Can extra home visiting to first-time parents improve parental health literacy (HL) in a Swedish multicultural neighborhood?

Submission date	Recruitment status	Prospectively registered			
06/02/2020	No longer recruiting	Protocol			
Registration date	Overall study status	Statistical analysis plan			
18/02/2020	Completed	[X] Results			
Last Edited	Condition category	Individual participant data			
06/08/2024	Pregnancy and Childbirth				

Plain English summary of protocol

Background and study aims

Poorer health, including child health, is displayed in several multicultural, socioeconomically disadvantaged areas of Stockholm, Sweden. Children growing up in disadvantaged areas face more difficulties in life than children in other areas. In Rinkeby, a disadvantaged area in Stockholm, more than 90% of the population has a migrant background, a large proportion is at risk of poverty and the unemployment rate is almost 50%. The proportion of children reported to social services because of difficulties in the family is four times higher than the county average. It is possible that parents living in disadvantaged areas require more support in order to ensure the healthy development of their child.

CHC services in collaboration with social services designed an extended home visiting program in one of the disadvantaged districts in order to improve child health since 2013. The program includes six postnatal home visits by CHC nurse and parental advisor from social services during the child's first 15 months to families where this is their first child (mother's first child).

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. Migrants are known to have generally lower HL. 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 multicultural settings and see if parental support programs can improve parental HL and future child health.

This research is aiming to study parental HL before and after the program in comparison to parents in another district that receives the ordinary Swedish CHC program. Parental HL and demographic background factors will be measured at the beginning (when their child is aged <2 months) and the end of the program (when their child is aged >15 months). Child health is followed in children's medical records (growth/development/language/visits within CHC) and studied in relation to parents' HL levels.

Who can participate?

First-time families, where the mother is expecting their first child

What does the study involve?

All first-time parents registering their child at Rinkeby Child Health Care (CHC) center are offered six home visits by a CHC nurse and a parental advisor form the social services during the child's first 15 months.

Within these visits, different 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 also include advice on how to relate to the child, emotional and physical contact, feeding, sleep, guiding the child, child safety, informing about child daycare and other services. Parents are encouraged to ask child-related questions. Each session lasts for approximately 1 hour.

First-time parents registering their children at another, Spånga-Tensta Child Health Care (CHC) center will act as a comparison, and receive the Swedish ordinary CHC program which includes a single home visit by a CHC nurse when the child is newborn and visits to the CHC center.

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

The parents of the children are interviewed twice – when the child is less than 2 months and 15 months or older, using a questionnaire about parental health, satisfaction with care and health literacy (HL).

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, so there might be 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?

Rinkeby Child Health Care Center (Sweden) and Spånga-Tensta Child Health Care Center (Sweden)

When is the study starting and how long is it expected to run for? April 2017 to January 2023

Who is funding the study?

The Public Health Agency of Sweden, Folkhälsomyndigheten (Sweden)

Who is the main contact? Mrs Kirsi Tiitinen Mekhail kirsi.tiitinen.mekhail@ki.se

Study website

https://ki.se/en/gph/extended-postnatal-home-visiting-programme

Contact information

Type(s)

Scientific

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Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

N/A

Study information

Scientific Title

Can an extended postnatal home visiting program to first-time parents improve parental health literacy (HL) in a Swedish multicultural setting?

Study objectives

Extended home visiting to first-time parents in multicultural settings may increase levels of parental health literacy and improve child health

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/09/2017, Stockholm Regional Ethics Review Board (Tomtebodavägen 18A, 171 65 Solna, Sweden; +46 0852487000; kanslir@stockholm.epn.se), ref. 2017/1587-31/5

Study design

Non-randomized study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

First-time parents, postnatal home visits

Interventions

All first-time parents registering their child at Rinkeby Child Health Centre (CHC) center are offered six postnatal home visits by a CHC nurse and a parental advisor form the social services during child's first 15 months. Within these visits, different 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 also 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.

First-time parents registering their children at another, neighbouring CHC center act as comparators, and receive the Swedish ordinary CHC program which includes a single home visit by a CHC nurse when the child is newborn and visits on the CHC center.

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

The parents of the children (in the intervention and control areas) are interviewed twice – when the child is <2 months and 15 (to 18) months, using a questionnaire about parental health, satisfaction with care and health literacy (HL).

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 and 18 months old.

Intervention Type

Other

Primary outcome measure

Parental health and satisfaction with care and parental health literacy (HL) levels are measured using the health literacy questionnaire (HLS_EU-Q16), including a question on self-rated health, and a question on satisfaction with care and health literacy, when their child is <2 months and 15 to 18 months.

Secondary outcome measures

- 1. Child health and growth/development is measured using height and weight at doctor/nurse visits at the ages of 1, 6, 12 and 18 months.
- 2. Language abilities of the child are measured using a Swedish child health screening instrument, at the ages of 1 and 5 years
- 3. Child care attendance is measured by a question at a parental interview when their child is 15 to 18 months old.

Overall study start date

01/04/2017

Completion date

01/01/2023

Eligibility

Key inclusion criteria

- 1. First-time families (mother's first child)
- 2. Registering their infant at Rinkeby CHC center (intervention centre) or Spånga-Tensta CHC center (control centre)
- 3. Informed consent to participate given during the recruitment period

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

200-240 (100-120 in each group)

Total final enrolment

193

Key exclusion criteria

Not meeting the inclusion criteria

Date of first enrolment

01/10/2017

Date of final enrolment

15/04/2019

Locations

Countries of recruitment

Sweden

Study participating centre Rinkeby Child Health Care Center

Skårbygränd 3 Spånga Sweden 16372

Study participating centre

Spånga-Tensta Child Health Care Center

Solhems Hagväg 10 Spånga Sweden 16356

Sponsor information

Organisation

Karolinska Institute

Sponsor details

Tomtabodavägen 18 A Stockholm SE 17177 Sweden Stockholm Sweden 17177 +46 8524 800 00 info@ki.se

Sponsor type

University/education

Website

http://ki.se/en/startpage

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

Publication and dissemination plan

- 1.Validation of the HLS-EU-Q16 instrument for parental health literacy (HL) in Swedish multicultural settings
- 2. Levels of parental health literacy before and after the extended postnatal home visiting program and the ordinary CHC program in two multicultural suburbs of Stockholm, Sweden
- 3. Parental health literacy in relation to child health within an extended home visiting program and the ordinary CHC program in multicultural settings, Stockholm, Sweden

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are not expected to be made available on the participant level as it is stated in the informed consent accepted by Ethical board that "information that is collected for the evaluation is treated in a way that no single person/family can be identified."

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Interim results article	Validation study	12/02 /2022	04/01 /2023	Yes	No
Interim results article		25/02 /2023	09/01 /2024	Yes	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
Results article		05/08 /2024	06/08 /2024	Yes	No