospital so that they can take care of important matters.

III. PROTOTYPE

A requirement for the Hugsy comforting set was that it should easily integrate into the NICU context, without creating extra effort from nurses or parents. The system should be easy to setup and use, and seamlessly integrate into existing routines. A swaddling/positioning tool to provide the simulation of the parent was therefore very appropriate, as hospitals are already currently using similar products, and therefore are familiar and comfortable with them. This also ensures the incubator is not filled with extra bulky equipment. The prototype was designed according to hospital protocols for washing and clinical safety.

Swaddling Blanket: The Hugsy swaddling blanket is a cotton polyester blend baby jogging fabric. The blanket has two 'arms' and a foot flap, which can be closed around the baby to create the swaddle. The arms can also be rolled or tucked around the baby to create support structures. The swaddling blanket also has a hood for the baby, used to keep cold draft away from the baby's head during KC. The hood has two ears on top, giving the blanket an animal-like appearance. There is no functional purpose to the ears; the blanket was given this cute appearance to put parents at ease seeing their child in a medical context. The blanket has two 'fixing loops' to secure the baby's tubes and wires. The KC support strap that is made from Lycra loops through the arms, and is used to wrap around the mother during KC. At the back of the blanket is a small pocket for placing the heartbeat playback speaker. The blanket is completely washable at 60 degrees.

Positioning Pillows: The Hugsy has three positioning pillows, which are weighted. The weight is created using polyethylene beads, which are encased in a cotton polyester blend baby jogging fabric. Two of the pillows are a long rectangular shape, and used to give support to the sides of the baby. One pillow is U shaped, used to give support at the baby's feet. The positioning pillows are washable at 60 degrees.

Heartbeat recorder and playback module: The heartbeat recorder and playback module is a rectangular shape with curved edges and houses the electronics. The housing was made by 3D printing using laser sintering, together with a vacuum formed plastic outer shell. The electronics consist of an Arduino FX soundboard, an Arduino Mini Pro, an amplifier, speaker, and pulse sensor. A heartbeat sensor (photoplethysmograph) is attached with a connection cable at one side of the box, and the speaker is attached with a

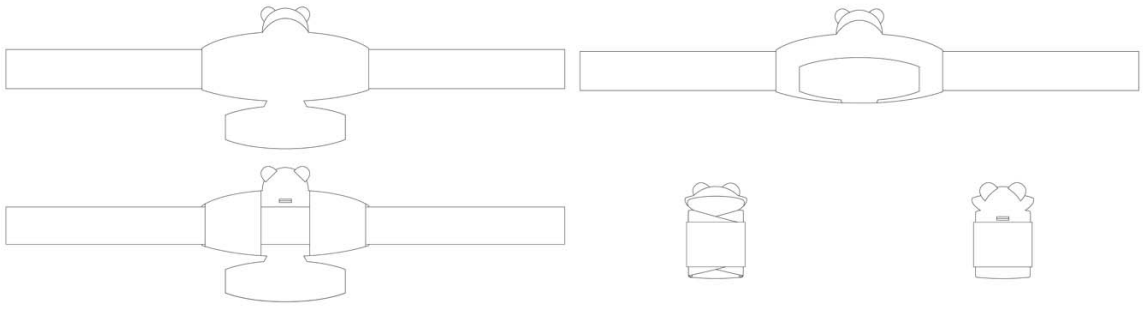

Figure 3 Technical drawings Hugsy swaddling blanket. Top left: Blanket open front, bottom left: blanket open back, top right: blanket open front with foot flap closed, bottom right: blanket closed front (left) and back (right) view.

connection cable at the other side of the box. LED indicators shine through the vacuum formed covering to indicate ON/OFF (green light), or PLAY/RECORD mode (green/red light). The module has two switches, one for turning the module on and off, and one for switching between play and record modes. The heartbeat sensor used is a photoplethysmograph, an optical sensor used to measure a pulse. The photoplethysmograph can detect variations in blood volume within tissues using a light source and detector. With change in blood volume being synchronous to the heartbeat, this method can be used to calculate the heart rate [13].

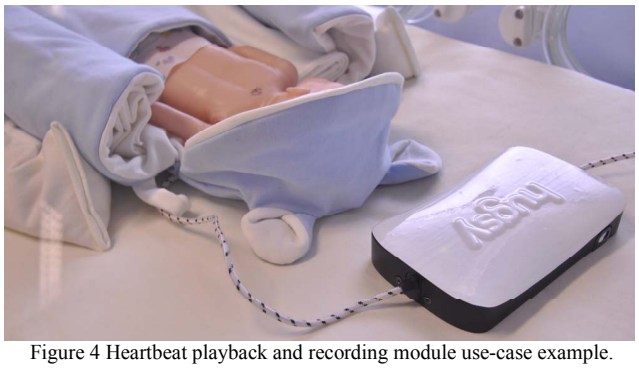

Figure 4 Heartbeat playback and recording module use-case example.

IV. CLINICAL STUDY

In order to test the viability of the Hugsy concept, a clinical study was conducted with the first prototypes. This study consisted of both a quantitative and qualitative analysis, of which the latter will be presented in this paper. Such a qualitative analysis does not indicate the physiological responses of the child, but it does provide an overview of the perceptions of the most important stakeholders.


Figure 5 First clinical trial patient swaddled in Hugsy inside the incubator.

A. Methodology

Hugsy was used in participants that were enrolled in a prospective observational study by signing an informed consent form. The medical ethical committee of the MMC approved this study.

Study Population: Twenty preterm infants were observed with a mean gestational age of 28 weeks + 4 days, and birth weight of 1082 gr. The average postmenstrual age during the study was 30 – 31 + 4 weeks. Exclusion criteria were mechanical ventilation, a current infection, a congenital anomaly or a severe brain pathology (periventricular leukomalacia or intraventricular hemorrhage grade III/IV). All patients were given twelve feeds a day with total volume of 140-160 ml/kg/day. Their cardiorespiratory conditions were stable, despite occasional bradycardias and desaturations.

Study Design: In this study we asked nurses and the parents to observe babies using Hugsy for eight days. In addition, for the quantitative analysis the routinely monitored COMFORTNeo scores [14] and ECG-data of those eight days were used. Four out of the eight days Hugsy was used during KC to capture the scent, warmth, and heartbeat of the parent, and placed in the incubator with the patient. The other four days the baby served as its own control by using the Hugsy in the incubator as a 'normal' incubator blanket. To eliminate the effect of maturation, the study design was as follows:

- 2 days with Hugsy (parental heartbeat, scent and warmth in incubator)
- 2 control days
- 2 days with Hugsy (parental heartbeat, scent and warmth in incubator)
- 2 control days

Additionally, parents and nurses were asked for their experiences of using the Hugsy in unstructured interviews.

B. Results

Follow up was done with nurses and parents to gather qualitative data that consisted of their observations and experiences using the Hugsy. Overall feedback on the Hugsy has been very enthusiastic, with some suggestions for improvements as well. Several mothers felt less sad to leave their baby behind when they had to leave the hospital. One mother of twins chose for her smallest baby to take part in the Hugsy trial first, since she thought this baby could use a little bit more support. She felt Hugsy was very comfortable to wear during KC, and thought it had a very cute appearance that put her at ease. She felt very strongly about having her maternal scent and heartbeat in the incubator with her little one, and really felt it would be helpful for the development of her baby. Another mother in the trial noted, "I thought the Hugsy was great, even though I couldn't always be there, my daughter could always have the feeling I was nearby. I noticed my daughter really came to be relaxed when using Hugsy."

Nurses were overall positive about the Hugsy, they felt it had more to offer than a standard incubator blanket and a very cute appearance. Moreover, they complimented its warmth, especially during transfers from the incubator and after KC when going back into the incubator, noting that these transfers usually represent a very stressful moment for neonates due to cold stress, and Hugsy aided in reducing

that stress point. Aside from the positive feedback about the heartbeat and maternal scent in the incubator, they really felt the Hugsy created a little supportive "nest" for the baby. One nurse said, "Hugsy is warm and protective during care moments. If I am washing the upper body, the Hugsy blanket can be used to support the lower body, and vice versa." Another nurse said, "A very smart creation for diverse positioning possibilities and temperature wishes, and then on top a friendly/likeable appearance!"

In addition, one nurse said that the patient she was caring for was "addicted" to Hugsy. That neonate had been in distress since birth, crying often, unable to be soothed. When using the Hugsy, the parents of this neonate stated they had never seen their child in such a relaxed state. They shared the nurses joke about their baby being "addicted" to the Hugsy, as whenever the Hugsy was taken away the baby came to an agitated state. Two babies showed increased fussiness when using the Hugsy, due to hyperthermia. This was resolved after adjusting the positioning of the cloth, enabling better temperature regulation. Temperature regulation was demonstrated to be an opportunity for improvement. Despite that, nurses indicated that they noticed a positive different in the comfort of their patients when using Hugsy compared to the standard incubator blanket. Differences in comfort are routinely registered using the COMFORTNeo score in the MMC. In addition to the ECG-analysis, results of the COMFORTNeo scores will be presented elsewhere.

V. DISCUSSION

This paper described in-depth the design, application, and evaluation of Hugsy, a solution designed to provide comfort to premature babies by creating a care situation that simulates parental contact. The Hugsy comfort set utilizes multiple non-pharmacological comforting techniques combined in one solution - skin to skin contact, swaddling, facilitated tucking, audible heartbeat, and aromatherapy.

The Hugsy consists of 3 parts, which make up the comfort set: a swaddling blanket, positioning pillows, and a heartbeat recording and playback module. The swaddling blanket can be used for swaddling and transferring the baby from the incubator, as well as on the parental chest for support during KC. Inside the incubator, the blanket can be used for supportive positioning and warmth, and providing the parental smell to the baby captured in the fabric. The positioning pillows aid in giving the feeling of support to the baby in the incubator. The heartbeat recording and playback module is used to record the parental heartbeat during kangaroo care, and playback the heartbeat to the baby inside the incubator.

Hugsy was evaluated in a qualitative clinical study. The study showed that the possibilities for temperature regulation while using Hugsy could be fine-tuned, but other than that there were no negative effects of the Hugsy on the neonates. Moreover, parents and nurses indicated that the Hugsy can have a positive effect on the comfort of the neonate. For practical reasons, nurses strongly suggested attaching all Hugsy parts to one another and creating Hugsy in a range of sizes, particularly smaller sizes for the youngest of premature infants, and larger sizes for more developed infants. This will be taken into account for future studies.

As the Hugsy is developed further, more trials can be completed at various hospitals to gain statistically significant data about the effect of the Hugsy on premature infants. In addition to the comfort on Hugsy-days versus control days, the physiological effects of Hugsy during transfers from the incubator to the chest and vice versa will be investigated in the quantitative analysis of this study using ECG-data. Those data provide insight into the behavior of the neonatal heart, reflecting differences in autonomic regulation. In a previous study, we used ECG-data to track changes in autonomic regulation across periods of KC and quantitatively established states of increased comfort [15].

VI. LIMITATIONS

This paper presents and evaluates only a qualitative clinical study of the proposed solution Hugsy from a technical perspective. The quantitative results will be presented elsewhere, and will give an indication into the accuracy of the proposed solution in simulating KC. These quantitative results include physiological responses of neonates using Hugsy evaluated using the COMFORTNeo Scale, and analysis of ECG-data. The aim of this paper was not to evaluate the accuracy of the proposed solution in simulating kangaroo care, but rather to outline and investigate the design and application of a novel comforting solution for preterm neonates. A paper presenting the design, application, and qualitative evaluation of the proposed solution was chosen for in order to provide background to the design and application of novel comforting solutions for preterm neonates, and acceptance of these solutions within the NICU context. As the sample size of the first study is a limitation in gaining statistically significant data, more trials will be completed at various hospitals, where more extensive quantitative and qualitative data will be collected. Next to COMFORTNeo Scores and ECG-data, other quantitative metrics for future trials are currently being investigated: growth rate, duration of hospital stay, intake of milk, duration of KC, alarm logging, and quality of movements. The objective of future trials will be to demonstrate whether comforting tools that simulate the KC experience have a positive effect on various patient outcomes.

Further, there are three elements to the Hugsy that need to be evaluated – smell, heartbeat, and giving of support. In this study these elements were evaluated in combination with one another. In future trials, these elements should also be evaluated independently to determine the efficacy of each.

VII. Conclusion

The team designed and implemented a new comforting solution for premature neonates that simulates and facilitates KC. Hugsy supports parents and their baby during KC sessions, and aims to simulate this experience within the incubator for the neonate when parents cannot be present. In a qualitative clinical study, parents and nurses were very enthusiastic about the proposed solution, and thought it was a promising concept, which could both comfort neonates and enhance parent-child bonding.

VIII. Acknowledgments

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