Staying smokefree: Maximising the public health benefits of smokefree prisons.

Protocol

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1. Background

In 2019, 14% of UK adults were smokers, with half saying they want to quit,[1] and UK governments have set targets for being tobacco-free (e.g. by 2034 for Scotland [2]). Yet, despite these ambitions,[3] inequalities in smoking [2, 4] have widened since 2012.[1] Restrictions on smoking in work, transport and public spaces reduced exposures to secondhand smoke in the community,[5] with direct health benefit,[6] but people in disadvantaged circumstances remain much more likely to smoke and to be exposed to secondhand smoke at home.[7] The current study builds on recently completed research, in particular the NIHR-funded Tobacco in Prisons (TIPs) study (described below)[8-18], an evaluation of developing and implementing smokefree prison policy in Scotland. Recognising that people in custody (PiC) come disproportionately from disadvantaged sectors of society, this project is designed to understand whether, and how, wider public health benefits can be gained from the recent introduction of smokefree prisons in the UK, through support to people leaving custody and the households they return to.

1.1. Smoking in prisons and the Tobacco in Prison (TIPs) study

Where still allowed, smoking is high amongst PiC, contributing to disproportionately high mortality.[19] A 2008 review reported that, in Europe, 64-88% of PiC smoke;[20] another in 2018 reported similar rates.[21] As in the general population, ~50% of imprisoned smokers are interested in stopping.[22] A further review concluded: "*because smoking prevalence is heightened in prisons, offering evidence-based interventions to nearly 15 million smokers passing through [prisons] yearly would improve global health*".[23]

In the UK, Welsh and pilot English prisons became smokefree in 2015,[24] with all English prisons becoming smokefree by 2018 (following the lead of New Zealand [25] and other jurisdictions). This reversed prisons' partial exemption from the UK's 2006/7 legislation banning smoking in public places and almost all workplaces.[26] However, prior to TIPs, evidence on the process and outcomes of prison smoking bans was very limited, although some research is emerging (see e.g. [27, 28] [29, 30]).

Our previous TIPs study is unique internationally in its pre-post, multi-method, natural experimental evaluation of the process and outcomes, and its comprehensiveness. Over three phases, TIPs researchers collected over 350,000 minutes of secondhand smoke exposure data,[13, 15, 16] across all prisons, survey data from over 3500 staff and ~6000 PiC,[17, 18] 34 staff focus groups[11, 12], and one-to-one interviews with ~140 prison staff and smoking cessation service providers and over 100 PiC [8] (supplemented by further interviews with 32 staff and 59 PiC in a CRUK-funded study of e-cigarettes[10]). We also analysed anonymised routinely collected data (e.g. 'canteen' (prison shop) spend data, deaths in custody, medications dispensed for PiC; sickness absence for staff) to further evaluate benefits and potential adverse outcomes.[14]

TIPs data has directly informed Scotland's policy. The CEO of the Scottish Prison Service (SPS) announced in 2017 at the press conference reporting our Phase 1 (baseline) findings on levels of secondhand smoke in Scotland's prisons that all prisons

would become smokefree in November 2018. TIPs measurements in the week of implementation of the ban are unique in showing immediate success in reducing markers of secondhand smoke (by 81%)[15]; and data collected six months later demonstrate sustained reductions.[13] This major organisational change was achieved despite challenges inherent in removing tobacco from a context in which use was normative and culturally embedded.[8, 11, 31, 32]

TIPs findings directly informed detailed implementation planning during Phase 2 (see [14], and [8, 10, 11, 17, 18]) and Phase 3 findings demonstrated the cost-effectiveness of smokefree prison policy over the short (*within-study*) and long term (*life-time model)*, but scenario analyses showed substantial *effects of varying smoking relapse rates after release*.[14] A systematic review of studies to July 2017 of relapse following release from smokefree prisons described the evidence base as "small, almost exclusively US-based", and "mostly methodologically weak" and noted ***"****an urgent need for high-quality research to inform interventions to reduce high smoking relapse rates upon release from smoke-free prisons, to extend the multiple benefits of continued smoking abstinence into the community"* (p1011).[33]

Shortly before smokefree policy came into effect, SPS allowed the sale and use of rechargeable e-cigarettes (hereafter 'e-cigarettes'). We found that these were seen, by staff and PiC, as potentially helpful in supporting PiC to cope with mandated tobacco abstinence.[10-12, 17] While some contention around vaping persists (e.g. around health risks of long term vaping), research to date suggests it is less harmful than smoking and may help smokers quit.[34-36] However, our CRUK-funded work suggests much higher use in PiC (>80% buy e-cigarette products), than in the general population (~6%),[1] and many vapers express interest in reducing or stopping vaping while in a (mandated) smokefree context.[10] [37] Our emerging findings supported NHS Health Scotland's guidance to support PiC who want to cut down or quit vaping (CDQV).[38] Whether or not they succeed in this may influence their likelihood of relapse to smoking after release.

TIPs thus provides strong evidence of benefits (and some challenges) of smokefree prison policy, but attention also needs to focus beyond the prison. Although primarily intended to protect PiC and prison staff from secondhand smoke *whilst living and working in prisons,* smokefree prison policy could deliver higher public health gain if tobacco-related harms could be eliminated or reduced *after people leave a smokefree prison*. PiC have particular needs in (preparing for) transition to the community. As most return to smoking,[39] there is a need to understand acceptable ways to support those who wish to stay smokefree. There is some evidence on smoking cessation interventions delivered whilst people are still in custody,[23, 40] but interventions to support them to stay smokefree (or to minimise tobacco-related harms) after release are only now being evaluated (e.g.[41]). This requires an understanding of a) any impacts of smokefree policy on family members and b) whether support targeting smoking behaviours could be provided to households that PiC return to. Thus a potential route for extending public health benefits, is via the communities and homes that PiC return to (a 'spillover effect'), where smoking rates remain disproportionately high**.**[42, 43] This could be achieved by supporting other household members to be tobacco-free, or where people do not wish or are not able to stop smoking, by measures or strategies to

encourage smokefree homes that reduce secondhand smoke exposure. Even if such interventions were only successful for a minority of people leaving prison and the households they return to (not least because some people have no home or family to return to after leaving custody), there could be an important impact on inequalities in smoking and health.

1.2. Supporting disadvantaged people/households to reduce tobacco-related harms; the AFRESH programme.

AFRESH is a modular, theory- and evidence-based intervention (developed by members of our research team with funding from the MRC's Public Health Intervention Development scheme)[44]. AFRESH aims to address the lack of feasible and effective smokefree home interventions [45, 46] and to take account of structural (e.g. lack of (access to) outside space) and other barriers to reducing tobacco-related harms for people living in disadvantaged households. It is designed to be delivered flexibly using face-to-face and/or remote techniques, with the option of using personalised household measurement information on household secondhand smoke levels and tailored support materials, including easy-read fact sheets and tools.

1.3. Evidence gaps.

The current study will be addressing the following key evidence gaps:

I. Relapse to smoking after release from prison is thought to be high, but evidence is lacking on how best to support people to remain smokefree, in preparation for - or after -release from a smokefree prison;

II. Sanctioned use of e-cigarettes in prison is recent and only allowed in some jurisdictions so little is known on how e-cigarette use in prison affects post-release tobacco use. Canteen spend data and TIPs qualitative interviews [10] suggested high initial uptake of vaping. Concerns expressed by some about their or others' vaping 6-months post-ban indicates a need for support with cutting down and quitting vaping if desired;

III. No research to date, in the UK or internationally, has asked family members if and how smokefree prison policy affects their lives (either positively or negatively);

IV. For people who live in a household with others after leaving a smokefree prison, there is no evidence on how tobacco use is affected (in all adult household members), and whether this could be an opportune time for intervention to reduce tobacco-related harms within the household.

2. Study Aims, Objectives and Research Questions

2.1. Aim and Objectives

Overall aim:

To understand a) if and how smokefree prison policy impacts families whilst a person is in custody or preparing for release, and b) how to reduce tobacco-related harms in people (soon to be) released from smokefree prisons and the household they return to.

Objectives:

I. work in close partnership with prison and health services and policymakers to build and share understandings of opportunities and challenges in reducing tobacco-related harms among people (soon to be) released from smokefree prisons and their families (WP1);

II. conduct scoping reviews to update evidence on a) supporting people to remain tobacco free (or reduce smoking) after leaving prison, and b) supporting people living in disadvantaged communities to establish smokefree lifestyles and/or homes (WP2);

III. understand experiences, opportunities and challenges for PiC as they (prepare to) leave or return to smokefree prisons, to help reduce tobacco-related harms (WP3);

IV. explore perceived impacts of prison smokefree policy on PiC's family; and opportunities and challenges for supporting reductions in tobacco-related harms in those released from prison and their families (WP4);

V. adapt and feasibility test a household-targeted intervention to assist people recently released from a smokefree prison, and their household, to cut down/quit smoking and/or create a smokefree home (or reduce secondhand smoke in the home), to reduce tobacco-related harms in the wider community (WP5);

VI. update estimated cost-effectiveness of smokefree prison policy; and investigate (if feasible) spillover effects of smokefree prison policy on family or household members (WP6);

VII. feed findings back into policy and practice in Scotland and other jurisdictions with smokefree prison policies (WP1).

2.2. Research questions

RQ1. What evidence is available on relapse to smoking (and effective interventions/ intervention components to prevent this) in people leaving (smokefree) prisons? (WP2)

RQ2. What evidence is there on supporting people (from disadvantaged backgrounds) to reduce tobacco-related harms in their home environment (through reducing/eliminating tobacco use and/or establishing smokefree homes)? (WP2)

RQ3. How do people serving long-term prison sentences, or preparing for release from a smokefree prison, experience mandated tobacco abstinence? (WP3)

RQ4. What are people's goals, needs, expectations and experiences as they transition in and out of prison in relation to tobacco and nicotine use? (How) does cannabis use impact on tobacco use among people released from smokefree prisons? (WP3)

RQ5. What do prison/health care staff think are the main opportunities and challenges for supporting people transitioning in and out of smokefree prisons (and families), particularly in relation to tobacco/nicotine use? (WP3)

RQ6. What are families' attitudes towards tobacco/e-cigarettes (including tobacco/e-cigarette abstinence/cessation) and smokefree prison policies? What are the perceived impacts of smokefree prison policies on families (if any)? (WP4)

RQ7. What is the perceived impact when a family member returns from prison on household tobacco/nicotine use? What are families' needs for support before and after a family member returns from prison, particularly in relation to tobacco/nicotine use? (WP4)

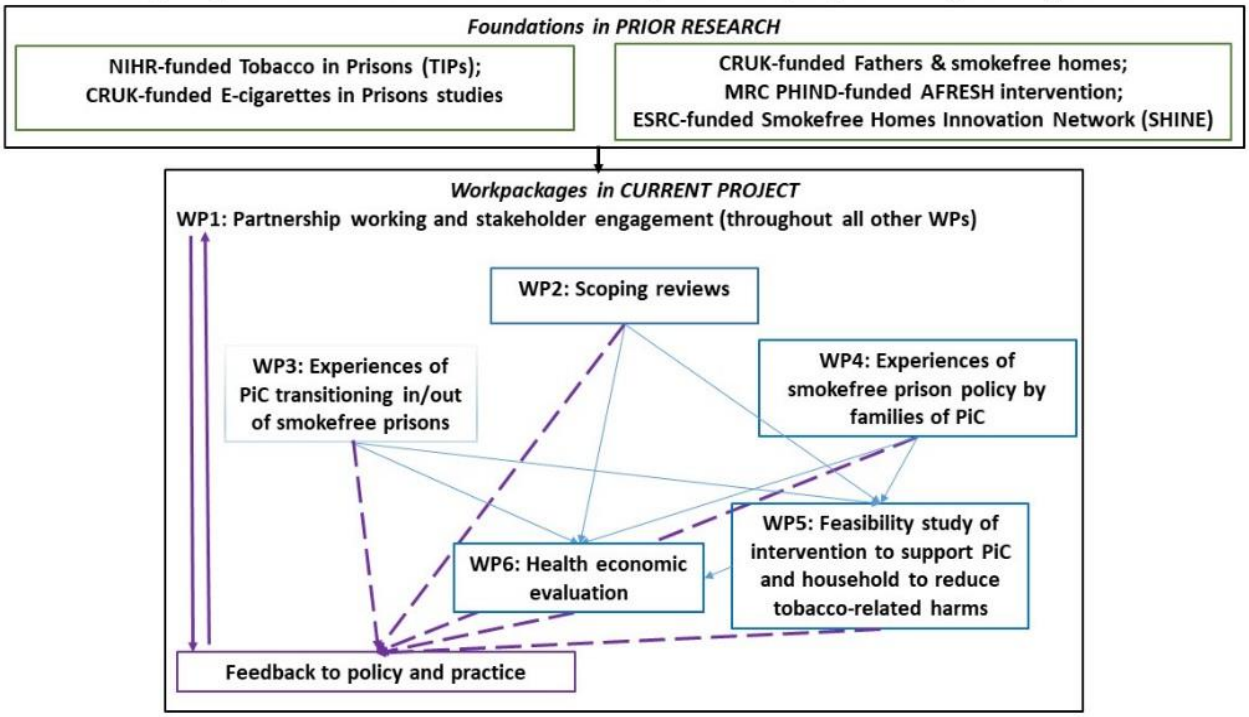
RQ8. Are household-based interventions to reduce tobacco-related harms acceptable to people (soon to be) released from a smokefree prison, their households and service providers? If so, is an adaptation of the AFRESH intervention acceptable and feasible for each of these groups? (WP3, WP4, WP5)

RQ9. How does inclusion of a) new evidence from scoping reviews, and b) potential impacts on family members of people in custody in or released from smokefree prisons, change the cost-effectiveness of smokefree prison policy? (WP6)

3. Research design and methods

We will address our research questions through six interconnecting workpackages (WPs) (Figure 1), to a) feedback into existing and developing policy and practice in the prison and health services (dotted arrows): and b) test the feasibility and acceptability of a household-based intervention to reduce tobacco-related harms among people released from smokefree prisons and their families.

Fig 1. Maximising the public health benefits of smokefree prisons for people leaving custody and their families



3.1. WP1: Partnership working and stakeholder engagement

We will continue to work in close collaboration with key partner organisations. Through regular meetings with tobacco control/health improvement specialists within SPS, Scottish Government, NHS (including NHS Boards and Public Health Scotland), we will discuss and agree final design and protocols for all WPs, and regularly feed back emerging findings from the study through verbal updates and written briefings. This process will also enable us to design a future evaluation of uptake, experiences and outcomes of providing support to PiC who wish to cut down or quit vaping whilst in a smokefree prison, using services outlined in the CDQV guidance.[38] We originally planned to include this evaluation component in this current study, but disruption to the prison regime, health service roles and delivery of CDQV and other services, from March-Nov 2020 (and into 2021) as a result of COVID-19 means that this work will be pursued in future studies.

3.2. WP2: Scoping reviews

Aim: to update understanding of:

I. the challenges and opportunities faced by people with respect to remaining abstinent from (or limiting consumption of) tobacco, as they prepare for, and after, release from smokefree prisons;

II. interventions that could support people to reduce tobacco-related harms following release from prison (with particular focus on family or household-based interventions);

III. the barriers and enablers that people recently released from prison and their household might face in creating/maintaining a smokefree home and/or lifestyle.

Methods: Following PRISMA guidelines,[47] we will conduct two scoping reviews which will be used to examine the extent, range and nature of existing research, identify gaps in the literature, synthesise relevant information for other workpackages and aid the planning of further research.[47, 48] Review 1 (Jan-August '22) will synthesise findings on the development, delivery and effectiveness of interventions aimed at changing smoking behaviours in the home (including barriers/enablers), to inform adaptation of AFRESH (or any more suitable intervention). Review 2 (Jan '22-Feb '23) will synthesise findings on prevalence of smoking after release from smokefree prisons and the factors influencing smoking/vaping behaviours after release from smokefree prisons.

For Review 1, we will build on the methods and findings of our recent scoping review.[7] We will incorporate broader search terms to focus on men/women rather than fathers specifically. We will search the literature for qualitative and/or quantitative primary data (including trials), published in English, since Jan 2012.[51] Databases searched will include Web of Science Citation Indices (Science Citation Index Expanded, Social Sciences Citation Index and Arts and Humanities Citation Index), PsycINFO and PubMed. Our search strategy will combine free-text and database-specific terms for smoking/secondhand smoke and homes. We will also search literature published since April 2019 using the terms "father" and "male caregiver" with our other search terms, to identify relevant papers published since our review[7] was undertaken. Studies will be included if they investigate smoking behaviour in the home (evidenced by self-report and/or changes in objective measures of secondhand smoke exposure (air quality, biological markers)); and/or changes in secondhand smoke attitudes or knowledge; and/or barriers and facilitators to changing smoking behaviour or creating a smokefree home/lifestyle. Search results will be downloaded to reference management software and duplicates excluded. Records will be single-screened for inclusion on titles initially. Potentially-relevant records will be double-screened. Disagreements on inclusion will be resolved by a third reviewer. Data will be extracted into a simple table, including study objective, sample size/strategy/characteristics, setting, country, study design, analysis method, intervention (if applicable), and relevant findings (extracted in verbatim text from the results/discussion sections for analysis). Study findings will be read and re-read by two reviewers to a) identify broad themes which will then be categorised as barriers or facilitators to creating a smokefree home/lifestyle, and b) identify efforts to test smokefree home interventions with a sample, or sub-sample of men, in discussion with the wider study team.

Review 2 will utilise the same methodological approach outlined above, and we will seek to build on published reviews.[33] Studies will be included if a) the population was

adults/young people (juveniles) (formerly) imprisoned in prisons where smokefree policies apply; and b) the study reports at least one of the following: (1) pre-release intention to smoke or remain abstinent following release; (2) smoking behaviour following release; or (3) quit attempts following post-release smoking relapse. Studies will be excluded if they report on smoking behaviours during imprisonment only. Our search strategy will combine free-text and database-specific terms for prison, tobacco use, release, relapse, prevention and cessation.

Our review findings will feed into other WPs as follows:

I. **Review 1**. Findings on the barriers/enablers faced in creating/maintaining a smokefree home will inform qualitative work with families in WP4 and WP5a, exploring opportunities and challenges for reducing tobacco-related harms by people released from smokefree prisons and their households. Review 1 findings on the development, delivery and effectiveness of interventions aimed at changing smoking behaviours in the home will inform the choice of intervention and any adaptations required. At the outset of the project, the AFRESH programme (carefully developed by team members using the six-step Intervention Mapping (IM) protocol [44] with MRC PHIND funding) is our preferred intervention, unless more suitable alternatives become apparent from our review). WP5a discussions with PiC and household members will support the most suitable (acceptable and feasible) ways of adapting the AFRESH[44] (or other more suitable intervention, if appropriate) to maximise engagement and 'buy-in', in preparation for assessing the feasibility of the intervention approach in WP5b.

II. **Review 2.** Findings on the rates and factors influencing smoking behaviours (relapse and abstinence) after release from smokefree prisons will inform work in WP3, WP5a, and WP6 to update and extend TIPs health economic modelling on pre-/post-release tobacco use.

3.3. WP3: Experiences of, and support for, transitions in and out of smokefree prisons

Aim: to understand experiences, opportunities and challenges for reducing tobacco-related harms among people released from smokefree prisons and any support needs.

Methods: In-depth interviews with: PiC at three key transition points, and those serving long sentences; and staff providing support to people leaving or entering smokefree prisons.

<u>Interviews with PiC</u>

Pre-release: We will conduct c.18 1-2-1 interviews (c.45 mins) with a purposively selected sample of PiC within 6 months of release who a) smoked before entering prison (if entered after 2019) or b) were in custody and smokers before prisons became

smokefree in 2018. Participants will be recruited from c.3 Scottish prisons, selected in consultation with the SPS (e.g. based on different liberation processes/arrangements for ensuring continuity of care). The research team will monitor participant characteristics on an ongoing basis and work with gatekeepers to address gaps in the sample where possible. We will follow practices which were successful and acceptable to SPS and prisons in TIPs [8, 10, 11], as outlined below.

PiC will be recruited through a point of contact in each prison. Following a phone call or meeting with the researchers, the contacts will be asked to provide information about the study to a sample of PiC nearing liberation, ensuring diversity by characteristics such as sentence length, vaping status and demographics. Researchers will then provide interested PiC with further study information, making it clear in the private setting of the interview that participation is entirely voluntary. Consent will be audio recorded or provided in writing by participants on a case-by-case basis, before any interview starts. Interviews will cover: PiC's background and time in prison; smoking/vaping history (including co-use of tobacco or e-cigarettes with cannabis products or NPS ('new psycho-active substances'), as far as is ethical given disclosure protocols in prison-based research); attitudes to smoking cessation and smokefree policy; views/experiences of e-cigarettes in prison, including adaptation of devices; aspirations/plans post-release (including for tobacco and e-cigarette use) and facilitators/barriers to realising these; expected ease/difficulty of transitioning out of prison; and support needs. Using the topic guides, researchers will formulate questions in their own words, probe for more detail if appropriate, and encourage participants to raise any relevant points. We will seek consent for a telephone interview post-release and for obtaining data to assist with arranging these (e.g. liberation date, contact information for participant/a close contact).

Post-release: We will conduct interviews by telephone (to maximise safety and minimise costs for researcher and participant) (n=c.14-18, c.30 mins) within 2 years of release. Interviews will be conducted using a topic guide to explore: time use, living arrangements, family/support networks, use of tobacco, e-cigarettes and other substances since release, and factors which made transition out of prison easier/more difficult. Researchers will be alert to perspectives and experiences of co-use of tobacco and cannabis (and co-use of e-cigarettes with other substances e.g. cannabis derivatives or NPS), given the potential implications for smoking cessation and other health outcomes. A £20 voucher will be offered as thanks. Strategies will be used to reduce attrition, particularly as these people will be going through a period of upheaval and may have many competing priorities, including: taking time to discuss the proposed follow-up at the initial interview; a relatively short follow-up period; using a range of re-contact strategies (e.g. telephoning, writing and emailing individuals directly, and via contact information they provide for family members/close friends); limiting follow-up interviews to 30 minutes; collecting data by telephone; and offering financial recompense for their time.[49] We propose a relatively small post-release sample to allow us to dedicate sufficient time and resources for follow-up post-release.

Return to prison: As many people return to custody after release from an earlier sentence, interviews (n=c.12, c.45 mins) with a purposively selected sample of smokers who have re-entered prison in the past 6 months will provide another opportunity to study experiences after leaving prison. We will select and recruit people using a similar approach to that above i.e. contacts in the prison service will be asked to invite a varied sample (remanded/convicted, demographics) of PiC to meet 1-2-1 with a researcher, in a private space, to be interviewed. Topics will include: (most recent) experience of leaving/re-entering prison, circumstances and aspirations pre-release, whether vaped or returned to smoking whilst liberated and any salient opportunities/challenges in their family, work and living circumstances whilst back in the community and support needs. Interviews will also explore experience of co-use of tobacco and cannabis (or other illicit drugs), and co-use of tobacco and e-cigarettes, as far as is ethical given disclosure protocols in prison-based research.

PiC serving long sentences: At SPS' request, we will interview c.8 PiC serving longer (>4 yr) sentences, to help SPS understand the opportunities and challenges of mandated smoking abstinence for this group. As above, PiC will be selected and recruited through prison staff contacts, seeking a range of demographic, prison-related (sentence length) and health behaviour (vaping status) as far as possible; and interviews will be in private spaces as arranged by local contacts, using a topic guide.

We are aware that we may need to make some adaptions to our plans to involve people in prison in our research due to the ongoing covid-19 pandemic. The safety of participants, interviews and others living and working in prisons and minimising disruption to the prison regime is paramount. Whether or not we are able to interview people in prison as planned will be determined by factors such as a) consultation and advice from Scottish Prison Service on the benefits/risks, feasibility and burden of data collection at the time of fieldwork, covid-related Government and University guidelines and completion of a University of Stirling fieldwork risk assessment that addresses the risks and mitigations in respect of covid-related risks. In the event that our proposed in-person data collection with people in prison is not feasible, we will explore and agree an adapted approach with the Scottish Prison Service and our Study Steering Group. Options might include: exploring whether any advances in the use of digital technology in prisons might be utilised for data collection, reducing the scale of in-prison data collection and/or conducting all/more interviews with people (recently) released from prison, with interviews covering both the pre and post release periods. If we shift our focus to interviewing people (recently) released from prison, then we may need to adapt recruitment and data collection methods as outlined below:

- Recruitment: We may use a wider range of recruitment channels, including gatekeepers from Scottish Prison Service and statutory and third sector organisations, social media (e.g. twitter/Facebook) and snowballing (where participants are asked or volunteer to share the participation information sheet with others who may interested in having the interview).

- Mode of data collection: Interviews might take place remotely (by phone or online) or in-person depending on factors such as a) budget and safety considerations and b) the preferences of the participant.
- Topic guides: The topic guide may be adapted to cover several transition points e.g. entering a smokefree prison, living in a smokefree prison, preparing to leave a smokefree prison and post liberation.

Given considerable challenges with recruitment and fieldwork in 2022 and 2023, due to ongoing pressures on the SPS and NHS, plans to involve people post-release have been adapted to make use of a wider range of recruitment channels and modes of data collection, as noted above.

Staff interviews

In-depth interviews (c.45 mins, n=15) with health, justice or voluntary sector staff supporting families affected by imprisonment, and people pre-release, resettling in the community or entering prison will explore the processes, opportunities and constraints to providing care for people entering or leaving prison, with a focus on management of substance use. Interviews will take remotely or in-person, depending on participant preference and Covid-19 risks. Prison or health service contacts will be asked to send emails about (or discuss) the study with potential participants in relevant work roles, using materials provided by the researchers. Interested parties will be invited to inform the staff contact or contact researchers directly, to discuss scheduling an interview. These interviews will cover: roles and responsibilities; perspectives/experiences of opportunities and challenges for providing through/aftercare and resettlement support, particularly in relation to substance use and health promotion. Interviews with staff caring for people entering prison (e.g. reception staff, 'First Night Centre', addiction services; QYW advisors) will explore views/experiences of successes and challenges in meeting smokers'/ vapers' needs in their first days in custody. We will ask staff to reflect on smokefree policy now it is fully embedded, for staff and PiC; and explore with SPS HQ staff/local management whether procedures are needed to record/retrieve data on new admissions' smoking/vaping status, to support monitoring, including estimates of smoking relapse rates post-release.

In-depth interviews (C.45 mins) will also be conducted with a broader range of stakeholders to understand the facilitators and barriers to keeping tobacco control high on the agenda inside prisons and in wider society. Stakeholders may include relevant staff working at SPS college/headquarters, staff in Scottish Government, and staff working in public health regionally or nationally with an interest in tobacco control/addictions in Scotland. Emails will be sent to potential participants in relevant work roles either by the research team or via gatekeepers, using materials provided by the researchers. As above, interested parties will be invited to inform the staff contact or contact researchers directly, to discuss scheduling an interview. Interviews will cover: professional roles and responsibilities, including in relation to tobacco control/substance

use, opinions on smokefree prison policy, understandings of the problem of (relapse) to smoking post-release from prison, perceptions of the extent to which tobacco control is high on the agenda in prisons/wider society and reasons for this, views on opportunities and challenges for trying to support people leaving prisons and families with reintegration (generally), views on opportunities and challenges for trying to support people leaving prisons and families to reduce smoking-related harms specifically, and perceptions of what, if anything, would need to change for more people to become smoking abstinent or create a smoke-free home post-release in the future.

3.4. WP4: Experiences of smokefree prison policy from a family perspective

TIPs and other studies to date have focused on exploring impacts of smokefree prison policy on PiC, prison systems and staff. Yet, such policies have potential to impact on families, e.g. because of changes in: economic resources/demands (due to removal of tobacco costs, with or without a switch to e-cigarette costs); or emotional wellbeing linked to how a family member in custody is managing without tobacco and the pressures families may feel (e.g. to smuggle tobacco into a prison to support them). Also smokefree prison policy could present a turning point for the long-term smoking behaviour of some PiC and their families. However, transitions out of prison can be challenging, for those leaving prison and for families,[50] and multiple barriers to tobacco reduction/cessation may need to be navigated.[33] Speaking to families about the impacts of smokefree prison policy and any opportunities/challenges for reducing tobacco-related harms and maintaining any existing smokefree home rules will address important evidence gaps, and inform prison and health service provision for families, and the work of WP5 and WP6.

Aim: To understand any perceived positive or negative impacts on family members of smokefree prison policy and explore perspectives on opportunities and challenges for reducing tobacco-related harms when a relative is released from smokefree prison.

Methods:

*Recruitment***:** We will recruit a purposively selected, sample of 20-30 family members of PiC due for release within 2-12 months. Family members will be recruited from people with a relative resident in prisons in central Scotland; focusing our recruitment geographically will minimise the time and resource needed to complete fieldwork on time and provide a good representation of prisoner populations. We anticipate that family participants may include (grand)parents/carers, spouses/partners and adult siblings/children, reflecting the different ages and home circumstances of PiC. As far as possible, we will include a mix of (adult) participants who are/are not smokers/e-cigarette users and include people whose family member is serving shorter or longer sentences. We will recruit through gatekeepers (e.g. family contact officers, prison visitor centres), using materials provided by the research team. Links with gatekeepers

will be facilitated by our partnerships with SPS and co-applicant Nancy Loucks, Chief Executive of Families Outside.

Data collection and analysis: We aim to involve c.30 participants in interviews/groups. Prior to further PPI work and given uncertainties remaining in relation to Covid-19, we are open to using the most appropriate method (we anticipate conducting small focus groups [max 3-4 participants], c.60 mins and/or 1-2-1 interviews, c.45 mins) and mode of data collection (in-person/remote). Decisions will be informed by PPI work with families, discussions with Families Outside and SPS, and any COVID-19 restrictions in place when fieldwork takes place. Working with stakeholder partners, careful consideration will be given to the composition of any groups, to avoid tensions that could arise between participants (e.g. families with known enmities) or stigma. Topic guides will explore: opinions on smokefree prison policy, perceived impacts (positive or negative) of this policy on any family members, including finance, behaviours (e.g. smoking/vaping), aspirations to change behaviours (including any 'rules' about smoking in the home), and mental and emotional wellbeing. Participants will be asked about expectations/experiences of the return of a family member from prison and for views on how best to support families anticipating a person's release from prison, including in relation to tobacco use. This exploratory WP will provide an overview of impacts on families, addressing an evidence gap internationally and feedback of a broader perspective on service needs and provision to health and prison services. It will also provide family views on potential adaptation of interventions for WP5.

3.5. WP5: Adaptation (WP5a), and feasibility study of delivery (WP5b), of intervention to reduce tobacco-related harms after release from prison, with the aim of extending benefits to families.

Aim: To test feasibility of delivering a household-targeted intervention to support: i) people leaving prison to maintain tobacco abstinence or harm reduction approaches; and ii) household members to cut down/quit smoking and/or create/maintain a smokefree home. Anticipated methods described below, are subject to change depending on the findings of WPs2-4, PPI and stakeholder engagement work, and any Covid-related constraints.

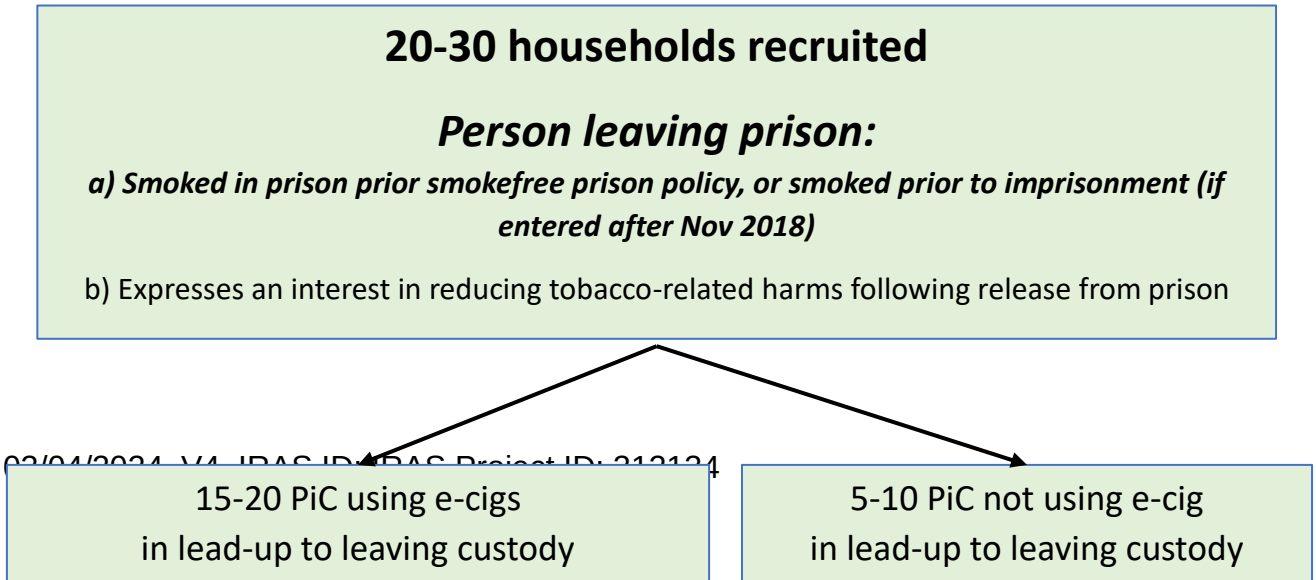
Methods: We aim to recruit 20-30 households[51] interested in reducing tobacco-related harms, including via: WP4 participants directly, referral from family contact officers and other prison staff, CDQV or smoking cessation services, prison visitor centres and Families Outside. All recruited people leaving prison will be previous smokers, either i) as a smoker while in prison prior to the smoking ban (if sentence started before Nov 2018), or ii) as a smoker at the point of prison entry from Dec 2018. We plan to only recruit men for WP5, as they account for c.90-95% of prison populations, depending on findings from earlier WPs. We will seek c.15-20 PiC who are current e-cigarette users and c.5-10 non-users of e-cigarettes (Figure 2).

Our inclusion criteria for the feasibility study will be based on the aspiration of the person leaving prison to remain tobacco-free on release, or to limit tobacco-related harms (secondhand smoke exposures) for other household members. We will employ a pragmatic approach to recruit a range of households covering those where: partners/other adult members smoke/do not smoke; outside space is/is not easily accessible from living space; the household defines itself as a smokefree or smoking-permitted home; children are/are not living in the home.

Intervention (Figure 3): At this stage we anticipate using a suitably adapted version (following recently developed guidance [https://decipher.uk.net/portfolio/the-adapt-study/]) of the AFRESH programme (see 1.2 above),[44] which provides information about the benefits of a smokefree home, the impact of indoor tobacco smoke on others, and practical measures to support a tobacco-free lifestyle and/or a smokefree home. From our knowledge of the literature, we judge to date that AFRESH will be the most appropriate intervention to adapt for this target group, although newer, more appropriate interventions may be identified through the scoping review.

WP5a will work with people soon to be leaving prison and adult household or family member(s) to develop expectations and agree the most suitable (feasible and acceptable), tailored approach that is likely to maximise reach, engagement and 'buy-in', and minimise drop-out from the intervention and attrition from follow-up. Whilst mindful of the need to understand more about people's aspirations at this juncture in their lives, we plan to investigate the feasibility of measuring likely primary outcomes for a future evaluation of the intervention (should it prove promising), including whether the person leaving prison is tobacco-free 12-weeks post-release (verified by exhaled carbon monoxide (eCO) measurement), whether other household members remain/become tobacco-free, and whether the home remains or becomes a smokefree space. Secondary outcomes are likely to include reductions in tobacco use amongst adults in the household, given the focus on reducing tobacco-related harms.

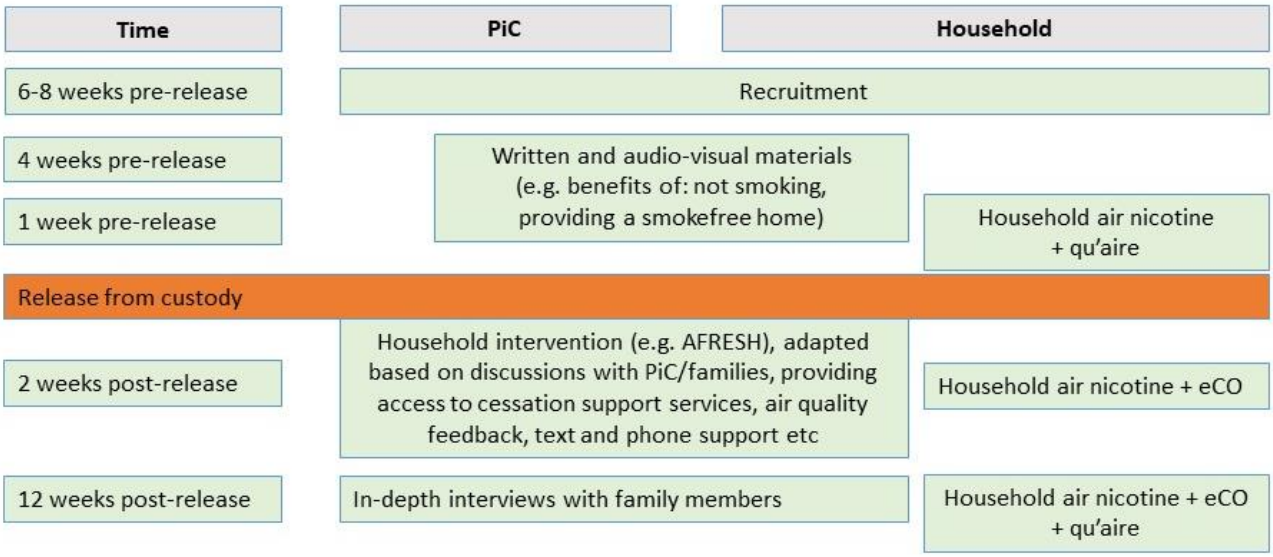
Figure 2. WP5 Intervention recruitment and sampling framework



***WP5a Intervention adaptation*:** We will involve both PiC and family members in the process of refining the intervention. Initial discussions will ensure that there is a family or household interest in reducing tobacco-related harms. In the four weeks prior to release, the team and prison/NHS staff will work with the PiC and family member(s) to discuss the intervention materials and the support that can be made available prior to release and for approximately twelve weeks post-release. AFRESH is a household level intervention. Adaptation of the AFRESH intervention will enable co-design of an approach based on the experience and knowledge of PiC and their families about potential barriers and challenges to remaining tobacco-free.[7, 52] Discussion of likely 'pinch-points' and ways of accessing or receiving support to overcome these will be key to this stage. For household members who smoke, we will explore how to support the most achievable aim ranging from quitting to cutting down through to creating a smokefree home. From a public health perspective, the ideal aim would be quitting but we will also explore other outcomes, such as a smokefree home where smoking activity takes place outside, to minimise secondhand smoke exposures to household residents and particularly children. Tailored post-release household support plans will be agreed with each person leaving prison and their household members.

WP5b Intervention delivery and feasibility study: Intervention delivery will span around 16 weeks, i.e. around 4 weeks prior to release and 12 weeks post-release (Figure 3).

Figure 3: Schematic of intervention delivery and outcome measurement points



Pre-release: In the 4 weeks prior to release, we will provide written and appropriate audio-visual materials, setting out the health, financial and other benefits of continuing a tobacco-free lifestyle after release from prison. This will include health benefits for children and other people living in a smokefree home. Where possible we will engage with PiC (in conjunction with the prison/health service staff most suited to deliver the intervention in future) through group and individual sessions. Similar materials and sessions will be provided to other adults in the household that the PiC will return to post-release, and will include discussions of potential (removal of) triggers for re-starting smoking in someone who has been living in a smokefree environment. Approximately one week before release, we will work with household members to measure household secondhand smoke concentrations using a simple passive badge nicotine device in the living-room over 5-7 days. These will be posted to the home for self-installation prior to the release date to provide data on pre-release airborne nicotine concentrations in the home.

Post-release: Tailored household support will be provided over the 12 weeks post-release. This is likely to include additional written materials, short videos delivered via social media, telephone support, text and email messaging, and the offer of personalised feedback of information on measurements of household secondhand smoke concentrations using Purple Air PA-II-SD air quality monitors (PurpleAir LLC, Draper, USA) to provide real-time data on airborne fine particulate matter ($PM_{2.5}$) [5]. Exhaled carbon monoxide (eCO) measurement will be used at week 2 and week 12 post-release to determine the smoking status of the person recently released from prison, and any adult(s) in the household engaging in a quit attempt. The eCO measurement will also be communicated to participants to provide feedback on progress of remaining tobacco-free or reductions in cigarette smoking. Other elements of the intervention will likely include support in accessing local NHS cessation and Nicotine Replacement Therapy services.

In-depth interviews with up to two adult, per household (in-person or by telephone) will be conducted at the final follow-up 12 weeks post-release to qualitatively explore any changes in knowledge, attitudes and behaviours and perceived success, positive or negative experiences of the intervention and its components, views on the measurements proposed and undertaken, and any ideas for improving the intervention or intervention components. We anticipate that eCO-verified tobacco-free/reduced smoking status of the released PiC at 12-weeks and/or household airborne nicotine concentrations will be the primary outcome(s) in a future evaluation of the intervention. Additional outcomes will be assessed and reported from data gathered by questionnaire one week pre-release and at final follow-up 12 weeks post-release, to assess self-reported changes from people released from smokefree prison and adult family members. Household nicotine concentrations will be assessed using the nicotine badges 2 and 12 weeks post-release to provide objective air quality measures, and where real-time $PM_{2.5}$ data was used as part of the personalised intervention process, this will be considered in the evaluation.

To minimise costs and maximise the feasibility of any general roll-out of the intervention in the future (should a later evaluation justify this) and for the safety of the research/delivery team, we aim to minimise the need for home visits. The AFRESH

programme is designed to be delivered remotely by telephone and through text. Our team have considerable experience with using postal, courier and telephone assisted set-up of the simple, low-cost devices we will propose to use to measure household airborne nicotine and real-time $PM_{2.5}$ concentrations. Questionnaire delivery and qualitative interviews may be carried out remotely or through meeting at a convenient community location.

The feasibility of the intervention will be assessed by looking at uptake/recruitment rates from the target population; rates of completion of involvement in the 12 week intervention process; identification of acceptability and practical problems in terms of real-world delivery of the intervention process (for both participants in the intervention and those delivering the intervention); and an estimate of the economic costs of the delivery in terms of direct resource and staff time (this final element will be reported within WP6). We will also use the MRC Process Evaluation guidance (https://www.ukri.org/publications/process-evaluation-of-complex-interventions/) to map out how we will assess fidelity of delivery ('dose') and the reach of the intervention, while qualitative data about participant experience will help us understand the context and mechanism(s) of action.

Data on the economic costs of the intervention will be identified and collected in WP5b, and an estimated cost of the intervention per PiC will be calculated as part of WP6. Cost categories will include staff time and materials used to deliver the intervention, and instrument costs for air quality measures ($PM_{2.5}$ and nicotine levels) and CO monitoring.

3.6. WP6 Update health economic evaluation of smokefree prison policy

In the health economic modelling in TIPs, two approaches assessed cost-effectiveness of smokefree prisons policy: a short-term within study analysis; and a lifetime model. Both incorporated costs and outcomes for staff and PiC.[14] The short-term analysis found smokefree policy was cost-effective for staff; for PiC, costs in a period with smokefree policy were less than without the policy, but quality of life was lower. The lifetime model found that smokefree policy resulted in lower costs and better quality of life for staff and PiC. However, there were important uncertainties in the models for PiC, notably in the reliability of estimates of how many people return to smoking after release from a smokefree prison. The TIPs base case model conservatively assumed everyone would relapse to smoking on release. Additionally, e-cigarettes were only introduced just before smokefree policy came into effect in 2018 and, as a novel technology in a context where any new product attracts interest and experimentation, initial uptake was high. However, some PiC expressed a desire to quit or concerns about (high rates) of vaping,[9] and the latest SPS prisoner survey suggests e-cigarette rates may be lower, potentially affecting both levels of nicotine addiction and harm-reduction strategies. Given the very limited evidence worldwide on the cost-effectiveness of smokefree

prison policy, this updated model would add significantly to the evidence base. Substantial groundwork was conducted on the TIPs lifetime model; the work proposed below would give us the opportunity to add novel elements, incorporating: 1) more accurate updated evidence on relapse to smoking on release and e-cigarette usage; and 2) 'spillover effects' of smokefree policy on family/household members (this area has not been well researched in health economics, with no gold standard on recommended approaches).

Aim: a) to update the lifetime model of the cost-effectiveness of smokefree prison policy for PiC, taking account of updated evidence on relapse to smoking after release and e-cigarette use; and b) to model impacts of smokefree policy on family members of PiC (adults and children).

Methods: The WP6 HE analysis has two facets.

I. updating TIPs lifetime models

Our updated modelling will be informed by several new strands of evidence:

• sourced via our scoping reviews (WP2), new evidence internationally on: smoking prevalence after release from/reported on (re)entry to, prison; e-cigarette use in prisons; evaluations of interventions to support relapse prevention in people leaving prison;

• updated information on e-cigarette use in Scottish prisons, as a proxy for reliance on nicotine. (The TIPs lifetime model applied e-cigarette costs to all PiC who were smokers before smokefree policy.) Sources are: self-report e-cigarette use in SPS' prisoner surveys in 2019 (published 16.10.20) and 2021; and an updated analysis of e-cigarette product purchase data through the prison 'canteen';

• data on smoking/vaping on (re)entry to smokefree prisons. With SPS, we will explore ways to collect simple data as part of routine records on smoking/vaping as people (re)enter prison. We will explore whether such anonymised aggregate data are available in other jurisdictions (in the UK/internationally);

• narratives from WP3 interviews with people who have recently left, or returned to, custody, or are pre-release, to inform assumptions about relapse, triggers for/timing of relapse, and facilitators of tobacco abstinence (with/without e-cigs) after leaving prison;

• routinely collected data from CDQV when/if service/data collection fully resumes post-COVID disruption to delivery of the service.

Should any substantive new evidence (e.g. systematic review) become available on long-term effects of e-cigarette use, this will also be incorporated.

Final decisions on the model structure and inputs will be determined by the format of new evidence collected, but we expect the following methods to be used. A Markov model will estimate a life-time incremental cost-effectiveness ratio (ICER) of mean cost per quality adjusted life-year (QALY), comparing two scenarios: 'with smokefree policy'

and ‘without smokefree policy’. The states in the model will mainly relate to smoking statuses, which will be assigned different morbidity and mortality transitions. The structure will be split into two time periods: ‘in prison’ (time in custody) and ‘post-prison’ (time after release). We will apply current practice methods when building the model.[53]

Costs will include intervention costs, smoking-related disease healthcare costs, and nicotine product costs. The outcome of the model will be the QALY, a preference-based measure of health-related quality of life, combining length and quality of life. Other key parameters in the model will include the age of PiC entering the model, length of time spent in the ‘in prison’ time period of the model, and the total PiC population number. Based on our scoping review (WP1), we plan to include: updated levels of tobacco smoking resumption on release from prison, updated levels of e-cigarette use in and out of custody, and varying assumptions about secondhand smoke exposure for ‘non-tobacco smokers’ in the ‘post-prison’ period. Where the evidence allows we will include separate data for men and women.

Uncertainty will be measured using probabilistic sensitivity analysis (PSA). This will be conducted by fitting appropriate distributions to parameter means as follows: relative risks characterised by lognormal; costs characterised by gamma distribution; and utility values characterised by beta distribution. Random picks will be taken from these distributions, and guidance on model convergence[54] will be followed. Appropriate sensitivity analyses will be conducted.

Results will be presented in line with current best practice guidance.[55] Mean costs and QALYs will be presented and differences between arms will be presented with a 95% confidence interval measure of uncertainty. PSA results will be displayed as estimates on a cost-effectiveness plane and cost-effectiveness acceptability curve.[56] Cost-effectiveness will be assessed using the current NICE threshold of £20,000 and results will be compared to any existing economic evaluation work in similar scenarios.

II. Extending TIPs lifetime models

We will extend the modelling to include any ‘spillover’ effects to families, via models assessing what the benefits would be if varying proportions of people leaving custody and family/household members were able to quit long-term or protect household members (particularly children) from secondhand smoke in the home. Including family spillover effects is an emerging technique in health economics (see Basu et al.[57]). Despite best practice advising the inclusion of spillover effects,[58] this advice is often not followed and definitions of ‘spillover’ effects are not well defined and often not included in economic evaluations.[59] Those which are included in focus mainly on the cost and outcomes related to caregivers (formal and informal). Research in this area and approaches for inclusion of the burden for caregivers and families are available (e.g.[60-62]), but the spillover of costs and outcomes on family members of adults quitting tobacco smoking are scarce, although recent work has been published on the

spillover effects of a pregnant woman quitting smoking on her unborn child, following mother and child for a life-time,[63] and on the effects of a spouse quitting smoking.[64]

This work will be informed by searching for and evaluating existing models incorporating spillover effects to family/household members of smoking and other harmful activities, including the costs of nicotine products and morbidity, and non-cost outcomes, combining these into a measure of cost-effectiveness. Current evidence on the effect of tobacco smoking on family members will be key. In particular we will look at the increased probability that a child of a smoker will take up smoking, the effects of secondhand smoke on adult and child health and quality of life, and the proportion of PiC who will return to a family home on release from prison.

4. Analysis

4.1. Statistical analysis

Analysis of data relating to airborne nicotine concentrations, secondhand tobacco smoke as measured as fine particulate matter (PM2.5) and participant smoking activity as assessed by exhaled CO will follow established methods of comparing pre and post intervention values to determine the scale, if any, of the intervention impact. Microsoft Excel and IBM SPSS will be used to generate measures of central tendency including arithmetic means, geometric means (GMs), medians, ranges, and percentiles where appropriate. For the $PM_{2.5}$ data, the percentage of time when measurements were above specific indoor air quality thresholds will be calculated using an Excel function. As $PM_{2.5}$ is not specific to SHS and can also arise from traffic and industrial air pollution, outdoor $PM_{2.5}$ data will also be gathered from the nearest available environmental monitoring station via the website www.scottishairquality.co.uk.

Similar methods will be employed for analysis of quantitative questionnaire data such as the number of cigarettes smoked.

Procedures for carrying out the health economic analysis are covered in *3.6*

4.2. Qualitative data analysis

After transcription, transcripts will be de-identified with particular care given the sensitivity of some topics discussed. De-identified transcripts will be summarised in a framework grid (column= themes; rows=participant), using a set of themes identified using a combination of inductive and deductive techniques. Data summaries and extracts will be examined to identify the range and diversity of opinions, experiences and impacts and to provide explanations for patterns in the data. Analysis will be finalised after an iterative process of discussion and refinement of emerging findings with key stakeholders.

5. Ethical Arrangements

Ethical approval will be obtained through both SPS Research Access and Ethics Committee and the University of Stirling General University Ethics Panel. We will seek advice on whether any work packages also require NHS ethics approvals. Research involving PiC and families, as with other potentially vulnerable groups, raises many issues and requires particularly careful attention to ethics. We will follow similar procedures to those that were successful in our TIPs work.

Permission for the participation of each prison will be required from SPS and the prison governor/delegated staff member. Participants will receive an information sheet, in plain English, prepared by the research team. This will explain that taking part is voluntary, they can choose not to answer questions and can stop at any time, and that strong measures are in place to keep data confidential (subject to any limits to confidentiality outlined in the study disclosure policy). Participants will be informed that, if they decide to withdraw from the study, we will destroy their data if they tell us before we have started analysing the data. It will be explained that extracts of what they say may be used in study outputs, attributed to a code (e.g. Participant 1) to protect their identity. However, we will also make participants aware that there is a small chance that they might be identifiable to people they know through study outputs. We will discuss this with anyone who expresses concerns about deductive disclosure and agree with them how best to manage risks. Care will be taken to minimise risks of deductive disclosure in the use of any extracts from participant interviews in all project outputs. Information sheets will make clear that the research team are independent of SPS and Scottish Government and that whether or not someone chooses to take part in the research will not influence their case management, care or treatment in prison. Written or verbal, recorded consent will be obtained for all participants once researchers have provided information about the study and answered any questions someone has.

Transcription will be undertaken by a specialist transcription service approved by the University of Stirling. Individual names and other direct identifiers will be redacted in transcribed interviews prior to analysis; we will follow SPS advice and guidance on de-identification of prisons. We will follow University of Stirling policy on the storage of research data. In line with this, personal data and other sensitive project files will be held securely on the University of Stirling's Sharepoint or Teams. Access to project files will be restricted to named members of research and support staff. Research data will be preserved for a minimum of 10 years after the study has completed; metadata will be deposited in the University of Stirling DataSTORRE repository. Subject to approval from SPS, de-identified qualitative data will be available for sharing outside of the research team where participant permission has been explicitly obtained. Where it is considered that additional redaction of the transcripts may be required, costs for this would need to be covered by the party making a request for data sharing.

Any research team member visiting a prison will be expected to complete any safety and security training that SPS recommend, in addition to training from the co-PIs and

WP leads on the study's fieldwork safety procedures. Training on fieldwork safety procedures for research team members will also be required for anyone conducting fieldwork in the community (e.g. interviewing people released from prisons and families), and research team members who are engaged in fieldwork will be required to work to carefully devised lone working protocols. Research will be carried out in line with relevant guidance and research practice from SPS. At all times safety and prison operational considerations will inform how research is conducted in each prison.

6. Research Governance

Project management and partnership working: The leadership of the research team, oversight of progress of the project, day-to-day management and partnership working with the SPS will be jointly undertaken by co-PIs KH and AB. They will discuss progress on all aspects of the project at least weekly. The co-PIs will meet at least fortnightly with the study researcher, and seek at least monthly updates/meetings with WP leads whilst each WP is in its active phase. The full project team will meet at least quarterly. All meetings will be virtual/in person as appropriate. Through WP1, we will be in regular consultation with SPS & provide early feedback of results; co-PIs AB/KH will provide this feedback, with invited input from other co-Is as appropriate.

Study Steering Committee: A study steering group will provide independent oversight and advice on the conduct of the research.

PPI: We will invite representatives from a range of PiC/people with experience of imprisonment and family members to participate (separately) in engagement sessions. ~6 PiC and ~6 family members will be recruited with the help of Gatekeepers, primarily: SPS, Families Outside and Prison Visitor Centres. We will seek to ensure diversity within our PPI groups as far as possible. The participation of family members and PiC will be on a voluntary and informed basis; the research team will provide information verbally and in writing to those who are interested prior to engagement activities. Family members will be reimbursed for their time. To minimise burden on individuals and service providers (and to work within any COVID-19 restrictions), we will be focused and flexible in how we engage with PiC and family members. We will develop detailed plans for engagement sessions, taking account of advice from SPS and Families Outside on approaches that are feasible and appropriate for the populations of interest. We will ask family members' preferences with respect to the scheduling (time/place/location) and delivery mode (in-person, remote) of sessions. If it does not prove feasible to get a small group of family members together for engagement sessions, we will bring together individuals in pairs/triads. For both groups, key PPI contributions will include views on the feasibility and acceptability of research plans for WP3 and WP4; and views on the feasibility and acceptability of household intervention and suggestions for what adaptions to the intervention might be desirable. We will also seek to ensure insights from family members and PiC inform data analysis. We believe this approach will be valuable and practical for this study, since it connects with people's

existing knowledge, skills and interests, does not require high levels of literacy and is time and resource efficient. Session plans will take account of potential barriers to participation by incorporating suitable elicitation/creative techniques (e.g. vignettes, card sorting) to facilitate discussion and sharing of views.

Our PPI work will complement and extend the extensive qualitative work we have planned for WPs3-5 and specifically, it will help to ensure that the perspectives of a diverse range of PiC, family members and service providers inform understandings about the acceptability of household interventions to reduce tobacco-related harms and decisions about adaptions of the household intervention.

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