SIPP (Safe Inhalation Pipe Provision): A study on providing safe inhalation pipes to people who use crack cocaine in England to reduce health risks and encourage their participation in services

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered	
09/03/2023		[X] Protocol	
Registration date	Overall study status	Statistical analysis plan	
15/03/2023	Ongoing	Results	
Last Edited	Condition category	Individual participant data	
28/02/2025	Mental and Behavioural Disorders	[X] Record updated in last year	

Plain English Summary

Background and study aims

Over 180,000 people use crack cocaine in England. Crack which can be smoked or injected, can cause serious health harms. People who use crack (PWUC) are vulnerable to infectious diseases, acute injuries and long-term respiratory problems. Engagement with this marginalised population is a challenge as UK drug treatment services have little to offer PWUC. Although services for people who use drugs can provide the equipment needed for safe injecting, supply of equipment to reduce risk when smoking crack is prohibited by law. This means most PWUC make the pipes they use to smoke crack from unsafe materials (increasing respiratory harm), share their pipes (blood borne virus & COVID-19 transmission risk) or inject drugs rather than smoke them (high risk for HIV, hepatitis C,& bacterial infections). Research, from countries such as Canada where crack pipe provision is legal, show that safe inhalation interventions increase PWUC engagement with services and reduce pipe sharing, drug injecting and related health harms.

The SIPP (Safe inhalation pipe provision) intervention has been developed with PWUC and with input from service providers. It consists of a kit with heat-resistant glass pipe, risk reduction information, and tailored training for service providers. The SIPP kit will be provided to PWUC for six months in rural and urban locations in Avon & Somerset and Nottinghamshire. We will work with three drug treatment services and three peer-led networks to deliver SIPP. We have local police force support. We will train and support peers to conduct research with PWUC who don't access services and to ensure our methods and materials are acceptable.

We will use quantitative and qualitative methods to understand the needs of the local community and evaluate SIPP. We will conduct a survey at two time points (before and after SIPP provision), recruiting through peer networks and treatment services, including at three comparison sites where there will be no intervention. Every time someone receives a SIPP kit

they will complete a brief questionnaire so we can measure change over time in individual risk practices. We will conduct interviews with PWUC and SIPP providers to understand SIPP acceptability.

Our aim is to evaluate a safe crack inhalation intervention distributed to people who use crack via drug treatment services and peer networks in order to reduce crack-related health harms and inform legislative review. Our main outcome will be an assessment of whether SIPP reduces pipe sharing. Outputs will include: optimised SIPP intervention; protocols for service implementation; crack risk reduction resources co-produced with PWUC; evidence for legislative review.

We are a multi-disciplinary team with expertise in working to improve health outcomes for marginalised populations. The proposal is the product of an academic, community and industry collaboration: team members include service users and providers. SIPP has potential to reduce health harms, including COVID transmission, and engage a hard to reach population with drug treatment services. Exchange Supplies, a well-regarded social enterprise, will co-develop and provide SIPP kits for free. We have permission from Nottinghamshire and Avon & Somerset police for drug services to participate without risk of prosecution. We will provide training to peers and providers in research methods and crack risk reduction. PWUC alongside other stakeholders (police, commissioners, treatment providers) will be involved throughout the project to ensure our methods are ethical and acceptable and that our findings and outputs are relevant.

Who can participate?

People aged 18 years or older who have used crack in the last 28 days.

What does the study involve?

Safe inhalation crack cocaine pipes will be distributed for a period of six months through drug treatment services and peer networks of people who use crack. The impact of this distribution will be evaluated by a mixed-methods evaluation using qualitative and quantitative methods.

The quantitative evaluation will involve a pre- and post-intervention survey which will measure changes in outcomes at baseline and follow-up among participants. We will examine evidence of a dose-response relationship between intensity of exposure to SIPP and primary (crack pipe sharing in the past 28 days) and secondary outcome measures (drug treatment service engagement; reduced injecting; acute injuries; use of homemade pipes; use of ash, respiratory risk markers).

Survey participants will be recruited via drug treatment services and through peer networks of people who use crack cocaine. Participants will complete a 20-30 minute structured closed questionnaire that will be administered by drug treatment service staff or peer researchers, with consent-taking built into the survey platform.

The qualitative evaluation will involve a combination of 32 interviews with PWUC (lasting up to 60 minutes), and 8 focus groups (lasting up to 120 minutes) comprised of PWUC, service provider staff, and other relevant stakeholders such as the police. This qualitative work will be complemented by observations conducted during fieldwork visits. The qualitative workpackage will assess SIPP acceptability, fidelity, and contextual mechanisms of impact, and will focus on understanding implementation experience and impact on practice from the perspective of people who use crack and drug treatment service staff, and the process of implementation in context.

What are the possible benefits and risks of participating?

Long term potential benefits of this study include sustained harm-reduction support from drug treatment services throughout the United Kingdom. This includes the provision of safe inhalation equipment which international evidence suggests reduces some of the risks associated with crack cocaine use (reduced viral transmission; reduced respiratory damage), and sustained engagement with drug treatment services among a highly marginalised population providing an opportunity to address broader health and social harms associated with crack use.

We recognise that discussing drug use, drug treatment care, and the possible experience of stigma due to crack use can be difficult. We also recognise that there is a risk of pre-existing stigma and prejudice, which can be a barrier to research engagement with PWUC and staff. Interviews with people who use crack will concentrate on their experiences of the health consequences of smoking crack; care seeking practices (self-care/medical care/drug treatment services); barriers and facilitators to engagement with drug treatment services; barriers and facilitators to safe crack pipes; crack use (smoking techniques/practices, e.g. home-made pipe use; crack use management); perceptions of the SIPP intervention; what 'safe' crack smoking might look like for each participant. Being asked to discuss some of these topics may cause embarrassment or distress for participants.

Where is the study run from? London School of Hygiene & Tropical Medicine (UK)

When is the study starting and how long is it expected to run for? June 2022 to May 2025

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact? Aubrey.Ko@lshtm.ac.uk

Study website

https://www.lshtm.ac.uk/research/centres-projects-groups/sipp

Contact information

Type(s)

Scientific

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Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

325186

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 55169, NIHR133118, IRAS 325186

Study information

Scientific Title

Safe inhalation pipe provision (SIPP): A mixed method evaluation of an intervention to reduce health harms and enhance service engagement among people who use crack cocaine in England

Acronym

SIPP

Study hypothesis

Study objectives:

- 1. Measure the effect and cost-effectiveness of SIPP on harms and risks associated with crack use (pipe sharing, presentation at drug services, using home-made pipes, cuts/burns, crack injecting).
- 2. Evaluate SIPP fidelity, reach and acceptability in diverse drug treatment and peer-network settings.
- 3. Explore the barriers and facilitators to SIPP uptake and service engagement among people who use crack.
- 4. Explore the mechanisms through which SIPP facilitates changes in health risks and access to

services, to inform implementation at scale.

- 5. Build peer-network research capacity and explore whether the quality and impact of their SIPP engagement with PWUC differ in comparison with SIPP engagement through drug treatment services.
- 6. Co-develop a scalable SIPP toolkit and harm reduction resources to enhance PWUC engagement with drug treatment services and to facilitate crack-related risk reduction practices.
- 7. Translate evidence to policy and advocacy outputs, including to inform legislative review.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/11/2022, Research Ethics Committee of London School of Hygiene & Tropical Medicine (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; ethics@lshtm.ac.uk), ref: 325186

Study design

Mixed methods cross-sectional

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Condition

Drug use

Interventions

This research study will evaluate a safe crack inhalation intervention distributed to people who use crack via drug treatments services and peer networks in order to reduce crack-related health harms and inform legislative review.

SIPP comprises of:

- 1. The SIPP kit: : A hard plastic case containing a straight stem borosilicate glass pipe; steel gauze filters/meshes; plastic mouth pieces and harm reduction information.
- 2. Provider training: an online crack harm reduction training module delivered to service providers prior to SIPP kit distribution.
- 3. Peer-to-peer training: a face-to-face risk reduction intervention developed by peers

We will employ a quasi-experimental design comprising of a pre-post comparison study with a non-equivalent control group and a nested qualitative study to identify impacts and predictors of SIPP use to inform intervention scale up and an assessment of its cost-effectiveness.

Our primary outcome measures are:

- 1. Crack pipe sharing in the past 28 days
- 2. Drug treatment service engagement; reduced injecting; acute injuries (cuts, burns); use of homemade pipes; use of ash, respiratory risk markers (difficulty breathing, chest pain, coughing blood).

The intervention will be evaluated through a mixed-methods process evaluation which includes quantitative and qualitative methods.

The quantitative evaluation will see a pre-and post-intervention survey measure the changes in outcome measures at baseline and follow-up amongst participants in intervention and control sites. We will examine evidence of a dose-response relationship between the intensity of exposure to SIPP and primary and secondary outcomes. Recruitment of participants will be via drug treatment services or through peer networks, and consent procedures will be built into the survey platform. Participants will receive £10 for participating in the survey.

The qualitative evaluation will consist of 32 interviews of PWUC which will last up to one hour each, and 8 focus groups lasting up to two hours comprised of PWUC, service provider staff, and other stakeholders such as the police. Interviews will also discuss the lived experience discuss drug use, drug treatment care, and stigma. Qualitative work will assess the acceptability, fidelity, and contextual mechanisms of impact of SIPP. They will also focus on understanding the experiences of implementing SIPP and the potential impact on practice from the perspectives of PWUC, drug treatment service staff and the process of implementation in context.

Intervention Type

Other

Primary outcome measure

Number of participants self-reporting sharing of crack pipes in the past 28 days measured using questionnaire at baseline, then 6 months.

Secondary outcome measures

Measured using questionnaire at baseline, then 6 months:

- 1. Number of new attendances at drug treatment service sites to obtain SIPP
- 2. Number of times injected in the last 28 days
- 3. Reporting of current acute injuries defined as cuts/burns to mouth or lips verified by interviewer observer
- 4. Number of participants who use homemade pipes in the last 28 days
- 5. Number of participants using ash as a crack suspension device
- 6. Number participants reporting respiratory risk markers defined as difficulty breathing, chest pain, coughing blood in the last 28 days

Overall study start date 01/06/2022

01/06/2022

Overall study end date

31/05/2025

Eligibility

Participant inclusion criteria

- 1. People who use crack: self-reported crack cocaine inhalation or injection within the past 28 days
- 2. Aged >18 years
- 3. Capacity to consent

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 1468; UK Sample Size: 1468

Total final enrolment

1473

Participant exclusion criteria

- 1. In secure services
- 2. Significant mental health problems

Recruitment start date

27/03/2023

Recruitment end date

30/06/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Bristol Drugs Project Limited

Bristol Drugs Project 11 Brunswick Square Bristol United Kingdom BS2 8PE

Study participating centre Pow

16 Independent Street Nottingham United Kingdom NG7 3LN

Study participating centre Change Grow Live

2 & 3 Sherwood Court Sherwood St Mansfield United Kingdom NG18 1ER

Study participating centre The Health Shop Nottingham

Nottingham Wellbeing Hub 73 Hounds Gate Nottingham United Kingdom NG1 6BB

Sponsor information

Organisation

London School of Hygiene & Tropical Medicine

Sponsor details

Keppel Street London England United Kingdom WC1E 7HT +44 (0) 20 7636 8636 rgio@lshtm.ac.uk

Sponsor type

University/education

Website

http://www.lshtm.ac.uk/

ROR

https://ror.org/00a0jsq62

Funder(s)

Funder type

Government

Funder Name

NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan

We will disseminate findings through community, policy, police and academic networks, including through initiatives led by PWUC. Our advisory board comprises service users and providers, police, international experts and policy makers who have input into the proposal, will oversee project delivery and aid translation of evidence into policy and practice. Additional specialised input will be sought as appropriate. We will target Local Authorities, Clinical Commissioning Groups, Drug Treatment Service providers, The Association of Police & Crime Commissioners and key stakeholders for research updates, tailored policy briefings and presentations, including through our teams existing memberships (e.g. Addiction Professionals).

We will coordinate communications teams within LSHTM, University of Bristol, Liverpool St John Moores University and collaborators such as Release, to foster effective findings dissemination. Peers will be actively involved throughout (including in the Advisory Board), with outputs cocreated and tailored to reach diverse audiences. We will work with our Universities' Press Offices to engage the wider public with the research and use our project's Twitter account to develop dialogue and gather feedback about findings and outputs.

We have long-standing collaborative working relationships with key drug treatment service providers, CGL; Turning Point and Humankind. Key learning will be shared across all applicable services nationally via established governance and service user forum structures. We will publicise and disseminate findings though key policing and drug treatment provider forums, such as Collective Voice, NHS Alliance and the Association of Police & Crime Commissioners. The project PI has presented the SIPP concept at The Annual Society for the Study of Addiction Conference, the CGL National Harm Reduction forum and in webinars lead by Hepatitis Scotland and the Westminster Drugs Project and would update at all fora on project findings.

Peer-review publication will prioritise multi-disciplinary dissemination, targeting high impact public health and social science journals (Addiction, PLOS One etc). We will present at

conferences attended by a range of professionals (Society for the Study of Addiction, RCGP & SMMGP Managing Drug & Alcohol Problems in

Primary Care Conference; National Needle Exchange Forum) and disseminate in partnership with international experts (such as Medecins du Monde). A report summarising main findings and recommendations will be publicly available through the LSHTM website and other appropriate forums.

The team are committed to disseminating research findings to community groups and project participants, including through social media (YouTube videos, blogs) and articles for community publications and websites such as DDN, Black Poppy and Injecting Advice. Article links will be sent to DrugWise Daily for inclusion in their news bulletin. We will present findings through community forums and at conferences attended by PWUC and providers such as DDN National Service User Involvement Conference and the International Harm Reduction Conference.

Intention to publish date

30/03/2026

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		23/01/2024	24/01/2024	Yes	No