

BarnSäkert – a safe environment for every child

Submission date 09/04/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/05/2020	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/10/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

BarnSäkert is a study that aims to evaluate the Safe Environment for Every Kid (SEEK) model within the Swedish Child Health Services (CHS). The SEEK model provides methods for identifying families with psychosocial problems, such as depression, stress, financial problems, alcohol problems and intimate partner violence, with the overarching goal of reducing the risk of child maltreatment.

All child health centers in the County of Dalarna have been offered to participate in the study to test the SEEK model in comparison with standard care and practice within the preventive child health services over two years. All CHS centers in the county of Dalarna will be randomly chosen to either use the SEEK model or standard and practice.

SEEK consists of:

1. Training of the CHS staff in the risk factors (financial problems, depression, parental stress, alcohol abuse, intimate partner violence) assessed in the SEEK parent questionnaire (PQ)
2. Use of the PQ at five predetermined ages during routine visits to the CHS
3. Discussion of parents' responses during the CHS visit
4. Guidance or referral to relevant support

Who can participate?

Parents/guardians of children aged 0 to 18 months and enrolled in the child health services in the county of Dalarna, Sweden

What does the study involve?

At SEEK centers, parents/guardians will be asked to fill in a web-based questionnaire and attend regular child health visits when the child is 6-8 weeks, 8-10 months, 18 months, 2.5 years, and 4 years old. The questionnaire contains 17 yes/no questions, takes about 5 minutes to complete and can be filled in on an electronic tablet (iPad).

During the visits, the nurse will talk with the parent about the answers to the questionnaire. The discussion is centered on the parents' thoughts and feelings about their own situation and how they view their need for support and change.

At the end of the visit, the nurse may offer advice and referral for assistance, support or treatment to existing health care, social services or other resources based on the wishes of the parent.

Parents may also be recruited to participate in a long term part of the study, which will include surveys before and after their experiences at the CHS centres about many issues such as the parent's and child's current physical and emotional health, the parents' quality of life, the child's behavior and the parent's attitudes towards upbringing practices, including corporal punishment.

What are the possible benefits and risks of participating?

Answering questions about problems at home can cause parents to feel sad, worried or upset. The safety of parents is important. Anyone who thinks they would feel bad or might be harmed by someone as a result of answering questions about stress, depression, financial problems, alcohol use or violence can decide not to participate in the study.

Questions about safety issues can be addressed to the lead researcher Steven Lucas according to the contact details below. All healthcare professionals have a legal obligation to report to the social services if they suspect that a child is being maltreated. If the nurse suspects, as a result of the answers to the questionnaire or the discussion during the visit to the child health centre, that a child is being maltreated, this may result in a report to the social services.

The participants who attend child health centres that use the SEEK model may get help earlier for problems they have, which might make it easier to be a parent. In these cases, children may be at less risk of being maltreated.

Where is the study run from?
Region Dalarna (Sweden)

When is the study starting and how long is it expected to run for?
October 2013 to December 2026

Who is funding the study?
World Childhood Foundation (Sweden), Stiftelsen Allmänna Barnhuset (Sweden), and Regionala forskningsrådet i Uppsala-Örebroregionen (Sweden)

Who is the main contact?
Dr Steven Lucas
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Contact information

Type(s)
Scientific

Contact name
Dr Steven Lucas

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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

BarnSäkert – a safe environment for every child: a cluster-randomised controlled trial of the SEEK model

Study objectives

1. Early identification of psychosocial risk factors in the child's home environment and provision of relevant support and assistance to the family according to the Safe Environment for Every Kid (SEEK) model can reduce the risk of child maltreatment and improve child health and family well-being.
2. Nurses who apply SEEK in their practice will report to a greater extent that they feel competent and confident in addressing these issues compared to nurses in the control group after two years of intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval 05/04/2017, Swedish Ethical Review Authority
(Box 2110, 75002 Uppsala, Sweden; registrator@etikprovning.se; +46 010-475 08 00), ref: 2017/009

Study design

Cluster-randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Preventive child health care

Interventions

The BarnSäkert intervention starts after randomization of the child health centers. Randomization was performed at the child health centre level, such that all nurses at each centre either the SEEK model or current clinical routines. All child health centres in the county of Dalarna (n=36) agreed to participate in the study. The centres were matched pairwise based on the number of children enrolled and sociodemographic factors including proportion of families of non-Swedish origin and Care Need Index. Allotment to the SEEK or control group was determined by coin-toss. Six centres had previously participated in a pilot study during the development of the methodology and these centres were therefore allotted to the SEEK group and matched with centres of similar size and with sociodemographic characteristics that were allotted to the control group. Two members of the project leadership performed the randomization and had no detailed knowledge of the child health centres or the staff who worked there.

The SEEK model consists of four elements:

1. Basic training of the CHS staff in the risk factors assessed in the SEEK parent questionnaire (child safety, financial problems, parental stress, depression, alcohol abuse, intimate partner violence)
2. Use of the SEEK parent questionnaire (PQ) in conjunction with predetermined routine visits to the CHS
3. Discussion of the parent's responses and possible outcomes in connection with the CHS visit
4. Suggestions for advice or referral to relevant support or healthcare agencies.

At SEEK centers, parents/guardians are offered to fill in a web-based PQ in connection with regular child health visits when the child is 6-8 weeks, 8-10 months, 18 months, 2.5 years, and 4 years old during the two year-intervention period. The PQ contains 17 yes/no questions, takes about 5 minutes to complete and can be filled in on an electronic tablet (iPad). People who are not guardians (for example grandparents) are not included in the study. Time is given for parents to fill in the form at the beginning of the visit in the nurse's room to ensure privacy. If two parents are present at the visit, they are both offered to fill in the form individually.

During the CHS visit, the nurse talks with the parent about the answers to SEEK-PQ based on the method of Motivational Interviewing (MI). Most nurses working in the CHS are familiar with MI and use the method in their daily work. The discussion is centered on the parents' thoughts and feelings about their own situation and how they view their need for support and change.

At the end of the visit, the nurse may offer advice and referral for assistance, support or treatment to existing health care, social services or other resources based on the wishes of the parent. In order to facilitate the nurse's discussion with the parent, there are specifically developed SEEK flow charts for each risk factor, including ways to respond to possible obstacles for the parent to seek or receive help.

The parents' anonymous responses to the SEEK-PQ as well as the nurses' action taken as a result of their meeting with the family will be transferred to the study database electronically at the end of the visit.

At Control CHS centers, nurses will continue to work according to the current routine, giving advice, support, and referral to relevant community institutions when perceived needs are identified or in response to the outcome at screening for post-partum depression.

In addition to the anonymous collection of data from the parents' responses to the PQ and nurses' information on actions taken in each case, parents from both SEEK and control centers will be recruited to participate in a more in-depth, longitudinal part of the study in which they answer surveys before, during and after the SEEK intervention. The surveys include questions about the parent's and child's current physical and emotional health, the parents' quality of life, the child's behavior and the parent's attitudes towards upbringing practices, including corporal punishment and several other aspects of parenting. The children enrolled in this part of the study will also be followed through the third grade of elementary school (maximum 9 years from baseline) with regard to a number of outcomes, including health care diagnoses, needs for special education resources, school attendance and performance on national examinations. Data regarding diagnoses and health care utilisation will be collected once at the end of the intervention and once when the children are in the third grade. Data from preschool regarding special education needs will be collected once when the children enter school and school-related data will be collected when the children have completed the third grade. Health economic analyses will be coupled to this part of the study.

Nurses from both control and SEEK CHS centers will be offered to participate in focus group interviews and surveys regarding how they view their competence and readiness to address psychosocial risk factors in the CHS setting before the implementation of SEEK and after the conclusion of the intervention. Parents at both SEEK and control centers will also be offered to provide their opinions through focus groups with regard to discussing psychosocial risk factors in the CHS before and after the intervention.

Intervention Type

Behavioural

Primary outcome(s)

1. Percentage of families reporting each respective psychosocial risk factor over the intervention period, determined from anonymous SEEK parent questionnaire (PQ) responses between at baseline and 24 months
2. Survey responses from parents who have consented to participate in the longitudinal part of the study, regarding psychosocial risk factors (financial difficulties, depression and anxiety, extreme stress, alcohol problems, intimate partner violence), quality of life, parenting sense of competence, assessment of child difficultness. Assessed through a web-based survey sent to parents at baseline, 12, and 24 months.
3. Diagnoses among children in the SEEK and control groups assessed through data extracted from electronic clinical records collected from 24 months to 9 years.
4. Social services reports for children in SEEK and control groups collected yearly from baseline to 9 years
5. School attendance and needs for support/special education in preschool and school for children in SEEK and control groups aged 3 to 10 years, collected from baseline to 9 years

Key secondary outcome(s)

1. Nurses' experiences of addressing psychosocial risk factors in their contact with families, measured using focus group interviews and survey results from SEEK and control nurses at 2

years

2. Parents' experiences of discussing psychosocial risk factors during the child health visit measured using focus group interviews with parents from the SEEK group at 2.5 years

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Parents/guardians of children aged 0 to 18 months
2. Parents/guardians of children enrolled in the child health services in the county of Dalarna, Sweden

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

852

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/08/2017

Date of final enrolment

31/01/2019

Locations

Countries of recruitment

Sweden

Study participating centre

Region Dalarna

Centrala barnhälsovården

Falu lasarett

Falun

Sweden
79182

Sponsor information

Organisation

Uppsala University

ROR

<https://ror.org/048a87296>

Funder(s)

Funder type

Charity

Funder Name

World Childhood Foundation

Alternative Name(s)

World Childhood Foundation Inc, Childhood USA, World Childhood Foundation USA, World Childhood Foundation (Childhood USA), Fondation pour l'Enfance Mondiale (Enfance USA), Fundación Mundial de la Infancia (Childhood USA), Fundação Mundial da Infância (Childhood EUA), WCF

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

Allmänna Barnhuset (Children's Welfare Foundation Sweden)

Funder Name

Regionala forskningsrådet i Uppsala-Örebroregionen (Regional Research Council in the Uppsala-Örebro Region)

Results and Publications

Individual participant data (IPD) sharing plan

Participant level data will not be publicly available, in accordance with ethical approval. A fully anonymised dataset will be available for future analyses, after the primary research manuscripts have been published in scientific journals. Data access requests are to be addressed to the chief investigator in writing, and access will be subject to obtaining ethical approval and pre-registration of intended analyses.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/10/2023	16/10/2023	Yes	No
Other unpublished results		08/08/2023	14/08/2023	No	No
Participant information sheet			27/05/2020	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes