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Evaluation of an intervention to promote the psychosocial health of children of incarcerated parents and their non-incarcerated carers

Submission date
21/11/2025

Recruitment status
Recruiting

Registration date
24/11/2025

Overall study status
Ongoing

Last Edited
24/11/2025

Condition category
Other

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Children of incarcerated parents comprise a greatly disadvantaged group with high needs that are largely overlooked by society. These children run a greater risk for a number of health-related outcomes, and own delinquency. Research suggests that these children need support that focus on their resilience. The non-incarcerated caregiver is key here, but the caregiver may also be negatively affected by a partner's incarceration and in need of support for the own well-being and to be able to support the child. Internationally, few support interventions for these children and caregivers have been evaluated scientifically. In Sweden, current support is uncoordinated, largely unavailable, and provided by non-profit organisations. In fact, the responsible stakeholder, the Social Services, largely lacks knowledge about the children's needs. Interventions to support child resilience in general focus on promotive factors of the child and context, where parenting is emphasised.
This project aims to assess the effects of an evidence-informed intervention for children of incarcerated parents and their non-incarcerated caregivers on psychosocial health and study the implementation process.

Who can participate?
Children aged 6-13 years who have an incarcerated parent in Sweden and their non-incarcerated caregivers.

What does the study involve?
The intervention is carried out by staff in the general social service units or by staff in civil society organisations that have a specific focus on families affected by incarceration.
Units (social service or civil society organisations) are randomised to deliver the intervention or service as usual (control). Children and carers who receive services will be included in the intervention and control group according to the randomisation of the unit into intervention or control group.
The intervention for the child-carer-dyad consists of 3 individual and separate sessions for children and carers. Sessions include psychoeducation and brief strategies for managing emotions and situations related to the incarceration.

A final, 4th session is provided for child and carer together to form a common understanding and basis for continued, joint handling of the incarceration after the intervention.
The control group is provided the standard support (TAU) by the units in the control group.
To test the effects of the intervention on psychosocial health, a variety of measurement on psychosocial health are self/adult-reported before, and after the intervention, three-months, and one-year after the intervention.
The implementation process is monitored during and after the intervention by self-reported measurements from children, carers, and professionals delivering the intervention.
What are the possible benefits and risks of participating?
The intervention is thoroughly designed to avoid risk but may inflict uncomfortable memories or emotions, which are to be handled within the intervention. Children and carers who participate may be benefited by a decreased emotional suffering and prevention of future ill health.

Where is the study run from?
Karolinska Institutet/Uppsala University, Sweden

When is the study starting and how long is it expected to run for?
Start in December 2025 and ending in December 2032 (last data collection)

Who is funding the study?
The Swedish Research Council for Health, Working Life and Wellfare

Who is the main contact?
Principal Investigator Dr. Åsa Norman, Karolinska Institutet/Uppsala University, asa.norman@ki.se, asa.norman@uu.se

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Åsa Norman

ORCID ID
https://orcid.org/0000-0002-0313-3066

Contact details
Nobels väg 9
Solna
Sweden
17165
+46(0)739204270
asa.norman@ki.se

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Åsa Norman

ORCID ID
https://orcid.org/0000-0002-0313-3066

Contact details
Akademiska sjukhuset
Uppsala
Sweden
751 85
+46(0)739204270
asa.norman@uu.se

Additional identifiers

Study information

Scientific Title
A cluster randomised controlled trial evaluating the effects of a parallel intervention for children of incarcerated parents and their non-incarcerated carers on psychosocial health, compared to treatment as usual

Study objectives
The overall aim of the project is to evaluate a newly developed two-generation intervention for children with incarcerated parents and their non-incarcerated carers with regard to the intervention effects on psychosocial health and with regard to the implementation process.

The main study hypothesis is that the intervention will have a significantly beneficial effect on primary and secondary outcomes compared to the control condition.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/10/2025, Swedish Ethical Review Authority (Box 2110, Uppsala, 750 02, Sweden; +46 (0)10-475 08 00; registrator@etikprovning.se), ref: 2025-05014-01

Primary study design
Interventional

Study design
Cluster randomized controlled study design with a parallel process evaluation

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of poor psychosocial health in children with incarcerated parents and their non-incarcerated carers

Interventions

The intervention for the child-carer-dyad consists of 3 individual and separate sessions for children and carers. Sessions include psychoeducation and brief strategies for managing emotions and situations related to the incarceration.
A final, 4th session is provided for child and carer together to form a common understanding and basis for continued management of the incarceration after the intervention.
The control group is provided the standard support (TAU) available at the units/organisations in the control group.
The intervention is carried out by staff in the general social service units or by staff in civil society organisations that have a specific focus on families affected by incarceration.

Randomisation to intervention or control group will be carried out on cluster level on a 1:1 allocation ratio. Clusters will comprise units within the social services and civil society organisations that agree to participate in the project. Children and carers who receive services will be included in the intervention and control group according to the randomisation of the unit into intervention or control group.

Intervention Type
Behavioural

Primary outcome(s)
Child:
Self/adult-reported KIDSCREEN-27 to measure children's well-being related to physical, psychological, and social, school, and parental/autonomy areas measured before the start of the intervention for each family, i.e. baseline (T0), at the end of the intervention (T1), at three-months follow up (T2), and one year after the intervention (T3).

Carer:
Self-reported SF-36 Health Survey to measure carer wellbeing through eight dimensions related to general health perceptions, physical-, and social functioning, vitality, bodily pain, role limitations due to physical-, and emotional problems, mental health measured before the start of the intervention for each family, i.e. baseline (T0), at the end of the intervention (T1), at three-months follow up (T2), and one year after the intervention (T3).

Key secondary outcome(s)
Secondary outcomes and mediators measured with children and carers before the start of the intervention for each family, i.e. baseline (T0), at the end of the intervention (T1), at three-months follow up (T2), and one year after the intervention (T3).
1. Child self-esteem is measured using the Rosenberg Self-Esteem Scale at T0, T1, T2, and T3
2. Child perceived stress is measured using the Perceived Stress Scale for Kids (PeSSKi) at T0, T1, T2, and T3
3. Child emotion regulation is measured using the Emotion Regulation Questionnaire for Children and Adolescents (ERQ-CA) at T0, T1, T2, and T3
4. Information on what the child has been told about the incarceration is measured using specific items reported by the carer at T0, T1, T2, and T3
5. Quality of the carer-child relationship is measured using the Child Parent Relationship Scale (CPRS) at T0, T1, T2, and T3
6. Carer parenting behaviour related to discipline is measured using the Parenting Scale at T0, T1, T2, and T3
7. Carer parenting stress and perceived social isolation are measured using the Parenting Stress Index (PSI) at T0, T1, T2, and T3
8. Carer perceived stress due to overwhelming or uncontrollable events is measured using the

Perceived Stress Scale (PSS-10) at T0, T1, T2, and T3
9. Child health outcomes including medical and psychiatric disorders, care, and medication are measured using national registries at five years post-intervention
10. Child academic achievement is measured using national registries at five years post-intervention
11. Carer health outcomes including medical and psychiatric disorders, care, and medication are measured using national registries at five years post-intervention
12. Carer socioeconomic indicators including income, employment, and education are measured using national registries at five years post-intervention
13. Acceptability of the intervention is measured using the Acceptability of Intervention Measure (AIM) at T1 for children and carers and at study end for deliverers
14. Appropriateness of the intervention is measured using the Intervention Appropriateness Measure (IAM) at T1 for children and carers and at study end for deliverers
15. Feasibility of the intervention is measured using the Feasibility of Intervention Measure (FIM) at T1 for children and carers and at study end for deliverers
16. Child usage experience is measured using a customized version of the Children's Usage Rating Profile (CURP) at T1
17. Implementation aspects are measured using a study-specific questionnaire for deliverers at study start and study end and an adapted version for carers after intervention
18. Fidelity is measured using structured logs completed by deliverers after each session throughout the intervention period
19. Dose is measured by recording the number of sessions attended by each participant throughout the intervention period
20. Cost-effectiveness is measured using the TiC-P Mini completed by carers at T0 and T3

Completion date
31/12/2032

Eligibility

Key inclusion criteria
Child:
1. Age 6-13 years old.
2. Have one or both parents (biological parent, non-biological parent/carer) in prison or jail in Sweden.
3. Have sufficient proficiency in Swedish to be able to understand the intervention material.

Carer:
1. Age 18 years or older.
2. Be the carer of (e.g. parent, foster parent, or other form of close carer on a regular basis for the child) at least one child aged 6-13 years with an incarcerated parent in prison or jail in Sweden.
3. Have sufficient proficiency in Swedish to be able to understand the intervention material.

Deliverer:
1. Work in one of the units included in the study.
2. If randomised to intervention group: have participated in the intervention training.

Participant type(s)
Carer, Health professional, Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
13 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
Child:
1. Be the victim of a serious crime committed by the parent, such as sexual abuse. The exclusion criterion will be closely monitored by deliverers in communication with researchers including licenced psychologists, and evaluated on an individual child basis. We have seen in interviews with children (yet unpublished) that children may be the victim of crime committed by the parent, such as witnessing violence committed towards the carer, but still be in need of support for handling the parent's incarceration. Therefore, this exclusion criterion will be closely monitored by researchers jointly with deliverers. All participating units have routines for these circumstances that we be taken into action and ensure that children will be provided additional support related to their vicitimasation.
2. Lack sufficient proficiency in Swedish to be able to understand the intervention material.
3. Have a parent in prison or jail in in another country than Sweden.

Carer:
1. Be the victim of a serious crime committed by the parent (see above child criteria, the same applies here).
2. Lack sufficient proficiency in Swedish to be able to understand the intervention material.

Deliverer:
1. Not work in one of the units included in the study.
2. If randomised to intervention group: Not having participated in the intervention training.

Date of first enrolment
10/12/2025

Date of final enrolment
31/12/2026

Locations

Countries of recruitment

Sweden

Study participating centre
Åsa Norman
Nobels väg 9
Solna
Sweden
17165

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type
Not defined

Funder Name
Swedish Research Council for Health, Working Life and Welfare

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available