#### ORIGINAL ARTICLE

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## Prevalence and perinatal risk factors of parent-reported colic, abdominal pain and other pain or discomforts in infants until 3 months of age - A prospective cohort study in PreventADALL

Åshild Wik Despriee RN, PHN, MSc, Assistant professor<sup>1,2</sup> [Caroline-Aleksi Olsson Mägi RN, MSc, PhD-student<sup>3,4</sup> | Milada Cvancarova Småstuen PhD, Professor<sup>2,5</sup> | Kari Glavin RN, PHN, PhD, Professor<sup>2</sup> | Live Nordhagen RN, PHN, MSc, Assistant professor<sup>1,2</sup> | Christine M. Jonassen PhD, Professor<sup>6,7</sup> | Eva Maria Rehbinder MD, PhD, Dermatology Resident<sup>1,8</sup> | Björn Nordlund RN, PhD, Associate professor<sup>3,4</sup> | Cilla Söderhäll PhD, Associent professor<sup>3,4</sup> | Karin Lødrup Carlsen MD, PhD, Professor<sup>1,9</sup> | Håvard Ove Skjerven MD, PhD, Pediatric Consultant<sup>1,9</sup>

<sup>1</sup>Faculty of Medicine, Institute of Clinical Medicine, University of Oslo, Oslo, Norway

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<sup>2</sup>VID Specialized University Oslo, Oslo, Norway

<sup>3</sup>Department of Women's and Children's Health, Karolinska Institutet, Stockholm, Sweden

<sup>4</sup>Astrid Lindgren Children's Hospital, Karolinska University Hospital, Stockholm, Sweden

<sup>5</sup>OsloMET University Oslo, Oslo, Norway

<sup>6</sup>Department of Chemistry, Biotechnology and Food Science, Norwegian University of Life Sciences, Ås, Norway

<sup>7</sup>Center for Laboratory Medicine, Østfold Hospital Trust, Kalnes, Norway

<sup>8</sup>Department of Dermatology, Oslo University Hospital, Oslo, Norway

<sup>9</sup>Division of Paediatric and Adolescent Medicine, Oslo University Hospital, Oslo, Norway

#### Correspondence

Åshild Wik Despriee, Diakonveien 14, 0170 Oslo, Norway. Email: Ashild.Wik.Despriee@vid.no

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#### Abstract

**Aims and objectives:** To estimate the prevalence and perinatal risk factors associated with parent reported colic, abdominal pain and pain or other discomforts in infants until 3 months of age.

**Background:** Infant colic is a common concern for parents and clinicians. The prevalence varies in different studies and its symptoms overlap with other conditions like abdominal pain and discomfort. Diagnosis criteria are challenging, pathogenesis unclear and risk factors are conflicting.

Design: This was a prospective cohort study.

**Methods:** The 1852 mother-child pairs from the PreventADALL prospective birthcohort answering the 3 months questionnaire were included. Information on perinatal risk factors was collected from the inclusion visit and questionnaires during pregnancy at 18 and 34 weeks, as well as birth charts. STROBE checklist was followed. **Results:** The reported prevalence of colic was 3% (59/1852), abdominal pain 22%

(415/1852) and pain or other discomfort 6% (119/1852), with a total of 26% (478/1852)

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infants. Mothers on sick leave in pregnancy and reporting any allergic diseases had a significantly higher odds of reporting infant colic, abdominal pain and pain or other discomforts. Mothers with higher perceived stress in pregnancy exhibited a trend towards higher odds for reporting infant pain. Mothers coming from Sweden were less likely to report infant abdominal pain compared to mothers from Norway.

**Conclusions:** The prevalence of abdominal pain and pain or other discomforts was higher than the prevalence of colic. Perinatal risk factors connected to maternal health were associated with all three symptoms.

**Relevance to clinical practice:** Colic and abdominal pain are stressful, symptoms overlap and risk factors for both can be identified in pregnancy. Our study suggests that it is difficult for parents to distinguish among infant colic, abdominal pain and other pain or discomfort and some report two or all three symptoms. Identifying the perinatal risk factors associated with infant pain may help target and support parents.

KEYWORDS

abdominal pain, colic, pain, prevalence, risk factors

#### 1 | INTRODUCTION

Infant colic is a common term used for excessive crying, abdominal pain and discomfort in the first months of life and can cause stress and concern for parents and clinicians (Keefe et al., 2006). Between crying episodes the infant with colic usually appears healthy, but the data on sequelae of colic are conflicting (Turner et al., 2018). There is little agreement on the definition, pathogenesis and the optimal management of colic, and at least twenty different definitions have been suggested (Turner et al., 2018; Zeevenhooven et al., 2018). Obstipation and infections seems most common diagnosis for abdominal pain (Neuman et al., 2021). Infant colic is influenced by both caregiver's experience and child's temperament. Mothers of infants with colic more commonly describe the infant behaviour as difficult and it has been suggested that this could affect the child care given in a negative way (Helseth & Begnum, 2002), also long term. Healthy parent-infant interaction is important for mental and physical development of the child and the relationship between child and parents (Zeifman & St James-Roberts, 2017). The challenges of colic may be similar to abdominal pain (Barr, 1993). Reust & Williams reported that 9% of all health care visits for infants, toddlers and children were acute abdominal pain (Reust & Williams, 2016). These conditions with reported abdominal pain are usually benign without evidence of underlying disease (Hijaz & Friesen, 2017).

In research, Wessels rule of three has often been used to define colic as fussing, irritability or crying that starts and stops without obvious reasons, appearing at least 3 h a day on at least 3 days per week at least 3 weeks in any baby aged 2 weeks to 4 months (Zeevenhooven et al., 2017). This rule has been excluded in ROME IV criteria of colic, because the duration of crying criteria was too strict, and an exact time limit for defining the problem has not been demonstrated clearly (Zeevenhooven et al., 2017). It has been challenging for parents to report duration of crying over time. An infant crying a few minutes or

# What does this paper contribute to the wider global community?

- The current study identifies prevalence and perinatal risk factors of infant colic, abdominal pain and other pain and discomforts in infancy
- Focus on parent-reported perspectives, highlighting the overlap between infant pain symptoms and risk factors.
- Implication for clinical use: Enable early targeting and support of parents with risk of having infants with colic, abdominal pain and/or pain or other discomfort that may negatively impact parent-infant interactions.

days less will fail the duration of crying criteria of colic but could still be affected by discomfort or stress (Zeevenhooven et al., 2017). In clinical settings, the definition of colic is less strict than "Wessels rule of three" (Zeevenhooven et al., 2018). It has been proposed that it is not clinically helpful to determine limits for abnormal or normal crying duration, because the experience of colic depends on the context (Barr, 1993).

#### 2 | BACKGROUND

The reported prevalence of infant colic, fussing, and crying ranges between 2%–73% in infancy (Vandenplas et al., 2015). The prevalence range reflect the multiple and diffuse criteria used in research (Steutel et al., 2014; Wolke et al., 2017). Parents perception is affected by the prevalence the intensity and duration of the crying episodes (Zeevenhooven et al., 2017).

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The characteristics of colic mentioned in literature is persistent crying and abdominal discomfort (Mai et al., 2018). It has been suggested that infant functional gastrointestinal symptoms may have an impact on future health outcomes in the infant (Vandenplas et al., 2015) and that general maternal distress in pregnancy influence the risks of colic (Wolke et al., 2017). Mothers of infants with colic more commonly describe the infant behaviour as difficult and it has been suggested that this could affect the child care given in a negative way (Helseth & Begnum, 2002). Furthermore, colic and intense crying is a risk factor for negative parent-infant interactions, abuse in infancy and has been associated with shaken baby syndrome (Barr, 2012; Steutel et al., 2014). Later in life, children with a history of colic are described by their parents as more emotional (Canivet et al., 2000) and with increased risk of abdominal pain (Steutel et al., 2014). In an overview by Sarasu et al. (2018) on infant colic, current knowledge is summarised and the complexity in diagnosing and treating the condition is described. Even if various etiological theories has been proposed, none can completely cover the condition, and therefore treatment beyond parent counselling is lacking (Sarasu et al., 2018). Some previously known risk factors for reporting colic are firstborn infants, and maternal cigarette smoking (Fazil, 2011; Shenassa & Brown, 2004; Talachian et al., 2008). Colic has been suggested as an early response to the presence of social tension in the family and allergies (Wessel et al., 1954), but the association between food allergies and infant colic is also controversial (Nocerino et al., 2015).

Maternal psychological and psychosocial factors seem to be related to increased risk for infant colic (Canivet et al., 2005). Reducing the parent's fear of their infant's colic may improve the relationship between the parents and the infant (Zeevenhooven et al., 2017). Adult brains have been shown to be hypersensitive to infant cries. Crying may increase parental stress, which in turn may trigger the infant to cry more (Scott-Jupp, 2018) in a negative feedback loop. Early preventive support of parents from pregnancy may help parents cope and increase tolerance and parenting abilities (Rautava et al., 1993). Health care professionals can play an important role in empowering parents-to-be and parents with a colicky infant to cope with the stressful colic period (Landgren & Hallström, 2011). The parents' experience of the infant's anxiety and crying seems to be important in understanding colic (Pauli-Pott et al., 2000).

Smith suggested that colic should be called an illness which is a subjective perception (Smith, 2019). The International Association for the Study of Pain (IASP) is expressing that "pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors," and "a person's report of an experience as pain should be respected" (International Association of the Study of Pain, 2020). The aspects of maternal perception and processing of colic should get more attention (Pauli-Pott et al., 2000). We have not found studies on identifying and comparing prevalence and perinatal risk factors for parent-reported colic, abdominal pain and other discomforts in infancy in the literature reviewed for this research.

The aim of this study was to estimate the prevalence and perinatal risk factors of parent-reported colic, abdominal pain and pain or other discomforts in infants until 3 months of age.

#### 3 | METHOD

#### 3.1 | Study design

This study was a part of the PreventADALL study (Preventing Atopic Dermatitis and ALLergy in children), an ongoing prospective interventional birth cohort study in Norway and Sweden. PreventADALL has two main objectives, to investigate the effect of primary prevention of allergic diseases by early skin care and early complementary food introduction, and to explore early life factors associated with non-communicable disease development. It is described in detail elsewhere (Lødrup Carlsen et al., 2018). In short, pregnant women were enrolled at the 18-week routine ultrasound scanning from December 2014 through October 2016, at Oslo University Hospital and Østfold Hospital in Norway, and at Karolinska University Hospital and collaborating obstetrical units in Stockholm, Sweden (Lødrup Carlsen et al., 2018).

The infants were included in the study within the first 24 h after birth. Exclusion criteria for the infants were severe neonatal disease and delivery before 35 weeks of gestation. Informed consent forms were signed by the women at 18 weeks enrolment as well as by both parents at birth of the infants. The study was approved by the Regional Committee in Norway (2014/518) and Sweden (2014/2242-31/4) and registered at clinicaltrial.gov (NCT02449850).

The current prospective cohort study used data retrieved from the mother-child cohort aiming to identify possible perinatal risk factors for reporting "infant colic," "abdominal pain" and "pain or other discomforts you have consulted the health care service for." Further, we aimed to estimate the prevalence and degree of overlap of the outcomes; "infant colic," "abdominal pain" and "pain or other discomforts you have consulted the health care service for" in infancy reported at 3 months of age. The colic and pain outcomes were reported by parents' subjective perception of the infants' pain. No common definition on the pain symptoms was used. STROBE checklist for cohort studies was followed in the manuscript (Appendix S1).

#### 3.2 | Study population

The study population was retrieved from the mother-child inclusion after birth, in total N = 2394 mother-child pairs from 2015–2017. Participants who answered the 3 months questionnaire were included in this study, in total N = 1852 (Figure 1).

#### 3.3 | Data collection

Data were collected by questionnaires and clinical visits at hospital facilities. Data collection in visits was collected by trained medical doctors or nurses. The completed electronic questionnaires were submitted directly, and data stored at Services for sensitive data (TSD) at the University of Oslo. The current study used data from questionnaires and/or visits at 18 and 34 weeks in pregnancy as well as at the birth and 3 months of age of the infant.

Perinatal variables

Age, body mass index (BMI), marital status, education, living area,

sick leave before 34 weeks pregnancy, country of origin, any allergy

diseases after enrolment, nicotine use after inclusion, Perceived Stress Scale (PSS) (Cohen, 1994) at 18 and 34 weeks, previous preg-

nancies. Father/partner: age, education, any allergy diseases, family

income, nicotine in household Infant: gender, birth weight, gesta-

Infant colic, abdominal pain and pain or discomfort is defined and reported by the perception of the parents at 3 months of age. The fol-

lowing question was asked: "In the last 3 months, did the infant have

any of the following?" with the corresponding three, non-mutual

exclusive reply options: "Colic," "Abdominal pain (not colic)," "Pain

or other discomforts you have consulted the health care service for."

The terms "pain or other discomforts" and "infant pain" have been

used to abbreviate "pain or other discomforts you have consulted the health care service for" and the combined three outcomes respectively throughout the aim and discussion in this document.

All statistical analysis was conducted in SPSS version 26 in services

for Sensitive Data (TSD). A statistician was consulted for plan-

ning, conducting and analysing the statistical methods and data.

Background analysis was done to assess and describe the differences

between respondents and non-respondents to the 3 months ques-

tionnaire using independent t-test on normal distributed continuous

variables, and Mann-Whitney U-test on not normally distributed

continuous variables. Chi-square test was conducted on categorical

variables. Analysis of prevalence was done with frequency, number

minimum) standard deviation (SD). Categorical variables were

Continuous variables were measured in mean (maximum-

and per cent of all three outcomes separately and together.

3.3.1

Maternal

tional age (GA).

Outcomes

**Statistical analysis** 

3.3.2

3.4

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# measured in number (N) and per cent (%). Logistic regression was conducted to obtain the relationship between the de-

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pendent variables and the independent variables. Univariate logistical regression and multiple regression was conducted with OR, CI95% and p-values. All variables with p-values < 0.1 in univariate regression were included and adjusted for in the multiple regression model to assess which or if variables are confounded or confounding. Missing data is handled as missing data, the number of responding participants are presented for each variable in the tables. Grouping of the three outcomes was filtered and conducted as a sensitivity analysis.

#### 3.4.1 | Protentional bias

The parental-reported infant pain outcomes are a subjective measurement and may be biased if reported wrong in the questionnaire. Of the mother-child pairs enrolled in the study who answered the 3 months questionnaire, a selection bias was possible if the responders were different from the non-responders. This was assessed.

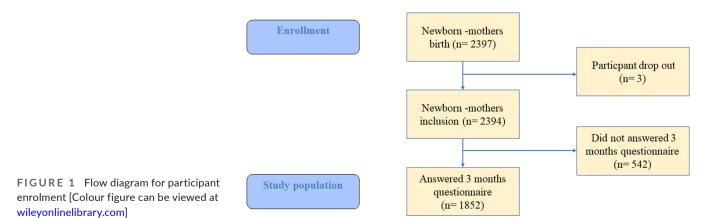
#### 4 RESULTS

## 4.1 | Characteristics of the study population compared to non-responders

Mothers of 1852 infants responded to the 3-month follow-up questionnaire, constituting 77.3% of the included 2397 infants, of whom three were withdrawn from the study (Table 1 and Figure 1). Responders had significantly higher family income, maternal education was higher and there were more first-time mothers compared to nonresponders (N = 542). For details, see Table S1.

#### Prevalence of pain outcomes 4.2

Infant colic was reported in 3% (n = 59), abdominal pain in 22% (n = 415) and other pain or discomfort in 6% (119) of infants, while



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 TABLE 1
 Characteristics of the study population

Variables (	perinatal risk factors) <sup>a</sup>	Colic, N 59	Abdominal pain, N 415	Pain or discomfort – visited health care, N 119	Not colic, abdominal pain or pain/discomfort, N 1374
Mother	Age (years) N	59	415	119	1374
	Mean (min-max) SD	31.9 (22-43) 4.4	32.7 (21.0-45.0) 3.8	32.6 (24.0-41.0) 3.6	32.4 (20.0-48.0) 4.1
	Country of origin N (%)				
	Norway	34 (63.0)	288 (73.3)	78 (71.6)	832 (65.3)
	Sweden	9 (16.7)	72 (18.3)	18 (16.5)	305 (23.9)
	Nordic	1 (1.8)	3 (0.8)	1 (0.9)	18 (1.4)
	Rest of the world	10 (18.5)	30 (7.6)	12 (11.0)	119 (9.3)
	Living area N (%)				
	City high/less populated	42 (77.8)	298 (75.8)	85 (78.0)	989 (77.6)
	Suburb	10 (18.5)	65 (16.5)	19 (17.4)	196 (14.3)
	Village/countryside	2 (3.7)	30 (7.6)	5 (4.6)	89 (6.5)
	Education N (%)				
	Primary or high school	9 (16.7)	38 (9.7)	12 (11.0)	127 (10.0)
	High ≤4 years	13 (24.1)	118 (30.2)	30 (27.5)	392 (30.9)
	High >4 years, PhD	32 (59.2)	235 (60.1)	67 (61.5)	748 (59.1)
	Marital status N (%)				
	Married	32 (59.3)	183 (46.3)	48 (43.6)	535 (46.9)
	Cohabitant	22 (40.7)	205 (51.9)	60 (54.5)	710 (55.6)
	Other	0 (0.0)	7 (1.8)	2 (1.9)	32 (2.5)
	Maternal BMI N	58	403	115	1357
	Mean (min-max) SD	24.7 (19.0-36.5) 3.2	24.6 (18.1-37.5) 3.4	25.0 (20.0-38.1) 3.4	24.9(17.2-48.2) 3.7
	Nicotine after inclusion N (%)				
	No	58 (98.3)	407 (98.1)	116 (97.5)	1358 (98.8)
	Yes	1 (1.7)	8 (1.9)	3 (2.5)	16 (1.2)
	Any allergy diseases, N (%)				
	No	25 (46.3)	205 (52.2)	52 (47.7)	767 (60.2)
	Yes	29 (53.7)	188 (47.8)	57 (52.3)	507 (39.8)
	Sick leave N (%)				
	No	18 (37.5)	158 (42.2)	39 (37.5)	668 (54.2)
	Yes	30 (62.5)	216 (57.8)	65 (62.5)	564 (45.8)
	Perceived Stress Scale (PSS) lov	w<28>high N (%)			
	PSS 18 weeks				
	Low	46 (85.2)	333 (84.7)	88 (80.7)	1090 (85.6)
	High	6 (14.8)	60 (15.3)	21 (19.3)	184 (14.4)
	PSS 34 weeks				
	Low	42 (79.2)	344 (86.0)	95 (82.6)	1164 (88.1)
	High	11 (20.8)	56 (14.0)	20 (17.4)	157 (11.9)
	Previous pregnancies, N (%)				
	0	30 (50.8)	244 (58.8)	71 (59.7)	863 (62.9)
	1	25 (42.4)	138 (33.3)	37 (31.1)	399 (29.1)
	2	3 (5.1)	30 (7.2)	9 (7.6)	96 (7.0)
	3+	1 (1.7)	3 (0.7)	2 (1.7)	14 (1.0)
	Mode of delivery N (%)				
	Vaginal normal	41 (69.5)	287 (69.5)	80 (67.2)	990 (72.2)
	Vaginal vacuum + forceps	7 (11.9)	65 (15.7)	21 (17.6)	155 (11.3)
	C- elective	6 (10.2)	21 (5.1)	8 (6.7)	77 (5.6)
	C- acute + catastrophe	5 (8.5)	41 (9.9)	10 (8.4)	150 (10.9)

#### TABLE 1 (Continued)

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Variables	(perinatal risk factors) <sup>a</sup>	Colic, N 59	Abdominal pain, N 415	Pain or discomfort – visited health care, N 119	Not colic, abdominal pain or pain/discomfort, N 1374
Infant	Gender N (%)				
	Воу	33 (35.9)	229 (55.2)	68 (57.1)	699 (50.9)
	Girl	26 (44.1)	186 (44.8)	59 (42.9)	675 (49.1)
	GA (days) N	59	414	119	1370
	Mean (min-max) SD	279.4 (249–295) 10.1	280 (247–296) 9.7	280.3 (252–295) 9.8	280.6 (245–298) 9.5
	Birth weight (g) N	59	414	119	1367
	Mean (min-max) SD	3586 (2198-4825) 539	3580 (2071-4782) 466	3614 (1933-4900) 478	3566 (1794-5632) 480
Father	Age (years) N	51	371	99	1190
	Mean (min-max) SD	34.9 (23-51) 5.9	34.9 (21-72) 5.4	34.7 (23-50) 5.1	34.7 (21-72) 5.4
	Education N (%)				
	Primary or high school	13 (22.2)	65 (17.5)	23 (21.3)	243 (20.0)
	High <4 years	29 (24.1)	115 (31.0)	27 (25.0)	362 (29.8)
	High >4 years, PhD	54 (53.7)	191 (51.5)	58 (53.7)	608 (50.1)
	Family income (NKR), N (%)				
	<600,000 low	10 (19.2)	42 (10.8)	10 (9.4)	165 (13.1)
	600,000-1,000,000 medium	20 (38.5)	169 (43.6)	50 (49.1)	526 (41.9)
	>1,000,000 high	22 (42.3)	177 (45.6)	44 (41.5)	565 (45.0)
	Asthma, allergies or eczema N	N (%)			
	No	44 (84.6)	333 (86.7)	99 (90.0)	1090 (87.1)
	Yes	8 (15.4)	51 (13.3)	11 (10.0)	161 (12.9)
	Nicotine in household, N (%)				
	No	52 (96.3)	381 (95.3)	102 (96.6)	1217 (95.5)
	Yes	2 (3.7)	19 (4.8)	7 (6.4)	57 (4.5)

<sup>a</sup>Continuous variables were measured in mean (maximum-minimum) standard deviation (SD). Categorical variables were measured in number (N) and percent (%).

any of these symptoms were reported in 26% (478) of the participating infants. The distribution is shown in Figure 2.

#### 4.3 | Perinatal risk factors of pain outcomes

Maternal sick leave during pregnancy, maternal allergic diseases, and living in Norway all significantly increased the odds for reporting colic, abdominal pain and/or other pain or discomfort in their infants (Table 3).

Maternal sick leave in pregnancy as well as reported any allergic disease increased the odds for reporting colic, abdominal pain as well as other pain and discomfort. Swedish mothers had lower odds of reporting abdominal pain in their infant compared to Norwegian mothers (Table 3). Although statistically significant associations were found between pain outcomes and numbers of pregnancies, maternal marital status and maternal PSS at 34 weeks in the univariate analysis (Table 2), these associations did not remain significantly different when adjusted for possible confounders in multiple regression. Our data revealed a trend of higher maternal stress at 34 weeks for reporting infant pains, but it was not statically significant (Table 3). The following variables were not statistically significant predictive factors of reporting colic, abdominal pain or pain and other discomfort with visits to health care units; infant sex, weight, gestational age, maternal age, education, maternal PSS at 18 and 34 weeks, nicotine use, living area, BMI, family income, or paternal age, education, allergic diseases or household smoking (Table 2).

### 5 | DISCUSSION

Infant colic, abdominal pain and/or pain or other discomfort were found in 26% of the infants by 3 months of age, with abdominal pain being the most prevalent reported symptom, with significant overlap between symptoms (Figure 2).

The prevalence of reported colic (3%) in the present study were in the low range of the findings of Vandenplas et al. (2015) with an average prevalence of colic around 20% with a range between 3%-72% in the reviewed papers. In the review of Steutel et al. (2014) the prevalence of colic was between 5%-25%. A study from Italy reported a prevalence of colic at 21% (lacono et al., 2005), while a study from Finland reported a prevalence of 13% (Lehtonen & Korvenranta, 1995). These wide ranges in studies can, at least partly, be explained by the imprecise concept of colic, with unclear criteria and different applications (Helseth & Begnum, 2002; Zeevenhooven et al., 2017). Other studies have suggested that an approach of

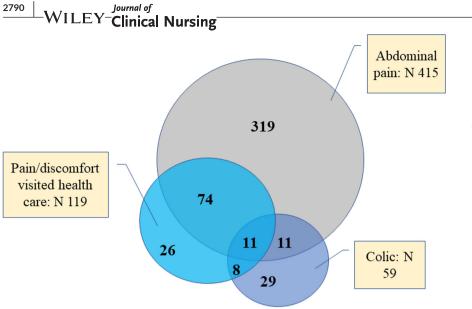


FIGURE 2 Prevalence of pain outcomes with overlap. Reported infant colic, abdominal pain and other pain or discomfort N 478/1852 (25.8%). Reported none of the symptoms N 1374/1852 (74.2%) [Colour figure can be viewed at wileyonlinelibrary.com]

parent perspectives and context can give a better picture, in practice, of the phenomenon colic than duration of crying, which is influenced by both the parent's experience and the infant's temperament (Barr, 1993; Helseth & Begnum, 2002; Zeevenhooven et al., 2017). Classification of infant crying was found challenging for parents in the study of Saavedra et al. (2003). In our study 6% of the infants visited health care with pain or other discomfort (Figure 2). We did not find other studies comparing prevalence on abdominal pain or pain and other discomfort leading to health care visits before 3 months of age. but abdominal pain is common (Smith & Fox, 2016). A study in primary care found that 9% of all doctor visits in childhood are due to acute abdominal pain (Reust & Williams, 2016).

Out of the 6% (119/1854) of infants visiting health care because of pain and other discomforts there were reported abdominal pain in 20% (85/415) and colic in 32% (19/59). Colic has previously been found to be the most common concern and reason of seeking medical advice in infancy (Kaley et al., 2011). It has been suggested that a more comprehensive definition of colic, including intensive crying, non-specific fussing and crying and food-related crying could help to understand colic data in clinical settings (Helseth & Begnum, 2002). This may be one explanation for why a common reason for visiting health care, shown in our results, was abdominal pain and pain and other discomforts. The pain symptoms are overlapping and can concern parents even if they do not label the pain symptom as colic.

In our population it was a low prevalence of reported infant colic and a higher prevalence of abdominal pain. Saavedra et al. (2003) claims that most mothers in their study misclassify the occurrence of colic according to the Wessel rule criteria (Saavedra et al., 2003). The strict Wessel rule of three was excluded from definition of colic in ROME IV criteria in 2016 (Zeevenhooven et al., 2017). Furthermore Barr (1993) suggested there was not clinical useful to set a limit for what is a cut off for normal crying if clinical diseases are ruled out. Our findings of overlap between outcome symptoms may contribute to understanding the challenge in using strict rules like duration of crying on what is colic, abdominal pain or pain or other discomforts in clinically settings, because context is as important (Zeevenhooven et al., 2017).

The prevalence of colic was in the low range in our study, and the odds for reporting abdominal pain was higher for Norwegians compared to Swedish mothers. Wolke et al. found there was different levels of reported colic, fussing and crying in different countries. Denmark was the country with the least crying infants, unfortunately Sweden and Norway was not included in this study, but according to Wolke different cultures handle this phenomenon differently (Wolke et al., 2017). These three Scandinavian countries could possibly be comparable with low prevalence of infant colic. Still, methods used to collect data about crying and parents' well-being are culturally dependent in infant care practices (Zeevenhooven et al., 2017). These differences in methods and contexts may be contributing to the different results of the prevalence in colic studies around the world (Barr, 1993; Vandenplas et al., 2015) and, if the culture aspect is true, it may be understandable that the results are different in different studies even if the methods were the same.

When exploring perinatal risk factors on reporting the three infant pain outcomes we found that mothers on sick leave in pregnancy or any allergic diseases had higher odds of reporting an infant with all pain outcomes. We did not find any studies on maternal sick leave in pregnancy and reporting of infant pain. In our study Swedish mothers had a significantly lower odds of reporting abdominal pain than Norwegian mothers.

There was a trend to report infant colic, pain and other discomforts by mothers with higher perinatal stress at 34 weeks compared to those who reported low stress. However, this assosiation was not statistically significant. Other findings on maternal stress were presented in Phelan et al.'s (2015) study where high prenatal maternal stress was a predictor of maternal reporting of gastrointestinal illness in the infant. Colic and crying infants are the most common concerns causing stress for parents in infancy (Keefe et al., 2006). Our result is from perinatal data, and development of infant colic

	Inicen												ESP
Total analyzed	N 1433, Colic n 59	c n 59			N 1789, Abc	N 1789, Abdominal pain n 415	n 415		N 1493, Pai	n or other dis	N 1493, Pain or other discomforts n 119		RIEE
Variables	N	OR	95% CI	<i>p</i> -Value	z	OR	95% CI	<i>p</i> -Value	z	OR	95% CI	<i>p</i> -Value	ET AL
Age													
Maternal (years)	1433	0.96	0.90-1.03	0.220	1789	1.02	0.99-1.04	0.283	1493	1.01	0.96-1.06	0.753	
Partner (years)	1190	1.01	0.96-1.06	0.760	1561	1.00	0.99-1.03	0.568	1288	1.00	0.96-1.06	0.753	
Infant (GA birth, days)	1370	0.99	0.96-1.01	0.355	1784	0.10	0.98-1.02	0.739	1489	1.00	0.98-1.02	0.739	
Maternal Country of origin													
Norway	866	1			1120	1			910	1			
Sweden	314	0.72	0.34-1.52	0.392	377	0.68	0.510-0.91	0.010	323	0.63	0.37-1.67	0.086	
Other Nordic	19	1.36	0.18-10.48	0.768	21	0.48	0.41-1.65	0.481	19	0.59	0.08-4.50	0.613	
Rest of the world (ref)	129	2.06	0.99-4.27	0.053	149	0.73	0.48-1.11	0.728	131	1.08	0.57-2.04	0.823	
Family Living area													
City high/less populated (ref)	1031	1			1287	1			1074	1			
Suburb	206	1.20	0.59-2.44	0.611	261	1.10	0.81-1.50	0.543	215	1.13	0.67-1.90	0.650	
Village/countryside	91	0.56	0.13-2.22	0.385	119	1.12	0.73-0.73	0.612	94	0.65	0.26-1.65	0.369	
Maternal education													
Primary or high school (ref)	255	1.66	0.77-3.55	0.230	165	0.95	0.64-1.41	0.807	139	1.06	0.56-2.01	0.871	
High <4 years	375	0.78	0.40-1.06	0.195	510	0.96	0.74-1.23	0.740	422	0.85	0.55-1.34	0.491	
High >4 years, phd	637	1			983	1			815	1			
Paternal Education													
Primary or high school	255	1.04	0.52-2.06	0.921	308	0.85	0.62-1.17	0.322	266	0.99	0.60-1.65	0.976	
High <4 years	375	0.75	0.39-1.47	0.404	477	1.01	0.78-1.32	0.934	389	0.78	0.49-1.26	0.310	
High >4 years, phd (ref)	637	1			799	1			666	1			
Marital status													Jou ⁻Cl
Married (ref)	567	1			718	1			583	1			rnal ini
Cohabitant	732	0.52	0.30-0.90	0.020	915	0.84	0.67-1.06	0.146	770	0.94	0.63-1.40	0.767	<sub>of</sub> cal
Other	32	0.00	0.00-xxx	0.998	39	0.64	0.28-1.47	0.294	34	0.70	0.16-3.00	0.627	N
Maternal BMI	1357	0.99	0.92-1.06	0.725	1760	0.98	0.95-1.01	0.202	1472	1.01	0.96-1.06	0.786	urs
Maternal Nicotine after inclusion	usion												ing
No (ref)	1374	1			1765	1			1474	1			g\
Yes		1.46	0.19-11.2	0.714	24	1.67	0.71-3.93	0.241	19	2.20	0.63-7.64	217	NI
Nicotine in household													[ <b>L</b> ]
No (ref)	1269	1			1650	1			1375	1			EY
Yes	59	0.82	0.20-3.46	0.788	71	1.22	0.71-2.08	0.470	61	2.07	0.99-4.32	0.052	r
												(Continues)	2791

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TABLE 2 Univariate regression

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TABLE 2 (Continued)												
Total analyzed	N 1433, Colic n 59	lic n 59			N 1789, Ab	N 1789, Abdominal pain n 415	n 415		N 1493, Pa	in or other di	N 1493, Pain or other discomforts n 119	
Variables	z	OR	95% CI	<i>p</i> -Value	z	OR	95% CI	<i>p</i> -Value	z	OR	95% CI	p-Value
Any allergy diseases Maternal												LEY
No (ref)	792	1			972	1			819	1		
Yes	536	1.76	1.02-3.03	0.044	695	1.39	1.11-1.74	0.005	564	1.66	1.12-2.46	0.011
Any allergy diseases												ical
Paternal												N
No (ref)	1134	1			1423	1			1189	1		lur
Yes	169	1.23	0.57-2.66	0.597	212	1.04	0.74-1.45	0.834	172	0.75	0.40-1.43	0.387
Maternal Sick leave												g
No (ref)	686	1			826	1			707	1		
Yes	594	1.98	1.09-3.58	0.025	780	1.62	1.28-2.05	>0.001	629	1.97	1.31-2.98	0.001
Maternal Perceived Stress Scale (PSS)low<28>high	scale (PSS)low	/<28>high										
PSS 18w Low (ref)	1136	1			1428	1			1178	1		
High	192	1.03	0.48-2.22	0.939	244	1.07	0.78-1.46	0.686	205	1.41	0.86-2.33	0.176
PSS 34 w Low(ref)	1206	1			1508	1			1559	1		
High	168	1.98	0.98-3.85	0.057	213	1.21	0.87-1.68	0.261	177	1.56	0.94-2.60	0.087
Maternal Previous	1372	1.22	0.88-1.71	0.236	1787	1.09	0.94-1.27	0.265	1491	1.10	0.85-1.42	0.489
pregnancies												
Mode of delivery												
Vaginal normal (ref)	1031	1			1277	1			1070	1		
Vaginal vacuum + forceps	162	1.10	0.48-2.47	0.836	220	1.45	1.05-1.99	0.023	176	1.68	1.01-2.97	0.047
C- elective	83	1.88	0.78-4.57	0.163	98	0.94	0.57-1.55	0.811	85	1.29	0.60-2.76	0.518
C- acute + catastrophe	155	0.81	0.31-2.07	0.652	191	0.94	0.65-1.36	0.755	160	0.83	0.42-1.63	0.579
(ref)												
Infant gender												
Boy (ref)	732	1			928	1			767	1		
Girl	701	1.23	0.73-2.07	0.447	861	0.84	0.68-1.05	0.124	726	0.78	0.53-1.13	0.190
Infant birth weight (g)	1367	1.00	1.00-1.00	0.747	1781	1.00	1.00-1.00	0.595	1486	1.00	1.00 - 1.00	0.295
Family income (NKR)												
<600,000 low	176	1.56	0.72-3.35	0.258	207	0.81	0.56-1.19	0.282	175	0.78	0.38-1.58	0.488
600,000-1,000,000	546	0.98	0.53 - 1.81	0.940	695	1.03	0.81-1.31	0.838	578	1.27	0.84-1.93	0.264
medium												
>1,000,000 high (ref)	587	1			742	1			609	1		
Note: Variables are measured with Odds ratio (OR), 95% Confidence intervals (Cl) and <i>p</i> -values.	with Odds ra	itio (OR), 95%	6 Confidence inter	rvals (Cl) and <i>p</i> -	-values.							

p-Values < 0.1 were further included in the multivariate analysis.

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has been associated with experience of stress and physical symptoms during pregnancy (Rautava et al., 1993). Wessel et al. (1954) claimed colic could be an early response to presence of tension in the family and allergies. This is similar to Canivet et al.'s (2005) findings on psychological and psychosocial factors and their relation to increased risk for infant colic. Our findings of higher odds of reporting infant pain at 3 months of age by mothers with maternal sick leave and any allergies in the pregnancy could be supported by other studies suggesting empowering parents-to-be as early as possible, to increase parental and infant health (Landgren & Hallström, 2011). Our population was a generally healthy population. This could possibly affect the results if the parents with challenges dropped out of the study.

We did not find statistically significant higher odds for reporting colic, abdominal pain or other pain and discomforts in the following variables: infant sex, weight, GA, or in maternal age, education, nicotine use, Maternal PSS at 18 and 34 weeks, number of pregnancies, delivery methods, living area, marital status, BMI, family income, or in paternal age, education, allergy diseases or household smoking. This is supported by findings of Fazil (2011) according to: sex, gestational age at birth, birth weight and type of delivery. However, Fazil found firstborn infants had higher rate for developing colic in their study. Except for birth order, no other variable was significantly associated with infant colic (Fazil, 2011) and according to Rautava et al. (1993) none of the sociodemographic factors were associated with colic. Crowcroft and Strachan found that maternal age (young), parity and socioeconomic (low) factors were the most important risk factors for reporting colic (Crowcroft & Strachan, 1997). Our study had a population with high maternal age and high socioeconomic status (education and family income) (Table 1). In our study outcome symptoms were not associated with perinatal factors such as maternal education and smoking habits found by Yalçın et al. (2010). Other studies have found an association to maternal or passive smoking (Reijneveld et al., 2000; Shenassa & Brown, 2004).

#### 5.1 | Strengths and weaknesses

A strength of the current study is that the data collection was a part of a large prospective RCT study with many infant visits and questionnaires. In our study, the reported questions on colic, abdominal pains (not colic) and other pains and discomfort in the questionnaires is a strength. Steutel et al. (2014) discussed in their review the difficulty of assessing the validity in definition of infant colic because half of the authors had their own definition of colic and the majority focused on the infants crying, this could be due to misclassification of infant colic and abdominal pains. This study is, to our knowledge the first to report the prevalence of abdominal pain before introduction of solid food.

The sample size of the RCT was according to power analysis >2000 mother-infant-pairs (Lødrup Carlsen et al., 2018). The prospective study design reduces the risk of recall bias (Laake et al.,

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2008). Although the study intention was to include a population diversity close to the general population, the enrolled participants ended up having higher socioeconomic status (education and family income) than enrolled non-responders and the dropouts. This is a challenge in prospective research (Laake et al., 2008) and in the current study participants had to attend several time consuming visits and fill out extensive questionnaires (Lødrup Carlsen et al., 2018). Our findings could possibly be generalised to similar populations with the same questionnaires on parent-reported pain symptoms. The presence of non-responders and drop outs could have caused some selection bias and thus influence the results, both regarding the prevalence of infant pain and risk factors.

In our study, the parents have reported according to their own subjective perception of infant pain on the behalf of their infant. Having only subjective measurement could be a weakness because it is not as easy to compare and recreate as objective variables. Pain is a subjective experience (International Association of the Study of Pain, 2020). Phenomenon like pain, especially when reported by a third person, will always be challenging to interpret.

#### 6 | CONCLUSION

In our study population, the most often reported infant pain symptom was abdominal pain (22%), followed by pain and other discomfort (6%). We have not found studies in the literature presenting different infant pain symptoms with this level of detail thus our results are not directly comparable. The prevalence of colic (3%) was low in our population and in the low range also compared to other studies. Many parents reported more than one pain symptom which indicates that the symptoms are likely to overlap. All three pain outcomes had some common risk factors like maternal sick leave and allergic diseases in pregnancy. In addition, Swedish mothers were less likely to report abdominal pain compared to Norwegian mothers. Mothers with higher PSS at 34 weeks were more likely to report infant colic and pain and other discomforts in their infants, however this association did not reach the level of statistical significance. Our results indicate that perinatal maternal health is associated with infant pain and could be an important factor to consider in understanding reporting and prevalence of infant colic, abdominal pain and pain or other discomforts leading to health care visits. Our study suggests that an overlap in pain symptoms and perinatal risk factors shows a contextual association between all three pain symptoms. Infant pain experiences involve many factors, therefore it is essential for clinicians to assess pain in infants with the best and most suitable methods to meet the needs of infants and their parents in the best possible way. Our results, with overlap on pain symptoms and risk factors suggests that in clinical settings it should be a focus on supporting parent's perceptions and concerns on infant pain, regardless of infant pain symptoms or duration of crying. Early targeting the families with risk factors may help to support them and prevent stress, negative parent-infant interactions as well as abuse.

Total analyzed (a)	N 1433 (filt	N 1433 (filtered (b)), Colic n 59	ic n 59		N 1789 (filt	ered(b)), Abd	N 1789 (filtered(b)), Abdominal pain n 415	5	N 1493 (fil	tered (b)), Pail	N 1493 (filtered (b)), Pain or other discomforts n 119	ITT N TTA
Variables	z	OR	c	<i>p</i> -Value	z	OR	C	<i>p</i> -Value	z	OR	G	<i>p-</i> Value
Maternal Any allergy diseases	ses											
No (ref)	718	1			884	1			744	1		
Yes	477	1.99	1.06-3.70	0.031	622	1.35	1.06-1.73	0.015	502	1.60	1.05-2.45	0.030
Maternal Sick leave												
No (ref)	644	1			783	1			666	1		
Yes	551	2.48	1.28-4.80	0.007	723	1.49	1.17-1.91	0.001	580	1.82	1.18-2.83	0.007
Marital status												
Married (ref)	510	1										
Cohabitant	657	0.58	0.38-1.10	0.095								
Other	28	0.00	0.00-xxx	0.998								
Maternal Country of origin	-											
Norway (ref)	784	1			1018	1			823	1		
Sweden	283	0.94	0,42-2.14	0.890	338	0.72	0.53-0.99	0.042	291	0.76	0.43-1.36	0.355
Nordic	19	1.81	0.23-14.41	0.575	21	0.54	0.16-1.87	0.333	19	0.74	0.10-5.70	0.771
Rest of the world	109	2.06	0.84-5.05	0.112	129	0.33	0.52-1.29	0.385	13	1.33	0.67-2.63	0.417
Mode of delivery												
Other modes (vaginal					1322	1			1099	1		
normal, c-sect elective. acute.												
catastrophe) (ref)												
Vaginal vacuum/forsept					184	1.36	0.96-1.92	0.089	147	1.62	0.92-2.85	0.097
Maternal Perceived Stress Scale (PSS) low<28>high	Scale (PSS) lov	v<28>high										
PSS 34 w Low(ref)	1206	1							1559	1		
High	168	1.56	0.70-3.48	0.281					177	1.20	0.66-2.20	0.545
Nicotine in household												
No (ref)									1269	1		
Yes									59	0.56	0.24-1.30	0.178

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## 7 | RELEVANCE TO CLINICAL PRACTICE

Colic and abdominal pain are common concerns for parents of infants and for clinicians in practice. The diagnostic criteria of colic and infant pain symptoms are not well defined in clinical practice and our study has contributed to explore possible associations between different parent reported infant pains, highlighting the overlap between pain symptoms and some common perinatal risk factors, mainly regarding maternal health. When identifying concrete perinatal risk factors for reporting infant pain, health care personal may early target and support mothers with these risk factors and their families, already in pregnancy. Supporting the families to cope could prevent possible stress, negative parent-infant interactions and abuse.

#### ACKNOWLEDGEMENTS

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#### CONFLICT OF INTEREST

The authors declare that they have no conflicts of interest associated with this article.

#### AUTHOR CONTRIBUTION

Åshild Wik Despriée carried out the data collection and data management in Norway, was responsible for the study design, data analysis and preformed and drafted the initial manuscript. Caroline-Aleksi Olsson Mägi carried out the data collection and data management in Sweden, contributed to the data analysis and preformed and drafted the initial manuscript. Håvard Skjerven, Karin Lødrup Carlsen and Kari Glavin has conceptualised, supervised the study and critically reviewed and revised the manuscript. Milada Cvancarova Småstuen was contributed on data analysis and overview data work and critically reviewed and revised the manuscript. Cilla Söderhäll has supervised, critically reviewed data analysis and revised the manuscript. Live Nordhagen carried out the data collection, critically reviewed data analysis and revised the manuscript. Christine M Jonassen, Eva Maria Rehbinder and Björn Nordlund local responsible leaders, critically reviewed data analysis and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

#### CLINICAL TRIAL REGISTRATION

The study was approved by the Regional Committee in Norway (2014/518) and Sweden (2014/2242-31/4) and registered at clini caltrial.gov (*NCT02449850*).

#### DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

#### ORCID

#### Åshild Wik Despriee D https://orcid.org/0000-0002-9234-5676

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