Healthy Dads Healthy Kids in Prisons: a feasibility study and pilot for an intervention to improve father-child relationships

Study Protocol

V1.0

18 March 2022

This protocol has regard for HRA guidance

FULL/LONG TITLE OF THE STUDY

Healthy Dads Healthy Kids in Prisons: a feasibility study and pilot for an intervention to improve father-child relationships

SHORT STUDY TITLE / ACRONYM

HDHK-P Feasibility and Pilot Study

PROTOCOL VERSION NUMBER AND DATE

Protocol Version: 1.0

Date: 18 March 2022

RESEARCH REFERENCE NUMBERS

IRAS Number:	This project has not been approved through the IRAS system, as it does not involve NHS patients, staff or institutions, or any of the other organisations, agencies or categories covered by IRAS. The study has been registered with Research Registry and has been allocated reference number: researchregistry7752
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This project is funded by the NIHR [Public Health Research Programme (NIHR129791)]. The views expressed are those of the author and not necessarily those of the NIHR or the Department of Health and Social Care.

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted, and that the co-Chief Investigators agree to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

We agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

We also confirm that we will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: 

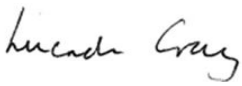
Date:
14/04/2022

.....

Name (please print): Dr Debra Stuart

Position: University of Glasgow Research Regulation and Compliance

Co-Chief Investigators:

Signature: 

Date:
18/03/2022

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Date:
18/03/2022

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Committees	University of Glasgow College of Social Sciences Research Ethics Committee Scottish Prison Service Research Access and Ethics Committee

STUDY SUMMARY

People who have been imprisoned (95% of whom are men) are at high risk of increased mortality and poor health. Children of imprisoned parents have poorer health, education and offending outcomes compared to other children. Around half of people in custody lose contact with their families while imprisoned. Delivering effective relationship-promoting interventions to fathers in custody can improve the mental health, wellbeing and self-esteem of fathers and their children, break possible inter-generational cycles of disadvantage, and reduce recidivism and inequalities.

A program known as Healthy Dads, Healthy Kids (HDHK) has shown significantly improved health outcomes and behaviours in fathers and children when delivered in community settings. For the first time internationally, the program has been adapted for delivery in prisons (HDHK-P). HDHK-P is designed to facilitate children's contact with their fathers and uses enjoyable joint physical activity and healthy eating sessions to improve their health, and father-child relationships. Completed development work means a first version of HDHK-P is available, which requires some further adaptation following changes in prison regimes during COVID-19. Physical Education Instructors (PEIs) in two prisons will then be trained to deliver the program.

Work package 1 (WP1) will adapt the current version of HDHK-P to reflect the new 'COVID prison context', before testing the feasibility of delivering the program to groups of fathers and their children in two prisons (HMP Perth and HMP Barlinnie). It will then further refine the program content and delivery process for the WP2 pilot. Meetings with key stakeholders in the two prisons and with those supporting men's families within the community will inform COVID-related adaptations, identify any recruitment and implementation issues, and explore the acceptability and feasibility of the proposed research methods.

WP2 will pilot two deliveries (A and B) of the optimised HDHK-P in the same two prisons (four deliveries in total) and will assess research procedures for a future full-scale evaluation. The research team will observe program sessions and conduct: in-depth interviews with the PEI facilitators, the participating fathers and the adults accompanying the children to program sessions; and group discussions with the participating children. Baseline and follow-up measures (at 9 weeks and 6 months for deliveries A and B, and at 9 months for delivery A) will collect data on fathers' mental health and wellbeing (likely primary outcome in a future full-scale evaluation), and a selection of the following potential secondary outcomes in a future full-scale evaluation (to be finalised in WP1): father and child self-esteem, father discretionary food/drinks prison canteen purchases, father and child self-reported dietary intake, father and child physical activity, father and child weight, child screen time, quality of the father-child relationship from both perspectives, and child socio-emotional health and self-worth.

WP3 will involve a wider prison consultation with regard to future full-scale evaluation and rollout. An optimized HDHK-P program will be a key output of the study. Progression to a full-scale evaluation will make use of a red-green-amber system designed to assess: positivity about the program among stakeholders; and aspects of delivery and sustainability that are pertinent to such an evaluation being possible. The possibility of embedding the program in the Scottish's Prison Service's Family Strategy will also be explored.

Study Title	Healthy Dads Healthy Kids in Prisons: a feasibility study and pilot for an intervention to improve father-child relationships
Internal ref. no. (or short title)	HDHK-P Feasibility and Pilot Study
Study Design	A mixed-method two phase feasibility study and before-and-after pilot evaluation
Study Participants	Incarcerated fathers and their children aged 8-11 years in two Scottish Prisons (HMP Perth and HMP Barlinnie)
Planned Size of Sample (if applicable)	Phase 1 Feasibility study: 16-20 fathers each with 1-2 children Phase 2 Pilot study: 32-40 fathers and 32-64 children (and HDHK-P facilitators (N=2-6), prison administrative/managerial staff (N=6-8) and adults accompanying children to attend intervention sessions at the prisons (N~16))
Follow up duration (if applicable)	Phase 1 Feasibility study N/A Phase 2 Pilot study 9 weeks, 6 months and 9 months
Planned Study Period	24 months

Research Question/Aim(s)	Overarching aims: To assess whether it is feasible and acceptable to imprisoned men, their children and families, and key prison staff to: a) implement the prison-based HDHK-P program delivered by trained prison physical education instructors (PEIs); and b) assess its potential to improve: fathers' mental health and wellbeing; fathers' and children's self-esteem and health behaviours; children's socio-emotional health, and father-child relationships. The study also aims to assess whether or not progression to a full-scale evaluation and rollout is justified. Specific research questions: RQ1 How do men, children, families, intervention facilitators and other prison staff experience HDHK-P program deliveries? RQ2 Is it possible to implement and deliver an intervention adapted from a successful community-based father-child program in the prison setting? RQ3 What is the potential of HDHK-P to deliver its target outcomes? RQ4 How do men, children, families, intervention facilitators and other prison staff view data collection methods, and what and how much is asked? RQ5 Are the proposed methods and outcomes for a future full-scale evaluation feasible, meaningful and acceptable to all parties?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
National Institute for Health Research Public Health Research. Project Manager Helen Buxton, helen.buxton@nihr.ac.uk	Research funding

ROLE OF STUDY SPONSOR AND FUNDER

The University of Glasgow will act as Sponsor, providing the necessary insurance to indemnify the study. The Sponsor will monitor the study commensurate with risk, as required.

The NIHR will fund the study, providing the necessary resources to conduct the study.

Beyond these roles, the Sponsor and the Funder will exercise no influence over data analysis and interpretation, manuscript writing or dissemination of results.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Three groups are involved in the co-ordination and management of this study. Complying with best practice, this project will be managed by a Project Management Committee (PMC) and overseen by an independent Study Steering Group (SSG). In addition, HDHK-P planning and delivery groups will be formed within each prison to ensure that the procedures and program content is optimised for children, families and relevant prison staff.

The PMC will comprise of all members of the project team including the co-CIs, Cindy Gray and Kate Hunt, the Investigators, Nicola McMeekin, Shaun Treweek, Catherine Best, Evangelia Demou, Ashley Brown, Stephanie Chambers and Philip Morgan, and the Research Associate. It will be responsible for overseeing all aspects of the project design and delivery, and will function as the executive committee responsible for all decisions made on the project. The PMC will meet via Zoom/Microsoft Teams once every six weeks on average to review progress, make key decisions and agree any risk mitigation actions required. There will also be a further core delivery team of the co-CIs Gray and Hunt and the Research Associate who will meet on a weekly basis to plan actions and review progress, referring to the PMC where necessary. Sponsor representatives will attend these meetings as required.

The full project team will meet at key milestones to agree actions. These include but are not limited to: project inception to establish actions for the full project; end of Phase 1 to share learning and agree the steps for Phase 2; and end of Phase 2 to share learning, agree outputs and dissemination activity, and review outcomes in relation to the progression criteria. Detailed notes of all meetings with action points will be produced and agreed, and the co-CIs will be responsible for ensuring that these actions are undertaken. A detailed project timetable will be produced, with dependencies clearly marked, shared with the whole team and used to track progress against key milestones.

The independent SSG will function as the executive committee overseeing the project, ensuring that the research is ethical and robust, and providing advice to the PMC where needed. Membership of this independent group will be voluntary, with no remuneration or formal arrangements made (beyond the terms of reference, which will be drafted and agreed by the group). For this project, the SSG will be asked to operate as a critical friend to the PMC and this will be reflected in their terms of reference. Membership will include the following: Chair: Professor Russ Jago (children and physical activity; additional members: Dr Steph Scott (marginalisation and health inequalities, including people in custody; young people, families and mental health); Professor Nancy Loucks (working with families affected by imprisonment); Ms Sara Corbett (families and children Policymaker); and Ms Alana Grant (young people and the criminal justice system). Co-CIs Cindy Gray and Kate Hunt will represent the project team. The SSG will meet on average every 6-12 months throughout the duration of the project, or as required, with the timing of meetings to reflect key milestones and decisions, for example prior to WP2 to discuss learning from WP1 and agree actions.

The HDHK-P planning and delivery groups will be formed at the start of the project, and will likely include the main PEI facilitators from HMP Perth and HMP Barlinnie, family contact officers and front-of-house representatives, as well as the Research Associate and co-CIs. The groups will meet regularly (every 2-3 months) throughout the first 12 months of the project and once at the end of the project to allow all appropriate prison staff to scrutinise family access issues and program content and delivery to ensure that HDHK-P is fully optimised for future full-scale evaluation and rollout.

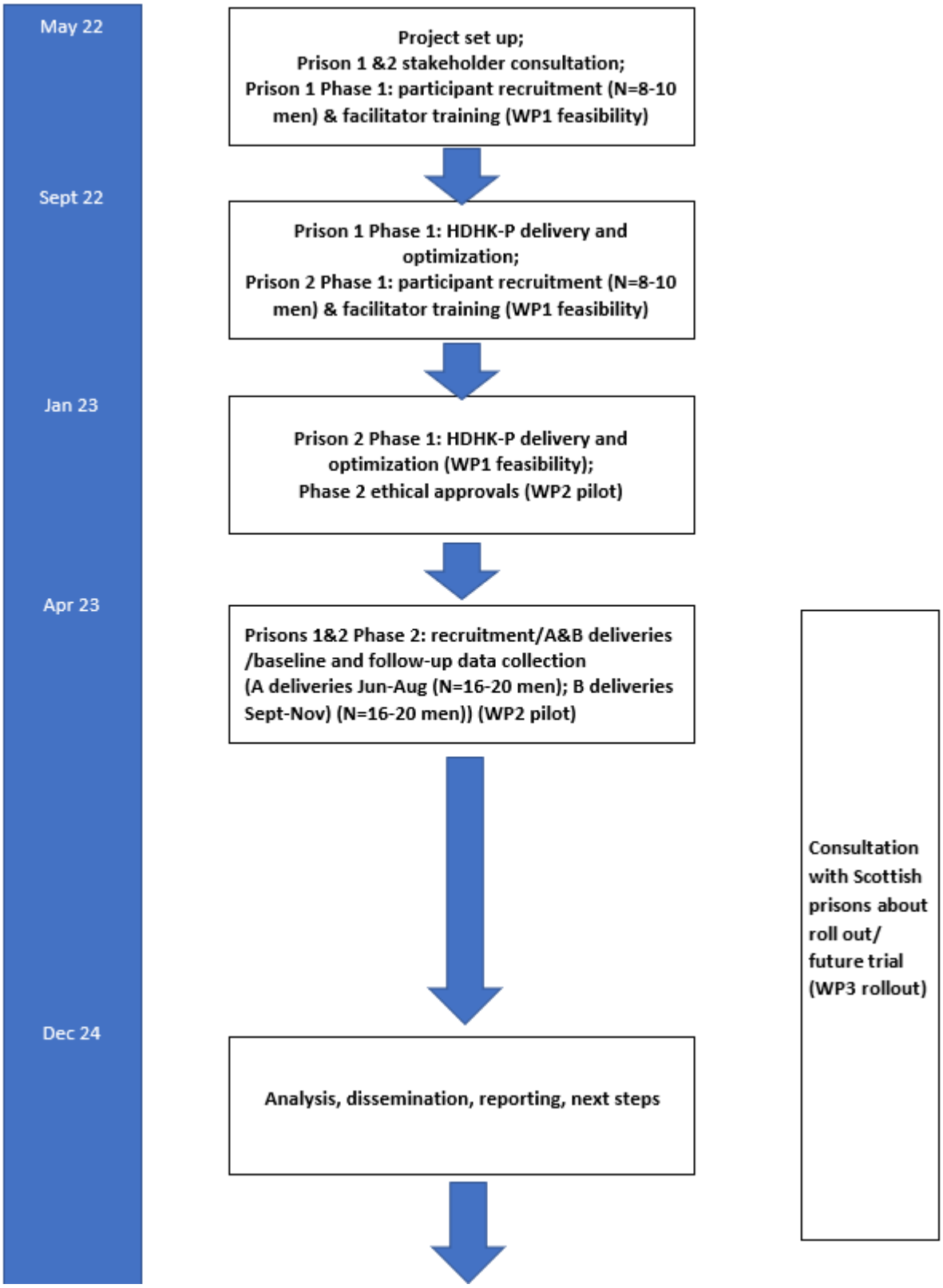
PROTOCOL CONTRIBUTORS

The study Sponsor, the University of Glasgow, exerted no control or influence over the final research design. The Funder, NIHR, exerted no direct control or influence, but did administer the peer review process through which the final research design was arrived at.

PEI Craig Mailer led discussions with men participating in Fit for LIFE within HMP Perth to ask them about the potential appeal of HDHK-P to fathers in custody. The co-CIs have also discussed the proposed project with PEI Charlie Ross at HMP Barlinnie and have had conducted initial meetings with family contact officers and prison management at both prisons. These consultations have informed the design of the study, including participant recruitment and target numbers, the initial adaptation of the intervention for the prison setting and the timing/duration/location of HDHK-P sessions.

KEY WORDS: prison, father-child relationships, mental health, wellbeing, physical activity, diet

STUDY FLOW CHART



STUDY PROTOCOL

Healthy Dads Healthy Kids in Prisons: a feasibility study and pilot for an intervention to improve father-child relationships

1 BACKGROUND

This study seeks to test an intervention to improve the health, wellbeing and self-esteem of fathers in custody, and their children. Those who have been imprisoned are at high risk of increased mortality and poor health (1), including mental health problems (2). Estimates suggest that around 30,000 Scottish children have a parent in prison (3). About half of people in custody, around 95% of whom are men, lose contact with their families while imprisoned (4). Growing evidence highlights poor health, education and offending outcomes for children of imprisoned parents compared to other children (5, 6, 7). Children of imprisoned parents are identified as a key group in current Scottish Government efforts to tackle child poverty and associated inequalities in health and social outcomes (8), and the Scottish Prison Service has a family strategy designed to improve outcomes for parents in custody and their families, with the rationale that positive relationships can reduce the likelihood of reoffending (9). Delivering effective relationship-promoting interventions to fathers in custody can improve the mental health, wellbeing and self-esteem of fathers and their children, break possible inter-generational cycles of disadvantage, and reduce recidivism and inequalities.

The proposed study aims to undertake a feasibility study (work package (WP1)) and pilot evaluation (WP2) (guided by the MRC complex interventions framework (10)) of Healthy Dads, Healthy Kids Prisons (HDHK-P). HDHK-P is an adapted version of an evidence-based healthy lifestyle intervention (Healthy Dads, Healthy Kids, (HDHK)) that has father-child relationships at its core and achieves positive outcomes in community settings. It will ascertain whether this adapted version is feasible and acceptable when delivered in the prison setting, and will explore its potential to: improve the mental health, wellbeing and self-esteem of imprisoned fathers, and the self-esteem and socio-emotional wellbeing of their children; improve health behaviours in imprisoned fathers and their children; and strengthen father-child relationships. The study will also explore whether or not progression to a full-scale evaluation and/or rollout is justified (in WP3). The proposal is underpinned by extensive formative work (co-creation, co-planning and discussion, visits and training) by the Investigators over a number of years with key members of staff within the Scottish Prison Service.

2 RATIONALE

The importance of imprisoned fathers maintaining contact with children, where possible, has been increasingly recognised by the Scottish Prison Service in recent years (9); and a number of positive developments have occurred which will facilitate delivery of HDHK-P. These include: policy commitments from the Scottish Prison Service to support family contact and implement relationship-building interventions for male prisoners; the introduction of Family Contact Officers; and new and improved visitor centres (9). Enabling imprisoned fathers to have meaningful contact with their families may improve their parenting skills, mental health and general wellbeing (11). At the same time, opportunities for meaningful parental contact may help to mitigate some of the difficulties experienced by children following the imprisonment of a parent, including the negative psychological and emotional impacts of separation, and breakdown of family ties. Importantly, family interventions delivered in prisons have the potential to deliver broader social benefits by supporting resettlement and desistance from crime (12), and additionally, HDHK-P targets key behaviours to promote health. Consistent with Scottish Government and Scottish Prison Service strategies, the introduction of HDHK-P is predicated on a view that positive family relationships are important for reducing reoffending (13).

Prisons, as largely closed systems, have the potential to engage the most disadvantaged in society in health promotion and behavioural change (14), and there is a clear need, and remit, for relationship-based interventions to be implemented in such a setting. The introduction of HDHK-P thus enables a route to reach disadvantaged fathers and their children in a cost-effective way. It will add to the efforts to facilitate children's contact with their imprisoned fathers, as family relationships have been shown to be key in supporting desistance (13), whilst encouraging fathers and their children to engage with and support each other in physical activity and other positive behaviour changes.

Whilst there is established evidence that relationship programs can be effective, the evidence base for interventions targeting fathers (rather than mothers) is much less developed (15), and particularly so for fathers in prison (16). Some conventional parenting interventions have been successfully implemented with high levels of engagement and retention within UK prisons, suggesting that relationship interventions can be highly acceptable to imprisoned men and prison staff (17). Such interventions have been shown to produce short term improvements in knowledge and attitudes (18); however, evaluations have tended to be conducted by those delivering the intervention, with little work evaluating the outcomes, wider changes to health and health behaviour or longer-term impact (16). The need for more rigorous evaluation of prison-based interventions has been recognised in order to inform policy and practice around maintaining positive family relationships whilst men are in custody, transitioning back to society and post-release (16).

Where children are actively involved in some of these interventions there is also potential for improvement in their outcomes. However, few interventions in the prison setting have been successful in actively involving children, and previous research has mainly focused on the challenges to implementing family interventions within the prison (16). This literature has informed discussions with Scottish prison staff to identify the changes needed to adapt HDHK for the prison setting. In designing both the HDHK-P intervention and the planned research, this consultation has been crucial for identifying potential and actual barriers to implementation. In addition, the skills and experience of project team members in working in prisons will ensure the study can contribute to pioneering research to facilitate further rigorous evaluations of prison-based health and social interventions (including follow-up of participants post-release), and provide valuable evidence for future implementation of such interventions in prisons in the UK and beyond (including within Australia where Investigator Morgan is based and HDHK was first developed). The study also builds on the growing body of evidence suggesting that sports settings (here prison gyms) and physical activity can be effective ways to attract and engage men in broader health interventions (19).

The Scottish Government is committed to tackling health inequalities across a range of key areas that HDHK-P aims to address for the men, children and families involved. There are currently national performance indicators around children's social and emotional health, including reducing the number of children aged 4-12 years with a borderline or high total difficulties score (20), and increasing the number of children that have positive relationships (21). Children and young people's mental health is given specific focus in the Scottish Government's Mental Health Strategy (22), with a commitment to identifying evidence-based interventions that can improve mental health and wellbeing. HDHK-P is a group-based, face-to-face, weekly program that centres around encouraging children to be more active alongside their fathers, and positively influencing their dietary habits (such as reducing intake of the sugar-sweetened beverages and other 'discretionary [snack] foods' that account for ~20% of the fat and calories and 50% of the sugar consumed) (23). The Scottish Government has highlighted the need to tackle both issues in their delivery plans for physical activity, diet and healthy weight (23, 24).

As well as benefitting from the large amount of formative work already undertaken to adapt HDHK-P with stakeholders, the proposed study builds on the project team's excellent track record of working in partnership with the prison service in Scotland, through the NIHR PHR-funded Tobacco in Prisons study led by co-CI Hunt (PHR 15/55/44), the CSO-funded development of the Fit for LIFE intervention led by

co-CIs Gray and Hunt supported by PEI Craig Mailer from HMP Perth (CSH-4-886) and with young male offenders on parenting and relationship programs (co-CI Hunt). The project team is thus very familiar with prison practices and constraints, and has experience of collecting a wide range of research data in all of Scotland's prisons. The study also builds on Investigator Morgan's well-developed body of research on the HDHK intervention, which has shown significantly improved health outcomes and behaviours in fathers and children when delivered in community settings (25-29).

While the primary focus is on assessing the feasibility and piloting the delivery of HDHK-P (initially in two prisons), and assessing the research procedures for a future full-scale evaluation, the proposed study will also address wider questions about ways to improve the health and wellbeing of men while in prison and following their release. First, the findings will be informative in planning the delivery and implementation of other prison-based parent/family health interventions that actively involve children, both in the UK and in countries with similar prison systems. Second, data collection methods, including in relation to following up men (and their families) post-release, will include developing processes and techniques appropriate to the challenging context of prison research. Reporting of these will be of use to others undertaking research within prison settings. Finally, HDHK-P may provide a foundation for developing interventions for people with convictions and their families in community settings (e.g., a transitional intervention for fathers and children spanning the pre-post release period).

3 THEORETICAL FRAMEWORK

HDHK is based on family systems theory (reciprocal relationships among family members) (30) and operationalises social cognitive theory constructs (self-efficacy, goals/intentions, outcome expectations) (31). HDHK has been developed over several years in community settings, largely in Australia. HDHK was originally designed to support overweight fathers of primary school-aged children in losing weight and to improve father-child engagement through interaction around physical activity and healthy eating. It comprises nine, group-based weekly sessions. In the community, every HDHK session includes: i) a 15-minute education session with fathers and children, conducted together; ii) 30-minute education sessions for fathers and children, conducted separately; and iii) a 45-minute practical session in which fathers and children participate together in fun physical activities that are designed to enhance children's physical and motor skills, and provide positive relationship-enhancing quality time. The HDHK team has a strong track record of adapting the program for different populations and HDHK-P has benefitted from the learning and resources generated from these adaptations. These include: Healthy Youngsters Healthy Dads (HYHD) for fathers and their pre-school children (32), and Daughters and Dads Active and Empowered (DADAE) for fathers and their primary school daughters, which has been widely implemented in New South Wales (33). Recently, Hispanic Healthy Dads, Healthy Kids, a cultural adaptation of HDHK has been delivered in a feasibility trial to disadvantaged and marginalised Hispanic fathers and children in the USA, and has been shown to successfully engage these hard-to-reach families (34, 35). Two randomised controlled trials of HDHK have demonstrated significantly improved health outcomes and behaviours in fathers and children, and a recent dissemination trial showed improvements were sustained 12 months post-intervention (in fathers' waist, BMI, resting heart rate, energy intake and physical activity; and in children's physical activity and adiposity) (25-29). Participation in HDHK also positively impacted on fathers undertaking physical activity with their child and on their beliefs about healthy eating, which mediated observed improvements in children's physical activity and diet (29).

While studies to date have focused on weight loss and physical activity, HDHK researchers have identified improved father-child relationships as a key outcome of their father-focused programs (e.g., 36). HDHK has accordingly evolved into a more holistic program targeting multiple outcomes (37) including mental health, wellbeing and self-esteem in both fathers and their children. This more holistic approach has informed adaptations for HDHK-P.

In each of the previous adaptations of the original HDHK, refinements have been made on which HDHK-P further builds, while retaining three core elements. First, the magic of reciprocal reinforcement, employed through motivating positive changes in fathers' lifestyle behaviours that are subsequently reflected in the child's behaviour, and vice versa. Second, improving family relationships through physical activity and healthy eating, as fathers spend quality time with their children using joint physical activity as the engagement medium as physical activity is well suited to fathers' masculine interaction styles, and facilitates fun and active play. This in turn fosters closeness between fathers and their children, as well as being an important way of engaging men in health behaviour interventions (38). Third, embedding motivators relevant to men to engage with them through the use of humour, language and content that caters for men's physical, psychological and sociological needs, as well as appealing to fathers' fundamental motivation to be good role models and do the best they can for their children.

The original HDHK protocol and materials have formed the basis for adaptations for delivery in the prison setting, to fathers in custody and their children. Through the sessions, the children learn the importance of being physically active and eating as healthy a diet as their circumstances allow, the problem with too much screen time, and how to be active and healthy with their father and families. Fathers learn about their important role as a father, proven parenting strategies to improve nutrition and physical activity for their children, and strategies to support health behaviour changes for themselves. The joint father-child 45-minute practical session is retained (shortened slightly to 40 minutes to fit with prison regimes), focusing on the three key areas of physical activity within HDHK: positive rough and tumble play; fitness; and fundamental movement skills (e.g., throwing, catching, bouncing and kicking). As in HDHK, fathers will be taught how to positively engage with and encourage their children in joint physical activity, and children will have a handbook of fun activities. Key adaptations are: first, that the fathers-only sessions take place the day or so preceding the joint father-child sessions to enable additional time to explain the key principles, as many of the men may have literacy problems, low education and may not have had recent regular contact with their child(ren). Second, child-only activities have been adapted to take account of their restricted access to their father outside HDHK-P sessions. The children will be encouraged to talk to their father about what they have done between sessions at their next in-person visit and/or by phone (since in-person visits were suspended during COVID-19, men in prison have typically had more access to phone calls with their families, and WP1 will explore the extent to which this enhanced phone contact can be utilised in HDHK-P). For example, the men and children will be given pedometers so they can self-monitor their physical activity and talk to each other about how and whether they achieve their step counts and other physical activity goals when they meet and during phone calls.

Further adaptations made following a considerable amount of formative work, involving visits to potential HDHK-P delivery facilities in the prisons, regular meetings, consideration of important offender outcomes, and training and workshops in Scotland and Australia, include: prioritising improvements in mental health, wellbeing, self-esteem and relationship quality; focusing on positive health behaviours generally (rather than prioritisation of weight management) through mutual support and increasing physical activity; raising the lower age range of participating children from 5 to 8 years; reducing/modifying between session father-children activities; incorporating accompanying mother/carer/other adult presence during sessions; and modifying post-program guidance for sustaining change. For example, it has been suggested that the prisons could facilitate regular fathers' groups (every 2-3 months) following completion of the intervention in order to promote sustained outcomes.

Inputs	Activities				Outcomes	
	Attracting men	**Engaging men**	**Initiating change**	**Maintaining change**	**Short term**	**Long term**
Relational • Facilitator and prison commitment to engage with program training package and preparation for each session **Physical** • Access to prison facilities • Program handbooks • Pedometers **Financial** • Resources to pay for materials and facilitator time	Draw on multiple motivations: • Desire to improve relationship with child/ren • Desire to improve aspects of health • Desire to fill time in prison constructively • Desire to spend more time with child/ren Appeal in ways that are congruent with masculine and fathering identities (fathers together, possible setting in prison gym)	Ensure men feel their decision to join the program is valued Encourage a team spirit (relatedness) through: • promoting similar interests (e.g., being a 'good father') • demonstrating and sharing similar challenges in relation to fathering and fathering in prison • use of pedometers Facilitate enjoyment in the sessions through positive interactions, fun and physical activity	• Demonstrate and encourage practice of self-monitoring, goal setting (through the handbook) and feedback around parenting behaviours and health behaviours • Promote men's understanding of the importance of their role as fathers • Appeal to men's sense of wanting to be 'a good father' • Promote practical ideas for activities to actively engage in with child/ren • Provide strategies for enhancing relationship with child/ren through meaningful contact • Promote competence in positive fathering behaviours • Enhance understanding of positive parenting in the prison context	• Build skills and competence through: i) Practice of behaviour change techniques ii) Optimal challenges in relation fathering in prison, and on release iii) Promoting reflection on fathering role • Encourage men to develop interests/activities with child/ren as routine hobbies/pass-times • Encourage recognition of the personal benefits of changing risk behaviour (e.g., less likelihood of return to custody, more money, higher self-esteem, more connected to children/family) • Encourage practice of strategies to maintain/build strong father-child relationships • Encourage a deepening sense of positive social connectedness with children/family • Help men to understand how to avoid and overcome setbacks in family relationships	**Behaviours** • Men spend more time engaging with child/ren • Men spend less time engaging in high-risk behaviours • Men feel more positive/confident about role as fathers **Health/Psycho-social** • Men/children improve mental health/wellbeing • Men/children improve self-esteem • Men feel more connected to children & vice versa • Men/children improved health behaviours	**Behaviours** • Men continue to spend more time engaging with children • Men continue to spend less time engaging in high-risk behaviours **Health/Psycho-social** • Continued improvement in mental health/ wellbeing/ self-esteem/ health behaviours • Decreased relationship problems • Decreased likelihood of (return to) custody • Men continue to have access to strategies to strengthen relationship with child/ren

Figure 1: Provisional HDHK-P logic model

There may also be continued opportunities for joint father-child physical activity post intervention, perhaps by linking into other initiatives happening in the prisons. These will be further explored with key stakeholders in the prisons at the start of WP1. The provisional HDHK-P logic model is provided in Figure 1.

For the WP1 feasibility study, much of the content of the nine, weekly HDHK father-child sessions will remain largely the same for HDHK-P (see Figure 2). Each session will last a total of 60 minutes (to fit with staffing and visiting times) during which ~40 minutes will be spent engaging in father-child activities and ~20 minutes will involve social time (including provision of healthy catering) with the accompanying adults; thus providing an opportunity for positive family contact whilst reinforcing positive messages about healthy eating. The accompanying adults will be in as close proximity as practical for the first ~40 minutes, with tea/coffee and magazines provided. When the fathers leave to be escorted back to their rooms at the end of the 60 minutes, the PEI facilitators will deliver a 5-10-minute child-only session, based on shortened HDHK child-only sessions. In the fathers-only sessions (held prior to the main sessions), additional material will be included to take account of: the imprisoned status of the father as a context for his relationship with his child(ren); specific work on constructive approaches to discipline; and the heightened importance of ensuring that 'rough and tumble' play is positive, appropriate and enjoyable for children. These adaptations build on the needs of some of the fathers identified in previous prison-based parenting interventions (39).

Session 1: Dads matter in children's health; rough and tumble play
Session 2: Behavioural change strategies for men; benefits of vegetables
Session 3: Being a healthy dad; importance of physical activity
Session 4: Healthy eating; fruit
Session 5: The unique and powerful influence of fathers; screen time
Session 6: Raising kids in an inactive world; water and hydration
Session 7: Switching on" your child's mind by "switching off"; sport skills
Session 8: Healthy fathering in a busy world; "sometimes [vs anytime] foods"
Session 9: Continuing the "Healthy Dad" journey; helping dad stay on track

Figure 2: The nine father-child HDHK-P sessions

The main HDHK-P sessions will be held to fit with prison routines and children's educational needs. This will likely be after school on weekdays, Friday afternoons during school time and/or during school holidays, with the final timings to be agreed during WP1 stakeholder consultations. The first sessions are likely to be delivered in the family visitor centre in each prison so that group bonds can be established initially in a space that children are likely to be familiar with, and so feel as comfortable, confident and safe as possible in the prison environment. Later sessions may be delivered in the prison gymnasium to allow a wider range of physical activities. When children are being escorted through any part of the prison, it is standard practice that a radio call is communicated to staff to ensure there is no movement of people in custody in that area at this time. The PPI work conducted as part of the stakeholder consultation in WP1 will ensure that the approaches and content described above are acceptable to all those involved and to other stakeholders within the prison system.

4 RESEARCH AIMS/OBJECTIVES

The primary aims of the research are to evaluate whether it is feasible and acceptable to imprisoned men, their children and families, and key prison staff to: a) implement the prison-based HDHK-P program delivered by trained prison physical education instructors (PEIs); and b) assess its potential to improve: fathers' mental health and wellbeing; fathers' and children's self-esteem and health behaviours; children's socio-emotional health, and father-child relationships. The study also aims to assess whether or not progression to a full-scale evaluation and/or rollout is justified.

4.1 Objectives

The research aims will be addressed through the following specific objectives:

Obj 1 To test the feasibility of delivering HDHK-P and the acceptability of using the methods proposed for the pilot evaluation, and to further refine and optimise the intervention, delivery and research protocols for the pilot (WP1: feasibility and optimisation).

Obj 2 To pilot the delivery of HDHK-P under research conditions, to assess the research procedures for a future full-scale evaluation of the optimised HDHK-P, and to refine the HDHK-P logic models (WP2: pilot).

Obj 3 To explore whether it is appropriate, and possible, to progress to a full-scale evaluation and/or rollout of HDHK-P delivery to other prisons (WP3: next steps).

4.2 Research questions

Each objective will, in turn, answer a number of specific research questions:

RQ1 How do men, children, families, intervention facilitators and other prison staff experience HDHK-P program deliveries? Issues to be addressed under this RQ include: What do they perceive as positive and negative outcomes of involvement in the program? How can children/families be involved and supported most effectively in such prison-based interventions in order to maximise positive health and relationships outcomes for children, as well as for the fathers in custody? What are the challenges for delivery from the perspective of prison staff and the wider prison system? (Obj 1, 2)

RQ2 Is it possible to implement and deliver an intervention adapted from a successful community-based father-child program in the prison setting? Issues to be addressed under this RQ include: What are the barriers and facilitators (including organisational and prison system factors) to recruitment and continued participation in HDHK-P for: a) fathers; b) children; and c) families? How transferable are the core components of the HDHK program to the prison setting? (Obj 1, 2, 3)

RQ3 What is the potential of HDHK-P to deliver its target outcomes? Issues to be addressed under this RQ include: To what extent, and how, does HDHK-P support positive changes in fathers' and/or children's mental health and wellbeing, socio-emotional health, self-esteem, health behaviours, parenting self-efficacy and relationship quality? Are there perceived intended or unintended benefits/costs for key stakeholders? (Obj 2)

RQ4 How do men, children, families, intervention facilitators and other prison staff view data collection methods, and what and how much is asked? Issues to be addressed under this RQ include: Are men, children and family members willing to provide data for the study? Are there any methods of data collection proposed for WP2 which are seen as impractical or off-putting? Where do potential participants think it is best to conduct any research procedures with children, family members and fathers post-release to minimise burden on families? (Obj 1, 2)

RQ5 Are the proposed methods and outcomes for a future full-scale evaluation feasible, meaningful and acceptable to all parties? Issues to be addressed under this RQ include: Can we recruit and retain fathers and children to 9 months in the pilot study? Is it feasible and acceptable to collect data on mental health, wellbeing, health behaviours and self-esteem using validated sets of questions? Can we conduct objective physical activity assessments for men and children in this context? Can we collect data on father-child relationships from children? Can we collect data at all time points (including in the community for any fathers who are released during the study period)? Is it possible to recruit other prisons to participate in a future full-scale evaluation of HDHK-P, and is progression justified? How would we undertake a large full-scale evaluation, including outcome, process and economic evaluations? (Obj 2, 3)

4.3 Outcomes

The study outcomes include:

Phase 1: optimisation of the HDHK-P delivery protocol and procedures; finalisation of participant recruitment strategies and procedures; refinement of the Phase 2 research methods and protocols; and development of the HDHK-P dark logic model.

Phase 2: feasibility of implementing and delivering HDHK-P in two Scottish prisons; response to the program content by fathers and children; acceptability of the program content, delivery and implementation procedures to fathers, children, accompanying mothers/carers (or other adults), PEI facilitators and other key prison staff; potential effectiveness of HDHK-P in achieving positive changes in fathers' and/or children's mental health and wellbeing, socio-emotional health, self-esteem, health behaviours, parenting self-efficacy and relationship quality; feasibility and acceptability to fathers, children and family members of data collection at baseline and follow-up to nine months; refinement of the HDHK-P logic model and dark logic model; next steps (e.g., design of a full-scale evaluation and rollout of HDHK-P to other prisons).

5 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

A sequential two-phase study will be conducted over 24 months, comprising a feasibility and optimisation phase (WP1) followed by a pilot evaluation phase (WP2) and an exploration of whether it is appropriate, and possible, to conduct a full-scale evaluation (e.g., a randomised controlled trial) of the intervention in the future and/or roll out delivery to other prisons (WP3). The approach is guided by the MRC complex interventions framework (10) and the 6SQuID model for intervention development and optimisation Steps 5 and 6 (40). The 6SQuID model identifies six essential steps of intervention development, the final two of which are: testing and adapting the intervention (Step 5); and collecting sufficient evidence of effectiveness to progress to a rigorous evaluation (Step 6).

5.1 Phase 1 Feasibility Study

5.1.1 WP1: feasibility and optimisation of HDHK-P (6SQuID Step 5) (Objective 1, RQs 1-2,4)

Implementation protocol development and planning: Meetings with key stakeholders in the two prisons (including prison management, HDHK-P PEI facilitators, heads of offender outcomes, family contact officers, front-of-house staff and imprisoned fathers) and in their local communities (including organisations supporting the families of people in custody, mothers/carers/other family members) will be undertaken to identify logistical issues, and potential risks, concerns, unintended harms and ethical issues in delivering HDHK-P to imprisoned fathers and their children, and to inform recruitment and other implementation issues. The findings will be used to finalise the recruitment strategies and procedures and detailed implementation protocol for the feasibility deliveries of HDHK-P, and to inform a dark logic model (41) in order to identify and monitor potential harms to participants (children, fathers, families, facilitators), other prison staff or non-participating people in custody (e.g., the resources required to deliver HDHK-P impinging on other opportunities for visits or use of the prison gym facilities).

Acceptability and feasibility of proposed research methods: The stakeholder meetings will also explore the feasibility and acceptability of the research methods proposed for the WP2 pilot evaluation: for example, in relation to the number and content of the tools used to measure outcomes at baseline and follow-up. The project team has considerable experience of conducting interviews and administering questionnaires to people in custody in Scotland (e.g., 42-48). The findings will be used to finalise the research tools and measures: for example, deciding whether it is feasible to ask the men and/or their children to wear accelerometers to gain objective measures of physical activity, in addition to self-reported physical activity. The aim will be to strike a balance between collecting sufficient data to support

future decision-making and collecting so much data that high quality follow-up inside and outside the prison will be put at risk.

Facilitator training: The lead HDHK-P facilitators from HMP Perth and HMP Barlinnie will undertake full training to deliver HDHK-P from the Australian HDHK team. This training will support their full understanding of the logic model underlying HDHK-P (see Figure 1) and of the importance of fidelity in delivery of its core components, whilst providing an understanding of where flexibility to accommodate group and individual characteristics is desirable. The training will also introduce them to a wide repertoire of activities to undertake in the joint father-child physical activity sessions (e.g., rough and tumble play), with time to discuss any modifications that may be needed. The training will be delivered face-to-face with the PEIs visiting Australia, or online if this is not possible.

Intervention deliveries: Two feasibility deliveries of HDHK-P will take place sequentially, one in each of HMP Perth and HMP Barlinnie.

Monitoring and evaluation: Building on previous work in co-developing the Fit for LIFE program with PEI facilitators and men in custody (49), members of the project team will attend the prisons for all program sessions to observe delivery and to engage in informal discussions with fathers, children, accompanying adults, HDHK-P facilitators and other prison staff. Detailed field notes will be written up electronically and analysed thematically, with a focus on feasibility, acceptability, safety and fathers', children's and accompanying adults' response to all aspects of the program and its implementation. The findings will inform the optimisation of the intervention and its implementation protocol for the WP2 pilot evaluation.

5.2 Phase 2 Pilot evaluation and wider prison consultation

5.2.1 WP2: pilot evaluation of HDHK-P (6SQuID Step 6) (Objective 2, RQs 1-5)
The optimised HDHK-P intervention will be piloted in two deliveries (A and B) in each prison (four deliveries in total).

Data collection: The following mixed-methods approach will be used to answer the research questions, adapted as necessary during the WP1 stakeholder consultations around acceptability and feasibility:

- Method 1 (RQs 1, 2): Observations of program sessions will assess attendance, engagement and fathers', children's and accompanying adults' response to the intervention, fidelity of delivery of the core components and ways in which HDHK-P supports/does not support men and their children to achieve the intended outcomes.

- Method 2 (RQs 1, 2, 4): In-depth qualitative interviews will assess the experiences of involvement in HDHK-P of: i) PEI facilitators and other relevant prison staff (e.g., administrative/managerial) focusing on recruitment, fidelity of delivery, barriers/facilitators to implementation, benefits to the wider prison system; ii) father participants (N~8 for each delivery, including those who do not complete the program) focusing on intervention acceptability, barriers/facilitators to engagement/achieving the intended outcomes, the perceived benefits/disadvantages of involvement in the intervention and research, and any suggestions for changes to the intervention; and iii) accompanying adults (N~4 for each delivery) focusing on involvement in the intervention, experience between sessions at home in supporting their children's engagement in the intervention, and any perceptions of changes in father-child relationships.

- Method 3 (RQs 1, 2, 4): Discussion groups with children (N~8 children – conducted in pairs, triads or small groups depending on the age of the children and dynamics) will assess intervention acceptability, barriers/facilitators to engagement/ achieving the intended outcomes, perceived benefits/disadvantages of involvement in the intervention and research, and any suggestions for changes to the intervention.

- Method 4 (RQs 3, 5): Baseline and follow-up measures (at 9 weeks and 6 months for both deliveries (A and B), and at 9 months for delivery A only) will collect data on candidate primary and secondary outcomes for a full-scale evaluation. The primary outcome is likely to be a measure of fathers' mental

health or wellbeing (such as the Patient Health Questionnaire (50) or General Health Questionnaire (51)). Secondary outcomes may include: fathers' and children's self-esteem (Rosenberg's Self-Esteem Scale (52)), fathers' discretionary food and drink purchases from the prison canteen (via routine prison data, which project team members have experience of analysing in relation to smoke-free policy implementation (42)); fathers' and children's self-reported dietary intake (using Scottish Health Survey measures (53) – sweets/chocolate; crisps/snacks; sugar-sweetened beverages; chips; processed meat; ice-cream), children's socio-emotional health (Strengths and Difficulties Questionnaire (20), Children's Society Good Childhood Index (54)), fathers' and children's physical activity (self-reported using pedometer step counts or objectively measured), fathers' and children's weight; children's screen time, quality of father-child relationships from the perspectives of both the father and child (Parent-Child Relationship Questionnaire) (55), and children's self-worth (the Self-Perception Profile for Children) (56). Not all of these outcomes will be collected: the WP1 key stakeholder consultations will inform final decisions about how much and what kind of outcome data it is acceptable to collect (and how). In addition, collecting health economics resource use data from prisoners and their children is likely to be problematic. Consultations with the Scottish Prison Service in WP1 will therefore be used to establish what economic information they would need for decision-making on whether to embed HDHK-P in the prison service, and test the feasibility and acceptability of collecting these data in WP2.

The extent to which, and how, follow-up measurements can be obtained from men who have been released from prison (and their children) during the study will also be explored. This is likely to involve building further on the relationships built up with men and their families during intervention delivery.

Data analysis: Qualitative data will be transcribed and analysed thematically using a framework approach (57) to explore: barriers and facilitators to program implementation and delivery; participant engagement, involvement and retention; and views on/the experience of/reported benefits and disadvantages of participation in the intervention. Data from the session observations, and the interviews/group discussions with the father and child participants, the accompanying adults, the PEI intervention facilitators and other prison staff will be triangulated to allow evaluation of HDHK-P from multiple perspectives. For outcome measures, the completion rates and change in these measures will be assessed. The economic analysis will assess the feasibility of resource use and outcome data collection and valuation. For resource data, the cost of the HDHK-P intervention will be explored, and the key cost drivers identified. A descriptive log of methodological issues will be kept and analysed.

5.2.2 WP3: wider prison consultation with regard to full scale evaluation and rollout (Objective 3, RQ 5)
Interviews with key staff (PEIs, family contact officers, governors and others) from all Scottish prisons (except those that house only young offenders or women) (N=13 prisons) will be arranged to explore views on any barriers to delivery in individual prisons (e.g., geography, meaning it would be difficult for families to attend deliveries of the intervention; open prison, meaning the enhanced contact is not seen as necessary by potential participants), willingness to participate in a future full-scale evaluation (e.g., a randomised controlled trial), and the potential for future scaling-up of HDHK-P across Scottish prisons.

Progression criteria: The criteria for progressing to a full-scale evaluation will make use of a red-amber-green system (58, 59) applied to the data collected in WP2, with respect to:

1) program content: green – over 75%; amber – 55-75%; red – below 55%, of fathers, accompanying adults and children who participate in the interviews/group discussions are largely positive about the intervention.

2) delivery and sustainability:
a. green – 8-10; amber – 6-7; red – fewer than 6 men and their children, on average, are recruited to each delivery;
b. green – over 70%; amber – 55-70%; red – below 55% of men screened are eligible for the program;

c. green – over 70%; amber – 55-70%; red – below 55% of eligible men agree to participate in the intervention;
d. green – over 70%; amber – 55-70%; red – below 55% of families/child(ren) of the eligible consenting men consent/assent to participate in the intervention;
e. green – over 70%; amber – 55-70%; red – below 55% retention of men at 6-month follow-up measures;
f. green – over 75%; amber – 50-75%; red – below 50% of PEI facilitators agree that the program content and delivery is appropriate and useful for incarcerated fathers and their children.
g. green – prison governors or their deputised authority at sufficient sites agree a full-scale evaluation can go ahead; red – agreement for a full-scale evaluation is not secured in sufficient sites;

The independent Study Steering Group (SSG) will consider these criteria in the context of the red-amber-green system and ensure that a decision on progression is made in a balanced way. For example, three green results will lead to progression, but any red results will mean there will be no progression. The dark logic model developed in WP1 will also be used to identify any unintended effects and harms that will mean progression should not occur.

Scalability and translation: The Physical Education Forum, a body comprised of PEIs throughout the Scottish Prison Estate, will be used to disseminate the results of the study and seek input into future implementation. If the pilot indicates that HDHK-P is promising, the Forum could be used to organise and deliver a Train the Trainers program across all prisons and to work with the research team to support the incorporation of HDHK-P into the Scottish Prison Service Family Strategy (9).

What might a future full-scale evaluation look like? A future full-scale evaluation would aim to generate high-quality evidence, ideally including randomised allocation to intervention or comparator in a randomised controlled trial (RCT) design. Because HDHK-P is group-based and prison staff must play a role in selecting which men are eligible (e.g., to avoid conflict during program sessions), randomisation would have to be done from a pool of men cleared for involvement in group activity. At this stage, it is anticipated that men would be randomised to two groups of ten within each prison: half receiving the intervention and half forming a wait-list comparator (to receive the intervention at the end of the trial). Individual randomisation would be appropriate, because the ‘active ingredient’ of the intervention is attendance at HDHK-P sessions, and therefore risk of contamination outside the program is low.

A full-scale evaluation would extend to prisons beyond those involved in the current study. The limited number of prisons in Scotland means the prisons in other parts of the UK may be involved. The sample size (informed by WP2) will inform the number of prisons needed to conduct an RCT and the number of deliveries needed in each prison. In the event that the duration of the RCT looks unfeasibly long (i.e., because multiple deliveries are needed in each prison to achieve an adequate sample size), WP3 would explore with decision-makers whether a smaller trial with lower confidence would still be sufficient to support decision-making with regard to program implementation.

The current study will inform decisions about the outcomes that would be collected in a future evaluation, but it is already known that follow-up once people are released from custody or transferred within the prison estate is challenging. The outcomes collected would therefore be focused on the minimum information needed by decision-makers to make a future implementation decision. The wider prison consultation with regard to trial and rollout (WP3) will inform decisions about randomisation, and an internal pilot to test the method selected would be part of the design of the future trial.

6 STUDY SETTING

The study will be conducted in two Scottish high-security prisons, HMP Perth (Prison 1) and HMP Barlinnie (Prison 2). HMP Perth is a large community facing prison, receiving male offenders predominantly from local courts in Perth and Kinross, Dundee, Angus and Fife (60). It holds around 680

men, including men on remand, short term offenders (serving less than four years), long term offenders (serving four years or more), life sentence offenders and sexual offenders. HMP Barlinnie is a large local prison, mainly receiving male offenders from courts in the west of Scotland (although recently Barlinnie has taken offenders from all over Scotland to facilitate a new building programme within the Scottish Prison Service) (61). It holds around 1,300 men, mainly those on remand or who are serving less than four years, but also life sentence offenders approaching a potential release date.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

The target population is imprisoned men at HMP Perth and HMP Barlinnie with primary school aged children who they would like to spend more time with.

7.1.1 Inclusion criteria

- Fathers in custody at HMP Perth or HMP Barlinnie.
- With children aged 8-11 living relatively close to the prison (likely ~45 minutes maximum travel time, but this criterion will be finalised during the WP1 stakeholder consultation).
- Who want to spend more time with their child/children.
- Who have been identified as suitable for the program by the PEIs and family contact officers at each prison.
- Whose families agree to take part in the study and for the mother/carer/other adult to accompany the child/children to HDHK-P sessions at the prison.

7.1.2 Exclusion criteria

- Men who are on remand.
- Men who are convicted sex offenders.
- Men who are due for release or transfer to another prison during the 9-week HDHK-P program.
- Men who themselves (or whose families) have a history of conflict with other men/families on the program.
- Men (or their family members) who cannot read/speak sufficient English to give informed consent.

7.2 Sampling

The Phase 1 feasibility study aims to recruit ~8-10 imprisoned men each with 1-2 children aged 8-11 years to two sequential deliveries of HDHK-P: one delivery in HMP Perth followed by one delivery in HMP Barlinnie. Total N: men 16-20; children ~16-32.

The Phase 2 pilot evaluation aims to recruit 8-10 imprisoned men each with 1-2 children aged 8-11 years to four deliveries of HDHK-P at HMP Perth and HMP Barlinnie. The program will be delivered sequentially twice (deliveries A and B) in each prison. Total N: men 32-40; children ~32-64.

Phase 2 will also include interviews with 4-8 HDHK-P facilitators, ~6-8 prison/Scottish Prison Service administrative/managerial staff, and ~16 of the adults accompanying children to HDHK-P sessions in the prison.

7.2.1 Size of sample

The target sample sizes have been guided by discussions with PEIs and family contact officers, who have suggested maximum group sizes of 8-10 fathers and 8-16 children would be practical and feasible for each HDHK-P delivery.

7.2.2 Sampling technique

Convenience sampling guided by advice from the PEIs and family contact officers will be used for both phases.

7.3 Recruitment and sample identification

The recruitment strategies and procedures finalised during the WP1 stakeholder consultations will be used to recruit the imprisoned fathers and their children to all HDHK-P deliveries. It is anticipated that family contact officers will liaise with the PEIs to identify suitable men and families to approach to ask whether they would like to take part in HDHK-P, based on their knowledge of potential participants. Established prison protocols will be used to minimise and manage any risks (for example, checking there are no existing or recent conflicts between the participating men and/or their families). It is expected that approaches to all men and their families will be made directly by the PEIs and family contact officers. All potential participants (men, families and children) will be asked to opt in to the study

7.3.1 Consent

Informed consent will be obtained from all fathers and accompanying adults before their participation in the study. Informed assent will be obtained from all participating children before the start of their involvement in the study. During recruitment, the PEIs and family contact officers will provide potential participants with the appropriate study information sheet, which will outline the purpose of the research, their role in it, and will explain that participation is entirely voluntary, confidential and can be stopped at any time. The PEIs and family contact officers will be trained to answer questions that people might have (as identified during the WP1 stakeholder consultation), and a member of the research team will be available to support them with additional information, as required.

The informed consent/assent procedure for fathers, their children and accompanying adults will be conducted by a trained member of the research team prior to participants' involvement in the study. The researcher will explain the aims of the study, and the benefits and potential risks to ensure that participants fully understand what taking part will mean for them, and will give them an opportunity to ask further questions about any aspect of the study. The researcher will also ensure they are satisfied that participants fully understand the nature and purpose of study, their involvement in it and that it is their choice to take part before they sign the consent/assent forms. The precise location of the informed consent/assent procedures will be confirmed during the WP1 stakeholder consultations.

HDHK-P facilitators and prison management/administrative staff will be provided with a study information sheet by a member of the research team and will be given an opportunity to ask questions and/or discuss any aspect of the research. The researcher will then take informed consent (as described above) prior to the facilitator's/staff member's involvement in the study (i.e., HDHK-P session delivery and/or interviews).

All study documentation will be carefully prepared to ensure it is appropriate for each potential participant group (including adults with low literacy levels and primary school aged children). It will be approved by university and prison research ethics committees.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The research is designed to optimise and pilot a prison-based intervention (HDHK-P) that will be delivered to imprisoned men and their children. People in custody and their families are amongst the most marginalised members of society, often experiencing socioeconomic disadvantage before imprisonment, which deepens even further following incarceration (16).

The research process is guided by the principles of informed consent, participatory collaboration, and of doing no harm to participants. Pertinent ethical considerations include ensuring that participation in HDHK-P is experienced as an enhanced form of family visiting at all times and does not detract from

existing family contacts for participating children and/or their siblings, and that HDHK-P deliveries are attuned both to the needs of imprisoned fathers and their children, and facilitate family ties characterised by the principles of reciprocity (62). In addition, the dark logic model developed in WP1 will be used to monitor potential harms throughout the study, and a safeguarding protocol will be developed during WP1, which will set out actions should any harm to those involved in the study be detected. Finally, it is important that there are attempts to sustain the father-child engagement promoted by HDHK-P following completion of the program. Stakeholder and family engagement conducted as part of WP1 will explore these issues, including whether/how the Scottish Prison Service or other agencies can deliver follow-on activities to the program. Potential follow-on activities for consideration include: fathers who participated in the program continuing to meet every 6-8 weeks; and initiatives to support ongoing father-child physical activity (e.g., Families Outside has worked with the Dennis Law Legacy Trust to deliver its Streetsport program to parents and children, and a Children in Need funded initiative has run sporting activities at some family visits at HMP Grampian).

Many prison-based interventions, including HDHK-P, seek to break cycles that make inequalities in health and other outcomes so persistent, as well as trying to address current inequalities (16). The children of imprisoned parents have been identified as key in current Scottish Government efforts to tackle child poverty, and the inequalities surrounding this (63). Overall, therefore, we believe that the benefits to the imprisoned men, their children, other family members, communities and society as a whole outweigh any possible discomfort or inconvenience to participants during the course of the study.

8.1 Assessment and management of risk

A number of potential risks have been identified as follows:

Discussion of sensitive topics: Talking about parenting and father-child relationships in a group context may be distressing for some fathers, as it may lead them to reflect negatively on their own parenting experiences and skills, and generate feelings of shame. The PEI facilitators, who are skilled at dealing with men in custody and the personal problems they present, will receive further training from the research team in how to deal with any relationship issues that may be revealed during HDHK-P (e.g., making time to talk to the father individually during/after a session). All issues raised will be reported to the co-CIs and, if appropriate, referred to the relevant support service within the prison. The precise safeguarding procedures to be followed will be developed during the WP1.

In addition, we will explore the experiences of taking part in HDHK-P in qualitative interviews/discussions with fathers, children, accompanying adults and PEI facilitators. Participants in these interviews/discussions will be reminded that they do not have to answer any question they do not want to, and that they can terminate the interview/leave the discussion at any point. Researchers will also be trained to be sensitive to the impacts of the interviews/discussions; they will monitor participants for signs of distress throughout and pause the interview/discussion if they feel that a participant needs a break.

If a participant discloses any intent to harm themselves or others at any time during participation in the study (HDHK-P sessions, interviews/discussions, measurements) the co-CIs and relevant prison authorities will be informed. All participants will be made aware of this during the informed consent process prior to their participation in the study.

Participants being transferred to another prison during the program: There is a significant amount of movement of men in custody from prison to prison within the Scottish Estate. We have assurance, however, that any men taking part in an intervention like HDHK-P are now routinely ring-fenced for the duration of the intervention and will not be transferred during this time, unless there are exceptional circumstances.

Poor quality relationships or conflict between participants/accompanying adults, or vice versa, during sessions: Family contact officers and PEIs will consider any known interpersonal conflicts between men and families when they select potential participants to approach for each delivery of HDHK-P, as they do routinely with all interventions to minimise these risks. The PEIs, family contact officers and their colleagues have detailed knowledge of the men and their families.

Low response rates at 6- and 9-month follow-up measures: Low response rates are more likely for men who have transferred to another prison (movement is only protected during the period of active delivery of the intervention) or who have been released, than for those remaining in the same prison. However, we believe that the strong connections developed with the men and their families by the researchers and the PEIs during HDHK-P sessions will facilitate follow-up even where men have been transferred or released. Efforts will also be made to maintain good communication with the families, as appropriate, following program completion (precisely how this will be done will be explored in the WP1 stakeholder consultations). In addition, we will stress to families the important role that they have in determining whether HDHK-P will be continued for other families in future, and hence the value of their participation. Finally, we will draw on the expertise of project team members in conducting prison research over many years to develop the procedures for follow-up in the community.

8.2 Research Ethics Committee

Ethical approval will be sought prior to the commencement of each work package from the University of Glasgow College of Social Sciences Research Ethics Committee, which is compliant with the ethics framework set out by UKRI's Economic and Social Research Council, and the Scottish Prison Service Research Access and Ethics Committee.

8.2.1 Regulatory review and compliance

The co-CIs will ensure that the appropriate ethical approvals are obtained before any participants are recruited.

8.2.2 Amendments

Should any amendments to this protocol be required, the co-CIs will consult all project team members. Any final decision to amend the protocol will be the responsibility of the co-CIs who will together decide whether the amendment is substantial or non-substantial. The co-CIs will also be responsible for seeking approvals for substantial amendments from the research ethics committees and funder, and for ensuring that the protocol is updated using version control and completing the Amendment History in Appendix 3.

8.3 Peer review

Before submission to the funder, the study was peer reviewed internally at the University of Glasgow by two academics with expertise in public health research. After submission, the study was reviewed twice (outline and full proposal) by independent experts convened by the NIHR Public Health Research programme. Recommendations made at the outline stage were addressed and incorporated into the full proposal. Recommendations made at the full proposal stage were subsequently agreed and incorporated into the design before the researchers signed a contract with the funder committing to deliver the study.

8.4 Patient and Public Involvement

A considerable amount of PPI formative work has guided the development of this protocol. Project team members (including Morgan from Australia) have visited facilities in the prisons, held a program adaptation workshop with PEIs, and have met regularly with prison staff, including PEIs, heads of offender outcomes and family contact officers (who have enthusiastically welcomed the prospect of HDHK-P as another component of their efforts to improve family links and relationships). The information gained has informed initial adaptations to HDHK-P including: changing the focus of the program to more

holistic health behaviours rather than weight loss; identifying the timing and duration of the sessions (and the involvement of accompanying mothers/carers/other adults); and adapting between-session father-child activities to reflect the limitations imposed by the prison setting. In addition, PEI Craig Mailer has led discussions with men participating in Fit for LIFE within HMP Perth to ask them about the potential appeal of HDHK-P to fathers in custody. These men's responses have been enthusiastic, including from those who might not otherwise be using the gym and engaging in physical exercise, but who are attracted to HDHK-P because of the opportunity it presents to extend positive contact and support good relationship-building with their child(ren).

The PPI work has also informed the research design, including: a focus on mental health, wellbeing, self-esteem and relationship quality as study outcomes; defining the target sample size to reflect the practicalities of group deliveries within the prisons; and raising the lower age range of participating children.

Going forward, much of the study is focused around continued active PPI work. WP1 involves extensive key stakeholder engagement (with prison management, PEI facilitators, heads of offender outcomes, family contact officers, front-of-house staff, imprisoned fathers, organisations supporting the families of people in custody – such as the Scottish Charity, Families Outside – and mothers/carers/other family members). These consultations will finalise the protocol for implementing HDHK-P within the prisons and the research design for the WP2 pilot evaluation, ensuring that they are acceptable to all those involved. In WP1 and WP2, a planning and delivery group in each prison (including the main PEI facilitator, a family contact officer, and a front-of-house representative) will oversee all feasibility and pilot HDHK-P deliveries to identify and address issues, and ensure the program is optimised for children, families and relevant prison staff. WP3 includes consultations with PEIs, family contact officers, governors and other key staff from 13 Scottish prisons, including through the Physical Education Forum, to explore practicalities and willingness for participate in a future full-scale evaluation, and the potential and practicalities for future rollout of HDHK-P.

Finally, we will continue to place the men's and their families' experiences of HDHK-P at the forefront of the study. We will work closely with Families Outside to ensure that mothers/carers are involved, even when the accompanying adult who visits the prison with the child is not the mother/carer. We will have at least one member of the public who has experience of being in custody or of a member of the family being in custody on the independent SSG, and will investigate whether separate research involvement groups will be valuable.

8.5 Protocol compliance

The research team are aware that accidental protocol deviations can happen at any time. Any deviations from the research protocol will be documented and reported to the co-Cis and the sponsor representative. Any deviations found to be occurring on a regular basis will initiate an immediate meeting of the co-CIs and representatives of the SSG to consider appropriate action, including termination of the research study. Decision making processes will be documented and shared with the sponsor, funder and ethics committees.

The research team will collect data using electronic data capture methods, where possible, and ensure that all data collection activities are recorded in encrypted server logs. This will provide a reference point for monitoring deviations from the data collection protocols.

The research team will also conduct observations of HDHK-P sessions, which will provide opportunities to identify and report on deviations from the program delivery protocol.

8.6 Data protection and patient confidentiality

We will protect participant confidentiality throughout the study, in line with the requirements of the General Data Protection Regulation 2018.

All interviews and group discussions will be audio-recorded, with participants' permission, using an encrypted recorder, with approval from the prison/prison services to take it into the prison. The recordings will be transcribed, and the transcripts and field notes will be identified using unique personal/group numbers, with the names corresponding with those numbers kept separately on a password protected list (which will be destroyed on completion of the project). Data will be uploaded and held in a managed storage environment on a secure, password-protected University of Glasgow server, accessible only by the research team.

Baseline and follow-up assessment data will be collected using electronic tablets and uploaded to the secure project University of Glasgow server as soon as possible following data collection. If this is not acceptable to the prisons, paper data collection will be necessary. Participants will be identified by a unique study number, with the names corresponding with those numbers kept separately on a password protected list (which will be destroyed on completion of the project).

All data will be stored at the University of Glasgow for 10 years after the project finishes. Any approved data transfers (e.g., to the collaborating universities) will use the University of Glasgow's secure file transfer system.

The University of Glasgow, as the Sponsor, is controller and processor. No real names will be used in reports/publications, and identifying details will be removed.

8.7 Indemnity

The University of Glasgow maintains research insurance which covers the study design and protocol.

8.8 Access to the final study datasets

All Investigators and the Research Associate employed by the study will have access to the final anonymised datasets. All participant documentation – information sheet and consent form – will make it clear that anonymised research data may be made available to other researchers for secondary analysis, but only where the co-CIs are confident that confidentiality would be maintained, the request is from a bona fide researcher, the research questions are deemed relevant and legitimate, and participants have given their explicit consent.

9 DISSEMINATION

9.1 Dissemination policy

On completion of the study, a Final Study Report will be prepared and submitted to the NIHR PHR programme for publication in its Public Health Research series, which is open access and publicly available via the NIHR's website. All research publications arising from the study will be submitted to open access peer-reviewed journals. The NIHR PHR programme will be acknowledged in these publications, but no NIHR staff or representatives will have influence or control over the content of these publications.

A lay report will be produced aimed at prison management, authorities and staff, policymakers, relevant third sector community organisations, and other non-academic audiences. Participants will be informed of results on request after the main findings from the study have been published.

Quantitative datasets generated as part of this study will be deposited in the University of Glasgow's online data repository. Qualitative data will also be deposited online only when doing so is possible without compromising participant anonymity. After an embargo period (likely two years from the study end-date) to enable publication of the main findings, requests for access to these data from other researchers will be considered by the co-CIs.

9.2 Authorship eligibility guidelines

All individuals who have had input into the research design, production and analysis of the data will be granted authorship on the final study report. This will include all of the study Investigators and the Research Associate. A publication proposal form will be developed and agreed by the research team, which Investigators will have to complete before being granted permission by the co-CIs to author papers for peer review journals. Authorship on these papers will adhere to the International Committee of Medical Journal Editors criteria.

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10. APPENDICES

10.1 Appendix 1- Required documentation

1. Study information sheets including versions adapted for adults with low literacy (fathers and accompanying adults), and for PEI HDHK-P facilitators, and other prison/Scottish Prison Service staff.
2. Informed consent/assent forms.
3. The current version of the protocol.
4. A list of the PEI facilitators approved to deliver the HDHK-P sessions and proof of training completion, signed off by the training lead for the study (Morgan) or a co-CI (Gray or Hunt).

10.2 Appendix 2 – Schedule of Procedures (Example)

Procedures	**Visits**					
	Study Information Session	Baseline	Weeks 1-9	Post-program	6 Months	9 months
Phase 1						
Informed consent	x					
Session observations			x			
Phase 2						
Informed consent	x					
Demographics		x				
Outcome measures		x		x	x	x
Session observations			x			
Interviews				x		
Group discussions				x		

10.3 Appendix 3 – Amendment History

Amendment No.	**Protocol version no.**	**Date issued**	**Author(s) of changes**	**Details of changes made**