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DESIGN AND DEVELOP BREAST MASSAGE DEVICE FOR POST-NATAL MOTHERS WITH BREAST ENGORGEMENT ADMITTED IN TERTIARY CARE HOSPITAL: A DELPHI STUDY

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ABSTRACT

Introduction: Breast engorgement is a common and distressing condition among postnatal mothers, particularly during the early postpartum period, causing pain, discomfort, and difficulty in breastfeeding. Inadequate management may lead to complications such as mastitis and decreased milk supply. Conventional methods often rely on proper technique and provide inconsistent relief, highlighting the need for a standardized and user-friendly intervention.

Methods: A research and development design was employed to develop and evaluate a breast massage device for managing breast engorgement. The device was designed and validated using the Delphi technique through multiple rounds of expert review. The study was conducted among postnatal mothers in a tertiary care hospital in Navi Mumbai using non-probability sampling. Data were collected using a demographic proforma, a checklist of existing practices, the Visual Analog Scale (VAS) for pain assessment, and a breast engorgement scale. The effectiveness of the device, incorporating controlled heat and gentle vibration, was evaluated through pre- and post-intervention comparisons using appropriate statistical methods.

Results: The findings revealed a high prevalence of breast engorgement among participants. The device demonstrated strong content validity based on expert consensus. A statistically significant reduction in pain and engorgement levels was observed following the intervention. Additionally, the device was found to be feasible and well accepted by postnatal mothers.

Discussion: The breast massage device proved to be an effective, safe, and non-invasive intervention for managing breast engorgement. It provides a standardized approach that enhances maternal comfort and promotes effective breastfeeding. Further studies with larger sample sizes are recommended to improve generalizability.

KEYWORDS: Breast engorgement, breast massage device, postnatal mothers, Delphi technique, pain, breastfeeding.

INTRODUCTION

Breastfeeding is the optimal source of nutrition for infants and provides substantial health benefits for both mothers and babies. The World Health Organization recommends initiating breastfeeding within one hour of birth, exclusive breastfeeding for the first six months, and continued breastfeeding along with complementary feeding up to two years or beyond.[1] Despite these recommendations, many mothers experience challenges during the early postpartum period, with breast engorgement being one of the most common and distressing conditions.

Breast engorgement usually occurs between the second and fifth postpartum day due to inadequate milk removal, resulting in breast pain, swelling, firmness, and difficulty in breastfeeding. If left unmanaged, it may lead to complications such as blocked milk ducts, mastitis, reduced milk supply, and early discontinuation of breastfeeding. Studies report that approximately 60–75% of breastfeeding mothers experience breast engorgement during the early postpartum period.[2]

Current management strategies include warm or cold compresses, manual breast massage, breast milk expression, and other supportive measures. However, these interventions often provide inconsistent relief and largely depend on proper technique, repeated application, and professional guidance.[3] Moreover, there is limited evidence supporting the superiority of existing interventions, highlighting the need for standardized and evidence-based approaches.

NEED OF THE STUDY

Although breast massage is commonly recommended to improve milk flow and relieve engorgement, manual techniques are often difficult to perform consistently and effectively[6]. At present, there is a lack of a standardized, user-friendly breast massage device specifically designed to manage breast engorgement. Developing a device that combines controlled heat and gentle vibration may provide a safe, consistent, and practical intervention for breastfeeding mothers[10]. Expert validation is essential to ensure that the device is clinically relevant, safe, feasible, and acceptable before clinical evaluation.

AIM OF THE STUDY

To design and develop a breast massage device for the management of breast engorgement among postnatal mothers using the Delphi technique.

OBJECTIVES

1. To study the prevalence of breast engorgement among post-natal mothers.
2. To assess the existing practices for management of breast engorgement and improving breast milk secretion.
3. To design, develop, and validate a breast massage device for the management of breast engorgement using the Delphi technique.

MATERIALS AND METHODS

Materials and Methods

A research and development (R&D) design was adopted to design and develop a breast massage device for the management of breast engorgement among postnatal mothers. The development process included an extensive literature review, identification of clinical requirements, conceptualization of the device, prototype development, and iterative refinement. The device was designed to incorporate controlled heat and gentle vibration with an ergonomic wearable cup, adjustable temperature settings, rechargeable power source, safety cut-off mechanism, and skin-friendly materials to facilitate milk flow and improve maternal comfort. The prototype was evaluated using the Delphi technique by a multidisciplinary panel of experts comprising lactation consultants, obstetric nursing experts, paediatric nursing experts, and biomedical professionals. Expert opinions regarding the design, functionality, ergonomics, safety, usability, and clinical applicability of the device were obtained through structured Delphi rounds, and modifications were incorporated after each round until consensus was achieved. Descriptive statistics were used to summarize expert responses, and the Item-level Content Validity Index (I-CVI) was calculated to determine agreement for individual components.

RESULTS

For tabulation and statistical analysis, the data was first obtained using a quantitative data collection method. The data analysis is arranged and displayed under the subsequent parts.

The breast massage device was developed through a systematic research and development process involving literature review, identification of user requirements, conceptual design, prototype fabrication, and expert consultation. The device was designed as a wearable breast cup incorporating controlled heat and gentle vibration to facilitate milk flow and relieve breast discomfort. The prototype consisted of an ergonomic breast cup, adjustable temperature regulator, vibration module, rechargeable battery, waterproof insulation, safety cut-off mechanism, and skin-friendly inner lining, making it suitable for both hospital and home use.

- **Analysis of Prevalence of Breast Engorgement among Postnatal Mothers**

Demographic variables of postnatal mothers shows the distribution of participants based on selected variables. Most of the mothers, 207 (58.3%), were multigravida, while 148 (41.7%) were primigravida. The majority, 221 (62.3%), were in the 20–30 years age group, followed by 134 (37.7%) in the 31–40 years group. Regarding education, the highest proportion, 108 (30.4%), had completed HSC, followed by 101 (28.5%) in the others category, 74 (20.8%) graduates, and 72 (20.3%) with SSC education. In terms of type of delivery, 181 (51.0%) underwent caesarean section, while 174 (49.0%) had normal vaginal delivery, indicating a nearly equal distribution.

n=355

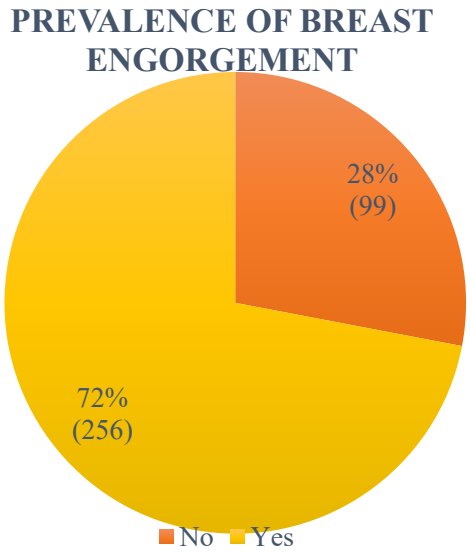

Figure 1- Prevalence of Breast Engorgement

Figure 1 reveal that 72% (254) of the participants experienced breast engorgement, whereas 28% (101) did not experience breast engorgement.

Distribution of mothers based on prevalence of level of pain
n=254

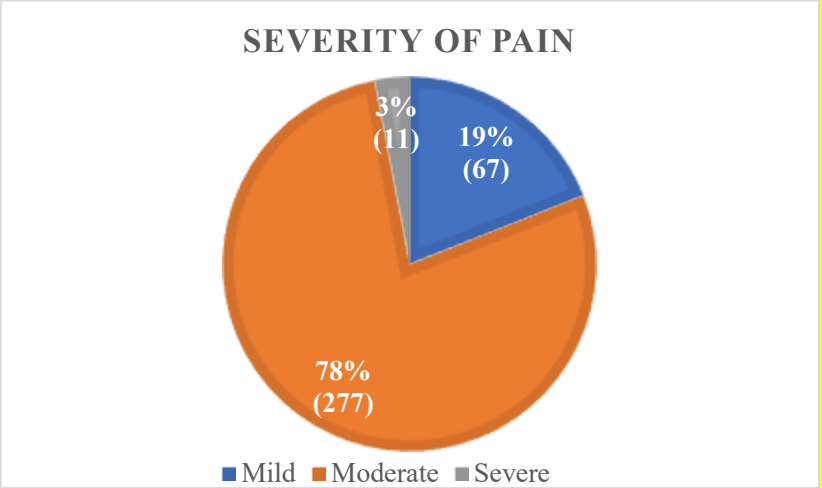

Figure 2- Level of Pain of post-natal mothers

Figure 2 illustrates the distribution of postnatal mothers according to the severity of pain experienced. It is evident that the majority of mothers (78%) experienced moderate pain, indicating that pain of moderate intensity is the most common during the postnatal period. A smaller proportion of mothers, 19%, reported mild pain, suggesting that fewer mothers experienced only minimal discomfort. In contrast, only 3% of the mothers experienced severe pain, showing that extreme pain is relatively uncommon among the study population.

Analysis of the existing practices of postnatal mother's regarding breast engorgement.
Existing practices of postnatal mother's regarding breast engorgement explains that distribution of practices followed by postnatal mothers for the management of breast engorgement. It is observed that less than half of the mothers followed recommended practices across most domains. Among breastfeeding practices, only 45.07% (160) included nighttime feeds, and 40.85% (145) maintained regular breastfeeding sessions, while practices such as proper latching 36.62% (130) and milk expression 35.21% (125) were less commonly followed. In terms of physiological well-being, 47.04% (167) of mothers routinely assessed breast conditions, and 43.66% (155) took preventive steps to avoid nipple damage. Regarding specific management practices, 42.82% (152) practiced breast massage, while fewer used warm compresses 41.69% (148) and cold compresses 38.03% (135). Supportive practices such as wearing a well-fitting bra 46.48% (165) and maintaining hydration and nutrition 49.30% (175) were followed by relatively higher proportions. However, only 39.44% (140) sought professional help when needed.

- **Analysis of demographic variables of Delphi experts**

A total of 50 multidisciplinary experts participated in the Delphi process. The majority were Lactation Consultants (55.56%), followed by experts with M.Sc. Obstetrics (22.22%), while M.Sc. Paediatrics and Biomedical/Technical experts each constituted 11.11% of the panel. Regarding designation, Assistant Professors (23.33%) formed the largest group, followed by Associate Professors (18.33%), Junior Residents (16.67%), Lactation Therapists (16.67%), Engineers (13.33%), and Professors/Heads of Department (11.67%). Most experts (40%) had 5–10 years of professional experience.
n=50

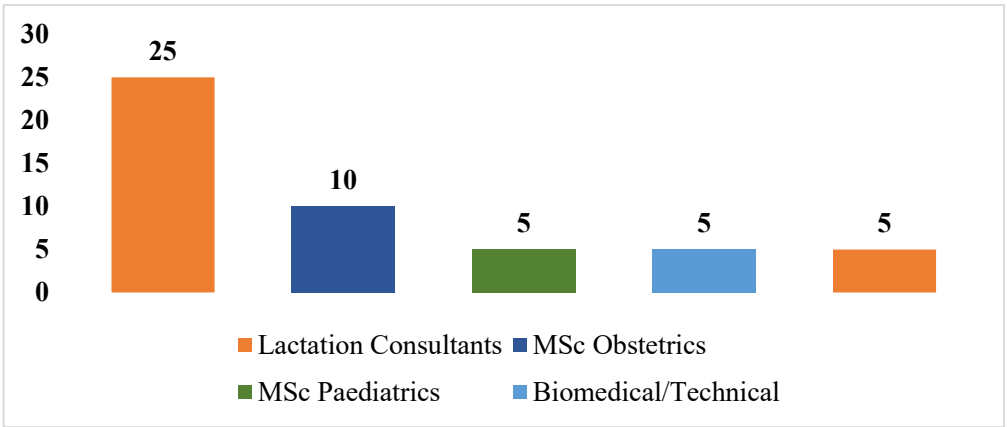

Figure 3- Qualification of Delphi Experts

Figure 3 illustrates the distribution of experts based on their qualifications. The highest number of experts, 25 (55.56%), are Lactation Consultants, indicating that most of the panel has specialized expertise in breastfeeding and lactation management. This is followed by 10 (22.22%) experts with MSc in Obstetrics, contributing strong clinical knowledge in maternal care. A smaller proportion of experts, 5 (11.11%) each, belong to MSc Paediatrics and Biomedical/Technical backgrounds, showing the inclusion of multidisciplinary perspectives.

n=50

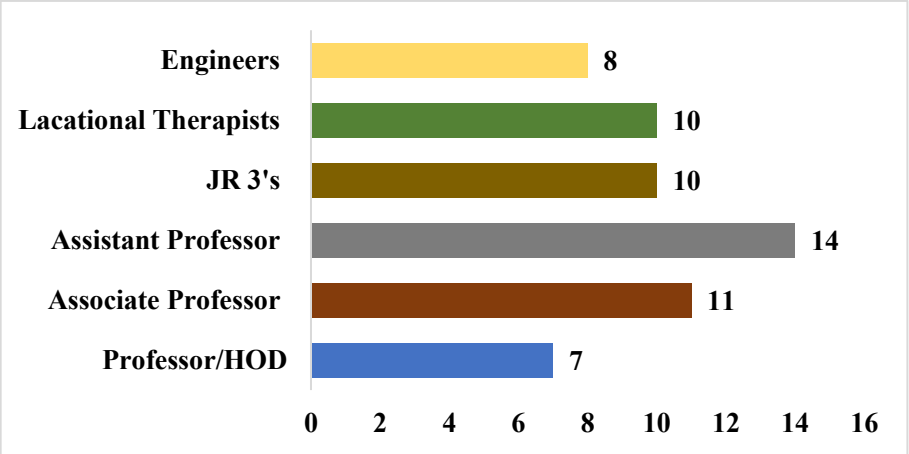

Figure 4- Designation of Delphi Experts

Figure 4 shows the distribution of experts according to their designation. The highest number of experts, 14 (23.33%), are Assistant Professors, indicating strong representation from mid-level academic professionals. This is followed by 11 (18.33%) Associate Professors and 10 (16.67%) Junior Residents (JR 3's) as well as 10 (16.67%) Lactation Therapists, showing a balanced contribution from both teaching faculty and clinical practitioners. A smaller proportion includes 8 (13.33%) Engineers and 7 (11.67%) Professors/HODs, ensuring inclusion of senior expertise and technical support.

n=50

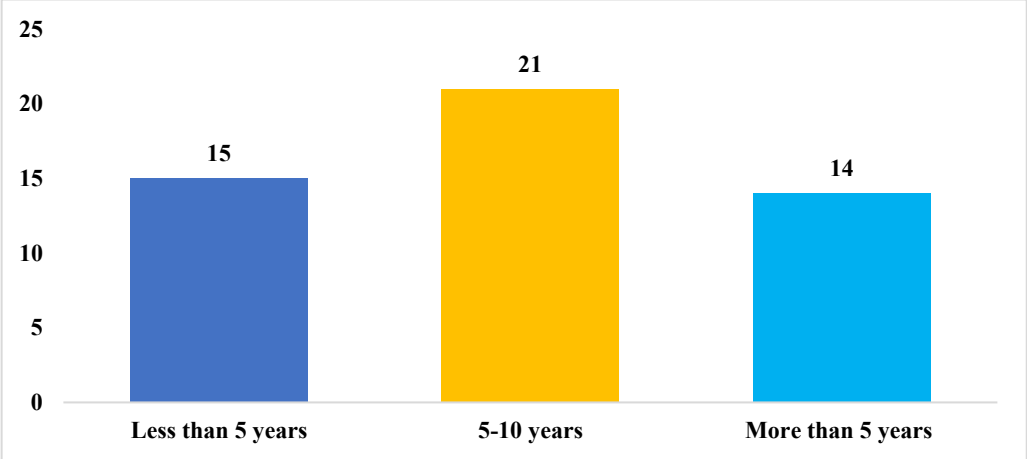

Figure 5- Experience of Delphi Experts

Figure 5 depicts the distribution of experts based on their years of experience. The majority of experts, 20 (40%), have 5–10 years of experience, indicating a strong representation of moderately experienced professionals. This is followed by 15 (30%) experts with less than 5 years and 15 (30%) with more than 10 years of experience.

Analysis of responses in round one and two for the development of protocol.

Table 1: Responses in round one and two n-50

Component	Round I I-CVI	Round II I-CVI	Final Decision
Wearable cup design	0.84	0.92	Accepted
Silicone lining/material	0.88	0.95	Accepted
Polyester/Rexine outer material	–	0.97	Accepted
Universal cup size	0.80	0.84	Accepted

Component	Round I I-CVI	Round II I-CVI	Final Decision
Lightweight design	0.98	0.78	Accepted
Hands-free operation	1.00	0.86	Accepted
Gentle rhythmic compression	–	0.95	Accepted
Electrical isolation and waterproofing	–	1.00	Accepted
Cleaning after each use	0.78	0.86	Accepted
Periodic disinfection	0.94	0.78	Accepted
Storage hygiene	0.82	0.57	Modified
Cost based on material	0.80	0.89	Accepted
Overall Content Validity Index (CVI)	0.75		Acceptable

Table 1 summarizes the expert consensus obtained through two rounds of the Delphi technique for the development of the breast massage device. In Round I, high agreement was observed for the wearable cup design (I-CVI = 0.84), silicone material (I-CVI = 0.88), hands-free operation (I-CVI = 1.00), lightweight design (I-CVI = 0.98), and periodic disinfection (I-CVI = 0.94). Based on expert recommendations, modifications were incorporated into the prototype and re-evaluated during Round II. Following revision, improved agreement was observed for polyester/rexine material (I-CVI = 0.97), silicone lining (I-CVI = 0.95), gentle rhythmic compression (I-CVI = 0.95), wearable cup design (I-CVI = 0.92), and electrical isolation and waterproofing (I-CVI = 1.00). The overall Content Validity Index of 0.75 indicated acceptable expert consensus, and the finalized breast massage device was considered suitable for further evaluation.

Analysis of responses in round three for the development of protocol.

Table 2: Responses in round three n=37

Component / Item	f	%	I-CVI
Design of the Device			
Wearable cup design	36	97.30	0.97
Material Applicable			
Polyester/Rexine	37	100	1.00
Sizes of the Cup			
Universal size	37	100	1.00
Ergonomics & Accessibility			
Lightweight	37	100	1.00
Hands-free operation	36	97.30	0.97
Functional Design			
Multi-point stimulation nodes	37	100	1.00
Visual mode indicator	35	94.59	0.95
Thermal application	36	97.30	0.97

Component / Item	f	%	I-CVI
Advantages of the Device			
Improved milk let-down reflex	37	100	1.00
Enhanced milk flow efficiency	36	97.30	0.97
Comfort & engorgement relief	37	100	1.00
Disadvantages			
Cultural acceptability issues	34	91.89	0.92
Safety Concerns			
Electrical isolation & waterproofing	37	100	1.00
Even heat distribution	36	97.30	0.97
Hygiene & Cleaning			
Hygiene & cleaning (overall)	37	100	1.00
Cleaning after each use	37	100	1.00
Periodic disinfection	37	100	1.00
Drying after each use	36	97.30	0.97
Storage hygiene	37	100	1.00
Cost of Device			
Approx. ₹500	32	86.49	0.86
Cost based on material	36	97.30	0.97
Overall S-CVI/Ave	**0.98**		

Table 2-The table shows that in Round Three, almost all items achieved very high content validity, with most I-CVI values ranging from 0.95 to 1.00, indicating strong consensus among experts. Key features such as polyester/rexine material (1.00), universal size (1.00), lightweight design (1.00), multi-point stimulation nodes (1.00), and hygiene practices (1.00) showed complete agreement. Items such as wearable cup design (0.97), hands-free operation (0.97), thermal application (0.97), and cost based

Analysis of Content Validity and Agreement among Delphi Experts
Opinion of Delphi experts in Round Two and Three (Kendall Tau's-B Test)

Table 3: Opinion Of Delphi Experts in Round Two and Three (Kendall Tau's-B Test) n=37

Component / Item	Rounds	Kendall's Tau-b	P-value	Significance (5%)
Design of the Device				
Wearable cup design	2 & 3	0.90	0.005	S
Material Applicable				
Polyester / Rexine	2 & 3	0.94	0.005	S
Silicone	2 & 3	0.89	0.005	S
Sizes of the Cup				
Universal size	2 & 3	0.87	0.005	S
Ergonomics & Accessibility				

Component / Item	Rounds	Kendall's Tau-b	P-value	Significance (5%)
Lightweight	2 & 3	0.85	0.005	S
Hands-free operation	2 & 3	0.90	0.005	S
Functional Design				
Multi-point stimulation nodes	2 & 3	0.82	0.005	S
Visual mode intensity indicator	2 & 3	0.80	0.005	S
Thermal application	2 & 3	0.92	0.005	S
Advantages of the Device				
Improved milk let-down reflex	2 & 3	0.91	0.005	S
Enhanced milk flow efficiency	2 & 3	0.88	0.005	S
Comfort & engorgement relief	2 & 3	0.87	0.005	S
Reduced stress during feeding/pumping	2 & 3	0.90	0.005	S
Disadvantages				
Cultural acceptability issues	2 & 3	0.84	0.005	S
Safety Concerns				
Electrical isolation & waterproofing	2 & 3	0.95	0.005	S
Even heat distribution	2 & 3	0.88	0.005	S
Hygiene & Cleaning				
Cleaning after each use	2 & 3	0.91	0.005	S
Periodic disinfection	2 & 3	0.88	0.005	S
Drying protocol / drying after each use	2 & 3	0.83	0.005	S
Storage hygiene	2 & 3	0.85	0.005	S
Cost of Device				
Approx. ₹500	2 & 3	0.82	0.005	S
Cost based on material	2 & 3	0.90	0.005	S
Overall Kendall's Tau-b value		**0.90**		

Table 3 presents the Kendall's Tau-b correlation between Round Two and Round Three responses of Delphi experts for various components of the breast massage device. The values of Kendall's Tau-b range from 0.80 to 0.95, indicating a strong positive correlation and a high level of agreement among experts across the two rounds. Higher agreement was observed for critical components such as electrical isolation and waterproofing (0.95), polyester/rexine material (0.94), thermal application (0.92), and cleaning after each use (0.91), reflecting strong consensus on safety, material, and hygiene aspects of the device. Similarly, items like wearable cup design (0.90), hands-free operation (0.90), and cost based on material (0.90) also demonstrated high agreement, indicating their importance in the final design. Moderately high agreement was observed for items such as universal size (0.87), comfort and engorgement relief (0.87), enhanced milk flow efficiency (0.88), and storage hygiene (0.85), suggesting consistent but slightly varied opinions among experts. Lower yet acceptable agreement was seen for visual mode intensity indicator (0.80) and multi-point stimulation nodes (0.82), indicating these features may require minor refinement. All items were found to be statistically significant ($p = 0.005$) at the 5% level, confirming that the observed agreement is not due to chance. The overall Kendall's Tau-b value of 0.90 indicates a high degree of consistency and stability in expert responses between the two rounds.

Analysis of feedback obtained from Delphi experts regarding the Breast Engorgement Management Protocol.

Table 4: Feedback from Experts n=37

Characteristics	Agreed		Disagreed	
	f	%	f	%
The device is appropriate to use in a hospital setting.	37	100.00	00	00.00
The device is compilate to all health care settings.	37	100.00	00	00.00

The device is convenient to use by medical workers.	37	100.00	00	00.00
The design of the device is appropriate.	37	100.00	00	00.00
The device is reliable.	37	100.00	00	00.00

Table 4 shows that all Delphi experts (100%) agreed on every aspect of the breast massage device, including its appropriateness in hospital settings, applicability across healthcare settings, convenience, design, and reliability. No disagreement was reported for any item. This indicates complete consensus among experts, reflecting high acceptability, feasibility, and reliability of the developed device.

DISCUSSION

The present study aimed to design and develop a breast massage device for the management of breast engorgement among postnatal mothers. The device was developed through a systematic research and development process incorporating evidence from the literature, ergonomic principles, and multidisciplinary expert recommendations. The final prototype integrated controlled heat, gentle vibration, ergonomic design, and safety features to provide a standardized, non-invasive approach for breast care.

The findings are consistent with those reported by Martin and Barnett (2012) who emphasized that user-centred medical device development improves functionality, usability, and clinical applicability through continuous expert involvement[7]. Similarly, Money et al. (2011) highlighted that iterative refinement based on multidisciplinary feedback enhances the quality, safety, and acceptability of healthcare devices.[8] The modifications incorporated during the present study, including improvements in material selection, ergonomic design, hygiene features, and safety mechanisms, reflect these recommendations and contributed to the development of a practical prototype.

The design features incorporated into the developed breast massage device were guided by existing evidence supporting the use of breast massage and thermal therapy for the management of breast engorgement. Mangesi and Dowswell (2010) highlighted the need for evidence-based interventions for breast engorgement[4], while Douglas (2022) emphasized interventions that promote physiological breastfeeding and effective milk removal. Accordingly, the developed device integrates controlled heat and gentle vibration within an ergonomic wearable design to provide a standardized and non-invasive approach for breast care.[5]

CONCLUSION

The present study successfully designed and developed a breast massage device for the management of breast engorgement using a systematic research and development approach. The device integrates controlled heat, gentle vibration, ergonomic design, and safety features into a standardized, user-friendly prototype intended to support breast care. The developed prototype represents an innovative and non-invasive approach that provides a foundation for future clinical evaluation and further refinement.

LIMITATIONS

- Further refine the breast massage device based on user feedback and technological advancements.
- Conduct usability and feasibility studies in different healthcare settings.
- Evaluate the safety, durability, and performance of the device under routine clinical conditions.
- Undertake multicentre studies to assess the applicability and scalability of the developed device.
- Conduct clinical trials to evaluate the effectiveness of the breast massage device in managing breast engorgement among postnatal mothers.

IMPLICATIONS

The findings of the study have important implications for nursing practice, administration, education, research, and professional development. The introduction of a validated and effective breast massage device provides a practical solution for managing a common postpartum problem and improving maternal care**.**

RECOMMENDATIONS

- Further refine and optimize the breast massage device based on user feedback and technological advancements.
- Conduct usability and feasibility studies among postnatal mothers in different healthcare settings.
- Evaluate the safety, durability, and performance of the device under routine clinical and home-use conditions.
- Undertake multicentre studies to assess the applicability and scalability of the developed device across diverse healthcare settings.
- Perform clinical trials to evaluate the effectiveness of the developed breast massage device in the management of breast engorgement and its impact on breastfeeding outcomes.

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