# Extended postnatal home visiting in a disadvantaged area in Stockholm

<b>Submission date</b> 30/06/2016	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li><li>[X] Protocol</li></ul>		
<b>Registration date</b> 11/08/2016	<b>Overall study status</b> Completed	<ul> <li>[] Statistical analysis plan</li> <li>[X] Results</li> </ul>		
Last Edited 12/09/2023	<b>Condition category</b> Other	Individual participant data		

#### Plain English summary of protocol

Background and study aims

Children growing up in disadvantaged areas face more difficulties in life than children in other areas. In Rinkeby, a disadvantaged area in Stockholm, 95% of the population has an immigrant 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. In this study, a new support program in which parents receive six home visits from a child health nurse is examined in order to find out if it can improve care and child development compared to standard practice.

#### Who can participate?

All first-time parents registering at Rinkeby Child Health Centre, Husby Child Health Centre, Akalla Child Health Centre, and Hässelby-Vällingby Child Health Centre who are willing to participate.

#### What does the study involve?

All first time parents registering their new-born at Rinkeby Child Health Centre are offered six home visits from a child health nurse when their child is aged between 2-15 months. At these visits, they are offered education and support to help strengthen them in their role as a parent. The sessions are adapted depending on what stage of development the child is at, and each sessions lasts for between one and one-and-a-half hours. First time parents registering at neighboring clinics receive standard care, which involves a single visit from a child health nurse when their child is two months old. Participants in both groups are interviewed when the child is two and 15 months old in order to find out what they think of the health care they have received. Medical records of children from both groups are also compared at a range of timepoints until the child is three years old to compare development.

What are the possible benefits and risks of participating?

Participants who take part in the support program benefit from receiving information and guidance on issues related to raising a small child, tailor-made to their needs, and more information regarding available services in Swedish society. Participants may also benefit from

gaining more trust in the Swedish health care system and form a closer relationship to the staff visiting them. A potential risk is that some participants may be stigmatized (negatively marked) for receiving this "extra" service, which is why Child Health Centres are not allocated to receiving the program at random.

Where is the study run from?

Participants are recruited from Rinkeby Child Health Centre, Husby Child Health Centre, Akalla Child Health Centre, and Hässelby-Vällingby Child Health Centre and the study takes place in participant homes (Sweden)

When is the study starting and how long is it expected to run for? August 2012 to December 2017

Who is funding the study? 1. Public Health Agency of Sweden (Sweden) 2. Stockholm County Council (Sweden)

Who is the main contact? Professor Bo Burström bo.burstrom@ki.se

## **Contact information**

**Type(s)** Scientific

**Contact name** Prof Bo Burström

#### **Contact details**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N/A

# Study information

#### Scientific Title

Extended postnatal home visiting to first-time parents in a disadvantaged area in Stockholm

#### Study objectives

Extended home visiting to first-time parents will strengthen parents in disadvantaged areas in their new role, which will improve health of parents and children

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** Regional Ethical Review Board, Stockholm, 12/06/2013, ref: 2013/877-31/1

**Study design** Non randomised 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 the contact details to request a patient information sheet

#### Health condition(s) or problem(s) studied

Optimising child health services in collaboration with social services

#### Interventions

All new parents registering at Rinkeby Child Health Centre who consent to participate in the study receive six home visits by a child health nurse and a parental advisor when the child is aged 2-15 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 invited to ask questions

and the home environment for the child is discussed. Each session lasts for approximately 1-1.5 hours.

Parents registered at neighbouring health centres act as a comparator, and receive standard care which involves receiving a single visit by a child health nurse when the child is aged about 2 months.

Participants in both groups continue to attend regular scheduled visits to the clinic.

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

Another source of information is the electronic child health record, where visits to the child health clinic but also to other health care establishments (clinics, emergency ward, hospital) are recorded, as well as vaccinations, growth, development and language (deviations). The child health programme follows a regular schedule of planned doctor visits, where these issues are registered (at 3, 6, 12, 18 months and 3 years of age).

A third source of data is administrative records including all children within the intervention and control areas, where participants cannot be distinguished from non-participants, for looking at emergency ward visits and hospitalisations. Time trends are analysed to see whether the development in intervention areas differ from control areas, and whether any change coincides in time with the intervention.

#### Intervention Type

Other

#### Primary outcome measure

1. Parental health and satisfaction with care are measured using a questionnaire (with a question on self-rated health, and a question on satisfaction with care) at child's age 2 months and 15 months

2. Child health and growth is measured using height and weight at doctor visits at age 3, 6, 12 and 18 months.

3. Language abilities of child are measured at age 3 years, using a Swedish child health screening instrument

4. Health care utilisation is measured using review of medical records at doctor visits at age 3, 6, 12 and 18 months

- 5. Dental caries in children are measured using dental examination at age 3 years
- 6. Child care attendance is measured by question at interview at 15 months of age

#### Secondary outcome measures

1. Vaccination coverage is measured by having completed all vaccinations at 2 years of age, from child health record

4. Emergency ward visits among children are measured by analysis of time series (2013, 2014, 2015 and 2016) of administrative data for children aged 0-1 and 1-2 years residing in intervention and control areas, respectively

5. Proportion of children with developmental deviations are measured at age 3 years, using a Swedish child health screening instrument at doctor visit

#### Overall study start date

01/08/2012

Completion date 31/12/2017

# Eligibility

#### Key inclusion criteria

All first-time parents registering at Rinkeby Child Health Centre (intervention centre), Husby Child Health Centre (control centre), Akalla Child Health Centre (control centre), and Hässelby-Vällingby Child Health Centre (control centre) who are willing to participate.

**Participant type(s)** Mixed

**Age group** Mixed

**Sex** Both

**Target number of participants** Aim was to have parents of 70+ first-born children

**Total final enrolment** 98

**Key exclusion criteria** No exclusion criteria used

Date of first enrolment 01/09/2013

Date of final enrolment 31/12/2014

## Locations

**Countries of recruitment** Sweden

Study participating centre Rinkeby Child Health Centre (intervention centre) 3, Rinkebysvängen 70D Spånga Stockholm Sweden SE 16372

#### **Study participating centre Husby child health centre (control centre)** Edvard Griegsgången 12 Kista Sweden 16432

**Study participating centre Akalla child health centre (control centre)** Sibeliusgången 20A Kista Sweden 16477

**Study participating centre Hässelby-Vällingby child health centre (control centre)** Hässelby torg 20 Hässelby Sweden 16521

### Sponsor information

**Organisation** Karolinska Institutet

**Sponsor details** Tomtebodavägen 18A Stockholm Sweden SE 17177

**Sponsor type** University/education

ROR https://ror.org/04hmgwg30

## Funder(s)

**Funder type** Government

**Funder Name** Public Health Agency of Sweden

Funder Name Stockholms Läns Landsting

Alternative Name(s) Stockholm County Council

**Funding Body Type** Government organisation

Funding Body Subtype Local government

**Location** Sweden

## **Results and Publications**

**Publication and dissemination plan** Planned publication in a high-impact peer reviewed journal.

Intention to publish date 31/12/2018

Individual participant data (IPD) sharing plan

Not provided at time of participation

#### IPD sharing plan summary

Not expected to be made available

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Protocol article</u>	protocol	28/01/2017		Yes	No
Results article	results	10/04/2018	11/06/2019	Yes	No
Results article	results	22/01/2019	11/06/2019	Yes	No
<u>Results article</u>	qualitative framework analysis	01/06/2022	08/06/2022	Yes	No