



# Gateway

A randomised controlled trial, economic and qualitative evaluation to examine the effectiveness of an out-of-court community-based Gateway intervention programme aimed at improving health and well-being for young adult offenders; victim satisfaction and reducing recidivism

## STATISTICAL ANALYSIS PLAN

Draft V1.1

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## 1. Document Version History

Version Number	Version Date	Summary of Changes
1.0	29/07/2021	<i>First signed off version</i>
1.1	28/01/2022	<p><i>In October 2021, the Trial Management Group reviewed progress and concluded that, despite our best efforts, it was not going to be possible to recruit to target. More significantly, it was not going to be possible to collect sufficient follow up data at any time point to enable the statistical analysis to provide an estimate of effect for the Gateway Programme.</i></p> <p><i>As a result recruitment to the study was halted in December 2021, and the statistical analysis plan has been amended in order to remove reference to formal statistical hypothesis testing. The analyses outlined in version 1.1 of the statistical analysis plan are purely descriptive in nature, and aim to give a comprehensive statistical report of the progress of the Gateway trial.</i></p> <p><i>An additional change was made to Table 5 in order to clarify that the SF-12 physical component and mental component will be reported separately.</i></p>

## 2. General

### 2.1 Document Scope

This statistical analysis plan (SAP) covers the reporting of the progress of the Gateway trial. Analyses relating to qualitative data and further exploratory post-hoc analyses are not covered by this SAP. Due to the study not reaching its recruitment and retention targets, it was decided that a health economic analysis was not feasible. As a result, health economic data will be summarised descriptively as part of the statistical reporting of the Gateway trial.

### 2.2 Glossary

CARA	Cautioning and Relationship Abuse
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case report form
HC	Hampshire Constabulary

IQR	Interquartile range
IMD	Index of Multiple Deprivation
ITT	Intention-to-treat
MAR	Missing at random
MCS	Mental component score
PCS	Physical component score
PNC	Police National Computer
RMS	Record Management System
SAP	Statistical analysis plan
SF-12	12-Item Short-Form Survey
SOP	Standard operating procedure
SSC	Study Steering Committee
TMG	Trial Management Group
UoS	University of Southampton
WaDE	Women and Desistance Engagement
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale
YTU	York Trials Unit

## 2.3 Procedural documentation

### 2.3.1 Standard operating procedures

The following YTU SOPs and guidance documents will apply to the conduct and documentation of the Gateway trial analysis.

S01	Statistical Considerations	Latest version: 6.0
SG02	Statistical Reporting Guidance	Latest version: 3.0

### 2.3.2 Associated documentation

Appropriate YTU standard forms apply. Any assumptions made during the processing and merging of data as well as for the analysis will be documented (internal document reference numbers in bracket) using a Trial Assumptions Form (F23). In the event of necessary changes or additions to analyses detailed here, these will be documented on a Statistical Analysis Plan Departure Form (F24). The statistical analysis will be signed off using a Primary Analysis Sign-off Form (F16) and Statistical Quality Assurance Checklist (C03).

## 3. Trial Summary

This section gives a summary of the Gateway trial. Full details are given in the Study Protocol.

### 3.1 Objectives

The aim of the study was to evaluate the effectiveness and cost effectiveness of the Gateway programme issued as a conditional caution compared to court summons or a different conditional caution (usual process).

## 3.2 Design

The Gateway trial is a pragmatic, multi-site, parallel group, randomised controlled superiority trial with an internal pilot phase, a concurrent economic evaluation, qualitative study and process evaluation.

## 3.3 Interventions

### 3.3.1 Gateway Conditional Caution (planned delivery)

The Gateway intervention is a police-led intervention delivered using a multi-agency approach. The conditions include a requirement to participate in all aspects of the Gateway intervention and not to re-offend. A breach of the conditions may result in the offender being charged for the original offence.

Part 1 consists of an initial assessment with the navigator. Within 3-5 working days of their disposal, the participant will meet with the Gateway navigator at the relevant Police Station. The Gateway navigator will conduct a thorough needs assessment. Based on identified needs, the navigator will assist the young adult into the appropriate services including Gateway partner agencies (e.g. alcohol, drug and mental health services). The Gateway navigators are trained practitioners, provided by third sector organisation, No Limits, and in the first two years also by Southampton City Council. The navigators will also mentor the individual through the programme.

Parts 2 involves attendance at two LINX workshops and part 3 is the undertaking not to reoffend during the 16 weeks of the conditional caution. Participation in Restorative Justice may be requested by the victim, but this is not part of the standard Gateway caution. In parallel to accessing other services, the Gateway programme integrates two LINX workshops, which aim to assist young adults in the development of cognitive and affective empathy and prevent future anti-social and/or violent behaviour.

LINX workshops for Gateway use carefully constructed experiential group work tools alongside a strong visual framework - 'Making the LINX to rebuild my life' wall, which represents the nine pathways to offending. LINX workshops enable the young adult to explore and share personal feelings on a variety of issues, particularly around their life experience. The various exercises and activities throughout LINX workshops are designed to take the young adult on a journey, enabling them to see how an experience can create a feeling, which can be translated into a set of behaviours that, for these young adults, can create risk, including risk of offending.

*Week 3:* Day one workshop: 10am - 3pm uses materials designed to build and develop a relationship with the young adults' personal navigator. They in turn will help the young adult identify risk factors leading to further offending. The first LINX workshop is delivered by the workshop leaders between week 2 and 3, and is aimed at addressing: journey of offending; sentences and out of court disposals; empathy, rights, respect and responsibility; impact of offending behaviour on victims/self and collateral damage to wider society; positive communication and relationship; restorative justice options and personal risk.

*Week 10:* Day two workshop: 10am-3pm will again be broken down into sections and topics. The 'Making the LINX to rebuild my life' wall will play a central part to the workshop. It will assist in consolidating the learning and building further on the young adults' strengths. They will assist young adults to understand resilience and the part it plays in spinning life's plates. Day two will include further examinations into personal risk and protective factors; the role self-esteem plays in keeping us and others safe; and identifying how positive communication

can support our goals and make amends. The second day will also assist the workshop leaders and navigators in understanding if there are gaps, whether new goals need to be set, and support to 'keep their wall in order. The second LINX workshop is delivered between weeks 5 and 6.

Running parallel to both days the leaders of the LINX workshops build on the support that the navigators give to the young adults and reinforce the motivation needed to access other services. If restorative justice has been added as an additional condition and the victim agrees, there will be a restorative justice element to the young adult's participation. Through restorative justice conferencing, the young adult will meet the victim face to face, in order to take positive steps and make amends for the crime committed.

The LINX workshops took place in a neutral venue as close as possible to where the offender lived. For example, for those living in the Southampton area, workshops were held at Southampton City West Quay facilities. The LINX workshops were delivered by the third sector organisation, The Hampton Trust. The first workshop was delivered at 3 weeks post-randomisation and the second delivered at 10 weeks post-randomisation.

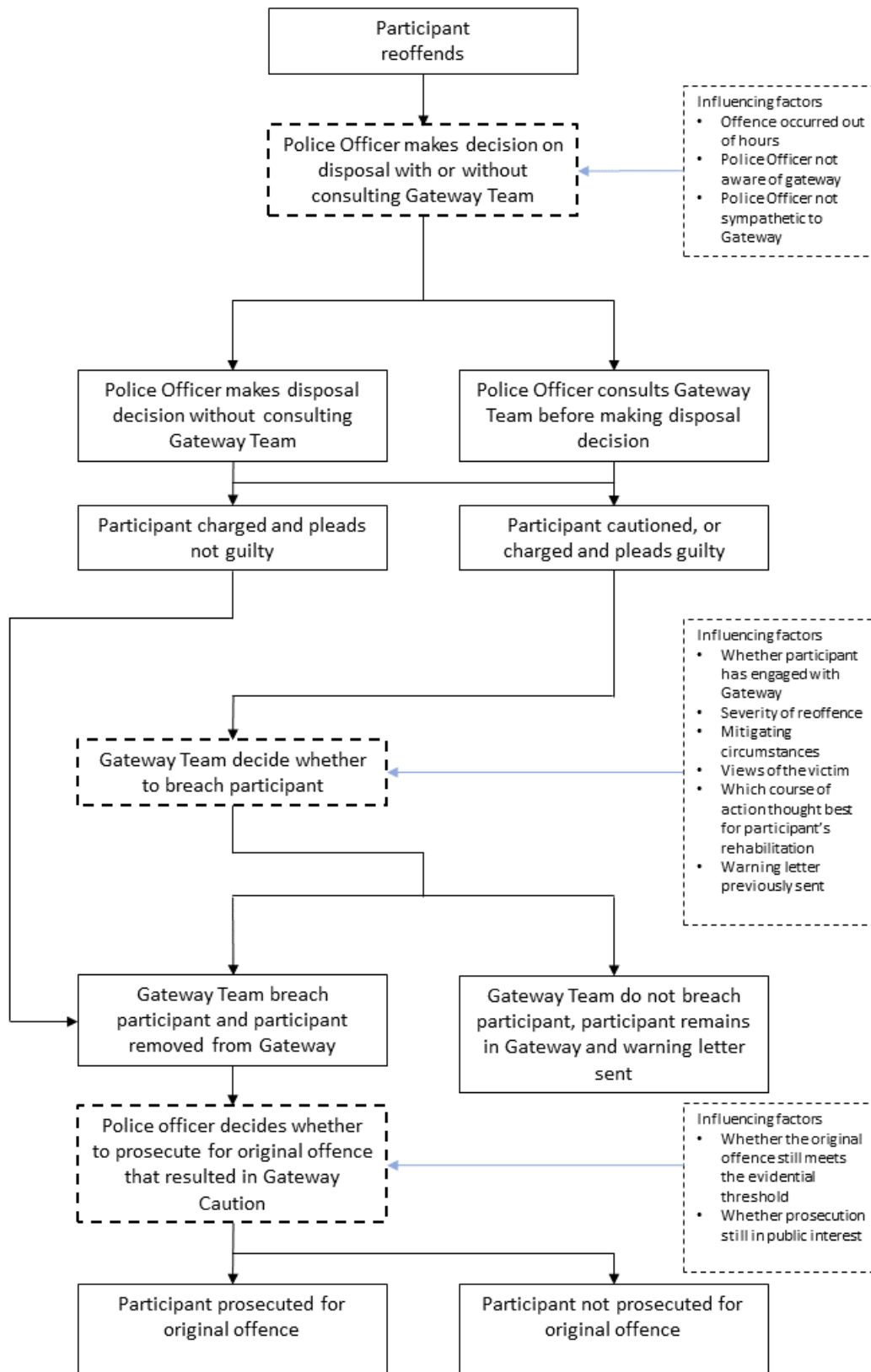
#### **3.3.1.1 Condition to not re-offend**

If a participant reoffends, it is the decision of the police sergeant (based on the recommendations of the navigator working with the offender) whether or not to 'breach' the participant. If a participant is breached they are removed from the Gateway intervention, and the case is returned to the sergeant who originally gave the Gateway Caution who then considers whether to prosecute the participant for the original offence that led to the Gateway Caution being issued.

Discretion can be applied by the sergeant when considering whether to breach a participant, with the decision to apply discretion based on a number of factors as outlined in Figure 1.



**Figure 1:** A flow diagram giving details on the process followed when deciding to apply discretion in breaching a participant for violating the condition to re-offend



### 3.3.2 Usual Process

Under current guidance, for young adults aged 18-24, where there is enough evidence for prosecution (known as Full Code Test) and where the individual admits responsibility, there are various possible outcomes. For less serious offences and where the offender has a limited background of convictions, they may receive a conditional caution. For more serious offences, or where the offender has a more in-depth background in relation to criminal convictions, the offender may be charged and given a court date, and would be eligible for the study if a custodial sentence was not anticipated.

#### 3.3.2.1 Conditional Caution

A conditional caution constitutes both an in-custody and out-of-custody process. In routine practice, where an offender has committed a lower level crime, the full code test has been met and the offender accepts responsibility for the crime, it may be more proportionate for this to be dealt with through an out of court disposal; for example, a conditional caution. The supervising officer (sergeant) is in charge of making this disposal decision. A record of conditional cautions is kept by the police. Conditions attached to conditional cautions must be appropriate, proportionate and achievable and must have one or more of the following objectives:

- Rehabilitation: conditions which help to modify the behaviour of the offender, serve to reduce the likelihood of re-offending and/or help to reintegrate the offender into society
- Reparation: conditions which serve to repair the damage caused, either directly or indirectly, by the offender
- Punishment: financial penalty conditions which punish the offender for their unlawful conduct.

Effective conditional cautions should have a mixture of conditions and it is important that the victim is consulted before the disposal decision is finalised. All conditions must be agreed by the offender and they must be achievable. Currently, examples of routine practice conditions include: apology letters, victim awareness courses, drug diversion courses, alcohol diversion courses and fines or compensation. Drug, alcohol and victim awareness courses are provided by the Police and Crime Commissioner (PCC) through various organisations, but the cost is charged to the offender. In deciding on the time period within which conditions must be completed, a decision-maker must consider any time limits affecting the commencement of proceedings for the original offence.

Furthermore, they must ensure that the option of prosecuting the original offence, in the event of non-compliance, remains available. All rehabilitative, reparative and punitive conditions must be capable of being completed within 16 weeks where it is a summary only offence. In exceptional circumstances, a period of longer than 16 weeks may be suitable for an offence triable either way (in either a Magistrates Court or a Crown Court) or an indictable-only offence. This will depend on the facts of the particular case but it must not exceed 20 weeks. A longer period must still be appropriate, proportionate and achievable. Periods of time start from the date that the conditional caution was given. If an offender fails to complete the conditions attached to the caution, they will be considered for prosecution of the original offence. The decision will go back to the supervising officer who determines if it is still in the public interest to prosecute. Should that be the case, a summons is raised, and a postal requisition sent to the offender for them to attend court.

### **3.3.2.2 Charge**

This is an in-custody process. Where an offender is arrested and brought to custody, they will be interviewed by the investigating officer. If the evidence reaches the full code test and the offender is not suitable for a conditional caution, due to the nature of the offence or their previous convictions, the offender will be charged with the offence and given a court date before release from custody. For cases where the offender pleads guilty, the court date is normally around 3 weeks from date of disposal and will usually be to attend a Magistrate's Court. From the offender being apprehended to entering a guilty plea at their first appearance at a Magistrate's Court, costs approximately £1500. If the full code test is not met and there are further outstanding enquiries, the offender will be released under investigation. A court summons will be raised if the full code test is subsequently met.

### **3.3.2.3 Court Summons**

This is an out-of-custody process. If it is not necessary to arrest an offender i.e. detain them in custody, then they are dealt with by way of voluntary interview. The offender can be interviewed under caution without arrest which means that they are free to leave at any time. When the investigating officer reaches the full code test, the file is submitted to the supervisor for a disposal decision. As the process has been conducted outside of custody, the offender is likely to be summoned. A postal requisition is sent to the offender with a court date for them to attend.

### **3.3.3 Changes to the intervention and usual care as a result of the Covid-19 pandemic**

Due to the Covid-19 pandemic, recruitment to the trial was paused on the 22<sup>nd</sup> March 2020. Between this date and the restart of the trial on 7<sup>th</sup> September 2020, it was not possible to deliver the Gateway intervention to new and existing study participants, due to the infeasibility of holding the face to face, group activities. In addition, Hampshire Constabulary were no longer issuing conditional cautions during this time period until 3<sup>rd</sup> August 2020.

The Navigators modified their practice to undertake the initial interview with clients by telephone or video conferencing where this had previously always been face to face. Subsequent meetings were also all by phone, where previously some of these may have been face to face meetings. The content and purpose of the initial interview and subsequent contacts remained the same.

The Hampton Trust modified the delivery of the workshops such that they were delivered one-to-one to the participant over the telephone, rather than taking place face-to-face in a group setting. Navigators are able to meet with the offender as a last resort if there are no other forms of communication. For such a face-to-face meeting to occur it would have to take place at a police station and be risk assessed for Covid.

Alongside the clear difference between face-to-face and telephone delivery, a further key difference was the reduction in workshop length from 10 hours to two hours, as research shows that in general people find it harder to concentrate over the telephone compared to face-to-face. The principles and key elements of the workshops were maintained in the telephone delivery mode.

Usual care options also changed as a result of the pandemic, as detailed below:

- Before the first Covid-19 lockdown (23<sup>rd</sup> March 2020)
  - Conditional cautions
    - Compensation
    - Fine

- Apology letter
  - Victim awareness course
  - Drugs awareness course
  - CARA (domestic abuse awareness course)
  - WaDE (female-only caution)
- Simple caution (no conditions)
  - Only used on rare occasions and not preferable
- Between the first Covid-19 lockdown and 3<sup>rd</sup> August 2020
  - Conditional cautions
    - Gateway
    - Compensation
    - Fine
    - Apology letter
  - Simple caution (no conditions)
    - More common due to there being fewer courses such as CARA and WADE being available
  - After 17<sup>th</sup> August 2020
    - Conditional cautions
      - Gateway
      - Compensation
      - Fine
      - Apology letter
      - CARA
      - WaDE
    - Simple caution (no conditions)
      - Only used on rare occasions and not preferable
  - After 17<sup>th</sup> December 2020
    - Conditional cautions
      - Gateway
      - Compensation
      - Fine
      - Apology letter
      - CARA
      - WADE
      - Victim, alcohol and drug awareness courses
    - Simple caution (no conditions)
      - Only used on rare occasions and not preferable

The length of time between disposal and a court date is likely to have increased as the backlog of cases for Courts to deal with grew as a result of reduced case load to comply with pandemic safety measures. Any impact from this would be limited to a small number of participants where it was anticipated they would plead guilty once they reached court.

### 3.4 Outcomes

#### 3.4.1 Primary Outcome

- *Warwick-Edinburgh Wellbeing Scale (WEMWBS)*: The WEMWBS is a 14-item questionnaire that measures mental health and wellbeing. The WEMWBS has established psychometric properties, that is, it has been found valid and reliable, in the UK general population from the age of 13 through to adulthood. Compared to other well-being indices, the WEMWBS was tested for response bias and showed

low correlation with both subscales of the Balanced Inventory of Desirable Responding: Impression Management and self-deception, which make it suitable for self-report (1).

- *Variable type:* Continuous
- *Range and polarity:* Each item can take a score from 1-5, and the total score ranges from 14-70. A score of 14 represents the lowest level of health and wellbeing, while a score of 70 represents the highest level of health and wellbeing.
- *Follow-up:* The WEMWBS was collected via CRF at 4-weeks, 16-weeks and 1-year post-randomisation.

### 3.4.2 Secondary Outcomes

- *12-Item Short-Form Survey (SF-12):* The SF-12 is a 12-item questionnaire assessing the impact of health on an individual's everyday life. The 12 items of the SF-12 provide a representative sample of the content of the eight health concepts (2) and the various operational definition of these concepts, including what respondents are able to do, how they feel, and how they evaluate their health status. The SF-12 is scored on two components, the mental component score (MCS) and physical component score (PCS)
  - *Variable type:* Continuous
  - *Range and polarity:* The total score ranges from 0-100, with 0 indicating the lowest level of health and 100 the highest level.
  - *Follow-up:* The SF-12 was collected via CRF at 4-weeks, 16-weeks and 1-year post-randomisation.
- *Alcohol Use Disorders Identification test (AUDIT):* The AUDIT tool is a 10-item questionnaire that is used to identify the early signs of hazardous and harmful drinking. The AUDIT has been validated in adolescent populations (3, 4).
  - *Variable type:* Continuous
  - *Range and polarity:* The total score ranges from 0-40, with 0 indicating the lowest level of alcohol use and 40 the highest level of alcohol use.
  - *Follow-up:* The AUDIT was collected via CRF at 4-weeks, 16-weeks and 1-year post-randomisation.
- *Adolescent Drug Involvement Scale (ADIS):* The ADIS is a 13-item questionnaire designed to capture recent and current drug use, and has been validated in adolescents and young adults (5).
  - *Variable type:* Continuous
  - *Range and polarity:* The total score ranges from 0-70, with 0 indicating the lowest level of drug involvement and 70 indicating the highest level of drug involvement.
  - *Follow-up:* The ADIS was collected via CRF at 4 weeks, 16 weeks and 1 year post-randomisation.
- *The total of the number of Record Management System (RMS) incidents and the number of Police National Computer convictions up to one-year post-randomisation:* All incidents in which an individual has had contact with the police in the county of Hampshire were recorded as incidents on the RMS i.e. RMS incidents. The definition of an RMS incident captured all forms of contact with the police. As well as including those who were part of an incident as an arrestee or suspect, the definition of an RMS incident also includes those who were a witness, or 'involved' i.e. present at an incident but not having any other status. In addition, the Police National Computer records criminal convictions outside the county of Hampshire. The total number of

RMS incidents and PNC convictions up to one-year post-randomisation is a measure of the amount of contact a participant has had with the police.

- *Variable type:* Count
- *Follow-up:* RMS incidents and PNC convictions were collected from the day after randomisation up to one-year post randomisation e.g. if the participant was randomised on 01/04/2020, RMS incidents taking place between 02/04/2020 and 02/04/2021 were collected.
- *The total of the number of RMS incidents resulting in being classed as a suspect and charged/cautioned and the number of PNC convictions up to one year post-randomisation:* RMS incidents were further classified based on whether the individual was classed as a suspect and charged in relation to the incident. The total number of RMS incidents up to one-year post-randomisation in which a participant was classed as a suspect and charged/cautioned and the number of PNC convictions is a measure of the severity of contact a participant has had with the police.
  - *Variable type:* Count
  - *Follow-up:* See above with regards to total number of RMS incidents and PNC convictions.
- *Charged with a 'summary' or 'either way' offence up to one year post-randomisation:* A summary offence is an offence that is heard in a magistrates' court, while an either way offence can be heard in a magistrates' court or a crown court.
  - *Variable type:* Binary (Yes/No)
  - *Follow-up:* See above with regards to total number of RMS incidents and PNC convictions.
- *Charged with an 'indictable only' offence up to one-year post-randomisation:* An indictable only offence is heard in a crown court
  - *Variable type:* Binary (Yes/No)
  - *Follow-up:* See above with regards to total number of RMS incidents and PNC convictions.

### 3.4.3 Exploratory Outcomes

- Accommodation status
  - *Variable type:* Binary (Homeless/Not homeless)
  - *Follow-up:* Accommodation status was collected via CRF at 4-weeks and 1-year post-randomisation.

### 3.4.4 Other Collected Data

- Screening (collected via SurveyGizmo, template data stores in Y:\Project -- Gateway - Statistics\SAP\Template data\SurveyGizmo\SurveyGizmo.xlsx)
  - Response ID
  - Date screening started
  - Date screening submitted
  - Collar ID of police officer carrying out screening
  - RMS number
  - Offender RMS ID
  - Eligibility criteria
    - Whether the disposal decision is for a conditional caution
    - Whether the supervisor has identified any reason why a Gateway Caution is not suitable
    - If the disposal decision is not for a conditional caution

- Whether the offence is a hate crime, domestic crime, knife crime, sexual offence or a drink/drive or endorsable traffic offence
  - Whether the offence is an indictable only offence
  - Whether the offence is a breach of court order or a sexual offences order
  - Whether a remand in custody is being sought
  - Whether the offence involved death or serious injury
  - Whether the offender is likely to receive a custodial sentence
  - Whether the offender has any serious previous convictions in the previous two years
  - Is the offence a summary offence that is more than 4 months old?
  - Is the person subject to court bail, prison recall, Red Integrated Offender Management or currently under probation?
- Demographics:
  - Date of birth
  - Sex
  - Marital status
  - Ethnicity
  - Highest level of education completed
- Change of Status CRF (Researcher and Police completed)
  - Reasons for withdrawal
  - Date of death (if applicable)
  - Reason for withdrawal from Gateway
- Huddle Master Data (template data stored in Y:\Project -- Gateway - Statistics\SAP\Template data\Huddle Master Data\Gateway university Dashboard template (empty).xlsm)
  - RMS ID
  - Entry route (conditional caution or prosecution)
  - Date of randomisation
  - Randomised allocation
  - Actual allocation (if overridden by custody sergeant)
  - Conditions of caution
  - Date consent form signed
  - Change of status
  - Date of change of status
  - Number of changes of status
  - Date of birth
  - Gender
  - Ethnicity
  - Team that completed randomisation
  - Whether study reminder phone call completed
  - Whether study link text/emailed
  - Offending history (cautions)
  - Offending history (convictions)
  - Total number of RMS incidents and PNC convictions one year pre-randomisation
  - The total of the number of RMS incidents resulting in being classed as a suspect and charged/cautioned and the number of PNC convictions one year pre-randomisation

- Re-offending
  - Date of re-offence
  - Court type of caution
  - Crime type
  - Sentence type
- Participant Contact with Navigators (template data stored in Y:\Project -- Gateway - Statistics\SAP\Template data\Participant Contact With Navigators\Engagement with Client Spreadsheet YTU.xlsx)
  - Contact with Gateway navigators (multiple contacts possible and expected)
    - Type of contact
    - Date of contact
    - Whether participant responded to contact
    - Duration of contact in minutes
    - Name of agency making contact
  - Attendance of LINX workshops
  - Delivery type of LINX workshops
- Blinding (collected via CRF at each follow-up time point)
  - Whether blinding was compromised during assessment
  - If blinding was compromised, which allocation the researcher thinks the participant received
- Use of discretion in overriding condition to reoffend (template data stored in "Y:\Project -- Gateway - Statistics\SAP\Template data\Discretion in Overriding Condition Not to Reoffend\Discretion\_Data\_Collection\_20201201\_v0.1.xlsx")
  - Re-offence type leading to potential breach
  - Whether police officer consulted Gateway team before making disposal decision
  - Disposal outcome
  - Whether participant was breached by Gateway Team
  - If breached, whether participant was prosecuted for original offence leading to Gateway Caution
- *Adverse Childhood Experiences Questionnaire (ACE)*: The ACE is an 11-item questionnaire designed to identify the number of childhood experiences of abuse and neglect.
  - *Variable type*: Continuous
  - *Range*: The total score ranges from 0-11, with 0 indicating the least number of adverse childhood experiences and 11 the highest number of adverse childhood experiences.
  - *Follow-up*: The ACE was collected via CRF 16-weeks post-randomisation only.
- *Index of Multiple Deprivation (IMD) Quintile*
  - This will be derived by a researcher using the participants postcode.

#### 3.4.4.1 Health Economic CRF Data

The following data was collected at 4-weeks, 16-weeks and 1-year post-randomisation:

- Whether the participant has been employed in the previous month
- Number of times the participant has used the following health/social care services in the previous month:
  - GP visits
  - Drug/alcohol service
  - Accident and emergency admission
  - Hospital in-patient



- Community mental health team
- Psychiatric services (in-patient)
- Other
- Medications prescribed in previous month, and reasons for prescription

### **3.5 Sample Size**

There is no widely accepted and established minimal clinically significant difference for the WEMWBS. It has been suggested that a change of three or more points is likely to be important to individuals, but different statistical approaches provide different estimates ranging from three to eight points. There is also variation in the standard deviation of the WEMWBS with estimates ranging from 6 to 10.8 (6) with the pooled estimate of 10 across all studies. Assuming 90% power, 5% 2-sided statistical significance, mean difference of 4 points on WEMWBS and a standard deviation of 10, 266 participants were required. Preliminary figures from The Hampton Trust's skills/attitudes workshops for domestic abuse (RADAR intervention) suggested a drop-out rate of approximately 15%. Conservatively, we accounted for 20% loss to follow up therefore 334 participants needed to be recruited and randomised.

### **3.6 Assessment of Eligibility and Randomisation**

Individuals were randomised to either the intervention or control group using a 1:1 allocation ratio. All investigators coming into contact with potential participants underwent training prior to the start of the study and were given a script for guidance when obtaining consent. Randomisation was conducted through a web-based eligibility checker and randomisation tool, hosted on Alchemer (formerly SurveyGizmo), a cloud-based feedback platform.

The tool was developed by Hampshire Constabulary in discussion with YTU and used a randomisation sequence approved by the trial statistician. The system was tested during the training of investigators, prior to the start of recruitment to the trial. A similar method for randomisation was adopted in an RCT of domestic abuse perpetrator intervention (CARA) conducted in Southampton Police District, where they were able to successfully recruit a similar population group (n=293) (7). This approach to consent and randomisation was shaped by the requirement by Hampshire Constabulary to be informed of the criminal justice destination prior to the young adult offender leaving the police station.

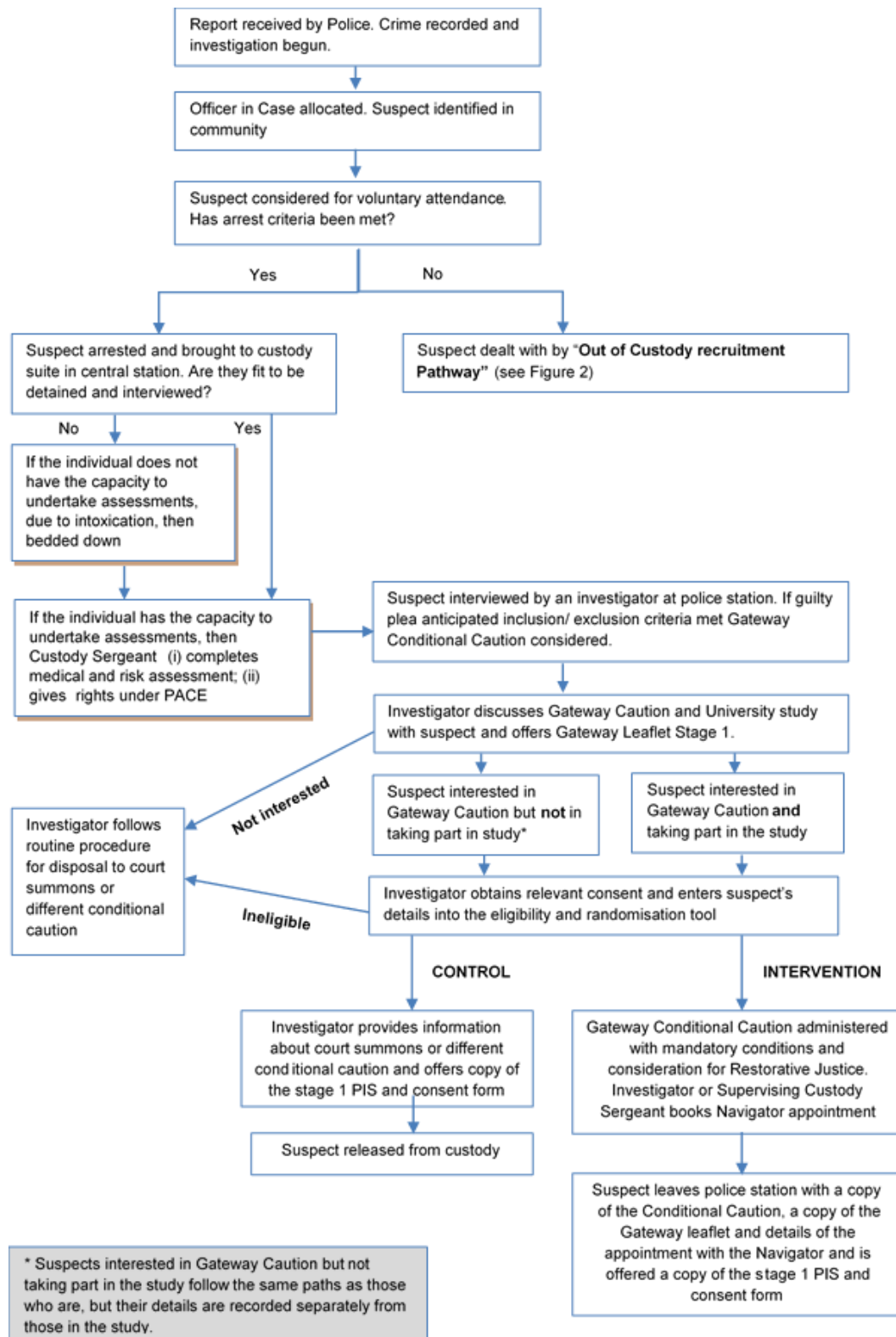
### **3.7 Participant Enrolment**

Potential participants may be recruited when in the custody suite, a specific secured area within the police station; or when suspects are being dealt with out-of-custody.

#### **3.7.1 In-Custody Recruitment**

In-custody recruitment involved obtaining written consent immediately prior to assessment of eligibility and randomisation. The participant was disposed from the custody suite knowing the conditional caution or that they would be receiving a court summons in the post. The in-custody pathway is set out in Figure 2.

**Figure 2: In-custody recruitment**

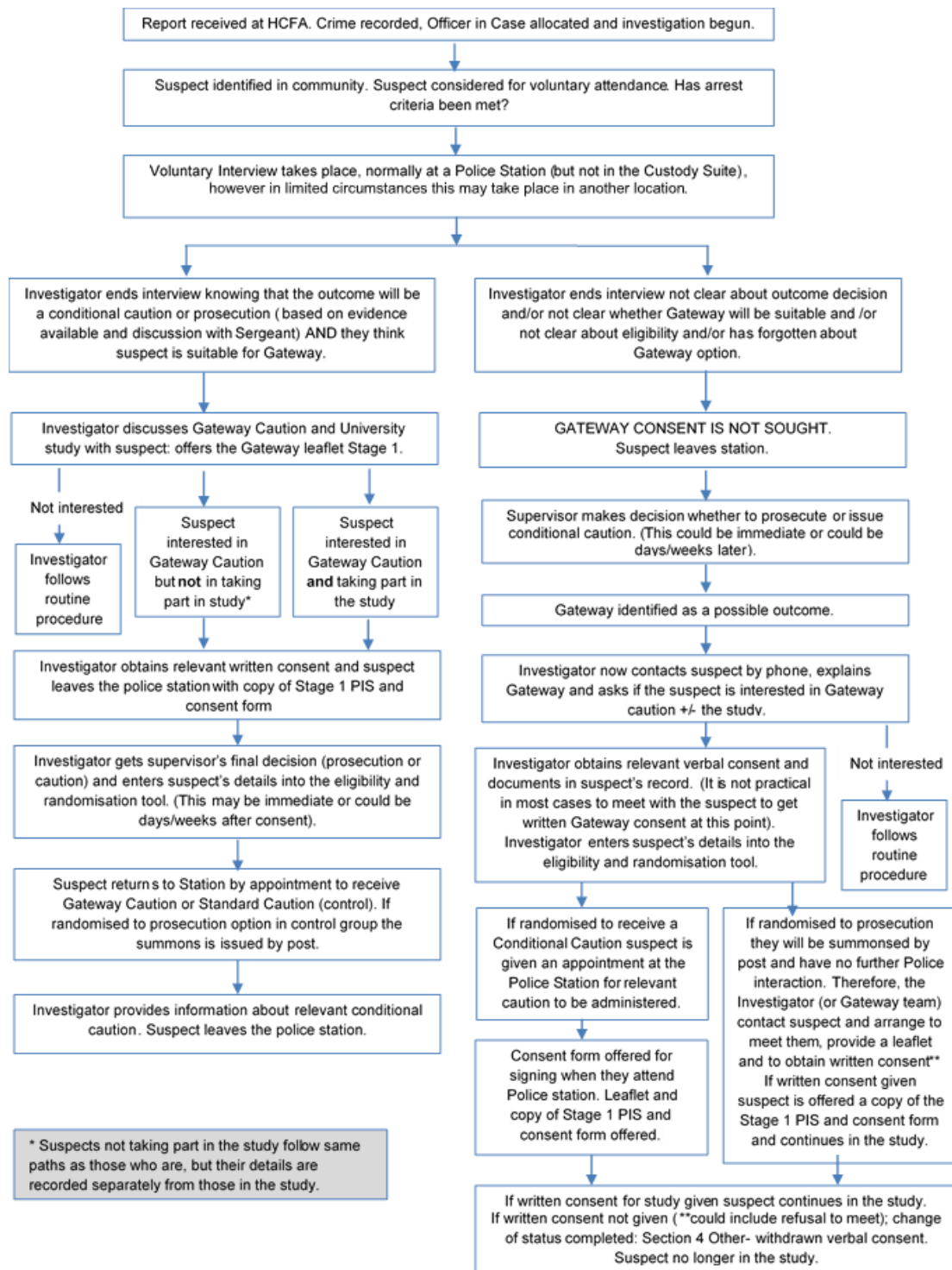


### 3.7.2 Out-of-Custody Recruitment

Out-of-custody was where the suspect attended a voluntary interview, normally at a police station (but not in the custody suite), however in limited circumstances the interview could take place in another location. Out-of-custody recruitment (Figure 2) could proceed in one of two different ways:

1. If the investigator ended the voluntary interview knowing or believing that the outcome would be a conditional caution or prosecution (based on the available evidence and prior discussion with the duty Sergeant), they explained the Gateway study and sought written consent. The suspect then left the police station and the investigator obtained their Supervisor's final decision (prosecution or caution). This decision could be made immediately or could take days or weeks. The investigator then entered the suspect's details in the eligibility tool and recorded the randomisation outcome. If the participant was to receive either a Gateway or other conditional caution, they attended an appointment at the Police Station where the caution was issued. If the participant was allocated to prosecution, a summons was issued by post.
2. If the investigator ended the voluntary interview unclear about the outcome decision and/or if the suspect was eligible, no information about Gateway was given and consent was not sought. The suspect left the police station. The Supervisor either immediately or in the following days or weeks, made the decision about whether to proceed. If the suspect was to be prosecuted or issued a caution, Gateway became a possible outcome. The Investigator contacted the suspect by phone using the standard police procedure for identification of the individual. The investigator explained the Gateway programme and sought verbal consent, as it was not practical for the suspect to attend the police station at this point. If verbal consent was given, the investigator recorded this in the RMS and entered the suspect's details in the eligibility tool and recorded the randomisation allocation. If the participant was randomised to a Gateway caution or a different conditional caution, the investigator invited the participant to the police station where the relevant caution was administered. The Stage 1 Consent form was then offered for signing; if signed, the participant carried on in the study. If the participant did not provide written Stage 1 consent or refused to attend the meeting, a change of status form was completed indicating withdrawal of verbal consent and they were no longer in the study. If the participant was randomised to prosecution, they received their summons by post and had no further Police interaction. In this instance (prosecution), the Investigator or the Gateway team contacted the participant and arranged to meet them to obtain written consent. If written consent was given, they continued in the study; if written consent was not given (could include refusal to meet) they were no longer included in the study and a change of status form was completed accordingly.

**Figure 3: Out-of-custody recruitment**



### 3.8 Follow-Up

Follow-up assessment of trial participants was undertaken at 4 weeks, 16 weeks and 1 year post-randomisation. Follow-up interviews for data collection could take place face-to-face or over the telephone. Interviews were carried out by telephone only after the implementation of the first lockdown on 23<sup>rd</sup> March 2020. Case report forms (CRFs) were not sent to participants in the post.

Ahead of each data collection time point, a total of four attempts could be made to establish contact via text and calls with the participants, with the aim of providing brief information about the study and gauge their availability. If these contact attempts were unsuccessful, a letter with a telephone number for the research team was sent in the post to the participant.

Once an appointment had been booked and the details were confirmed to the participant, a text confirmation was sent to their mobile number, as well as one or more text reminders prior to their booked appointment, depending on the timing of booking and individual circumstances.

If the participant cancelled an interview or missed it without notice, the researchers attempted to re-establish contact in order to reschedule. Up to four attempts were ordinarily made, and a combination of texts and calls could be used. If these attempts were unsuccessful, ahead of the next time point up to four attempts were made to re-establish contact and assess availability.

The number of contact attempts suggested was indicative, rather than prescriptive. Similarly, some flexibility was allowed in relation to the timing of data collection points, with the latter influenced by participants' and the researchers' availability.

At the beginning of the study, participants were given a high street shopping voucher worth £10 for each follow-up completed. In order to boost follow-up rates, the Trial Management Group (TMG), which includes a PPI lead, took the decision to increase the amount of financial incentives on offer. As a result, the study protocol was amended such that participants would receive a £30 shopping voucher for completing the week 4 follow-up, a £40 shopping voucher for completing the 16-week follow-up and a £50 shopping voucher for completing the 1-year follow-up.

### **3.8.1 Out-of-Custody Recruitment and 4 Week Follow-Up**

For some participants recruited out-of-custody, the investigator did not have all the evidence required to make a decision on the final outcome for the participant. Hence, these participants left the station with their outcome pending. In some cases, where the investigator was clear the category of decision would make the individual eligible for the study, they would obtain consent and randomise but not tell the participant of the outcome. In other cases, where the likely outcome was not yet clear, verbal consent and randomisation were carried out by telephone; meaning date of written consent was after randomisation, but more likely to have been the same as the date of disposal (they had to come to the police station to be disposed to a caution).

In all these cases there was a delay of days and sometimes weeks until the final disposal was agreed and the potential participant informed (date of disposal). For some participants this meant the date of disposal actually took place after the 4-week post-randomisation follow-up was due to be carried out, and therefore the participant would not be aware of their allocation at the 4-week follow-up.

## **3.9 Blinding**

Research team members involved in obtaining consent procedures and data collection were blinded to participant allocation as far as possible. Randomisation was undertaken by police investigators who were not involved in data collection for the study. Information on whether blinding was or may have been compromised during the face-to-face and telephone data collection interviews was recorded.

## **4. Study Data Sources**

### **4.1 Case Report Forms**

Blank CRFs were printed at YTU and sent to UoS/HC. These CRFs were then completed by researchers at the UoS and/or officers at HC who also added in the participant ID and site ID.

Once completed, CRFs were sent in paper format to YTU and scanned in by the data management team. Copies of the CRFs annotated with all variable names from the database are kept in the YTU analysis directory (Y:\ Project – Gateway - Statistics).

Data from the following CRFs will be available:

- Demographics, to be used at week 16 or 1 year, if required (completed by researchers)
- Week 4, with demographics section (researchers)
- Week 16 (researchers)
- Year 1 (researchers)
- Change of Status (researchers)
- Change of Status (Completed by one of the Gateway police officers who are part of the study team)

In order to maximise collection of demographic data, the Demographics CRF could be completed at any of the study follow-ups, if not completed at week 4. This was in anticipation of the scenario where a participant may not attend their 4-week follow-up but may attend a later follow-up.

A participant could be reported as withdrawing completely from the study either by a researcher or a member of the Gateway police study team, using their version of the Change of Status CRF. A member of the Gateway police study team could in addition report a participant withdrawing from the Gateway intervention.

### **4.2 Document Management Spreadsheet**

The Document Management Spreadsheet was used instead of the YTU Management Database, which can be found in *Y:\Project -- Gateway - Shared\DataManagement*. It was used by researchers at YTU to track consent and randomisation of participants, and also to record due and received dates of the CRFs. In addition, the Document Management Spreadsheet also recorded participant status changes.

### **4.3 Other Data**

#### **4.3.1 Screening data**

Screening data were collected using Survey Gizmo and received on a monthly basis. The study statistician cleaned the screening data on a monthly basis, with any queries being resolved by the HC study team.

#### **4.3.2 Police Record Management System (RMS) Incidents and PNC convictions**

The Police RMS is a database used as part of routine practice by Hampshire Constabulary to record individual incidents reported to police as well as all crimes. The Police National Computer is a system that stores and shares criminal records information across the UK.

### **4.3.3 Huddle**

Huddle is a commercial, off-the-shelf case management system used in Gateway under a license for recording and sharing data on participants in the study with the Universities of York and Southampton. It was used by navigators to store records of all interactions carried out and work done with participants in the intervention group. In addition, data on the control group participants were also stored in Huddle, alongside data on recruitment to Gateway, data obtained from the Police RMS and data obtained from the PNC.

### **4.3.4 Participant Contact with Navigators (Intervention group only)**

A bespoke spreadsheet designed by the study team with input from the navigators was used to record information on contact with participants receiving Gateway. The spreadsheet was completed by navigators for each participant during their 16-week caution period. This spreadsheet will also record LINX workshop attendance.

## **4.4 Management of CRF Data and Verification**

Upon receipt, returned CRFs were checked manually for inconsistencies and missing data, which were resolved with the member of the study team who completed the form where possible. Automated electronic checks according to comprehensive data validation plans for each CRF included checks for completeness, internal consistency as well as appropriate data formatting and range checks. Copies of the validation plans are held by data management and the study statistician. Violations of the validation rules were queried with sites as required. All violations and any resulting changes to the data were documented in an error log file for each CRF, and data fields for which error log entries exist were completed as '555' or another error code as advised by the data management team in the data.

At the end of the trial, all CRF data, error logs and relevant management database data will be handed over to the study statistician. The statistician will merge the data and conduct further data checks including checking for consistency of data across questionnaires. Any queries and resulting changes will be processed between the soft and hard lock of the data. The statistician will generate any necessary derived variables in the statistical master data set. Any further data changes and assumptions made to the hard-locked data will be documented on a Trial Assumptions Form.

## **4.5 Location of Data and associated Files**

Data and documents relevant to the statistical analysis will be kept electronically in a folder on the Y Drive (Y:\ Project -- Gateway - Statistics).

# **5. Analysis**

## **5.1 Analysis Principles**

### **5.1.1 General Principles**

Data will be analysed and reported in accordance with CONSORT guidelines (8). All analyses will be conducted following the principle of intention-to-treat unless stated otherwise.

### **5.1.2 Principles Relating to the Covid-19 Pandemic**

Due to the Covid-19 pandemic, alterations to the delivery of the intervention were made several times throughout the trial. The date each alteration was made will be reported,

alongside details of the alteration and reasons the alteration was made. The number of participants receiving each iteration of the intervention will be summarised descriptively.

## 5.2 Principles Relating to Timing of Completion of Follow-Up Data

A challenge of working with this study population was that participants were difficult to contact, and therefore more flexibility was allowed in when a participant could complete their follow-up e.g. if a researcher managed to contact a participant 14 weeks post-randomisation, they would still complete the 4-week CRF, even though this CRF would have been due 10 weeks earlier. However, in this scenario, the data from this CRF would have been collected closer to the 16-week follow-up due date than to the 4-week follow-up due date, and therefore the following rules will be implemented during the SAP:

- If a follow-up CRF is completed more than or equal to 3 weeks post-randomisation and less than or equal to 12 weeks post-randomisation, the data from this CRF will contribute to the 4-week time point. A start date for acceptance of 3 weeks post-randomisation will be used as this is when researchers first initiate contact with the participants. An end date for acceptance of 12 weeks post-randomisation is derived from an 8 week window for acceptance of follow-ups.
- If a follow-up CRF is completed more than 12 weeks post-randomisation and less than or equal to 24 weeks post-randomisation, the data from this CRF will contribute to the 16-week time point. The start date for acceptance of 12 weeks post-randomisation is derived from the previous point, while the end date for acceptance of 24 weeks post-randomisation is derived from an 8 week window for acceptance of follow-ups.
- If a follow-up CRF is completed more than or equal to 51 weeks post-randomisation and less than or equal to 60 weeks post-randomisation, the data from this CRF will contribute to the 1-year time point. A start date for acceptance of 51 weeks post-randomisation will be used as this is when researchers first initiate contact with the participants. An end date for acceptance of 60 weeks post-randomisation is derived from an 8 week window for acceptance of follow-ups.

## 5.3 Scoring of Questionnaire Data

The following sections outlined how the participant completed questionnaires will be scored. Copies of all questionnaires are provided in the Appendix (Section 8.1).

### 5.3.1 WEMWBS

The WEMWBS is scored by summing the scores for each of the 14 items.

If more than 3 of the 14 items of the WEMWBS are missing, the total WEMWBS score will not be calculated, as advised by the official WEMWBS user guide (a copy of which can be found in *Y:\Project -- Gateway - Statistics\SAP\Questionnaire scoring\WEMWBS\7551-WEMWBS User Guide Version 1 June 2008.pdf*). If 1, 2 or 3 items are missing, the score for the missing items will be replaced with the mean of the non-missing items, and the total WEMWBS score will then be calculated (this follows the guidance outlined in (*Y:\Project -- Gateway - Statistics\SAP\Questionnaire scoring\WEMWBS\c145WEMWBS workshop workbook FINAL.pdf*)).

### 5.3.2 SF-12

The SF-12 is scored using norm-based methods based on a representative sample of the general population in the USA. Example code can be found in (*Y:\Project -- Gateway - Statistics\SAP\Questionnaire scoring\SF-12\SF-12\_Example\_Code.do*). For example, for the



PCS, the scoring starts with a constant (56.57706). Then, starting with the first item of the SF-12, a usually negative weight is added corresponding to the response given to the item e.g. if the response to the first question on general health is 'Excellent', a weight of - 1.31872 is added. This process is then repeated for the remaining 11 items. A similar process is followed when scoring the MCS. Both the PCS and MCS each have six key items which contribute predominantly to the scale.

Participants with missing responses to an item consequently have missing weights, and therefore the MCS and PCS cannot be calculated. Missing weights will be imputed using the mean weight in the study population, as suggested by Purneger and Burnand (10). To again use the PCS as an example, if a participant is missing a response to the first question on general health, and the mean weight for this item is -1.5, then the missing weight for this participant would be imputed as -1.5. This process will only be followed if 3 or less key items for the component being scored are missing. If more than 3 key items are missing, the score for that component will be set to missing.

### **5.3.3 AUDIT**

The AUDIT is scored by summing the scores for each of the 10 items.

If a response is missing for more than two items, the total AUDIT score will not be calculated. If 1 or 2 items are missing, the score for the missing items will be replaced with the mean score of the non-missing items, and the total AUDIT score will then be calculated.

### **5.3.4 ADIS**

The ADIS is scored by summing the scores of the first 12 items only.

Items that are not applicable and left blank will be assumed to have a score of zero.

### **5.3.5 ACE**

The ACE is scored by calculating the total number of adverse childhood experiences reported.

### **5.3.6 Index of Multiple Drug Use**

For item 13 of the ADIS, the Index of Multiple Drug Use will be derived by summing the weights for each drug.

## **5.4 Interim Analyses**

There are no planned interim analyses and no formal stopping rules for the Gateway trial.

## **5.5 Trial Progression**

The flow of participants from eligibility, randomisation to follow-up and analysis of the trial will be presented in a CONSORT flow diagram (Figure 4).

## **5.6 Demographic and Baseline Data**

All participant demographic baseline characteristics will be summarised descriptively by trial group, both for all participants randomised and participants who provided the WEMWBS for at least one time point (11). No formal statistical comparisons of characteristics will be undertaken between groups (12). Continuous measures will be summarised using descriptive statistics (n, mean, standard deviation, median, IQR, minimum and maximum), while categorical data will be reported as counts and percentages.

## 5.7 Intervention and Usual Care Delivery

Information on the delivery of the Gateway intervention will be summarised including the following: number of LINX workshops attended, delivery mode of LINX workshops, number of contacts attempted and made by the Hampton trust staff and total duration of contacts (excluding LINX workshops), will be summarised descriptively (Table 2). Referral to third-party agencies by the navigator will be summarised descriptively.

For Gateway participants, and participants in the usual process group who were cautioned, the conditions attached to each caution will be summarised by treatment group (Table 3).

## 5.8 Primary Analysis

The WEMWBS will be summarised descriptively at each collected time point by randomised trial group (Table 4)

The primary analysis will be checked by a second statistician before the release of any results.

## 5.9 Secondary Analyses

### 5.9.1 Treatment Compliance

For participants randomised to the Gateway intervention, compliance as defined by the following definitions will be summarised descriptively:

1. *Minimal compliance*: for a participant to be classed as having met the conditions for minimal compliance to the intervention, they should:
  - a. Engage with their navigator for the initial, midway and final assessment
  - b. Attend the two LINX workshops
  - c. Not be breached for reoffending during the duration of the conditional caution (as discussed previously, discretion can be applied when deciding whether to breach a participant who has reoffended)
2. *Full compliance*: for a participant to be classed as having met the conditions for full compliance, they should meet the conditions for minimal compliance, and in addition engage with external agencies organized by the navigator. Participants who meet the conditions for minimal compliance, but did not have any interactions with external agencies organized by the navigator, would be classed as having met the conditions for full compliance.

### 5.9.2 Missing data

The amount of missing data amongst participants will be summarised descriptively, along with reasons for missing data. The number of participants who were contactable at each time point will also be summarised descriptively.

## 5.10 Analysis of Secondary Outcomes

The analysis of the continuous secondary outcomes will be carried out and presented in exactly the same manner as the primary analysis (Table 5).

## 5.11 Exploratory Outcomes

### 5.11.1 Accommodation Status

Accommodation status will be dichotomised in the following manner:

- Homeless
  - Rough sleeping
  - Sofa surfing
  - Direct access or emergency hostel
- Not homeless
  - Living with parent
  - Housing association
  - Private tenant
  - Living with extended family
  - Supported accommodation
  - Shared living accommodation

Dichotomised accommodation status at 4-weeks and 1-year post-randomisation will be summarised descriptively by treatment group (Table 6).

## **5.12 Other Analyses**

### **5.12.1 Number of contacts to first conversation at each follow-up time point**

For each follow-up time point, for participants who were contacted using a method other than letters, the number of contacts required to be able to hold a conversation about the study with the participant will be presented by treatment group (Table 7). In addition, information on the type of contact used will also be presented descriptively by treatment group.

The number and proportion of participants contacted using a letter will be presented by treatment group. In addition, the number and proportion of participants who could not be contacted will be presented by treatment group.

### **5.12.2 Participants informed of their disposal decision after their 4-week follow-up was due**

As outlined in Section 3.8.1, the disposal decision for some participants was made after their 4-week follow-up was due. The number and proportion of these participants will be presented by treatment group. For each participant the number of days between date of randomisation and date of disposal will be reported, alongside whether the participant attended their 4-week follow-up.

### **5.12.3 Reporting of the use of discretion in overriding the condition to not reoffend**

The number and proportion of participants in the intervention group who violated the condition to reoffend will be presented. For these participants, the following information will be presented (Table 8):

- Whether the police consulted the Gateway Police Study Team before making a disposal decision
- Whether the participant was cautioned, charged and pleaded guilty or charged and pleaded not guilty
- Whether the participant was breached by Gateway Police Study Team
- If breached, whether the participant was prosecuted for the original offence that resulted in the Gateway Caution

### **5.12.4 Index of Multiple Drug Use**

The Index of Multiple Drug Use will be summarised descriptively at each time point by treatment group.

### 5.12.5 ACE

The total number of ACEs reported will be summarised descriptively by treatment group.

Additional analyses, including the examination of the association of the total number of ACEs with study outcomes, will be carried out, however these analyses will be carried out independently from the main study analysis which will be carried out by the study statistician and presented separately, and therefore details of said analyses are not specified in this SAP.

### 5.12.6 Health Economic Data

Health economic CRF data will be summarised descriptively by randomised treatment group at each time point (Table 10, Table 11 and Table 12).

### 5.12.7 Withdrawals

The number of withdrawals and reasons for withdrawal at each time point will be summarised descriptively by treatment group.

## 5.13 Analysis Software

All analyses will be conducted in Stata Version 16 or later (16).

## 6. Signatures of Approval

### 6.1 Contributions

Alex Mitchell and Catherine Hewitt drafted the statistical analysis plan, however, sections of this document have been copied and adapted from the trial protocol. This document will be reviewed by members of the TMG and SSC.

### 6.2 Signatures

Sign-off of the Statistical Analysis Plan by, as a minimum, the person writing the SAP, a relevant senior statistician, and the Chief Investigator.

Name	Trial Role	Signature	Date
[REDACTED]	Chief Investigator	[REDACTED]	
[REDACTED]	Senior Statistician	[REDACTED]	28/01/2022
[REDACTED]	Trial Manager	[REDACTED]	28/01/2022
[REDACTED]	Study Statistician	[REDACTED]	28/01/2022

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## 8. Appendices

### 8.1 Questionnaires

#### 8.1.1 WEMWBS

Below are some statements about feelings and thoughts.

Please put a cross in the box that best describes your experience of each statement over the last 2 weeks:

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future WEMWBS_01	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
I've been feeling useful WEMWBS_02	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling relaxed WEMWBS_03	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling interested in other people WEMWBS_04	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've had energy to spare WEMWBS_05	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been dealing with problems well WEMWBS_06	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been thinking clearly WEMWBS_07	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling good about myself WEMWBS_08	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling close to other people WEMWBS_09	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling confident WEMWBS_10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been able to make up my own mind about WEMWBS_11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling loved WEMWBS_12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been interested in new things WEMWBS_13	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I've been feeling cheerful WEMWBS_14	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Warwick-Edinburgh Mental Well-being Scale (WEMWBS)  
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## 8.1.2 SF-12

### Section 2: Your Health and Well-Being

This section asks for your views about your health. This information will help us keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please cross the one box that best describes your answer.

1. In general, would you say your health is:

	Excellent	Very Good	Good	Fair	Poor
	▼	▼	▼	▼	▼
SF12_01	<input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

		Yes, limited a lot	Yes, limited a little	No, not limited at all
		▼	▼	▼
a	Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	SF12_02 <input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3
b	Climbing <u>several</u> flights of stairs	SF12_03 <input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
		▼	▼	▼	▼	▼
a	Accomplished less than you would like	SF12_04 <input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5
b	Were limited in the kind of work or other activities	SF12_05 <input checked="" type="radio"/> 1	<input type="radio"/> 2	<input type="radio"/> 3	<input type="radio"/> 4	<input type="radio"/> 5

SF-12v2™ Health Survey © 1992-2002 by Health Assessment Lab, Medical Outcomes Trust and QualityMetric Incorporated. All rights reserved. SF-12® is a registered trademark of Medical Outcomes Trust. (ICOLA SF-12v2 Standard, English (United Kingdom) 8/02)

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
		▼	▼	▼	▼	▼
a	Accomplished less than you would like	SF12_06 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
b	Did work or other activities less carefully than usual	SF12_07 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

5. During the **past 4 weeks**, how much did pain interfere with your normal work (including both work outside the home and housework)?

	Not at all	A little bit	Moderately	Quite a bit	Extremely
	▼	▼	▼	▼	▼
SF12_08	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks**...

		All of the time	Most of the time	Some of the time	A little of the time	None of the time
		▼	▼	▼	▼	▼
a	Have you felt calm and peaceful?	SF12_09 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
b	Did you have a lot of energy?	SF12_10 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>
c	Have you felt downhearted and low?	SF12_11 <input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

7. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	▼	▼	▼	▼	▼
SF12_12	<input type="text" value="1"/>	<input type="text" value="2"/>	<input type="text" value="3"/>	<input type="text" value="4"/>	<input type="text" value="5"/>

*Thank you for completing these questions!*



1.

### 8.1.3 AUDIT

**Section 4: This section asks about how much alcohol you drink.**

Now I am going to ask you some questions about your alcohol drinking over the last year. I will put a cross in the box against your answer.

How often do you have a drink containing alcohol?

Never	AUDIT_01	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

If you drink alcohol, how many units of alcohol do you have on a typical day when you are drinking?

1 or 2	AUDIT_02	3 or 4	5 or 6	7 to 9	10+
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

**One Standard Drink is**

 Half pint of regular beer, lager or cider	 1 small glass of wine	 1 single measure of spirits	 1 small glass of sherry	 1 single measure of aperitifs
---	---	---	---	---

**The following quantities of alcohol contain more than 1 standard drink**

 2	 3	 1.5	 2 440ml	 4 440ml	 2	 9
Pint of Regular Beer/Lager/Cider	Pint of Premium Beer/Lager/Cider	Alcopop or can/bottle of Regular Lager	Can of Premium Lager or Strong Beer	Can of Super Strength Lager	Glass of Wine (175ml)	Bottle of Wine

How often do you have 6 or more units on a single occasion?

Never	AUDIT_03	Less than monthly	Monthly	Weekly	Daily or almost daily
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

How many times in past year have you found that you were not able to stop drinking after you had started?

Never	AUDIT_04	Less than monthly	Monthly	Weekly	Daily or almost daily
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

How often in the last year have you failed to do what was normally expected of you because of your drinking?

<b>Never</b>	AUDIT_05	<b>Less than monthly</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or almost daily</b>
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

<b>Never</b>	AUDIT_06	<b>Less than monthly</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or almost daily</b>
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

How often during the last year have you had guilt or remorse after drinking?

<b>Never</b>	AUDIT_07	<b>Less than monthly</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or almost daily</b>
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

How often during the last year have you been unable to remember what happened the night before because you had been drinking?

<b>Never</b>	AUDIT_08	<b>Less than monthly</b>	<b>Monthly</b>	<b>Weekly</b>	<b>Daily or almost daily</b>
0 <input type="checkbox"/>		1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

Have you or someone else been injured as a result of your drinking?

<b>No</b>	AUDIT_09	<b>Yes, but not in the last year</b>	<b>Yes, during the last year</b>
0 <input type="checkbox"/>		2 <input type="checkbox"/>	4 <input type="checkbox"/>

Has a relative, friend, doctor or other health worker been concerned about your drinking or suggested you cut down?

<b>No</b>	AUDIT_10	<b>Yes, but not in the last year</b>	<b>Yes, during the last year</b>
0 <input type="checkbox"/>		2 <input type="checkbox"/>	4 <input type="checkbox"/>

AUDIT score =   (staff use only)

Researcher: please add scores from side of each crossed box and enter in AUDIT score box.

### 8.1.4 ADIS

The answers you give to these questions will be kept confidential and not shared with the police. Please just answer the questions and don't give any additional information as this may by law have to be reported.

Please tell me the answers which best describe your use of the drug(s) you use most. Even if none of the answers seems exactly right, please pick the ones that come closest to being true. If a question doesn't apply to you, we will leave it blank.

1. How often do you use drugs?

- ADIS\_01
- 1 a. never
  - 2 b. once or twice a year
  - 3 c. once or twice a month
  - 4 d. every weekend
  - 5 e. several times a week
  - 6 f. every day
  - 7 g. several times a day

2. When did you last use drugs?

- ADIS\_02
- 1 a. never used drugs (End this section here if never been a drug user)
  - 2 b. not for over a year
  - 3 c. between 6 months and 1 year ago
  - 4 d. several weeks ago
  - 5 e. last week
  - 6 f. yesterday
  - 7 g. today

3. What usually makes you start to use drugs? (CROSS ALL THAT ARE TRUE)

- ADIS\_03a  1 a. you like the feeling
- ADIS\_03b  1 b. to be like your friends
- ADIS\_03c  1 c. to feel like an adult
- ADIS\_03d  1 d. because you feel nervous, tense, full of worries or problems
- ADIS\_03e  1 e. you feel sad, lonely, sorry for yourself

4. How do you get your drugs? (CROSS ALL THAT APPLY)

- ADIS\_04a  1 a. use at parties
- ADIS\_04b  1 b. get from friends
- ADIS\_04c  1 c. get from parents
- ADIS\_04d  1 d. buy my own
- ADIS\_04e  1 e. other (please explain)

ADIS\_04e\_Oth

5. When did you first use drugs?

- ADIS\_05  1 a. never
- 2 b. recently
- 3 c. after age 15
- 4 d. at ages 14 or 15
- 5 e. between ages 10-13
- 6 f. before age 10

6. What time of day do you use drugs? (CROSS ALL THAT APPLY)

- ADIS\_06a  1 a. at night
- ADIS\_06b  1 b. afternoons
- ADIS\_06c  1 c. before or during school or work
- ADIS\_06d  1 d. In the morning or when I first awake
- ADIS\_06e  1 e. I often get up during my sleep to use drugs

7. Why did you first use drugs? (CROSS ALL THAT APPLY)

- ADIS\_07  1 a. curiosity
- ADIS\_07b  1 b. parents or relatives offered
- ADIS\_07c  1 c. friends encouraged me
- ADIS\_07d  1 d. to feel more like an adult
- ADIS\_07e  1 e. to get high

8. Who do you use drugs with? (CROSS ALL THAT ARE TRUE)

- ADIS\_08a  1 a. parents or relatives
- ADIS\_08b  1 b. with brothers or sisters
- ADIS\_08c  1 c. with friends own age
- ADIS\_08d  1 d. with older friends
- ADIS\_08e  1 e. alone

9. What effects have you had from drugs? (CROSS ALL THAT APPLY)

- ADIS\_09a  a. got high
- ADIS\_09b  b. got wasted
- ADIS\_09c  c. became ill
- ADIS\_09d  d. passed out
- ADIS\_09e  e. overdosed
- ADIS\_09f  f. freaked out
- ADIS\_09g  g. used a lot and next day didn't remember

10. What effect has using drugs had on your life? (CROSS ALL THAT APPLY)

- ADIS\_10a  a. none
- ADIS\_10b  b. has interfered with talking to someone
- ADIS\_10c  c. has prevented me from having a good time
- ADIS\_10d  d. has interfered with my school work
- ADIS\_10e  e. have lost friends because of drug use
- ADIS\_10f  f. has gotten me into trouble at home
- ADIS\_10g  g. was in a fight or destroyed property
- ADIS\_10h  h. has resulted in an accident, an injury, arrest, or being punished at school for using drugs

11. How do you feel about your use of drugs? (CROSS ALL THAT APPLY)

- ADIS\_11a  a. no problem at all
- ADIS\_11b  b. I can control it and set limits on myself
- ADIS\_11c  c. I can control myself, but my friends easily influence me
- ADIS\_11d  d. I often feel bad about my drug use
- ADIS\_11e  e. I need help to control myself
- ADIS\_11f  f. I have had professional help to control my drug use

12. How do others see you in relation to your drug use? (CROSS ALL THAT APPLY)

- ADIS\_12a  a. can't say or no problem with drug use
- ADIS\_12b  b. when I use drugs I tend to neglect my family or friends
- ADIS\_12c  c. my family or friends advise me to control or cut down on my drug use
- ADIS\_12d  d. my family or friends tell me to get help for my drug use
- ADIS\_12e  e. my family or friends have already gone for help for my drug use

13. For each drug listed below, circle the one category which best fits the participant's response:

**SCORING IS AS HIGHLIGHTED**

	Never used	Tried but quit	Several times a year	Several times a month	Week-ends only	Several times a week	Daily	Several times a day
Cannabis or Weed ADIS_13a	1	2	3	4	5	6	7	8
Crack cocaine (rocks, white) ADIS_13b	1	2	3	4	5	6	7	8
Cocaine (Coke, Charlie) ADIS_13c	1	2	3	4	5	6	7	8
Barbiturates, (Quaaludes, Sopors, downers, reds) ADIS_13d	1	2	3	4	5	6	7	8
PCP (angel dust) ADIS_13e	1	2	3	4	5	6	7	8
Heroin (smack) ADIS_13f	1	2	3	4	5	6	7	8
Other Opiates (opium, morphine, etc.) ADIS_13g	1	2	3	4	5	6	7	8
Vallium, other tranquilizers ADIS_13h	1	2	3	4	5	6	7	8
MDMA/Ecstasy/ Mandy/Pills ADIS_13i	1	2	3	4	5	6	7	8
Ketamine ADIS_13j	1	2	3	4	5	6	7	8
Magic (Mushrooms, Shrooms) ADIS_13k	1	2	3	4	5	6	7	8
Nitrous Oxide (Nox, Laughing Gas) ADIS_13l	1	2	3	4	5	6	7	8
Alkyl Nitrites (Poppers, Amyls, Liquid Gold NPS - previously known as 'legal highs': - Synthetic cannabinoids/Spice/ Blue Cheese/Black Mamba/Mandown - Other Synthetic drugs ADIS_13m	1	2	3	4	5	6	7	8

2.



## 8.1.5 ACE

I'd like to ask you some questions about events that happened during your childhood. This information will allow us to better understand problems that may occur early in life, and may help others in the future. This is a sensitive topic and some people may feel uncomfortable with these questions. At the end of this section, I will give you a phone number for an organization that can provide information and referral for these issues. Please keep in mind that you can ask me to skip any question you do not want to answer. All questions refer to the time period before you were 18 years of age. Now, looking back before you were 18 years of age—

### NOTE THE SCORING

1. Did you live with anyone who was depressed, mentally ill, or suicidal?

1 Yes

2 No

7 Don't know/  
not sure

9 Refused

ACE\_01

2. Did you live with anyone who was a problem drinker or alcoholic?

1 Yes

2 No

7 Don't know/  
not sure

9 Refused

ACE\_02

3. Did you live with anyone who used illegal street drugs or who abused prescription medications?

1 Yes

2 No

7 Don't know/  
not sure

9 Refused

ACE\_03

4. Did you live with anyone who served time or was sentenced to serve time in a prison, jail, or other correctional facility?

1 Yes

2 No

7 Don't know/  
not sure

9 Refused

ACE\_04

5. Were your parents separated or divorced?

1 Yes

2 No

8 Parents not  
married

7 Don't know/  
not sure

9 Refused

ACE\_05

6. How often did your parents or adults in your home ever slap, hit, kick, punch or beat each other up?

1 Never

2 Once

3 More than  
once

*Do not read:*  
 7 Don't know/  
not sure

9 Refused

ACE\_06

**NOTE THE SCORING**

7. Before age 18, how often did a parent or adult in your home ever hit, beat, kick, or physically hurt you in any way? Do not include spanking. Would you say:

- 1 Never     
  2 Once     
  3 More than once     
 *Do not read:*  7 Don't know/not sure     
  9 Refused

ACE\_07

8. How often did a parent or adult in your home ever swear at you, insult you, or put you down?

- 1 Never     
  2 Once     
  3 More than once     
 *Do not read:*  7 Don't know/not sure     
  9 Refused

ACE\_08

9. How often did anyone at least 5 years older than you or an adult, ever touch you sexually?

- 1 Never     
  2 Once     
  3 More than once     
 *Do not read:*  7 Don't know/not sure     
  9 Refused

ACE\_09

10. How often did anyone at least 5 years older than you or an adult, try to make you touch them sexually?

- 1 Never     
  2 Once     
  3 More than once     
 *Do not read:*  7 Don't know/not sure     
  9 Refused

ACE\_10

11. How often did anyone at least 5 years older than you or an adult, force you to have sex?

- 1 Never     
  2 Once     
  3 More than once     
 *Do not read:*  7 Don't know/not sure     
  9 Refused

ACE\_11

As I mentioned when we started this section, I will give you a phone number for an organization that can provide information and referral for these issues. Would you like me to give you that number?

- 1 Phone number declined  
 2 Phone number requested and given

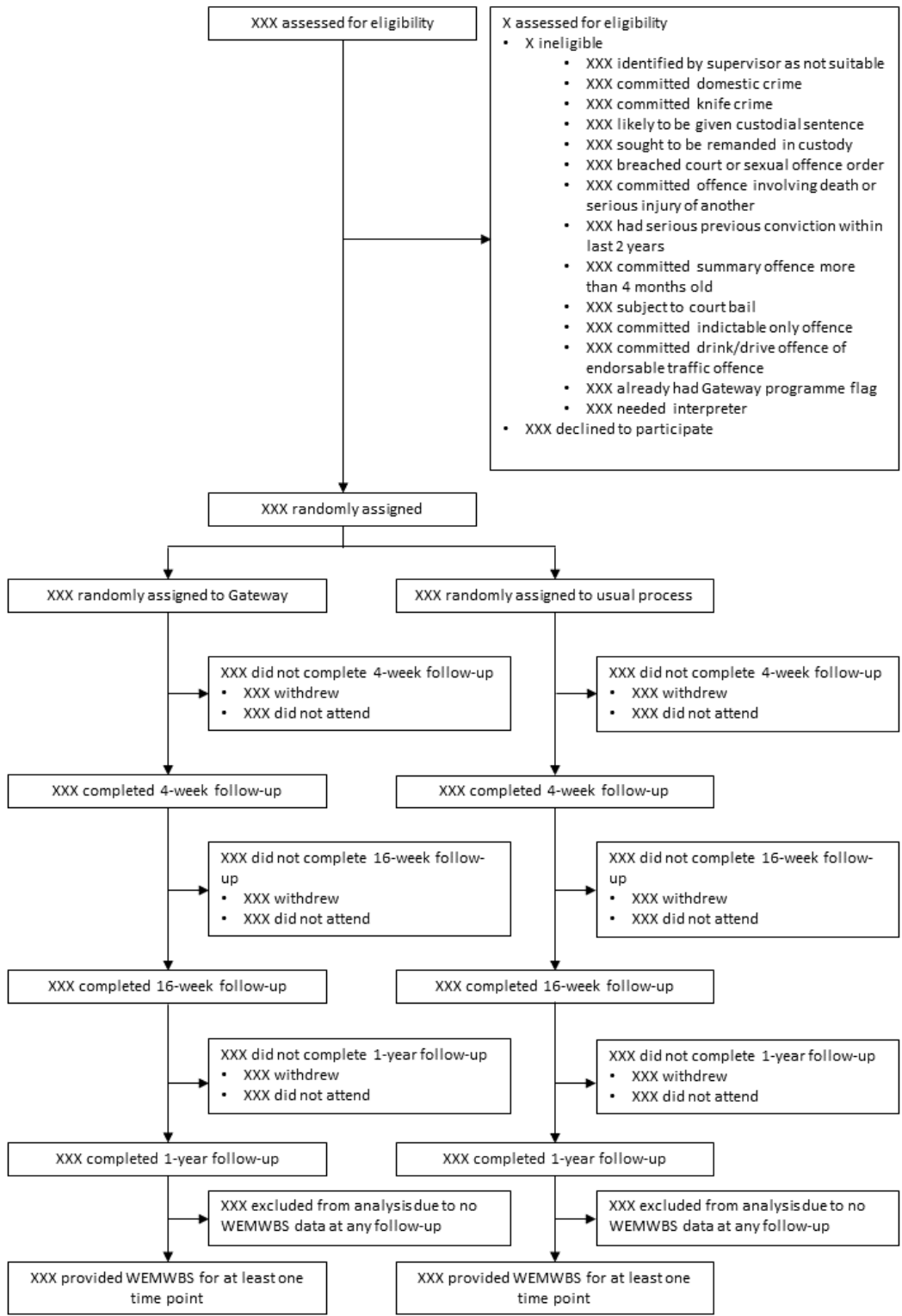
Centers for Disease Control and Prevention (CDC). Behavioral Risk Factor Surveillance System Survey Questionnaire. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention



## 8.2 Planned Tables and Figures

### 8.2.1 Trial Progression

Figure 4: CONSORT flow diagram



## 8.2.2 Demographics and Baseline Characteristics

**Table 1:** Demographic and baseline characteristics presented by treatment allocation for the ‘as randomised’ and ‘as analysed’ participants.

	As randomised (n=)		Provided WEMWBS for at least one time point (n=)	
	Gateway Conditional Caution (n=)	Usual Process (n=)	Gateway Conditional Caution (n=)	Usual process (n=)
<b>Age at randomisation, n (%)</b> n (%) Mean (SD) Median (IQR) Min, Max				
<b>Sex, n (%)</b> Male Female Rather not say Missing				
<b>Marital status, n (%)</b> Single/unmarried Living with partner Married Separated Divorced Widowed Other Not known				
<b>Ethnicity, n (%)</b> White British White European Mixed ethnicity Asian/Asian British Black/Black British Gypsy/traveler Other Missing				
<b>Highest level of education, n(%)</b> Degree or higher 2 or more A-levels Apprenticeship 5 GCSEs or more 1-4 GCSEs No qualifications				
<b>Entry route</b> Caution Prosecution				

	As randomised (n=)		Provided WEMWBS for at least one time point (n=)	
	Gateway Conditional Caution (n=)	Usual Process (n=)	Gateway Conditional Caution (n=)	Usual process (n=)
<b>Total number of RMS incidents and PNC convictions 1 year pre-randomisation</b> n (%) Mean (SD) Median (IQR) Min, Max				
<b>Previously cautioned, n (%)</b> Yes No				
<b>Previously convicted, n (%)</b> Yes No				
<b>IMD quintile, n (%)</b> 1 2 3 4 5				

### 8.2.3 Intervention Delivery

**Table 2:** Information on delivery of the Gateway intervention.

	Allocated to gateway (n=)
<b>LINX workshops attended, n (%)</b> 0 1 2	
<b>Delivery of LINX workshops, n (% of workshops attended)</b> Face-to-face Telephone	
<b>Contacts attempted by navigator (excluding LINX workshops)</b> n (%) Mean (SD) Median (IQR) Min, Max	
<b>Successful contacts made by navigator (excluding LINX workshops)</b>	

	<b>Allocated to gateway (n=)</b>
n (%) Mean (SD) Median (IQR) Min, Max	
<b>Duration of successful contacts, minutes</b> n (%) Mean (SD) Median (IQR) Min, Max	

**Table 3:** Information on simple cautions, and conditions attached to conditional cautions presented by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Simple caution, n (%)</b> Yes No	NA NA	
<b>Conditional caution, n (%)</b> Yes No		
<b>Conditions attached to conditional caution, n (%)</b> Fine Compensation Apology letter Drug awareness course Alcohol awareness course Other		

#### 8.2.4 Primary Analysis

**Table 4:** WEMWBS score presented descriptively by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Week 4</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Week 16</b> n (%) Mean (SD)		

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
Median (IQR) Min, Max		
<b>Year 1</b> n (%) Mean (SD) Median (IQR) Min, Max		

## 8.2.5 Secondary Analyses

**Table 5:** Secondary outcomes presented descriptively by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b><i>SF-12 physical component</i></b>		
<b>Week 4</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Week 16</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Year 1</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b><i>SF-12 mental component</i></b>		
<b>Week 4</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Week 16</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Year 1</b> n (%)		

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
Mean (SD) Median (IQR) Min, Max		
<b>AUDIT</b>		
<b>Week 4</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Week 16</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Year 1</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>ADIS</b>		
<b>Week 4</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Week 16</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Year 1</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Total RMS incidents and PNC convictions 1 year post-randomisation</b>		
n (%) Mean (SD) Median (IQR) Min, Max		
<b>Total RMS incidents 1 year post-randomisation resulting in participant being classified as a suspect and charged/cautioned and PNC convictions</b>		
n (%) Mean (SD) Median (IQR) Min, Max		

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b><i>Charged with a summary or either way offence up to one year post-randomisation</i></b>		
Yes		
No		
<b><i>Charged with a indictable only offence up to one year post-randomisation</i></b>		
Yes		
No		

## 8.2.6 Exploratory Outcomes

### 8.2.6.1 Accommodation Status

**Table 6:** Accommodation status presented descriptively by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Week 4, n (%)</b> Homeless Not homeless		
<b>Year 1, n (%)</b> Homeless Not homeless		

## 8.2.7 Other Planned Analyses

### 8.2.7.1 Number of contacts at each follow-up time point

**Table 7:** Number of attempts required to get in touch with the participant at each follow-up time point, presented by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual process (n=)</b>
<b>Week 4, n (%)</b> One attempt Two attempts Three attempts Four attempts Contacted by letter Failed to contact		
<b>Week 16, n (%)</b> One attempt Two attempts Three attempts Four attempts Contacted by letter		

Failed to contact		
<b>Year 1, n (%)</b> One attempt Two attempts Three attempts Four attempts Contacted by letter Failed to contact		

### 8.2.7.2 Reporting of the use of discretion in overriding the condition to not reoffend

**Table 8:** Information on the use of discretion in overriding the condition to not reoffend.

	<b>Allocated to Gateway (n=)</b>
<b>Reoffended, n (%)</b> Yes No	
<b>Offence type, n (%)</b>	
<b>Police consulted Gateway Team before making disposal decision, n (% of those who reoffended)</b> Yes No	
<b>Disposal decision and plea, n (% of those who reoffended)</b> Cautioned Charged and pleaded not guilty Charged and pleaded guilty	
<b>Participant breached by Gateway team, n (% of those who reoffended)</b> Yes No	
<b>Prosecuted for original offence, n (% of those breached by Gateway Team)</b> Yes No	

### 8.2.7.3 Index of Multiple Drug Use

**Table 9:** Index of Multiple Drug Use at each time point, presented by treatment group.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Week 4, n (%)</b> n (%) Mean (SD) Median (IQR)		



Min, Max		
<b>Week 16, n (%)</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Year 1, n (%)</b> n (%) Mean (SD) Median (IQR) Min, Max		

### 8.2.8 Health Economic Data

**Table 10:** Health economic data summarised at the 4-week time point.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Employed in previous month, n (%)</b> Yes No Missing		
<b>Number of times visited GP in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used drug/alcohol services in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times visited accident and emergency in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times admitted to hospital as inpatient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used community mental health team in previous month</b>		

n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used psychiatric services as in-patient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Used the following prescribed medications in previous month, n (%)</b> Medication 1 Medication 2 Medication 3 ...		
<b>Reason for using prescribed medications in previous month, n (%)</b> Reason 1 Reason 2 Reason 3 ...		

**Table 11:** Health economic data summarised at the 16-week time point.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Employed in previous month, n (%)</b> Yes No Missing		
<b>Number of times visited GP in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used drug/alcohol services in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times visited accident and emergency in previous month</b> n (%) Mean (SD)		

Median (IQR) Min, Max		
<b>Number of times admitted to hospital as inpatient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used community mental health team in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used psychiatric services as in-patient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Used the following prescribed medications in previous month, n (%)</b> Medication 1 Medication 2 Medication 3 ...		
<b>Reason for using prescribed medications in previous month, n (%)</b> Reason 1 Reason 2 Reason 3 ...		

**Table 12:** Health economic data summarised at the 1-year time point.

	<b>Gateway Conditional Caution (n=)</b>	<b>Usual Process (n=)</b>
<b>Employed in previous month, n (%)</b> Yes No Missing		
<b>Number of times visited GP in previous month</b> n (%) Mean (SD) Median (IQR)		

Min, Max		
<b>Number of times used drug/alcohol services in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times visited accident and emergency in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times admitted to hospital as inpatient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used community mental health team in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Number of times used psychiatric services as in-patient in previous month</b> n (%) Mean (SD) Median (IQR) Min, Max		
<b>Used the following prescribed medications in previous month, n (%)</b> Medication 1 Medication 2 Medication 3 ...		
<b>Reason for using prescribed medications in previous month, n (%)</b> Reason 1 Reason 2 Reason 3 ...		