INFANT HEALTH

Supporting infants' mental health and
healthy weight development through
community health nurses, promoting
sensitive parenting

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Content

1 Summary

The project is the first to explore intervention within municipality settings to target the earliest developmental trajectories of mental health problems and overweight via promoting sensitive parenting of infants of cognitive and regulatory vulnerabilities.

Mental health problems and overweight are major challenges to public health in the 21st century. These conditions often co-occur, they have their origin in early childhood, and research evidence suggest a key role of cognitive, emotional, and behavioral regulation in the developmental trajectories of both mental health problems and overweight, with mounting evidence pointing to public health strategies of intervention starting in infancy and building on strategies of sensitive parenting. The research group behind this project has validated the conditions on which to build preventive intervention in infancy within the settings of Danish community health nurses, and we have developed a basic program in which community health nurses are educated to address infants' mental health and development, The PUF (In Danish Psykisk Udvikling og Funktion) program. Still, though urgently needed, an effective intervention to serve the most vulnerable infants is lacking.

The Infant Health project aims to develop and test an intensified intervention as an add-on to the PUF-program, to address infants with major cognitive and regulatory vulnerabilities identified at age 9-10 months and adapted to the settings of community health nurses. The intervention (VIPP-PUF) will be created from an evidence-based method, the Video-based Intervention to Promote Positive Parenting (VIPP), to comprise six therapeutic sessions delivered by the community health nurse during home visits over a three-month-period. The VIPP-PUF builds on teaching the health nurses to promote parents' sensitivity to meet infants' cognitive and regulatory vulnerabilities, while taking in account the particular needs of families of psycho-social disadvantage. A main part of the project is the development and testing of an intensive educational program for community health nurses.

The Infant Health project is conducted in 16 municipalities across Denmark, and it builds on an already well-established cooperation between the community health nurses and the research group. We use the Intervention Mapping approach as the study frame and integrate the best practice of the community health nurses. The project includes a pilot phase to assess the fidelity and feasibility of the study measures, prior to a randomized controlled step-wedge study of intervention efficacy. The project has strong potentials of providing new research evidence on options of prevention to break the developmental trajectories of mental health problems and overweight in early childhood.

2 Background

2.1 The public health challenges of mental health problems and overweight

Mental health problems and overweight are major challenges to population health in modern societies. Both are highly prevalent, also among children, and both have severe long-term prognoses regarding mental and physical health, social functioning, and premature death (1-5). Mental health problems and overweight often co-exist, they share risk factors (6, 7), and they share an origin early in development (6-8). Among children in Western European countries, including Denmark, about 15% of the population suffer from mental health disorders (9-14), with a higher prevalence in psycho-socially deprived populations, and the highest prevalence is seen in children from families of psycho-social disadvantage (11, 13, 15-17). As mental health disorders, overweight is a frequent public health concern, affecting about 20% of the child population from Western European countries, and among Danish children, one in eight is overweight when starting school (18, 19). Furthermore, the psycho-social risk factors associated with mental health problems are also associated with childhood overweight (5, 20-22).

Public health strategies are urgently needed to reduce the prevalence of these common conditions (23-26), but so far, no strategies have shown to be effective (3, 27-32), leaving a gap in knowledge on novel ways of preventing mental health problems and overweight in the early stages of the child's development.

2.2 State of the art: Predictors of mental health problems

The majority of children's mental health problems have their origin within the first years of living (8, 26, 28, 33, 34). Psycho-social disadvantage plays an important role in the risk mechanisms, and increased risk has repeatedly been found in children of young parents, single parents, and parents of low education, parents of foreign ethnicity, and mentally ill parents (7, 13, 35-37). Pre- and perinatal adversities and cognitive and psycho-motor difficulties in infancy are associated with an increased risk of neuro-developmental disorders (13, 37), with infancy problems of language development, inattention, and deviant contact and communication being predictive of autism spectrum disorders, and disorders of hyperactivity and inattention, ADHD (33, 35, 38-41). Regulatory problems of eating, sleep, and emotional and behavioral regulation have shown to be highly predictive of mental health problems and disorders later in preschool to school age (26, 40, 42, 43). Regulatory problems are thus considered to represent the first manifestations of persistent dysregulation trajectories (41, 42, 44), showing an up to tenfold increased risk of mental health

problems later in childhood, in particular ADHD, eating problems, and emotional- and behavioral problems (45-48).

Overall, and across areas of mental health vulnerability, the early parent-child relation seems to be a main moderator of risk and resilience (26, 49, 50), and challenges to parenting are considered to play a key role in the development of enduring problems (45, 51-55).

2.3 State of the art: Predictors of childhood overweight

Mounting evidence points to the early childhood origin of overweight, and a high risk of persisting health problems in children, who are overweight in infancy (20, 22, 56-60). A study of Danish children has shown that 4% of the infant population in Denmark is classified as overweight according to WHO z-scores, and about 0.5% classified as obese (18, 61) with a more than sevenfold increased risk of persistent overweight from infancy to age 5-8 years, independent of child and family factors (18). The studies of Danish children have replicated findings from the international literature regarding psycho-social risk factors (23, 60, 62, 63) and they show that factors such as young parental age, low maternal education, single parent families, and ethnic minorities are highly associated with an increased risk of overweight in infancy (18, 21). The mechanisms behind the social pattern of overweight are suggested to include the gene-environment interaction (5). Early childhood is also a critical period for the development of regulation processes involved in eating, which have been highlighted as potentially modifiable asset linked to child weight outcomes (64). The way parents feed their children is suggested to impact children's eating behavior as well as related health outcomes such as weight development (65, 66). Maternal obesity impacts the infant's feeding pattern and overall risk of overweight (67, 68) via difficulties related to breastfeeding, a higher risk among obese mothers to introduce high energy and fat foods very early, and difficulties for obese parents to regulate their appetite themselves, leaving them more or less responsive to the infant's hunger and satiety cues. Accordingly, parents with overweight have a tendency of excess food provision and the "overriding" of the infant's internal satiety cues (69-71). Moreover, parents with overweight have an increased risk of contemporary mental health problems, e.g. ADHD and depression, which may further challenge their parenting (72).

Among measures to identify children at risk of overweight, weight and length are the most widely used, but increasing evidence suggest that these are poorly associated with true body composition and is especially problematic in the pediatric population because the relative contributions of fat mass (FM) and fat-free mass (FFM) to body weight vary by age, sex, and ethnicity (73, 74).

2.4 Co-occurrence of children's mental health problems and overweight

Mental health problems often co-occur with overweight (75-82), and prospective longitudinal data indicate that among children and adolescents, the mental health problems tend to precede the development of overweight (75, 79, 82). The potential mechanisms include cognitive vulnerability regarding inhibitory control/reward sensitivity and sustained attention (83-88) leading to impulsive eating, and difficulties in delaying gratification, which are core features in feeding and eating behaviors demonstrated in children with disorders of hyperactivity and inattention, ADHD and co-occurrent overweight (75, 76, 81, 89). Infants' emotional regulation concern their ability to maintain an affective homeostasis confronted with stress-full experiences (50), and problems with emotion regulation are suggested to precede childhood emotional and behavioral problems (42, 54) and emotional eating (88, 90). Emotional eating is considered to develop through pathways of physiological stress responses, and through cardiac reactivity influencing appetite (6, 91). Also, stress exposures may induce hyper- or hypo-activation of the hypothalamic-pituitary-adrenal (HPA) axis, and potentially promote fat accumulation in visceral adipose tissues. These hormonal responses potentially influence appetite and attraction to sweet and fatty foods, mainly by stimulating reward pathways (91-94). Among the few prospective studies published in this area, a study of self-regulation skills and obesity in early childhood has shown that poor emotional regulation and lower inhibitory control at age 2 years is predictive of higher BMI at 5 years of age (86). Another prospective cohort study has linked regulatory difficulties at 9 months of age with higher obesity risk at preschool age (95). Further studies have found associations between problems with emotional regulation and emotional eating (88, 91), while others have linked infant temperament, defined as "individual differences in reactivity and self-regulation" (96), with obesity (83, 97, 98) as well as impulsive eating (99) and eating in the absence of hunger (100). Yet, the underlying mechanisms behind this is not well understood but may include that easily distressed infants tend to elicit more feeding for soothing (101, 102) or that children with emotional and behavioral dysregulation may possess a relatively underdeveloped self-regulatory capacity including impulsive eating and overeating (99, 103).

2.5 State of the art: Early intervention to target childhood mental health problems and overweight

Prevention of mental health problems and overweight must start early in life and should include universal strategies as well as targeted interventions for children and families at risk (22, 23, 28, 31,

55). To be effective, the preventive strategies should start no later than infancy (26, 104) and include intervention to reduce risk exposures (25, 27), as well as targeted intervention to the infants most vulnerable (105-107). Across areas of infant vulnerability, the preventive strategies should include the parent-child relation and strategies to promote parents' sensitivity to understand and handle the infant's vulnerability, called *sensitive parenting* (55, 108). Regarding mental health vulnerability, most preventive programs address pregnancy and perinatal adversities, or exposures associated with psycho-socially disadvantage, such as teenage parents or mothers with mental health problems (109-111), or they address specific problems in high-risk infants, e.g. developmental or behavioral problems, or problems related to attachment (109, 110, 112). Programs to promote parenting mainly target behavioral problems in toddlers or older children and most are group-based, whereas individually targeted interventions mainly target attachment difficulties in younger children (109, 110, 112). Overall, no preventive interventions have been published that systematically address the range of mental health vulnerabilities seen in the youngest children. Among the methods published so far, the Video-feedback Intervention to Promote Positive Parenting, VIPP, takes an outstanding position however (113), in being highly effective in reducing both behavioral dysregulation and communicative problems in infants and toddlers (114) and being successfully used in families of psycho-social disadvantage, including mothers with eating problems (115, 116).

Regarding early prevention of overweight, universal public health programs are recommended to start in pregnancy, to promote healthy weight for mother and child, and to optimize breastfeeding and promote healthy nutrition in infancy (23, 31, 62). Moreover, targeted intervention is recommended for families with limited psycho-social resources to optimize the conditions of healthy weight development across early childhood and beyond (23, 30). Still, although the evidence for obesity prevention in early childhood is growing (23, 30, 117), research on effective strategies is sparse and the outcomes associated with the available strategies have been modest (29, 118, 119). Across the literature on the early childhood trajectories of overweight, the importance of parenting holds a key position (6, 118), with the suggested risk trajectories linking infancy dysregulation to overweight being highly influenced by parenting. Sensitive parenting has been shown to moderate the negative effect of early adversities on childhood obesity (71, 120-122) and specifically to promote healthy eating habits (123). Sensitive parenting is correlated with responsive feeding, defined as a feeding practice in which parents perceive the child's hunger and satiety signals and respond to them promptly and appropriately (124, 125). Responsive feeding is

suggested to promote and reinforce children's ability to self-regulate their energy intake because the parent will not override the child's satiety cues (69, 70). Indeed, promoting responsive feeding has shown to be associated with several beneficial health outcomes for young children, such as healthy eating behavior and reduced risk of overweight (125-128). However, it has recently been suggested that responsive feeding might not be sufficient to promote healthy outcomes (120, 129). The overall emotional quality of the parent-child relationship is an important but overlooked factor in the development of child eating behaviors and weight (71, 120, 122, 130, 131), in particular among children at high risk of eating problems (103). Taking novel research evidence on cognitive and regulatory vulnerabilities regarding unhealthy weight development and overweight into account, approaches that address the promotion of sensitive parenting are theoretically sound (6), however not yet fully explored (132).

In sum, there is a strong scientific rationale for public health interventions that include strategies to promote sensitive parenting across the range of cognitive and regulatory vulnerabilities seen in children below two years of age, to address the shared vulnerability traits in the early trajectories of mental health problems and overweight.

Promoting sensitive parenting has the potential of optimizing parents' understanding and regulation of their infant's cognitive, physiological, emotional, and behavioral vulnerabilities, and thereby optimize the child's healthy mental development and healthy weight.

2.6 The challenges of intervention in disadvantaged families

The literature on interventions that address childhood mental health problems and overweight converges on the importance of parents' resources (7, 21, 28, 36, 133-135). The parents are key mediators of healthy mental development as well as healthy weight development in their child (23, 26, 34, 52, 136). Still, the current literature indicates that parents with a background of mental illness, low education, low income, and young age at the child's birth, more often experience challenges in providing a healthy and stimulating environment for their child, due to their own psychological vulnerabilities, and due to an associated risk of limited social and psychological resources in the external environment (36, 137, 138). Notably, families of ethnic minorities, socioeconomic adversity, and families in which parents suffer from mental health problems have an increased risk of not benefitting sufficiently from universal efforts (25, 105, 139).

Regarding targeted interventions, parents may experience challenges, if the intervention implies that they have to change behaviors and habits that are integrated in their lifestyle and overall way of

living (140). Therefore, to compile with the challenges in vulnerable families, the targeted intervention should address the specific needs and vulnerabilities of the family, e.g in families of ethnic minorities and in families in which the parents suffer from mental health problems (139). The challenges experienced by parents with limited cognitive, mental, and social resources and in particular, the vulnerabilities of parents with psychiatric problems are often overlooked aspects in the planning of preventive interventions. Still, these aspects must be considered both in the ethical considerations and in the detailed planning of an intervention, and they have to be included in the teaching and supervision of the professionals, who deliver the intervention.

2.7 Denmark as a lab for research in community-based strategies to address mental health and healthy weight in infancy

Public health intervention research in childhood has unique opportunities in Denmark, due to a municipality child health surveillance attended by more than 95% of infant families (141, 142) and the comprehensive Danish population registries which comprise data on health and social conditions of all citizens recorded through the unique civil registration system (143). Hereby it is possible to reach and invite all families for research, and to ensure the valid tracking of subjects for examinations and follow-ups, and to assess the influences on study findings due to nonparticipation (142).

The child health surveillance in Denmark includes home-visits to all families with an infant, delivered by a community health nurse, CHN, and anchored in the municipality social services (26, 111). The CHN assesses child health and development, and measures length and weight, at an average of four times within the first year of the child's life.

It is a part of the standard services that parents are given advice regarding e.g breastfeeding, nutrition, and the overall infant care, as well as advice regarding the stimulation of the child's psycho-motor development and the parent-child relations. Within the administrative and economic limits set by the individual municipality, the CHN may extend the services to target specific problems and needs of the child and the parents. About 20% of all infants receive more visits than included in the standard care, mostly in the form of elaborated parent counseling, e.g. concerning infant problems of eating and sleeping, or regarding emotional reactions, or the parent-child relation, or maternal mental health problems (144, 145).

The CHNs follow national guidelines regarding children's eating, meal habits and physical activity (146). Still, no validated intervention is available that specifically address the CHNs' actions to prevent infants' mental health problems and risk of overweight.

2.8 Targets and potentials of preventive intervention explored in municipality settings

The lack of preventive intervention to address mental health and healthy weight development in infancy, leaves parents and CHNs without tools to reduce the impact of infants' cognitive and regulatory vulnerabilities, even in a society as the Danish with an otherwise well-functioning child health surveillance.

Pioneering work to specifically address the gap in knowledge on effective prevention within the child health surveillance has been ongoing in Denmark since 2000 (147). Among the results from this work, the recordings of the CHNs' observations and assessments of child health and development have been standardized, and they are currently validated in a collaboration comprising 33 Danish municipalities and the Child Health Database, located at the National Institute of Public Health (147). Research embedded in this collaboration has provided solid evidence on the specific needs and challenges for specified prevention regarding mental health and overweight (13, 18, 26, 35, 41, 44, 61, 90, 147-149). Thus, reliable markers of mental health vulnerabilities have been identified, showing that problems of language, attention, activity and interests, contact and communication, and problems of eating, sleep and emotional regulation are highly predictive of mental health problems later in preschool age (26, 35, 41, 90). The research based on the settings of CHNs in Denmark has replicated international research findings and underscored that the parent-child relation acts as the main moderator of risk and resilience, across domains of child vulnerabilities (26). Notably, the child age of 8 to10 months has been identified as a window of opportunity regarding the valid identification and subsequent intervention concerning infants' cognitive and regulatory vulnerabilities (149), and a standardized measure has been developed (150), and thoroughly validated (150-152). Hereby, a valid starting point for intervention has been identified in a period of life in which prevention is considered to have the highest impact (34, 153). The measure called PUF (in Danish Psykisk Udvikling og Funktion) has recently been integrated in a program of basic intervention, the PUF-program (154). The program includes education, training, and guidelines of action within the existing routines. Pilot-testing has demonstrated high face validity and feasibility of the basic PUF-program, which is now implemented in 17 Danish municipalities (154).

Still, the pilot study of the basic PUF-program has highlighted a group of particularly vulnerable infants in need of a more specific and intensive intervention that address major cognitive, physiological, emotional, and behavioral problems. Also, the challenges faced by psycho-socially

vulnerable parents have been highlighted, and the importance of taking the specific needs of these parents into account in the planning of a more specified intervention has been underscored.

The lack of an effective and feasible preventive intervention for the most vulnerable infants and their families stands in contrast to the mounting evidence on the developmental impact and long-term consequences of mental health problems and overweight in early childhood.
Notably, the promotion of sensitive parenting via specified and intensive support from CHNs to parents stands out as a promising avenue of intervention to capture cognitive and regulatory precursors of mental health problems and overweight, but the specific contents and the potentials within existing services lack to be systematically explored.

2.9 Objectives and hypothesis
The study aims

- to develop an intervention to promote sensitive parenting of infants with developmental and regulatory problems at ages 9-10 months, which is based on the VIPP-method adapted to the PUF-program (the VIPP-PUF intervention) to be implemented within the settings of CHNs, and
- to examine the feasibility, fidelity, and the effectiveness of the VIPP-PUF intervention with the outcome early in childhood, and specifically at child ages 18 and 24 months.

The primary hypothesis:

The VIPP-PUF intervention is hypothesized to be feasible within the municipality settings of CHNs. Among infants with high levels of developmental, and regulatory problems at age 9-10 months, adding the VIPP-PUF intervention to treatment as usual, will reduce mental health problems (primary outcome).

The secondary hypothesis

1. Among children with high levels of developmental, and regulatory vulnerabilities at age 9-10 months, adding the VIPP-PUF intervention to treatment as usual will promote healthy weight development (secondary outcome).
2. Among infants with high levels of developmental, and regulatory vulnerabilities at age 9-10 months, adding the VIPP-PUF intervention to treatment as usual will reduce infant cognitive and regulatory problems (secondary outcome).

3. Among infants with high levels of developmental, and regulatory vulnerabilities at age 9-10 months, adding the VIPP-PUF intervention to treatment as usual will reduce parents' experiences of stress and promote sensitive parenting and parents' feeling of competence and relatedness.

4. Among infants with high levels of developmental, and regulatory vulnerabilities at age 9-10 months adding the VIPP-PUF intervention to treatment as usual will reduce the development of dysregulation from infancy to age 24 months.

5. Among infants with high levels of developmental, and regulatory vulnerabilities at age 9-10 months adding the VIPP-PUF intervention to treatment as usual will promote decreasing levels of non-responsive parental feeding practices, higher levels of child eating self-regulation, and fewer problematic eating behaviors in the first two years of life

3 Methods

The development, implementation and evaluation of the intervention is guided by the Intervention Mapping approach (155), guides for development of complex interventions from the UK Medical Research Council (156) and the RE-AIM-method (157, 158).

3.1 Study area, settings, and population

The study is anchored in the settings of CHNs in the municipalities of the Child Health Database, CHD, (159) and conducted among the municipalities who have implemented the basic PUF-program in 2018-2019 (154) and 2020. The study municipalities are overall representative of the municipalities in the Child Health Database and the Danish population regarding key background characteristics (160).

Anticipated number of participants

By 1st of October 2020, a total of sixteen municipalities consented to participation, and we expect all of them to complete participation in the study. The 16 participating municipalities have around 8280 births per year in total (161). Based on the primary planned recruitment period of 16 months (1.3.2021-30.6.2022) an estimated ~10,350 infants will reach 9-10 months during the data collection period. Based on data from the Child Health Database (162), we expect around 88% of the children (~9,100) born in the study municipalities to receive home visits at age 9-10 months and be assessed by the PUF-measure as well. Based on previous research (26, 147, 150, 152, 154), we

estimate that about 16% of children assessed with the PUF method have three or more (≥3) problems indicating major developmental or regulatory problems. Children will be excluded from study if they have severe mental or physical disabilities or if their parents have major problems in speaking or understanding Danish or English. It is expected that a total of 5% of the population meet the exclusion criteria, which leaves us with ~8,650 children estimated to be eligible for the PUF assessment and around ~1,380 children eligible for participation in the study.

Status October 2022:

The outbreak of the COVID pandemic in the beginning of March 2020 has had an immense influence on the study-flow and the recruitment rate in the participating municipalities, which at times has ranged from 70% in some municipalities to zero in others. Consequently, we have had to extend the overall study period including the recruitment period, and strong efforts have been made to intensify the recruitment in the individual municipalities. The PUF-program education to correctly identify the vulnerable children, has thus been boosted, delivering regular brush-up courses by special educated project CHNs. A total of seven of these project CHNs have been allocated to the Infant Health Study, to further intensify the identification of children meeting the criteria of inclusion, and specifically, to intensify the support to the CHNs in municipalities having low rates of recruitment.

During 2021-2022, the recruitment aims have been adjusted. Firstly, the launch of the recruitment period has been postponed to August 16, 2021, and next, the period of recruitment has been extended to October 31, 2023. Based on the frequency of children identified with three or more vulnerabilities so far, we have adjusted the overall expected identification rate from 16 pct. to 10 pct. of the screened children, with some municipalities recruiting up to 70 % of what we expect, while others only recruit 30% or even less. Still, throughout the recruitment period we have realized a relatively high rate of participation among eligible children invited for participation.

Per October 2022, the recruitment aims are adjusted to comprise around 780 children at baseline, and around 460 children available for the follow-up at 24 months (see Figure 1).

For further sample size justification please see section 4.2.

<mark>*Supplementary information October 2024*</mark>

June 2024-october the data collection in project was forced to pause caused by discrepancies in the ethical evaluations completed by the Research Ethics Committee REC University of Southern

Denmark in 2020 and 2022, and the local Committees on Health Research Ethics in the Capital Region of Denmark June 2024. After approval of the project continuation in the remaining period of data collection from the local Committees on Health Research Ethics, research activities were re up taken October 2024.

Per October 2024, the around 471 children available for the follow-up. At that time, participation of controls and cases at ages the 18 months assessments were 90% and 83%.

3.2 Design

We have chosen the stepped wedge cluster randomized design (163-165) mainly for two reasons. First, it is more feasible to randomize at the municipality level as compared to the level of the individual child or CHN. An RCTs based on randomization of the individual child or nurse would be associated with more logistical demand on the individual municipality or nurse as compared to the stepped wedge design as they would be having both the intervention and the control condition running simultaneously. For practical reasons, all municipalities cannot be trained at the same time but have to be split into three groups, and with the stepped wedge design we utilize this and randomly allocate the 16 participating municipalities to the time at which their health nurses have been trained and start offering the intervention to families. Also, with the SWD spill over is reduced by the randomization of clusters as compared to individual randomization. Second, in the stepped wedge design, interventions are introduced in a stepwise manner to all participating clusters (municipalities in this case) which encourages participation for those who would otherwise have been randomized to the control condition. Initial feedback from our interactions with the municipalities reveals that their motivation is strongly associated with being able to offer the intervention, as many municipalities prioritize early intervention highly. Also, with the stepped wedge design control families are recruited in the early phases of the trial, which enhances the recruiting of a control group with the level of usual care offered at the beginning of the trial. In the control period no participants receive intervention and sequential random crossover to the intervention cannot be reversed (166).

An important advantage of the stepped wedge design is that families only need to consent to participate in a research study and not to be randomized. In our experience this makes a big difference not only to the families, but also the front personnel who are recruiting the families. With a longer recruitment period and higher expected acceptance rates, the stepped wedge design will

result in a larger sample size and less frustration about recruitment among the CHNs who find it very hard to deliver standard care to families, when they have introduced an intervention, they believe is superior. Thus, we believe that the stepped wedge design is associated with the least dropout.

On a practical level, the 16 participating municipalities will be randomly distributed into three clusters (6+5+5), and clusters will be randomized to initiate intervention at three different time points, according to the stepped-wedge design (see Figure 1, flow diagram revised October 2022) (Detailed overview of the design, see Appendix 1).

Figure 1. CONSORT diagram

Randomization and screening (PUF) at child-age 9-10 months
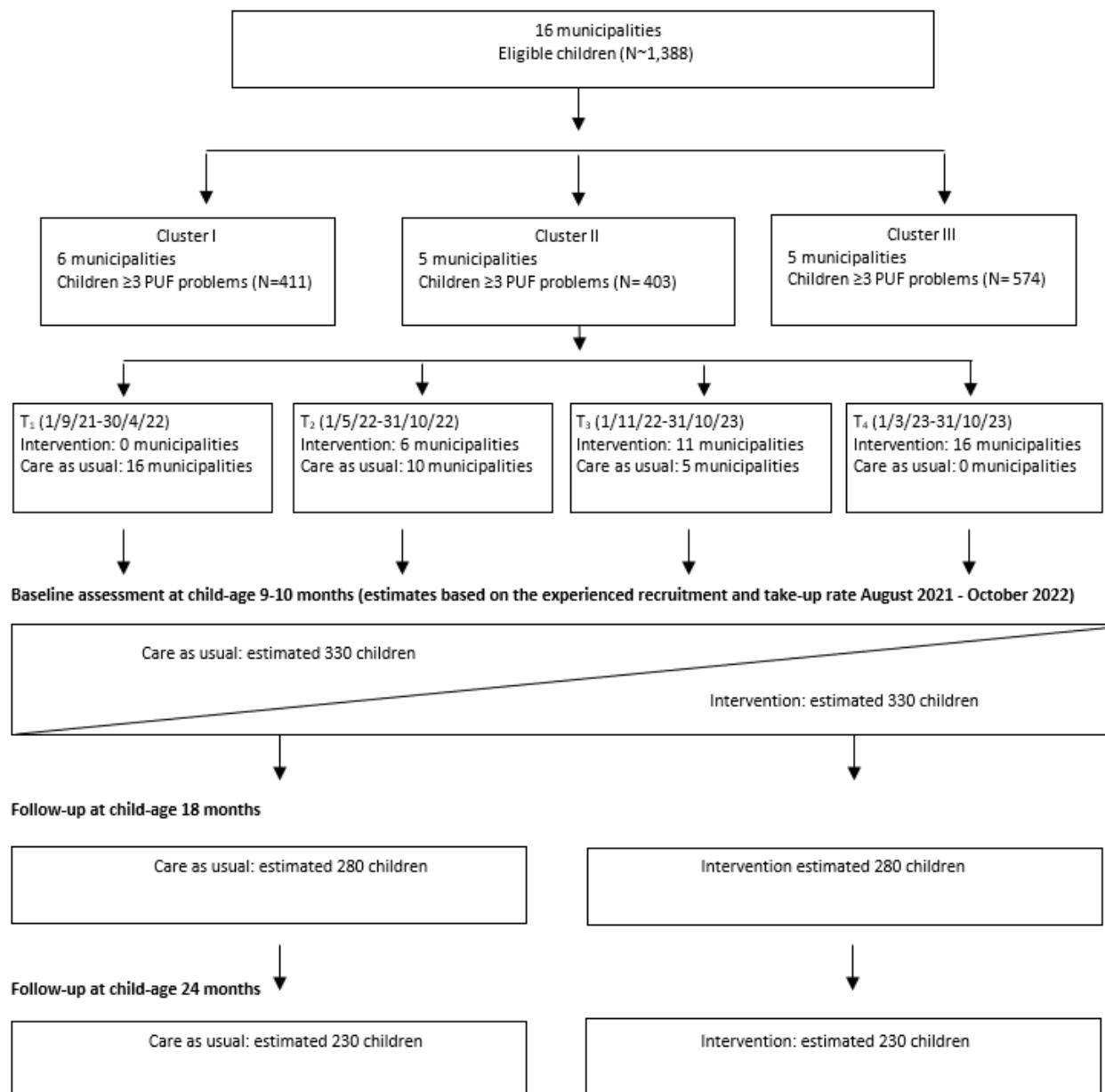
According to the randomization of municipalities, all children assessed to have ≥3 problems will function as controls and receive care as usual from Step 0 until the municipalities initiate the intervention in Step 1- 3, respectively.

*Recruitment of municipalities, children, and parents*

All municipalities that have implemented the basic PUF-program are invited, and the leading CHNs from the becoming study municipalities are invited to join the study planning group as key stakeholders.

In the participating municipalities, the parents of children becoming 9-10 months in the study period are informed about the project by the CHNs, and via written folders and information on the study home page (https://www.sdu.dk/da/sif). At the scheduled home visit at child ages 9-10 months, the CHNs complete PUF-assessment and offer the parents feedback in accordance with the basic PUF-program and the existing routines. All parents of children who have been assessed to have three or more problems are offered extended service, in the control phase of the study this is delivered in accordance with the existing routines of the CHNs in the particular municipalities (care as usual), whereas the CHNs offer the VIPP-PUF intervention to parents in the intervention phase. The CHN informs all parents of infants full-filling the study criteria of inclusion about the details in the Infant Health project, and if parents are interested, they are invited for participation by e-post. Parents make their final agreement for participation by answering the web-based questionnaires at the study website.

Across the stage of recruitment, the CHNs assist parents in gaining information about the study, and if needed assistance in completing the questionnaires (e.g parent with cognitive difficulties).

Participating parents join a lottery with gift certificate of about 40 euro.

Figure 2. The Work Packages (WP) of the project
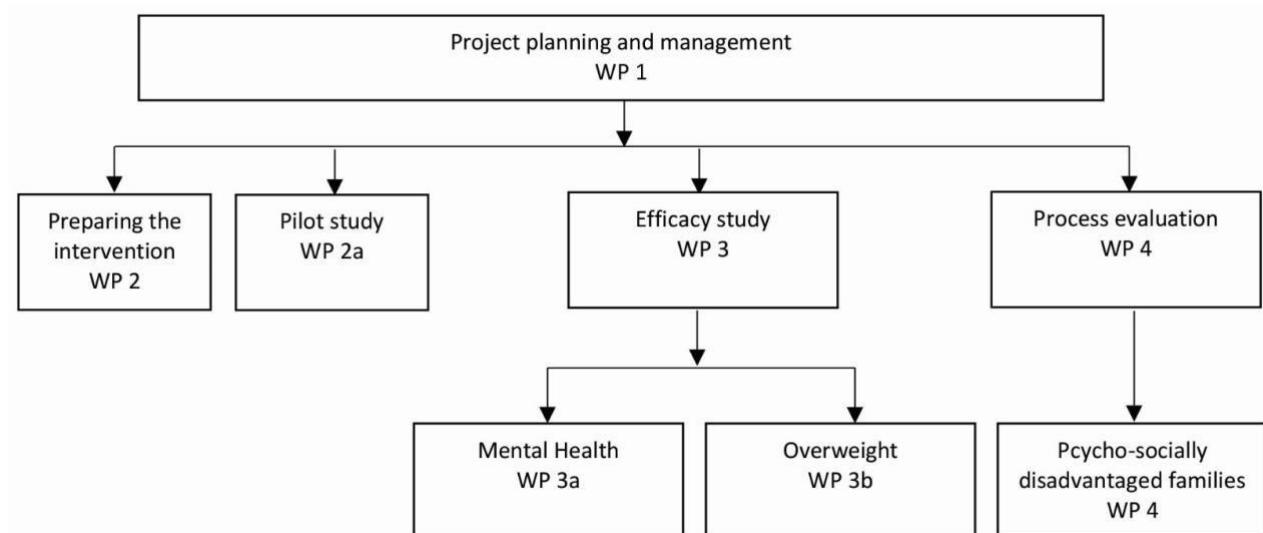
3.3 Measurements

Social and emotional development at ages 9-10, 18 and 24 months

The Ages and Stages Questionnaire, Social-Emotional 2, ASQ:SE 2 (version for children aged 1 to 60 months) (167) is used to measure the child's self-regulation, compliance, communication, and adaptive functioning. It comprises 19 to 33 items rated by parents and includes a box, in which parents can check if the behavior is a concern for them. The ASQ:SE2 is well-validated, and the most commonly used measure of young children's social and emotional development, internationally as well as in Denmark (168-170).

Mental health problems at ages 18 months

The Child Behavior Checklist, CBCL-version for children aged 1 ½ -5 years answered by parents (171) is used to measure problems of eating, sleep, emotional problems, behavioral problems and problems of hyperactivity, concentration, communication, language, and social interaction (42, 46-48, 172-174). The CBCL *1 ½ -5 years* comprises 99 items, including problems of overeating and problems of dysregulation (174). CBCL is predictive of persistent emotional and behavioral dysregulation, including overt symptoms of ADHD (172, 173). It is one of the internationally most used and validated psychometric tools (175), and the version for children aged 1 ½ -5 years has been used in several population-based studies in Denmark (13, 152).

Developmental status at ages 24 months

The Ages and Stages Questionnaire, Third Edition (ASQ-3) (176) is a 30-item measure of child developmental progress. The ASQ-3 consists of the following subscales: communication, gross motor, fine motor, problem-solving, and personal-social. Each developmental area is scored from 0 to 60, and the total score range is 0-300 with higher scores indicating better development. Cronbach's alpha ranges from 0.67 to 0.81 for the five subscales for the version for children aged 24 months (177).

Mental health problems at ages 24 months

The Strengths and Difficulties Questionnaire (SDQ) is a well-validated tool for assessing the mental health in children aged 2–17 years. This study uses the parent-version of the SDQ including the impact supplement (see also www.sdqinfo.org) (178). The SDQ t is a short and feasible measure consisting of 25 items, in which parents answer questions covering main areas of child mental health within the following subgroups: hyperactivity, emotional problems, behavioral problems,

peer problems, and the child's prosocial strengths. Afterwards, the parent is asked to reflect on how impactful the difficulties are to the child and its family. The answers are scored to produce a scale from 0 to 10 for each subgroup, with higher scores reflecting higher levels of difficulty. Each scale can be categorized into three groups, indicating whether the child has a normal, borderline normal or abnormal score.

The SDQ is highly predictive of persistent child mental health problems and has been shown suitable for the prospective investigation of mental health from ages 24 months and onwards (178, 179). SDQ has been validated for use in children down to the age of 2 years (180, 181), and is used in epidemiological research worldwide (181), also in Danish populations, with Danish norms being available on children older than five years (35, 182) (www.sdq.dk). Comparable normative data on children down to the ages of three years is available from Sweden and The Netherlands (183, 184).

Anthropometry measures at ages 9-10 months and 24 months
Weight and lengths are measured by CHNs at four home visits between ages 0-10 months using a handhold beam scale (In Danish: Bismervægt) or a handhold hanging scale (In Danish: babyvægt/hængevægt) and a tape measure, as described in the Danish National guidelines (111). At age 24 months, length and weight will be measured on all children. Furthermore, we will measure body composition on a subsample of 50 children. Recumbent length is measured nearest to 0.1 cm using the Seca 210 Mobile Measuring Mat for Infants and Toddlers. Weight is measured nearest to 0.1 g using Seca 878. Weight-for-length z-scores will be calculated using the software program, the World Health Organization (WHO) growth standards and including the infant's sex. These standards have been recommended for use in children younger than 24 months of age (185).

Body composition. The increasing prevalence of childhood overweight highlights the need of validated measures to accurately identify individuals' risk for the development of overweight and overweight-related diseases. Growing evidence acknowledges that assessment of body composition during infancy and early childhood is the most valid measure to accurately identify individuals at risk of overweight in both clinical as well as in research settings. Several technologies exist to measure body composition by defining fat mass and fat-free mass in infancy. However, the equipment is typically large, and thus not readily portable, is expensive and requires a qualified operator. Among the measures available to the valid assessment of body composition in young

children, bioimpedance is simple, easy to use, safe, and feasible for use in children aged 24 months (186, 187). We will measure bioimpedance using the Impedimed SFB7 device (ImpediMed, Brisbane, Australia) to calculate fat (FM) and fat-free mass (FFM) on a subsample of 50 children. Based on previous literature on young children, we will use reference values for body composition for children to identify excess adiposity (74).

Child eating behavior and parental feeding practices at ages 18 and 24 months
Parental Feeding Practice. Based on face and content validity of the Preschooler Feeding Questionnaire (PFQ) and the Child Feeding Questionnaire (CFQ), we will include these measures in toto or with relevant subscales at ages 18 and 24 months to assess parent's perception of their feeding practices. The PFQ is a 32-item questionnaire developed and validated for children between the ages 2 to 5 years (188) compromising nine subscales. The Child Feeding Questionnaire (CFQ) in its original form is a 28-item questionnaire validated for children aged 2-11 years (189). All subscales included in this study have been demonstrated to have good reliability and internal consistency (189). Response options for the CFQ and PFQ are five-categories expressing agreement (disagree, slightly disagree, neutral, slightly agree, agree) or frequency (never, rarely, sometimes, often, always) depending on the item. Mean scores are calculated for each scale with higher mean scores indicating higher expression of that behavior.

Child Eating Behavior. The Child Eating Behavior Questionnaire (CEBQ) will be used at age 24 months to measure parent's perceptions of their child's eating behavior. The CEBQ includes 8 subscales covering 35 items (190), in which the parents respond whether their child demonstrates the behavior described in each item. Response options range from 1 (never) to 5 (always). Mean scores are calculated for each scale with higher mean scores indicating higher expression of that behavior. The CEBQ has acceptable internally reliability and test-retest reliability (191). The CEBQ has not been validated in a Danish context but has been validated in a Swedish context among children aged 1-6 years (192). The questionnaire is translated into Danish by a professional translator, then back translated and checked by the researcher team for cross-cultural adaptation.

Video-recordings of sensitive parenting and sensitive feeding
Video recordings at child ages 24 months are used to examine child and parent behavior as well as parent-child interaction during feeding and play using the Coding Interactive Behavior (CIB) (193)

to analyze and code, which is describes in the following section. Video recordings are analyzed on a subsample of 100 children.

Parenting and parental stress and family impairment at child ages 9-10, 18 and 24 months
The Mother and Baby Interaction Scale, MABISC (at 9-10 months) (194, 195); the Being a Mother, BaM13 (at 18 and 24 months) (196); the Parental Stress Scale, PSS, (197, 198); and the WHO-5 well-being index, WHO-5 (199, 200); all well validated, internationally and in Danish public health settings (109, 168).

Sensitive parenting will be examined from observer-ratings of video recordings of parent-infant interactions at 24 months of age using the Coding Interaction Behavior (CIB) system (193) to assess the parent-child relationship (201). The CIB system contains of 22 parent behavior codes, 16 child behavior codes, and five dyadic codes which can be aggregated into the following composites: sensitivity, intrusiveness, limit setting, involvement, withdrawal, compliance, dyadic reciprocity, and dyadic negative states. The CIB system has been validated in normative as well as high-risk populations, and shows stability over time, predictive validity, and adequate psychometric properties (193, 202-205). Coders will be trained to intercoder reliability ICC > .65, Pearson's r > .70, and regular meetings and checks will be organized to prevent coder drift.

Child physical health and the social-economic conditions of the family
Data on pregnancy, birth, perinatal factors, and physical and mental health problems diagnosed at hospital are obtained from the Medical Birth Registry and Danish patient registries (160, 206). Information on ethnicity, parental age, family structure, parents' education, and family economic position are obtained from Danish population registries (160, 206). Information on mental health problems in parents and parent-child relation problems recorded by CHNs at home visits between the child's birth and age 6 months are obtained from the Child Health Database (144-146, 159).

3.4 Project planning and management (WP 1)
The project is an extension of our previous work in the study municipalities, and we have previously evaluated the organizational capacity and the structure and content of CHNs' home visits, including descriptions of themes covered in the existing routines at home visits, such as child development and nutrition.
It is a core feature of this project that we use the settings and the best practices of the CHNs as the starting point to develop the specified VIPP-PUF intervention. In line with the Intervention

Mapping approach, the first phase of the study includes the establishing of a participatory planning group comprising the principal investigators and the leading CHNs. Furthermore, CHNs from each participating municipality will join the project planning and will be trained in the original VIPP method (99), from which the VIPP-PUF will be developed. These CHNs function as municipality stakeholders; they facilitate the municipality supervision-groups to be established, and they function as the first generation of VIPP-PUF co-trainers and supervisors in the municipality.

The participatory planning group are thus involved in the decisions of measurements in the efficacy study to be completed in WP 2 and pilot-tested in WP 2a.

Our ongoing collaboration with the CHNs (159) and our previous research related to the implementation of the basic PUF-program (150, 154, 159) has provided a thorough knowledge on local political priorities of child health prevention related to structure and resources for the CHNs' visiting practice and administration, e.g. manpower, number of CHNs, and the administrative structure of CHNs daily work. Further, we have assessed the capacity of implementation and evaluated specific local challenges (e.g. high proportion of families of ethnic minorities or with low socioeconomic status) and local staff competences, interest and engagement, training, and management support.

The information already available from our close collaboration with managing and practicing CHNs in the study municipalities is currently updated in WP 1, and they will be taken into account, when developing the VIPP-PUF intervention, and in the strategies necessary to ensure fidelity and deliver valid results for the efficacy trial.

Overall, the VIPP-PUF will be designed as an add-on to the basic PUF-program for use in the CHNs' ordinary routines between child ages 9 and 14 months, considering the traditions and strategies of the particular municipality, and the recommendations from the National Board of Health (111) that include guidelines regarding the prevention of overweight (146).

Notably, the VIPP-PUF intervention will be embedded in the already existing need-based health visiting system, in which practice is already established and working well. As such our intervention could be viewed as further specialization or professionalization of the current health visiting practice. The thorough organizational capacity assessment already done will ensure that the VIPP-PUF is relevant and applicable to the administrative and practical organization of the current homebased health visiting system.

3.5 Preparing the VIPP-PUF intervention (WP 2)

The goal, scientific foundation and setting of the intervention

The overall goal is to develop a targeted intervention that 1) address infants of particular vulnerability regarding mental health problems and the development of overweight, and specifically target cognitive and regulatory problems, and which 2) can be delivered by CHNs, and 3) is feasible within the municipality child health surveillance.

The intervention will be designed as an add-on to the basic PUF-program (154), which includes a) a basic education of CHNs, b) the CHNs' systematic evaluation of infants aged 9-10 months, c) their communication with parents about the infant's needs, and d) the planning of support within the existing service-settings, all in accordance with the manualized guidelines of the basic PUF-program (207). According to these guidelines, the basic PUF program builds on the existing municipality care to address the needs the individual families and in particular the needs of families of socio-economic and psycho-social disadvantage. The primary focus of the VIPP-PUF intervention is to educate CHNs in promoting sensitive parenting, and the VIPP-PUF will be developed to full fil the following demands:

1. address infants with major vulnerabilities regarding mental health problems and healthy weight development indexed as three or more problems of cognitive and regulatory functioning at the PUF assessment at age 9-10 months (children with two or less problems receive care as usual including the basic PUF-program),

2. be acceptable for parents, considering challenges experienced by families of immigrants, young parents, and parents with limited cognitive, mental and social resources,

3. not stress the participating children or families,

4. be sustainable and integrated into the existing structure of CHNs' home visiting program and education,

5. adhere to the official guidelines within the CHNs' practice,

6. be acceptable and appropriate for the CHN, who will be the main responsible professional for the implementation and delivery of the intervention.

Parenting as a core ingredient of intervention to promote healthy development in early childhood

The VIPP is basically a highly structured intervention to promote parents' observational skills and capacity to empathize with the child (208). The intervention is delivered at home, by health professionals and across six to seven sessions of about one hour. Each session is standardized and

includes education of the parents on topics covering infant and toddler development, using video recordings and feedback to promote parents' sensitive responsiveness and sensitive discipline (209). The VIPP is based on attachment theory and theories of social learning (210, 211). The method has been thoroughly validated as a cost-effective tool to promote parental sensitivity and child attachment in vulnerable infants (210, 211), and has been shown to be modifiable to various areas of infant mental health (209) e.g. regulatory problems (212); feeding and eating problems (209), and behavioral problems (213); and it has shown to be feasible in various cultural settings and populations, e.g. families of ethnic minorities, and families of limited cognitive or psycho-social resources (214), and mothers with eating problems (115, 116). Meta-analyses of RCT studies of VIPP show a substantial combined effect size for increased caregiver sensitivity, and a robust combined effect size for improved child outcomes (215). Importantly, being short and with a clear behavioral focus, VIPP has shown to be more effective compared to longer lasting programs (114). The VIPP has been developed in the Netherlands, in populations comparable to the Danish and the fidelity has been documented in community settings, and also in families of socio-economic and psycho-social disadvantages, e.g. families of immigrants, young parents and parents with limited cognitive, mental and social resources (113).

Adapting the VIPP to the PUF-program to address infant vulnerabilities within the settings of community health nurses

The VIPP method does not systematically address the full range of infancy vulnerabilities regarding mental health and healthy weight, and the measure has not been tested in settings like the Danish CHNs. Still, we consider the VIPP method to be an obvious starting point for the development of the focused intervention in Danish municipality settings. Firstly, because VIPP is short, effective and highly feasible in populations which are comparable to the Danish. Secondly, because it has shown effectiveness regarding intervention towards a range of infant problems and parental vulnerabilities as e.g. families of ethnic minorities, socio-economic adversity, and parental mental health vulnerabilities including parental eating problems. Accordingly, we collaborate with the VIPP Institute and the PI of the VIPP research professor Marian Bakermans-Kranenburg to adapt the VIPP to the PUF-program.

The VIPP-PUF intervention is planned to be of a duration and frequency like the core VIPP methods (209), comprising a package of six to seven sessions of approximately 60 minutes.

Moreover, the VIPP-PUF will build on actual practices in the Danish home-visiting program, and experiences from the pilot-testing of the PUF-program (111, 154).

Education and supervision of community health nurses

The education builds on the education in the PUF-program, which covers baseline knowledge for CHNs regarding infants' health and developmental vulnerabilities (207). The active ingredient in the VIPP-PUF is the CHN's training and supervision in the VIPP based video-feedback approach to promote parents' knowledge and understanding of age-related behavior and reactions. Specifically, the CHNs are trained and supervised to address the promotion of parents' sensitivity and sensitive responsiveness regarding the cognitive and regulatory difficulties identified in the child.

Initially, a group of 11 CHNs were educated in the original VIPP method to enable them to contribute to the adaptation of the VIPP into the VIPP-PUF intervention. Further, these CHNs participate in the pilot testing of the VIPP-PUF, and they function as co-trainers and supervisors of the next generation of CHNs educated in the VIPP-PUF during the project period.

Based on estimates of the number of vulnerable infants fulfilling the criteria of inclusion and the need of minimum two CHNs educated in the PUF-VIPP method per municipality, a total of 49 CHNs have been educated in the VIPP-PUF method since June 2021. The VIPP-PUF education consists of a four-days course including teaching in the theoretical basis of the VIPP, building on attachment theory and theories of mentalization and social learning, as well as the developmental approach of the PUF-program integrating case-based learning and practical exercises. The initial VIPP-PUF course is followed by training in using the VIPP-PUF intervention to parents of a child aged 9 to 12 months, notably a child without problems and from a non-vulnerable family. During this training the CHNs receive individual supervision in groups by a certified supervisor from the VIPP- Institute, Leiden, the Netherlands, delivered before each of the five home visits in the training period. Next the CHNs receive a one-day booster course in the VIPP-PUF method around one week ahead of intervention start in their municipality. During her first VIPP-PUF intervention to a vulnerable child, the CHN receives two sessions of individual supervision by a certified supervisor, alternating with peer-supervision in groups led by experienced VIPP-PUF CHNs

The evaluation of the VIPP-PUF intervention includes an evaluation of the needs of educating specific Danish VIPP-PUF supervisors in collaboration with the VIPP Institute, this to ensure the sustainability of the VIPP-PUF training and supervision during the project period and beyond.

Development of intervention components

The specific tools and activities of the intervention will be developed in a participatory planning group and in dialogue with the Project Steering Group.

Educational experts, graphic- and web-designers, videographers and writers will be consulted to develop the web-platform and extended scripts, plans, visual and written outlines (booklets, leaflets/handouts/newsletters) and video demos (visual presentation of information, skills training, and case situations).

Focus discussions involve CHNs from the study area and parents, recruited by local CHNs (WP4).

3.6 The pilot studies (WP 2a) conducted 2021-2022

The aim of the pilot studies is a) to evaluate the face validity and feasibility of the VIPP-PUF intervention developed in WP2; and b) to assess face validity and feasibility of baseline and outcome measurements. The pilot studies include a comprehensive evaluation of 1) the recruitment procedures, 2) the feasibility and effectiveness of the CHNs education and training, 3) the feasibility of the VIPP-PUF intervention within the existing routines of CHNs 4) the parents' motivation, compliance and acceptance of the intervention, 5) the function of the web-platform, and 6) pilot studies of the practical procedures and feasibility and parents experiences regarding the assessments and questionnaires used at 9-10 months, at 18 months and at 24 months. Specifically, we will 7) evaluate the measures of the efficacy study (WP3), adjust the process evaluation (WP4), and to evaluate 8) the overall study frame, the particular delivery tools, and to assess the overall feasibility of the primary, intermediate and secondary measures.

Methods: The pilot studies are conducted in two strategically sampled municipalities of at least 500 births a year with estimated 6-10 CHNs and considering diversities regarding background population and municipality resources.

To evaluate the feasibility of the VIPP-PUF intervention, the acceptability and usefulness of the web-based questionnaires, web-platform (RedCap, e-box delivery, and dunning procedures) and the needs of assistance to the parents of limited cognitive or psycho-social resources, the strategic sample includes high as well as low resource families, families of different ethnic and cultural backgrounds, and in particular families of disadvantaged psycho-social conditions.

Procedures: The practical procedures are elaborated by the Participatory Planning Group and tested in the two pilot study municipalities.

Parents of infants going to be assessed at age 9-10 months according to existing routines are invited for participation 2-4 weeks prior to the home-visit at age 9-10 months. Parents of infants becoming 18 and 24 months during the study period are invited for participation in the testing of intermediate and outcome measures at these ages, including the measurement of weight and length and body composition at an extra home visit at child ages 24 months. Also, the video-recording-study (CIB-study) will be pilot tested.

Estimated 2-4 infants per CHNs will have ≥3 problems at the PUF assessment and therefore be offered intervention, of which estimated 2-3 of the families agree to participate, leaving a total of 4-6 infant families to participate in the pilot-intervention and asked to fill out the parent questionnaires at child ages 9-10 months. Further, four families per municipality, who have infants previously tested with the PUF-measure at ages 9-10 months and are invited for the pilot testing of web-questionnaires and practical procedures at ages 18 and 24 months, including the procedures concerning parents' video-recordings of feeding and play to be coded by CIB.

The feasibility of the VIPP-PUF intervention is evaluated as part of the overall process evaluation (see the separate protocol of the WP 4-study), which run in parallel to the preparing process (WP1), the intervention planning (WP2) and the pilot-studies, involving both CHNs and parents. The evaluation includes questionnaires to CHNs regarding the adherence to the intervention e.g. the extent to which activities are possible to implement in accordance with the intervention designed. Further, the process evaluation comprises participant observations at home visits, focus group interviews with participating CHNs and with parents involved in the pilot-intervention (detailed description of the process evaluation - see section 3.7 and the separate WP 4 protocol).

Included in the pilot study is the assessment of the test-retest and interrater-reliability of the anthropometric measures at ages 9-10 and 24 months, and the coding of sensitive parenting (CIB) at ages 24 months.

Focus group interviews of CHNs will be pilot tested and further expanded in the WP 4 to evaluate the feasibility and effectiveness of CHNs education, training and supervision, and to explore the recruitment procedures, the function of the web-platform (RED-CAP), the feasibility of the

practical procedures related to the VIPP-PUF intervention, and regarding the follow-up assessment, including the parents need of CHN's assistance to fill out the questionnaires.

Also, the CHNs' experiences in using the specified intervention will be explored.

Semi-structured interviews of parents of infants with ≥3 problems will be pilot tested to be further used in the WP4. The pilot testing will contribute with preliminary knowledge on the parents' experiences of the recruitment procedures and the web-based questionnaires. Both mothers and fathers are invited, and we will evaluate the needs in families of different social and cultural-ethnic composition, and to what extent parents of limited cognitive or psycho-social resources need specific support.

Also, pilot-testing is conducted prior to WP 4 to get preliminary knowledge on the parents' experiences regarding recruitment, information, and communication about the VIPP-PUF intervention; and the parents' evaluation of the frame, setting and content of the intervention.

Data analyses and results: We will assess face validity, feasibility, and reliability of core measures of the main study and use the results from the pilot studies to adjust the study measures. Also, findings from these studies are used to decide the further progress of the study, including a stop-go decision or the continuing of WP3 and WP4. Notably, major problems of recruitment (municipalities and/or families) will elicit considerations about the feasibility of the full trail, or whether minor needs of adjustment have to be implemented.

3.7 The effectiveness study (WP 3)
The effectiveness of the VIPP-PUF intervention is measured as a significant reduction in mental health problems (WP 3a) and a healthy weight development at age 24 months (WP 3b) among vulnerable infants, comparing infant who have received the VIPP-PUF intervention to infants, who have received care as usual.

Outcomes
The primary child outcome is child mental health at age 24 months measured by the Strengths and Difficulties Questionnaire, SDQ (178).

The secondary outcomes measured at child age 24 months include weight-for-length z-scores, body composition, measures of child development (Ages and Stages Questionnaire 3) and of parental well-being, parental stress, and parents' experiences of family impairment (Being a Mother- questionnaire, BaM1 (196); the Parental Stress Scale, PSS, (197, 198); and the WHO-5 well-being index, WHO-5 (199, 200)). Also, parental feeding practices, child eating behavior, parental sensitivity and parent-child interactions during mealtimes will be assessed by the Preschooler and Child Feeding Questionnaires, PFQ and CFQ (188, 189); the Child Eating Behavior Questionnaire, CEBQ (190); and by video recordings coded using the Coding Interactive Behavior, CIB (216).

Intermediate outcomes at child-age 18 months include child mental health and development measured by the Ages and Stages Questionnaire, Social-Emotional 2, ASQ-SE2 (167) and the Child Behavior Checklist, CBCL-version for children aged 1 ½ -5 years (171), which includes information on regulatory problems of eating, sleep, emotions, and behavioral and cognitive functions (42, 46-48).

The intermediate outcomes at age 18 months include measures of sensitive parenting, the Mother and Baby Interaction Scale, MABISC (at 9-10 months) (194, 195); and measures of parents' wellbeing and feeling of competence and relatedness, and parents' experiences of stress, the Parental Stress Scale, PSS, (197, 198) and the WHO-5 well-being index, WHO-5 (199, 200) as well as measures on parental feeding practices, the Preschooler and Child Feeding Questionnaires, PFQ and CFQ (188, 189).

WP 3a: The effectiveness of the intervention on the child' mental health
The effectiveness of the VIPP-PUF intervention is measured as differences scores of mental health difficulties (SDQ total score) among vulnerable infants, comparing infants receiving intervention to infants receiving care as usual. Analyses of the intermediate effect of the VIPP-PUF intervention will also be carried out by comparing scores on the CBCL and ASQ:SE2 at 18 months between the two groups.

As potential prognostic factors we include the CHNs' records of infant development and regulatory functions at age 2-4 weeks, together with their records at ages 2-3 months and 4-6 months. Parents answers to the ASQ:SE2 at child-age 9-10 months will also be included, to indicate the socio-emotional development at the baseline assessment. Other potential risk-factors will be included in

the analyses such as parents' socio-economic status, parental age, parental mental health problems, marital status, child gender, birth parameters. Exploratory analyses of the intervention effect on parental well-being (assessed by various repeated parental questionnaires), and to what degree that effect alternates the intervention effect on the primary outcome will be carried through.

WP 3b: Weight development

The effects of the VIPP-PUF intervention on weight development is measured as differences in weight-for-length z-scores among children with cognitive and regulatory problems at age 9-10 months who receive the VIPP-PUF intervention compared to infants who receive care as usual, CAU. Furthermore, we will investigate the effect of the VIPP-PUF intervention on body composition at age 24 months, and whether the VIPP-PUF intervention can promote decreasing levels of non-responsive parental feeding practices, higher levels of child eating self-regulation and fewer problematic child eating behaviors in the first 2 years of life.

Planned analyses include weight-for-length z-score at birth (217, 218), and the role of pre-and postnatal risk factors for childhood overweight on weight-for-length z-score at age 24 months (219, 220). Also, we plan to analyze examine weight trajectories from birth to age 9-10 months, as well as the influences of early feeding, eating, sleep and overall regulatory problems between ages 2 and 6 months as evaluated by CHN's at home visits ages 2-4 weeks, 2-3 and 4-6 months. These evaluations are based on the CHNs overall conclusion about the infants' feeding/eating/ sleep or crying and rated by the CHNs as being of concern or not (159).

The role of ethnicity, socioeconomic position of the parents and parental mental health problems will be addressed, using data from National registries or from the Child Health Database, including recorded by CHNs at home visits between ages 0 and 6 months. Specifically, we will explore whether trajectories of feeding and eating behavior and of dysregulation (eating, sleep, and emotional expression) measured between 2 and 9 months (44) and 18 and 24 months will be modified by the intervention, and to what degree eating behavior and dysregulation influences the weight-for-length-z scores at ages 24 months. Also, we will investigate the influences of parental experienced stress and parent-child relational problems at ages 9 month and 18 months on weight-for-length z scores at age 24 months.

3.8 Process evaluation- What works for the vulnerable families? (WP 4)

The aims of the overall process evaluation are 1) to document the development of the VIPP-PUF intervention, 2) to explore and analyze the implementation process of VIPP-PUF to obtain knowledge about activities and effects, and to extend the understanding of the relationship between the intervention and the outcome (221). The WP 4 of the Infant Health Study now include a specific in-depth mixed methods study, WP 4a, and an ethnographic study exploring the context of the Danish municipality child health care targeting infant families, WP 4b (See the separate WP 4 protocol description). Pursuing the second aim of the process evaluation, we will have a specific focus on vulnerable families, which include infants with major vulnerabilities regarding development and regulation, as well as vulnerable parents, i.e. parents of psycho-social adversities such as mental illness, low education, low income, and being ethnic minorities (36, 137, 138).

Data collection and analysis will run in parallel to the, the intervention planning (WP2), the pilot study (WP 2a), and the efficacy study (WP3), and includes questionnaires and interviews of the CHNs, parents and stakeholders.

Ad 1) The process of intervention development and pilot testing (WP2 and 2a) involves both CHNs and parents. We include participant observations at home visits (222), focus groups interviews (223) with participating CHNs and individual, semi-structured interviews (224) with the involved parents.

Ad) 2 Based on established process evaluation frameworks (221, 222, 225-228), we will explore recruitment to the intervention, evaluate whether the intervention is implemented as intended (fidelity), and whether and to what degree it has reached all families within the intended target group and across various risk groups (reach), as well as barriers and facilitators of implementation. Also, we will assess participant responsiveness among CHNs and parents, and their appreciation of and satisfaction with the intervention program, to get a deeper understanding of how, why and for whom the intervention was effective or not (222) (please see Table 1 for the applied process evaluation concepts).

In the in-depth mixed methods study (See separate protocol) we will thoroughly explore whether the VIPP-PUF intervention has reached all families across various risk groups and assess the particular needs and experiences among families of high vulnerability and low socio-economic position (WP4a).

For this part of the process evaluation, we will combine quantitative and qualitative methodologies (229, 230). Data collection and analysis run in parallel to the WP3, and will be based on questionnaires and interviews of the CHNs, parents and stakeholders in the study area concerning the implementation of the study e.g. the fidelity and reach of the intervention.

Fidelity
In order to gain a comprehensive picture of the implementation of the intervention, we will measure implementation by multiple aspects of implementation fidelity, such as structural aspects, adherence to the intervention and dosage of implementation. Also, we will explore procedural aspects, such as quality of delivery and participant responsiveness (221, 225).

Table 1. Applied process evaluation concepts

Process evaluation concept	Definition/operationalization	Data collection
Recruitment	Description of procedures used to approach and attract participants, and characteristics of participants and non-participants.	Information on child and family characteristics (see page 11-12 for elaboration) are obtained from national population registries and the Child Health Database as described in the main protocol of the Infant Health Study. Focus group interviews with CHNs will be used to nuance the understanding of the recruitment process and the nature of perceived barriers and facilitators of their recruitment of different types of families. CHN's will systematically register parents' reasons for declining the invitation. Additionally, recruitment barriers will be explored through interviews with families, who end up with non-participation either because they decline the invitation or because the CHN consider the families to be ineligible to participation.
Reach	The proportion of the target population that participates in the Infant Health Study compared to those who do not.	Data on child and family characteristics will be collected from national registries and the Child Health database. Information on the degree of participation will be

		collected through questionnaires among participating families.
Dose delivered	The amount of the intended units of intervention delivered by the intervention providers, e.g., number of conducted home visits.	Data will be collected through CHNs' self-monitoring checklists for each VIPP-PUF intervention session.
Fidelity	Information on the extent to which the intervention was implemented and delivered as planned (quality and integrity of the intervention delivery), including information on adaptations and reasons for adaptations.	Data will be collected through leading CHNs' recordings and through CHNs' self-monitoring checklists for each VIPP-PUF intervention session relating to all main elements of the VIPP-PUF intervention as described in the manual. Examples include the specified video recordings during daily situations at home visits; themes of the program delivered for each session and successively elaborated during the intervention period; the CHNs' use of the manualized instruction for feed-back to the parents; and the delivery of written material on sensitive parenting including sensitive responding in daily situations about e.g., eating and feeding. Also, fidelity is explored through participant observations of 10-15 home visits where the program is used and through interviews with the CHNs (see p.15-17 for elaboration of the qualitative methods).
Participant responsiveness	Information on participants' (receivers and providers) receptiveness and acceptability, how they respond to, are engaged by, and enact an intervention, their enthusiasm and interest, their judgement about the outcome, relevance, and usefulness and how far they accept the responsibility of the intervention and holds the attention.	Data will be collected through questionnaires to parents and CHNs as well as through individual interviews with parents and CHNs.

Barriers and facilitators of participation	Knowledge on what barriers and facilitators CHNs and parents experience when participating in VIPP-PUF.	Data on what families and CHNs experience as either facilitating or hindering their participation in the intervention will be collected through questionnaires and individual interviews with both parts.

Interview guides will be developed for both the focus groups and the semi-structured individual interviews. Interviews will be audio-recorded and transcribed verbatim and anonymized (231).

The separate WP 4 study (See the protocol for WP4-version January 2022) includes in-depth ethnographic explorations within the settings of municipality child health care as a context of early identification and preventive interventions, WP 4b (232-235). We will explore the current preventive practice as well as the specific implementation of the VIPP-PUF. Hereby, the study will inform a profound understanding of the complexities in the implementation process, which are needed in the interpretation of the outcomes of VIPP-PUF. The study will include the perspectives of parents, CHNs and leading CHNs regarding based on semi-structured interviews with parents, CHNs and leading CHNs, focus group interviews with CHNs and participation observations of home visits.

For further details regarding the process evaluation, please see the protocol for WP4 a and WP4 b (version January 2022).

3.9 Health economic evaluation

Health economic expertise will be consulted to plan the evaluation of the cost-effectiveness of the VIPP-PUF intervention, including data from Danish national registers and data on service use from the Child Health Database.

4 Data analysis

4.1 Analyses of qualitative data

The empirical material (i.e. transcriptions of interviews and field notes) will be analyzed following general principles for qualitative data analysis (236, 237). We will perform a systematic coding approach to identify important themes across the empirical material. We will read through and code the material in order to group the codes and categories into overall themes. Recurrent topics will be

identified, compared and categorized. Different forms of theory will be applied in the analyses to reach new theoretical insights e.g., on vulnerability. The analytical process will be inspired from 'collaborative data analysis' (238), through which different perspectives are brought to bear on the analysis and interpretation of the data. The analysis and interpretation of results will be brought into dialogue with the existing research on the research topic.

Thematic analyses of interview and focus group data will be driven by the research question and allow for more inductive analysis whereby emergent themes are also identified (236).

4.2 Statistical analyses

Statistical analyses will be carried out according to the intention to treat principle, where the participants are analyzed according to their CAU/intervention recruitment group. For continuous outcomes (including the primary outcome measured as the SDQ total difficulties score), linear mixed models will be fitted to compare the control group receiving care as usual (CAU) and the VIPP-PUF intervention group. For binary outcomes (e.g., border line/abnormal versus normal SDQ score), logistic mixed-effects regression models will be fitted to compare the control and intervention groups. All models include municipality-specific random effects, allowing for the correlation between outcomes of children from the same municipality. Likewise, cluster-specific random effects will be included.

Differences in weight-for-length between intervention and control groups will be evaluated using analysis of covariance (ANCOVA). Associations between weight-for-length z-score and selected risk factors based on their associations with infant behavior and preschool obesity in the published literature will be explored using linear regression. To assess differences in parental feeding practice and infant eating behavior between intervention and control groups, mean scores on the feeding and eating questionnaires subscales are calculated and analyzed using linear mixed models for repeated measurements, including participant-specific random effects. Further, exploratory analyses regarding feeding practices, eating behavior, and weight development will be carried out.

Other prognostic factors identified from the literature á priori will be included in analyses. Examples include parents' education, employment status, household income, ethnicity, parental age, parental mental health problems and marital status (all obtained from national registers) (160); at the child level, sex, birth parameters, weight-for-length z-scores from birth to age 9 months, regulatory problems from ages 2-9 months, and ASQ:SE2 score at 9-10 months; and at the

municipality level, e.g., level of social disadvantage. Interaction terms will be included to explore possible differences in intervention effect (on the primary outcome SDQ score only) between gender, pre-defined subgroups based on weight-for-length z-scores 0-9 months, low versus high scores of regulatory problems 2-9 months (0-2 problems versus ≥3 problems of eating, sleep or emotional dysregulation); low versus high baseline ASQ:SE2 scores and parental characteristics. Also, additional analyses of effect modification will further explore the effect by different population groups (socio-economic position, family structure, and migration status).

We will use path analysis to explore whether the effect of the intervention on weight-for-length z-score at age 18 and 24 months is mediated through the above-mentioned risk factors for childhood overweight. Using path analysis, we can assess the direct effect of the intervention, corresponding to the proportion not mediated through risk factors for child overweight, and the indirect effects of the intervention, corresponding to the proportion mediated through selected risk factors for childhood overweight. The total effect is the sum of the direct and indirect effects.

(Please see the WP4 protocol, WP 4b (Version January 2022) for further details regarding the statistical analyses of the process evaluation).

Sample size re-calculation

Based on recent research (239), an updated sample size calculation has been carried out for testing the primary outcome (the SDQ total score). The mean SDQ total score at the baseline, in children with ≥3 problems, is expected to be 13 (182) and the intervention group is now expected to reduce the mean SDQ total score to 11 (179). Consequently, to detect a difference in the SDQ total score of 2 while assuming a standard deviation of 5.7 (239), a small cluster effect (assuming an intraclass correlation of 0.001 as there are only 3 large clusters involved), and a significance level of 0.05 and with 80% power, we need a total sample size of 306 participants (240) (21). We expect a participation rate of 85% at the baseline and a 30% dropout rate by the 24-month follow-up assessment, leaving a total of 460 children available for assessments of the primary outcomes, conditioned a recruitment of about 780 children at baseline.

5 Ethics

The study is approved by the Research Ethics Committee of the University of Southern Denmark, case nr. 20/61404; and registered and approved by the University of Southern Denmark in accordance with the Data Protection Regulation and the General Data Protection Regulation (GDPR) (EU) 2016/679; Notification number: 11.090.

The parents are informed that their participation is fully voluntary, and that families who do not wish to participate, receive care as usual. It is underscored that at any stage of the project, the parents can withdraw their participation, and then receive care as usual.

The study comprises a specified intervention as an add-on to existing services provided by CHNs in the study municipalities. Families are offered an extra home visit when the infant is 24 months of age where weight, length, and body composition are to be measured. The usual care of CHNs, which is well accepted and used by more than 90% of the population, already involves assessment, counselling and information on sensitive issues related to challenges of the health and well-being of the child e.g. mental health and overweight. In this study, the CHNs use a more standardized and specified method to address the needs of the most vulnerable infants and their families, which more than 20% of the population is offered already within the existing routines. Video-feedback which is a core ingredient of the VIPP-PUF intervention, is already frequently used among Danish CHNs as a pedagogic way of communicating infants needs to the parents (241), and experiences show that the video-feedback approach is well accepted among parents and regarded as a helpful supplement for the parents to understand the CHNs guidance (242).

Supplementary information October 2024

The project was June 2024 reviewed by the Committees on Health Research Ethics in the Capital Region of Denmark who concluded that the project should have been approved in accordance with the law of Committees and had to be paused until a formal approval from Committees on Health Research Ethics in the Capital Region of Denmark was obtained. October 2024 the project was approved and registered to be completed by 31-12-2026 with the following remarks: *"Generally, an approved project is valid throughout the accepted period, and a regular confirmation of the approval does not take place. Unless otherwise stated, the approval includes all documents listed in the approval letter. Extension of a study might be approved when applied for later. According to Danish law all health research taking place in Denmark must be approved by an Ethical Committee and must comply with Danish legislation. Please note, that "GCP" and "ICH-GCP" rules are only partially implemented in Danish law. For additional inquiries, please contact the Secretariat for*

the Committees on Health Research Ethics in the Capital Region at +45 3866 6395 or by e-mail vek@regionh.dk

6 Timeline and economy

The project was planned to be conducted from January 2020 through December 2024. Due to the COVID-19 situation and low recruitment rates, the overall study has been delayed in total 14 months and is expected to have completed the data collection by January 2025. (For a detailed and updated timeline with milestones, see Appendix 2)

The Infant Health project has received 5.8 mill DKK from the Independent Research Fund Denmark, and in total 27 mill DKK from the Novo Nordisk Foundation (Main project 20 mill.; the separate WP 4 study 7 mill).

7 The project organization

The study is hosted at the National Institute of Public Health, NIPH, University of Southern Denmark, SDU, associated to the Center for Intervention Research and the Research group of Child and Adolescent Health (www.sdu.dk/da/sif) and led by Anne Mette Skovgaard (PI) and Janni Ammitzbøll (co-PI). The PI and co-PI will take responsibility for the daily transactions of the study activities, and the NIPH will provide support for the project including the Data Manager clerical support to the trial, organizing all aspects of the postal questionnaires (mailing, tracking, and entering returned data using the study web-based data entry portal) and the web-page administrator maintaining the study webpage.

Research group

Anne Mette Skovgaard, MD, DM SCI, Professor in Child mental health and psychopathology, NIPH, Faculty of Health Sciences, SDU, experienced in research in community-based studies of developmental epidemiology of mental health (WP 1-4).

Janni Ammitzbøll, Health nurse, MPH, PhD, Researcher, NIPH, SDU, experienced in community health nursing, and research collaborations with CHNs (WP 1-3).

Katrine Rich Madsen, MSc, PhD, Postdoc, NIPH, SDU experienced in process evaluation and social inequality (WP 4)

Stine Kjær Wehner, MSc, PhD, Postdoc, NIPH, SDU, experienced in process evaluation and qualitative ethnographic methods (WP 4)

Tine Tjørnhøj-Thomsen, MA, PhD, Professor in Anthropology, NIPH, SDU (WP 4)

Christion Ritz MSc, PhD, Professor in Statistics and Epidemiology, NIPH, SDU (WP 3)

Rodney Stephen Taylor, PhD, Professor in Health Services Research, University of Glasgow and Exeter, and adjunct Professor at NIPH, SDU. Main methodological research expertise in medical statistics and clinical trial design, in particular complex interventions, and design of trials to inform reimbursement and health policy (WP 3).

Maiken Pontoppidan, PhD, Senior Researcher, the Danish Center for Social Science Research,

Health Department. Experienced in RCT studies of CHNs' interventions in municipality settings (WP 2, WP 3).

Marian Bakermans-Kranenburg, PhD, Professor, Clinical Child and Family Studies, ISPA Lisbon, Lisboa, Portugal. Leading international expert in the dynamics and efficiency of parent-based interventions to young children, and the developer of the VIPP method (WP 2).

Trine Pagh Pedersen, MSc, PhD, Project Manager and research leader of the Child Health

Database, NIPH, SDU (WP 2)

Ida Voss, Msc, Research assistant, NIPH, SDU (WP 2-3)

Therese Alexandra Evald, MSc, PhD Student, Efficacy study (WP 3) and Mental Health (WP 3a)

Clara Barfod Parellada, MD, PhD Student. Efficacy study (WP 3) and Weight (WP 3b)

Maria Helene Jacobsen, MSc, PhD Student. Process evaluation and Psycho-socially disadvantaged families (WP 4).

Consultant health economic expert (WP 3)

Project Steering Group

The study will be supervised by a Project Steering Group (PSG). The chair of this group will be

Anne Mette Skovgaard and will consist of *Janni Ammitzbøll, Katrine Rich Madsen, Maiken Pontoppidan,* leading health nurse *Helle Erstling Rasmussen*, municipality of

Roskilde, leading health nurse *Ulla Dupont,* municipality of Vejle, leading health nurse *Lone Dahlstrøm*, municipality of Høje-Tåstrup and *Anna Paldam Folker*, Head of NIPH research. The

role of the PSG is to monitor and   support the progress of the study. The PSG will meet monthly for the first six months and every second month hereafter.

Participatory Planning Group

The chair of the Participatory Planning Group (PPG) will be *Janni Ammitzbøll* and will consist of *Anne Mette Skovgaard*, the *VIPP-PUF health nurses* and *leading health nurses* from all participating municipalities. The role of the PPG is to participate in the development of tools and intervention to strengthen the fidelity and acceptability among stakeholders and CHNs in the municipalities. The PGG will meet monthly from June 2020 to March 2021 hereafter among every fourth month until the end of the intervention.

Trial and Data Steering Committee

An independent Trial and Data Steering Committee (TDSC) will be convened. The chair of the committee will be Professor PhD *Pia Jeppesen*, University of Copenhagen, further the committee will consist of Associate professor *Sarah Fredsted-Villadsen*, Department of Public Health, University of Copenhagen, Professor PhD *Helle Terkildsen Maindal*, Department of Public Health, Section for Health Promotion and Health Services Research, University of Aarhus; Associate professor PhD, *Katrine Strandberg-Larsen*, Department of Public Health, Section of Epidemiology, University of Copenhagen, Leading Health Nurse *Ulla Dupont, Vejle,* PI *Anne Mette Skovgaard, co-PI Janni Ammitzbøll*. The role of the TDSC is to provide the overall supervision of the trial and assess the progress of the trial, the safety of data, and the critical efficacy endpoints. Specifically, the TDSC monitors the progress of the trial and advises on scientific credibility, monitor the accumulating trial data, and make recommendations to the Project Steering Group (PSG) as to whether the trial can continue or underline if there are any ethical or safety issues that may necessitate a modification to the protocol or closure of the trial, or if there is evidence of systematic recruitment or attrition bias. The TDSC ultimately carries the responsibility for deciding whether the trial need to be stopped on grounds of efficacy or safety. The TDSC will meet twice a year in the data collecting period and ad hoc.

8 Publication strategy

The Infant Health study is registered in www.ClinicalTrials.gov; IDNCT04601779; Protocol ID 95-110-21307 25 June 2021, and the Study Protocol published in BMC Public Health January 2022

(243). We expect to publish 10-12 scientific manuscripts, including the study design paper (243), papers on process evaluation (3), and papers on effect evaluation within the areas explored, mental health (3), weight (3) and psycho-social disadvantaged families (2) to be submitted to international peer-reviewed journals. Moreover, three PhD thesis will be produced.

All publications follow the Vancouver declarations on authorship and comply with the SDU Open Science Policy including Open Access publishing of results.

The results will be presented at international meetings and conferences, and presented to the public via the home pages of the institutes (www.sdu.dk/da/sif/forskning) and public medias.

9 Perspectives

The project's scientific and potential societal perspectives and relevance.

This project is the first to examine the mental health and weight outcome at 24 months of a focused intervention delivered at child ages 9-12 months, addressing sensitive parenting of infants of developmental and regulatory vulnerability. Future follow-up at age 36 and 60 months are planned (243) to explore the long-term outcomes.

The project is innovative in that it systematically targets the range of developmental and regulatory, problems in infants from the general population, targeting vulnerability markers of mental health problems and overweight in infancy, and using methods to promote sensitive parenting, which are delivered by CHNs. Using an already well-established collaboration between the research group and CHNs as the frame, and including data from a well-established municipality database, as well as information from Danish national registries in a randomized controlled design, the project will provide important knowledge on future effective, individually targeted and much needed public health interventions to address mental health problems and overweight in early childhood.

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