

Scaling up a post-natal extended home visiting program for a good start in life in disadvantaged areas in Gothenburg, Sweden

Submission date 16/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/09/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

A Swedish-developed infant home visiting program, created and evaluated in Rinkeby, a marginalized district in the city of Stockholm has the promise of contributing to the attainment of sustainable development goals. To attain positive outcomes with home visiting programs, careful attention to the implementation process is needed. This study seeks to describe the scale-up of the program in a new context from a variety of perspectives and measure outcomes and effects of the program both short and long-term. The study also seeks to highlight the collaborative role of social services. The evaluation is based on qualitative and quantitative methods from interviews, focus groups, questionnaires, journal data and documentation. In the foundation research, two studies explore the perspective of professionals, and two studies explore parents' perspectives. An indicator study explores the potential health-related effects of the program during the child's first 18 months of life, and a pilot study followed up with children at 30 months of age. Two additional implementation studies explore the experience of facilitators, barriers, and solutions in the pre-implementation phase of the scale-up, and program fidelity by analyzing data submitted by professionals following each home visit.

Who can participate?

All first-time parents, or parents having their first child in Sweden aged between 20 and 50 years old, registered to receive the ordinary universal child health care services in the following child health centers are eligible for the study: Västra Frölunda Närhälsan Opaltorget, Angered Centrum Närhälsan, Angered Centrum Capio, Angered Gårdsten, Angered Lövgärdet, Friskvåderstorget Närhälsan, Biskopsgården Nötkärnan.

What does the study involve?

All first-time parents registering their newborn in one of the seven participating child health centers (above) are offered six home visits from a child health nurse and social worker from preventive social services between the child's birth and 15 months of age. 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 session lasts for between one and one-and-a-half hours. Participants complete questionnaires when the

child is two months and 15 months, and a purposeful sample of parents will also be interviewed after the program to find out what they think of the health care they have received. Medical records of children from participating families are compared to aggregated health data at 18 months and compared with a subset of nonparticipating families from control child health centers at 30 months to compare health indicators and development.

Documentation from the pre-implementation planning period as well as provider ratings of program fidelity following each home visit will be analyzed to study the implementation process and quality. Staff delivering the program will be interviewed about their experiences and the significance of the program.

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 healthcare system and forming a closer relationship with the staff visiting them. A potential risk is that some participants may be stigmatized (negatively marked) for receiving this "extra" service.

Where is the study run from?

The study is run from the participating CHCs listed above, and the intervention takes place in the families' homes.

When is the study starting and how long is it expected to run for?

The study period is from October 2018 to June 2022

Who is funding the study?

The research was jointly funded by Region Västra Götaland and The City of Gothenburg

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Scaling up a post-natal extended home visiting program for a good start in life in disadvantaged areas in Gothenburg, Sweden

Acronym

HOMEVISITSGBG

Study objectives

Extending the number of home visits during the infancy period will improve parents' satisfaction with healthcare and social services, parenting self-efficacy and well-being, as well as short- and long-term child-related health indicators. The program will contribute towards increased health equity in Sweden. The method will be scaled up with fidelity. Providers delivering the method will find it feasible and meaningful to work with. Lessons will be learned from stakeholders responsible for securing good conditions for the implementation about facilitators and barriers in the scale up process.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 18/06/2019, Regional Ethical Review Board, Gothenburg (Box 2110, Uppsala, 750 02, Sweden; +46 010-475 08 00; registrator@etikprovning.se), ref: Dnr 2019-03392, Dnr 2020-02077, Dnr 2021-06548- 02

Study design

Non-randomized implementation research study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Community, Medical and other records

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Scaling up an evidence-based early childhood parent support model for better health equity

Interventions

Rinkeby extended home visiting program: All new parents registering at participating Child Health Centers in seven prioritized areas of Gothenburg will be offered the intervention and asked to consent to participate in the study. The program entails six home visits by a child health nurse and a parent support social worker from birth to 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, and informing about child daycare 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.

Intervention Type

Behavioural

Primary outcome measure

The primary measures of effects on child health indicators are measured by comparing child health journal data with aggregated child health statistics at 18 months, and comparison of program participants with non-participant controls at 30 months (pilot study).

Secondary outcome measures

1. Parents' perspectives are measured using self-reported satisfaction with the program, health, and parenting self-efficacy before and after program participation, as well as via interviews. Provider perspectives are evaluated using interviews.
2. Fidelity is measured with a mixed methods analysis of questionnaire data submitted by professionals after each visit. Implementation quality is measured by an analysis of documentation. Pre-implementation facilitators and barriers are measured with mixed methods.

Overall study start date

01/10/2018

Completion date

30/06/2022

Eligibility

Key inclusion criteria

First-time parents and parents having their first child in Sweden in seven prioritized geographic areas characterized by socioeconomic disadvantage

Participant type(s)

Health professional, Service user

Age group

Adult

Lower age limit

20 Years

Upper age limit

50 Years

Sex

Both

Target number of participants

400

Total final enrolment

317

Key exclusion criteria

There are no participant exclusion criteria.

Date of first enrolment

01/08/2019

Date of final enrolment

28/02/2022

Locations

Countries of recruitment

Sweden

Study participating centre

Child Health Center Närhälsan Opalatorget

Zirkongatan 7

Västra Frölunda

Sweden

42164

Study participating centre

Child Health Center Angered Centrum Närhälsan

Kultivatorgatan 5

Angered

Sweden

424 65

Study participating centre

Child Health Center Angered Centrum Capio

Kultivatorgatan 3

Angered

Sweden

424 65

Study participating centre

Child Health Center Gårdsten, Angered

Muskotgatan 10

Angered

Sweden

42441

Study participating centre

Child Health Center Angered Lövgärdet

Vaniljgatan 28

Angered
Sweden
424 45

Study participating centre
Child Health Center Biskopsgården Friskvåderstorget
Friskvåderstorget 8
Göteborg
Sweden
418 38

Study participating centre
Child Health Center Närhälsan Biskopsgården
Höstvädersgatan 1
Göteborg
Sweden
418 33

Sponsor information

Organisation
Region Västra Götaland

Sponsor details
Center for Progress in Children's Mental Health, Kungsgatan 12, 6th floor
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Sponsor type
Government

Website
<https://www.vgregion.se/halsa-och-varld/vardgivarwebben/amnesomraden/psykisk-halsa/utvecklingscentrum-for-barns-psykiska-halsa/>

ROR
<https://ror.org/00a4x6777>

Organisation

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Sponsor type

Government

Website

<https://goteborgsregionen.se/kunskapsbank/fouivast.5.76b3d79b17bcd4916ae44513.html>

Organisation

City of Gothenburg, Department of Equity

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Sponsor type

Government

Website

<https://goteborg.se/wps/portal/enhetssida/jamlikt-goteborg>

Funder(s)**Funder type**

Government

Funder Name

Gothenburg Regional Health and Medical Council

Funder Name

Results and Publications

Publication and dissemination plan

Main results have been disseminated in a local report. One article has been published in a peer-reviewed journal. One article is expected to be submitted to a peer-reviewed journal in August, 2024

Intention to publish date

30/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Julie Lundgren, julie.lundgren@vgregion.se.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results	in Swedish	01/04/2022	16/08/2024	No	No
Funder report results	in Swedish	30/08/2023	16/08/2024	No	No
Results article		18/03/2024	16/08/2024	Yes	No