**HRA Protocol Compliance Declaration:**
This protocol has regard for the HRA guidance

**Full Title of Study**
Evaluation of a public health pathway for alcohol and substance users in the criminal justice setting

**PROTOCOL VERSION NUMBER AND DATE**
Version1.00

**RESEARCH REFERENCE NUMBERS**

**IRAS Number:**

**FUNDERS Number: NIHR135411**

**SIGNATURE PAGE**

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees 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.
I 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
I also confirm that I 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.

**Chief Investigator:**
Signature: ...

Date:
...4.../.5../..2022.
...

.....
Name: (please print):
.....Susie Sykes
.....

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**KEY STUDY CONTACTS**

| | |
|---|---|
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| Sponsor | London South Bank University |
| Joint-sponsor(s)/co-sponsor(s) | N/A |
| Funder(s) | NIHR |
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**STUDY SUMMARY**

| | |
|---|---|
| Study Title | Evaluation of a public health pathway for alcohol and substance users in the criminal justice setting |
| Study Design | Mixed-methods evaluation |
| Study Participants | Staff and service-users |
| Planned Study Period | Sept 2021-May 2023 |
| Research Aim / Question(s) / Objective(s) | To generate policy and service recommendations for CJ substance abuse services through a robust, mixed-methods evaluation of an innovative pilot<br><br>Research questions:<br>How is a public health pathway for alcohol and substance users in the criminal justice setting developed and implemented?<br><br>And:<br><br>Does it achieve: co-ordination between services, acceptability, engagement and short-term outcomes?<br><br>Research objectives:<br>• To explore the context and the process of development and implementation of the pilot<br>• To evaluate the experience, acceptability and perceived impact of service providers in delivery<br>• To evaluate the experience and acceptability among service-users in each tier and across population groups |

## FUNDING AND SUPPORT IN KIND

| **FUNDER(S)**<br>(Names and contact details of ALL organisations providing funding and/or support in kind for this study) | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
|---|---|
| NIHR | This study forms part of a grant of £2.5million |

## ROLE OF STUDY SPONSOR AND FUNDER

PHIRST South Bank is one of 6 UK Public Health Intervention Responsive Studies Centres funded by NIHR. It is hosted by London South Bank University.

## ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

PHIRST South Bank Centre Executive Committee (CEC)

The CEC sits within the sponsor organisation, LSBU. It has management and governance responsibility for PHIRST South Bank and is made up of the Centre Co-Investigators, senior academic staff at LSBU and a lay representative from LSBU's People's Academy

PHIRST South Bank Advisory Group

The Advisory Group provides overall supervision for the project on behalf of the Project Sponsor and Project Funder and ensures that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice. Membership has been approved by NIHR.

Project Stakeholder Group

A local stakeholder group is in place to ensure liaison between the research team, the local project leads and PPIE representatives. The group is represented by Greater Manchester Combined Authority and representatives of the projects included within the Communities Against Gambling Harm programme.

## KEY WORDS:

Criminal justice, substance misuse, alcohol misuse

## STUDY PROTOCOL

### 1. BACKGROUND

*Policy context*
The policy and service context of Criminal Justice (CJ) services is rapidly evolving. Recent national policy has set out plans for increased funding for substance misuse services and a key policy aim is to increase referrals into treatment in the criminal justice system (HM Government, 2021). Yet, significant variation exists at the local level, following the end of the nationally mandated Drug Intervention Programme (DIP) in 2013 (Sondhi and Eastwood, 2021). CJ services that operate in the custody suite are a mix of DIP and alcohol arrest referral schemes (Sondhi and Eastwood, 2021) while NHS "Liaison and Diversion" (L&D) services have achieved national spread, amidst increasing interest in specifically public health (rather than public safety) strategies (Chariot and Heide, 2018; Marlowe, 2003). While national policy aspires to partnership working and joined-up, service provision (HM Government, 2021), precisely how the various services in operation can be coordinated locally remains to be seen.

*Intervention of interest*
This project evaluates an alternative and innovative way of working from the DIP model of custody suite engagement. The model consists of a new referral process within the custody suite that will allow for a proactive, targeted and layered approach for addressing the needs of different cohorts in Nottinghamshire. It is more proactive than DIP and involves the coordinated input of a range of stakeholders, such as the police, probation, women's aid and other support providers. The model has been developed by Change Grow Live (CGL), who have delivered Nottinghamshire's integrated substance misuse service since October 2014. The focus of the CGL team is to support people with their offending behaviour and substance misuse needs.

Central to CGL's new model is a layered menu of interventions, with service-users being assigned to one of three Levels after an initial assessment in the custody suite:

- Level 1 – universal provision of a wellbeing pack that consists of information that is tailored to the service-users substance abuse behaviours. The pack includes information about alcohol and substance abuse, harm reduction advice and contact details for CGL and other providers. The inclusion of alcohol represents a break from the DIP model, which focused solely on heroin and crack cocaine, and represents rising awareness of the crucial role of alcohol in violent crime.
- Level 2 – selective provision of the standard CGL offer, including 1 to 1 counselling sessions, support from volunteers and referral options to a variety of treatment and support services. Level 2 is targeted at repeat offenders and may be entered into on a voluntary or mandatory basis.
- Level 3 – assertive outreach to engage the most prolific of offenders (i.e., offenders who commit more than three offences within six months). A multi-agency panel undertake a mandatory initial assessment for these offenders which is followed by assertive outreach support for a time-limited period from a CJ Recovery Coordinator. The service will work with up to 18 people at Level 3.

The three levels aim to more effectively address service-user needs and enhance their engagement with the service. The model is underpinned by person-centred philosophy and is proactive in the sense that it aims to identify people earlier in their journey through the CJ system and facilitate intensive support for the most prolific offenders.

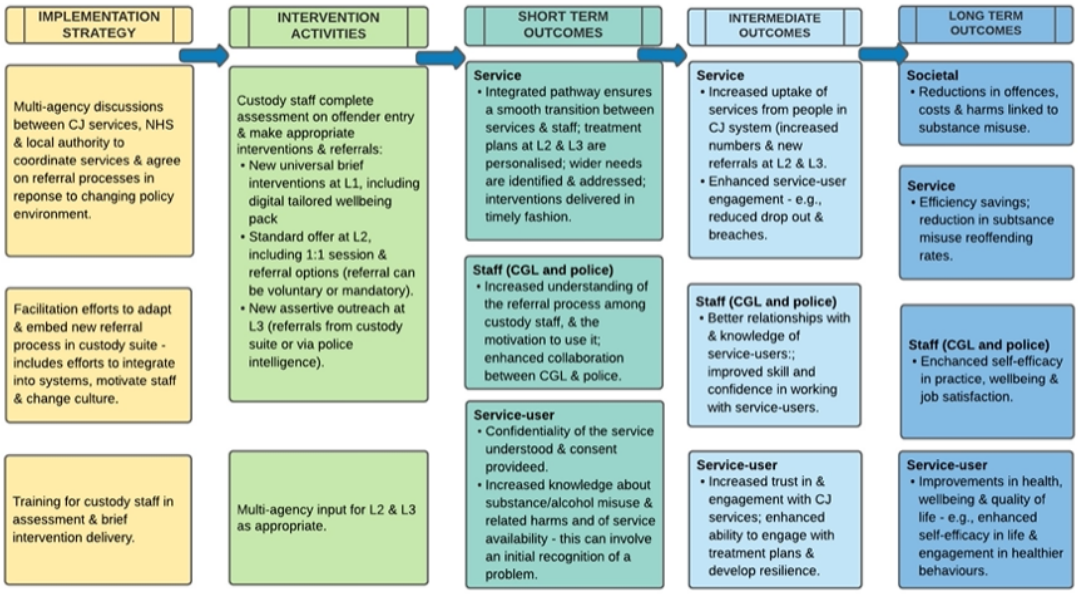
## 2. RATIONALE

The CGL Nottinghamshire service presents a unique opportunity to evaluate the early implementation of a new public health and CJ collaboration that consists of a new referral process and service pathway that may more effectively coordinate person centred local services. In a rapidly changing policy and service context in which local services are highly varied and lacking in coordination (Sondhi and Eastwood, 2021), local stakeholders need evidence to guide their efforts if the policy goal of reduced substance use-related crime is to be achieved (HM Government, 2021). This is vitally important as substance use-related crime may be increasing at significant cost to those directly affected and the wider society (Allen and Tunnicliffe, 2021). The evaluation has been specifically designed to generate learning from the Nottinghamshire pilot for CJ services in other areas. The timing of the evaluation also presents an opportunity to consider the local impact of recent national policy; insight about the effectiveness of national policy to facilitate local, service coordination is anticipated

## 3. THEORETICAL FRAMEWORK

A logic model of the CGL service redesign is represented in Figure 1. This was developed through a series of co-design workshops with local stakeholders, using Theory of Change (ToC) methodology (Breuer et al., 2016). The evaluability assessment carried out during the co-design workshops revealed that the pilot is not yet fully live and processes for implementation are still in development. While CGL stakeholders had a clear ToC for the intervention during the workshops, they recognised that a rapidly changing policy context meant that adaptations to the planned intervention would be required. Discussions were planned with diverse stakeholders, including local authority commissioners and NHS L&D services, about how to improve coordination across services; it was anticipated that the proposed service re-design would change, as a result of these discussions. Furthermore, the implementation strategy for the new referral process had not been planned and it was anticipated that the pathway would have to be adapted on delivery in order to, for example, embed in local systems and routines. An iterative rollout was therefore planned for the custody suite. Hence, a separate, implementation strategy column was incorporated into the logic model to reflect the significance of local stakeholder efforts in facilitating the pilot's implementation (see Figure 1).

**Figure 1: Logic model of Nottingham CJ service**




The logic model will be developed and refined over the course of this evaluation through a combination of qualitative research and surveys, across three work packages. Senior stakeholders, frontline staff and service-users will participate. Normalisation Process Theory (NPT), which identifies and characterises key mechanisms that promote or inhibit the implementation of complex interventions (May et al., 2018), will provide sensitising concepts for WP1 and WP2, as these focus on the implementation of the pathway and staff and service provider perspectives. NPT highlights the dynamic role of context in implementation processes and provides concepts for characterising mechanisms, barriers and enablers. The use of NPT will enrich interpretations of what is implemented in the pilot and the factors that explain success or failure. Elsewhere, for example, NPT has been used to theorise factors peceived by GPs to affect the implementation of an internet-based cognitive behavioural therapy intervention (Wilhelmsen et al., 2014).

Close attention to implementation and staff views and experiences in WP1 and WP2 will be complemented, in WP3, with an investigation of service-user experience and acceptability. This will be crucial to evaluating the core intervention mechanisms and for assessing, for example, the effectiveness of the levelled, referral approach to coordinate services around service-user needs. The work package will involve a survey to explore service-user readiness to change behaviour at Level 1 which will be framed by the COM-B framework, which has been extensively applied in substance abuse therapy (Gilchrist et al., 2021). The logic model will provide a framework for integrating insights gleaned from across the work packages and will be developed using techniques for modelling complex interventions (Mills et al., 2019; Mills et al., 2022).

## 4. RESEARCH QUESTION/AIM(S)

### 4.1 Aim:

- To generate policy and service recommendations for CJ substance abuse services through a robust, mixed-methods evaluation of an innovative service re-design

### 4.2 Questions:

- How is a public health pathway for alcohol and substance users in the criminal justice setting developed and implemented?

  And

- Does it achieve: co-ordination between services, acceptability, engagement and short-term outcomes?

### 4.3 Objectives

1. To explore the context and process of development and implementation of the pilot
2. To evaluate the experience, acceptability and perceived impact of service providers in delivery
3. To evaluate the experience and acceptability among service-users in each tier and across population groups

### 4.4 Outcomes

- An empirically informed Theory of Change – including logic model and accompanying narrative – of a public health pathway for alcohol and substance users in a criminal justice setting
- Evidence-informed policy and service recommendations for commissioners and service providers aiming to enhance the coordination of criminal justice services around the service-user

## 5. STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

### 5.1. Overview of work packages

WP1 will address research objective 1 via reflective diaries, document analysis and interviews with senior stakeholders at commissioning and management level. A final workshop will bring key CGL stakeholders together for a final reflection on the logic model. WP2 and WP3, which respectively address objectives 2 and 3, will initiate once the CJ pathway has been implemented in the custody suite. These work packages will primarily be based on small-scale surveys, qualitative interviews and focus groups to develop insight about the experience and acceptability of the pathway for service providers/staff and service-users; longer-term outcome evaluation is not feasible because of the intervention's early stage of development. Table 1 summarises each of the work packages and maps them to the 3 research objectives.

**Table 1: Overview of work packages**

| WP summary | Data collection method and sample | Rationale | Research objectives |
|---|---|---|---|
| **WP1:** implementation study | Reflective diaries kept by 2 CGL staff, researcher field notes, document analysis of national policy documents and local service documentation, semi-structured interviews with senior staff stakeholders (n-8 to 12), 1x final workshop | The reflective diaries and researcher field notes will capture details of the process of implementation; analysis of relevant policy and service documentation and the interviews with senior staff will explore crucial macro-level policy and meso-level organisational factors for understanding the pilot context; the interviews and final workshop will enable logic model development | 1 |
| **WP2:** staff acceptability and experience study | Qualitative interviews (n-12 to 24) and small-scale survey (n-12) with staff involved in delivering, referring into or working with service-users along the pathway; summative, end-point interviews with core CGL staff (n- 2 to 4) | Qualitative interviews with service managers and frontline staff will explore the practical implementation and use of the pathway and provide insight into the perceived value and benefit to staff of the various agencies involved; the survey will capture a broad array of views about the pathway among custody suite staff; the summative interviews will tap into the final views and learning of core CGL staff | 2 |
| **WP3:** service-user acceptability and experience study | Survey research, qualitative interviews (n-16 to 24), case study research and the descriptive analysis of service data | Survey research at Level 1 will enable the research team to evaluate service user's experience of the initial assessment in the custody suite and the welcome pack, in terms of it's potential to facilitate behaviour change; survey research at Level 2 will assess experience and acceptability among services while qualitative interviews will assess these in greater depth; case study research of a small number of cases, including observations and interviews, will provide insight into user experiences at Level 3; descriptive analysis of service data will provide insight into referrals and interventions across the levels during the pilot, as well as information on demographics and health needs | 3 |

## Work package 1:

### *Overview*

This qualitative work package will address research objective 1: it will investigate the context and process of development and implementation of the pilot. It will develop and refine the ToC set out in Figure 1 ahead of WP2, taking into account adaptations made in light of national policy changes.

*Reflective diaries, document analysis and stakeholder interviews*

Two core staff with development responsibility (representing Public Health Commissioning and Change, Grow, Live). who are leading the pilot will record observations in reflective diaries as they develop and implement the pilot. They will be provided with a prompt sheet that outlines some key questions that the research team are interested in to ensure that notes are relevant to WP1's aim (see Appendix). CGL staff will be asked to record interactions with key stakeholders and identify candidates for possible interview, based on their perceived relevance to the pilot and emergent questions of interest. Members of the research team will also keep reflective diaries and will capture details of conversations with the core development staff to capture information that may be missed in the CGL staff diaries.

Document analysis of key national policy documents (e.g., HM Government, 2021) will identify key policy objectives for CJ substance misuse services and anticipated mechanisms for achieving them; document analysis of local service documentation will provide insight into historic arrangements and services across Nottinghamshire and how these are changing in response to national policy. Senior stakeholders at commissioning and management level will be sampled for interview via a combination of purposive sampling and snowballing techniques. This will ensure relevance and flexibility in the sample, as WP1 unfolds. Senior staff leads of services central to the scheme or who refer to and/or regularly liaise with the core service will be invited to participate, including senior staff from CGL, the police, the local authority public health department and the NHS. The research team is anticipating that n-8 to 12 interviews will be undertaken, based on initial discussions with CGL staff and some flexibility to allow snowballing to occur. NPT (May et al., 2018) will provide sensitising concepts to guide topic guide development to ensure that key factors that affect the quality of implementation are covered. Interviews will explore how senior CGL staff and wider, senior stakeholders perceive the proposed CJ pathway and barriers and enablers to its implementation. The organisation of CJ services locally will be explored, along with the impact of, and responses to recent national policy. The aim will be to provide a picture of how the local service context is being shaped by national policy and to draw out the implications of this for the pilot.

A final workshop with the CGL staff will refine the logic model set out in Figure 1, with the workshop being recorded and transcribed for later analysis; the 3x initial workshops will also be transcribed for later analysis. The final workshop will also provide a forum to finalise thinking about the sample sizes for WP2 and WP3; WP1 insights will also inform topic guides and survey questions in later work packages.

## Work package 2:

### *Overview*

This qualitative work package will address research objective 2: it will investigate the experience, acceptability and perceived impact of the CJ pathway among service providers and staff involved in its delivery and use.

*Qualitative interviews and survey research*

Qualitative, semi-structured interviews will be carried out with key staff members to ascertain their views of the CJ pathway during the pilot. Given the need to avoid placing excessive research demands on busy service personnel, the research team will engage local stakeholders to organise these at a convenient time. Service managers who have a role managing relevant frontline staff will be purposefully sampled for the interviews, along with the frontline staff themselves. It is not possible to estimate precise sample sizes for these cohorts; the numbers provided here are early estimates, based on initial discussions with CGL staff. WP1 will inform decisions about sample sizes and also the precise staff groups and agencies involved. Topic guides will be framed by NPT to ensure that key factors that affect implementation are covered (May et al., 2018). For example, the interviews will explore the "coherence" of the pathway to service managers, along with other NPT constructs: N-4 to 8 service managers are anticipated for interview. A survey of and interviews with custody staff will explore their views and experience of the pathway, and barriers and enablers to its use: an estimated n-12 participants for the survey and n-2 to 4 participants for the interviews are anticipated. In addition, interviews with key CGL staff (n-2 to 4) and staff of the various agencies (n-4 to 8) who refer into, or deliver interventions as part of the pathway will be carried out. These interviews will explore staff's practical experience of engaging with service-users, from the point of referral in the custody suite through the interventions provided at Levels 1, 2 and 3. Finally, n-2 to 4 summative interviews at the end-point of the pilot, with core CGL and PH Commissioning staff, will ascertain their final views on the effectiveness of the proposed pathway on the various outcomes specified in the logic model (Figure 1).

## Work package 3:

### *Overview*

This work package will address research objective 3: it will examine the experience and acceptability of the CJ pathway among service-users in each level of service and across population groups.

*Survey research, qualitative interviews, observations and case studies*

Data collection methods will differ for each level of service:

- At Level 1, a brief survey will be integrated into the computerised assessment that service-users have, as part of the CJ pathway, on entry into the custody suite. CGL staff will be trained in how to administer the survey, including the taking of informed consent. Survey questions will explore service-user readiness and motivation to change their behaviour in relation to their substance use, and their knowledge about potential sources of support. This will enable the research team to assess whether the information pack is congruent with service-user motivation to change and whether it is proving an effective mechanism for conveying information about services. The COM-B framework, which has been extensively applied in substance

abuse therapy (Gilchrist et al., 2021), will frame survey questions. The survey will be open for a 3-month window during the pilot.

- At Level 2, a further survey will explore the experience and acceptability of the CJ pathway to service-users while n-4 to 6 semi-structured qualitative interviews will be carried out. This figure is based on initial discussions with CGL stakeholders about what is a feasible number, given likely service-user footfall and engagement, and may change as a result of WP1 learning. The interviews will explore how service-users have found the experience of the referral process in the custody suite, subsequent contact with CJ services and any interventions provided. CGL staff and local PPI personnel will assist in the recruitment process in both the survey and qualitative interviews, with the survey being open to all service-users at Level 2 for a 3-month window during the pilot. For the interviews, service-users will be purposely sampled to ensure diversity across key population groups and whether service-user engagement is on a mandatory or voluntary basis. The location and timing of the interviews will be decided by the research team, staff and the service-users on a case-by-case basis. This may help service-users feel at ease and make them more likely to open up about their experiences. The data gleaned from the interviews will provide crucial insight into the impact of the new pathway on service-users and whether it contributes to improved service-user outcomes listed in the logic model (see Figure 1).
- At Level 3, in-depth case studies with n-4 to 6 service-users will explore their experience and acceptability via rapid ethnography (Vindrola and Vindrola-Padros, 2018) and interviews. The figure for the sample size is an estimate at this stage, based on discussions with CGL stakeholders about what is a feasible number, and may change as a result of WP1 learning. Purposive sampling will ensure diversity across key population groups, with CGL staff and local PPI personnel once again assisting in the recruitment process. Researchers will observe key interactions between staff and the service-users along the pathway, including activities such as needs assessments, follow-ups and the delivery of substance-misuse treatments. Researchers will record their observations in field notes. The observations will provide crucial insight into the operation of the pathway on the ground, and how the wider pathway re-design is affecting micro-level interactions and relationships between staff and service-users. X2 interviews with the service-users in the sample will explore, in detail, their experiences of the pathway and the interventions they receive along it, barriers and enablers to their engagement the service and, specifically, their views on the assertive, outreach support component, which is unique to Level 3.

*Routine, descriptive data*

Routine descriptive information about service-users, referrals and interventions delivered will be obtained to provide insight about service-users and activity over the course of the pilot. This data will be obtained from the National Drug Treatment Monitoring System (NDTMS)-CJIT dataset. Referral and intervention data gleaned from this dataset will provide insight into how the CJ pathway is functioning during the pilot and provide context to the qualitative research. The service-user data and information about substance-misuse problems will also enable the research team to consider how service-user demographics and local health needs shape the pathway's effectiveness. This will be important for considering the potential transferability of the CJ pathway to other areas. This information will also enhance future service planning and the wider public health agenda by identifying if there is under or over representation in service use amongst different groups.

### 5.2 Data analysis

All qualitative data will be organised and analysed using the Framework Method (Gale et al., 2013). Data coding and analysis will proceed iteratively alongside data collection and multiple perspectives will be involved to ensure the validity and reliability of emergent theory and themes (Noble and Smith, 2015). NVIVO, MS word documents and MS Excel spreadsheets will be utilised, at appropriate points, in the organisation and analysis of the data. NPT will provide sensitising constructs to interpret the quality of implementation and staff engagement in WP1 and WP2 while thematic analysis of all qualitative data will draw out the key learning points of the work packages combined. The initial logic model (see Figure 1, above) will provide a framework for integrating findings from across the work packages and will be iteratively tested and refined during the research, using techniques for modelling complex interventions (Mills et al, 2019; Mills et al, 2022). The routine, descriptive data on service-users, referrals and interventions delivered will provide insight into how the pathway is functioning during the pilot and contextual information about service-user demographics and local health needs.

## 6. STUDY SETTING

WP1 and WP2 interviews will be carried out remotely over Teams. The study settings for WP3 will reflect where service interventions take place and include CGL and police service areas and locations where the assertive outreach component is delivered.
The precise timing and location of the research activities will be sensitive to service-user preferences in an attempt to maximise their engagement. CGL staff and local PPI personnel will assist in the recruitment process.

## 7.SAMPLE AND RECRUITMENT

**WP1**

- The 2 CGL staff will be recruited at the start of the research for the reflective diaries via purposive sampling; recruitment of n-8 to 12 senior stakeholders will proceed via purposive sampling and snowballing; CGL stakeholders will be invited to attend the final workshop to refine the logic model, ahead of WP2.

**WP2**

- Recruitment of staff, including core CGL staff, senior managers and frontline staff, will proceed via purposive sampling and snowballing; n-14 to 28 are anticipated for interview while n-12 are anticipated for the small-scale survey of custody staff. WP2 sample sizes are estimates based on discussions with CGL stakeholders and will be finalised over the course of WP1.

**WP3**

- All service-users will be made aware of the survey at Level 1, during their initial assessments, via whole population sampling: the survey will be open for a 3-month period. Similarly, all service-users will be made aware of the survey at Level 2, with the survey being open for a 3-month period. Recruitment of service-users into the qualitative research across Levels 2 and 3 will be informed by purposive sampling to ensure a diversity in the sample across key population groups and whether service-user engagement is on a mandatory or voluntary basis: n-16 to 24 interviews are anticipated across Levels 2 and 3, with the Level 3 interviews being conducted as part of n-4 to 6 in-depth case studies. WP3 sample sizes for the qualitative research are estimates based on discussions with CGL stakeholders and will be finalised over the course of WP1.

## 8. ETHICAL AND REGULATORY CONSIDERATIONS

### 8.1 Research Ethics Committee (REC) and other Regulatory review & reports

**Ethical oversight**

The research will receive ethical oversight from LSBU, IRAS NHS Ethics and also CGL and the local police force as required. This oversight will include the study protocol and all participant facing documentation, and a favourable opinion will be secured before any data collection takes place. Any adverse events will be reported to the above bodies. All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants

All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. Any information regarding participants e.g., case studies that is shared with others (for instance in reports, publications) will also have pseudonyms used, which will prevent the identification of people involved in the study. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

All research will be conducted in line with LSBU ethics panel code of conduct for research involving human participants and the British Psychological Society's ethical guidelines. These guidelines include principles of holding participants rights and dignity, anonymity, and freedom to choose to participate or not. Research will also be conducted and reviewed the way which makes it compliant with GDPR (or replacement legislation). Each strand of the research presents a number of particular ethical risks.

### 8.2 Assessment and management of risk

*Table 3: Risk register*

| Key risk | Likelihood | Impact on participants | Impact on project | Mitigation |
|---|---|---|---|---|
| COVID19 interferes with the availability of the research team and/or key stakeholders | Moderate | n/a | Moderate | Depth of team, clear project planning to facilitate handover, lines of alternative communication established, agreement to support the evaluation through a Memorandum of Collaborations between LSBU and CGL |
| Access to key stakeholders, including staff and service-users | Low | n/a | Moderate | Ongoing collaboration with CGL |
| Data not available from partners | Low | n/a | Moderate | Agreement with partners on data and ongoing stakeholder involvement, agreement in place to support the evaluation through a Memorandum of Collaborations between LSBU and CGL |
| National policy or local service decisions mean that the pilot does not become fully operational | Low | n/a | Moderate | Ongoing reviews with CGL to monitor progress. WP1 will capture the decision-making process and options will be explored with CGL stakeholders to adapt the focus of the WP1 and WP2 if a very different pathway is implemented to the one anticipated. |
| Complex process of ethical procedures and data sharing agreements due to the cross-sectoral nature of the research results in a delay to the start of the research | Low | n/a | Moderate | An ethics application for WP1, which does not involve service-users, frontline staff or routine service data, will be submitted separately; ongoing reviews with ethics panels and CGL will ensure the research team have the information to regularly review the situation |

### 8.3 Amendments

Amendments to the protocol will be directed to the PHIRST South Bank Centre Executive Committee for approval and where necessary to the LSBU HSC research ethics committee. All revisions will be submitted to NIHR for approval.

### 8.4 Peer review

This protocol will receive a proportionate review by PHIRST South Bank and the NIHR.

### 8.5 Patient & Public Involvement

Two service-users attended some of the 3x workshops for coproducing this evaluation. They made helpful contributions throughout, which informed the evaluation design and focus. Going forward, a PPIE advisory group of five people will be formed, including the two people who were involved in the workshops. This PPIE advisory group will oversee the ongoing development of the protocol, ethics applications and data collection tools. Options for direct involvement in research will be explored with the group, including the writing up of experiences for future publications. As some of the service-users who will be involved in the PPIE advisory group continue to work closely with CGL, they will assist in the recruitment of services-users and the setup of the service-user interviews. All PPIE representatives will be renumerated for their time and offered support in line with the PHIRST LSBU PPIE strategy.

### 8.6 Data protection and patient confidentiality

Where data is collected on third party data collection platforms outside of LSBU (e.g. Qualtrics) data will be anonymised at the point of download, and the third party copy of the data deleted. All data will be kept in an anonymous or pseudo anonymous format and stored on LSBU secure servers. Any key files will be kept on a secure server, encrypted and passwords shared separately from files. Data may be stored indefinitely with participant consent.

Where data is offered to online repositories (see *Dissemination*, below), it will be rendered fully anonymous prior to upload.

Pseudonyms will be adopted during audio recordings to maintain confidentiality. All information which is collected during the course of the research will be kept confidential by using password protected computerised records. All written transcripts will be kept in a secured locked filing cabinet, when not in use. Any information regarding participants that is shared with others (for instance in reports, publications or shared with a supervisor) will also have pseudonyms used, which will prevent the identification of people involved in the study. All data will be secured in a locked filing cabinet for as long as required for the duration of the study and will then be destroyed 18 months after the completion of the project.

### 8.7 Indemnity

Indemnity will be provided by LSBU for the research activity undertaken by its staff.

## 9. DISSEMINIATION POLICY

***Dissemination and output plans*** LSBU will own foreground IP arising from the project, including the final dataset(s) and transcripts. Details of IP ownership and usage rights will be finalised in a collaboration agreement between LSBU and Nottinghamshire County Council and a data sharing agreement with Change Grow Live.

Key research outputs will include:

1) Interim report of findings

2) A final report of finding

3) Peer review journal articles

We will also offer a workshop event in which the study findings are presented to CGL, and other stakeholder meetings on an ad-hoc basis as required. Data (including interview transcripts and comments) will not be lodged on an Open Science Framework due to the nature of the data; it may not be possible to fully anonymise these data. In this case, in compliance with the General Data Protection Regulation, data will be kept for 10 years from study completion and will then be destroyed.

## 10. MILESTONES

| STAGE | ACTIVITY | DATE – week commencing |
|---|---|---|
| Inception | Introductory meetings | Sept 2021 |
| | Identification of project team | Sept 2021 |
| | Identification of local stakeholder group | Sept 2021 |
| | 3x workshops | Nov-Jan 2022 |
| | Evidence scoping | Nov-Jan 2022 |
| | Design and protocol development | Jan-Feb 2022 |
| | Collaboration Agreement | Feb-Apr 2022 |
| | Local PPI recruitment | Feb-March 2022 |
| | WP1 Ethics application | By April 2022 |
| | WP2 and WP3 Ethics application | By June 2022 |
| | Research Governance Approval for WP1 | By April 2022 |
| | Research Registration for WP1 | By April 2022 |
| | Data collection tool development and piloting for WP1 | Feb-March 2022 |
| | Research Governance Approval for WP2 and WP3 | By June 2022 |
| | Research Registration for WP2 and WP3 | By June 2022 |
| | Data collection tool development and piloting for WP2 and 3 | April-June 2022 |
| Data Collection | WP1 reflective diaries, qualitative interviews and final workshop | April-June 2022 |
| | WP2 staff interviews and surveys | June-Nov 2022 |
| | WP3 surveys, qualitative interviews, case studies, service data | June-Nov 2022 |
| Analysis | WP1 analysis | April-Sept 2022 |
| | WP2 and WP3 analysis | June-Feb 2023 |
| | Revised theoretical framework | Jan-Mar 2023 |
| Project Management and Reporting | Local PPI meetings | Mar 2022 – May 2023 |
| | PPI feedback and impact monitoring | Mar 2022 and ongoing |
| | Reviews with and reporting to stakeholder group | Ongoing |
| | Interim findings report and programme of presentations | Oct 2022 |
| | NIHR interim report | Oct 2022 |
| | Finalise dissemination plan | Feb 2023 |
| | Final report | May 2023 |
| | Workforce outputs | Mar-July 2023 |
| | Programme of local presentations | Mar-July 2023 |
| | Programme of national dissemination | Mar-July 2023 |
| | Internal dissemination | Mar-July 2023 |
| | Academic publications | Mar-July 2023 |

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## APPENDIX

### Reflective diary template for CJ study: guidance

The aim of the reflective diary is for fieldworkers to capture details of what is occurring 'on the ground'. We are interested in building a qualitative understanding of the process you are going through as you attempt to implement the pilot. We would like you to capture your experiences and learning as this will be useful and relevant to CJ services in other areas who may be attempting a similar service redesign. We'd also like you to keep a record of the key stakeholders that you're interesting with: we can then interview them later, as part of the research.
The questions listed below aim to convey what we, as the evaluation team, are interested in. They are flexible prompts for you to think about when writing your observations down. Your observations can be as detailed or as brief as you like. You can decide to record observations for a particular day, or for longer periods such as a week or a month. If you're attending the custody suite, please record the number of visits you make and the time you spend there.

**Questions:**

- The pilot: How are your efforts to implement the pilot going? What are the key enablers or barriers that you're experiencing? How have you attempted to overcome the barriers you have experienced?
- Policy and service coordination: How is the new policy agenda (e.g., From Harm to Hope…) impacting on your efforts? There is an expectation that local organisations (e.g., CJ services, local authorities and the NHS) will seek to integrate services: how is this going in your area? How are you adapting the proposed CJ referral process following the discussions you've had with other organisations?
- Custody suite: How did custody suite staff view and respond to the new CJ pathway over this period? What do you think shapes the responses you've observed? How has the new CJ pathway affected the service that service-users receive? How are service-users (reported to be) finding the changes?

**Name of fieldworker:**

| Entry | Dates covered and activity detail | Observations |
|---|---|---|
| 1. | | |
| 2. | | |
| | | |