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# Development of a complex intervention to strengthen municipality-based breastfeeding support to reduced social inequity in breastfeeding

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## Abstract

**Background** Breastfeeding is the ideal nutrition for infants and protects infants and mothers from a range of adverse health outcomes during their lifespan. In Denmark, while the breastfeeding initiation rate is high, only 14% of mothers meet the World Health Organization's recommendation of exclusive breastfeeding at six months. Furthermore, a notable social inequity exists among those who achieve this recommendation. Knowledge of effective interventions to reduce breastfeeding inequity is limited. A previous hospital-based intervention succeeded in increasing breastfeeding duration. However, most breastfeeding support is provided in Danish municipalities by health visitors. This called for adapting the intervention to the health visiting program and developing an intensified intervention addressing the social inequity in breastfeeding. This article describes the adaptation and development process of a municipality-based intervention.

**Methods** During a 15-month period in 2020–21, the municipal intervention was iteratively developed using a three-stage framework for developing complex health interventions described by Hawkins et al. The three stages were 1) need assessment and stakeholder consultation, 2) co-production and 3) prototyping. The process was inspired by O'Cathain et al.'s principles for a user-centred, co-created and theory- and evidence-based approach, involving parents and health visitors.

**Results** In stage 1, we identified the needs and priorities of the target groups of the intervention. In stage 2, the intervention was developed through action research design and inspired by Duus' 'learning cycles' as the method to enhance motivation and ownership and to strengthen the implementation process by creating a joint room for learning and reflection with health visitors and developers. In stage 3, the intervention was tested for feasibility and usefulness during a 2.5-month period accompanied by monthly dialogue meetings with health visitors and developers. In this period, the intervention was refined based on the gathered experiences and was subsequently prepared for evaluation.

**Conclusion** The description of the development of this complex intervention, aimed at increasing breastfeeding duration and reducing inequity, offers breastfeeding practitioners and researchers a transparent foundation for continuously improving breastfeeding support and a methodology for complex intervention development.

**Trial registration** Registered at Clinical Trials NCT05311631.

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**Keywords** Breastfeeding, Complex intervention, Development, Municipality, Inequity, Co-production, Action research, Health visitor, Young mothers, Social inequality

### Text box 1. Contributions to the literature

- There are considerable differences in breastfeeding duration due to social inequities.
- We lack knowledge on effective complex interventions to reduce breastfeeding inequity.
- Prior research encourages transparency into the development process of complex public health interventions.
- This research provides insights into a co-creation process, where a breastfeeding intervention to reduce social inequity was developed.
- This research facilitates the ongoing qualification of breastfeeding support for the benefit of new parents and their infant.

## Background

Exclusive breastfeeding is recognized by the World Health Organization (WHO) as the ideal nutrition globally for infants in their first six months of life, with continued breastfeeding recommended until the child reaches two years of age or beyond [1]. A meta-analysis shows that the positive effects of breastfeeding benefit both mother and child during a lifespan [2]. However, globally less than half of all infants are breastfed as recommended [3]. In Denmark, where more than 97% of all mothers initiate breastfeeding [4], 86% and 61% of infants are fully breastfed at the age of two weeks and four months, respectively [5].

In high-income countries, socio-demographic factors such as young age and low socio-economic position (SEP) can lead to early breastfeeding cessation [2, 6, 7]. In Denmark, for instance, only 37% of mothers under 20 years and 39–50% with a short-term vocational education breastfeed for four months [8]. This highlights the need for action [6]. Addressing breastfeeding among mothers with a low SEP has been associated with increased odds of the child's upward social mobility [9]. Breastfeeding may therefore also have social benefits [10]. Research shows insights into effective components of breastfeeding support for mothers at high risk of early breastfeeding cessation. The prognostic effect of education on the duration of exclusive breastfeeding seems to disappear when adjusting for psychosocial factors such as breastfeeding self-efficacy and sense of security [11]. This indicates that a strengthening of these psychological factors may diminish social inequity in breastfeeding duration.

A Cochrane review found that mothers at risk of early breastfeeding termination need more support from

health professionals to obtain their own breastfeeding goals [12]. Thus, women in this group may need strengthened feedback and recognition of their efforts, which contribute to increasing their self-efficacy [13–17]. Despite insights from these basic research studies, to our knowledge, the number of comprehensive breastfeeding intervention studies targeting social inequity in breastfeeding is limited. From the general population, we know that interventions based on breastfeeding self-efficacy and evidence-based breastfeeding support can improve breastfeeding rates [18, 19]. Thus, a need exists for the development of a complex intervention to reduce social inequity in breastfeeding.

As improved breastfeeding support is a multifaceted intervention that operates across various structural layers, engaging multiple healthcare sectors, providers and families within their respective societal, local, and familial contexts, it can be defined as a complex intervention [20]. To inform the development phase of public health interventions, Hawkins et al. developed a three-stage framework consisting of 1) evidence review and stakeholder consultation, 2) co-production and 3) prototyping [21]. Furthermore, O'Cathain et al. point to five key working principles, which are described as dynamic, iterative, creative, open to change and looking towards evaluation, and ten key actions (plan the process, involve stakeholders, bring together a team, review published literature, draw on existing theories, articulate program theory, undertake primary data collection, understand context, pay attention to future implementation, design and refine) for development of complex interventions [22]. Importantly, they encourage the publication of the development process to enable others to understand the challenges inherent in intervention development, to promote transparency about the choices made and to facilitate reflection on the link between intervention development and evaluation results [22].

A municipality-based intervention (hereafter MBI), aiming to reduce social inequity through breastfeeding support has been developed in Denmark. The intervention builds on a previous hospital-based breastfeeding support intervention (hereafter HBI) for all families, which Nilsson et al. developed and implemented from 2013–14 in Denmark [19], see Supplementary Table 1

for further intervention description. The HBI trial analysis documented increased exclusive breastfeeding at six months and reduced infant readmissions within the first week of life in mother-infant dyads. However, breastfeeding self-efficacy was not affected [19]. Subsequently, health visitors in the municipalities have requested an intervention for breastfeeding support following discharge that is aligned with the HBI.

The aim of this study is to present a systematic report of the adaptation and development phase of the MBI. Its overall purpose was to adapt the universal HBI to a municipality setting and add a newly developed intensified intervention for mothers with sociodemographic vulnerability (young age and low educational attainment) (Fig. 1). The intervention was implemented in Denmark using a cluster-trial design. Elaboration of the evaluation design can be found elsewhere [23].

**Methods**

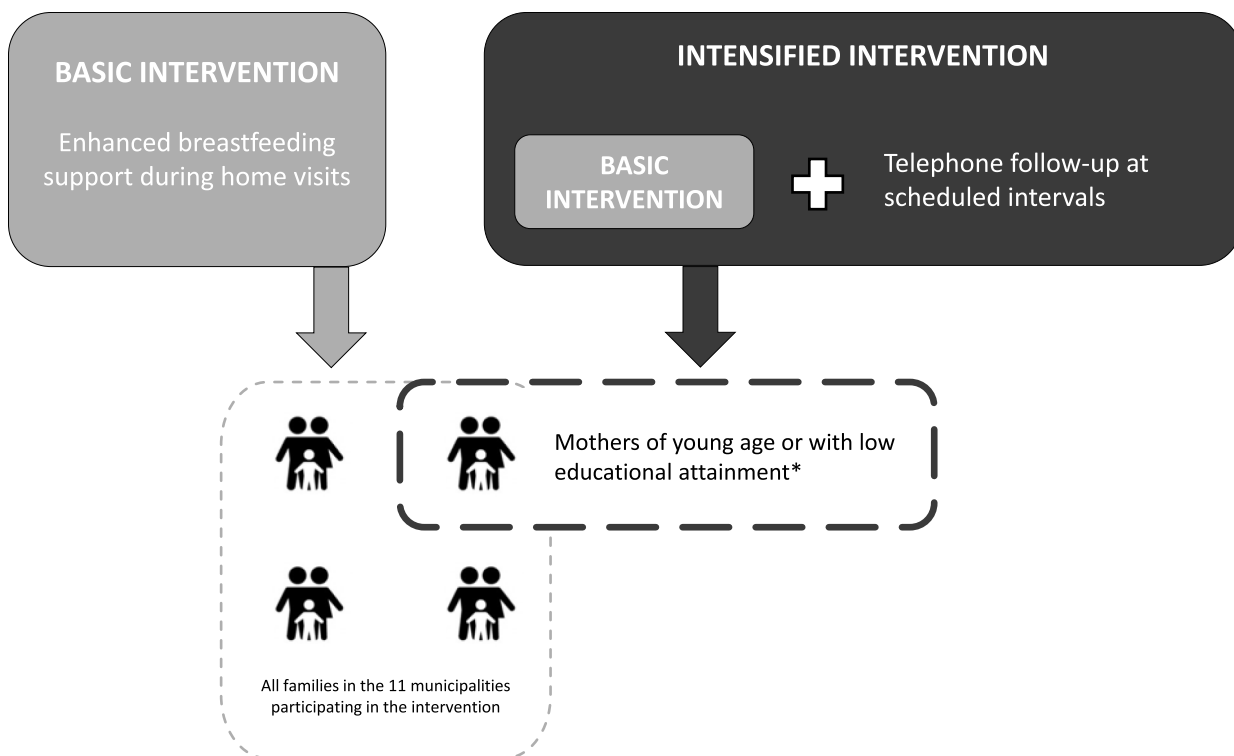
**Target groups and setting**

The MBI had two target groups: the group receiving and the group delivering the intervention. The recipients were all new mothers and their partners. A specific subgroup

of mothers, characterised by being under 25 years of age and/or having low educational attainment, would receive an intensified intervention as these sociodemographic aspects are associated with an increased risk of early breastfeeding cessation. Health visitors in the municipalities were the group that delivered the intervention.

The adaptation and development study took place from August 2020 until December 2021 in 10 intervention municipalities in two Danish regions. These municipalities had a high frequency of mothers matching our target group, and breastfeeding rates were among the lowest in Denmark. Several of these municipalities had a high frequency of English-speaking inhabitants.

In Denmark, families are offered breastfeeding support at the maternity ward after giving birth. After discharge, a universal, tax-financed, municipality-based health visiting program provides support in the families’ homes [24]. Given the short duration of hospitalisation after birth, the health visitors provide most of the breastfeeding support. About 97% of all new parents participate in the health visiting program. Danish health visitors are nurses with a minimum of three years of full-time clinical experience and subsequently 1.5 years of training.



*\*Young age is defined as under 25 years, and low educational attainment is defined as having completed primary school or vocational training as the highest level of education*

**Fig. 1** The Municipality-based intervention

**Methods**

The overall framework used during the development of the MBI was the UK’s Medical Research Council (MRC) guidance for developing and evaluating complex interventions [25] and later accompanying guidance supplements [26]. The more practical processes in the developmental phase were informed by Hawkins et al.’s three-stage framework for the development of public health interventions [21] and O’Cathain’s five key working principles and ten key actions for development [22]. A model of the method used is shown in Fig. 2. The reporting follows the GUIDED, a guideline for reporting intervention development studies in health research [27].

The research group was divided into two: one primarily responsible for the development phase (hereafter the developers) one, for the evaluation phase (hereafter the evaluators).

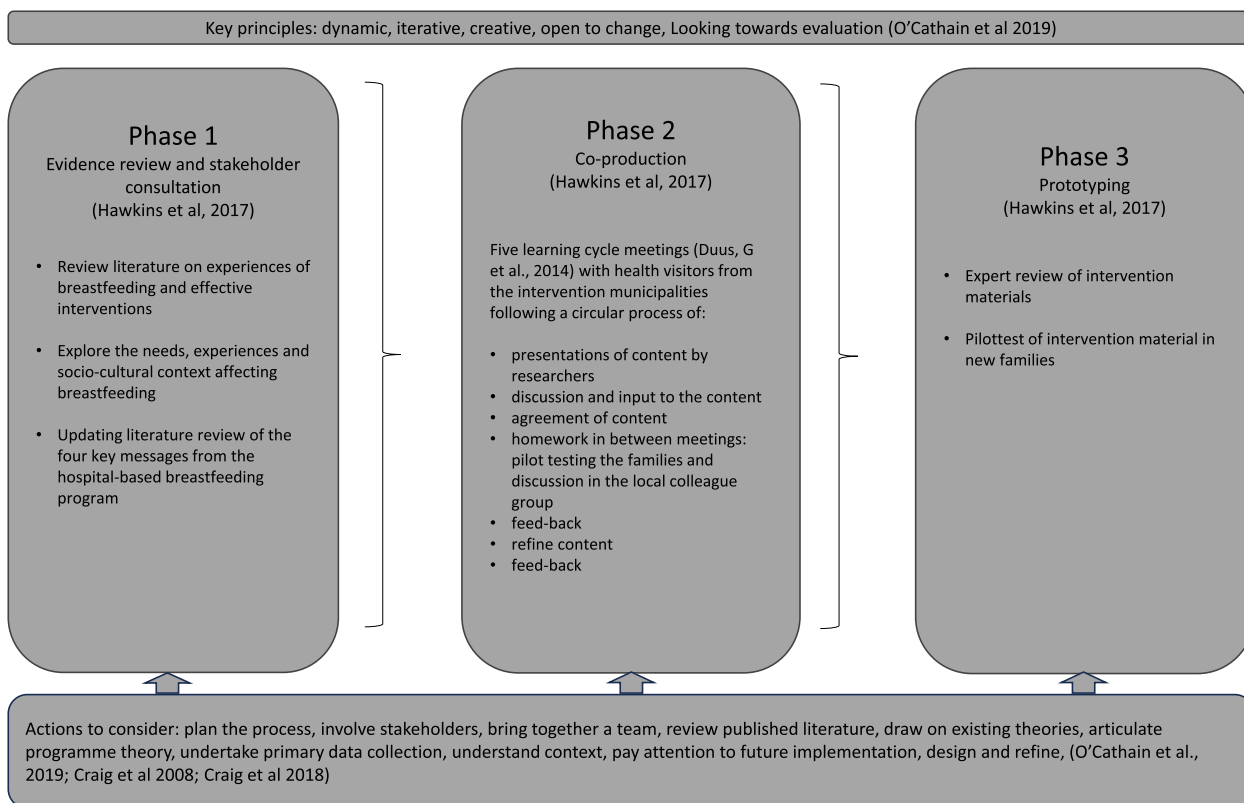
The following describes the methods used during the three stages of development; however, the actual process had an iterative nature.

**Stage 1: Evidence review and stakeholder consultation**

The MBI emerged from the evidence and experience of the HBI. To align the MBI with the HBI, the adaption process focused on tailoring it to the municipal setting

and families’ needs from week one after birth. Consequently, the essential elements of the new program were grounded in the four core evidence-based principles of the HBI: skin-to-skin contact, frequent breastfeeding, proper positioning and joint parenting tasks including theory-based communication. This part leaned on Bandura’s theory on self-efficacy [29] and Kreuter’s theory of tailoring [30]. The intervention used the same overall strategies, training of healthcare professionals and educational material, to improve breastfeeding support. Furthermore, as the aim was to address social inequity in breastfeeding, the first step sought to build an understanding of the needs of young mothers and mothers with low educational attainment, and their partners’ needs, to develop an intensified intervention component to meet their specific breastfeeding support needs.

To get an overview of existing literature, we used Green et al.’s framework for narrative reviews [31] to identify existing literature about experiences of being a mother and breastfeeding, effective breastfeeding interventions and the role of self-efficacy among young mothers and mothers with short education. The review included peer-reviewed publications in English and Nordic languages from 2000 to September 2020. Additionally, contemporary national reports and unpublished academic theses



**Fig. 2** The method used during the development phase [21, 22, 25, 26, 28]

were also incorporated in the report [32]. Search terms included combinations of the words breastfeeding, clinical trials, maternal educational achievement, and maternal age. Searches were made in PubMed and Cinahl.

To further understand the need for an intervention, several qualitative methods were employed: individual interviews with mothers and fathers in the families' homes, observations of health visitors' home visits and observations of mother support groups offered by the municipality and led by health visitors. Inclusion was based on maternal age and length of education as defined earlier, whereas the fathers were the ones living with the included mothers and were therefore not covered by the maternal inclusion criteria. Finally, to include the health professionals' perspectives, focus group interviews with health visitors were performed. All interviews and observations were led by semi-structured guides.

Audio recordings of the individual and focus group interviews were transcribed verbatim and analysed along with field notes from the observations using Malterud's four-step systematic text condensation [33] and led by the study question "How do mothers of young age and short educational attainment and their partners experience breastfeeding and breastfeeding support and what has been supportive or challenging". For more details on the method and analysis, see elsewhere [16].

### Stage 2: Co-production

In order to ensure a needs-based intervention, to qualify the interaction between theory and practice and to support the implementation process, we used a combined user-centred, co-creation and theory- and evidence-based approach [22]. In the co-creation process, we wanted to enhance motivation and ownership and strengthen the implementation process by creating room for learning and reflection with health visitors and developers. The parents were involved through the interaction with health visitors.

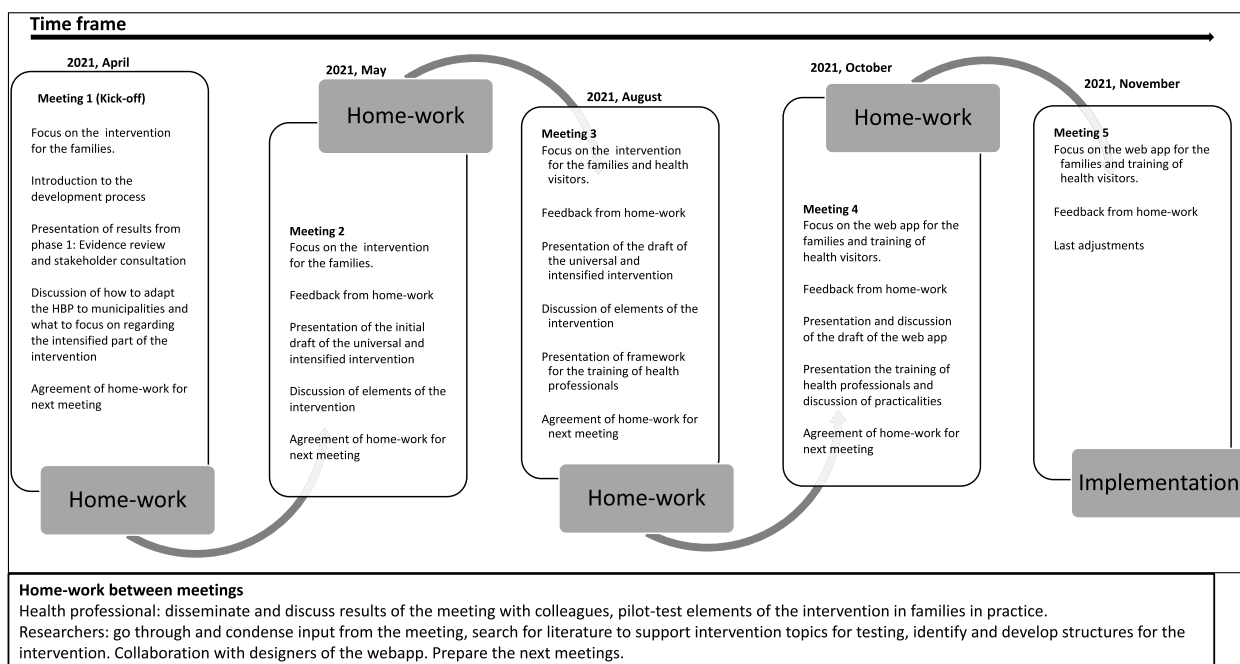
A working group was formed consisting of two intervention developers from the National Competence Centre for Breastfeeding (IN and MBR) and one or two health visitors from each intervention municipality. Health visitors were appointed by the manager of the health visiting program in each municipality based on being certified as international lactation consultants (IBCLC) or having a say in the local group of health visitors. A total of 13 health visitors from the 11 intervention municipalities and two developers were part of the working group, of which 11 were IBCLC. The health visitors were reimbursed for the time used for the project. The method 'learning cycles' was used. Inspired by Duus et al., researchers and health professionals met and

worked together to develop new knowledge for practice [28].

A core element of the co-production process was the learning cycle meetings (LCM) [28]. At these meetings, the working group met for five 6-h meetings during the development phase to discuss, propose and test ideas generated in stage 1, and give feedback on the agreed homework in between meetings. Homework included pilot-testing of intervention elements in the families for feasibility and discussion of the usefulness and practical adaptability of the elements with their local colleagues. We initiated the development in the first LCM by presenting results from stage 1 and subsequently performing a future workshop [34] to stimulate ideas for the optimal breastfeeding intervention. In the municipalities, as breastfeeding support takes place for a longer period than in hospitals, the four key messages had to be adapted to include relevant information and address challenges that matched the recommended period for exclusive and partial breastfeeding. Literature was consulted to support the decision-making, and external resource persons were involved when needed. During LCM, the intervention contents and materials were developed and tested in a back-and-forth process according to the key principles outlined by O'Cathain. This process continued until the group was satisfied with the products [22]. During these meetings, researchers also had the opportunity to get important information about the context in which the MBI should be implemented [22]. Details about the process and content of LCM are found in Fig. 3.

Concurrently with the co-production of the intervention, the developers and evaluators developed a program theory [22] and the evaluators communicated with the health visitors in the working group to ensure an optimal recruitment of trial participants and data collection. Hence, health visitors in the working group acted as important links between the health visitors in each municipality and the developers, along with evaluators, to qualify the processes throughout the entire project as also recommended by MRC [22, 26].

To support the project and the working group during development, implementation and evaluation and ensure broad expertise and competence in decision-making, a reference group was established, representing managers of the health visiting programs in the participating municipalities, representatives from relevant professional associations and representatives from the National Health Authority, the national association of municipalities and Danish Regions, which are responsible for hospitals in Denmark. The reference group met twice a year during the entire project.



Inspired by Duus G et al, 2012.

**Fig. 3** Content of learning cycle meetings

**Stage 3: Prototyping**

A website for parents was tested for functionality by an IT expert and a research colleague, its content and usefulness by parent couples. A theoretical manual of breastfeeding knowledge and intervention activities for health visitors was reviewed by two experts in breastfeeding. The coherent intervention was tested for feasibility in a 2.5-month implementation period in the municipalities after health visitors had received training. The implementation was substantiated by dialogue meetings among the health visitors from the working group and facilitated by the developers. The program theory was finalised to inform the evaluation.

**Results**

The following are the outcomes from the three stages of the development and implementation processes.

**Stage 1: Evidence review and stakeholder consultation**

**Narrative review**

The unpublished narrative review included 32 publications, a report from the Danish National Institute of Public Health and a master thesis from the University of Copenhagen [32]. Most of the studies reported on young mothers, only a few on mothers with no or low educational attainment.

For understanding this group of mothers’ experiences of the transition to motherhood, we found six

qualitative peer-reviewed studies [13, 17, 35–38] and one master thesis [39]. Generally, young mothers experience motherhood positively, seeing it as a new chance and a possibility for stability in life. However, they also faced discrimination due to their age and stigmatisation because their maternal competencies were questioned. Some mothers wanted to prove their competence in motherhood, and breastfeeding their baby was an important symbol of that. Stigmatisation was found to impact their confidence, and some mothers rather consulted their network than health professionals if experiencing problems. Generally, mothers found it natural and desirable to breastfeed, but their intention to continue was challenged if breastfeeding after birth was difficult and demanding. Finally, mothers stressed the importance of short, concrete and visual support, and voiced their need for recognition.

The review of effective breastfeeding interventions targeting young mothers and mothers with low educational attainment included seven intervention studies [40–46]. They were difficult to summarise due to heterogeneity in content, timing, outcome measures and limited descriptions of the interventions. However, face-to-face interventions and interventions that included multiple elements seemed to positively impact breastfeeding duration. A general call for interventions based on psychosocial theories and interventions involving fathers or

other close relations was found as social relations had a strong impact on breastfeeding outcomes.

Drawing on four peer-reviewed studies [14, 47–49] and a master thesis [39], the review underscored the importance of self-efficacy in breastfeeding among the target group. Experiences and attitudes towards breastfeeding in their close network influenced their own confidence in their ability to breastfeed. Moreover, the mothers described how concrete breastfeeding support, confirmation and personal recognition contributed to motivating and maintaining breastfeeding when facing challenges, stressing the importance of targeting self-efficacy in interventions.

### **Stakeholder consultation**

The needs assessment was based on interviews with eight mothers and five fathers, observations of seven health visitors' home visits, observation of one mother support group with 15 young mothers, and four focus group interviews with 24 health visitors [16]. All mothers in the interviews and observations had a low educational attainment and six of the eight mothers were younger than 25 years.

Albeit selected to represent mothers in vulnerable positions, the participants experienced considerable differences in their life situations due to differences in degrees of stability in work, economy, cohabitation and mental health; challenges in their maternal role; experiences of stigmatisation; and support from their network. These contextual differences influenced their breastfeeding journey and their breastfeeding self-efficacy, which again emphasised the importance of individual breastfeeding support and a positive, recognising relationship between parents and health professionals. Parents themselves also explicitly underscored the importance of individualised support.

During pregnancy, all parents wanted their baby to be breastfed. Because they thought breastfeeding would come naturally, parents in general and the fathers in particular saw no need for preparation in pregnancy, which both parents ended up regretting. After birth, most parents were surprised that breastfeeding was not as easy as they had expected and that they faced several practical challenges, like good positioning, timing of breastfeeding and getting the baby to latch on. Understanding the baby's cues was difficult for some mothers, and a crying baby was experienced as a marker for breastfeeding problems and sometimes also as a critique of them as parents. Hence, a thorough, realistic breastfeeding preparation covering the practical challenges was important to include in the intervention.

Most parents experienced challenges during breastfeeding, mostly pain and experiences of insufficient milk

production. They stressed that their choice of breastfeeding support depended on accessibility, usefulness and attitudes like their own towards breastfeeding. Moreover, many preferred receiving help from their social network. They used the internet to search for assistance and valued short, practical answers and videos. The use of health visitors for assistance depended on the meeting between health visitors and the parents, including the relationship, communication with both parents and the importance of working towards the same goal. Especially the health visitors stressed the importance of visits during pregnancy to initiate the good relation, facilitate a preparation process and involve the fathers. In the MBI, it would be important to include relational and communicative elements. Moreover, it could be important to combine face-to-face support with digital support, which is accessible 24 h a day.

For many mothers, it took time to establish successful breastfeeding, and the emotional impact of their breastfeeding experiences had a major effect on their breastfeeding self-efficacy. Insecurity about whether the baby got enough milk and about the family's general well-being were essential in all families regardless of the feeding method. Frequent breastfeeding, especially during night, insecurity of whether the baby got enough milk and having time for yourself were arguments for cessation of breastfeeding. On the other hand, a strong motivation and confidence in breastfeeding were driving forces for breastfeeding. None of the mothers who had stopped breastfeeding had asked for support from the health visitors during the decision-making process, which was also the health visitors' general experience, causing a great deal of frustration. In the end, all that mattered was that parents were certain that their baby got enough food; whether it was bottle-feeding or breastfeeding was secondary. However, if bottle-feeding was chosen, the mothers retained a big wish to breastfeed their next baby but were also in doubt about their ability to do so. Informed by this needs assessment, the new families might benefit from a self-efficacy-supported intervention with a specific focus on how to assess that the baby was getting enough milk and a proactive approach that might catch early breastfeeding problems before they lead to termination of breastfeeding among mothers wishing to breastfeed.

### **Stage 2: Co-production**

The findings from stage 1 and the HBI were the basis for the co-production in the working group, where the intervention was created, including supportive materials such as a dialogue sheet, a pamphlet to assess the infant's thriving, a postcard including the four main messages, a website with text, videos and podcasts, and a manual for

**Table 1** Overview of identified attention points and needs addressed in the Municipality Breastfeeding Intervention

Identified attention points and needs	Addressed in the Municipality Breastfeeding Intervention
Attention towards the feeling of stigma due to age and the need for recognition	Creating a good relationship between health visitor and family, supported by a dialogue sheet introduced during the pregnancy visit Recognition and support tailored to individual needs, wishes and goals of the family using communication based on theory of self-efficacy
Attention towards challenged breastfeeding if early breastfeeding was difficult and demanding	Close proactive follow-up by health visitors in the first two months following birth Podcasts with experiences of other parents to increase self-efficacy (vicarious experiences)
Need for short, concrete and visual support	Practical face-to-face support in concrete situations and practical and concrete online videos are needed to provide the family with good experiences to enhance self-efficacy and action competence
Need for the involvement of both parents	One of the four key messages Promoting the importance of the father/partner being part of the home visits Videos and podcasts of fathers' experiences of his role as a father to a breastfed baby
Attention towards the impact of contextual factors, including a close network of the individual parents on breastfeeding	Individual support is based on the parents' concrete entire situation Use of a dialogue sheet for the first meeting to support initiating an individual need-based counselling Knowledge about the positive and negative impacts of breastfeeding from the close network
Need for realistic expectations towards breastfeeding during pregnancy	Pregnancy visits by the health visitor include identifying expectations, wishes and motivation for breastfeeding Knowledge of breastfeeding initiation available online, including breastfeeding experiences provided by other parents
Need for knowledge of practical breastfeeding matters	Practical knowledge of breastfeeding positions, understanding baby's cues, sucking techniques, signs of thriving etc., including instructive videos A pamphlet on assessing if the baby was getting enough milk, what to do if the baby got too little and when to ask for professional help
Need for specific support regarding breastfeeding pain and experiences of insufficient milk production	An online toolbox was available with concrete, practical proposals to solve pain and experiences of insufficient milk production, including instructive videos
Need for a respectful and appreciative relationship with the health visitor	Focus on establishing a good relationship with the parents
Attention towards not asking health visitors for support if breastfeeding is challenging	Explicitly communicate that the health visitor is there to help parents achieve their desired goals Communicate to the parents what they can use the health visitor for
Need for valid online access to breastfeeding support 24 h a day	Website with evidence-based knowledge on breastfeeding
Need for access to knowledge of how to bottle-feed the baby	Podcasts on how to bottle-feed the baby and parent's experiences with bottle-feeding

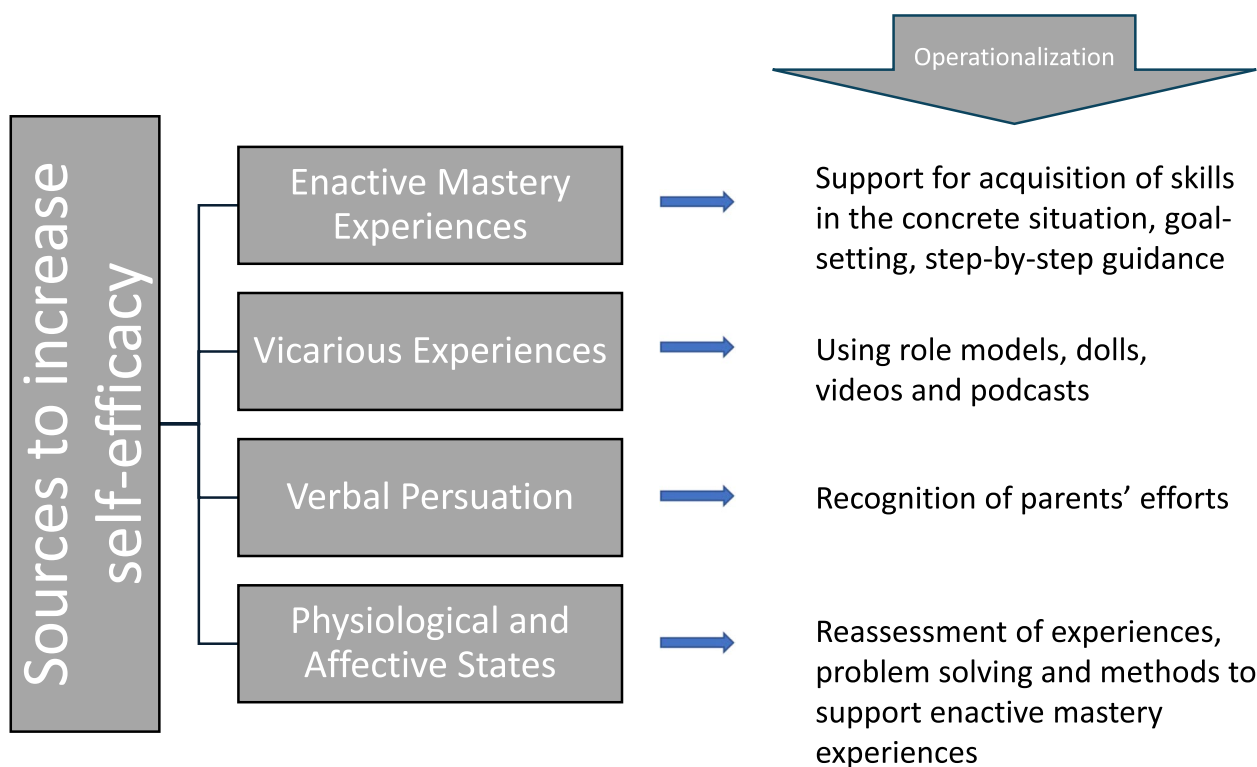
health visitors. Table 1 shows how the needs and attentions were addressed in MBI.

In the adaptation process of the HBI to match the community setting, we identified differences between the two interventions and what to add under each of the four messages. Skin-to-skin contact was proposed to be used much more in the municipalities for creating peace, positive relations, and solving breastfeeding problems. In the HBI, we emphasised frequent breastfeeding in the initiation period, whereas in the MBI, the focus shifted to needs-based breastfeeding. First choice of breastfeeding position should be the laid back position unless the

mother had other preferences, and early involvement of the father should be prioritised, preferable in pregnancy.

The communication part was informed by Bandura's theory of self-efficacy, including the four sources to enhance self-efficacy: enactive mastery experiences, vicarious experiences, verbal persuasion and physiological and affective states [29]. Self-efficacy is a modifiable determinant of breastfeeding duration [11], which can be increased by a targeted use of the four before mentioned sources. The operationalisation of the four sources to enhance self-efficacy is described in Fig. 4. Kreuter's theory of tailoring was used to individualize knowledge sharing [30] and was operationalized by a four-step





**Fig. 4** Operationalisation of Bandura's four sources to increase self-efficacy

process: 1) identifying the parent's perspective, 2) achieving a common understanding of the problem, 3) sharing of needed knowledge, and 4) evaluation of the family's understanding of the guidance [50]. The theories were integrated into all communicative parts of the intervention, from the instructions for the face-to-face support in the manual for health visitors to the texts, videos, and podcasts on the website for parents. Concurrently, health visitors in each municipality revised the digital routine record system to allow for reporting of the intervention activities.

The routine home visit profile of the health visitors is determined by municipal policies (as a local area of government) and therefore varies slightly between the participating municipalities. We found no effective profile in the literature for scheduled home visits. Therefore, the profile for the basic intervention was developed based on the health visitors' experiences and knowledge about when potential breastfeeding problems might arise in the families. In most of the municipalities, a home visit was offered when the baby was 4 months old. During this visit, families were guided to introduce complementary foods to the baby. Our hypothesis was that this visit might arouse parents' curiosity and stimulate them to introduce complementary food for the baby before

intended, thereby shortening the exclusive breastfeeding duration. Thus, in the MBI, the 4-month visit was substituted by a 4-month telephone call during which the health visitor and the family would plan a home visit for the introduction of complementary food according to the individual family's breastfeeding process and needs. The final profile of the home visits and telephone calls are shown in Supplementary Table 2.

For the MBI intensified intervention, we wanted to enhance needs-based communication by enabling more frequent contact between the families and the health visitors. The purpose of this was to identify early breastfeeding challenges, support with problem-solving and thereby address the identified problem in stage 1 of mothers not reaching out to the health visitor when needing support. Therefore, we decided that the MBI intensified intervention should consist of scheduled proactive calls. Inspiration was found in a Danish study where proactive telephone calls were found to enhance exclusive breastfeeding at 3 months with a factor 2.5 in a group of overweight/obese mothers [51]. Hence, the MBI intensified intervention offered a higher dose of the intervention based on the same breastfeeding principles as in the basic intervention. It was a balancing act to ensure consistency between health visitors' support and offer an

individual approach. We made supportive guidelines for all visits and telephone calls (not to be followed slavishly). To stimulate an individual approach, we designed the initiation of the visit to be an open question to the family about their general well-being, how breastfeeding was going and if anything worried them. The final profile of home visits was approved by the managers of the health visiting program.

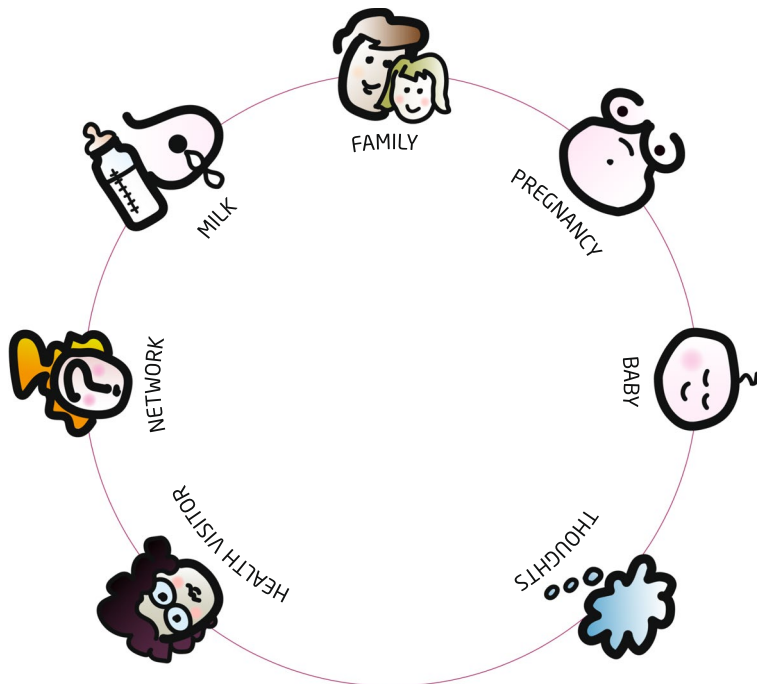
In addressing social inequity in breastfeeding during the development process, we constantly strove to find a balance between reaching the group of young mothers and mothers with low educational attainment and not labelling and stigmatising them. In stage 1, we identified the importance of a good relationship built on trust and a sense of security between the mothers in this group and the health visitors to address this issue.

To enable the health visitors to engage in tailored and individualised support to the families, we developed a communication tool aiming to open a conversation about the families' unique needs and goals for breastfeeding.

The tool underwent a complicated back and forward adaptation process. Initially, we proposed a mind-mapping technique, which was introduced at an LCM and tested in role-play exercises. However, after testing it out with families, the health visitors found it too demanding for this project. We opted for a simpler tool, entitled the dialogue sheet (see Fig. 5), where the health visitor and the family in a joint process were supposed to identify the unique needs and wishes based on icons of essential elements of importance to breastfeeding. The dialogue sheet should optimally be introduced at the pregnancy visit or alternatively at the first home visit after birth.

In stage 1, both parents and health visitors proposed a website with simple, practical, evidence-based knowledge about breastfeeding and instructive videos that were available when needed 24/7. Based on the needs in stage 1, we presented and agreed on a frame for the web app with nine topics at the LCM. The web app had three layers, which accommodated different levels of knowledge among users, and the four key messages were the

# DIALOGUE SHEET



The Ressource Center for Breastfeeding 2022

**Fig. 5** Dialogue Sheet used to identify the unique needs and wishes of the families

foundation of all information. Fifteen practical videos were produced with voice-over, explaining and describing what the videos were showing and thereby focused on vicarious experiences as a source to increase self-efficacy. The topics of the videos were, among others, breastfeeding positions, baby's feeding cues, sucking technique and preparing for breastfeeding in pregnancy. Eight podcasts were produced to provide parents with experiences and tips from other parents with among others breastfeeding initiation and how partners supported the breastfeeding mothers. The topic 'preparing for breastfeeding' included a quiz, where parents could compete on knowledge and myths about breastfeeding to stimulate their interest in breastfeeding during pregnancy and contribute to providing a realistic perspective on breastfeeding. Finally, the web app included a toolbox of proposals for solving the two main problems causing early cessation of breastfeeding: pain and perceived insufficient milk.

Other materials produced during stage 2 were a postcard with the four key messages, a link to the web app, and a pamphlet to support parents considering whether their baby got enough milk, including information on a minimum number of daily breastfeedings, normal stool and urination, feeding cues, other signs of well-being, a 'what to do guide' if things were not as described, and when to contact health professionals for more assistance. A similar pamphlet had earlier been used in one region in Denmark. The pamphlet was valued by parents and health professionals because it provided parents with the competence to act and self-efficacy when insecure about their baby's thriving. The pamphlet was updated according to evidence and redesigned to fit the other materials of the MBI. All materials were produced in Danish and English versions, including the web app and all the videos.

A new intervention training program was developed based on the HBI but adapted to the families' post-discharge needs and the health visitors' needs and context. A draft of a program was presented and discussed at the LCM. When the municipalities agreed to participate in the project, they signed a document permitting all health visitors to participate in a course encompassing three hours of e-learning and a subsequent two-day training course. The theoretical e-learning preceding the training course gave us the possibility to include more interactive learning in the course, such as discussions, reflections, exercises and role-plays to enhance the health nurses' self-efficacy and action competency to deliver the intervention, as also recommended in previous interventions [52, 53]. The final program of the e-learning consisted of theoretical input about the anatomy and physiology of

breastfeeding, skin-to-skin contact, self-efficacy and an introduction to the dialogue sheet. The two-day training course covered the following topics: Breastfeeding – a joint parental task, the social context of breastfeeding and its impact on breastfeeding, preparing for breastfeeding, the relation between health visitor and parents, breastfeeding positions and suckling technique, breastfeeding on demand, pain and sore nipples, how to tailor support to the individual family, and enhancing self-efficacy in practice. The intervention material was activated during the training. A detailed program theory for the training program and evaluation of effectiveness on health visitors' breastfeeding knowledge, self-efficacy and action competence is described elsewhere [54].

The entire MBI was mapped in a program theory, including activities, mechanisms, output, outcomes, impact and context for both target groups. See Fig. 6a and b.

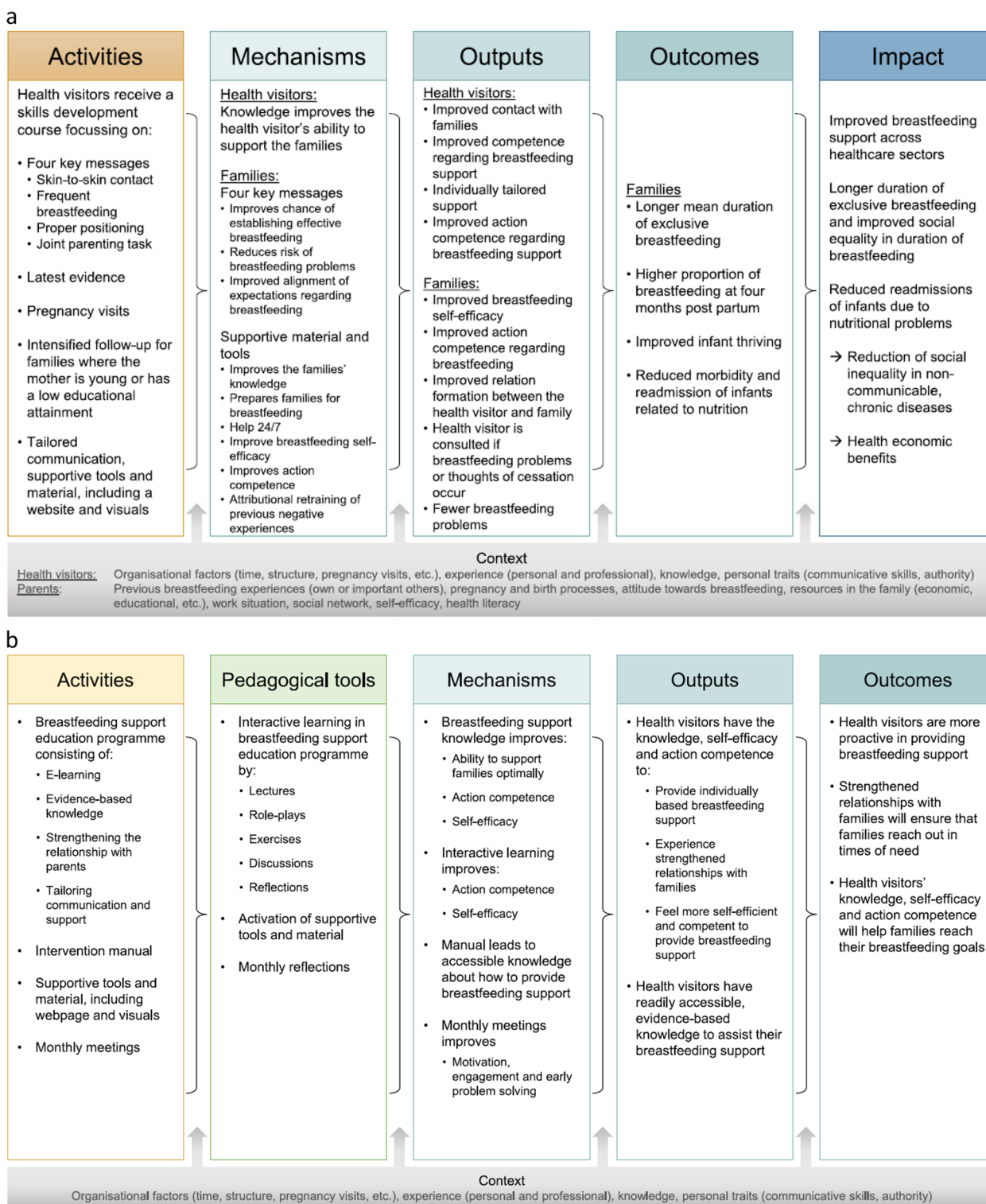
### Stage 3: Prototyping

Most of the pilot testing was performed during the co-production stage as described earlier. Feedback from the health visitors' testing and discussions with colleagues in the LCM gave rise to several changes, such as the dialogue sheet mentioned above. Other material was tested in families and found useful, such as the pamphlet to support parents' assessment of the baby's thriving. The review of the manual [54] by two breastfeeding experts gave rise to small adjustments.

The web-app was carefully tested by experts to identify potential dead ends and ensure that links were working as intended. Five parent couples were asked to assess the content for usefulness and relevance. Consequently, the quiz was divided into three parts as it was found too long for a single session.

A pilot test of the MBI was conducted after all health visitors in the 10 intervention municipalities had completed the training course. During the 2.5-month implementation period health visitors implemented the MBI in the families. Tips and challenges were collected and solved at dialogue meetings in the working group, and the MBI was revised accordingly. Especially practical problems with the web-app were identified as were also challenges implementing the dialogue sheet in the initial home visits after birth. Hence, we decided that the dialogue sheet should be used in the families only during pregnancy visits when undisturbed dialogue is more feasible. This decision was made to address the challenges of engaging in such discussions after birth when families are adjusting to life with a newborn.

After the final approval by the health visitors, the MBI was ready for evaluation.



**Fig. 6 a** Programme theory of parents' gain from the municipality-based breastfeeding Intervention. **b** Programme theory of health visitors' gain from the training program

## Discussion

This study contributes to the evidence on how to optimize breastfeeding support to new families after discharge from maternity hospital in general and young mothers and mothers with low educational attainment in particular. Moreover, it contributes with insights into the development of a complex public health intervention by testing Hawkin's three-stage framework including 1) evidence review and stakeholder consultation 2) co-production and 3) prototyping [21], informed by O'Cathain's five key working principles and ten key actions for development [22].

The MBI consisted of four essential evidence-based components and a theory-based approach to communication. Previously, other interventions have shown positive effects of similar components in a hospital setting [19] and when targeting young mothers in high-income countries [42, 46]. The proactive telephone calls aimed at strengthening the support even more for women in socially vulnerable positions. This component was inspired by an effective breastfeeding intervention among overweight mothers [51], and it will be interesting to see, if this aspect can activate mechanisms of improved communication and thus strengthened supervision for our target group.

Stigmatization was a matter of concern during the implementation of the intensified intervention and might cause health visitors to refrain from offering the proactive telephone calls and the parents to refrain from accepting the offer. Stigmatization has also been a concern in other interventions aiming at reducing health inequity postpartum [55]. We focused on qualifying the relationship and communication between the health visitor and the parents to reduce the risk of stigma as underscored in the initial need assessment [16] and also found in other studies [13, 55].

This study is one of few that transparently exhibits the development process, the context, and the content of a complex intervention to support breastfeeding. A previous intervention study from US found that home visits increased breastfeeding rates among low-income, urban women [56]. The authors attribute this to mechanisms of psychoeducation, guidance, and support, and highlight important contextual aspects: participants were often racial/ethnic minority women, and the visitors were either local human service workers or public health nurses. However, the study lacks detailed insights into how these intervention components were designed to meet the local needs and how were the visitors to engage with the families during the visits? Understanding these details would have enabled us to consider adapting their intervention to the Danish welfare state scenario with health visitors. In Australia, a home-visiting

breastfeeding support intervention showed no effects on breastfeeding rates, primarily due to poor implementation dose and reach. The authors stress the importance of considering organisational contexts and fit [57]. However, they did not incorporate co-creation during the development process. Thus, the thorough development process involving the health visitors in our study will hopefully facilitate implementation. According to Duncan et al. a detailed guidance on intervention description is necessary for policymakers and practitioners to judge the quality and relevance of the intervention and guide their decision about whether to implement the intervention within their specific context [27]. The latest Cochrane review of support for healthy breastfeeding mothers stress that *"a key issue in this review was lack of reporting on intervention details"* [12]. Yet, the present study fits into this gap and can enable transferability and adaption of the intervention in other settings. Likewise, transparency in the development process contribute to the bank of methodological knowledge to inform future intervention development studies.

Following Hawkin's three-stage framework and O'Cathain's working principles was crucial for tailoring the intervention content to the target group and the setting during the design stage. While this process was time-consuming, it proved very valuable. The working principles suggest an iterative, creative and open-minded process. We followed these principles and found them especially valuable for the intervention when considering the inclusion of a digital solution and for developing an instrument for supporting a tailored and individual approach (dialogue sheet). The democratic and joint learning back-and-forth processes between developers and health visitors in the working group took time. Having a time schedule with space for unforeseen issues was therefore paramount. However, this approach also assumes strict time management as it would be tempting to keep on working to get the optimal solution, an experience shared by other developers of complex interventions [58].

The framework and the working principles also suggested a co-creation approach. In this study, we involved health visitors from the participating municipalities during all three stages. Parents were involved in stage 1 (stakeholder consultation) and stage 3 (intervention prototyping). The development process might have benefited even more if parents had been involved in the entire process, bringing their opinions into the discussions. A process evaluation, which is about to be published, has shown that the dialogue sheet was not adopted in its entirety by the health visitors, although it was valued especially by the fathers. Thus, further testing during the development stage could have been warranted. Bringing

the two target groups together might have been beneficial for discussing the usefulness and the final production of the instrument. This collaboration would have been an important step in targeting breastfeeding support to the families' unique needs.

Among health visitors, the co-creation process resulted in great engagement and ownership of the intervention, which was a driving force during its implementation. A prerequisite for the municipalities' involvement of health visitors from practice was reimbursement for the time spent during the development phase. Therefore, the budget for the entire research project must include payment to the municipalities to ensure that involvement in the project does not negatively impact the support offered to families during this period.

The two developers' central positioning in the breastfeeding landscape in Denmark may have played a positive and important role during the development of the intervention. Being advisors to the National Board of Health, the authors of the national recommendations, breastfeeding trainers of health visitors in Denmark and having a good insight into health visitors' field of work have possibly positively influenced the development of the new intervention and facilitated its subsequent implementation. However, it might also have introduced bias into the process due to blind spots or an uneven perception of breastfeeding authority, potentially causing the visiting nurses to withhold ideas and perspectives.

## Conclusion

This comprehensive description of the development of a complex intervention based on the framework of Hawkin and O'Cathain is an example of how to co-produce and prototype a breastfeeding intervention aimed to increase the duration and reduce inequity in breastfeeding in collaboration with parents and health professionals. We illuminate how the needs and attentions identified in stage 1 are processed and addressed in the intervention and how the intervention is tested and adapted to the specific context during stages 2 and 3. This project partly mitigates the limited guidance and research on the development stage. The description provides breastfeeding practitioners and researchers with a transparent foundation for the ongoing qualification of breastfeeding support and methodology on complex intervention development.

## Abbreviations

HBI	Hospital-Based Intervention
LCM	Learning Cycle Meeting
MBI	Municipality Based Intervention
MRC	Medical Research Council
SEP	Socio-economic position

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13690-024-01401-6>.

Supplementary Material 1.

Supplementary Material 2.

## Acknowledgements

First and foremost, the authors thank mothers, fathers and health visitors for participating in the study. Likewise, we thank Anne Oehlers for her assistance during the focus-group interviews and the subsequent transcriptions.

## Authors' contributions

IN, MBR and SFV have made substantial contributions to the conception of the research, the design of the work, the acquisition, and the interpretation of data. IN has drafted the work and SFV and IN has substantively revised it. IN, MBR and SFV have approved the submitted version and agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

## Funding

This study was supported by NordeaFonden (grant number 02–2019-00267) and Det Obelske Familiefond (grant number 29763). The funding sources had no influence of the study during the entire process from idea to decision to submit the article for publication.

## Availability of data and materials

The data used for stage 1 are available from the first author on reasonable request.

## Data availability

No datasets were generated or analysed during the current study.

## Declarations

### Ethics approval and consent to participate

According to the Helsinki Declaration, all participants were informed about the study both verbally and in writing. Informed written consent to collect and safely store data and publish results of the study was obtained. Hence, participant information and data protection comply with the General Data Protection Regulation (GDPR). As this study is not a trial and does not include human tissues, ethics approval is not required by Danish law.

### Competing interests

The authors declare that the funding interests may be considered as potential competing interests. However, the funding sources had no influence of the study during the entire process from idea to decision to submit the article for publication.

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Received: 30 June 2024 Accepted: 17 September 2024

Published online: 02 October 2024

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