Can extra home visiting to first-time parents improve parental health literacy and parental self-efficacy in socioeconomically disadvantaged, neighbourhoods in Stockholm, Sweden?

Submission date	Recruitment status	Prospectively registered
15/04/2021	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/05/2021	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
02/09/2025	Other	

Plain English summary of protocol

Background and study aims

Poorer health, including child health, is displayed in several socioeconomically disadvantaged areas of Stockholm, Sweden. Children growing up in disadvantaged areas face more difficulties in life than children in other areas. Swedish Child Health Care system is universal, offering free support and follow-up of health to all families with children until the school-start.

Rinkeby is one of the socioeconomically disadvantaged neighborhoods of Stockholm, having also a waste majority of foreign-born inhabitants. Since 2013 have Child Health Care services in collaboration with Social Services worked according to an extended postnatal home visiting program to first-time parents in order to improve child health in Rinkeby. The program includes six joint postnatal home visits by Child Health Care nurse and parental advisor from Social services during the child's first 15 months to all first-time families (mother's or father's first child).

The home visiting program, developed in Rinkeby has been implemented in several other socioeconomically disadvantaged areas in the capital area since 2018, which are the target group of the evaluation in this research project.

This research project was initiated as the intervention was expanded to other areas than Rinkeby and the initial evaluation from Rinkeby shows several positive results such as increased parental self-efficacy, improved knowledge about the Swedish society and support/services that are targeted to families, improved knowledge about the Swedish health care system, increased MRR immunization coverage and declined days in hospital and visits in the emergency rooms among those families that got five or six visits within the program. Furthermore, oral health has been observed to be better among the children belonging to families that received the extended home visiting intervention.

This study aims to study parental self-efficacy and health literacy at baseline when the child is <2 months with follow up when the child is 18 months. Even parental satisfaction with midwives, Child Health Care nurses and parental advisors from social services are studied as well as if parents have access to social support from their social networks. Further aims are to explore how many parents choose to participate in the home visiting program, if they experience problems with sleep and child-feeding and if they visit open pre-school that society offers freely to all the parents in Sweden. Some other indicators such as percentage of Rota and MRR immunization at the age of 18 months, oral health at the 18 months and problems with speech/communication at the age of 3 years and reports of concern to Social services are reviewed either from the child's medical records or from the annual Swedish Child Health Care statistics.

Parental self-efficacy can be defined as caregiver's belief about how she or he can act successfully as a parent and can also include beliefs about the caregiver's ability to positively influence the child's behavior and development.

Health literacy (HL) is related to the complex demands that our modern societies require of their citizens in order to access health care systems and health-related information. Low HL is known to have negative health outcomes while increasing HL is seen to be one of the evidence-based strategies to reduce health inequalities. Parents play a key role in providing and promoting health to their children and for that reason, it is important to study parental HL in socioeconomically disadvantaged settings that many times also have many foreign-born parents and see if parental support programs can improve parental HL and future child health.

Who can participate?

Parents in families with one or two first-time parent/s that register their child at any of the Child Health Care Centers that are involved in the research project.

What does the study involve?

The study involves families with first-time parents in two different groups. They are interviewed on two occasions (when their child <2 months and 18 months) and information is collected from the children's medical records if parents consent when the child is 18 month and 3 years. The intervention group receives the extended postnatal home visiting program together with the ordinary Swedish Child Health Care program. The comparison group is a group of first-time parents that receive only the ordinary Swedish Child Health Care program.

What are the possible benefits and risks of participating?

The study requires time participating in the two interviews but also provides an opportunity for participants to express their points of view about parental support in Sweden. Participants with weaker Swedish language skills and those in need of interpreters are included in the study, which might lead to interview situations when the participants and the interviewer have limited communication. Participants have the right to access the data collected in the study and if any incorrect information is collected about them and/or their child, they will have the right to get the information changed the party responsible for the data of the study.

Where is the study run from?

Karolinska Institutet, Department of the Global Public Health. the local Child Health Care centers are involved.

When is the study starting and how long is it expected to run for? From November 2019 to June 2023.

Who is funding the study? The Public Health Agency of Sweden, Folkhälsomyndigheten (Sweden)

Who is the main contact? Docent Lene Lindberg lene.lindberg@ki.se

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Can an extended home visiting program improve first-time parental health literacy and parental self-efficacy in socioeconomically disadvantaged Swedish neighbourhoods?

Study objectives

Extended home visiting to first-time parents in socioeconomically disadvantaged neighborhoods may increase levels of parental health literacy and parental self-efficacy and improve child health.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 04/11/2019, Uppsala Ethical Review Board (BOX 2110, 750 02 Uppsala, Sweden; +46104750800; registrator@etikprovning.se), ref: 2019-04086

Study design

Interventional non-randomized study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

First-time parents postnatal home visits

Interventions

The participants are divided into intervention or comparison group based on which Child Health Centre they are registering their child.

Intervention arm

All first-time parents (mother's or father's first child) registering their child at following Child Health Care Centers in Stockholm county: Hässelby, Kista, Rissne, Rågsved and Skärholmen are offered six joint postnatal home visits by a Child Health Care nurse and a parental advisor form the Social Services during child's first 15 months (intervention group). Within these visits, following themes are discussed:

- 1. Welcoming your child
- 2. Getting to know your child
- 3. Being together
- 4. To show the world
- 5. To lead and follow
- 6. Being a family

Sessions are adapted to phases of the development of the child and include advice on how to relate to the child, emotional and physical contact, feeding, sleep, guiding the child, child safety, informing about child day care and other services. Parents are encouraged to ask child-related questions. Each session lasts for approximately 1 hour.

Comparison arm

First-time parents registering their children at following Child Health Care Centers in Stockholm county: Farsta, Vantör, Vårberg and Skogås act as comparators (comparison group), and receive the Swedish ordinary CHC program which includes generally a single home visit by a CHC nurse when the child is newborn and regular visits on the CHC center.

Participants in each group continue to attend regular scheduled visits to the CHC center.

Data collection

The project uses repeated measures design and parents of the children (in the intervention and comparison groups) are interviewed twice – when the child is <2 months and 18 months. Data in collected in face-to face interviews in the local Child Health care caters through interviews or in through phone calls.

A structured questionnaire is used for data collection including questions about parents' background factors, satisfaction with health care, parental and child health as well as parental self-efficacy, and health literacy. The questionnaire includes ten qualitative questions about child-related issues that are important during the child's first 18 months of life.

Another source of information is the electronic child health record, where visits to the child health care centers are recorded, regarding vaccinations, growth/development abnormalities, development and language. The child health programme follows a regular schedule of planned doctor visits, where these issues are registered when the child is 1, 6, 12, 18 months and 3 years old.

Intervention Type

Behavioural

Primary outcome(s)

- 1. Parental health literacy measured by using HLS-EU-Q16 Swedish modified version at baseline when the child is <2 months and at follow-up when the child is 18 months
- 2. Parental self-efficacy is measured by using Parental Self Efficacy-PSE at baseline when the child is <2 months and at follow-up when the child is 18 months

Key secondary outcome(s))

- 1. Percentages of parents who experience problems with sleep asked when child is < 2 months and 18 months
- 2. Percentages of parents who experience problems with child feeding when child is <2 months and 15 months
- 3. Percentage of children who received Rota virus immunization according to Swedish immunization program, followed at the child's medical record when child is 18 months
- 4. percentage of children who received MRR immunization according to the Swedish child immunization program, followed at the child's medical record when the child is 18 months
- 5. Percentages of children with dental caries, followed at the children's medical records at the age of 18 months
- 6. Percentages of reports of concern to the Social services through CHC center, followed through CHC statistics until the end of the study
- 7. Percentages of children with language-related communication problems at the age of 3, followed through child's medical record

Completion date

30/06/2023

Eligibility

Key inclusion criteria

- 1. First-time families (mother's or father's first child)
- 2. Registering their infant at one of the CHC centers that included in the intervention group (Hässelby, Kista, Rissne, Rågsved and Skärholmen) or in the comparison group (Farsta, Vantör, Vårberg and Skogås).
- 3. Informed consent to participate given during the recruitment period

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Sex

ΔII

Total final enrolment

253

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

04/12/2019

Date of final enrolment

25/08/2020

Locations

Countries of recruitment

Sweden

Study participating centre Hässelby BVC

Hässelby torg 20 Hässelby Sweden 16555

Study participating centre Kista BVC

Hanstavägen 55 F Kista Sweden 16453

Study participating centre Rissne BVC

Rissne torg 3 Sundbyberg Sweden 17457

Study participating centre Rågsved BVC

Rågsvedsslingan 12 B Bandhagen Sweden 12465

Study participating centre Skärholmen BVC

Storholmsgatan 27 Skärholmen Sweden 12748

Study participating centre Farsta BVC

Farstagången 24 Farsta Sweden 12347

Study participating centre Vantör BVC

Högdalsplan 11 Bandhagen Sweden 12454

Study participating centre Vårbergs BVC

Vårbergstorget 5 Skärholmen Sweden 12743

Study participating centre Skogås BVC

Melodivägen 6 Skogås Sweden 14240

Sponsor information

Organisation

Karolinska Institute

ROR

https://ror.org/056d84691

Funder(s)

Funder type

Government

Funder Name

Folkhälsomyndigheten

Alternative Name(s)

Public Health Agency of Sweden

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and analysed during the current study will be available upon request from Lene Lindberg (lene.lindberg@ki.se), from June 2022 until December 2025. Data will be pseudonymized. Access is conditional to a new ethical approval and a new permission from .

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Basic results		01/09 /2025	02/09 /2025	No	No
Other publications	Young children's screen habits and first-time parents' reflections on screen use in socioeconomically disadvantaged Swedish settings: a mixed methods study	29/07 /2024	30/07 /2024	Yes	No
Participant information sheet			24/05 /2021	No	Yes

Participant information sheet			24/05 /2021 No	Yes
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025 No	Yes
<u>Study</u> <u>website</u>	Study website	11/11 /2025	11/11 /2025 No	Yes