

BMJ Open Evaluation of the For Our Children's Sake intervention, parental support in prison to influence positive parenting: study protocol for a controlled trial

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ABSTRACT

Introduction Children of incarcerated parents comprise a greatly disadvantaged group in society and positive parenting constitutes an important factor for children's healthy development. Internationally developed parenting interventions for incarcerated parents suggest an impact on parenting outcomes, but no such evaluation has been undertaken in Sweden.

This study aims to investigate the effects of the parenting programme currently offered in prisons in Sweden, For Our Children's Sake (FOCS), through a controlled trial with a parallel implementation process evaluation.

Methods and analysis The effectiveness trial is carried out as a non-blinded controlled trial with a parallel investigation of the implementation process using mixed methods. Participants comprise incarcerated parents (men and women) in Swedish prisons with a target sample size of 76 parents. Eligible parents have a child aged 0 to 18 years, no prohibition to contact or committed a crime against the child, or a violent crime against the other parent. The FOCS intervention is carried out in group format over 10 weeks. The primary outcome is closeness in parent-child relationship measured with the Child Parent Relationship Scale. Secondary outcomes comprise parent-child contact, parental criminal attitude and interest in other treatment programmes. Mediators comprise attitude to parenting, and self-efficacy. Outcome data are self-reported and collected over four time points: baseline (September to December 2019), mid and after intervention, and at 3 months follow-up. Implementation data is collected during and after intervention. Intervention fidelity is monitored through audio recordings, dose is registered per participant, reach comprise included versus eligible number of parents and acceptability is investigated through semi-structured interviews. Factors influencing implementation will be investigated using a questionnaire.

Ethics and dissemination Ethical permission has been obtained by the Swedish Ethical Review Authority 2019-04227. Findings will be published in peer-reviewed journals, presented at scientific conferences and presented to participants in writing.

Trial registration number NCT04101799; Pre-results.

INTRODUCTION

In an international perspective, children of incarcerated parents comprise a greatly

Strengths and limitations of this study

- This is the first controlled study evaluating a parenting intervention in a prison context with a national focus on rehabilitation of prisoners such as the prison context in Sweden and other Nordic countries.
- This study includes a full investigation of the hypothesised mechanistic chain of the intervention to produce change through mediating mechanism.
- The effectiveness evaluation in the overall project is complemented by a parallel investigation of the implementation process where mixed methods are applied.
- In the implementation evaluation, incarcerated parents are included and will voice their experiences and needs, voices that are seldom heard in the research field.
- The lack of randomisation is a limitation to the study, as is the potential exclusion of participants due to limitations regarding the primary outcome measurement or a lack of parent-child contact.

disadvantaged group in society with risk of poor well-being.¹⁻³ These children run a greater risk of social, emotional and behavioural problems, as well as poorer mental health.¹⁻³ Meta-analyses, including Swedish samples, show that children with incarcerated parents have a 10% increased risk for behavioural problems, compared with children without an incarcerated parent⁴ and run a higher risk of own delinquency through an intergenerational effect, where parental delinquency is carried on to the child.²⁻⁵⁻⁶ In Sweden, children (mean age of 11 years) of incarcerated parents themselves and their non-incarcerated caregiver report poorer child mental health compared with the normal child population.⁷ The children express negative and traumatic feelings in relation to the incarceration of the parent, struggling to keep the incarceration a secret, being bullied

when revealing the situation, and experiencing the need for emotional support.⁷

Studies in high-income countries have shown that, for the incarcerated parent, separation from the child through incarceration can lead to stress, despair and powerlessness in relation to parenting.^{8, 9} Positive parenting comprises an important factor for children's healthy development.¹⁰ Incarcerated parents may have difficulties to engage in positive parenting due to disadvantaged situations affecting parenting negatively such as drug addiction, poverty or lack of experience of positive parenting in their own childhood. Previous research has suggested that interventions to prevent the intergenerational effect of criminality should be targeting family factors¹¹ where positive parenting has been emphasised.⁵

Internationally developed parenting interventions for incarcerated parents suggest an impact on parenting outcomes such as positive parent-child interaction, parenting knowledge, empathy, parent stress, increased child contact and active parenting and cooperation with the other caregiver.¹²⁻¹⁴ Intervention effects have also been found on improved child behaviours,^{12, 13, 15} and a possible decrease in parental recidivism.¹⁶ However, the majority of international interventions evaluated to date have been conducted in countries with a prison and probation context with limited generalisability to the Swedish system where focus on rehabilitation is emphasised. In Sweden, the parenting programme for incarcerated parents, For Our Children's Sake (FOCS) was developed between 2012 and 2014 with the aim to support positive parenting for the child's healthy development and is currently delivered in Swedish prisons. A non-controlled pilot from 2015 to 2016 found that the programme was well received by parents and group leaders. To date, no controlled trials on the effects of parenting intervention for incarcerated parents on outcomes related to parenting have been conducted in the Swedish or Nordic setting.

The aim of this project is to evaluate the effects of the FOCS parenting programme on parenting outcomes through a controlled trial with a parallel implementation process evaluation.

Research questions and hypotheses:

- ▶ What are the effects of the FOCS intervention on parenting, criminal attitude and parent-child contact?
 - Hypothesis: the intervention group will have significantly increased parenting outcomes, decreased criminal attitudes and increased parent-child contact compared with the control group.
- ▶ With what fidelity was the intervention conducted and what are the barriers and facilitators to implementing the FOCS intervention as perceived by deliverers and participants?
- ▶ Are the intervention effects on parenting mediated by attitude to parenting and parental self-efficacy?
 - Hypothesis: effects on parenting outcomes, criminal attitudes and parent-child contact is mediated by attitude to parenting and parental self-efficacy.

- ▶ What are the perceptions and experiences of incarcerated parents' parenting among the parents themselves, group leaders and correctional inspectors?

METHODS AND ANALYSIS

Study design

The study was carried out as a controlled trial with a parallel process evaluation. Allocation to intervention and control condition is based on the existing operation planning at each prison. Prisons where a FOCS group was planned during autumn 2019 were allocated to the intervention condition, whereas prisons planning to conduct FOCS during 2020 were allocated to the control condition. As the study was conducted within ongoing practice, randomisation was not possible to apply as the prisons had already set their operation planning at the time of recruitment. In addition to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidance¹⁷ the Template for Intervention Description and Replication (TIDieR) guidance¹⁸ has been followed for SPIRIT item 11. A SPIRIT checklist is provided covering allocation, enrolment and assessments (table 1).

Setting

The evaluation of the FOCS intervention was conducted in high, medium, and low security prisons throughout Sweden. All prisons in Sweden are divided based on sex and run by the governmental authority The Swedish Prison and Probation Services (SPPS) with 45 prisons in total, of which six are for women. A likely number of participating prisons in this study is 20, including four prisons for women only. The SPPS system has, in line with the other Nordic countries, an extensive focus on rehabilitation of prisoners to function as non-criminal citizens in society. This is, for example, signalled by the core value of the SPPS 'Better Out', that is, prisoner should have a better capacity to lead a life without criminality when leaving prison than when entering.

Participants

Inclusion and exclusion criteria are specified for participation in the study itself, but also for inclusion in the measurements of the primary outcome. The primary outcome, quality in relationship between parent and child assumes parent-child contact, which is not possible for all parents, and scales are not developed for all ages of a child. Parents fulfilling the exclusion criteria for the primary outcome will still be included in the measurements regarding attitude to parenting and parental self-efficacy (see mediator below), and criminal attitude (see secondary outcome below). This decision was taken as it is of great use to investigate the mediators and secondary outcomes among this parent group in Sweden which has not been done previously, and as the measurements are of essential theoretical importance to parenting interventions for the target group.

Inclusion criteria for participating parents in the study and regarding the primary outcome:

Table 1 Standard Protocol Items: Recommendations for Interventional Trials checklist for the evaluation of *For Our Children's Sake*. Schedule for enrolment, informant, intervention and assessments.

	Time point						
	Unit/informant	Pre-study	Baseline	Mid intervention	After intervention	3-month follow-up	Post follow-up
		-T0	T0	T1	T2	T3	
Enrolment							
Eligibility screen	Prison/parent	X					
Allocation*	Prison	X					
Informed consent	Parent/group leader/head of prison	X					
Intervention							
Intervention group							
Control group							X
Outcome assessments							
Primary outcome – CPRS	Parent		X		X	X	
Secondary outcome – parent-child contact	Parent		X		X	X	
Secondary outcome – MCAA	Parent		X		X	X	
Secondary outcome – treatment interest	Parent		X		X	X	
Mediator – AAPI-2	Parent		X	X	X	X	
Mediator - PSE	Parent		X	X	X	X	
Demographics	Parent/group leader/head of prison		X				
Implementation process assessments							
Adverse event reporting	Group leader					X	
Treatment fidelity – group session audio recordings	Group leader						
Intervention dose and reach	Parent/group leader/head of prison			X			
Qualitative data – interviews – acceptability of intervention	Parent/group leader/head of prison						X

*Participant allocation based on the existing operation planning at each prison. Prisons where a parenting group is planned for the autumn 2019 will be allocated to the intervention condition, whereas prisons planning to conduct parental groups during 2020 are allocated to the control condition. AAPI-2, Adult-Adolescent Parenting Inventory 2 ; CPRS, Child-Parent Relationship Scale; MCAA, Measures of Criminal Attitudes and Associates; PSE, parental self-efficacy, scale specifically developed for the project.

- ▶ Serving a sentence at any of the included prisons.
- ▶ Having at least one child in the ages between 0 and 18 years.
- ▶ Being in contact with the child/children in any form.
- ▶ Having the legal right to contact the child.
- ▶ Not committed either a crime against the child or any violent crime against the other parent.
- ▶ Sufficient proficiency in the Swedish language, as evaluated by the group leader.

Exclusion criteria for parents' participation in the study:

- ▶ Not fulfilling the inclusion criteria. No other exclusion criteria are applied.

Exclusion from analysis of the primary outcome:

- ▶ Having a child aged 0 to 2 and 13 to 18 years as the measure is not developed for these age groups.
- ▶ Not being in contact with the child, thus the primary outcome is not applicable.

Recruitment

Recruitment was undertaken in two phases. Group allocation was determined in the first recruitment phase. First, prisons were recruited. All prisons with currently trained group leaders or with staff planned for group leader training during 2019 to 2020 were invited to participate through the head of prison. Prisons planning to conduct FOCS with start-up during September to December 2019 were allocated to the intervention group, all other prisons were allocated to the control group. Second, incarcerated parents were recruited, starting in September 2019. Eligible parents were identified by prison staff and recruitment of parents in the intervention and control condition was undertaken in the same manner. As researchers were prohibited to enter prisons due to confidentiality regulations, identified parents were invited to participate by the prison staff, where parents were provided with the information sheet (online supplementary file 1) and could discuss queries with the staff. Parents who wished to participate signed the consent form (online supplementary file 2). Prison staff were in close contact with the researchers throughout the recruitment phase.

Intervention

The programme 'For Our Children's Sake'

The FOCS programme aims to support positive parenting for a child's healthy development. FOCS was developed by the Swedish non-governmental organisation working with children of incarcerated parents, 'Barn och ungdom medförälder/familjemedlem i fängelse' (BUFFF, In English: Child or adolescent with parent/family member in prison), in collaboration with the SPPS. None of the researchers undertaking the evaluation were part of developing the intervention (ÅN, PE). During the first decade of the 21st century the Swedish government increased focus on parental support overall, stating that support should be available for parents in all parts of society, that parental support should be based on the Convention on the Rights of the Child (CRC), and

strive for gender equality. The priorities set by the government guided the search for suitable programmes to be used within Swedish prisons. At the time of programme development in 2012, the responsible developers did not identify any internationally developed and available parenting programmes for incarcerated parents suitable for the priorities and needs in the Swedish prison context. Therefore, the developers decided to develop a new programme for the Swedish prison context specifically. The development process was conducted in phases to identify needs to be targeted, and components to be included in the programme, as well as mode of delivery, format, structure and needs of deliverers. A review of the literature on parenting programmes, needs of incarcerated parents and their children was conducted. Also, a survey including SPPS staff working with the child perspective, and interviews with staff, incarcerated parents and their children were conducted. Experts in relevant fields such as child psychology, parenting in the prison context, children's rights, domestic violence and substance dependence were consulted. The final FOCS programme includes manualised group leader material, group leader training and participant material. The programme targets incarcerated mothers and fathers serving a sentence within the SPPS and is based on developmental psychology, attachment theory, social cognitive theory and the CRC.¹⁹ The programme includes ten 2-hour group sessions delivered weekly in the prison setting. The sessions focus on specific themes related to parenting and children's needs and include information, exercises and reflections as illustrated in [table 2](#). Each session is introduced with the session agenda and participants' summary of the previous session, and ends with a closing summary of each participant's reflection of the current session. Each parent receives a workbook, which is structured according to the sessions' themes and includes information and worksheets for the different activities included in each session. The intervention is delivered by two group leaders who are instructed to use Motivational Interviewing as a mode of delivery. Group leaders comprise prison officers or employees from non-governmental organisations working for children's rights. All group leaders are trained for 5 days including seminars, workshops and exercises covering the theoretical background, contents of material and mode of delivery. The training is performed according to a set format by a team of head trainers employed by the SPPS.

[Table 3](#) presents the programme theory of the FOCS intervention describing its intervention characteristics, process and outcome evaluations and depicting the hypothetical chain in which the FOCS interventions impacts on outcomes through mediators. Given appropriate input of training and time, the FOCS intervention is hypothesised to have a positive effect on parent-child relationship quality through increases in the mediators parenting attitude (based on protective factors for child healthy development), and parental self-efficacy (based on social cognitive theory).

Table 2 Description of the contents, theoretical underpinnings and activities in the *For Our Children's Sake* intervention

Session	CRC article in focus	Aim with session	Theoretical underpinning	Core activities	Material
(1) Welcome to the group	No specified article	<ul style="list-style-type: none"> ▶ Get to know each other ▶ Group structure ▶ Reflect on parenting and children's needs 		<ol style="list-style-type: none"> 1. Introducing the child and your relationship 2. Group rules 3. Group reflection on the meaning and feelings related to parenting 4. Setting individual goals 	<ol style="list-style-type: none"> 1. List of children in a drawn heart which is then present in all sessions 2. List of rules 3. Group reflection from a text 4. Writing goals in the workbook
(2) Me as a parent (cooperation between the parents)	18	<ul style="list-style-type: none"> ▶ Reflect on how the childhood influences parenting ▶ Increase understanding for the other parent ▶ Reflect on how I want to evolve as a parent 		<ol style="list-style-type: none"> 1. Values from own childhood/parents – what do I want to keep in my own parenting 2. Differences between me and the other parent, how can we cooperate 3. Parenting to me 4. An important person in my own childhood 	<ol style="list-style-type: none"> 1. Group reflection from a text, list of values on white board 2. Group discussion, writing own suggestion in workbook 3. Group reflection from a text, discussion on what a good parent is 4. Describing the person in the workbooks
(3) Children's thoughts and feelings	12	<ul style="list-style-type: none"> ▶ Increase understanding for children's feelings when parents commit crime ▶ Provide knowledge of the importance for children to be informed about the situation 	Research on children of incarcerated parents ⁴¹	<ol style="list-style-type: none"> 1. Taking the child's perspective on parental incarceration 2. Reflection on thoughts and feeling related to watching the film 'Emilia', including tips on how to tell the child about crime and custody 	<ol style="list-style-type: none"> 1. Film 'Emilia' – the child's perspective on when a father is put in custody, including real stories from several children 2. Discussion in smaller groups aided by text on separation, guilt and shame and advice on how talk to the child about crime and custody
(4) Children's development and needs	27	<ul style="list-style-type: none"> ▶ Provide knowledge on child development ▶ Discuss risk and protective factors ▶ Map persons of importance to your child 	Developmental psychology ⁴² Risk and protective factors ⁴³ Sense of coherence ⁴⁴	<ol style="list-style-type: none"> 1. Children's age specific needs 2. Children's adaptation to rules 3. Risk and protective factors for children's healthy development 4. Mapping of persons of importance in the own child's life 	<ol style="list-style-type: none"> 1. Discussion and sharing of own experiences aided by text on children's needs 2. Discussion on what happens to a child who gets too strict and too loose rules 3. Reflections on factors in the child's life and positive parental support aided by text on risk and protective factors 4. Child network map in the workbook
(5) Children of incarcerated parents	9	<ul style="list-style-type: none"> ▶ Provide knowledge on child of incarcerated parents ▶ Discuss how to be a good parent from a distance ▶ Increase understanding of children's perceptions and needs in the situation 	Risk and protective factors for child of incarcerated parent ⁴¹ Attachment theory ²¹	<ol style="list-style-type: none"> 1. Children's reaction to parental incarceration 2. How children are affected by parental incarceration 3. Common questions and worries of children 4. Specific needs of children with incarcerated parents and how I can help my child 	<ol style="list-style-type: none"> 1. Group reflection from a text on the own child's reaction and my own response as a parent 2. Discussion on how the child is affected, what the child does not dare to ask and how to help the child to ask and talk 3. Discussion and sharing of ideas aided by text on children's needs, questions and worries
(6) Conflicts, violence and security	19	<ul style="list-style-type: none"> ▶ Provide knowledge of the effect of violence on a child ▶ Discuss how to handle anger 	Developmental psychology ⁴² Risk/protective factors ⁴³	<ol style="list-style-type: none"> 1. Reflection on my own expressions and reactions of anger 2. Discussion on how children are affected by violence 3. Taking the child's perspective on violence 4. My own view on children and violence 	<ol style="list-style-type: none"> 1. Writing reflections and potential change in the workbook aided by text on violence and advice on anger management 2. Group discussions from text and examples 3. Film 'I said I had a nightmare' – the child's perspective on experiencing violence and group discussion afterwards 4. Value-based activity with group reflections
(7) My challenges	No specified article	<ul style="list-style-type: none"> ▶ Reflect on personal challenges as parent ▶ Establish course of action to become the parent I want 	Self-efficacy – Social Cognitive Theory ²⁶	<ol style="list-style-type: none"> 1. Reflection on how I want to be as a parent versus what I do 2. Discussion on challenges that can be influenced 3. Reflection on the parent I want to be 	<ol style="list-style-type: none"> 1. Discussion in smaller groups aided by text 2. Poem read to the group followed by discussion on challenges, list examples on white board and divide as possible/not possible to influence 3. Resources I need and steps I will take to become the parent I want to be, written in workbook

Continued

Table 2 Continued

Session	CRC article in focus	Aim with session	Theoretical underpinning	Core activities	Material
(8) Five parenting roles	5	<ul style="list-style-type: none"> ▶ Explore parenthood based on five roles ▶ Identify strengths and target for change in my parenting 	Theory on five different roles in parenting ⁴⁵	<ol style="list-style-type: none"> 1. Reflection on my own relation to the five different roles in parenthood 2. Discussion on challenges that can be influenced 	<ol style="list-style-type: none"> 1. Group reflection based on text on the five roles, 'lover giver', 'caregiver', 'teacher of life', 'teacher of relations' and 'boundary setter', what the roles include and the function, examples of situations with a child for each role, how much do I have of the role
(9) Fresh start, reunion and group closure	No specified article	<ul style="list-style-type: none"> ▶ Discussing the importance of preparing yourself and the family for the reunion ▶ Reflect on my own development 		<ol style="list-style-type: none"> 1. Discussion on challenges and facilitators for reunion 2. Discussion on not getting to reunite and 3. Looking back on values and learning from the previous sessions 	<ol style="list-style-type: none"> 1. Discussion based on an example in text, and discussion on how form a good reunion aided by advice in text 2. Discussion on feelings and how to help the child without reunion 3. Going through the workbook and writing down things to bring into the continued parenting
(10) Topic of choice	No specified article	Included as sessions 3 to 9, never as the last session.		Topic of importance for the group, for example, drug addiction, social services, parenting organisations, child psychiatry	

CRC, Convention on the Rights of the Child.

Control condition

Parents in the control group will receive treatment as usual, which includes continuing the activities as he or she has done prior to study start. This may include being in contact with their child, participating in activities in non-governmental organisations working for children's rights and counselling. Activities related to parenting that the parent has participated in will be monitored at the measurement after intervention. Parents in the control condition were offered to participate in the FOCS programme after the follow-up measurement in accordance with the operation planning at each prison.

Outcome evaluation

Primary outcome

The primary outcome was positive change from baseline in relationship quality between incarcerated parent and child as self-reported by the parent via the instrumented Child-Parent Relationship Scale (CPRS)²⁰ measured on a 5-point Likert scale. Treatment success was considered as significant differences in change in the mean score of the scale between intervention and control groups. The primary outcome point was the after-intervention measurement (T2). The CPRS scale has been used by numerous previous studies, which facilitates comparison. In this study the subscale closeness (seven items) was used, which has shown good internal consistency ($\alpha=0.74$) when used for parents of 4-to 6-year-old children.²⁰ As incarcerated parents have limited contact with their children, no measurement reflecting specific parental behaviour in situations together with the child were used. The CPRS measure reflects the parent's own perception of the relationship and thus reflects no specific situation together with the child which makes the measure applicable to this study. The CPRS scale is based on attachment

theory²¹ and the closeness subscale measures the degree to which the parent experiences the relationship with the child as affectionate and warm with open communication²⁰ If the incarcerated parent had more than one child aged 3 to 12 years, one index child was chosen by the researchers for whom the parent responded to the CPRS scale.

Secondary outcomes

Secondary outcomes comprise self-reported contact frequency between the incarcerated parent and child/children, parental criminal attitude and parental interest in other treatment programmes. Treatment success was considered as significant differences in change from baseline between intervention and control group at the measurement immediately after intervention.

Criminal attitude was measured on a 5-point Likert scale via the Measures of Criminal Attitudes and Associates (MCAA), which has been validated in a Swedish context with good validity and reliability.²² The mean score of eight items in the subscale antisocial intent was used in this study. The scale has shown good internal consistency in a Swedish context ($\alpha=0.90$).

Interest in other treatment programmes was measured with one item on an 11-point scale (0 no interest, 10 very high interest).

Contact frequency between parent and child was reported as type of contact (meeting face-to-face (visit/during leave), telephone, letter) and how often. Difference in mean number of contacts between the groups was used in the study, with the quality of contact as a descriptive measure as it was affected by prison regulations that the parent may not be able to influence.

Table 3 Programme theory of the *For Our Children's Sake* intervention, describing intervention characteristics, process and outcome evaluations and the hypothesised chain of impact of intervention on outcomes through mediators

Intervention characteristics			Process evaluation		Outcome evaluation			
Input	Intervention components	Material	Implementation strategies	Intermediate outcomes/mediator outcomes	Implementation outcomes	Short-term outcomes	Long-term outcomes (not assessed)	Distal outcomes (not assessed)
Group leader training	Ten group sessions, 'FOCS'	Group leader manual	Pre-group interviews	Parental attitude (AAPI-2)	Fidelity	Quality of CPRS	Child health related quality of life	Child delinquency
Time to prepare, administer and conduct groups		Parent workbook	Leadership engagement	Parental self-efficacy	Dose	Parental criminal attitudes (MCAA)	Child school results	Child employment rate
					Reach	Parent-child contact		Teen pregnancies
					Acceptability	Treatment interest		Parent delinquency
						Parenting practices (not assessed)		

AAPI-2, Adult-Adolescent Parenting Inventory 2 ; CPRS, Child-Parent Relationship Scale; FOCS, For Our Children's Sake ; MCAA, Measures of Criminal Attitudes and Associates .

Mediators

Mediators hypothesised to influence the outcomes comprise attitude to parenting, and self-efficacy to engage in positive parenting measured on 5-point Likert scale. As this study targeted incarcerated parents who had very little face-to-face contact with their children, cognitive measures were deemed the most appropriate. However, such measures developed and used by other studies, and that also suited the intervention themes and activities were difficult to find. The two measures used in the study comprise cognitive, and hypothetical items that were suitable for parents with limited contact with the children, of which one measure (self-efficacy) had been designed for this study specifically.

Attitude to parenting was measured using The Adult-Adolescent Parenting Inventory 2 (AAPI-2), which is based on developmental theory and risk factors for child abuse and neglect.²³ The AAPI-2 has been used in several international studies targeting parenting among incarcerated parents. The scale has undergone several psychometric testing, which all show acceptable results, but indicate that subscales may vary to a high degree between different samples and that items may be better used as one single scale.^{24 25} The 13 items deemed most relevant and with the highest loadings over the different psychometric studies have been chosen for the study. Items cover important concepts for child development: inappropriate parental expectations, parental lack of an empathic awareness of children's needs, parent-child role reversal, oppressing children's power and independence.²³ A significant difference between groups in change of the mean score of the items was used in the study. The items underwent pilot testing with incarcerated parents before use.

Self-efficacy comprises a central construct and driver for behaviour change in social cognitive theory²⁶ and refers to a person's belief in their own capability to perform a behaviour which produces an expected result, for example, performing a parenting behaviour that produces a secure situation for the child. In this study, self-efficacy to engage in positive parenting was measured through a questionnaire that relate to parents' self-efficacy in recognising children's emotional needs in five different cognitive and emotional states. No existing instrument was deemed suitable, so a study-specific scale was developed. The instrument was pilot-tested before use. Significant difference between groups in change of the mean score of the items will be used.

Demographic data

For incarcerated parents, demographic data was collected regarding sex, age, country of birth (and years residing in Sweden), education, employment before incarceration, number of children, age and sex of children, custody of children, co-habiting status with the other parent, total number of convictions, length of current conviction, living together with own parents in childhood. Number of convictions was related to children's' future

delinquency in previous studies,⁴ and cohabiting with a child was related to decreased parent recidivism.¹⁶ For group leaders and correctional inspectors, demographic data was collected regarding age, sex, education, position, years in current position (correctional inspectors) and number of FOCS conducted (group leader).

All demographic data was used as descriptive characteristics of the sample, and as potential moderators of effects.

Sample size calculation

As the number of individuals per prison was very small (about five participants), a sample size on individuals was used. The G*Power software²⁷ was used to calculate sample size, assuming that equal distribution of participants between intervention and control groups. The sample size calculation was based on desired change in the primary outcome CPRS. Regarding the closeness subscale, previous studies have described that an average mean difference of 0.5 scale steps (range 0 to 5)^{28 29} is of clinical importance. These changes render a medium to large effect size. However, as the scale has not been used in the target group of incarcerated parents, we wanted the possibility to detect changes of smaller effects sizes. With 85% power and 5% significance level, a total of 76 parents were needed to detect a significant difference between the groups of a medium effect size ($f^2=0.15$). Thus, the target number of parents to be included in the study was 76. As some participants would have a child <3 or >12 years of age, over-recruitment was applied in order to cater to dropout and to increase the possibility to reach the estimated sample size for the primary outcome. As the mediator measure AAPI-2 was used extensively in the target group, we also wanted to explore how the sample size calculation applied to significant differences for this measure. Considering the desired effect size described for the primary outcome, differences in changes in the ranges of medium and medium-to-small effect sizes were found in previous studies using the AAPI-2 in the target group.^{30 31} However, for the power calculation of mediation analyses, no previous study was performed on the AAPI-2 scale, nor does G*Power allow for such calculation. Therefore, the Fritz and MacKinnon's³² estimated required sample size table for single-mediator models was used to estimate an appropriate sample size for the mediation analyses. Their estimation for mediation analyses using the bias-corrected bootstrap medium effect sizes on both the α and the β path rendered a sample size of 71 parents.

Data collection

Data from the intervention group was collected at baseline before the first group session from September to December 2019 (T0), mid-intervention, after session 6 (T1), after the last session from January to March 2020 (T2); it will also be done at 3 months follow-up from April to June 2020 (T3). All outcomes and mediators will be measured during T0, T2, and T3. To decrease participants'

burden, the T1 measurement includes mediators and the primary outcome only in order to follow changes in the hypothesised mechanism of change in line with the programme theory. Data from the control group will be collected during the same time period: T1 – 6 weeks after T0, T2 – 10 weeks after T0 and T3 – 3 months after T2. T0 differs between prisons (September to December 2019) according to the specific operation planning at each prison. Data collection was conducted using paper questionnaires and collected by group leaders according to a checklist provided by the researchers. Due to the nature of the study, it was not possible to apply blinding of participating parents, delivering group leaders, or responsible researchers.

Process evaluation

When assessing intervention effectiveness, it is important to monitor the implementation process to determine that the intervention was conducted as intended, and to gain information on factors that need revision for large-scale implementation.³³ This process evaluation will be conducted in parallel with the outcome evaluation using a mixed methods approach.³⁴ The process evaluation will monitor the implementation of the intervention through quantitative data while the qualitative data will provide insight into possible points for revision of the intervention to further enhance possible effects and embrace parents' needs.

Data and data collection

Quantitative data

► **Factors influencing implementation:** a questionnaire regarding personal, organisational and intervention factors influencing implementation will be used. To target multilevel factors that are known to influence implementation, the questionnaire is based on the Consolidated Framework for Advancing Implementation Science (CFIR).³⁵ The CFIR is a consolidation of concepts influencing implementation in health service research found in 19 implementation frameworks into one typology with a common terminology. In total, CFIR comprises 37 specific constructs/factors spread over five overarching domains/levels; (1) intervention characteristics, (2) outer setting/society, (3) inner setting/the organisation, (4) characteristics of individuals/deliverers and (5) process of implementation. No questionnaire suitable for the study currently exists. Therefore, a new study-specific scale will be used, with items based on two previous scales,^{36 37} adapted to the prison context. The scale will be pilot-tested before use. The questionnaire will provide a wide view of barriers and facilitators to the implementation of the FOCS programme as it will be responded to by all parents, group leaders and correctional inspectors in the intervention and control group. Parents in the intervention group will respond to nine items, and parents in the control group to four items. In both intervention and control

groups, group leaders will respond to 17 items and correctional inspectors to 16 items.

- **Fidelity:** Group leaders in the intervention group will audio record each group sessions. Recordings will be coded for group leaders' fidelity to intervention components and mode of delivery by researchers. The dimension knowledge (of the programme and underlying theory), structure (balancing activities and keeping an orderly flow) and clinical process (creating a safe and supportive context) within the Fidelity of Implementation Rating System will be used. This rating system was developed for fidelity ratings of group leaders delivering parenting programmes and has shown good predictive validity.³⁸ Group leaders will also fill in a short, structured log after each session. The log will be provided by the researchers and group leaders will note if central themes, as stated by the programme manual, were covered during the session, adaptation of the session and how the session was received by the participants.
- **Dose:** Group leaders in the intervention group will note the number of sessions attended by each participant.
- **Reach:** Group leaders will report the number of parents participating in the intervention compared with the number of eligible parents in the unit.

Qualitative data

Semi-structured interviews using open-ended questions with interview guides was developed based on CFIR.³⁵ The interviews will cover themes related to perception of participation in the FOCS programme, needs for conducting and sustaining the FOCS programme within the prison setting, possible needs of revision of the group material and perceptions of own/ incarcerated parents' parenting. The qualitative data will provide in-depth information regarding acceptability, feasibility, possibly needs of revision and barriers and facilitators to the implementation of the FOCS programme. Thirty-minute interviews, either face-to-face or on the telephone, will be conducted with a purposeful sample of parents (n=15), group leaders (n=5) and correctional inspectors (n=5) in the intervention group. Reimbursement of 20€ will be offered to parents participating in the interview. Interviews will be audio recorded and transcribed verbatim.

Plan for data analysis and data management

All data will be anonymised by exchanging personal data to codes. Linkage between code and personal data will be kept separate in a secure and locked place. Data on paper will be entered into digital form by the researchers. Data on paper will be stored securely at Karolinska Institute, and digital data will be stored on secured data servers at Karolinska Institute, with access for the responsible researchers only. Folders containing raw data will be stored separately from the data being used in analysis.

Quantitative data will be processed using SPSS 26.0 software package (Chicago, Illinois, USA), and R V.3.6.0.³⁹

Descriptive analyses on baseline data will be performed using t-test and χ^2 . Effects of intervention on outcomes will be evaluated using mixed model regression, including repeated measures which accounts for auto-correlations and models data that includes missing cases. Analysis will be performed according to an intention to treat approach, and per protocol. All parents in the control and interventions groups with measurements at T0 will be included in intention-to-treat approach, whereas control group and parents in the intervention group who participated in all 10 intervention sessions will be included in the per protocol analysis. The effect of intervention will first be tested in a crude model for outcomes with group as the predictor and adjusted for baseline values of the relevant outcome will be tested. Second, moderators will be added to the model. Moderated analyses will be performed using demographic data, including parental sex, level of education, number of sentence, and whether the parent was living together with a child before the current sentence. Models will be compared according to -2 Log Likelihood values to assess the model fit. Level of significance will be set to 0.05 and all test will be two-tailed. Mediated effects on relationship quality as a result of change in parenting attitude and self-efficacy will be analysed through structural equation modelling. Bias-corrected bootstrapping will be used with 500 bootstrap resamples. Direct, indirect, total effect and proportion-mediated effect will be assessed with group as the predictor and adjusting for baseline values of outcomes and mediators.

Quantitative data will be analysed using descriptive statistics and correlations. Qualitative data will be analysed using qualitative content analysis.⁴⁰ Results of the analyses will be synthesised and interpreted as a whole.

Patient and public involvement

No patient involved.

ETHICS AND DISSEMINATION

Ethical permission has been obtained by the Swedish Ethical Review Authority 2019–04227. The trial will be conducted in accordance with the ethical principles of the Declaration of Helsinki. A trial steering group with researchers and staff from the SPPS has been formed to guide the trial and ensure that ethical guidelines are followed. Findings will be published in peer-reviewed journals, presented at national and international conferences and presented to participating parents in written form.

Contributors ÅN and PE conceived the study design and methods. ÅN drafted the manuscript and both authors have approved the final version.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Not required.

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