Breastfeeding support: What works?

A population-based pragmatic trial and a multi-ethnic cohort study

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CONTENTS

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SUMMARY

Although the breastfeeding prevalence is higher in Norway than in most other high-income countries, there is a gap between recommendations and current breastfeeding practice. The aims of this thesis were to assess the effectiveness of the Baby-Friendly community health services on breastfeeding and maternal satisfaction in a pragmatic trial in 54 municipalities. Socioeconomic inequalities in breastfeeding have persisted in Norway for several decades. Therefore, we conducted an observational study nested within the trial to explore whether socioeconomic inequalities in exclusive breastfeeding could be explained by established determinants of breastfeeding. Furthermore, we investigated inequalities in breastfeeding related to gestational diabetes and ethnic origin, using data from the Stork Groruddalen cohort.

Women in the intervention group were more likely to exclusively breastfeed compared to those who received routine care: 17.9% vs 14.1% until 6 months (cluster adjusted odds ratio 1.33; 95% confidence interval (CI) 1.03 to 1.72). The intervention had no effect on breastfeeding until 12 months. Maternal satisfaction with the breastfeeding experience did not differ, neither did perceived breastfeeding pressure.

We observed that socioeconomic inequalities in exclusive breastfeeding were largely explained by other sociodemographic factors, smoking habits and breastfeeding difficulties.

In the Stork Groruddalen cohort it has been found that women with an origin from South Asia and the Middle East were much more likely to be diagnosed with gestational diabetes than women from Western Europe. It has previously been shown that breastfeeding may reduce the risk of type 2 diabetes in mothers with recent gestational diabetes. We found that gestational diabetes was associated with earlier cessation of predominant breastfeeding: (adjusted hazard ratio 1.33, 95% CI 1.01 to 1.77). Women with an origin from South Asia and the Middle East ended predominant breastfeeding earlier than Western European women.

The Baby-friendly community health services had a significant impact on exclusive breastfeeding. As a supplement to this population-based intervention, targeted approaches may be necessary to reduce inequalities in breastfeeding related to socioeconomic position, ethnic origin and gestational diabetes.

LIST OF PAPERS

Paper I

Anne Bærug, Øyvind Langsrud, Beate F. Løland, Elisabeth Tufte, Thorkild Tylleskär, Atle Fretheim.

Effectiveness of Baby-friendly community health services on exclusive breastfeeding and maternal satisfaction: a pragmatic trial.

Maternal & Child Nutrition 2016; 12: 428-39.

Paper II

Anne Bærug, Petter Laake, Beate Fossum Løland, Thorkild Tylleskär, Elisabeth Tufte, Atle Fretheim.

Explaining socioeconomic inequalities in exclusive breastfeeding in Norway.

Arch Dis Child 2017; 102: 708-714.

Paper III

Anne Bærug, Line Sletner, Petter Laake, Atle Fretheim, Beate Fossum Løland, Christin W. Waage, Kåre I. Birkeland, Anne Karen Jenum.

Earlier cessation of predominant breastfeeding in mothers with recent gestational diabetes in a multiethnic population

Under review.

ABBREVIATIONS AND DEFINITONS

BFHI	Baby-friendly Hospital Initiative
BMI	Body Mass Index
CI	Confidence interval
EPDS	Edinburgh Postnatal Depression Scale
GDM	Gestational diabetes
HDI	United Nations Human Development Index
HR	Hazard ratio
ICC	Intracluster correlation
IQR	Interquartile range
IHID	Inequality-adjusted Human Development Scale
OGTT	Oral glucose tolerance
PROBIT	Promotion in Breastfeeding Intervention Trial
TEDDY	The Environmental Determinants of Diabetes in the Young cohort study
RCT	Randomized controlled trial
REK	Regional Committees for Medical and Health Research Ethics
SPSS	Statistical Package for the Social Sciences
USPSTF	United States Preventive (Service) Task Force
WHO	World Health Organization
WHO 1999	GDM by the WHO 1999 criteria
WHO 2013	GDM by the WHO 2013 criteria

DEFINITIONS

Cluster randomised trials	Trials were groups of individuals (such as community health services, hospitals) rather than individuals are randomly assigned to intervention or comparison groups.[1]
Pragmatic trials	Trials that assess whether and intervention work in normal practice (effectiveness), versus explanatory trials (efficacy) conducted in 'ideal' settings with less direct relevance to normal practice.[2]

DEFINITIONS: Breastfeeding indicators recommended by WHO, used in main references, and in paper I, II and III

Indicator	Definition	Age group or at age	Method of estimation	References
Exclusive breastfeeding under 6 months	Only breast milk, allows: vitamins, minerals, medicines	From birth until just under 6 months	Infants 0-5 months of age who received only breast milk the previous day/ Infants 0-5 months of age	WHO (2007)[3]
Predominant breastfeeding	Breast milk, allows water, water-based drinks, fruit juice, and vitamins, minerals medicines	From birth until just under 6 months	Infants 0-5 months of age who received breast milk plus water, water-based drinks, fruit juice the previous day/ Infants 0-5 months of age	
Continued breastfeeding	Breast milk; allows any food or liquid	Proportion of children 12 – 15 months of age who are fed breast milk	Children 12-15 months of age who received breast milk during the previous day/ Children 12-15 months of age	
Full breastfeeding	Exclusive and predominant breastfeeding			WHO (1991)[4]
Lactation Intensity Ratio [LIR]	Lactation Intensity Ratio [LIR] [Score from 0= 100% formula feeding to 1= 100% breast milk)	Previous 24 hours, or Previous 7 days	LIR [n, month]= (#breastfeedings)/ (#breastfeedings) + (#formula feedings) + (#milk feedings)	Piper et al. [5] Gunderson et al.[6]
Breastfeeding intensity, summary score for 12 months			(LIR1 + LIR2 + LIR3…LIR12)	Gunderson et al.[6]
Exclusive breastfeeding until 6 months	Exclusive breastfeeding at 5 completed months	Assessed at 5 completed months with retrospective questions covering the period from birth to 5 completed months	Do you breastfeed now? If no; when did you stop breastfeeding? Separate questions asking about the age of introduction of: - water, water based drinks, fruit juice - infant formula - any solid or other liquids	Paper I Paper II
Predominant breastfeeding	Breast milk, possibly with only water	Mean age 14 weeks [8 – 18 weeks]	Similar method as in Paper I and II, but without a question about age of introductions of water	Paper III
Breastfeeding/ Any breastfeeding	Breast milk; allows any food or liquid			Paper I, II, III

1 INTRODUCTION

1.1 Background

Breastfeeding has been shown to benefit the nutrition, health and development of the child, and also the mother's health.[7] In early life, breastfeeding protects against infections, promotes healthy growth, and probably reduces the risk of sudden infant death. Early life course environmental exposures may also influence the development of diseases in adult life,[8,9] and breastfeeding is one of the key exposures that may influence future health. Current research indicates that breastfeeding increases intelligence, and probably reduces the risk of overweight and diabetes. In mothers, breastfeeding protects against breast cancer, and may also reduce the risk of ovarian cancer, and type 2 diabetes.[7]

The World Health Organization (WHO) recommends exclusive breastfeeding until 6 months and duration of any breastfeeding for at least 2 years.[10] In line with this, the recommendation from the Norwegian Directorate of Health states that 'Breast milk is the best food for the baby, and the baby can safely be given breast milk exclusively for the first six months, only supplemented with vitamin D, as long as the child is thriving and the mother is content. If possible, infants should be breastfed throughout the first year of life – or longer, if mutually desired.'[11] Although breastfeeding rates in Norway are higher than in most other high-income countries,[7] there is a gap between recommendations and current breastfeeding practice.[12] The WHO strategy 'Ambition and action in nutrition 2016 – 2025',[13] and the Norwegian Ministries National Action Plan for a Healthier Diet have stated quantitative goals for increasing the proportion of breastfed infants.[14] In Norway the targets set for 2021 are to increase the proportion of infants who are exclusively breastfed for 4 months from 44% to 60% and for 6 months from 17% to 24%, and to increase the duration of breastfeeding for 12 months from 35% to 50%.

Re-establishing a breastfeeding culture in high-income countries has proven to be challenging as breastfeeding is affected by determinants that operate at multiple levels.[15-17] The health services, however, play a crucial role in supporting breastfeeding. The WHO/UNICE Baby-friendly Hospital Initiative (BFHI) has been shown to be one of the most effective interventions in maternity facilities for improving breastfeeding rates worldwide.[18,19] In Norway, the standard of the BFHI is now part of the routine care in hospitals, with regular reassessments.[20] Today, mothers are discharged from hospital earlier than before; thus efforts to promote breastfeeding need to focus more on the support from the community health

services. The question on how best to support breastfeeding in the community health services remains,[21-23] and system-level interventions such as the Baby-friendly Initiative adapted for the community health services has been called for.[24,25]

Studies from Norway and other high-income countries have consistently found that high socioeconomic position is associated with longer duration of both exclusive breastfeeding and any breastfeeding.[7,26] Socioeconomic inequalities in health and health related factors from early life are of particular concern.[27,28] Little is known about mechanisms by which low socioeconomic position translate into breastfeeding practices.[29] Identifying possible factors that may explain socioeconomic inequalities in breastfeeding with a potential of being amenable to change, could inform strategies to reduce socioeconomic inequalities in breastfeeding.

Maternal health is one of the determinants of breastfeeding practice.[30] Gestational diabetes is a common complication of pregnancy which increases the risk of future type 2 diabetes in the mother.[31] Previous studies suggest that breastfeeding reduces the risk of conversion of gestational diabetes to type 2 diabetes in women with recent diabetes.[32,33] Women of South Asian origin have an increased risk of developing type 2 diabetes 1-2 years postpartum, compared to Western European women.[34,35] Breastfeeding may thus be of particular importance in some ethnic minority populations. Therefore, knowledge about breastfeeding practices in women with recent gestational diabetes and in ethnic minority groups is needed.

Improving the quality of breastfeeding support within the health services is an on-going process of assessing the effectiveness of interventions, assessing and explaining socioeconomic inequalities, and identifying groups who may need tailored support.When new insight is gained, this should lead to new interventions or revision of existing standards of care.

1.2 Breastfeeding trends in Norway

Figure 1 shows breastfeeding rates in Norway from 1860 until 2013. We have extended the original version of the curve by Liestøl, Rosenberg and Walløe from 1860 - 1984,[36] with more recent data.[12,26,37] From 1860 to 1920 breastfeeding practices were quite stable, except for a decline in the proportion of women who breastfed for more than a year. From 1920 breastfeeding rates in the first year of life began to decline, first modestly, then more steeply.

The lowest point was reached around 1967 when about 30% breastfed for 3 months and as few as 5% did so for 9 months. This was a turning point, as the downward trend was replaced by a distinct upward trend.[36] The latest point in the original version of the curve indicated that a plateau was reached around 1980. In the 1990s, however, there was a new upturn in breastfeeding rates, but from 2007 to 2013 a decline in breastfeeding duration was observed for the first time since 1967. It is noteworthy that throughout the whole period, in spite of great fluctuations in the duration of breastfeeding, almost all mothers have initiated breastfeeding. The most recent breastfeeding statistics from 2013, found that 99% initiated breastfeeding, 17% breastfed exclusively until 6 months, and 35% continued any breastfeeding for at least a year.[12]

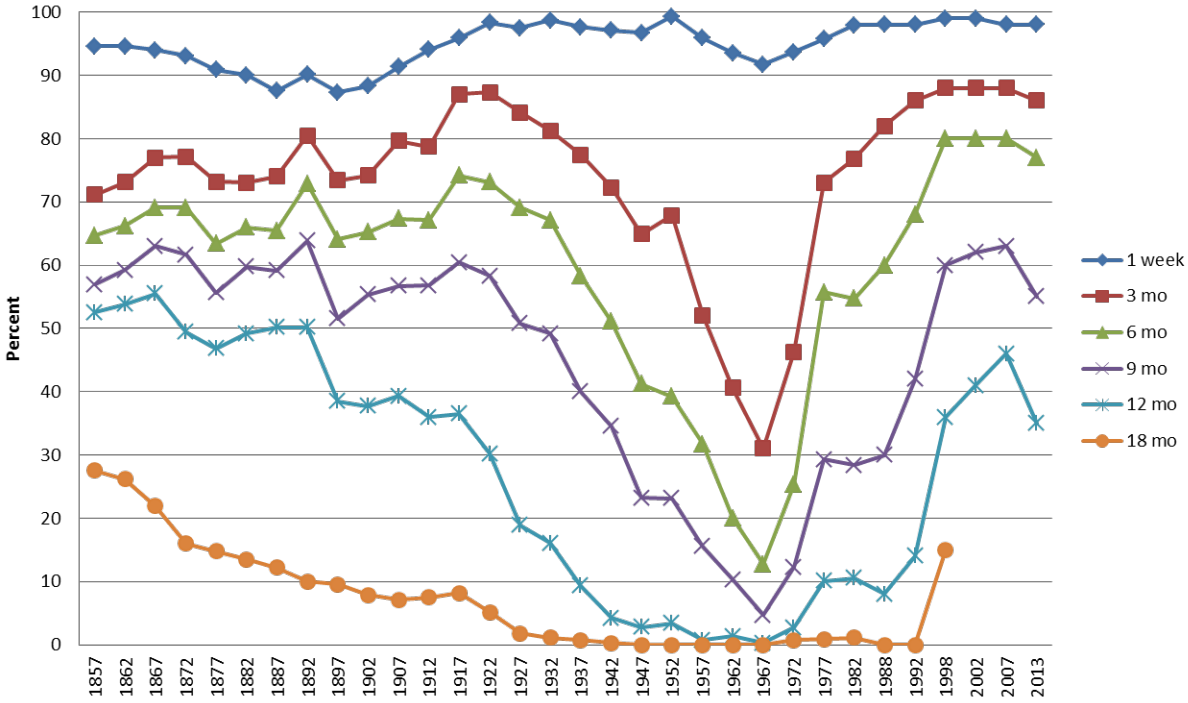


Figure 1. Breastfeeding in Norway from 1860 to 2013
Adapted and modified version of Liestøl K, Rosenberg M, Walløe L. *Breast-feeding practice in Norway 1860 – 1984.* J. Biosoc. Sci. 1988; 20: 45-58. Additional data from: Norwegian Institute of Public Health, SYSBARN (1982-1994), Norwegian Directorate of Health (1998-99), (2006-2007), (2013).

The dramatic change in breastfeeding practice in Norway around 1970 was related to complicated and profound changes in the society.[36] A sociocultural shift took place, away from medicalised infant feeding practices towards a more natural way of feeding babies. The mother-to-mother support group, Ammehjelpen, was founded in 1968 and strongly reinforced this process by empowering women, offering practical advice to mothers and lobbying for

better conditions for breastfeeding mothers. Gradually, hospital routines for breastfeeding support improved.[36,38] In 1981 the WHO adopted the International code of marketing of breast-milk substitutes.[39] The aim of this Code is 'to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.' In 1983 the International code was adopted in Norway as a voluntary agreement between the Directorate of Health and the infant food industry and health professional organizations. The EU Commission Directive on infant formulae and follow-on formulae, which includes some of the paragraphs in the WHO International Code, has since 2008 been included in the agreement between Norway and The European Economic Area.[40]

The new up-turn in breastfeeding duration in the 1990's was observed after the implementation of the WHO/UNICEF Baby-friendly Hospital Initiative in Norway[41] and increases in the duration of the maternity leave.[42] We do not know the reasons for the decline in breastfeeding duration between 2006 and 2013, but one possible factor could be that the mothers' possibility for taking parental leave was reduced in this period.[42]

1.3 Determinants of breastfeeding

Nearly all women are biologically capable of breastfeeding,[15] although some recent studies suggest that there may be physiological reasons for the lower prevalence of breastfeeding in some groups.[15,30] Thus the fluctuations in breastfeeding rates by time demonstrate how vulnerable breastfeeding practices are to environmental factors. The conceptual model by Rollins and coauthors illustrate how determinants at multiple levels affect breastfeeding practices (Figure 2).[15]

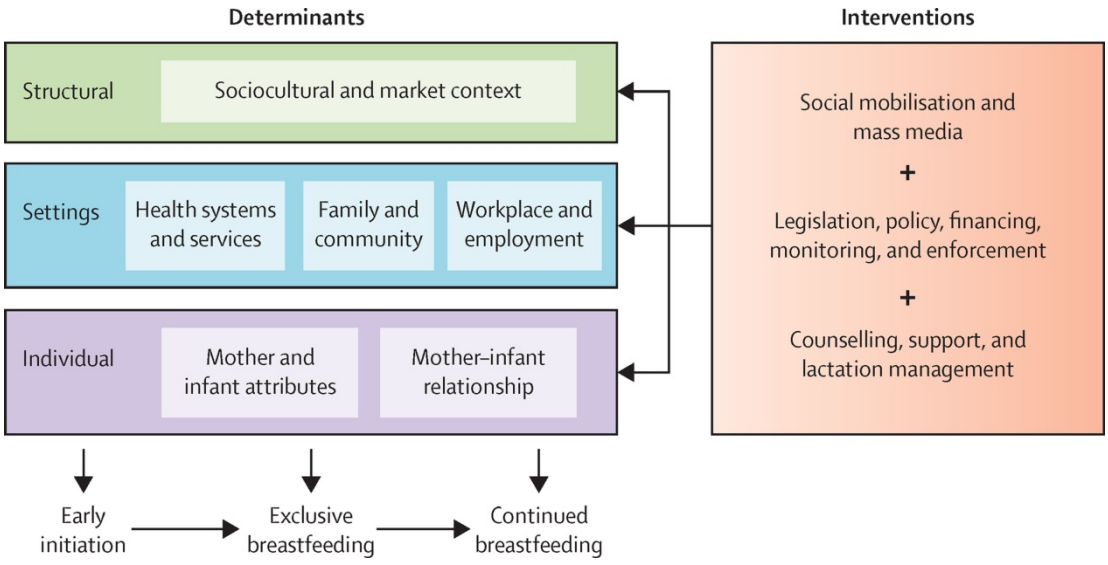


Figure 2. Determinants of breastfeeding and the components of an enabling environment for breastfeeding - a conceptual model
Reprinted from The Lancet, 387, Rollins et al. *Why invest, and what it will take to improve breastfeeding practices?* p 491-504, Copyright (2017), with permission from Elsevier.

The *structural level* refers to the social factors that affect the whole population, such as sociocultural trends, media and advertising. These factors are distal and the effect on pregnant women and mothers occurs through various interactions, attitudes, practices, and information in the three main *settings*: health services, family and community, and workplace and employment. At the most intimate *individual level*, women's breastfeeding behavior is influenced by personal characteristics such as her age, weight, education, health and by characteristics of her baby. Interactions between mother and baby, including whether the baby is thought to be satisfied and content, are results of the mother's internalisation of the influences at the level of structural determinants and settings.[15] This model also shows how interventions at various levels may influence breastfeeding.

Identifying determinants of breastfeeding is necessary for informing the interventions to support breastfeeding. In Norway, the national surveys of infant feeding[12,26,37] have shown that longer maternal education, higher maternal age and non-smoking habits were strongly associated with higher breastfeeding rates. Also, the fathers educational level, marital status, parity and birth weight were associated with breastfeeding duration.[26] Studies based on the Norwegian Mother and Child Cohort have found that Caesarean section,[43] pre-pregnant overweight and obesity, and high gestational weight gain were associated with lower

breastfeeding prevalence.[44] A similar pattern of determinants is seen in other high-income countries.[15,45] These are mainly *individual level* determinants of breastfeeding.

The *health service setting* has an important role in supporting women to breastfeed. Häggkvist et al.,[43] found that supplementation of breastfed newborn in the Norwegian maternity wards was associated with earlier cessation of full breastfeeding. Avoiding supplementary feeding to breastfed newborns unless medically indicated is a key step in the WHO/UNICEF Baby-friendly Hospital Initiative (BFHI). The BFHI has been shown to be an effective intervention in maternity wards for improving breastfeeding rates globally.[18,19]

Characteristics of *families, social networks and community settings* influence breastfeeding. In Norway, breastfeeding rates are higher in urban areas than in rural areas.[37] Grewal et al. [46] found that Norwegian-Somali and Norwegian-Iraqi mothers ended exclusive breastfeeding significantly earlier than ethnic Norwegian mothers, while the duration of breastfeeding was at similar level as in the national surveys.

Structural determinants such as sociocultural trends, policies, media and legislations on maternity protection and marketing of breastmilk substitutes are of profound importance, but the impact is difficult to assess. Liestøl et al.[36] in their historical report on breastfeeding trends from 1860 to 1984, discussed possible influences of structural determinants. Pérez-Escamilla et al.[47] compared the breastfeeding policies in two countries, Brazil and Mexico, with different breastfeeding trends. In Brazil, a comprehensive breastfeeding policy was associated with an upward trend in breastfeeding, while in Mexico several policy elements were lacking and breastfeeding rates did not improve.

Of particular interest for this thesis are determinants related to interventions in the community health service setting, determinants that may explain socioeconomic inequalities in breastfeeding, and ethnic background and maternal health, i.e. gestational diabetes.

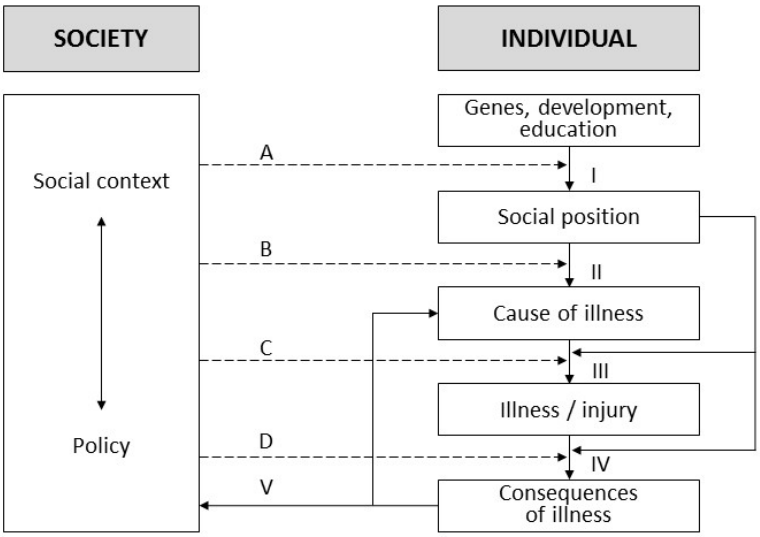
1.3.1 Socioeconomic position and breastfeeding

Reducing socioeconomic inequalities in health is a public health priority.[48,49] Socioeconomic inequalities in health and health related factors emerge in infancy.[50,51] Therefore preventive efforts should begin in early life.[28] The WHO Commission on social determinants of health defines socioeconomic position based on three dimensions: economic resources, prestige or access to life chances and power related to the political context.[52] Educational level,

occupational category and income are the most used indicators of socioeconomic status and health inequalities.[53] In a life-course perspective, there is a temporal and possibly causal relation between education and occupation and income.[54]

Until World War II, breastfeeding in Norway was more common among mothers from lower social classes, but since then the gradient has reversed.[36] The Norwegian infant feeding surveys have shown that women with higher education are more likely to breastfeed than those with less education, with an odds ratio (OR) of exclusive breastfeeding at 4 months of 3.14 and a 95% confidence interval (95% CI) of 1.54 to 6.38.[26] A similar pattern of social inequality in breastfeeding is observed in other high-income countries.[7]

Socioeconomic position is necessarily associated with health and health related factors, such as breastfeeding, via more proximal exposures or risk factors.[29,55] The Diderichsen model gives a theoretical overview of five causal mechanisms behind social inequality in health: (1) Social stratification as a result of e.g. heritage, ethnicity (2) Differential exposure to risk factors (3) Differential vulnerability i.e. causes of illnesses acting synergistically (4) Differential disease outcome (5) Consequences of health outcomes might also feed back into causal pathway.[56]



I=effect of social position on health through differential exposure; II=differential vulnerability; III=differential consequences of disease; IV=consequences of disease might also feed back into causal pathway; A=modifying effect of social context and policy on social stratification; B=policies affecting differential exposure; C=policies affecting differential vulnerability; D=policies affecting differential social consequences of disease.

Figure 3. Mechanisms of socioeconomic inequalities in health (I-V) and policy entry points for tackling them (A-D)[56]

We will apply the Diderichsen model in the discussion of mechanisms that may explain socioeconomic inequalities in breastfeeding by substituting 'illness' with 'early cessation of breastfeeding'.

Any aspect of health, e.g. breastfeeding, that varies across individuals or according to socially defined groupings can be characterized as a health inequality.[57] In contrast, the notion *health inequity* is a specific type of health inequality that is an unjust difference in health. Health differences that are preventable and unnecessary are denoted as health inequities, thus inequity implies a moral judgment of the inequality as being wrong.[58,59] In general, social group differences in health, such as those based on race or religion, are considered health inequities because they reflect an unfair distribution of health risks and resources.[57]

1.3.2 Ethnic origin and breastfeeding

In 2013 almost one in four newborns in Norway had an immigrant mother. Among newborns with two immigrant parents, the majority had an origin from Pakistan, Somalia, Vietnam, Iraq and Turkey.[60] According to Bhopal,[61] ethnicity refers to the social group a person belongs to, and either identifies with or is identified with by others, as a result of a mix of cultural and other factors including language, diet, religion, ancestry, and physical features. The breastfeeding pattern in many low-income countries such as South Asia and the Middle East is characterized by late initiation of breastfeeding, short periods of exclusive breastfeeding, but long duration of any breastfeeding.[62,63] In low- and middle income countries socioeconomic inequalities in exclusive breastfeeding are small, but poorer people consistently tend to breastfeed for a longer period.[7] The process of migration is associated with breakdown of networks, loss of socioeconomic position and social exclusion,[64] causing increased vulnerability which may also influence breastfeeding practices. Apart from studies on breastfeeding practices of Norwegian-Iraqi, Norwegian-Somali,[46,65] and Norwegian-Pakistani mothers,[66] we have limited knowledge about breastfeeding practice in ethnic minority groups in Norway.

1.3.3 Gestational diabetes and breastfeeding

Gestational diabetes mellitus (GDM) is defined as carbohydrate intolerance resulting in hyperglycaemia of variable severity with onset or first recognition during pregnancy, excluding those with diabetes in pregnancy likely to represent those with overt diabetes.[67]

During the course of pregnancy the woman adapts her metabolism to supply the fetus with nutrients, with increasing insulin resistance resulting in higher concentrations of glucose for fetal growth.[68] In healthy women, pancreatic β-cells compensate for the pregnancy-induced insulin resistance by increasing the production of insulin. If the insulin secretion is inadequate to meet the insulin demands, the pregnant woman may develop hyperglycaemia. Hyperglycaemia has been found to be associated with adverse pregnancy outcomes.[69-71] In most women, glucose level is normally restored to non-pregnancy levels shortly after delivery, but women with a history of GDM have up to seven-fold increased risk of developing type 2 diabetes.[31]

The Stork Groruddalen study is a population-based multiethnic study from eastern Oslo, Norway. From May 2008 to May 2010, healthy pregnant women attending maternal and child community health services were invited to participate. Overall, 823 (74% of invited women) were included, and of these 59% had ethnic minority background.[72] The prevalence of gestational diabetes in the total cohort was 31.5% with the WHO 2013 criteria.[73]

Pregnancy and breastfeeding has been considered as a continuum, with breastfeeding supporting "resetting" of the adverse metabolic profile that develops as part of a normal pregnancy (Figure 4).[74]

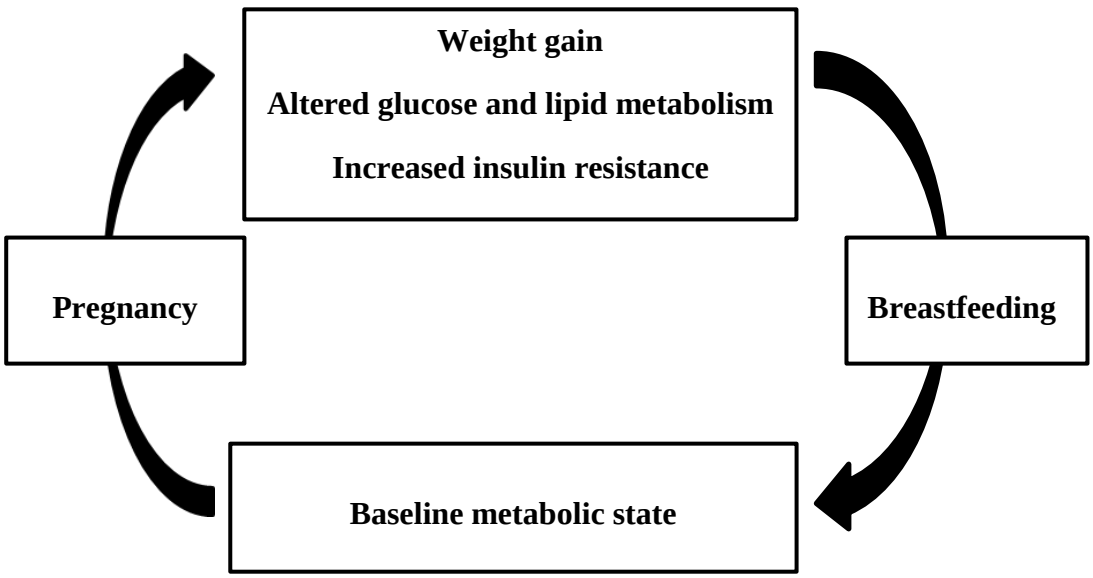


Figure 4. Adapted from Stuebe A, Rich-Edwards JW. The reset hypothesis: lactation and maternal metabolism. Am J Perinatol 2009; 26: 81-88.

When breastfeeding is not practiced, women may maintain an elevated risk of type 2 diabetes and also cardio-metabolic diseases.[74,75] In healthy mothers, a systematic review from 2013 showed that breastfeeding was associated with lower risk of diabetes type 2.[76] Studies published after this review support this finding.[77-79] In mothers with a history of gestational diabetes, a review from 2017 including nine studies found that breastfeeding was associated with lower risk of type 2 diabetes.[33]

The mechanisms to explain the lower risk of conversion to type 2 diabetes with intensity and duration of breastfeeding are not clarified. Some studies,[80,81] but no all,[79] suggest that lactation may preserve β-cells, and an inverse association has been observed for lactation intensity and insulin resistance.[79,82-85] One proposed mechanism for the improved glucose regulation could be that carbohydrate stores are mobilized and used for lactose production, a major nutrient in human milk.[86] As breastfeeding requires energy; another possible mechanism could be reduced weight retention after delivery. In our Stork Groruddalen cohort, exclusive breastfeeding was not associated with increased postpartum weight loss at mean 14 weeks postpartum compared to non-exclusive breastfeeding.[87] The observation period for assessment of weight retention in our study may have been too short, as other studies from Norway have shown that postpartum weight in breastfeeding mothers decreased throughout the first year,[88] and even up to three years postpartum.[89] In the Norwegian Nord-Trøndelag Health Study (HUNT2) an inverse association was observed between lifetime duration of breastfeeding and body mass index and waist circumference among women 50 years of age or younger.[90] A review of 54 articles assessing the association of breastfeeding on postpartum weight retention ≤ 2 years postpartum was inconclusive,[91] and long-term studies from other countries show conflicting results.[92, 93, 94] Possible reasons for the conflicting results could be different intensities and duration of breastfeeding,[79,95] and differences in post-delivery energy consumption and expenditure.[88]

In the child, being breastfed has been associated with reductions in overweight and type 2 diabetes,[7] although findings from studies of children of mothers with GDM were inconsistent.[96] A review of postnatal prevention of childhood obesity in offspring prenatally exposed to gestational diabetes, suggests that a longer duration of breastfeeding may be necessary to show an effect among children born from diabetic mothers compared to non-diabetic mothers.[97] This could possibly be explained by a different composition of the

breastmilk of diabetic mothers, that normalizes as glycaemia returns to normal ranges after delivery.[98]

Despite growing evidence for a preventive effect of breastfeeding on future type 2 diabetes in women with previous GDM, there has been little research on the duration of exclusive breastfeeding in these women. Studies suggest that women with recent gestational diabetes have lower rates of initiation of exclusive breastfeeding.[99-101] The few studies on duration of exclusive breastfeeding, however, showed mixed findings.[102-105] From previous studies, it is known that women of South Asian origin have an increased risk of developing type 2 diabetes 1-2 years after delivery, compared to European women.[34,35] As breastfeeding may have greater rewards in women with recent GDM, more knowledge is needed about the prevalence of breastfeeding in these women.

1.4 Interventions to support breastfeeding in the health services

Interventions to support breastfeeding can be broadly categorized as individual-level and system-level interventions.[23] System-level interventions include policies and programmes usually implemented within hospitals or health care systems. Individual-level interventions include one-to-one support of health professionals or peers, and education sessions.[23] Another categorization is population-based and high-risk prevention strategies.[106] Population based preventive strategies attempt to influence the determinants of breastfeeding in the whole population, e.g. by improving the quality of support in health services, and to shift the whole distribution in a favorable direction. High-risk preventive strategies focus on groups that are at high risk of e.g. early breastfeeding cessation.[106]

The first system-based intervention to support breastfeeding for large scale implementation in hospitals was the WHO/UNICEF Baby-friendly Hospital Initiative (BFHI) launched in 1991. The Ten Steps that form the basis of BFHI serve as a quality assurance system based on highly interrelated specific actions. The BFHI designation is awarded to hospitals deemed to have reached a minimum externally auditable standard related to the 'Ten steps to successful breastfeeding'. For detailed information about the BFHI and the Ten Steps see: http://www.who.int/nutrition/publications/infantfeeding/bfhi_trainingcourse/en/

The BFHI was developed to reverse the medicalisation of infant feeding that occurred during the twentieth century, e.g. by separation of mothers and newborns and rigid schedules for

frequency and duration of feeds. Until 1991, there was limited research-based evidence for best practice breastfeeding support in maternity wards, and the 'Ten Steps' were primarily the result of personal experiences by women who were trying to help other mothers to breastfeed.[107] Research underpinning the 'Ten steps' accumulated, and in 1998, WHO published 'Evidence for the 'Ten steps' to successful breastfeeding'.[108] On the 3rd of November 2017 the World Health Organization published updated evidence for the BFHI entitled 'Protecting, promoting and supporting breastfeeding in facilities providing maternity and newborn services': http://www.who.int/nutrition/publications/guidelines/breastfeeding-facilities-maternity-newborn/en/ On the basis of this updated evidence, a revised version of the BFHI has been drafted, but this was not publicly available by December 2017.

Recent reviews show that the BFHI has been one of the most effective interventions in maternity facilities for improving breastfeeding rates.[18,19] Also experiences from Norway indicate that BFHI lead to increased breastfeeding rates.[41] We set out to adapt the Baby-friendly Hospital Initiative for the community health services, and to assess the effectiveness on breastfeeding and maternal satisfaction. Every healthcare intervention comes with the risk of unintended adverse effects.[109] One possible down-side of population-based interventions is that they may widen socioeconomic inequalities in health outcomes,[110] but few studies have examined the effectiveness of breastfeeding interventions across socioeconomic groups.[111,112] Another risk in interventions that seek to influence personal behaviour, such as breastfeeding practice, is that it may be perceived as a pressure.[113,114] To our knowledge, there are no previous studies that have assessed how an intervention influenced mothers' perception of being pressurized to breastfeed.

2 AIMS OF THE THESIS

The overall aim of this thesis was to obtain further knowledge about effectiveness of interventions in the community health services to support breastfeeding and to gain knowledge about inequalities related to socioeconomic position, ethnic origin and maternal health that may inform future interventions.

The specific objectives were:

1) To assess the effectiveness of the Baby-friendly Initiative in community health services on exclusive breastfeeding until six months in a pragmatic cluster quasi-randomised trial. Secondary outcomes were duration of any breastfeeding, maternal satisfaction with the breastfeeding experience and perceived breastfeeding pressure. We also explored possible differential effects of the intervention across educational groups. (Paper I)

2) To explore factors that may explain socioeconomic inequalities in breastfeeding by conducting an observational study nested within the cluster quasi-randomised trial. (Paper II)

3) To examine timing of cessation of predominant breastfeeding in mothers with recent gestational diabetes compared to mothers without gestational diabetes, and in relation to ethnic origin in the Stork Groruddalen cohort study. (Paper III)

3 METHODS

This thesis is based on data from two studies, and the methodology will be described separately.

I. A pragmatic cluster quasi-randomised trial (Paper I and Paper II)

II. The STORK Groruddalen multi-ethnic cohort study (Paper III)

3.1 Study design (Paper I)

3.1.1 Design and study sample

We evaluated the effectiveness of the Baby-friendly community health service[115] in a pragmatic cluster quasi-randomised controlled trial in collaboration with Statistics Norway.[1,2] To minimize contamination between the intervention and comparison groups, we allocated municipalities rather than maternal and child community health sevices because all community health services within a municipality are under a shared management. The study was undertaken in predominantly rural and semiurban municipalities in six of the 19 counties in Norway; Østfold, Vestfold, Nord-Trøndelag, Hordaland, Telemark and Finnmark.

Sample size calculation

We anticipated that the intervention would lead to an increase in the proportion of exclusive breastfeeding for 6 months of 5 percentage points, from approximately 9% based on national figures, to 14%.[116] Furthermore, we considered it realistic to recruit 50 municipalities. Based on these assumptions, and a significance level of 5% for a two-sided test, statistical power of 80% and an intracluster correlation coefficient (ICC) of 0.01, we estimated a needed sample size of at least 1950 mother-infant pairs (Practihc 2007). As we expected a participation rate of about 55%, we planned to invite 3500 mother-infant pairs to take part in the study.

Allocation of municipalities

Fifty-five municipalities consented to participate in the trial, but two municipalities were merged by the authorities during the study period, leaving 54 municipalities in the study. Consent to participate in the trial was given by the managers of the maternal and child community health services before the group allocation. As described in our protocol, the

municipalities were meant to be allocated randomly to intervention or comparison groups by computer generated randomization, but due to a misunderstanding, allocation was by alternation: An adviser from Statistics Norway, neither involved in the intervention nor the data analyses, prepared a list of the 54 municipalities ranked according to the number of births in the previous year. For each consecutive pair of clusters, the first was allocated to the intervention and the second to the comparison group.

Timeframe

We identified the mothers in the municipalities through the National Population Register. We conducted a pre-intervention postal questionnaire survey to all mothers with infants of 5 or 11 completed months in the municipalities, from August 24, 2009, to January 12, 2010. The Baby-friendly community health services was initiated in all intervention municipalities in December 9, 2009, and continued until the post-intervention survey commenced in May 7, 2012. Data-collection ended August 19, 2013 (Figure 5). The questionnaire asked about breastfeeding practices (see 'Abbreviations and definitions' and Appendices) and covariates as shown in table 1. The questionnaires were only offered in Norwegian. A reminder was sent by sms or letter after 4-5 days, and a second reminder with questionnaire after 3 weeks.

	2009				**2010**				**2011**				**2012**				**2013**				**2014**				**2016**
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
Design of intervention, from 2008	x	x																							
Pilot testing		x																							
Recruitment of municipalities		x																							
Randomisation			x																						
Pre-intervention survey			x	x	x																				
Implementation; designation				x	x	x	x	x	x	x	x	x	x	x											
Post-intervention survey: Data collection (5.5 mo)														x	x	x	x								
Effect survey: Data collection (11.5 mo)																x	x	x	x						
Data analysis , publication																				x	x	x	x	x	x

Figure 5. Timeframe for the pragmatic trial

Inclusion criteria and participants

Figure 6 shows the flow of municipalities and mother-infant pairs in the post-intervention study. For the post-intervention study we invited 3498 mothers with infants of 5 completed months to participate, and 2032 (58.1%) agreed to participate. Mother-infant pairs were

included in the data-analyses if they had given birth to a singleton infant of ≥37 gestational weeks and a birth weight of ≥2000 g, leaving 1906 mother-infant pairs for the analysis.

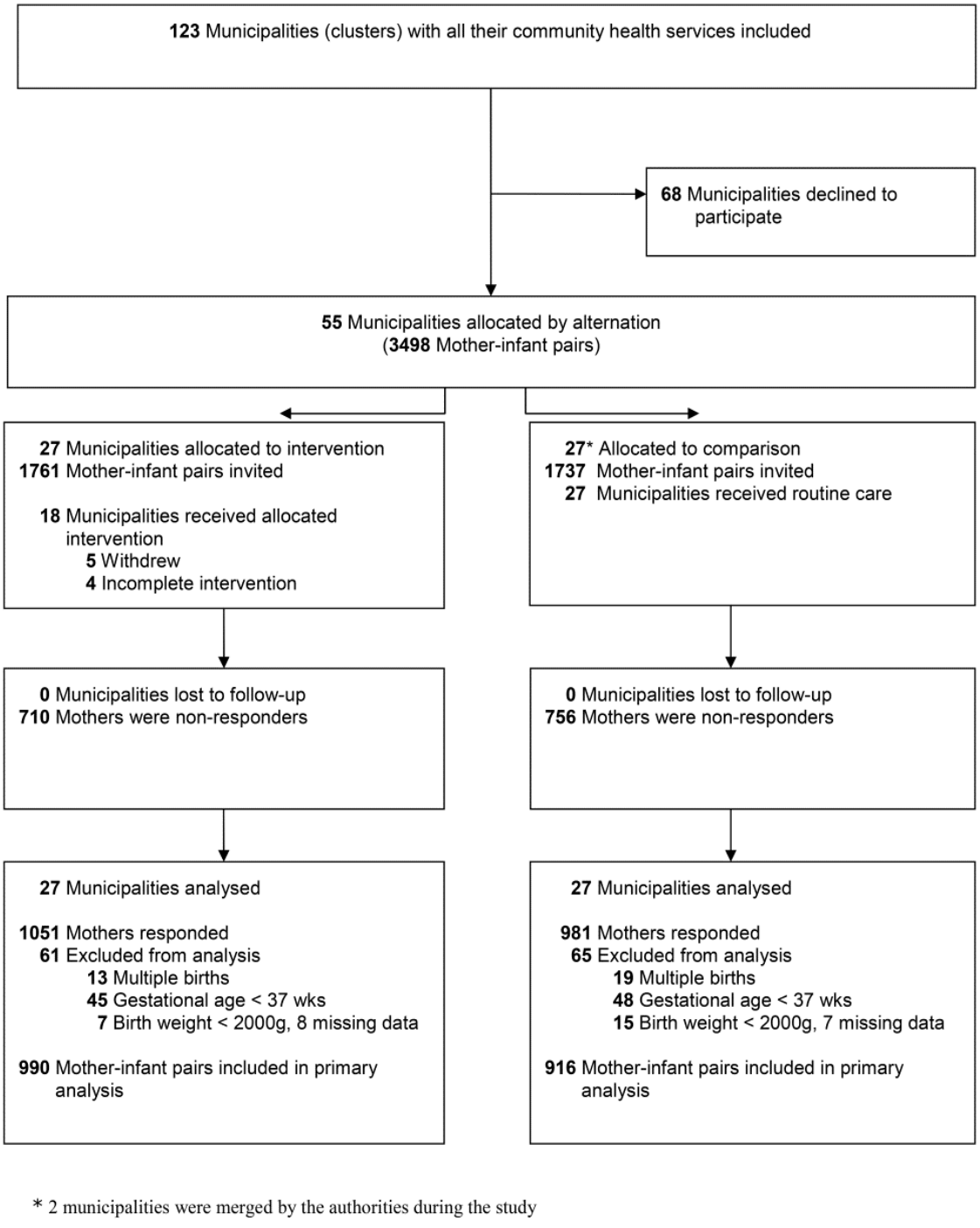


Figure 6. Flowchart of municipalities (clusters) and mother-infant pairs

3.1.2 Intervention

The intervention is an adaptation of the Baby-friendly Hospital Initiative,[117] for integration into routine antenatal and child care in the community health services.[115] The process of becoming a Baby-friendly community health service is illustrated in Paper I, figure 1.[118] Municipalities allocated to the intervention group received a manual on how to become Baby-friendly, outlining a quality standard for breastfeeding counselling in 6 steps.

Baby-friendly community health services should:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff at the maternal and child community health service.
2. Train all health care staff in the knowledge and skills necessary to practice in accordance with the breastfeeding policy.
3. Inform pregnant women about the benefits and management of breastfeeding.
4. Establish a reliable system of communication to ensure continuity of care between antenatal care, hospitals and community health services. The community health services should give mothers contact details of breastfeeding support groups.
5. Show mothers how to breastfeed and how to maintain lactation.
6. Give mothers appropriate information and support to maintain exclusive breastfeeding for the first six months. After introduction of solid foods breastfeeding should be sustained up to the end of the first year and beyond as long as mutually desired by mother and child.

For detailed information about the Baby-friendly community health services: https://oslo-universitetssykehus.no/fag-og-forskning/nasjonale-og-regionale-tjenester/nasjonal-kompetansetjeneste-for-amming-nka/mor-barn-vennlig-initiativ-mbvi/ammekyndig-helsestasjon#nyttige-dokumenter

The community health services were offered tools for assessment, action and re-assessment, and were supervised by two specially trained part-time public health nurses from the Norwegian National Advisory Unit on Breastfeeding. In the first phase of the process staff at the community health services mapped breastfeeding practices, using a 24-hours recall, and examined the reasons for breastfeeding cessation in 20 infants who attended their 5- or 12-month routine consultations. The second phase was a self-appraisal questionnaire completed by the staff in order to clarify existing practices. During the third phase, staff were to develop a written breastfeeding policy and a training programme based on the 6-step quality standard, and send these to the national advisory unit for approval. The minimum requirement of training for all health professionals was 12 hours, including the reading of a 200 page book

with 100 study questions,[119] as well as training and demonstration of practical skills. About three months after approval and implementation of the breastfeeding policy, the Norwegian National Advisory Unit on Breastfeeding would undertake a user survey among pregnant women and mothers of 6 weeks old babies. Final designation as a Baby-friendly community health service was based on the approval of the breastfeeding policy, as well as at least 80% of pregnant women and mothers confirming that received counseling was in accordance with the 6-point quality standard. One year after designation, the community health service mapped the breastfeeding prevalence again, to stimulate a continuous process of assessment and action.

Routine maternal and child care in the community health services

The comparison municipalities continued offering routine health services, which comprise both antenatal care and preventive health care from hospital discharge through childhood and adolescence (see box for further information).

Maternal and child community health services

In Norway, the community health services offers free of charge antenatal care and preventive care for the child from hospital discharge through childhood and adolescence.
In the study period, the routine preventive programme for infants included a home-visit between 0-2 weeks, and consultations at 6 weeks, and 3, 4, 5, 6, 7-8, 10, 11-12 months for vaccination, anthropometric measurements, screening and lactation counselling.
In 2014, after the study period, the Norwegian Directorate of Health launched revised recommendations for the routine preventive programme. Now, a home-visit by midwife is recommended the first or second day after hospital discharge for primipara and within three days for multipara women with previous good experiences. The first home-visit by the public health nurse should take place within 7-10 days after delivery, with further consultations as in the previous guideline.

Reference: Norwegian Directorate of Health. National guideline on maternity care. Barselomsorgen. Nasjonal faglig retningslinje for barselomsorgen. [In Norwegian] Oslo: Norwegian Directorate of Health, 2014.

3.1.3 Outcome variables and covariates

The primary outcome was exclusive breastfeeding until 6 months, specified as exclusive breastfeeding for at least 5 completed months.[3] Secondary outcomes were exclusive breastfeeding until 5 months (at least 4 completed months), any breastfeeding until 6 and 12 months, and maternal satisfaction with the breastfeeding experience and perceived breastfeeding pressure. The questionnaires were sent to mothers the week after their child was 5 and 11 completed months old. Breastfeeding status was assessed at both ages, using similar questions as in the Norwegian infant feeding surveys.[116] Those who had ended breastfeeding were asked to tick off on a scale at the age breastfeeding was stopped. To assess the duration of exclusive breastfeeding, three similar scales were used to report the age of introduction of infant formula, water and water-based liquids and solid foods (see 'Abbreviations and definitions' and questionnaire in Appendices). Consistent with the WHO definition,[3] infants were considered exclusively breastfed if they were given only breast milk, and no other food or liquid, even water. 'Any breastfeeding' included both breastfeeding without and with additional food and liquid.

We conducted subgroup analyses to explore possible differential effects across socioeconomic groups. Maternal education was used as an indicator for socioeconomic status as it reflects both material resources and knowledge.[29]

Similar to Labarere et al.[120] we assessed how the intervention affected overall maternal satisfaction with the breastfeeding experience. We asked the participants to respond to the question 'How was your overall experience of breastfeeding?' on a 5 point single-item scale ranging from very poor to very good. We also asked the mothers 'Have you felt pressured to breastfeed for a longer period than you wanted to?'

Table 1 shows the covariates included in paper I.

Table 1. Covariates in paper I, II and III

Variable	Categorization	Population-based pragmatic trial		Stork Groruddalen cohort
		Paper I	Paper II	Paper III
Sociodemographic variables				
Maternal education	Primary and secondary school (≤10 years), high school (12 years), college/university (≤4 years), college/university (>4 years)	X	X	
	High school or less, college/university			X
Employment status	Employed/student, Not employed/student		X	
Mother's age[1]	<25, 25-29, 30-34, ≥35 years	X	X	
	<30 , ≥30 years			X
Marital status	Married, cohabitant, single	X	X	
Parity	Primipara (1 child), multipara (≥2 children)	X	X	X
Ethnic background	Western European, South Asian, Middle Eastern, Other			X
Life style				
Smoking habits	Current daily and occasional smoking, no smoking at 5 months	X	X	
	Smoking in pregnancy (daily)			X
Maternal health and health related factors				
Prepregnancy BMI	< 30 kg/m^2, ≥30 kg/m^2			X
Gestational weight gain	≥13 kg, < 13 kg			X
Depression in pregnancy	EPDS ≥10, EPDS <10			X
Delivery and child characteristics				
Mode of delivery	Vaginal, instrumental, caesarean			X
Child sex	Boy, girl	X	X	
Birth weight[2]	<2500 g, 2500-4000 g, >4000 g		X	
	Mean (SD), g	X		
	<25, 25-75, >75 percentile			X
Apgar score, 1 min	≥8, < 8			X
Gestational age[2]	<37; ≥37 weeks		X	
Breastfeeding				
Feeding status at hospital discharge	Exclusive, any or no	X		
Quality of counselling: Nurse observed breastfeeding	No, mother did not deem it necessary, yes		X	
Breastfeeding difficulties	Difficulties with latching on, perceived milk insufficiency, pain during breastfeeding, sore nipples, plugged ducts, mastitis, poor weight gain, other		X	

[1]From the National Population Register [2] In paper I: Exclusion criteria were birth weight <2000 g and gestational age <37 weeks.

3.1.4 Statistical analysis

The statistician performing the main data-analysis was neither involved in the implementation of the intervention nor the allocation process, and group affiliations were masked. To account for within municipality clustering, the intervention effects on the binary outcome variables, i.e. exclusive breastfeeding and any breastfeeding, were analyzed by mixed effects logistic regression with municipalities as random effects. Intra-class correlation was calculated

accordingly.[121] The following adjustment variables were included as fixed effects in the model; feeding status at hospital discharge,[43] maternal education, maternal age, number of children, and smoking habits (Table 1).[26]

We used intention to treat analysis as our main analytical approach, i.e. data from all participants were analyzed according to their original allocation to intervention or comparison group. We conducted subgroup analyses to explore possible differential effects across socioeconomic groups. For this purpose, the interaction between intervention and education was included in the model. We also ran a per protocol analysis, based on the 18 of 27 municipalities which actually completed the intervention, and corresponding comparison clusters of similar size.
The questionnaire to assess breastfeeding until 12 months was not sent to mothers who had ended breastfeeding before 6 months, since their answers were considered as known.
To avoid that this group was overrepresented, non-response weighting was applied. The estimated regression coefficients were transformed to odds ratios. Statistical analyses were performed with the R program using the lme4 package, and SPSS statistical software, version 21 (IBM Corporation, New York, USA). In addition a randomization test was programmed manually in R to assess the robustness of the results from the mixed-effects logistic regression.

Originally, we planned to estimate intervention effects as the difference between changes in the proportions of exclusive breastfeeding from the pre-intervention to the post-intervention survey, for the intervention and comparison groups (i.e. difference in difference). Instead, we simply compared the post intervention prevalence in the two groups. We made this change for two reasons: 1) We found no important differences between the groups in the pre-intervention survey (see Paper I, Results). 2) We conducted the pre-intervention survey 2-4 years before the post intervention survey, making it likely that the findings were too old to reflect differences between the actual intervention and comparison groups.

3.2 Study design (Paper II)

3.2.1 Design and study sample

We conducted an observational study nested within the cluster quasi-randomised trial (paragraph 3.1) to explore whether socioeconomic inequalities in exclusive and any breastfeeding could be explained by other sociodemographic factors, smoking habits, birth characteristics, quality of counselling and breastfeeding difficulties. We used data from the 5 completed month questionnaire of the trial, combining data from the two study arms. We included only women born in Norway since the association between socioeconomic status and infant feeding practices vary by country of origin.[122] The questionnaire was offered only in Norwegian, thus number of participants from different ethnic minority groups were too small for meaningful analysis in these groups. We also excluded twins due to their particular challenges for breastfeeding,[123] leaving a study sample for data analysis of 1598.

3.2.2 Outcome variables and covariates

The outcome variables were exclusive and any breastfeeding. The breastfeeding indicators were assessed as described under 'Abbreviations and definitions' and Appendices. Consistent with the WHO definition,[3] infants were exclusively breastfed if they were given only breast milk. We used education, categorised as in table 1, as the indicator of socioeconomic position.[124] As in a similar study by van Rossem et al.,[29] we conceptualized that educational level was the most distal factor in the causal pathway determining breastfeeding behavior,[124] while other sociodemographic characteristics, smoking habits, birth characteristics, quality of breastfeeding counselling and breastfeeding difficulties are factors that could potentially explain socioeconomic inequality in exclusive and any breastfeeding. Table 1 shows the covariates included in paper II.

3.2.3 Statistical analysis

In paper I the cluster effect was taken care of by using a mixed effects logistic regression with municipalities as random effects. The intra-class correlation coefficients found in our trial were very low. In the analyses in paper II we therefore disregarded the cluster effect.

We used multiple logistic regression to assess how the covariates influenced the association between the mother's educational level and exclusive and any breastfeeding at 5 completed

months. As in the study by van Rossem et al.[29] our starting point was the association between educational level and breastfeeding. We then examined how adding various known determinants influenced the association between education and breastfeeding. We added sociodemographic characteristics, or birth characteristics, or lifestyle characteristic i.e. smoking habits, our indicator of quality of counselling, and breastfeeding difficulties. Finally, we added all covariates simultaneously. We adjusted all models for participation in the intervention arm or comparison arm of the trial. The log likelihood test was used to test the significance of the difference between each model with or without maternal education included. We used SPSS statistical software, version 21 (IBM Corporation, New York, USA) for the statistical analyses.

3.3 Ethical considerations (Paper I and Paper II)

Breastfeeding is the recommended mode of infant feeding, and a sensitive issue. Efforts to promote and support breastfeeding may cause reactions such as guilt and anger. Messages that only idealize breastfeeding, or that exaggerate its benefits may be unethical. The recommendation to breastfeed should be accompanied by skilled support. The main purpose of the trial was to measure the effect of an intervention to increase skills in lactation counselling, based on mothers' own reports. The identification and explanation of socioeconomic inequalities in breastfeeding could be perceived as stigmatizing by mothers, and this inference should not be made at the individual level.

In connection with the questionnaires, mothers received written information about the purpose of the study and that participating in the survey was voluntary and withdrawal at any time would not affect the services available to them at the community health service. For mothers, consent was implied by their response to the questionnaire. Statistics Norway was responsible for establishing a de-identifiable data file. The Norwegian National Advisory Unit for Breastfeeding, Oslo University Hospital received the de-identifiable dataset for research purpose. The data file is stored at the research server of the hospital. The Regional Committees for Medical Research Ethics approved the study protocol (REK Sør-Øst C Ref:S-09277c 2009/5783), and the Privacy Ombudsman for Research (20090518). This trial is registered in clinicaltrials.gov as NCT01025362.

3.4 Study design (Paper III)

3.4.1 Design and study sample

The Stork Groruddalen study is a population-based cohort study of healthy pregnant women and their offspring, living in three city districts of Oslo (Bjerke, Grorud and Stovner administrative districts in Oslo).[72] The main objectives of the Stork Groruddalen cohort study were to present population-based data on the prevalence of gestational diabetes (GDM) in a multi-ethnic population, and explore predictors of GDM and adverse pregnancy outcomes. All pregnant women attending the maternal and child community health services between May 6, 2008 and May 15, 2010 were eligible if they were (1) living in the districts, (2) planned to give birth at one of the two study hospitals, (3) were in gestational week < 20, and (4) could communicate in any of the nine following languages: Norwegian, Arabic, English, Sorani, Somali, Tamil, Turkish, Urdu and Vietnamese. Exclusion criteria were pre-gestational diabetes or other conditions necessitating intensive hospital follow-up during pregnancy.

Recruitment

Information to promote the study in the nine languages was widely distributed via e.g. pharmacies, shopping centres, general practitioners and institutions for Norwegian classes and public service centres. Of the 823 women enrolled, 616 mothers with singletons and data on both GDM status and predominant breastfeeding were included in the present analysis. (Figure 7).

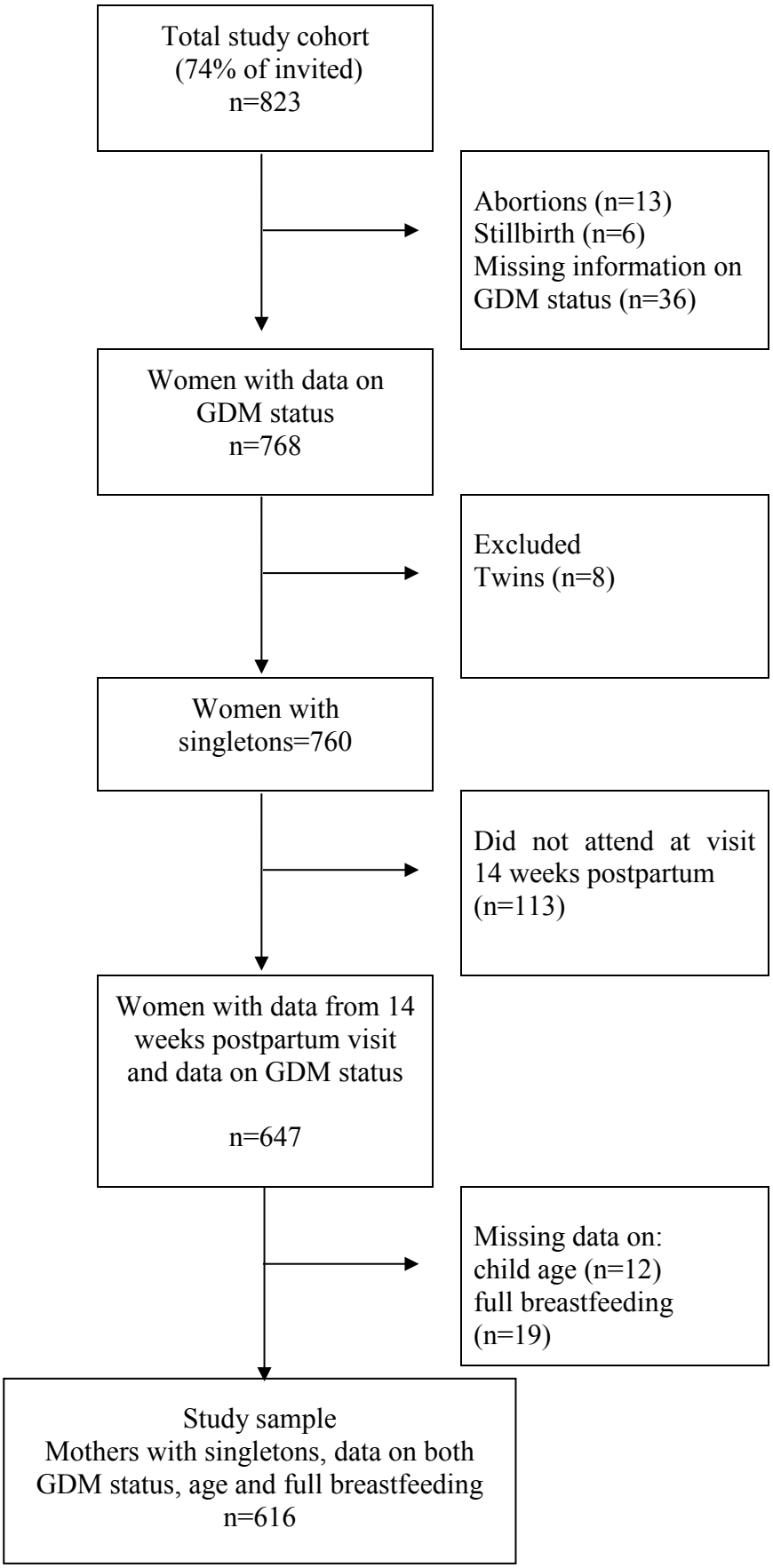


Figure 7. Flowchart of participants in paper III from The Stork Grouddalen cohort

3.4.2 Outcome variables and covariates

Data were collected at three visits: at mean 15 and 28 weeks of gestation and 14 weeks' postpartum. Specially trained midwives at the maternal and child health services in the three city districts collected the data in face-to-face interviews. Professional interpreters assisted during interviews, if needed. For further details of the design of the Stork Groruddalen cohort, see Jenum et al.[72]

Breastfeeding

Breastfeeding status was assessed around 14 weeks' postpartum (range 8-18 weeks), with retrospective questions covering the period since birth, using similar questions as in the Norwegian infant feeding survey,[26] and in Paper I and II. In accordance with the WHO criteria for indicators for assessing breastfeeding,[3] we used the term 'predominant breastfeeding' for infants who received breastmilk, possibly also with plain water, but no other food or liquid (see 'Abbreviations and definitions').

Gestational diabetes

A 75 g oral glucose tolerance test (OGTT) was performed at 28 weeks gestation, and venous 2 hour-blood glucose was measured on site with a HemoCue+ (HemoCue AB, Ängelholm, Sweden), calibrated for plasma.[72] In the present study, we used WHO 2013 criteria for GDM;[67] fasting plasma glucose $\geq$5.1mmol/L or two-hour glucose $\geq$8.5 mmol/L, one-hour values were not available. For further details see Jenum et al.[72,125]

Ethnic origin

Ethnicity was defined as country of birth or participants mother's country of birth if the participants mother was born outside of Europe or North America,[126] and categorized as shown in table 2.

Covariates

Table 1 shows the included covariates in the analysis in paper III.

Table 2. Ethnic origin of the women included in the current study from the Stork Groruddalen cohort

	Western Europe *(n=261, 42%)*	**South Asia** *(n=154, 25%)*	**Middle East** *(n=87, 14%)*	**Other** **(n=114, 19%)**
Norway	243 (93%)			
Other Scandinavian	11 (4%)			
North-America	7 (3%)			
Pakistan		97 (63%)		
Sri Lanka		48 (31%)		
India		9 (6%)		
Afghanistan			9 (10%)	
Iraq			22 (25%)	
Morocco			19 (22%)	
Turkey			21 (24%)	
Other North-African, Central Asian, Middle Eastern			16 (19%)	
Eastern European				36 (32%)
Philippines				10 (9%)
Vietnam				15 (13%)
Other East Asian				10 (9%)
Somalia				20 (17%)
Other African				17 (15%)
South-American				6 (5%)

3.4.3 Statistical analysis

We used logistic regression to assess the association between GDM and breastfeeding at the ages of one and two completed weeks after delivery. As breastfeeding status was assessed at different ages from 8 to 18 weeks after delivery, Kaplan-Meier survival analyses were used to compare the end of predominant and any breastfeeding in mothers with and without GDM using the log-rank chi-square test. Cox proportional regression analysis was used to assess whether GDM was associated with predominant or any breastfeeding in two models. The age of the child when breastfeeding ended was used as the time to event. Similar to The Environmental Determinants of Diabetes in the Young (TEDDY) birth cohort study (13), we included the following potentially confounding factors in model one: obesity in pregnancy, gestational weight gain, ethnic background, maternal age, education, smoking before pregnancy, parity, depression in pregnancy. In model two, we additionally included mode of delivery, birth weight, gestational age and Apgar score. We conducted interaction analyses to explore possible effect modification of ethnic origin on the effect of relevant covariates (GDM, obesity, depression in pregnancy, maternal education, parity) on predominant breastfeeding. The statistical analyses were performed using the SPSS statistical software, version 23 (IBM Corporation, New York, USA).

3.5 Ethical considerations (Paper III)

All pregnant women were given written and oral information when they were invited to participate in the study at the first antenatal appointment at the maternal and child community health service. Information material was available in different languages, and mothers were asked if they needed an interpreter. The women were informed about their right to withdraw or restrict their data from analyses at any stage. Women gave informed written consent before study enrolment. All data were anonymised prior to analysis.

The study protocol was approved by The Norwegian Regional Committee for Medical Research Ethics for South Eastern Norway (ref: 478-07249a. 1.2007/894) and the Norwegian Data Protection Authority (ref: 07/01355-2/MOF). Data are stored in accordance with the standards by the Norwegian Data Inspectorate.

4 RESULTS

4.1 **Paper I**

Effectiveness of Baby-friendly community health services on exclusive breastfeeding and maternal satisfaction: a pragmatic trial
Maternal & Child Nutrition 2016; 12:428-39.

Baseline characteristics of mothers and infants were similar in the intervention and comparison municipalities. Compared with routine care, the Baby-friendly Initiative in the community health services increased rates of exclusive breastfeeding until six months; 17.9% vs. 14.1% until 6 months [cluster adjusted odds ratio (OR)=1.33; 95% confidence interval (CI): 1.02, 1.72; P=0.03]. The intervention did not impact on any breastfeeding until 12 months.

The majority of mothers were satisfied with their breastfeeding experience, with no statistically significant difference between intervention and comparison sites. Perceived breastfeeding pressure from staff in the community health services was low, and there was no statistically difference between the two groups (intervention 5.7% vs. comparison 4.6%, *P*=0.37).

We did not detect statistically significant differences in effect size across socioeconomic subgroups in exclusive breastfeeding until 6 months (*P* value for interaction= 0.163)

The per protocol analysis, based on the 18 intervention municipalities which had completed the intervention and 18 corresponding comparison municipalities, yielded comparable effect estimates to our intention to treat analysis.

4.2 Paper II

Explaining socioeconomic inequalities in exclusive breastfeeding in Norway

Arch Dis Child 2017; 102: 708-714.

In ethnic Norwegian mothers, socioeconomic inequalities in exclusive breastfeeding were present from the beginning and persisted for 5 completed months. We used educational attainment as the indicator of socioeconomic position. At 5 completed months, 22% (72 of 335) of the most educated mothers breastfed exclusively compared to 7% (11 of 150) of the least educated women [odds ratio (OR) 3.39, 95% confidence interval (CI) 1.74 to 6.61]. We conceptualized that educational level is the most distal factor in the causal pathway determining breastfeeding practice. When exploring how various known determinants of breastfeeding influenced socioeconomic inequalities in exclusive breastfeeding, we observed that sociodemographic factors, smoking habits and breastfeeding difficulties decreased the differences between educational groups. After adjustment for all covariates, the odds ratio was reduced and lost statistical significance. Also, socioeconomic inequalities in any breastfeeding increased over time. At 5 completed months, 86% (289 of 335) of the most educated mothers breastfed compared to 57% (86 of 150) of the least educated mothers (OR 4.60, 95% CI 2.93 to 7.21). After adjustment for all covariates, the odds ratio for inequalities in any breastfeeding was reduced, but remained statistically significant. The decrease in odds ratio for socioeconomic inequality in any breastfeeding seemed to be mainly due to sociodemographic factors and smoking habits.

4.3 **Paper III**

Earlier cessation of predominant breastfeeding in mothers with recent gestational diabetes in a multiethnic population

Under revision.

Of the 616 mothers with singleton babies included, 190 (31%) women had gestational diabetes (GDM) with the WHO 2013 criteria.[67] The proportions identified with GDM differed by ethnicity, as women with an origin from South Asia (65/154, 42%) and the Middle East (33/87, 38%) were much more likely to be diagnosed with gestational diabetes than women from Western Europe (62/261, 24%) and women from 'other' countries (30/114, 26%). Breastfeeding was initiated in 99% of both GDM and non-GDM mothers. From the second week, significant differences between GDM and non-GDM mothers emerged as 78% of GDM mothers and 88% of non-GDM mothers breastfed predominantly ($p < 0.01$). Predominant breastfeeding in mothers with GDM ended significantly earlier than in non-GDM mothers after adjustment for sociodemographic factors, ethnic origin, body mass index, gestational weight gain, smoking, depression in pregnancy, and factors related to mode of delivery and to the newborn [Hazard ratio (HR) 1.33, 95% Confidence interval (CI) 1.01-1.77, $p < 0.05$].

In unadjusted analyses predominant breastfeeding ended significantly earlier in mothers of South Asian (HR 1.54, 95% CI 1.13-2.10, $p < 0.01$) and Middle-Eastern origin (HR 1.47, 95% CI 1.02-2.12, $p = 0.04$) compared with Western European women. This association remained statistically significant in women with a South-Asian origin in the fully adjusted model (HR 1.53, 95% CI 1.04-2.25, $p = 0.03$), but not in mothers with a background from the Middle-East. There was no statistically significant interaction between ethnic origin and GDM on predominant breastfeeding (p value for interaction=0.417)

5 DISCUSSION

In brief, the main finding from our pragmatic trial was that the Baby-friendly community health services increased the prevalence of exclusive breastfeeding until 6 months. Socioeconomic inequalities in exclusive breastfeeding until 6 months were largely explained by sociodemographic factors, but also modifiable factors such as smoking habits and breastfeeding difficulties. In the Stork Groruddalen cohort we saw that women with an origin from South Asia and the Middle East were much more likely to be diagnosed with gestational diabetes than women from Western Europe. We found that gestational diabetes was associated with earlier cessation of predominant breastfeeding. Women with an origin from South Asia and the Middle East ended predominant breastfeeding earlier than Western European women.

The methodological considerations for the pragmatic trial (Paper I) and the observational studies (Paper II and III) will be discussed separately. As breastfeeding indicators were the primary outcomes in the three papers, and assessed with the same type questions, we will start by discussing the validity of the breastfeeding indicators.

5.1 Validity of primary outcomes

The primary outcomes in the three papers; exclusive, predominant and any breastfeeding, were assessed with detailed questions around the time point the mothers received the questionnaire (see 'Abbreviations and definitions'). Consistent with the WHO definition,[3] infants were considered exclusively breastfed if they were given only breast milk (Paper I and II), and predominant breastfeeding if possibly only water was given in addition to breast milk (Paper III). If the infant had received any additional drink or food at e.g. 4 months of age, the duration of exclusive breastfeeding was 3.5 months.

The recall periods in our papers of 5 completed months (Paper I and II) and mean 14 weeks (Paper III) for the assessment of exclusive breastfeeding, has been shown to give valid results.[127] We used questions similar to the Norwegian infant feeding surveys to be able to compare with national figures.[12,26,37] These questions to assess exclusive breastfeeding have, however, not been validated. We cannot exclude the possibility that social desirability influenced the response about the duration of exclusive and any breastfeeding.

5.2 Methodological considerations of the population-based pragmatic trial (Paper I)

The randomised controlled trial (RCT) is viewed as the optimal design for determining whether a cause-effect relation exists between an intervention and outcome.[128] Cluster-randomised controlled trials allocate social units or clusters, such as municipalities and hospitals, and collect data from individuals of those social units.[1]

The Cochrance Collaboration`s tool for assessing risk of bias in trials cover six domains of bias: selection bias, performance bias, detection bias, attrition bias, reporting bias and other biases.[129] *Internal validity* is the degree to which a study is free from bias in the way data is collected, analyzed, and interpreted.[130] When a study is considered internally valid, the *external validity* or the generalizability of the findings to the more general target population can be assessed.[131]

5.2.1 Internal validity (Paper I)

Selection bias

Selection bias in trials is systematic differences between baseline characteristics of the groups that are compared. The RCTs minimize the risk of selection bias by two main features: In RCTs participants to intervention and comparison groups are randomly distributed with respect to known and unknown confounding variables that may affect the outcome. Furthermore, the allocation process should be concealed.[129] A rule for allocating participants to intervention and comparison groups based on some chance (random) process, must be specified. Furthermore, this schedule must be implemented in a rigorous way to prevent foreknowledge of intervention assignment among those recruiting participants to a trial. Foreknowledge of forthcoming allocation at the time that participants are recruited to the trial may cause selective enrolment of participants on the basis of perceived outcome, and thus bias the allocation.[129] Randomisation and concealment of the allocation sequence prevents selection bias.

In our study, the allocation by alternation was a potential source of selection bias. The main disadvantage of the alternate allocation is that the schedule for allocation is known and predictable.[109,132] Since all municipalities were allocated at the same time using a fixed list,

there was little room for manipulation, in practice.[109,132] The allocation was carried out by a person not involved in the intervention or data analysis. Furthermore, all remained in the trial and provided data for the analysis. The intervention group systematically included the largest municipality from each pair on the ranking list, which might, perhaps have skewed the results as the proportion breastfeeding are generally higher in urban areas with more than 100 000 inhabitants.[37] None of the included municipalities were, however, that large (the largest municipality had 72.207 inhabitants in 2009).

According to Chalmers,[132] there is no reason, in principle, why alternation should not result in unbiased comparison groups. An important aspect that requires special attention in cluster-randomised controlled trials, is the risk of imbalance in number of participants and covariates (e.g. educational level) between the intervention and comparison groups.[133 109] Although baseline balance may not be judged as a bias as such,[109] this may decrease statistical power and face-validity.[133] Restricted randomisation methods has been proposed as a way to minimise imbalances in baseline covariates in cluster randomized trials; including block randomization, stratification, matching, minimization, and covariate-constrained randomization.[133] Although the allocation by alternation resulted in similar characteristics of mother-infant pairs in the intervention and comparison groups in the current study, some form om restricted randomization method, e.g. blocked randomization, would have been a more appropriate method of allocation.[133 1]

Performance bias refers to systematic differences between the groups in exposure to other factors than the exposure of interest, due to lack of blinding. Blinding or masking of trial personnel and participants regarding which study group they were allocated to, was not feasible in our pragmatic trial. The cluster-design reduced the risk that the comparison group would be contaminated by the intervention. However, as staff from the comparison municipalities was informed about the ongoing programme, some elements of the intervention may have influenced practice in comparison centers, possibly reducing the effect estimate.

Detection bias refers to systematic differences between groups in how outcomes are determined. This may occur due to lack of blinding of outcome assessment.[129]
As the group affiliation was masked, and the statistician performing the main data-analysis was neither involved in the implementation of the intervention, nor the allocation process, we consider that the risk of detection bias was low.

Attrition bias refers to systematic differences between the intervention and comparison groups in withdrawals from the trial. The response rate was low as in other Norwegian population based postal questionnaire surveys,[12,26,134] but similar in the intervention and comparison groups. Although there was baseline balance in covariates, we cannot exclude the possibility that characteristics of those who refused to participate may have differed between the study arms. Also, women in the intervention group may have been less inclined to respond if they failed to exclusively breastfeed until 6 months. If so, this would have biased our results. We think this is unlikely, for the following reasons: This was a low-keyed intervention primarily aimed at health care providers in the community health service, and not a community campaign directly targeting the women. Also, mothers received the questionnaires by post, not from the public health nurse. Finally, only about 5% of mothers reported feeling pressurized by the public health nurse to breastfeed. The use of intention-to-treat analyses in the estimation of outcomes, as well as the balance in prognostic covariates in the intervention and comparison groups, reduced the risk of attrition bias.

Reporting bias refers to selective reporting of findings. We have reported analyses and outcomes according to the protocol, and specified any deviations.

Other biases

This evaluation was initiated by the Norwegian National Advisory Unit on Breastfeeding that was also responsible for the development and implementation of the intervention. This represented a risk of bias. We recruited external independent experts for assistance with the protocol development, data collection and the analysis. The interpretation and presentation of results were also done in collaboration with external independent researchers.

Concept validity assesses the degree to which the data reflect the variables under investigation that cannot be recorded directly.[131] Our single question on maternal satisfaction with the breastfeeding experience might have been too general. Validated scales, such as the comprehensive 'Maternal Breastfeeding Evaluation Scale'[135] or the self-efficacy scales,[136] were not chosen as we attempted to keep the number of questions at a minimum in order to achieve an acceptable participation rate. We are not aware of any validated variable of perceived breastfeeding pressure, but it has been described as a form of 'quiet coercion' or as an 'exercise of power'.[114]

Taken together, we consider the risk of bias to be low and our findings to be internally valid.

5.2.2 **External validity (Paper I)**

The key strength of this study was that it was a pragmatic, population-based, controlled trial, conducted in a real world community health services setting. The intervention was implemented in small and large community health services, and we judge the results to be valid for other community health services in Norway. Whether our findings could be generalized across countries, will likely depend on how the community health services are organized.

5.3 **Methodological considerations of observational studies (Paper II and III)**

Before concluding that the results from an observational study are valid, one must consider possible sources of error that could provide an alternative explanation of the findings. In contrast to random errors, which lead to larger variance, systematic errors or bias may result in incorrect effect estimates. Bias is traditionally classified as selection bias, information bias, and confounding.[131] *Selection bias* has been described as a deviation of the results caused by non-representative selection of participants.[131] This may occur if the participants in a study are systematically different from those who are not participating due to non-response or drop-out. If the association between exposure and outcome is different among participants and non-participants there is a selection bias.[137] *Information bias* is a systematic deviation of the results where the outcome affects the exposure data. It occurs when a flaw in measuring exposure, covariate, or outcome variables results in different levels of quality information among the compared groups.[130] *Confounding* implies that an observed association is actually between the outcome and a covariate other than the exposure under study.[131] Confounding occurs when all or part of an apparent association between exposure and the outcome is in fact accounted for by other variables that affect the outcome and are not themselves affected by the exposure.[130] As previously described, *concept validity* assesses the degree to which the data reflect the variables under investigation that cannot be recorded directly.[131]

5.3.1 **Validity (Paper II)**

In paper II we used data from the 5 completed month questionnaire of the trial (3.1), combining data from the two study-arms, i.e. a cross-sectional design. As data in cross-sectional studies are collected at a set point in time, one cannot draw conclusions about causal relationship. It is, however, possible to include questions about the participants past, that may circumvent the disadvantage of this design to some extent.[131]

Concept validity

We used educational attainment as an indicator of socioeconomic position. Other important indicators are occupational status and income level, capturing different dimensions of socioeconomic position.[28,52] By using only education as an indicator of a multifactor construct like socioeconomic position, inequalities may have been underestimated.[138] It is, however, considered as a valid indicator for socioeconomic position in young mothers, typically in a transition period between education and employment.[139] Education reflects both access to knowledge, economy, and early life socioeconomic position, and is a strong indicator for future employment and income.[28,52,139]

In the current study we conceptualized that educational level is the most distal factor - or exposure - in the pathway determining breastfeeding practice. This assumption could be questioned. Maternal age could also have been considered as the most distal factor as age influences both duration of education and breastfeeding. Only 15% of the mothers in our study were, however, younger than 25 years, therefore we may assume that the majority had completed their education.

Covariates

The included covariates (Table 1) partially explained some of the socioeconomic inequality in breastfeeding, but we lacked information about some other potentially important factors, e.g. obesity and diabetes.

Selection bias

In total, 3498 mothers were invited to participate in our trial and 2032 (58%) responded. In general, non-participation and loss to follow-up tend to be higher among less educated and less healthy groups.[140] Some studies indicate that this causes minimal bias in some exposure-outcome associations,[134] but few studies have examined possible bias in estimates of

socioeconomic inequalities in health outcomes.[140] Howe et al.[140] found that considerable attrition may result in underestimation of socioeconomic inequalities in several outcomes, including breastfeeding. Qualitative conclusions and approximate magnitude of inequalities, however, did not change.

In our study, Statistics Norway had access to data on the educational level also for non-participants, and table 3 shows the response rate according to educational level, and the resulting estimated weights (100%/ response%).

Table 3. Response rate according to educational level, and estimated weight

Educational level completed	Non-responders (R=0)	Responders (R=1)	Response rate (%)	Weight
Primary/ secondary school (≤10 y)	611	404	39.8	2.51
High school (12 y)	470	584	55.41	1.80
College/ university ≤4 y	325	840	72.10	1.39
College/ university >4 y	60	204	77.27	1.29

To adjust for the biased response rates, the proportion being breastfed in each educational category were weighted according to the weights estimated from data in table 3. As the response rate was lowest in the lowest educational category, this group got the highest weight. When using weighted data, the proportion being exclusively breastfed at 5 completed months in the total sample was reduced from 16% to 15%, and any breastfeeding from 70% to 68% (Table 4).

Table 4. Unweighted and weighted proportions of breastfeeding indicators

Breastfeeding indicator	Unweighted numbers		Unweighted proportions	Weighted numbers		Weighted proportions
	R=1	R=0		R=1	R=0	
Exclusive breastfeeding at 5 completed months	301	1570	16.09	476	2741	14.80
Any breastfeeding at 5 completed months	1311	556	70.22	2179	1029	67.92

R=1 Responders, R= 0 Non-responders

Although the non-response rate seemed to have limited influence on the duration of exclusive and any breastfeeding, we cannot rule out the possibility that socioeconomic inequalities in breastfeeding in our study sample and the source population differed.

Information bias

Information bias would be present if there was different quality of the exposure-, covariate- or outcome variables according to educational level. There is no reason to believe that there was information bias related to socioeconomic groups due to the recall period.[127] Social desirability may have influenced the response about duration of breastfeeding and smoking habits, and we cannot exclude the possibility that this has influenced our findings.

Internal and external validity

This was an observational study exploring factors associated with and possibly explaining educational inequalities in breastfeeding. As discussed, this study has several limitations, thus the findings are suggestive. The findings from this study may be valid for the Norwegian population as the study sample was recruited from different parts of Norway.

A similar pattern of socioeconomic inequalities in breastfeeding and prognostic covariates is found in other high-income countries.[15] The results from a similar study from the Netherlands, however, differed somewhat from our findings. Thus our findings may have limited external validity outside Norway.

5.3.2 Validity (Paper III)

Strengths and limitations of the study

The main advantage of a cohort design is that exposures are assessed before the outcomes.[131] The strengths of the Stork Groruddalen cohort study were the multiethnic, population-based cohort design, universal screening by OGTT in gestation week 28 and the high participation rates also in ethnic minority groups that are often excluded in research protocols.[72] The response rate was high compared to other cohort studies in Norway.[26,134] A follow-up period for around 14 weeks postpartum is a relatively short period for assessing breastfeeding, but were sufficient to identify different breastfeeding patterns related to gestational diabetes and ethnic origin. A follow-up period for at least a year would have informed about breastfeeding practices in relation to national recommendations for infant feeding.[11]

Selection bias

The source population in the Stork Groruddalen study was all pregnant women in the study districts, and 823 (74%) of invited women agreed to participate.[72] When comparing characteristics of the Stork Groruddalen study sample with data from the Norwegian Birth Registry, results were fairly similar, lending support to the representativeness of the sample.[141] In paper III 616 mother-infant pairs were included (Figure 7). The main reason for non-participation was non-attendance at the postpartum visit and missing information on exposure or outcome data. The reduced number of women attending the maternal and child community health services for the postpartum visit, were mainly due to resource limitations in the community health services.

Information bias

As breastfeeding practice was assessed at around 14 weeks, the risk of recall bias was small[127] (see general discussion on the breastfeeding indicators in 5.1). Exclusive breastfeeding for a longer period is not common in many countries in South Asia and the Middle East (see Paper III, Appendix S3), thus social desirability may not have influenced the response from mothers with an origin from these regions. A study of Norwegian-Somali and Norwegian-Iraqi mothers found that the concept of exclusive breastfeeding was poorly understood.[46] As we did not use this term in the questionnaire, but instead asked the mothers if and when they started to introduce other foods and liquids in addition to breastfeeding, we consider the risk of information bias to be limited.

Gestational diabetes

For the diagnosis and handling of women with gestational diabetes mellitus (GDM) in the Stork Groruddalen cohort the WHO 1999 criteria were used (fasting plasma glucose level of ≥ 7.0 mm mmol/L or a 2-h plasma glucose level ≥7.8 mmol/L). The on-site analysed glucose values, using HemoCue 201+ (HemoCue AB, Ängelhom, Sweden), and the laboratory values were monitored and compared throughout the study. The procedures were extensively evaluated to reduce bias.[125] In paper III, we used the WHO 2013 definition for GDM (fasting plasma glucose level of ≥5.1 mmol/L or a 2-h plasma glucose level of ≥8.5 mmol/L).[67] The WHO 2013 criteria are known to increase the proportion of women identified with GDM two to three times.[125] All biomarkers assays have an inherent analytical coefficient of variance, and the coefficient of variance for glucose was relatively small in the current study.[142]

Ethnic origin

Ethnicity was defined according to womens' country of birth or the country of birth of the mother of the participating women.[72] Thus, we also included women who were born and raised in Norway. We stratified into four groups to have sufficient numbers for analyses: Western European, South Asian, Middle Eastern and others. The categorization of women with an origin from Pakistan, Sri Lanka and India into a South Asian category is commonly used in medical research related to type 2 diabetes mellitus diabetes.[143] This categorization was possibly less appropriate for assessing breastfeeding, as Sri Lanka stand out, with 79% of mothers exclusively breastfeeding 0-5 months, compared with 17% in Pakistan.[62] We did, however, not observe any statistically significant difference in predominant breastfeeding between women with an origin from Pakistan and Sri Lanka in the study period (data not shown). A longer observational period and larger study samples may have given another result.

Confounding

The Stork Groruddalen cohort study offered an opportunity to adjust for many confounding variables, but one can never exclude the possibility of residual confounding in observational studies.

Internal and external validity

We consider the study results to be internally valid. As we do not know whether or to what extent the findings are related to biological limitations in women with gestational diabetes and their babies, or to how breastfeeding was practiced, or the hospital management of these mother-infant pairs, the study findings may have limited external validity.

5.4 Discussion of main findings

5.4.1 Effectiveness of the Baby-friendly community health services

In this pragmatic cluster quasi-randomised trial, the Baby-friendly community health services led to a significant increase in exclusive breastfeeding until 6 months. For the secondary outcome, breastfeeding duration until 12 months, we were unable to show any significant effect. The majority of mothers were satisfied with their breastfeeding experience, and the intervention did not impact on this outcome. Perceived breastfeeding pressure from staff in the community health services was low and did not differ among the two groups. The Baby-friendly community health services did not seem to have differential effects across socio-economic groups.

In an observational study from Bergen in 2010-2011, Halvorsen et al.[144] were able to collect data from 85.6% of all infants due to the implementation of an electronic medical records system. They reported that 24.7% of women attending Baby-friendly community health exclusive breastfed at 6 months compared to 17.0% of those attending non-designated services. Thus, the effect estimate in our trial was unlikely to be an overestimation.

Reviews and meta-analysis have found that interventions to support breastfeeding impact on breastfeeding prevalence.[15,18,22,23,145] The most recent of these meta-analyses, from the US Preventive Service Task Force (USPSTF) in 2016, on primary care interventions to support breastfeeding concluded with moderate certainty that interventions to support breastfeeding have a moderate net benefit. [23,25]

The USPSTF meta-analyses categorized interventions to support breastfeeding as *individual-level interventions* and *system-level interventions*. While system-level interventions include policies and programs usually implemented within the health services, individual-level interventions include one-to-one support of health professionals and peers, or education sessions.[23] The USPSTF meta-analysis, also including interventions in maternity facilities, found that *individual level* interventions comprising prenatal, peripartum, or postpartum, were associated with statistically significant higher likelihood of exclusive breastfeeding for 3 to <6 months [Relative Risk (RR) 1.20 (95% Confidence Interval (CI) 1.05-1.38)] and at 6 months [1.16 (95% CI 1.02-1.32)]. The USPSTF review did not include pooled analyses for system-level interventions, due to the small number of such studies. Our Baby-friendly community

health services was a system-level intervention, and the effect estimate for exclusive breastfeeding until 6 months was, when converted from odd ratio to relative risk, 1.27 (95% CI 1.03-1.56).

In contrast with two other reviews on the impact of the WHO/UNICEF Baby-friendly Hospital Initiative (BFHI), concluding that this was the most effective hospital intervention to improve breastfeeding prevalence,[18,19] the USPSTF-review suggested that there was only limited, mixed evidence of an effect of Baby-friendly Hospital designation.[25] This conclusion is somewhat challenging as our intervention in the community health services was an adaption of the Baby-friendly Hospital Initiative. The USPSTF-review included only studies from countries with a "very high" (<0.9) score of development on the 2014 United Nations Human Development Index Scale (HDI)[146] to ensure that the evidence was applicable to a U.S. setting. The large Promotion of Breastfeeding Intervention Trial (PROBIT) assessing the impact of the BFHI in Belarus[147] was excluded due to a HDI of 0.786 in Belarus. When we compared the living conditions in the US and Belarus using the 2014 United Nations *Inequality-adjusted* Human Development Scale, (IHID)[146] the countries scored, however, almost the same (IHDI: US 0.760 and Belarus 0.741). In the US in 2015, 45% of children younger than the age of 3 years of age lived in low-income families, and 23% in poor families.[148] The majority of the U.S. studies included in the USPSTF-review were conducted in low-income groups. We therefore question the basis for the exclusion of the large, high-quality PROBIT-study documenting a strong impact of the BFHI on exclusivity and duration of breastfeeding. Inclusion of this trial in the review would likely have resulted in another conclusion regarding the impact of the BFHI and of system-level interventions. Our study, published after the inclusion of studies in the USPSTF meta-analyses, adds evidence to the effectiveness of system-level interventions based on the adaption of BFHI for the community health services. The effect sizes of both our Baby-friendly community health services and the individual-level interventions in the USPSTF review were moderate. The USPSTF gives the primary care interventions to breastfeeding support a grade 'B' recommendation, meaning that the evidence is strong enough that it should be part of routine care.[23]

A system-level intervention, like the Baby-friendly community health services, attempts to translate research knowledge into practice through multiple levels;[149] from the national level, via the municipality level, to the community health service, and to the health professional before affecting the mother and infant. To influence performance of breastfeeding counselling through these multiple levels requires a strong intention to perform this "behavior", no

environmental constraints that make it impossible to perform this behavior, and the skills necessary to perform the behavior.[150] In individual-level interventions, it is usually not necessary to pass through multiple levels, and those in charge of the intervention have more direct control of the implementation. The potential for scaling up system-level interventions are likely to be higher compared with individual-level interventions.

There is no "magic bullet" to changing professional practice, and the effectiveness of interventions is sensitive to context.[151] The high breastfeeding initiation rate indicates that Norwegian mothers are motivated for breastfeeding, offering a context receptive for breastfeeding interventions. On the other hand, the prevalence of breastfeeding in Norway is higher than in most other high-income countries, possibly leaving less room for improvements. We need to know not only the effectiveness of an intervention, but also why it works, for whom and under what circumstances. Therefore, data for a process evaluation has been collected, but results are not yet published. Sixteen public health nurses and midwives from community health services that were designated as Baby-friendly, were still in progress or had withdrawn, were interviewed. The health personnel were asked how the decision to participate was taken, their experience with the different elements in the process to become designated, what motivated them to complete the process, how it influenced cooperation with colleagues and their experience of breastfeeding counselling before and after the intervention. This process evaluation will hopefully enlighten our understanding of what facilitated or hindered the implementation. Hoddinott et al.[16] studied the implementation process of a randomised controlled trial that failed to improve breastfeeding prevalence, although results differed between included localities. In localities were the intervention had no effect, the managers focused on hindrances for the implementation, lack of personnel resources and organizational change. In contrast, in localities were breastfeeding prevalence increased, there was less emphasis on these aspects, but more evidence of leadership, focus on the intervention and reflective action cycles, demonstrating the importance of leadership.

When considering the potential for improved effectiveness of the Baby-friendly community health services, it is likely that offering earlier and more frequent breastfeeding support after hospital discharge could further increase breastfeeding prevalence, as most breastfeeding problems occur during the first days and weeks after birth.[152,153] Kronborg et al. [154] found that standardised breastfeeding support with face-to-face contact and continuous support during the first 5 weeks following birth, prolonged the period of exclusive breastfeeding.

Maternal satisfaction and breastfeeding pressure

Maternal satisfaction with the breastfeeding experience is an important outcome of breastfeeding interventions. The concept of 'satisfaction' has been defined as the 'fulfilment of one's wishes, expectations, or needs, or the pleasure derived from this'.[155] The majority of mothers were satisfied with their breastfeeding experience, with no significant difference between intervention and comparison groups. Labarere et al.[156] have suggested that the seemingly contradiction of maternal satisfaction despite non-compliance with the breastfeeding recommendations, could be due to mothers' ability to modify breastfeeding expectations as they acquire experiences. Health professionals offering breastfeeding counselling should support women in reframing their breastfeeding experiences to support maternal satisfaction.[155]

'Breastfeeding pressure' has been reported in the media and explored in qualitative studies, voicing mothers' feeling of coercion.[113,157] In our study, the large majority of mothers did not report being exposed to breastfeeding pressure from health personnel, and there was no significant effect of the intervention on this outcome. When a behavior, such as breastfeeding, is a norm, it is monitored, protected and promoted through the power of public opinion and the health services.[114] Mothers referred to themselves as the main source of breastfeeding pressure suggesting that they had internalised this societal norm.

Effectiveness of the interventions in different socioeconomic groups

This will be discussed in paragraph 5.4.2

5.4.2 Explaining socioeconomic inequalities in exclusive breastfeeding

Societal organization and structures have been identified as the main drivers of socioeconomic inequalities in health.[28,55,158] Breastfeeding practices are determined by the same social determinants that shape health inequalities and inequities.[159] Little is known, however, about the mechanisms by which low socioeconomic position translates into poor health or early cessation of breastfeeding. Identifying possible modifiable factors is necessary in our attempts to narrow the gaps in breastfeeding between socioeconomic groups. In our study, socioeconomic inequalities in exclusive breastfeeding at five completed months were largely explained by sociodemographic factors, including i.e. maternal age and parity, smoking habits and breastfeeding difficulties.

Socioeconomic inequalities and inequities

Health differences that are preventable and unnecessary are denoted as health inequities.[57] Thus, socioeconomic inequalities in breastfeeding that could be reduced by policies and/or interventions may be considered as inequities affecting both the child and the mother. Generally, health differences based on age are considered unavoidable and not unjust, since older people were once younger people and younger people will someday become older.[57] Whether this applies to the socioeconomic inequalities in breastfeeding that may be explained by sociodemographic factors such as maternal age and parity, is questionable. The lower prevalence of exclusive breastfeeding in young and primiparous mothers may be related to lack of experience and later onset of secretory activation of copious milk production. These hindrances could possibly be mitigated by closer, targeted follow-up with lactation counseling. When considering whether socioeconomic inequality in breastfeeding explained by smoking may also be judged as an inequity, we need to acknowledge that smoking is strongly linked to economic, familiar, and cultural contexts.[160] Offering tailored breastfeeding support to mothers who continue to smoke, may reduce inequalities. Breastfeeding difficulties are largely modifiable, either by preventing or solving them, thus we consider that socioeconomic differences in breastfeeding due to such difficulties qualify as inequities.

Applying the Diderichsen model to socioeconomic inequalities in breastfeeding

Applying the model by Diderichsen et al.[56] on causal mechanisms behind socioeconomic inequality in health may enhance our understanding of socioeconomic inequalities in breastfeeding.

The Diderichsen et al.[56] model (Fig. 3) illustrates the most important mechanisms of socioeconomic inequalities in health outcomes (I-V), and four policy entry points for tackling them (A-D). Arrows indicate cause-effect relationships that might be modified both by individual factors and policies or interventions. Determinants of early childhood development and health may influence later social position.[161,162] We have substituted ‘illness/ injury’ in the model with ‘early cessation of exclusive and any breastfeeding’.

I. Social stratification: Socioeconomic position, as indicated by educational level in our study, was associated with early cessation of exclusive and any breastfeeding. As in most

other high-income countries, early cessation of breastfeeding were highest among women with less education.[163]

II. Differential exposure: Depending on the social position of mothers, they are to a varying degree exposed to a wide range of risk factors for early breastfeeding cessation through their work and community. Mothers with less education may have less flexible working time, compared to mothers in higher social positions. A study from Sweden showed that the breastfeeding prevalence differed by neighborhood purchasing power, indicating that characteristics of the community may influence breastfeeding.[164] Breastfeeding is, like eating, smoking and exercise, constrained by social norms.[165] Social norms, good or bad, is a network phenomenon that spreads in droves across social ties.[166] If mothers feed their babies differently from their friends, it may be inconvenient.

III. Differential vulnerability: The effect of exposure to risk factors for early cessation of breastfeeding, depend on the vulnerability of the mother. Most women need to learn how to breastfeed, and experience various breastfeeding difficulties. Whether these difficulties will lead to breastfeeding cessation, is often dependent on the existence of other risk factors for cessation acting synergistically. Because groups with less education are frequently exposed to several different social and behavioral risk factors for early breastfeeding cessation, the effect of one given risk factor, such as breastfeeding difficulties, is likely to be stronger in these groups. Examples of such synergistically acting risk factors are smoking and obesity. Access to qualified breastfeeding support from the health services could have a potential for mitigating differential vulnerabilities to early breastfeeding cessation.

IV. Differential consequences: Illnesses may have different social and health consequences.

Increased risk of e.g. infections due to early cessation of breastfeeding combined with exposure to smoking may aggravate respiratory infections.

V. Disease consequences for the individual and society: Social consequences of illness often augment social inequality in health. Studies suggest that breastfeeding is associated with improved long-term performance in intelligence that might have an important effect in real life, by increasing educational attainment and income in adulthood.[167 168]

The policy entry point for tackling socioeconomic inequalities (A) in the Diderichsen model act on the effect that early childhood development and health have on the social position an

individual may attain as an adult.[161,162] As breastfeeding has been shown to increase chances of upward social mobility,[168] supporting breastfeeding may be one measure to reduce social inequities from early life. Breastfeeding policies including maternity leave, regulation of marketing of infant formula, as well as access to qualified and tailored lactation counselling from the health services may mitigate socioeconomic inequalities related to differences in exposure of risk factors (B) and vulnerability (C) for early breastfeeding cessation.

Effectiveness of the Baby-friendly community health services across socioeconomic groups

One possible downside of population-wide interventions is that socioeconomic inequalities may persist or widen.[110]Although the Baby-friendly community health services seemed to improve duration of exclusive breastfeeding in all socioeconomic groups, inequalities in breastfeeding between groups persisted.[118] We are aware of only two other studies, from Belarus[111] and Brazil,[112] that assessed the effect of breastfeeding interventions across socio-economic groups. Contrary to the situation in Norway, socioeconomic differences in breastfeeding were negligible in the general populations when these studies started, but emerged in the intervention groups. As the Baby-friendly community health services did not seem to reduce socioeconomic inequalities in breastfeeding, more targeted approaches may be needed.

5.4.3 Inequalities in predominant breastfeeding related to gestational diabetes

In the present substudy from the Stork Groruddalen cohort, 190 of 616 (31%) women had gestational diabetes (GDM) with the WHO 2013 criteria (19), six were treated with medication. We saw that women with an origin from South Asia (65/154, 42%) and the Middle East (33/87, 38%) were much more likely to be diagnosed with gestational diabetes than women from Western Europe (62/261, 24%) and women from 'other' countries (30/114, 26%). The high prevalence of gestational diabetes was related to the use of the WHO 2013 criteria, the high proportion of high-risk ethnic groups, and universal screening with OGTT.[125]

In line with most previous studies, [99,100,102,169-171] but not all,[172,173] we observed lower rates of predominant breastfeeding in the first and second week after delivery in mothers with recent GDM. Our finding of an earlier end of predominant breastfeeding after GDM, supports those

of studies from Denmark[104] and Spain.[105] This was also found in a multicentre TEDDY-study, but country-specific differences were observed, with strong association between recent GDM and earlier end of exclusive breastfeeding in Sweden, and earlier also in USA, but not in Finland and Germany.[103]

The association between recent GDM and earlier cessation of predominant breastfeeding may relate to characteristics of both mother and child, but also to early breastfeeding practice and to the medical management of these mother-infant pairs.

GDM has been found to increase the risk of adverse pregnancy outcomes,[69] and some of these are also associated with earlier discontinuation of breastfeeding; [174] premature delivery, large for gestational birth weight, intensive neonatal care, caesarean section, shoulder dystocia, and instrumental delivery.[45,175] The newborn of a mother with gestational diabetes is at risk of hypoglycaemia that has been found to be strongly associated with transient hyperinsulinism in the newborn.[69] Hyperinsulinism prevents normal activation of metabolic pathways producing glucose and ketone bodies, and causes increased glucose consumption by tissues.[176] Delayed onset of lactation may further increase the risk of hypoglycaemia.

In our study, instrumental vaginal delivery (vacuum extraction or forceps delivery) seemed to reduce the duration of predominant breastfeeding, while caesarean delivery seemed to reduce the duration of any breastfeeding. The first hours after delivery are crucial for establishing breastfeeding, and the influence of caesarean section might be mediated through processes that delay the onset of lactation and disrupt mother-infant interaction, or inhibit infant suckling.[177] A systematic review including 53 studies, found that prelabour (elective) caesarean, but not in-labour caesarean section (emergency) was associated with lower rates of initiation of breastfeeding compared to vaginal delivery.[177] The authors suggest that the metabolic or endocrine milieu of labour is important for the initiation of breastfeeding. Importantly, in mothers who initiated breastfeeding, mode of delivery had no apparent effect on exclusive or any breastfeeding at 6 months.[177] We did not differentiate between prelabour and in-labour caesarean section in our analysis. There is limited knowledge about breastfeeding in women who have had instrumental deliveries, but our findings are in line with some studies from other countries. [178-181] As these are women who have been in labour, possible mediating factors might be exhaustion due to longer duration of labour, and less awareness among health personnel of instrumental delivery as a risk factor for earlier cessation of breastfeeding.

We did neither have information about timing of secretory activation of milk production after delivery nor supplementation in the maternity facility, but our finding of an increased level of non-exclusive breastfeeding in the first and second week of life could indicate delayed onset of lactation defined as copious milk coming later than three days postpartum.[182] A systematic review, including 10 studies, consistently identified that women with diabetes during pregnancy were at an increased risk of delayed onset lactation, increasing the risk of excessive neonatal weight loss.[182] Most of the studies included were of women with type 1 diabetes, only three studies of women with gestational diabetes were included. The authors also cautioned that the presence of many potential confounding factors should to be acknowledged.[182]

At present, it is not clear whether or to what extent there are physiological barriers to lactation in mothers with recent GDM.[183] Gene expression research from Lemay et al. [184] indicate that insulin may be important for milk production, and some other studies suggest that insulin resistance interferes with lactogenesis.[185] The disturbances in insulin and glucose metabolism may influence the hormonal pathways involved in the onset of lactation and delay the onset of lactation.[182] This raises the question about causal direction. Breastfeeding may prevent type 2 diabetes, but gestational diabetes may also prevent breastfeeding.[186]

Medical management and the quality of breastfeeding support for women with GDM, and their newborns,[187] may also influence breastfeeding. A study from the US observed that mothers with recent GDM were less likely to report pro-breastfeeding support such as breastfeeding within the first hour after delivery and responsive feeding.[188] In a study of women with type 1 and type 2 diabetes, the number of feedings in the first 24 hours was a significant predictor of breastfeeding prevalence at 4 months.[189] The Academy of Breastfeeding Medicine has developed a clinical protocol for the management of newborn at risk of hypoglycaemia, while establishing and maintaining maternal milk supply.[190]A study from the UK, found that a 'Baby-friendly neonatal hypoglycaemia pathway' with dextrose gel as the first-line treatment was associated with reduces rates of admissions for transitional hypoglycaemia and improved breastfeeding rates at three months.[187] Colostrum has been shown to stabilize glucose concentrations more effectively than infant formula.[191] In some countries, clinicians encourage women with diabetes in pregnancy to express and store breastmilk late in pregnancy to manage potential hypoglycaemia in the newborn. It has been shown that there was no harm in advising women with diabetes in pregnancy at low risk of complications to express breastmilk from 36 weeks of gestation. In Norway, hospitals have

different procedures for the management of newborns and their mothers when there is a risk of hypoglycaemia (Hansen MN, Norwegian National Advisory Unit on Breastfeeding. Personal communication).

Lifestyle interventions are the pillar in the therapeutic strategy for women with GDM, but when the glucose levels remain above treatment target medication is recommended.[192] A Cochrane review found no evidence for an effect of lifestyle interventions, such as education, diet, exercise and self-monitoring of blood glucose on the risk of type 2 diabetes in mothers with previous GDM.[193] Mothers in the lifestyle groups were, however, more likely to have met their weight goals one year after birth and the risk of large-for-gestational birth weight decreased. Two trials included in this review,[194,195] found no impact of lactation counselling as part of lifestyle interventions on breastfeeding in mothers with GDM. After the final inclusion date for the Cochrane review, a cluster randomized controlled trial was published showing that women with GDM who received tailored breastfeeding support were less likely to stop breastfeeding early compared to those who received routine care.[196] In the experimental group 62% of women reported high-intensity breastfeeding at 6 weeks, defined as >80% of feedings as breast milk, compared with 36% of wait-list control group women. More studies are needed to investigate the potential of tailored support to improve exclusivity and duration of breastfeeding in women with recent gestational diabetes, and the impact on future risk of type 2 diabetes.[95]

5.4.4 Ethnic origin, gestational diabetes and breastfeeding

In our study, we did not detect statistically different associations between GDM and predominant breastfeeding in the different ethnic groups. Sample sizes may, however, have been too small for the interaction analyses. We are not aware of any studies from South Asia or the Middle East on breastfeeding in women with recent gestational diabetes. To our knowledge, only the study by Chamberline et al.,[169] have assessed the association of GDM and breastfeeding in different ethnic groups within a country. They found lower rates of in-hospital predominant breastfeeding in women with GDM, and in particular among Indigenous women.

We found that a South Asian and Middle Eastern origin was associated with a shorter period of predominant breastfeeding, compared to Western European mothers. When adjusting for gestational diabetes, obesity, sociodemographic and lifestyle factors, this association

remained statistically significant in women with a background from South Asia, but not in those from the Middle East. This was possibly related to low statistical power due to small sample size of Middle Eastern women. Grewal et al.[46] found that compared with ethnic Norwegian mothers, exclusive breastfeeding ended earlier in women with an origin from two countries in the Middle East; Somalia and Iraq. In these groups, the proportions breastfeeding at 12 months were similar as in their countries of origin and in the Norwegian national surveys (see Paper III, Appendix S4). A population based study from Denmark found lower rates of full breastfeeding in mothers with an origin from Pakistan and Turkey, compared with Danish and other Nordic women.[197] They also observed that descendants of Turkish and Pakistani immigrants had even lower rates of full breastfeeding than first generation immigrants from these countries, indicating that acculturation may not have favored breastfeeding.

Breastfeeding may be of particular importance in ethnic groups with a high risk of type 2 diabetes. Gupta and Kalra has proposed an 'ABCDEFG of postpartum care' in India and Pakistan after gestational diabetes; A: Assessment - regular follow up with oral glucose test, B: Breastfeeding, C: Contraception, D: Dietary modification, E: Exercise (physical activity), F: Family involvement and G: Goals.[198] The potential of culture-specific, targeted breastfeeding support to improve breastfeeding rates in ethnic minority women should be investigated.

6 CONCLUSIONS AND PUBLIC HEALTH IMPLICATIONS

Our study showed that the Baby-friendly Initiative in community health services worked, as women in the intervention group were more likely to breastfeed exclusively until 6 months than those in the comparison group who received routine care. The intervention did not impact on breastfeeding duration until 12 months. The majority of mothers were satisfied with their breastfeeding experience, and the intervention did not impact on this outcome. Perceived breastfeeding pressure from staff in the community health services was low and did not differ among the two groups. The Baby-friendly community health services did not seem to have differential effect across socio-economic groups.

Socioeconomic inequalities in breastfeeding have persisted in Norway for several decades. The socioeconomic inequalities in exclusive breastfeeding were largely explained by other sociodemographic factors, smoking habits and breastfeeding difficulties.

We identified inequalities in predominant breastfeeding related to maternal health. Gestational diabetes (GDM) is a common complication of pregnancy, and there is growing evidence for a protective effect of breastfeeding on the risk of future type 2 diabetes. In the Stork Groruddalen cohort it has been shown that women with an origin from South Asia and the Middle East were much more likely to be diagnosed with gestational diabetes than women from Western Europe. Despite potential greater rewards, mothers with recent GDM ended predominant breastfeeding earlier than mothers without GDM. Women of South Asian and the Middle Eastern origin ended predominant breastfeeding earlier than Western European mothers.

When assessing whether an intervention could be of public health importance, it requires not only an assessment of effect, but also feasibility, scalability and the need of additional resources. The Baby-friendly community health services has been considered to be of public health importance in Norway, and increasing the number of designated community health services is a target in the Norwegian National Action Plan for a Healthier Diet (2017 – 2021).[14]

It is likely that offering earlier and more frequent breastfeeding support after hospital discharge could further improve breastfeeding prevalence, as most breastfeeding problems occur during the first days and weeks after birth. In 2014 the Norwegian Directorate of Health recommended a home-visit by midwife during the first one-two days after hospital discharge

and another home-visit by a public health nurse within 7-10 days after birth,[199] but this has still to be implemented in many municipalities. Lack of support in this vulnerable period is a serious system-based weakness that is likely to contribute to early breastfeeding difficulties and cessation.

Population-wide interventions are considered as the main strategy for reducing socioeconomic inequalities in health.[28] The Baby-friendly Initiative in community health services increased exclusive breastfeeding in all socioeconomic groups, but socioeconomic inequalities persisted. As a supplement to this population-based intervention, targeted approaches may be necessary to reduce inequalities in breastfeeding related to socioeconomic position, ethnic origin and gestational diabetes.

7 FUTURE RESEARCH

Several research questions have emerged from this thesis:

- What is the sustained effectiveness of the Baby-friendly community health services?
- What is the impact of earlier and more frequent follow-up after hospital discharge on breastfeeding and maternal satisfaction?
- What are the determinants for perceived breastfeeding pressure?
- How does a revised version of the Baby-friendly community health service, including targeted approaches to young and primipara mothers, and mothers who continue to smoke, influence socioeconomic inequalities in breastfeeding?
- What is the prevalence of delayed onset of lactation among mothers in Norway, and what are the determinants?
- Does breastfeeding intensity and duration influence glucose metabolism?
- What is the effectiveness of a tailored programme to support breastfeeding in women with gestational diabetes on breastfeeding?
- What is the effectiveness of a tailored programme to support breastfeeding in ethnic minority groups on breastfeeding?
- How valid are data on exclusive breastfeeding in our studies and in the Norwegian infant feeding surveys?

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PAPER I

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Original Article

Effectiveness of Baby-friendly community health services on exclusive breastfeeding and maternal satisfaction: a pragmatic trial

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Abstract

The WHO/UNICEF Baby-friendly Hospital Initiative has been shown to increase breastfeeding rates, but uncertainty remains about effective methods to improve breastfeeding in community health services. The aim of this pragmatic cluster quasi-randomised controlled trial was to assess the effectiveness of implementing the Baby-friendly Initiative (BFI) in community health services. The primary outcome was exclusive breastfeeding until 6 months in healthy babies. Secondary outcomes were other breastfeeding indicators, mothers' satisfaction with the breastfeeding experience, and perceived pressure to breastfeed. A total of 54 Norwegian municipalities were allocated by alternation to the BFI in community health service intervention or routine care. All mothers with infants of five completed months were invited to participate ($n = 3948$), and 1051 mothers in the intervention arm and 981 in the comparison arm returned the questionnaire. Analyses were by intention to treat. Women in the intervention group were more likely to breastfeed exclusively compared with those who received routine care: 17.9% vs. 14.1% until 6 months [cluster adjusted odds ratio (OR) = 1.33; 95% confidence interval (CI): 1.03, 1.72; $P = 0.03$], 41.4% vs. 35.8% until 5 months [cluster adjusted OR = 1.39; 95% CI: 1.09, 1.77; $P = 0.01$], and 72.1% vs. 68.2% for any breastfeeding until 6 months [cluster adjusted OR = 1.24; 95% CI: 0.99, 1.54; $P = 0.06$]. The intervention had no effect on breastfeeding until 12 months. Maternal breastfeeding experience in the two groups did not differ, neither did perceived breastfeeding pressure from staff in the community health services. In conclusion, the BFI in community health services increased rates of exclusive breastfeeding until 6 months.

Keywords: Baby-friendly Hospital Initiative, breastfeeding, primary health care, breastfeeding support, cluster quasi-randomised controlled trial, evidence based practice.

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Introduction

Human milk is tailored for infants, and breastfeeding is associated with improved child and maternal health (Ip *et al.* 2009; Horta and Victora 2013). Enabling women to breastfeed is, therefore, a public health priority (Norwegian Ministry of Health and Care Services 2007; HM Government 2010; U.S. Department of Health and Human Services 2011). In Norway, 98% of mothers initiate breastfeeding, 17% breastfeed exclusively until 6 months and 35% continue partial breastfeeding for at least a year (Norwegian Directorate of Health 2014). Although these are high levels compared with most other high-income countries, they fall short of recommendations from the World Health Organization (WHO/UNICEF 2003). The Promotion of Breastfeeding Intervention Trial (PROBIT) provided foundational evidence of the effect of the WHO/UNICEF Baby-friendly Hospital Initiative (BFHI) (Kramer *et al.* 2001).

Today, mothers are discharged from hospital earlier than before; thus, efforts to promote breastfeeding

need to focus more on the community level (UNICEF UK Baby Friendly Initiative 1999; Lawrence 2011; Haiek 2012; Macaluso *et al.* 2013; Hernandez-Aguilar *et al.* 2014). While the PROBIT study and most systematic reviews have looked at the combined effect of breastfeeding interventions in hospitals and primary care (Spiby *et al.* 2009; Beake *et al.* 2012; Renfrew *et al.* 2012; Haroon *et al.* 2013; Skouteris *et al.* 2014; Sinha *et al.* 2015), a systematic review by the US Preventive Service Task Force focused on interventions in primary care (Chung *et al.* 2008). This review found that breastfeeding interventions could be more effective than usual care in increasing breastfeeding rates; however, most findings were not statistically significant. Re-establishing a breastfeeding culture in high-income countries is challenging (Hoddinott *et al.* 2011), and the question on how best to support breastfeeding in community health services remains (Centers for Disease Control and Prevention 2013). Thus, evaluations of structured programmes targeting changes at the organizational service delivery level, such as the Baby-Friendly Initiative (BFI) in community health services, are called for (Beake *et al.* 2012). Important aspects of breastfeeding interventions are how they impact on maternal satisfaction with their breastfeeding experience and perceived breastfeeding pressure, but so far, these outcomes have been poorly reported (Renfrew *et al.* 2012).

One possible downside of population-wide interventions is that they may widen socio-economic inequalities in health (Macintyre *et al.* 2001). In Norway, as in most Western countries, breastfeeding rates are consistently lower in low socio-economic groups (Kristiansen *et al.* 2010; Yang *et al.* 2014). Few studies have examined how an increase in breastfeeding resulting from an intervention benefits different socio-economic groups (Yang *et al.* 2014).

The aims of our trial were to assess the effectiveness of the BFI in community health services on exclusive breastfeeding until 6 months. Secondary outcomes were exclusive breastfeeding until 5 months, any breastfeeding until 6 and 12 months, maternal satisfaction with the breastfeeding experience and perceived breastfeeding pressure.

Participants and methods

Study design and population

We assessed the effects of the BFI in community health services, in a cluster quasi-randomised controlled trial (Higgins and Green, 2011). We decided to allocate municipalities rather than health centres because all health centres within a municipality are under a shared management, and to minimize contamination between the intervention and comparison groups.

The study was undertaken in 54 municipalities in six Norwegian counties, (Østfold, Vestfold, Nord-Trøndelag, Hordaland, Telemark, Finnmark), where the BFI in community health services had not yet been introduced. These are predominantly rural or semi-urban districts. Consent to participate in the trial was given by the managers of the community health services before the group allocation. As described in our protocol, the municipalities were meant to be randomised, but due to a misunderstanding, allocation was by alternation: An adviser from Statistics Norway, neither involved in the intervention nor the data analyses, prepared a list of the 54 municipalities ranked according to the number of births in the previous year. For each consecutive pair of clusters,

Key messages

- The Baby-friendly Initiative in community health services increased exclusive breastfeeding until 6 months.
- There was no significant difference in effect size in the different socioeconomic groups.
- The majority of mothers were satisfied with their breastfeeding experience and did not feel pressurized to breastfeed.
- Considering the limited need of additional resources, the local anchorage, scalability and sustainability, the effectiveness of this structured intervention may be of public health importance.

the first was allocated to the intervention and the second to the comparison group. All mothers with babies of five completed months living in the study area were invited to participate in a postal questionnaire survey, with a follow-up questionnaire when the child passed 11 months. We identified the mothers through the National Population Register. The questionnaire asked about infant feeding practices, maternal satisfaction with the breastfeeding experience, perceived breastfeeding pressure, sociodemographic factors and smoking habits. The questionnaires were only offered in Norwegian.

We conducted a pre-intervention postal questionnaire survey to all mothers with infants of 5 or 11 completed months in the municipalities, from 24 August 2009 to 12 January 2010. The BFI in community health services was initiated in all intervention municipalities in 9 December 2009 and continued until the post-intervention survey commenced in 7 May 2012. Data-collection ended 19 August 2013. Those who returned a completed questionnaire were entered into a lottery of ten and five vouchers, approximately valued $130 and $650, respectively. Mothers were included in the data-analyses if they had given birth to a singleton infant of ≥ 37 gestational weeks and a birth weight of ≥2000 g. The statistician performing the main data-analysis was not involved in the implementation of the intervention or the allocation process and was masked to the group affiliation.

Intervention

The intervention, developed by the Norwegian National Advisory Unit on Breastfeeding, is an adaptation of the BFHI, for integration into routine antenatal and child care services at the community level (WHO/UNICEF 2003). Municipalities allocated to the intervention group received a manual on how to become Baby-friendly, outlining 6 points, which collectively describe a quality standard for breastfeeding counselling. The community health services were supervised by two specially trained part-time public health nurses from the national advisory unit (Norwegian National Advisory Unit on Breastfeeding 2012). We used a cycle approach, i.e. community health services were offered tools for assessment, action and re-assessment (Fig. 1). In the first stage of the process, public health nurses mapped breastfeeding practices, using a 24-h recall, and examined the reasons for breastfeeding cessation in 20 infants who attended their 5-month or 12-month routine appointments. The second stage was a self-appraisal questionnaire completed by the staff in order to clarify existing practices. During the third stage, staff were to develop a written breastfeeding policy and a training programme based on the 6-point quality standard and send these to the national advisory unit for approval. The minimum requirement of training for all staff was 12 h, including reading of a 200 page book with 100 study questions, as well as training and demonstration of practical skills, in line with the WHO/UNICEF 20 h course. About 3 months after approval and implementation of the breastfeeding policy, the Norwegian National Advisory Unit on Breastfeeding would undertake a user survey among pregnant women and mothers of 6-week old babies. Final designation as a Baby-friendly community health centre was based on the approval of the breastfeeding policy, as well as at least 80% of pregnant women and mothers confirming that received counselling was in accordance with the 6-point quality standard. One year after designation, the community health centre mapped the breastfeeding prevalence again, to stimulate a continuous process of assessment and action.

The comparison municipalities continued offering routine health services, which comprises both antenatal care and preventive health care from hospital discharge through childhood and adolescence. The routine preventive programme for infants includes a home-visit between 0–2 weeks, and consultations at 6 weeks, and at 3, 4 5, 6, 7–8, 10 and 11–12 months for vaccination, anthropometric measurements, screening and lactation counselling.

Outcomes

The primary outcome was exclusive breastfeeding until 6 months, specified as exclusive breastfeeding for at least five completed months (World Health Organization 2008). Secondary outcomes were exclusive breastfeeding until 5 months, any breastfeeding until 6 and 12 months and maternal satisfaction with the breastfeeding experience and perceived breastfeeding

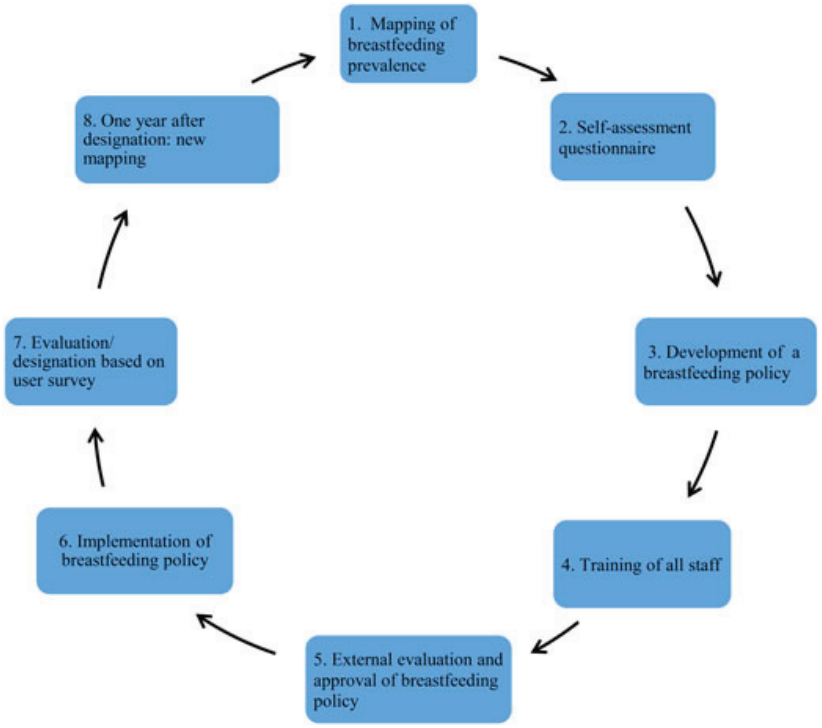

Fig. 1. The Baby-friendly Initiative in community health services – the process.

pressure. The questionnaires were sent to mothers the week after their child was 5 and 11 completed months old. Consistent with the WHO definition (World Health Organization 2008), infants were considered exclusively breastfed if they were given only breast milk. To assess duration of exclusive breastfeeding, we asked both if and for how long they had breastfed, and at what age the infant was introduced to infant formula, water and water based drinks or solids.

We assessed overall maternal satisfaction with the breastfeeding experience by asking the participants 'How was your overall experience of breastfeeding?' on a 5 point single-item scale ranging from very poor to very good (Labarere *et al.* 2005). We also asked the mothers 'Have you felt pressured to breastfeed for a longer period than you wanted to?' We conducted subgroup analyses to explore possible differential effects across socio-economic groups. Maternal education was used as an indicator for socio-economic status as it reflects both material resources and knowledge (van Rossem *et al.* 2009).

Statistical analysis

We anticipated that the intervention would lead to an increase in the prevalence of exclusive breastfeeding for 6 months of 5 percentage points, from approximately 9% based on national figures to 14% (Øverby *et al.* 2008). Furthermore, we expected to recruit 50 municipalities. Based on these assumptions, and a significance level of 5% for a two-sided test, statistical power of 80% and an intracluster correlation coefficient of 0.01, we estimated a needed sample size of at least 1950 mother–infant pairs (Practihc 2007). As we expected a participation rate of about 55%, we planned to invite 3500 mother–infant pairs to participate.

We used intention to treat analysis as our main analytical approach, i.e. data from all participants were analyzed according to their original allocation to intervention or comparison group. Missing data, ranging from 0% to 2.5% across the different items in the questionnaire, were excluded. No data were discarded. To account for within municipality

clustering, the intervention effects on the binary outcome variables were analyzed by mixed-effects logistic regression. In this model, the effects of municipalities were regarded as random, and the corresponding variance estimate was the basis for the computation of intra-class correlation (Rodriguez and Elo 2002). The following pre-defined adjustment variables were included in the model: feeding status at hospital discharge (Haggkvist *et al.* 2010), maternal education, maternal age, mother with one child or more and smoking habits (Kristiansen *et al.* 2010). To conduct subgroup analyses according to mothers' education (proxy for socioeconomic status), the interaction between intervention and education was included. To assess the robustness of our findings, we conducted randomisation tests, which make no distributional assumptions. In this analysis, the *P*-values of the logistic regression coefficients were computed by re-randomizing pairs of clusters (Edgington 1995). We also ran a per protocol analysis, based on the 18 of 27 municipalities, which actually completed the intervention, and corresponding comparison clusters of similar size. The questionnaire to assess breastfeeding until 12 months was not sent to mothers who had ended breastfeeding before 6 months, because their answers were considered as known. Non-response weighting was applied to avoid that this group was overrepresented because of no no-response. Therefore, to assess the impact on breastfeeding until 12 months, three groups were weighted according to their non-response: mothers who did not receive the 12 month questionnaire as they had ended breastfeeding before 6 months, non-responders of 6 month questionnaire and mothers breastfeeding until 6 months (Appendix S2). The estimated regression coefficients were transformed to odds ratios. Statistical analyses were performed with the R programme using the lme4 package and SPSS 21.

Deviations from the protocol

Originally, we planned to estimate intervention effects as the difference between changes in rates of exclusive breastfeeding from the pre-intervention to the post-intervention survey, for the intervention and comparison groups (i.e. difference in difference). Instead, we simply compared the post intervention prevalence in the two groups. We made this change for two reasons: (1) We found no important differences between the groups in the pre-intervention survey (see Results). (2) We conducted the pre-intervention survey 2–4 years before the post intervention survey, making it likely that the findings were too old to reflect differences between the actual intervention and comparison groups. As described earlier, another deviation from the protocol was that allocation of municipalities was by alternation.

Ethical approval

The Regional Committees for Medical Research Ethics approved the study protocol (REK Sør-Øst C Ref:S-09277c 2009/5783), and informed consent was obtained from the mothers. This trial is registered in clinicaltrials.gov as NCT01025362.

Results

Figure 2 shows the flow of municipalities and mother–infant pairs in the study. All the 123 municipalities in the six counties were invited to participate, and 55 accepted. The main reason for declining was lack of capacity. Twenty seven municipalities were allocated to the intervention group and 28 to the comparison group. During the study period, two municipalities in the comparison arm merged, resulting in a total of 54 clusters. The number of community health centres per municipality ranged from one to seven. For the post-intervention survey, we invited 3498 mothers with infants of five completed months to participate, and 2032 (58.1%) agreed to take part; 1051/1761 (59.7%) from the intervention group and 981/1737 (56.5%) from the comparison group. One thousand nine hundred and six mother–infant pairs were eligible for data analysis, 990 in the intervention group and 916 in the comparison group.

Data from the pre-intervention study showed similar characteristics of mother, infants, levels of breastfeeding and maternal satisfaction at the intervention and comparison sites (Appendix S1). In the post-intervention study, the two arms were similar

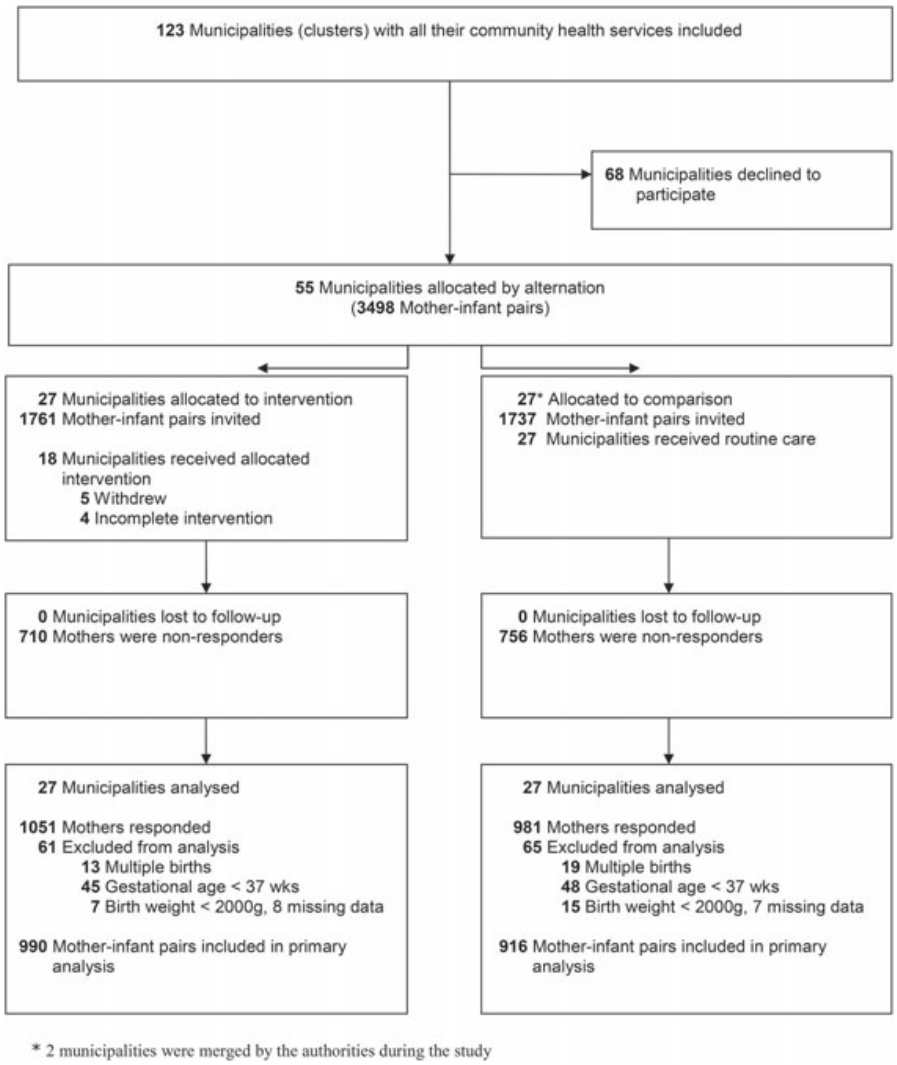

Fig. 2. Flowchart of municipalities (clusters) and mother-infant pairs.

in all respects, except that a lower percentage of women in the intervention group were smoking than in the comparison group (10.1% vs. 13.0%, $P = 0.05$) (Table 1).

At the time of the post-intervention survey, 18 of the 27 intervention municipalities were designated as Baby-friendly community health centres, four municipalities were still in the process of becoming designated, and five municipalities had dropped out of the programme.

Table 2 shows our main findings. Women in the intervention group were more likely to breastfeed exclusively than those in the comparison group who received routine care; 17.9% vs. 14.1% until 6 months [cluster adjusted odds ratio (OR) = 1.33; 95% confidence interval (CI): 1.02, 1.72; $P = 0.03$] and 41.4% vs. 35.8% until 5 months [cluster adjusted OR = 1.39; 95% CI: 1.09, 1.77; $P = 0.01$]. Rates of any breastfeeding until 6 months were 72.1% in the intervention group vs. 68.2% in the comparison group [cluster adjusted OR = 1.24; 95% CI: 0.99, 1.54; $P = 0.06$]. There was, however, no significant difference in rates of breastfeeding until 12 months, 224 (27.8%) of 807 in the intervention group and 204 (27.9%) of 732 in the

Table 1. Characteristics of mothers and infants in intervention and comparison groups in post-intervention study (2012–2013)

Characteristics[†]	Intervention	Comparison
Number of clusters (municipalities)	27	27*
Age of mother, *n* (%)		
16–24 years	156/990 (15.8)	128/916 (14.0)
25–29 years	338/990 (34.1)	311/916 (34.0)
30–34 years	320/990 (32.3)	293/916 (32.0)
35–44 years	176/990 (17.8)	184/916 (20.0)
Education of mother, *n* (%)		
Primary and secondary school	92/967 (9.5)	115/892 (12.9)
Comprehensive school	326/967 (33.7)	300/892 (33.6)
Academy/college/university (≤4 years)	330/967 (34.1)	295/892 (33.1)
Academy/college/university (>4 years)	219/967 (22.6)	182/892 (20.4)
Marital status, *n* (%)		
Married	432/983 (43.9)	411/904 (45.5)
Cohabitant	517/983 (52.6)	448/904 (49.6)
Not married/cohabitant	34/983 (3.5)	45/904 (5.0)
Parity, *n* (%)		
Primiparous	446/985 (45.3)	392/910 (43.1)
Smoking status, *n* (%)		
Smoking 5 months after birth	100/990 (10.1)	119/915 (13.0)
Feeding status at discharge from hospital, *n* (%)		
Exclusively breastfed	761/983 (77.4)	722/909 (79.4)
Infant, *n* (%)		
Female	514/990 (51.9)	440/916 (48.0)
Birth weight, mean (SD),g	3606 (522)	3606 (493)

No significant differences in characteristics of intervention and comparison groups ($P > 0.05$); smoking, $P = 0.50$. *Two municipalities were merged by the authorities during the study, leaving 27 municipalities in the comparison group. [†]Excluded: Birth weight < 2000 g, gestational age <37 weeks, multiple births.

Table 2. Primary and secondary*outcomes

	Intervention group	Comparison group	Crude odds ratio	Adjusted odds ratio	*P*-value	ICC[§]
Outcomes	*n*/*N* (%)	*n*/*N* (%)	(95% CI)[†]	(95% CI)[‡]		
Primary outcome						
Exclusive breastfeeding until 6 months	174/971 (17.9)	127/900 (14.1)	1.33 (1.04, 1.70)	1.33 (1.03, 1.72)	0.03	<0.001
Secondary outcomes						
Exclusive breastfeeding until 5 months	402/971 (41.4)	322/900 (35.8)	1.31 (1.06, 1.62)	1.39 (1.09, 1.77)	0.01	0.018
Any breastfeeding until 6 months	699/969 (72.1)	612/898 (68.2)	1.21 (0.99, 1.48)	1.24 (0.99, 1.54)	0.06	<0.001
Mother satisfied with breastfeeding experience	719/944 (76.2)	660/880 (75.0)	1.07 (0.86, 1.33)	1.16 (0.92, 1.46)	0.22	<0.001
Perceived pressure to breastfeed (generally)	139/945 (14.7)	123/877 (14.0)	1.05 (0.81, 1.37)	0.99 (0.76, 1.30)	0.95	<0.001
Pressure from staff at child health centre	54/945 (5.7)	40/877 (4.6)	1.26 (0.83, 1.92)	1.21 (0.79, 1.87)	0.37	<0.001

*Breastfeeding until 12 months in Appendix S2 and Results. [†]Only adjusted for cluster effects. [‡]Adjusted for cluster effects, breastfeeding at hospital discharge, maternal education, age, parity and smoking habits. [§]Intra Cluster Correlation CI, confidence interval

comparison group; weighted proportions 30.7% in the intervention group and 32.3% in the comparison group, $P = 0.34$ (Appendix S2).

A majority of mothers were satisfied with their breastfeeding experience, and the intervention did not seem to impact on this outcome. Perceived breastfeeding

pressure from staff in the community health services was low and did not differ between the two groups (Table 2).

We did not detect statistically significant differences in effect size across socio-economic subgroups in exclusive breastfeeding until 6 months (*P*-value for interaction = 0.163) (Appendix S3).

The per protocol analysis, based on the 18 intervention municipalities, which had completed the intervention and 18 corresponding comparison municipalities, yielded comparable effect estimates to our main analysis, though the effect on exclusive breastfeeding until 6 months was not statistically significant (Appendix S4). Nonparametric randomisation tests yielded similar results as our main analysis (data not shown).

Discussion

In this pragmatic cluster quasi-randomised controlled trial, the BFI in community health services increased the duration of exclusive breastfeeding until 6 months, compared with routine care. The study was undertaken in a period with a downward trend in breastfeeding rates (Norwegian Directorate of Health 2014). The estimated effect size was moderate. Staff from the comparison municipalities was informed about the ongoing programme; thus, contamination between intervention and comparison groups was likely and may have reduced the effect size. Our findings are largely in agreement with findings from a meta-analysis of primary care based interventions in developed countries, although most of their findings were not statistically significant (Chung *et al.* 2008; Sinha *et al.* 2015) . The PROBIT trial achieved a stronger impact than ours, but the effect of the post-discharge component of their intervention was not assessed per se (Kramer *et al.* 2001). In our setting, the Baby-friendly standard was already part of the routine care in hospitals. Interventions to support breastfeeding are often implemented as adjuncts to routine health services, are time-intensive or rely on specifically trained nurses or peer counsellors (Labarere *et al.* 2005). For example, in two recent trials where lactation consultants were integrated into routine primary care, they achieved a threefold to fourfold increase in exclusive breastfeeding at 3 months (from around 3% to 11%) among low-income women. This indicates a potential for a stronger effect of more intensive, high-quality support (Renfrew *et al.* 2012; Bonuck *et al.* 2014). Our strategy with the BFI in community health services was to strengthen the existing health services, without offering extra resources. Whereas any breastfeeding for 6 months seemed to increase, we were unable to show any significant effect on breastfeeding duration until 12 months. Few other studies have found any effect on breastfeeding duration up to this age (Chung *et al.* 2008; Renfrew *et al.* 2012). Factors outside the domain of the health services are probably increasingly important in the second half of infancy.

In line with the findings from most other trials in the community health services, the intervention had no effect on maternal satisfaction with the breastfeeding experience (Labarere *et al.* 2005). The majority of mothers were satisfied, although only a minority complied with the infant feeding recommendations. This seemingly contradiction may be due to mothers' ability to modify breastfeeding expectations as they acquire experience (Labarere *et al.* 2005). Our question on overall maternal satisfaction might have been too general, but we also asked specifically about perceived 'breastfeeding pressure', which has been debated widely in the media and explored in qualitative studies (Andrews and Knaak 2013). In Norway, breastfeeding is perceived as a social norm, and deviance from the recommended behaviour may cause a feeling of failure. In our study, however, the large majority of mothers did not report being exposed to breastfeeding pressure from health personnel, instead most mothers referred to themselves as the main source of pressure suggesting that they had internalized the societal norm. The focus of our intervention was on improving counselling skills in lactation management, it was not designed as a 'breast is best' campaign. This may explain why the perceived pressure to breastfeed did not increase.

Our BFI in community health services did not seem to have differential effects across socio-economic groups. To our knowledge, the PROBIT study in Belarus is the only previous study that has assessed the effect of a breastfeeding intervention in different socio-economic groups. Contrary to the situation in Norway, the socio-economic inequalities in breastfeeding in Belarus were negligible before the intervention started

but emerged in the trial's intervention group (Yang *et al.* 2014). As breastfeeding may increase chances of upward social mobility (Sacker *et al.* 2013), future trials of interventions to promote breastfeeding should include analysis of effect sizes across socioeconomic groups.

The key strength of this study was that it was a controlled trial and conducted in a real world community health service setting. The cluster-design reduced the risk that the comparison group would be contaminated by the intervention. However, as staff from the comparison municipalities was informed about the ongoing programme, some elements of the intervention may have influenced practice in comparison centres. The primary outcome, exclusive breastfeeding until 6 months, was assessed prospectively. Breastfeeding practices at earlier ages were assessed with no more than 6 months recall, which has been shown to give valid results (Li *et al.* 2005). The allocation by alternation was a potential source of bias, but because all municipalities were allocated at the same time using a fixed list, leaving little or no room for manipulation, we believe the risk was negligible (Chalmers 1997). Furthermore, all remained in the trial and provided data for the analysis. The intervention group systematically included the largest municipality from each pair on the ranking list, which might, perhaps, have skewed the results as breastfeeding rates are generally higher in urban areas with more than 100,000 inhabitants (Lande *et al.* 2003). None of the included municipalities were that large. The pre-intervention survey found similar characteristics of mother-infant pairs in the intervention and comparison groups. The breastfeeding rates were non-significantly lower in the intervention municipalities (Appendix S1). As in other Norwegian population-based postal questionnaire surveys, participation rate was low. In general, non-participation tends to be more pronounced among lower educated people (Howe *et al.* 2013). The response rate in both study arms were, however, similarly higher in women with high education (data not shown). Women in the intervention group may have been less inclined to respond if they failed to breastfeed until 6 months. If so, this would have biased our results. We think this is unlikely, for the following reasons: This was a low-keyed intervention primarily aimed at health care providers in the community health service and not a community campaign directly targeting the women. Also, mothers received the questionnaires by post, not from the public health nurse. Finally, only about 5% of mothers reported feeling pressurized by the public health nurse to breastfeed.

The authors of a recent survey from child health centres in the city of Bergen were able to collect data from 85.6% of all infants because of the recent implementation of an electronic medical records system. They reported exclusive breastfeeding at 6 months among 24.7% of women attending BF community health services and 17.0% among those attending non-designated services (Halvorsen *et al.* 2015).

One out of three municipalities had not completed the intervention within the timeframe of the study. This could indicate that the intervention is difficult to implement in practice. However, some municipalities continued the process towards designation after the study period, and by November 2015, three out of four municipalities were designated as Baby-friendly. Contrary to what we would have expected, the protocol analysis yielded a slightly smaller effect estimate for the primary outcome than our main analysis, but not for the secondary breastfeeding outcomes. One possible explanation is that the intervention centres not yet designated Baby-friendly had partially implemented the intervention. The difference between the main and the per protocol analysis may also simply reflect random variation. By November 2015, 100 of the 428 Norwegian municipalities, serving about 50% of the infant population, were designated as Baby-friendly community health services.

Conclusion

In this large, pragmatic trial, the BFI adapted for community health services increased exclusive breastfeeding until 6 months. Considering the limited need for additional resources, the local anchorage, scalability and sustainability, the effectiveness of this structured intervention may be of public health importance. Whether our findings could be generalized across countries, will likely depend on how the community health services are organized.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Contributions

AB proposed the hypothesis, contributed to the study design, data analysis and interpretation and wrote the first draft of the manuscript. AF was the senior author who proposed the study design, contributed to data analysis and interpretation and to the first draft of the article. ØL analysed the data and contributed with data interpretation and writing of the article. BFL contributed to the writing of the final version of the protocol, contributed with the interpretation of data analysis and writing of the article. ET proposed the hypothesis, contributed with the draft study protocol and with writing of the article. TT contributed with the study design and participated in writing of the article. Statistics Norway was responsible for cluster allocation and data collection. All authors contributed to and approved the final version of the manuscript.

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Supporting information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site.

Supplementary webappendix

Effectiveness of Baby-friendly community health services on exclusive breastfeeding and maternal satisfaction: A pragmatic trial

Appendix S1. Characteristics of mothers and infants in intervention and comparison groups before intervention (2009-10)

Characteristics[A]	Intervention	Comparison	*P* value
Number of clusters (municipalities)	27	28*	
Age of mother, n (%)			0.71
16-24 years	85/561 (15.1)	88/537 (16.3)	
25-29 years	163/561 (29.1)	161/537 (30.0)	
30-34 years	212/561 (37.8)	185/537 (34.5)	
35-44 years	101/561 (18.0)	103/537 (19.2)	
Education of mother, n(%)			0.75
Primary and secondary school	45/546 (8.2)	50/517 (9.7)	
Comprehensive school	195/546 (35.7)	191/517 (36.9)	
Academy/college/university (≤4 years)	204/546 (37.4)	188/517 (36.4)	
Academy/college/university (>4 years)	102/546 (18.7)	88/517 (17.0)	
Parity, n (%)			0.96
Primiparous	225/557 (40.4)	223/532 (41.9)	
Smoking status, n (%)			0.48
Smoking 5 mo after birth	88/558 (15.8)	76/534 (14.2)	
Feeding status at hospital discharge, n (%)			0.77
Exclusively breastfed	459/561 (81.8)	437/537 (81.4)	
Birth weight, mean (SD), g‡	3646 (503)	3618 (503)	0.36
Outcome variables			
Exclusive breastfeeeding, n (%)			
Until 6 mo	108/561 (19.3)	105/537 (19.6)	0.78
Until 5 mo	230/561 (41.0)	232/537 (43.2)	0.32
Any breastfeeding, n (%)			
Until 6 mo	406/556 (73.0)	372/529 (70.3)	0.61
Until 12 mo	154/423 (36.4)	178/427 (41.7)	0.20
Maternal satisfaction with breastfeeding, n (%)			0.59
Satisfied	431/542 (79.5)	397/515 (77.1)	
Both satisfied and dissatisfied	56/542 (10.3)	66/515 (12.8)	
Dissatisfied	55/542 (10.2)	52/515 (10.1)	

No significant differences in characteristics of intervention and comparison groups.
*2 municipalities were merged by the authorities during the study, leaving 27 municipalities in comparison group. [A] Excluded: Birth weight < 2000g, gestational age <37 wk, multiple births. ‡ Independent sample t-test, otherwise Chi-square test.

Appendix S2. Non-response weighting of the 11 completed month data

The follow-up questionnaire (11 completed months) was not sent to mothers who had ended breastfeeding at 5 completed months, as their answers at 11 completed months were given. When combining these data with answers from the mothers who responded at 11 months, we subjected the data to non-response weighting. The weighting was based on three groups: Breastfeeding at five months, no breastfeeding at five months and non-response at five months. The calculation of weights appears from the following table:

Answer at 5 completed months	Response 11 completed months	Non-response completed 11 months	Total	Response rate (%)	Weight
Breastfeeding	854	528	1382	61.79	1.618
No breastfeeding	597	0	597	100.00	1.000
Non-response	188	1331	1519	12.38	8.080

Mothers with already known answer (no breastfeeding at 5 completed months) had 100% ñresponse rateò and their weight is set at 1.000. Mothers still breastfeeding at five months had 61.79% response rate, and their weight is therefore 1/0.6179=1.618. After this weighting, we considered the two groups comparable. In addition, we have the group of non-responders at five months, who also received the 11 month questionnaire. As expected, this group had a low response rate at 11 months and their weight was therefore high. One could argue that such a high weight should not be allowed. An alternative is to use 1.618 as weight for this group, as well.

Note that the weights above are calculated from the uncorrected data (i.e. no exclusions due to low birth weight, gestational age or multiple births). The reason is that information on the exclusion variables is not available for the non-response group. Below, the weights will, however, be applied to corrected data.

The unweighted and weighted results for breastfeeding at 11 completed months are summarized below:

Data	Breastfeeding	Unweighted	(%)	Weighted	(%)
All	NO	1111	(72.2)	2234.5	(68.3)
	YES	428	(27.8)	1035.1	(31.7)
Control	NO	528	(72.1)	1036.1	(67.5)
	YES	204	(27.9)	498.1	(32.5)
Intervention	NO	583	(72.2)	1198.4	(69.1)
	YES	224	(27.8)	537.0	(30.9)

After weighting, the percentages of breastfeeding in the control and intervention groups are 32.5 and 30.9, respectively. The interesting question is whether this difference is statistically significant. The percentages are calculated from a 2Ĭ 2 table with approximately the following numbers: 1036, 499, 1199 and 536. An ordinary significance test (Fisher's Exact Test) results in non-significance (OR=0.928, p-value = 0.33). When taking into account the clustering and the weighting, the difference is more uncertain than assumed here. Therefore, there is no need to make or find an advanced method which handles clustering and weighting. A similar (and

also incorrect) analysis can be done by weighted logistic regression (OR=0.932, p-value = 0.35). In the logistic regression we can also include the adjustment variables, but all these variables are only available for the five months responders. Using the available data for such an analysis results in no sign of significant differences (OR=1.025, p-value = 0.81).
Above it was mentioned an alternative weighting method which uses 1.618 as weight for all mothers who did receive the questionnaire. The results for this alternative weighting are shown below:

Data	Breastfeeding	Unweighted	(%)	Weighted	(%)
All	NO	1111	(72.2)	1459.1	(67.8)
	YES	428	(27.8)	692.6	(32.2)
Control	NO	528	(72.1)	680.7	(67.3)
	YES	204	(27.9)	330.1	(32.7)
Intervention	NO	583	(72.2)	778.4	(68.2)
	YES	224	(27.8)	362.5	(31.8)

The difference between intervention and control is here even smaller.
In summary, from various approaches to the analysis of the 11 completed month data, we can conclude that there was no significant difference in rates of breastfeeding at 11 completed months. The rate of breastfeeding is about 32% in both groups.

Appendix S3. Effect on exclusive breastfeeding until 6 months in intervention and comparison groups by maternal education

Maternal education	Intervention n/N	Comparison n/N	Ratio of adjusted odds ratio (95% CI)*	*P*-value for test of interaction
College/university ≥4 years	56/219	30/182	1.00	
College/university <4 years	70/330	55/295	0.74 (0.39, 1.41)	0.16
Comprehensive school	34/326	35/300	0.50 (0.24, 1.03)	
Primary/Secondary school	13/92	5/115	1.37 (0.46, 4.10)	

*Adjusted for cluster effects, breastfeeding status at hospital discharge, maternal age, education, smoking, parity.

Appendix S4. Outcomes in per protocol analyses

Outcomes	Intervention group n/N (%)	Comparison group n/N (%)	Crude odds ratio (95% CI)*	Adjusted odds ratio (95% CI) À	*P*-value
Primary outcome					
Exclusive breastfeeding until 6 months	118/685 (17.2)	83/584 (14.2)	1.25 (0.92, 1.70)	1.22 (0.89, 1.67)	0.23
Secondary outcomes					
Exclusive breastfeeding until 5 months	282/685 (41.2)	202/584 (34.6)	1.38 (1.06, 1.79)	1.47 (1.06, 2.04)	0.02
Any breastfeeding until 6 mo	491/685 (71.7)	381/581 (65.6)	1.33 (1.05, 1.69)	1.33 (1.03, 1.73)	0.03
Mother satisfied with breastfeeding experience	510/668 (76.3)	418/568 (73.6)	1.18 (0.89, 1.55)	1.30 (0.94, 1.81)	0.12
Perceived pressure to breastfeed (generally)	94/670 (14.0)	82/567 (14.5)	0.97 (0.71, 1.34)	0.94 (0.68, 1.31)	0.72
Pressure from staff at child health centre	42/699 (6.0)	28/594 (4.7)	1.29 (0.79, 2.11)	1.28 (0.77, 2.13)	0.34

*Only adjusted for cluster effects. ÀAdjusted for cluster effects; breastfeeding at hospital discharge, maternal education, age, parity, smoking habits.

PAPER II

PAPER III

10 APPENDICES

Appendix 1 Pragmatic trial: Questionnaire 5 completed months in Norwegian and English

Appendix 2 Pragmatic trial: Information letter

Appendix 3 Stork Groruddalen cohort: Questionnaire at mean 15 weeks of gestation in Norwegian and English

Appendix 4 Stork Groruddalen cohort: Questionnaire at mean 14 weeksô postpartum in Norwegian

Appendix 1 a
Appendix 1 a

Evaluering av helsestasjonens ammeveiledning

Skjemaet fylles ut **før** barnet fyller seks måneder. Dersom du har tvillinger eller trillinger skal du svare for det barnet som ble født først.

1 **Vennligst fyll inn datoen for utfylling av skjemaet**

☐☐ dag ☐☐ måned

2 **Hvilken helsestasjon går du til med barnet?**

3 **Når ble barnet født i forhold til ultralydstermin?** Sett kun ett kryss.

☐ Til ultralydtermin → **Gå til** **5**
☐ Før ultralydstermin
☐ Etter ultralydtermin

4 **Vennligst oppgi antall dager:**

☐☐ dager

5 **Hva var barnets fødselsvekt?**

☐☐☐☐ gram

6 **Hvor gammelt er barnet i dag?** Sett kun ett kryss. Dersom barnet f.eks. er 5 måneder og 7 dager, brukes svaralternativet 5 måneder og 1 uke. Dersom barnet f.eks. er 5 måneder og 6 dager, brukes 5 måneder og 0 uker.

- ☐ 5 måneder og 0 uker
- ☐ 5 måneder og 1 uke
- ☐ 5 måneder og 2 uker
- ☐ 5 måneder og 3 uker
- ☐ 5 måneder og 4 uker
- ☐ 6 måneder og 0 uker
- ☐ 6 måneder og 1 uke
- ☐ 6 måneder og 2 uker
- ☐ 6 måneder og 3 uker

7 **Hva slags melk og/eller annen drikke fikk barnet den dagen dere ble utskrevet fra sykehuset?** Flere kryss er mulig.

- ☐ Morsmelk
- ☐ Morsmelkerstatning
- ☐ Vann
- ☐ Sukkervann
- ☐ Annet, vennligst spesifiser:
- ☐ Vet ikke

8 **Hvordan fikk barnet næring den dagen dere ble utskrevet fra sykehuset?** Flere kryss er mulig.

- ☐ Amming fra brystet
- ☐ Amming med brystskjold
- ☐ Kopp
- ☐ Flaske
- ☐ Skje, sonde, sprøyte eller lignende
- ☐ Vet ikke

9 **Får barnet morsmelk nå**? Sett kun ett kryss.

- ☐ Ja → **Gå til 12a**
- ☐ Nei, barnet har aldri fått morsmelk → **Gå til 11**
- ☐ Nei, men barnet har fått morsmelk tidligere

10 **Hvor gammelt var barnet da det sluttet å få morsmelk?** Sett kun ett kryss

- ☐ 1 uke
- ☐ 2 uker
- ☐ 3 uker
- ☐ 4 uker
- ☐ 5 uker
- ☐ 6 uker
- ☐ 7 uker
- ☐ 2 måneder
- ☐ 2,5 måneder
- ☐ 3 måneder
- ☐ 3,5 måneder
- ☐ 4 måneder
- ☐ 4,5 måneder
- ☐ 5 måneder
- ☐ 5,5 måneder
- ☐ 6 måneder
- ☐ 6,5 måneder

11 **Hva er den viktigste og nest viktigste grunnen til at du har sluttet å amme eller aldri har ammet dette barnet?** Sett ett kryss for viktigste grunn og ett kryss for nest viktigste grunn.

	Sett kun ett kryss i hver kolonne	
	Viktigste grunn	Nest viktigste grunn
Mor var syk/ brukte medisiner	☐	☐
Barnet var sykt/ for tidlig født	☐	☐
Sugeproblemer	☐	☐
Barnet ville ikke	☐	☐
Kolikk/ urolig barn	☐	☐
Barnet biter (har fått tenner)	☐	☐
For lite melk	☐	☐
Bekymring/ stress/ sliten	☐	☐
Brystbetennelse	☐	☐
Tilstoppede melkeganger	☐	☐
Såre brystknopper	☐	☐
Brystoperert	☐	☐
Mor begynte å arbeide/ studere	☐	☐
Ingen spesielle problemer, men ønsket ikke å amme/amme lenger	☐	☐
Ble rådet til å slutte	☐	☐
Andre grunner	☐	☐
Trodde barnet ville sove bedre	☐	☐

Gå til spørsmål 12 neste side

12a **Hvor mange ganger i døgnet får barnet vanligvis morsmelk nå?**
Regn også med de gangene barnet bare får morsmelk til trøst eller kos, dag og nattetid.

- ☐ 1 gang
- ☐ 2-3 ganger
- ☐ 4-5 ganger
- ☐ 6-7 ganger
- ☐ 8-9 ganger
- ☐ 10 ganger eller flere

12 **Får barnet morsmelkerstatning /annen melk i tillegg til eller i stedet for morsmelk?**

- ☐ Ja
- ☐ Nei → **Gå til 15**

13 **Hvor gammelt var barnet da det begynte å drikke morsmelkerstatning /annen melk?**
Sett kun ett kryss.

☐ 1 uke	☐ 2 måneder	☐ 5,5 måneder
☐ 2 uker	☐ 2,5 måneder	☐ 6 måneder
☐ 3 uker	☐ 3 måneder	☐ 6,5 måneder
☐ 4 uker	☐ 3,5 måneder	
☐ 5 uker	☐ 4 måneder	
☐ 6 uker	☐ 4,5 måneder	
☐ 7 uker	☐ 5 måneder	

14 **Har helsestasjonen gitt deg informasjon om hvordan du tilbereder og bruker morsmelkerstatning?**

- ☐ Ja
- ☐ Nei
- ☐ Hadde ikke behov for informasjon

15 **Får barnet vann, juice, saft eller annen vannbasert drikke?** Tran eller kosttilskudd regnes ikke som drikke.

- ☐ Ja
- ☐ Nei → **Gå til 17**

16 **Hvor gammelt var barnet da det begynte å få dette?** Sett kun ett kryss.

☐ 1 uke	☐ 2 måneder	☐ 5,5 måneder
☐ 2 uker	☐ 2,5 måneder	☐ 6 måneder
☐ 3 uker	☐ 3 måneder	☐ 6,5 måneder
☐ 4 uker	☐ 3,5 måneder	
☐ 5 uker	☐ 4 måneder	
☐ 6 uker	☐ 4,5 måneder	
☐ 7 uker	☐ 5 måneder	

17 **Får barnet fast føde?** Med fast føde menes alle matvarer, også most mat og velling, men ikke drikke.

- ☐ Ja
- ☐ Nei → **Gå til 19**

18 **Hvor gammelt var barnet da det begynte å få dette?** Sett kun ett kryss.

☐ 1 uke	☐ 2 måneder	☐ 5,5 måneder
☐ 2 uker	☐ 2,5 måneder	☐ 6 måneder
☐ 3 uker	☐ 3 måneder	☐ 6,5 måneder
☐ 4 uker	☐ 3,5 måneder	
☐ 5 uker	☐ 4 måneder	
☐ 6 uker	☐ 4,5 måneder	
☐ 7 uker	☐ 5 måneder	

19 **Når du tenker tilbake på det siste døgnet, hva har barnet drukket eller spist fra i går morges og til i dag tidlig?** Flere kryss er mulig.

- ☐ Morsmelk
- ☐ Morsmelkerstatning/annen melk
- ☐ Vann
- ☐ Juice, saft og lignende
- ☐ Fast føde; det vil si most mat, velling og alle andre matvarer unntatt drikke
- ☐ Annet, vennligst spesifiser:

20 **Når tok helsestasjonen første gang kontakt med deg etter at du kom hjem fra sykehuset?**
Sett kun ett kryss.

- ☐ Den første uken etter at jeg kom hjem
- ☐ Den andre uken
- ☐ Den tredje uken
- ☐ Den fjerde uken eller senere
- ☐ Tok selv kontakt
- ☐ Husker ikke

21 **Har du ammet barnet etter at du kom hjem fra sykehuset?**

- ☐ Ja
- ☐ Nei → **Gå til 27**

22 **Etter at du kom hjem fra sykehuset, i hvilken grad har du opplevd noen av følgende ammeproblemer?**
Også de som ikke har hatt problemer bes krysse av. Sett ett kryss for hver linje.

	Ingen problemer	Små problemer	Middels problemer	Store problemer
Vansker med å få barnet til å ta brystet	☐	☐	☐	☐
Usikkerhet om barnet får nok melk	☐	☐	☐	☐
Smerter ved amming	☐	☐	☐	☐
Såre brystknopper	☐	☐	☐	☐
Melkespreng	☐	☐	☐	☐
Tilstoppede melkeganger	☐	☐	☐	☐
Brystbetennelse	☐	☐	☐	☐
Dårlig vektøkning hos barnet	☐	☐	☐	☐
Andre problemer, vennligst spesifiser nedenfor:	☐	☐	☐	☐

23 **Har du fått den hjelpen og oppfølgingen fra helsestasjonen som du trengte for å løse ammeproblemer?**
Dersom du ikke har hatt ammeproblemer, krysser du av for Har ikke hatt ammeproblemer. Sett kun ett kryss

- ☐ Ja, jeg fikk den hjelpen jeg trengte og problemene løste seg
- ☐ Ja, jeg fikk hjelp, men ikke alle problemene lot seg løse
- ☐ Nei, jeg har ikke fått hjelp og ingen av problemene ble løst
- ☐ Nei, jeg fikk ikke hjelp, men klarte å løse problemene selv
- ☐ Nei, jeg fikk hjelp et annet sted
- ☐ Har ikke hatt ammeproblemer

24 **Har helsesøster noen gang observert ammingen?** Sett kun ett kryss

- ☐ Ja
- ☐ Nei
- ☐ Jeg syntes ikke det var nødvendig

25 **Alt i alt, hvor fornøyd eller misfornøyd er du med ammeveiledningen du har fått på helsestasjonen?**
Dersom du ikke har fått slik veiledning, krysser du av for Har ikke fått veiledning. Sett kun ett kryss.

- ☐ Svært fornøyd
- ☐ Ganske fornøyd
- ☐ Verken fornøyd eller misfornøyd
- ☐ Ganske misfornøyd
- ☐ Svært misfornøyd
- ☐ Har ikke fått veiledning

26 **Alt i alt, hvordan har din opplevelse av å amme vært?** Sett kun ett kryss.

- ☐ Svært dårlig
- ☐ Ganske dårlig
- ☐ Verken god eller dårlig
- ☐ Ganske god
- ☐ Svært god

26b **Har du følt deg presset til å amme lenger enn du selv hadde lyst?**

- ☐ Ja
- ☐ Nei → **Gå til 27**

26c **Hvem følte du presset deg?** Flere kryss er mulig.

- ☐ Personalet på barsel
- ☐ Personalet på helsestasjonen
- ☐ Barnets far
- ☐ Familien forøvrig
- ☐ Andre mødre/venner
- ☐ Media/folk generelt
- ☐ Din egen følelse av at ”du burde”
- ☐ Andre

27 **Hvordan har du opplevd helsestasjonens veiledning om amming og/eller bruk av morsmelkerstatning**? Sett ett kryss for hver linje.

	Ja	Delvis	Nei	Har ikke fått veiledning
Fikk du den informasjonen du ønsket?	☐	☐	☐	☐
Var informasjonen lett å forstå?	☐	☐	☐	☐
Lyttet helsesøster til det du hadde å si?	☐	☐	☐	☐
Ble din mening og oppfatning respektert?	☐	☐	☐	☐
Følte du at det var mulig å stille spørsmål?	☐	☐	☐	☐

28 **Hvor mange barn har du født i alt?** Sett kun ett kryss.

- ☐ 1 barn → **Gå til 30**
- ☐ 2 barn
- ☐ 3 barn
- ☐ 4 barn eller flere

29 **Hvor lenge ammet du ditt forrige barn?** Sett kun ett kryss.

- ☐ Ammet ikke
- ☐ 0-3 mnd
- ☐ 4-6 mnd
- ☐ 7-9 mnd
- ☐ 10-12 mnd
- ☐ 13-18 mnd
- ☐ 19-24 mnd
- ☐ Mer enn 2 år

30 **Hva er nåværende familiestatus?** Sett kun ett kryss.

- ☐ Samboer
- ☐ Gift
- ☐ Bor alene med barna
- ☐ Annet

31 **Hva er din høyeste fullførte utdanning?** Sett kun ett kryss.

- ☐ 9/10- årig grunnskole eller kortere
- ☐ 9/10-årig grunnskole og folkehøgskole eller annen ett-årig utdanning
- ☐ Videregående opplæring (gymnas/fagbrev)
- ☐ Fagskoleutdanning
- ☐ Høgskole- eller universitetsutdanning på 4 år eller mindre
- ☐ Høgskole- eller universitetsutdanning på mer enn 4 år
- ☐ Annet
- ☐ Vet ikke

32 **Hva er barnets fars høyeste fullførte utdanning?** Sett kun ett kryss.

- ☐ 9/10- årig grunnskole eller kortere
- ☐ 9/10-årig grunnskole og folkehøgskole eller annen ett-årig utdanning
- ☐ Videregående opplæring (gymnas/fagbrev)
- ☐ Fagskoleutdanning
- ☐ Høgskole- eller universitetsutdanning på 4 år eller mindre
- ☐ Høgskole- eller universitetsutdanning på mer enn 4 år
- ☐ Annet
- ☐ Vet ikke

33 **Hvordan var din arbeidssituasjon før du ble gravid?** Dersom flere alternativ passer, kryss av for det alternativet som passer best

- ☐ Utearbeidende heltid
- ☐ Utearbeidende deltid
- ☐ Hjemmearbeidende
- ☐ Sykemeldt
- ☐ Permisjon
- ☐ Uføretrygdet
- ☐ Under attføring
- ☐ Student/ skoleelev
- ☐ Arbeidsledig
- ☐ Annet

34 **Røyker du nå?** Sett kun ett kryss.

- ☐ Ja, daglig
- ☐ Ja, av og til
- ☐ Nei

35 **Her kan du skrive eventuelle kommentarer til spørreskjemaet:**

Tusen takk for hjelpen!

Appendix 1 b

Assessment of the Maternal and child health centre's breastfeeding counselling

This form should be completed **before** the child is six months old. If you have twins or triplets the form should be completed for the first born.

1 Please enter the date of form completion

☐☐ day ☐☐ month

2 Which Maternal and child health centre do you attend with your child?

3 When was the child born in relation to the ultrasound due date estimation? Check one box only.

- ☐ On the ultrasound due date — **Proceed to 5**
- ☐ Before the ultrasound due date
- ☐ After the ultrasound due date

4 Please enter the number of days discrepancy:

☐☐ days

5 What was the child's birth weight?

☐☐☐☐ grams

6 How old is the child today? Check one box only. If the child is e.g. 5 months and 7 days old, check the box for 5 months and 1 week. If the child is e.g. 5 months and 6 days old, check the box for 5 months and 0 weeks.

- ☐ 5 months and 0 weeks
- ☐ 5 months and 1 week
- ☐ 5 months and 2 weeks
- ☐ 5 months and 3 weeks
- ☐ 5 months and 4 weeks
- ☐ 6 months and 0 weeks
- ☐ 6 months and 1 week
- ☐ 6 months and 2 weeks
- ☐ 6 months and 3 weeks

7 What kind of milk and/or other fluid did the child receive the day you were discharged from the hospital? You may check multiple boxes.

- ☐ Breast milk
- ☐ Infant formula
- ☐ Water
- ☐ Sugar water
- ☐ Other, please specify:
- ☐ Don't know

8 How did the child receive nourishment on the day you were discharged from the hospital? You may check multiple boxes.

- ☐ Breastfeeding by breast
- ☐ Breastfeeding using nipple shields
- ☐ Cup
- ☐ Bottle
- ☐ Spoon, feeding tube, syringe or the like
- ☐ Don't know

9 Is the child being breastfed today? Check one box only.

- ☐ Yes ——— **Proceed to 12a**
- ☐ No, the child has never received breast milk ——— **Proceed to 11**
- ☐ No, but the child has received breast milk earlier

10 How old was the child when he/she stopped receiving breast milk? Check one box only.

- ☐ 1 week
- ☐ 2 weeks
- ☐ 3 weeks
- ☐ 4 weeks
- ☐ 5 weeks
- ☐ 6 weeks
- ☐ 7 weeks
- ☐ 2 months
- ☐ 2,5 months
- ☐ 3 months
- ☐ 3,5 months
- ☐ 4 months
- ☐ 4,5 months
- ☐ 5 months
- ☐ 5,5 months
- ☐ 6 months
- ☐ 6,5 months

11 What is the most important and the second most important reason why you stopped breastfeeding or have never breastfed this child? Check one box for the most important reason and one for the second most important reason.

	Check only one box in each column	
	Most important reason	Second most important reason
Mother was ill / used medicines	☐	☐
Child was ill / premature	☐	☐
Sucking problems	☐	☐
The child doesn't want to	☐	☐
Colic / agitated child	☐	☐
The child bites (has teeth)	☐	☐
Too little milk	☐	☐
Worry / stress/ fatigue	☐	☐
Mastitis	☐	☐
Plugged milk ducts	☐	☐
Sore nipples	☐	☐
Breast surgery	☐	☐
Mother started working / studying	☐	☐
No specific problems but didn't want to breastfeed/ breastfeed any longer	☐	☐
Was advised to stop breastfeeding	☐	☐
Other reasons	☐	☐
Thought the child would sleep better	☐	☐

Proceed to question 12 on the next page

12a How many times during the day does the child usually receive breast milk now?
Include the times the child receives breast milk for comfort or cuddles, day and night

- ☐ 1 a day
- ☐ 2-3 times
- ☐ 4-5 times
- ☐ 6-7 times
- ☐ 8-9 times
- ☐ 10 times or more

12 Does the child receive infant formula / other milk in addition to or instead of breast milk?

- ☐ Yes
- ☐ No ——— **Proceed to 15**

13 How old was the child when he/she began drinking infant formula / other milk?
Check one box only.

☐ 1 week	☐ 2 months	☐ 5,5 months
☐ 2 weeks	☐ 2,5 months	☐ 6 months
☐ 3 weeks	☐ 3 months	☐ 6,5 months
☐ 4 weeks	☐ 3,5 months	
☐ 5 weeks	☐ 4 months	
☐ 6 weeks	☐ 4,5 months	
☐ 7 weeks	☐ 5 months	

14 Did the Maternal and child health centre give you information about how to prepare and use formula?

- ☐ Yes
- ☐ No
- ☐ Did not require information

15 Does the child receive water, juice, squash or other water based drinks?
Cod liver oil and supplements are not considered fluids.

- ☐ Yes
- ☐ No ——— **Proceed to 17**

16 How old was the child when he/she began receiving this? Check one box only.

☐ 1 week	☐ 2 months	☐ 5,5 months
☐ 2 weeks	☐ 2,5 months	☐ 6 months
☐ 3 weeks	☐ 3 months	☐ 6,5 months
☐ 4 weeks	☐ 3,5 months	
☐ 5 weeks	☐ 4 months	
☐ 6 weeks	☐ 4,5 months	
☐ 7 weeks	☐ 5 months	

17 Does the child receive solid food? Solid food is defined as all foods, including mashed food and gruel, but not fluids.

- ☐ Yes
- ☐ No ——— **Proceed to 19**

18 How old was the child when he/she began receiving this? Check one box only.

☐ 1 week	☐ 2 months	☐ 5,5 months
☐ 2 weeks	☐ 2,5 months	☐ 6 months
☐ 3 weeks	☐ 3 months	☐ 6,5 months
☐ 4 weeks	☐ 3,5 months	
☐ 5 weeks	☐ 4 months	
☐ 6 weeks	☐ 4,5 months	
☐ 7 weeks	☐ 5 months	

19 Thinking back over the past 24 hours, what has your child drunk or eaten from yesterday morning until this morning? You may check multiple boxes.

- ☐ Breast milk
- ☐ Infant formula / other milk
- ☐ Water
- ☐ Juice, squash or the like
- ☐ Solid food; i.e. mashed food, gruel and all other foods except for fluids
- ☐ Other, please specify:

20 After you were discharged from hospital, when did the Maternal and child health centre contact you for the first time? Check one box only.

- ☐ The first week after I came home
- ☐ The second week
- ☐ The third week
- ☐ The fourth week or later
- ☐ I initiated contact
- ☐ Don't remember

21 Have you breast fed the child after you came home from the hospital?

- ☐ Yes
- ☐ No ——— **Proceed to 27**

22 After you came home from the hospital, to what extent have you experienced any of the following breastfeeding problems? Please complete this question even if you haven't experienced any problems. Check one box for each line.

	No problems	Minor problems	Some problems	Major problems
Latching on difficulties	☐	☐	☐	☐
Unsure if the child is receiving enough milk	☐	☐	☐	☐
Pain during breastfeeding	☐	☐	☐	☐
Sore nipples	☐	☐	☐	☐
Breast engorgement	☐	☐	☐	☐
Plugged milk ducts	☐	☐	☐	☐
Mastitis	☐	☐	☐	☐
Child's lack of weight gain	☐	☐	☐	☐
Other problems, please specify below:	☐	☐	☐	☐

23 **Have you received the assistance and follow up you needed to solve your breastfeeding problems from the Maternal and child health centre?** If you have not had any breastfeeding problems please check the box Have not had breastfeeding problems. Check one box only.

- ☐ Yes, I received the help I needed and the problems were solved
- ☐ Yes, I received help but not all the problems were solvable
- ☐ No, I did not receive any help and none of the problems were solved
- ☐ No, I did not receive any help but I managed to solve the problems by myself
- ☐ No, I received help elsewhere
- ☐ Have not had breastfeeding problems.

24 **Has a public health nurse observed the breastfeeding at any point?** Check one box only.

- ☐ Yes
- ☐ No
- ☐ I didn't think it necessary

25 **Overall, how satisfied or dissatisfied are you with the breastfeeding counselling you have received at the Maternal and child health centre?** If you have not received such counselling please check the box Have not received counselling. Check one box only.

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied
- ☐ Have not received counselling

26 **Overall, how has your experience of breastfeeding been?** Check one box only.

- ☐ Very bad
- ☐ Moderately bad
- ☐ Neither bad nor good
- ☐ Moderately good
- ☐ Very good

26b **Have you felt pressured into breasfeeding for longer than you wanted to?**

- ☐ Yes
- ☐ No ——— **Proceed to 27**

26c **Who did you feel pressured by?** You may check multiple boxes.

- ☐ Personnel at the maternity ward
- ☐ Personnel at the Maternal and child health centre
- ☐ The child's father
- ☐ Other family members
- ☐ Other mothers / friends
- ☐ The press / people in general
- ☐ Your own feeling that "you should"
- ☐ Other

27 How have you experienced the Maternal and child health centre counselling about breastfeeding and/or the use of infant formula? Check one box for each line.

	Yes	Partly	No	Have not received counselling
Did you receive the information you needed?	☐	☐	☐	☐
Was the information easy to understand?	☐	☐	☐	☐
Did the nurse listen to everything you had to say?	☐	☐	☐	☐
Were your opinions and understanding respected?	☐	☐	☐	☐
Did you feel it was easy to ask questions?	☐	☐	☐	☐

28 How many children have you given birth to? Check one box only.

- ☐ 1 child ——— **Proceed to 30**
- ☐ 2 children
- ☐ 3 children
- ☐ 4 children or more

29 For how long did you breastfeed your last child? Check one box only.

- ☐ Did not breastfeed
- ☐ 0-3 months
- ☐ 4-6 months
- ☐ 7-9 months
- ☐ 10-12 months
- ☐ 13-18 months
- ☐ 19-24 months
- ☐ More than 2 years

30 What is your current family situation? Check one box only.

- ☐ Cohabiting
- ☐ Married
- ☐ Living alone with the child(ren)
- ☐ Other

31 What is your highest level of education? Check one box only.

- ☐ 9/10- years education or less
- ☐ 9/10-years education or Folk High School or other one-year education
- ☐ Secondary education (high school/certificate of apprenticeship)
- ☐ Vocational schooling
- ☐ Academy/college/university - 4 years or less
- ☐ Academy/college/university - more than 4 years
- ☐ Other
- ☐ Don't know

32 What is the child's father's highest level of education? Check one box only.

- ☐ 9/10- years education or less
- ☐ 9/10-years education or Folk High School or other one-year education
- ☐ Secondary education (high school/certificate of apprenticeship)
- ☐ Vocational schooling
- ☐ Academy/college/university - 4 years or less
- ☐ Academy/college/university - more than 4 years
- ☐ Other
- ☐ Don't know

33 What was your work situation before you became pregant?
If several alternatives fit, check the one that is the best fitting.

- ☐ Employed outside the home, full time
- ☐ Employed outside the home, part-time
- ☐ Working at home
- ☐ On sick leave
- ☐ On leave
- ☐ Disability Benefit recipient
- ☐ Rehabilitation Benefit recipient
- ☐ Student
- ☐ Unemployed
- ☐ Other

34 Do you currently smoke? Check one box only.

- ☐ Yes, daily
- ☐ Yes, sometimes
- ☐ No

35 If you have any comments with regards to the questionnaire please note them here:

Thank you for your participation!

Appendix 2

Statistisk sentralbyrå
Statistics Norway

Oslo, 8. mai 2012
Saksbehandler: Aina Holmøy
Avdeling for datafangst, telefon: 800 83 028 (mandag til fredag 08-15)

Hvordan opplever du helsestasjonens ammeveiledning?

Statistisk sentralbyrå gjennomfører nå en undersøkelse om helsestasjonenes ammeveiledning på oppdrag fra Nasjonal kompetansetjeneste for amming. Du er en av 3 500 mødre med barn på fem måneder som er trukket fra Folkeregisteret til å delta i undersøkelsen.

Mange kvinner opplever små eller store ammeproblemer. For at så mange kvinner som mulig skal få den veiledningen og støtten de ønsker, arbeider nå helsestasjonene for å gi bedre hjelp til kvinner som ammer. Gjennom denne undersøkelsen ønsker vi å få del i dine erfaringer. På den måten kan du bidra til at ammeveiledningen i framtiden blir enda bedre. Formålet er å undersøke om prosjektet *Ammekyndig helsestasjon*, som pågår ved enkelte helsestasjoner, fører til bedre kvalitet på ammeveiledningen og at en større andel kvinner får den hjelpen de trenger. Du kan lese mer om undersøkelsen i den vedlagte brosjyren.

Du kan svare elektronisk ved å gå inn på nettsiden **http://intervju.ssb.no/amming,** eller du kan fylle ut og returnere det vedlagte spørreskjemaet i den frankerte svarkonvolutten. Vi vil gjerne at du svarer innen ti dager og før barnet blir seks måneder. Ønsker du å svare elektronisk, bruker du følgende bruker-ID og passord:

Bruker-ID: **Passord**

For at resultatene skal bli så gode som mulig, er det viktig at alle som er trukket ut blir med. Vi kan ikke erstatte deg med en annen. Det er imidlertid frivillig å delta, og du kan når som helst trekke deg og kreve opplysninger slettet. **Alle som deltar vil være med i trekningen av ett gavekort på 10 000 kroner, fem gavekort på 5 000 kroner og ti gavekort på 1 000 kroner.**

Alle som arbeider med undersøkelsen i Statistisk sentralbyrå har taushetsplikt, og det vil aldri bli kjent utenfor Statistisk sentralbyrå hva enkeltpersoner har svart. Nasjonal kompetansetjeneste for amming vil kun få tilgang til data hvor alle fødselsnummer, navn og adresser er fjernet. Helsestasjonen vil ikke få vite at du har deltatt i undersøkelsen. Innen utgangen av 2015 vil alle kjennetegn som kan identifisere enkeltpersoner bli fjernet fra datamaterialet. Opplysninger om ditt fødeland vil bli hentet fra folkeregisteret. I brosjyren kan du lese mer om personvern.

Når barnet blir elleve måneder, vil du få tilsendt et kort oppfølgingsskjema.

Har du spørsmål om forskningsprosjektet, kan du kontakte prosjektledelsen ved Nasjonal kompetansetjeneste for amming, Rikshospitalet, Oslo Universitetssykehus, ved helsesøster Ragnhild Alquist på tlf. 23 07 54 04 eller e-post elisabeth.tufte@ous-hf.no. Ønsker du mer informasjon om gjennomføringen av undersøkelsen, kan du ringe Statistisk sentralbyrå på telefon 800 83 028.

Med vennlig hilsen

Hans Henrik Scheel
adm. direktør i Statistisk sentralbyrå

Anne Bærug
leder, Nasjonal kompetansetjeneste for amming

Statistisk sentralbyrå
Statistics Norway

Oslo, 8. mai 2012
Saksbehandlar: Aina Holmøy
Avdeling for datafangst, telefon 800 83 028 (måndag til fredag 08-15)

Korleis opplever du ammerettleiinga ved helsestasjonen?

Statistisk sentralbyrå utfører no ei undersøking om ammerettleiinga ved helsestasjonane på oppdrag frå Nasjonal kompetanseteneste for amming. Du er ei av 3 500 mødre med barn på fem månader som er trekt frå Folkeregisteret til å vere med i undersøkinga.

Mange kvinner opplever små eller store ammeproblem. For at så mange kvinner som mogleg skal få den rettleiinga og støtta dei ønskjer, arbeider no helsestasjonane for å gi betre hjelp til kvinner som ammar. Gjennom denne undersøkinga ønskjer vi å få del i dine erfaringar. På den måten kan du gjere ditt til at ammerettleiinga i framtida blir enda betre. Føremålet er å undersøke om prosjektet *Ammekyndig helsestasjon,* som finn stad ved enkelte helsestasjonar, fører til betre kvalitet på ammerettleiinga og at ein større del kvinner får den hjelpa dei treng. Du kan lese meir om undersøkinga i den vedlagde brosjyren.

Du kan svare elektronisk ved å gå inn på nettsida **http://intervju.ssb.no/amming**, eller du kan fylle ut og returnere det vedlagde spørjeskjemaet i den frankerte svarkonvolutten. Vi vil gjerne at du svarer innan ti dagar og før barnet blir seks månader. Ønskjer du å svare elektronisk, nyttar du følgjande brukar-ID og passord:

Brukar-ID: **Passord**

For at resultata skal bli så gode som mogleg, er det viktig at alle som er trekte ut blir med, Vi kan ikkje erstatte deg med ei anna. Det er likevel frivillig å delta, og du kan når som helst trekkje deg og krevje opplysningane sletta. **Alle som deltek vil vere med i trekkinga av eitt gåvekort på 10 000 kroner, fem gåvekort på 5 000 kroner og ti gåvekort på 1 000 kroner.**

Alle som arbeider med undersøkinga i Statistisk sentralbyrå har teieplikt, og det vil aldri bli kjend utanfor Statistisk sentralbyrå kva enkeltpersonar har svart. Nasjonal kompetanseteneste for amming vil berre få tilgang til data der alle fødselsnummer, namn og adresser er fjerna. Helsestasjonen vil ikkje få vite at du har vore med i undersøkinga. Innan utgangen av 2015 vil alle kjenneteikn som kan identifisere enkeltpersonar bli fjerna frå datamaterialet. Opplysningar om ditt fødeland vil bli henta frå folkeregisteret. I brosjyren kan du lese meir om personvern.

Når barnet blir elleve månader, vil du få tilsend eit kort oppfølgingsskjema.

Dersom du har spørsmål om forskingsprosjektet, kan du kontakte prosjektleiinga ved Nasjonal kompetanseteneste for amming, Rikshospitalet, Oslo Universitetssykehus, ved helsesyster Ragnhild Alquist på tlf. 23 07 54 04 eller e-post elisabeth.tufte@ous-hf.no. Ønskjer du meir informasjon om gjennomføringa av undersøkinga, kan du ringje Statistisk sentralbyrå på telefon 800 83 028.

Med venleg helsing

Hans Henrik Scheel
adm. direktør i Statistisk sentralbyrå

Anne Bærug
leiar, Nasjonal kompetansetjeneste for amming

Appendix 3 a

44546

Unikt pas. løpenummer: ☐☐☐☐

STORK Groruddalen

CRF 1. TRIMESTER - SKJEMA 1

Kode intervjuer ☐☐

Intervjuers initialer ☐☐☐

Undersøkelsesdato ☐☐.☐☐.☐☐

Svangerskapsuke ☐☐

Kvinnens fødselsdato ☐☐.☐☐.☐☐

Bosteds-postnummer ☐☐☐☐

Undersøkelsesbydel ☐☐

Fylles ut hos alle ved første besøk på helsestasjonen i graviditeten - gjelder nesten uten unntak spørsmål som stilles for å fylle ut helsekortet - gjøres samtidig med det, unngår da å spørre om det samme to ganger. Hvis kvinnen ikke inkluderes, makuleres skjemaet. Kommentarfelt til slutt.

Forklaring til utfyllingen:
Bruk blå eller svart kulepenn. De fleste steder settes kryss eller tall. Bruk ellers store bokstaver og en bokstav per rute. Sett kryss mest mulig midt i avkryssningsboksen. Dersom feil i utfyllingen, marker dette ved å sette tre streker over boksen og kryss av på vanlig måte i den riktige boksen. Dersom behov for å notere ned ytterligere informasjon ut over hva det er avsatt plass til på skjemaet, kan du notere dette i margen. Bare sørg for at du ikke skriver i avkryssningsboksene eller notatfelter.Eksempel på utfylling:

☒ ja ☐ nei 2256 gram

Tekst i kursiv under spørsmålet, før svarkategoriene, er informasjon til intervjueren og skal ikke leses opp for kvinnen.

DEMOGRAFI

1. Hvilken sivilstand har du nå?

☐ Gift ☐ Partnerskap ☐ Samboer ☐ Enslig ☐ Skilt/separert ☐ Enke ☐ Annet

2. Hvilken utdannelse har du nå?

Kryss først av for høyeste fullførte eller avsluttede-, og evt. pågående utdanning, og angi deretter antall år for disse kategoriene. Se evt. prosedyrebok 2.4.2

			Antall år
Under 7 års skolegang	☐ Fullført	☐ Holder på med	☐☐
Grunnskole (7-9-årig skolegang)	☐ Fullført	☐ Holder på med	☐☐
1-2-årig gymnas/videreg./yrkesskole(10-11år)	☐ Fullført	☐ Holder på med	☐☐
3-årig gymnas/videreg./yrkesskole(12år)	☐ Fullført	☐ Holder på med	☐☐
Distriktshøgskole, universitet, inntil 4 år (Sykepleier, lærer, Bachelor)	☐ Fullført	☐ Holder på med	☐☐
Høgskole, universitet > 4 år (Hovedfag, Master, embetseksamen)	☐ Fullført	☐ Holder på med	☐☐

Unikt pas. løpenummer: | | | | |

3. Hva var arbeidssituasjonen for deg da du ble gravid?

- ☐ Under utdanning
- ☐ Hjemmeværende
- ☐ Arbeidssøkende/permittert
- ☐ Attføring/ufør
- ☐ Ansatt i offentlig virksomhet
- ☐ Ansatt i privat virksomhet
- ☐ Annet

Hvis annet, hva?:

4. Hva er ditt yrke? Besvares selv om du er midlertidig fraværende pga. sykdom/permisjon.
Angi yrke/stillingstittel

Angi Yrkessiffer, normalt med 4 siffer, i forhold til STRYK-klassifikasjonen. Se prosedyrebok 2.4.2, evt eget hefte. 1.siffer fremgår av nummer på hovedklassen. Hvis ikke det siste siffer er kjent, skriv de 3 første og la den siste boksen stå tom.

1.Administrative ledere og politikere	
2.Akademiske yrker	
3.Yrker med kortere høyskole og universitetsutdanning og teknikere	
4.Kontor- og serviceyrker	
5.Salgs-, service- og omsorgsyrker	
6.Yrker innen jordbruk, skogbruk og fiske	
7.Håndverkere	
8.Prosess- og maskinoperatører, transportarbeidere mv	
9.Yrker uten krav til utdanning	
0.Militære yrker og uoppgitt	
Hjemmeværende	

Hvis yrket ikke er klassifiserbart, angi:

44546

Unikt pas. løpenummer: ☐☐☐☐

5. Hvilket trossamfunn\religion tilhører du? *Se evt. prosedyrebok 2.4.2*

- ☐ Kristne kirkesamfunn *
- ☐ Den Ortodokse kirken
- ☐ Den Koptiske kirken **
- ☐ Den Katolske kirken
- ☐ Adventister
- ☐ Jehovas vitner
- ☐ Mormonere
- ☐ Islam
- ☐ Hinduisme
- ☐ Sikhisme
- ☐ Buddhisme
- ☐ Taoisme***
- ☐ Ingen trossamfunn

** fellesbetegnelse, for frimenigheter og statskirken i Norge, samt den anglikanske kirken.*
*** spesielt Etipoia, Eritrea og Egypt.*
**** Tradisjonell kinesisk religion. Spesielt kinesere og vietnamesere.*

6. Hvilket land er du født i?:

- ☐ Sverige
- ☐ Danmark
- ☐ Storbritannia
- ☐ Tyskland
- ☐ Tyrkia
- ☐ Irak
- ☐ Iran
- ☐ Pakistan
- ☐ Sri Lanka
- ☐ Vietnam
- ☐ Marokko
- ☐ Somalia
- ☐ Polen
- ☐ Russland
- ☐ Serbia
- ☐ Albania
- ☐ Kosovo
- ☐ Kina
- ☐ Thailand
- ☐ Chile
- ☐ Eritrea
- ☐ Etiopia
- ☐ Ghana
- ☐ Nigeria
- ☐ Annet europeisk land
- ☐ Annet afrikansk land
- ☐ Annet asiatisk land
- ☐ Annet amerikansk land
- ☐ Oceania/Australia

- ☐ Født i Norge av to norske foreldre
- ☐ Født i Norge av to utenlandske foreldre
- ☐ Født i Norge av en norsk + utenlandsk foreldre

7. Statsborgerskap i hvilket land?

- ☐ Sverige
- ☐ Danmark
- ☐ Storbritannia
- ☐ Tyskland
- ☐ Tyrkia
- ☐ Irak
- ☐ Iran
- ☐ Pakistan
- ☐ Sri Lanka
- ☐ Vietnam
- ☐ Marokko
- ☐ Somalia
- ☐ Polen
- ☐ Russland
- ☐ Serbia
- ☐ Albania
- ☐ Kosovo
- ☐ Kina
- ☐ Thailand
- ☐ Chile
- ☐ Eritrea
- ☐ Etiopia
- ☐ Ghana
- ☐ Nigeria
- ☐ Annet europeisk land
- ☐ Annet afrikansk land
- ☐ Annet asiatisk land
- ☐ Annet amerikansk land
- ☐ Oceania/Australia

Hvis etnisk skandinavisk, gå til spørsmål 12.
Hvis fødeland og etnisk tilhørighet ikke synes å stemme (eks "inder", men født i Kenya, Uganda, Sør-Afrika) - besvar spørsmål 8. Ellers, gå til spørsmål 9.

8. Hvilken etnisk gruppe(felles språk, kultur, historie) føler du at du tilhører?

Angi land: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

9. Hva er ditt morsmål?

- ☐ Urdu
- ☐ Arabisk
- ☐ Somali
- ☐ Tamilsk
- ☐ Tyrkisk
- ☐ Vietnamesisk
- ☐ Sorani
- ☐ Kinesisk
- ☐ Persisk
- ☐ Fransk
- ☐ Spansk
- ☐ Portugisisk
- ☐ Engelsk
- ☐ Tysk
- ☐ Flamsk/Nederlansk
- ☐ Annet eruopeisk språk
- ☐ Annet afrikansk språk
- ☐ Annet asiatisk språk
- ☐ Annet

10. Hvis ikke etnisk skandinavisk: Hvor gode vil du si dine norskkunnskaper er?

☐ Svært gode ☐ Gode ☐ Middels gode ☐ Litt dårlige ☐ Dårlige

11. Bruker du vanligvis tolk når du er hos lege?

☐ Ja, profesjonell ☐ Ja, familie/venn ☐ Nei

TIDLIGERE SVANGERSKAP/HELSEFORHOLD

12. Har du vært gravid tidligere? (Tenk også på svangerskap som endte med aborter eller dødfødsler)

☐ Nei ☐ Ja

Hvis nei, gå til spørsmål 14

Hvis ja:

Antall levende fødte: ☐☐ Antall dødfødte: ☐☐ Antall spontanaborter: ☐☐

Antall provoserte aborter: ☐☐ Antall svangerskap utenfor livmor: ☐☐

44546

Unikt pas. løpenummer: ☐☐☐☐

13. Jeg vil nå spørre deg om tidligere svangerskap som har vart mer enn 22 uker.

Hvis mer enn 1 barn per svangerskap, la tvilling 1 telle som det aktuelle nummer på barnet, tvilling 2 som neste barn.

1.barn:

Fødselsår: ☐☐☐☐ Svangerskapsuke for fødsel: ☐☐ Fødselsvekt i gram: ☐☐☐☐ Kjønn: ☐ Gutt ☐ Jente

Fødested:
☐ Norge
☐ Eget fødeland
☐ Annet

Hvis flerlingefødsel:
☐ Tvillinger
☐ Trillinger

Forløsningsmetode:
☐ Vanlig vaginal
☐ Tang
☐ Vakuum
☐ Keisersnitt

Frisk i første leveuke?:
☐ Ja
☐ Nei

Hvis nei:
☐ Frisk nå
☐ Syk nå
☐ Død

2.barn:

Fødselsår: ☐☐☐☐ Svangerskapsuke for fødsel: ☐☐ Fødselsvekt i gram: ☐☐☐☐ Kjønn: ☐ Gutt ☐ Jente

Fødested:
☐ Norge
☐ Eget fødeland
☐ Annet

Hvis flerlingefødsel:
☐ Tvillinger
☐ Trillinger

Forløsningsmetode:
☐ Vanlig vaginal
☐ Tang
☐ Vakuum
☐ Keisersnitt

Frisk i første leveuke?:
☐ Ja
☐ Nei

Hvis nei:
☐ Frisk nå
☐ Syk nå
☐ Død

3.barn:

Fødselsår: ☐☐☐☐ Svangerskapsuke for fødsel: ☐☐ Fødselsvekt i gram: ☐☐☐☐ Kjønn: ☐ Gutt ☐ Jente

Fødested:
☐ Norge
☐ Eget fødeland
☐ Annet

Hvis flerlingefødsel:
☐ Tvillinger
☐ Trillinger

Forløsningsmetode:
☐ Vanlig vaginal
☐ Tang
☐ Vakuum
☐ Keisersnitt

Frisk i første leveuke?:
☐ Ja
☐ Nei

Hvis nei:
☐ Frisk nå
☐ Syk nå
☐ Død

4.barn:

Fødselsår: ☐☐☐☐ Svangerskapsuke for fødsel: ☐☐ Fødselsvekt i gram: ☐☐☐☐ Kjønn: ☐ Gutt ☐ Jente

Fødested:
☐ Norge
☐ Eget fødeland
☐ Annet

Hvis flerlingefødsel:
☐ Tvillinger
☐ Trillinger

Forløsningsmetode:
☐ Vanlig vaginal
☐ Tang
☐ Vakuum
☐ Keisersnitt

Frisk i første leveuke?:
☐ Ja
☐ Nei

Hvis nei:
☐ Frisk nå
☐ Syk nå
☐ Død

44546

Unikt pas. løpenummer: ☐☐☐☐

5.barn:

Fødselsår: ☐☐☐☐

Svangerskapsuke for fødsel: ☐☐

Fødselsvekt i gram: ☐☐☐☐

Kjønn: ☐ Gutt ☐ Jente

Fødested:
- ☐ Norge
- ☐ Eget fødeland
- ☐ Annet

Hvis flerlingefødsel:
- ☐ Tvillinger
- ☐ Trillinger

Forløsningsmetode:
- ☐ Vanlig vaginal
- ☐ Tang
- ☐ Vakuum
- ☐ Keisersnitt

Frisk i første leveuke?:
- ☐ Ja
- ☐ Nei

Hvis nei:
- ☐ Frisk nå
- ☐ Syk nå
- ☐ Død

Hvis mer enn 5 barn - legg til ekstraark og stift dette sammen med resten.

14. Har du, eller har du hatt noen av følgende sykdommer? Hvis ja, angi årstall når diagnosen ble stilt.
*Sett inn årstall i boksene til høyre: *Bruk evt. kommentarfelt siste side. Se evt prosedyrebok 2.4.2*

Diabetes type 1	☐ Ja	☐ Nei	☐☐☐☐
Diabetes type 2	☐ Ja	☐ Nei	☐☐☐☐
Stoffskiftesykdom *	☐ Ja	☐ Nei	☐☐☐☐
Astma	☐ Ja	☐ Nei	☐☐☐☐
Allergi	☐ Ja	☐ Nei	☐☐☐☐
Gjentatte urinveisinfeksjoner	☐ Ja	☐ Nei	☐☐☐☐
Kronisk nyresykdom	☐ Ja	☐ Nei	☐☐☐☐
Vedvarende høyt blodtrykk	☐ Ja	☐ Nei	☐☐☐☐
Leddgikt/Bechterew	☐ Ja	☐ Nei	☐☐☐☐
Hjertesykdom *	☐ Ja	☐ Nei	☐☐☐☐
Epilepsi	☐ Ja	☐ Nei	☐☐☐☐
Underlivs-sykdom/operasjon *	☐ Ja	☐ Nei	☐☐☐☐
Ufrivillig barnløshet > 1 år	☐ Ja	☐ Nei	☐☐☐☐
Sykdom i mage/tarm	☐ Ja	☐ Nei	☐☐☐☐
Psykisk sykdom *	☐ Ja	☐ Nei	☐☐☐☐
Annet	☐ Ja	☐ Nei	☐☐☐☐

15. Hvor gammel var du da du fikk din første menstruasjon?

Angi alder i år: ☐☐

16. Har du hatt svangerskapsdiabetes i tidligere svangerskap?

Hvis ja - i hvilke(t) svangerskap? I hvilken svangerskapsuke fikk du stilt diagnosen? Brukte du insulin?

	Svangerskapsuke	Insulin
1.svangerskap	☐☐	☐ Ja ☐ Nei
2.svangerskap	☐☐	☐ Ja ☐ Nei
3.svangerskap	☐☐	☐ Ja ☐ Nei
4.svangerskap	☐☐	☐ Ja ☐ Nei
5.svangerskap	☐☐	☐ Ja ☐ Nei
6.svangerskap	☐☐	☐ Ja ☐ Nei
7.svangerskap	☐☐	☐ Ja ☐ Nei
8.svangerskap	☐☐	☐ Ja ☐ Nei

17. Er det arvelige sykdommer i familien?

☐ Ingen kjente ☐ Ja

Hvis ja, angi:

☐ Hjerte-kar sykdom ☐ Psykisk sykdom

☐ Diabetes ☐ Leddsykdom

☐ Kreftsykdom ☐ Muskelsykdom

☐ Nevrologisk sykdom ☐ Annet

Hvis annet, angi: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Hvis diabetes eller hjertesykdom, henvis til CRF 1.3 for mer detaljer

18. Er du og barnets far i slekt?

☐ Ja ☐ Nei

Hvis ja, er barnefaren din:

☐ Fetter ☐ 3-menning ☐ 4-menning ☐ Onkel ☐ Nevø ☐ Annet

19. Har du noen gang røykt/brukt snus?

Røyk:

☐ Aldri ☐ Av og til ☐ Ja, daglig

Snus:

☐ Aldri ☐ Av og til ☐ Ja, daglig

Hvis aldri på begge, gå til spørsmål 23.

20. Røykte du/brukte du snus de siste 3 månedene før du ble gravid denne gangen?

Røyk: ☐ Aldri

☐ Ja, av og til

☐ Ja, daglig

Antall sigaretter/dg ☐☐

☐☐

Snus: ☐ Aldri

☐ Ja, av og til

☐ Ja, daglig

44546

Unikt pas. løpenummer: ☐☐☐☐

21. Røyker du/snuser du nå?

Røyk: ☐ Aldri — Antall sigaretter/dg ☐☐

☐ Ja, av og til

☐ Ja, daglig ☐☐

Snus: ☐ Aldri

☐ Ja, av og til

☐ Ja, daglig

22. Hvor gammel var du da du begynte å røyke? *Angi alder:* ☐☐

Hvis du har røykt tidligere, men ikke røyker nå, hvor gammel var du da du sluttet? *Angi alder:* ☐☐

23. Ditt alkoholforbruk:

Siste 3 mnd før svangerskap:

☐ Aldri ☐ Av og til ☐ Ja, daglig — Antall alkoholenheter vanligvis: ☐☐

Nå:

☐ Aldri ☐ Av og til ☐ Ja, daglig — Antall alkoholenheter vanligvis: ☐☐

Antall alkoholenheter - 1 enhet er: 1 glass vin, 0,33l øl, 1 likørglass

AKTUELT SVANGERSKAP

24. Siste menstruasjons 1.blødningsdag:

Dato: ☐☐.☐☐.☐☐☐☐

25. Termin før ultralyd:

Dato: ☐☐.☐☐.☐☐☐☐ ☐ Sikker ☐ Usikker

26. Anslå din vekt i kg:

Rett før du ble gravid: ☐☐☐ 25 år gammel: ☐☐☐ 18 år gammel: ☐☐☐

27. Anslå din høyeste og laveste vekt (i kg) utenom graviditet etter at du var 18 år.

Høyeste: ☐☐☐ Laveste: ☐☐☐

Kommentar hvis forskjell >20kg ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

EVENTUELLE VIKTIGE SUPPLERENDE KOMMENTARER TIL SVAR PÅ SPØRSMÅL:

Spørsmålsnummer: ☐☐ Kommentar ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Spørsmålsnummer: ☐☐ Kommentar ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Spørsmålsnummer: ☐☐ Kommentar ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Spørsmålsnummer: ☐☐ Kommentar ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Du kan også gi ytterligere utfyllende kommentarer her:

TAKK FOR AT DU HAR TATT DEG TID TIL Å SVARE PÅ SPØRSMÅLENE!

Appendix 3 b
Appendix 3 b [engelsk]

FORM 1.1 (CRF 1.1)

(For information: If: The interviewer must fill in the right category/code)*

1. What is your current marital status?

☐ Married ☐ Partnership ☐ Cohabitant ☐ Single ☐ Divorced/separated ☐ Widow ☐ Other

2. What is your level of education?

	Completed	Attending now	No. of years
Less than 7 years' schooling	☐	☐	☐☐
Primary school (7-9 years' schooling)	☐	☐	☐☐
1-2 years' upper sec./vocational school (10-11 yrs)	☐	☐	☐☐
3-year upper sec./vocational school (12 years)	☐	☐	☐☐
District college, university, up to 4 years (Nurse, teacher, Bachelor's degree)	☐	☐	☐☐
University college, university, more than 4 years (Master's, PhD)	☐	☐	☐☐

3. What was your work situation when you became pregnant?

☐ Attending educational institution

☐ Housewife

☐ Job-seeker/laid off

☐ Rehabilitation/disabled

☐ Employed in the public sector

☐ Employed in the private sector

☐ Other If other, what?:……

4. What is your occupation? State occupation/job title* …….
(Answer even if you are temporarily not working due to illness/leave)

5. Which religious community/religion do you belong to?* …….....

6. Which country were you born in? Indicate which country*…….....
If Norway:

☐ Born in Norway of two Norwegian parents

☐ Born in Norway of two foreign-national parents

☐ Born in Norway of one Norwegian + one foreign-national parent

7. Citizenship in which country? Indicate which country*……..

8. *(If the country of birth and ethnic group do not appear to agree (e.g. "Indian" but born in Kenya, Uganda, South-Africa)* **Which ethnic group (common language, culture, history) do you feel you belong to?: ……..**

9. What is your native language? State language* ……

10. How do you rate your Norwegian language skills?
☐ Very good ☐ Good ☐ Fair ☐ Not very good ☐ Poor

11. Do you normally use an interpreter for doctor's appointments?
☐ Yes, professional ☐ Yes, family/friend ☐ No

12. Have you been pregnant before? (Also consider pregnancies that ended in miscarriage/ abortion or with a stillbirth)
☐ No ☐ Yes If yes:
Number born alive: ☐☐ Number stillborn: ☐☐ Number of spontaneous miscarriages: ☐☐
Number of induced abortions: ☐☐ Number of ectopic pregnancies (outside the uterus): ☐☐

13. I am now going to ask you about earlier pregnancies that have lasted more than 22 weeks.
(If more than 1 child per pregnancy, count twin 1, twin 2.)

(For each child)
Year of birth: ☐☐☐☐ Pregnancy week for birth ☐☐ Baby's weight in grams ☐☐☐☐
Gender: Boy ☐ Girl ☐ Place of birth: ☐ Norway ☐ Own native country ☐ Other
Method of delivery: ☐ Normal vaginal ☐ Forceps ☐ Vacuum ☐ Caesarean section
If multiple birth: ☐ Twins ☐ Triplets
Healthy the first week?: ☐ Yes ☐ No If no: ☐ Healthy now ☐ Ill now ☐ Dead

14. Do you have/have you had any of the following illnesses?
(Some diagnoses will mean that the woman cannot take part in the study)
(If yes, state the year the diagnosis was made).

		Year
Diabetes type 1	☐ Yes ☐ No	☐☐☐☐
Diabetes type 2	☐ Yes ☐ No	☐☐☐☐
Asthma	☐ Yes ☐ No	☐☐☐☐
Allergy	☐ Yes ☐ No	☐☐☐☐
Repeated urinary tract infections	☐ Yes ☐ No	☐☐☐☐
Chronic liver disease	☐ Yes ☐ No	☐☐☐☐
Prolonged high blood pressure	☐ Yes ☐ No	☐☐☐☐

Heart disease	☐ Yes ☐ No	☐☐☐☐
Arthritis/Bechterew's disease	☐ Yes ☐ No	☐☐☐☐
Epilepsy	☐ Yes ☐ No	☐☐☐☐
Disease of the uterus/operation	☐ Yes ☐ No	☐☐☐☐
Involuntary infertility more than 1 year	☐ Yes ☐ No	☐☐☐☐
Mental illness	☐ Yes ☐ No	☐☐☐☐
Abdominal/intestinal disorder	☐ Yes ☐ No	☐☐☐☐
Metabolism disorder	☐ Yes ☐ No	☐☐☐☐
Other: ……	☐ Yes ☐ No	☐☐☐☐

15. How old were you when you menstruated for the first time? State age in years: ☐☐

16. Have you had pregnancy diabetes during a previous pregnancy?
If yes - which pregnancy? In which pregnancy week were you diagnosed? Did you use insulin?

	Pregnancy week	Insulin
1st pregnancy	☐☐	☐ Yes ☐ No
2nd pregnancy	☐☐	☐ Yes ☐ No
3rd pregnancy	☐☐	☐ Yes ☐ No
4th pregnancy	☐☐	☐ Yes ☐ No
5th pregnancy	☐☐	☐ Yes ☐ No
6th pregnancy	☐☐	☐ Yes ☐ No
7th pregnancy	☐☐	☐ Yes ☐ No
8th pregnancy	☐☐	☐ Yes ☐ No

17. Are there any inheritable diseases in the family?
☐ None I know of ☐ Yes If yes, tick the appropriate box/boxes:

☐ Cardio-vascular disease ☐ Diabetes
☐ Cancer ☐ Neurological disease
☐ Mental illness ☐ Arthritis
☐ Muscular disorder ☐ Other If other, state:……..

18. Are you and the father of the child related?
☐ Yes ☐ No

If yes, is the father of the child your:

☐ Cousin ☐ 3rd cousin ☐ 4th cousin ☐ Uncle ☐ Nephew ☐ Other

19. Have you ever smoked/used snus?

Smoked: ☐ Never ☐ Sometimes ☐ Yes, daily

Snus: ☐ Never ☐ Sometimes ☐ Yes, daily

If the answer is never to both, go to question 23.

20. Did you smoke/use snus during the last 3 months before this pregnancy?

Smoking:		Snus:
☐ Never	Number of cigarettes/daily	☐ Never
☐ Yes, sometimes	☐☐	☐ Yes, sometimes
☐ Yes, daily	☐☐	☐ Yes, daily

21. Do you smoke/use snus now?

Smoking:		Snus:
☐ Never	Number of cigarettes/daily	☐ Never
☐ Yes, sometimes	☐☐	☐ Yes, sometimes
☐ Yes, daily	☐☐	☐ Yes, daily

22. How old were you when you started to smoke? State age: ☐☐

If you have smoked previously, but do not smoke now, how old were you when you quit?

State age: ☐☐

23. Your alcohol consumption:

Last 3 months before pregnancy:

☐ Never ☐ Sometimes ☐ Yes, daily Amount of alcohol units, normally: ☐☐

Now: ☐ Never ☐ Sometimes ☐ Yes, daily Amount of alcohol units, normally ☐☐

(Number of alcohol units – 1 unit is: 1 glass of wine, 0.33 litres of beer, 1 glass of liquor)

24. Last menstruation's 1st day of bleeding:

Date:….. ….

25. Term before ultrasound:

Date:……. ☐ Certain ☐ Uncertain

26. Estimate your weight in kilos:

Right before you became pregnant: ☐☐☐ 25 years old: ☐☐☐ 18 years old: ☐☐☐

27. Estimate your highest and lowest weight (in kilos), not including pregnancies, after you turned 18 years of age.

Highest: □□□ Lowest: □□□

Comment if the difference as greater than 20 kilos ……

THANKS FOR TAKING THE TIME TO ANSWER THESE QUESTIONS!

Appendix 4

42746

Unikt pas. løpenummer: ☐☐☐☐

STORK Groruddalen

CRF 3 - 3 MÅNEDER ETTER FØDSEL

Kode intervjuer ☐☐

Intervjuers initialer ☐☐☐

Undersøkelsesdato ☐☐.☐☐.☐☐

Antall uker etter fødsel ☐☐

Kvinnens fødselsdato ☐☐.☐☐.☐☐

Bosteds-postnummer ☐☐☐☐

Undersøkelsesbydel ☐☐

Forklaring til utfyllingen:
Bruk blå eller svart kulepenn. De fleste steder settes kryss eller tall. Bruk ellers store bokstaver og en bokstav per rute. Sett kryss mest mulig midt i avkrysningsboksen. Dersom feil i utfyllingen, marker dette ved å sette tre streker over boksen og kryss av på vanlig måte i den riktige boksen. Dersom behov for å notere ned ytterligere informasjon ut over hva det er avsatt plass til på skjemaet, kan du notere dette i margen. Bare sørg for at du ikke skriver i avkrysningsboksene eller notatfelter.
Eksempel på utfylling:

☒ ja ☐ nei 2256 gram

Tekst i kursiv under spørsmålet, før svarkategoriene, er informasjon til intervjueren og skal ikke leses opp for kvinnen.

1. Hvilken sivilstand har du nå?

☐ Gift ☐ Partnerskap ☐ Samboer ☐ Enslig ☐ Skilt/separert ☐ Enke ☐ Annet

2. Hvordan var din opplevelse av svangerskapet i det store og det hele?

Veldig god 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ Veldig dårlig

Hvordan følte du deg ivaretatt under svangerskapet?

Av dine nærmeste	☐ Svært godt	☐ Godt	☐ Dårlig	☐ Svært dårlig
Av fastlegen	☐ Svært godt	☐ Godt	☐ Dårlig	☐ Svært dårlig
Av jordmor på helsestasjonen	☐ Svært godt	☐ Godt	☐ Dårlig	☐ Svært dårlig
Av jordmor på sykehuset*	☐ Svært godt	☐ Godt	☐ Dårlig	☐ Svært dårlig
Av lege på sykehuset*	☐ Svært godt	☐ Godt	☐ Dårlig	☐ Svært dårlig

* Hvis aktuelt

3. Hvordan var din opplevelse av fødselen i det store og det hele?

Veldig god 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ Veldig dårlig

4. Hvor redd var du under fødselen?

Overhodet ikke redd 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10 ☐ Svært redd

5. Følte du at dine nærmeste ga hjelp og viste omsorg i dagene rundt fødsel?

☐ Ja, i stor grad ☐ Ja, i noen grad ☐ I liten grad

42746

Unikt pas. løpenummer: | | | | |

Hvor ivaretatt følte du deg under fødselen?

På fødeavdelingen ☐ Svært godt ☐ Godt ☐ Dårlig ☐ Svært dårlig

På barselavdelingen ☐ Svært godt ☐ Godt ☐ Dårlig ☐ Svært dårlig

---

6. Hvordan er helsen din nå?

☐ Dårlig ☐ Ikke helt god ☐ God ☐ Svært god

7.Har du den siste måneden hatt smerter i noen av de følgende kroppsdeler?
Intervjuer ber kvinnen peke på aktuelt sted på egen kropp. Sett kryss for aktuell lokalisasjon.
Du kan sette flere kryss. se evt. prosedyrebok 2.4.2

I korsryggen uten utstråling til bein(a)	☐ Nei	☐ En del plaget	☐ Sterkt plaget
I korsryggen med utstråling til bein(a)	☐ Nei	☐ En del plaget	☐ Sterkt plaget
Foran i bekkenet, over kjønnsbeinet(symfysen)	☐ Nei	☐ En del plaget	☐ Sterkt plaget
Bak, over det ene bekkenleddet	☐ Nei	☐ En del plaget	☐ Sterkt plaget
Bak, over begge bekkenleddene	☐ Nei	☐ En del plaget	☐ Sterkt plaget
Foran og bak på ene siden av bekkenet	☐ Nei	☐ En del plaget	☐ Sterkt plaget
Foran og bak på begge sider av bekkenet	☐ Nei	☐ En del plaget	☐ Sterkt plaget

---

8. Har du fått noen av disse sykdommene de siste 6 månedene? *Bruk evt. kommentarfelt siste side. Se evt prosedyrebok 2.4.2

Diabetes type 1	☐ Ja	☐ Nei	Kronisk nyresykdom	☐ Ja	☐ Nei
Diabetes type 2	☐ Ja	☐ Nei	Vedvarende høyt blodtrykk	☐ Ja	☐ Nei
Stoffskiftesykdom *	☐ Ja	☐ Nei	Leddgikt/Bechterew	☐ Ja	☐ Nei
Astma	☐ Ja	☐ Nei	Hjertesykdom *	☐ Ja	☐ Nei
Allergi	☐ Ja	☐ Nei	Epilepsi	☐ Ja	☐ Nei
Gjentatte urinveisinfeksjoner	☐ Ja	☐ Nei	Sykdom i mage/tarm	☐ Ja	☐ Nei

---

Har det noen gang i livet ditt vært sammenhengende perioder på to uker eller mer, da du:

Følte deg deprimert, trist eller nedfor	☐ Ja	☐ Nei
Hadde problemer med matlysten eller spiste for mye	☐ Ja	☐ Nei
Var plaget av kraftløshet eller mangel på overskudd	☐ Ja	☐ Nei
Virkelig bebreidet deg selv og følte deg verdiløs	☐ Ja	☐ Nei
Hadde problemer med å konsentrere deg eller vanskelig for å ta beslutninger	☐ Ja	☐ Nei
Hadde minst tre av de problemene som er nevnt over samtidig	☐ Ja	☐ Nei

---

9. Hvordan var barnets helse straks etter fødselen? (sett ett eller flere kryss)

☐ Barnet var friskt

☐ Barnet ble innlagt på barneavd,men var ikke alvorlig syk

☐ Barnet ble innlagt på barneavd. og var alvorlig syk

Årsak til innleggelse:

42746

Unikt pas. løpenummer: ☐☐☐☐

Hvordan er barnets helse nå? (sett ett eller flere kryss)

☐ Barnet er friskt

☐ Barnet er sykt

☐ Barnet døde

Type sykdom/problem:

10.1. Får barnet morsmelk nå, evt. noe i tillegg til morsmelk?
Tenk på de siste 14 dager. Med fast føde menes alle andre matvarer enn juice, saft eller andre sukkerholdige drikker, vann og kosttilskudd. Sett ett kryss.

- Ja, bare morsmelk (og evt. tran eller annet kosttilskudd) (gå til spm. 10.6) ☐
- Ja, morsmelk og juice, saft eller andre sukkerholdige drikker ☐
- Ja, morsmelk og fast føde og evt. juice, saft eller andre sukkerholdige drikker ☐
- Ja, morsmelk og morsmelkerstatning/annen melk ☐
- Ja, morsmelk og morsmelkerstatning/annen melk og juice, saft eller andre sukkerholdige drikker ☐
- Ja, morsmelk og morsmelkerstatning/annen melk og fast føde og evt. juice, saft eller andre sukkerholdige drikker ☐
- Nei, men barnet har fått morsmelk tidligere ☐
- Nei, barnet har aldri fått morsmelk ☐

Hvis barnet har fått morsmelk tidligere, men ikke får morsmelk nå:
10.2. Hvor gammelt var barnet da det sluttet å få morsmelk? Sett ett kryss

Uker							Måneder				
1	2	3	4	5	6	7	2	2,5	3	3,5	4
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Hvis barnet har fått morsmelkerstatning (evt. i tillegg til morsmelk):
10.3. Hvor gammelt var barnet da det begynte med morsmelkerstatning/annen melk i tillegg til eller i steden for morsmelk? Her regnes både det som drikkes og det som du selv tilsetter i grøt eller annen mat. Sett ett kryss

Uker							Måneder				
1	2	3	4	5	6	7	2	2,5	3	3,5	4
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10.4. Dersom barnet får juice, saft eller andre sukkerholdige drikker nå, hvor gammelt var barnet da det begynte å få dette? Sett ett kryss

Uker							Måneder				
1	2	3	4	5	6	7	2	2,5	3	3,5	4
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10.5. Dersom barnet får fast føde nå, hvor gammelt var barnet da det begynte å få dette? Sett ett kryss

Uker							Måneder				
1	2	3	4	5	6	7	2	2,5	3	3,5	4
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10.6. Målinger av barnet ved ca 3 måneders alder: Kjønn: ☐ Jente ☐ Gutt

Alder (hele uker): ☐☐ Vekt i gram: ☐☐☐☐ Lengde(cm): ☐☐,☐ HO(cm): ☐☐,☐

Tvilling 2:

Alder (hele uker): ☐☐ Vekt i gram: ☐☐☐☐ Lengde(cm): ☐☐,☐ HO(cm): ☐☐,☐

Kjønn: ☐ Jente ☐ Gutt

42746

Spiseproblemer

Unikt pas. løpenummer: ☐☐☐☐

11. Hvilken av følgende påstander passer best på deg?

- ☐ Vekt eller kroppsform påvirker ikke i det hele tatt hva jeg synes om meg selv
- ☐ Vekt eller kroppsform betyr noe for hva jeg synes om meg selv
- ☐ Vekt eller kroppsform betyr en del for hva jeg synes om meg selv
- ☐ Vekt eller kroppsform betyr mye for hva jeg synes om meg selv
- ☐ Vekt eller kroppsform betyr alt for hva jeg synes om meg selv

13. I dag, bruker du noen av følgende metoder for å kontrollere vekten?

Fremkalle brekninger for å kaste opp	☐ Aldri	☐ En eller to ganger	☐ Ukentlig	☐ Daglig
Ta avføringsmidler	☐ Aldri	☐ En eller to ganger	☐ Ukentlig	☐ Daglig
Trene mer enn to timer per dag	☐ Aldri	☐ En eller to ganger	☐ Ukentlig	☐ Daglig
Faste eller ikke spise i 24 timer eller mer	☐ Aldri	☐ En eller to ganger	☐ Ukentlig	☐ Daglig

20. I dag, hender det du har perioder med overspising, dvs anfall der du har spist store mengder mat i løpet av kort tid? Hvis nei - gå til sp.25 ☐ Ja ☐ Nei

21. Hvis ja, føler du da at du ikke kan kontrollere spisingen?

☐ Ikke i det hele tatt ☐ Litt ☐ Noe ☐ Mye ☐ Veldig mye

22. Hvor mange ganger per måned skjer dette? ☐☐☐

23. Hvor lenge har perioden med overspising vart?

☐ Mindre enn en måned ☐ 1-2 mnd ☐ 3-5 mnd ☐ 6-12 mnd ☐ Lengre enn et år

24. Fører episodene med overspising til at du blir opprørt eller ulykkelig?

☐ Ikke i det hele tatt ☐ Litt ☐ Noe ☐ Mye ☐ Veldig mye

25. Spiser du mer når du er engstelig, stresset eller opprørt?

☐ Alltid ☐ Ofte ☐ Noen ganger ☐ Nei, jeg spiser heller mindre

Svangerskapsdepresjon

26. Har du siste 7 dager kunnet le og se det komiske i en situasjon?

- ☐ Like mye som vanlig
- ☐ Ikke riktig så mye som jeg pleier
- ☐ Klart mindre enn jeg pleier
- ☐ Ikke i det hele tatt

27. Har du siste 7 dager gledet deg til ting som skulle skje?

- ☐ Like mye som vanlig
- ☐ Ikke riktig så mye som jeg pleier
- ☐ Klart mindre enn jeg pleier
- ☐ Ikke i det hele tatt

28. Har du siste 7 dager bebreidet deg selv uten grunn når noe gikk galt?

- ☐ Ja, nesten hele tiden
- ☐ Ja, av og til
- ☐ Ikke særlig ofte
- ☐ Nei, aldri

29. Har du siste 7 dager vært nervøs eller bekymret uten grunn?

- ☐ Nei, slett ikke
- ☐ Nesten aldri
- ☐ Ja, iblant
- ☐ Ja, veldig ofte

42746

Unikt pas. løpenummer: ☐☐☐☐

30.Har du siste 7 dager vært redd eller fått panikk uten grunn?

- ☐ Ja, svært ofte
- ☐ Ja, noen ganger
- ☐ Sjelden
- ☐ Nei, aldri

31.Har du siste 7 dager følt at det har blitt for mye for deg?

- ☐ Ja, jeg har stort sett ikke fungert i det hele tatt
- ☐ Ja, iblant har jeg ikke klart å fungere som jeg pleier
- ☐ Nei, for det meste har jeg klart meg bra
- ☐ Nei, jeg har klart meg like bra som vanlig

32.Har du siste 7 dager vært så ulykkelig at du har hatt vanskeligheter med å sove?

- ☐ Nei, ikke i det hele tatt
- ☐ Ikke særlig ofte
- ☐ Ja, iblant
- ☐ Ja, for det meste

33.Har du siste 7 dager følt deg nedfor eller ulykkelig?

- ☐ Ja, det meste av tiden
- ☐ Ja, ganske ofte
- ☐ Ikke særlig ofte
- ☐ Nei, ikke i det hele tatt

34.Har du siste 7 dager vært så ulykkelig at du har grått?

- ☐ Ja, nesten hele tiden
- ☐ Ja, veldig ofte
- ☐ Ja, det har skjedd iblant
- ☐ Nei, aldri

35.Har tanken på å skade deg selv streifet deg, de siste 7 dagene?

- ☐ Ja, nokså ofte
- ☐ Ja, av og til
- ☐ Ja, såvidt
- ☐ Aldri

Urinlekkasje

36.Hvor ofte lekker du urin? Kryss av i kun en boks

- ☐ Aldri
- ☐ Omtrent en gang i uken eller sjeldnere
- ☐ 2-3 ganger i uken
- ☐ Ca. en gang per dag
- ☐ Flere ganger per dag
- ☐ Hele tiden

37.Vi vil gjerne vite hvor mye urin du lekker. Hvor mye urin lekker du vanligvis (enten du bruker beskyttelse eller ikke)? Kryss av i kun en boks

- ☐ Ikke noe
- ☐ En liten mengde
- ☐ En moderat mengde
- ☐ En stor mengde

38.Hvor mye påvirker urinlekkasje ditt hverdagsliv? Her bruker vi en skala fra 0-10.

Ikke i det hele tatt — Svært mye

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

39.Når lekker du urin? Kryss evt. av i flere bokser

- ☐ Aldri, jeg lekker ikke urin
- ☐ Lekker før jeg når toalettet
- ☐ Lekker når jeg hoster eller nyser
- ☐ Lekker når jeg sover
- ☐ Lekker når jeg er fysisk aktiv/trimmer
- ☐ Lekker når jeg er ferdig med å late vannet og har tatt på meg klærne
- ☐ Lekker uten noen opplagt grunn
- ☐ Lekker hele tiden

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Unikt pas. løpenummer: ☐☐☐☐

40. Røyker du/snuser du nå?

Røyk: ☐ Aldri — Antall sigaretter/dg ☐☐

☐ Ja, av og til

☐ Ja, daglig ☐☐

Snus: ☐ Aldri

☐ Ja, av og til

☐ Ja, daglig

41. Ditt alkoholforbruk nå:

☐ Aldri ☐ Av og til ☐ Ja, daglig — Antall alkoholenheter vanligvis: ☐☐

Antall alkoholenheter - 1 enhet er: 1 glass vin, 0,33 liter øl, 1 likørglass

42. Har du opplevd noen av de følgende livshendelser eller problemer de siste 6 måneder?

Du har selv vært utsatt for alvorlig sykdom, skade eller overfall	☐ Ja	☐ Nei
En i din nærmeste familie (mor eller far, ektefelle/samboer, barn eller søsken) har vært alvorlig syk, utsatt for skade eller overfall	☐ Ja	☐ Nei
En i din nærmeste familie (mor eller far, ektefelle/samboer, barn eller søsken) er avgått ved døden	☐ Ja	☐ Nei
Du er separert/skilt, eller har brutt et langvarig forhold	☐ Ja	☐ Nei
Du har hatt problemer/store bekymringer med barna dine (oppdragelse, skole, disiplin)	☐ Ja	☐ Nei
Du har blitt arbeidsledig, eller søkt forgjeves etter jobb i mer enn 1 måned	☐ Ja	☐ Nei
Du har opplevd andre belastende forhold, som et alvorlig problem med en nær venn, nabo, slektning eller partner, alvorlige økonomiske bekymringer, noe du satte stor pris på ble mistet eller stjålet, dødsfall hos annen nærstående, eller opplever store problemer på jobb	☐ Ja	☐ Nei

43. Tenk tilbake på de siste 14 dager. Har du tatt/brukt tran/trankapsler og/eller andre kosttilskudd i løpet av disse dagene? Hvis ja, angi antall kapsler/tabletter/skjeer per dag på rett frekvens

	Aldri	<1g/uke	1-2g/uke	3-4g/uke	5-6x/uke	Daglig
Tran/Trankapsler	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Fiskeoljekapsler	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Seloljekapsler	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Folat	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Jerntilskudd	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Multivitaminer uten mineraler (som Sanasol,BioVit,Vitaplex oa)	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Multivitaminer m/mineraler (som Vitamineral,Kostpluss oa)	☐	☐☐	☐☐	☐☐	☐☐	☐☐
Andre kosttilskudd	☐	☐☐	☐☐	☐☐	☐☐	☐☐

Angi navn på kosttilskudd 1:

Angi navn på kosttilskudd 2:

Angi navn på kosttilskudd 3:

Angi navn på kosttilskudd 4:

Angi navn på jerntilskudd:

44. Har du brukt faste medisiner de siste 3 måneder? Angi legemiddel navn - og evt. sykdom/plage

Angi legemiddelnavn	Evt sykdom/plage
Angi legemiddelnavn	Evt sykdom/ plage
Angi legemiddelnavn	Evt sykdom/ plage
Angi legemiddelnavn	Evt sykdom/ plage
Angi legemiddelnavn	Evt sykdom/ plage

☐ P-piller ☐ Minipiller ☐ Spiral

Merke

Øvrige kommentarer, relater til spørsmålsnummer:

TAKK FOR AT DU HAR TATT DEG TID TIL Å SVARE PÅ SPØRSMÅLENE!