Full study title: 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

Short study title: An evaluation of Gateway – an out-of-court community-based intervention programme

Study Protocol

ERGO Number: 31911

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2 PROTOCOL SUMMARY

Short title	An evaluation of Gateway an out-of-court community-based intervention programme
Protocol Version	2.6
Protocol Date	8th May 2020
Funder	NIHR Public Health Research Programme
Grant Reference	16/122/20
Chief Investigator	Professor Julie Parkes
Study design	A pragmatic randomised controlled trial (RCT) of young adult offenders (aged 18-24) within the Hampshire Constabulary Force Area (HCFA) with an economic evaluation, process evaluation and qualitative study.
Study intervention	Gateway is an out-of-court community-based intervention (OCBI) with three components: assessing health and social care needs (triaging) and mentoring; empathy workshops; and restorative justice conferencing.
Control group	Disposal as usual to court summons or a different conditional caution (i.e. not Gateway)
Population group	18-24 year-old offenders residing within the HCFA where the Gateway programme is being provided, who have been arrested for a low level criminal offence and meet the eligibility criteria.
Primary research question	What is the effect of the Gateway intervention on: ● health and wellbeing including, alcohol and substance use? ● access to health and social services? ● quality of life?
Secondary research questions	What are the views and experiences of victims? How is the Gateway intervention being implemented: what is the quality and quantity of what is being delivered, what are the external barriers to its effects and causal mechanisms? What are the cost consequences (e.g. cost and benefits) of the Gateway intervention compared to usual care? What are the differences, if any, on reoffending between Gateway and usual care?
Primary outcome	Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
Secondary outcomes	SF-12; Alcohol Use Disorders Identification Test (AUDIT); Adolescent Drug Involvement Scale (ADIS); Adverse Childhood Experiences (ACE); reoffending type and frequency; resource use (health and social care).
Study sites	Southampton, Portsmouth, Isle of Wight and Basingstoke, and surrounding areas: all within HCFA.
Sample size	334 participants
Study funding duration	41 months (01 March 2018 to 31 July 2021) Extension to 30 June 2023 required (an additional 23 months)

3 PLAIN ENGLISH SUMMARY

Aims: The study aims to determine whether a new out of court programme, named Gateway, improves the health and wellbeing of young adult offenders aged 18-24, and influences their chance of offending again, and gives victim satisfaction.

Background: Young adult offenders commonly have a range of health and social needs, making them vulnerable to mental health problems. If you are aged between 18-24 years old and have committed a crime, you may need to attend court and face convictions such as prison. However, many believe that more should be done to prevent young adults from entering the criminal justice system in the first place.

The Gateway programme is issued as a conditional caution and has been developed by Hampshire Constabulary, in partnership with local community groups, with an aim to improve the life chances of young adult offenders. In the programme, a mentor assesses the needs of each adult and develops a care pathway with referrals to healthcare. The young adult offenders then attend two workshops about empathy, and the causes and consequences of their behaviour. Such programmes are believed to improve the health and well-being of young offenders and reduce criminal behaviour. However, there is currently little information about the extent of this improvement.

Design: To find out whether the programme works, this research study compares a group of young adult offenders taking part in the Gateway programme as a conditional caution with a group part of non-participants who are given a court conviction or a different conditional caution.

Once charged with an offence, in or out-of-custody, the consenting participants will be randomly allocated to either group using a computer program. This randomisation will allow researchers to compare whether the Gateway programme is more, or less effective at improving offenders' outcomes, as compared to a court conviction or different conditional caution. Participants will be followed up for one year. Their outcomes will be monitored and compared at different time points across that period. Specifically, we will explore differences in mental health and well-being, quality of life, criminal and/or anti-social behaviour, substance abuse and access to health and social care.

In addition to the randomised controlled trial, we will undertake qualitative research and an economic evaluation. Some of the group allocated to Gateway will be asked to participate in restorative justice, which is a meeting between the offender and the victim. The offender has the opportunity to discuss and make amends for the crime they committed. To explore how satisfied the victims are with this, and with Gateway in general, victims of crime will be interviewed. To understand what works, where and for whom, further interviews will be undertaken with groups delivering the programme in other counties. To understand the costs of the programme, the amount spent on each group, as well as any associated health improvements will be compared.

Patient and Public Involvement: To develop the current study design, groups of young offenders previously engaged with the criminal justice system were consulted. One stated '*It would have helped me at that age. I was in and out of prison about seven times when I was younger; nothing addressed the root of what was the matter.*' The groups will be consulted again at later dates to ensure that they feel the study is acceptable and appropriate. A Public Participation Panel (PPP) will be established to ensure that the concerns and attitudes of the wider community are represented.

Dissemination: The study results will be presented in a formal report as well as a short summary report, which will be written so that it is easily understood by the public. The study findings will be shared with all groups and partners involved in the study, including the offender and victim groups, the PPP, academics and policy-makers locally and nationally.

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5 ABBREVIATIONS

ACE	Adverse Childhood Experiences questionnaire
ADIS	Adolescent Drug Involvement Scale
AUDIT	Alcohol Use Disorders Identification Test
BRFSS	Behavioural Risk Factor Surveillance System
CARA	Conditional Cautioning and Relationship Abuse
CI	Chief Investigator
CPS	Crown Prosecution Services
CRF	Case Report Form
CSRI	Client Service Receipt Inventory
DMEC	Data Monitoring and Ethics Committee
HCFA	Hampshire Constabulary Force Area
HMPPS	Her Majesty Prison and Probation Services
HYOT	Hampshire Youth Offenders Team
IoW	Isle of Wight
NHS	National Health Service
NOMS	National Offender Management Services
OCBI	Out of Court Community Based Intervention
OR	Odds Ratio
PI	Principal Investigator
PIS	Participant Information Sheet
PPI	Patient and Public Involvement
PPP	Public Participation Panel
REC	Research Ethics Committee
RCT	Randomised Controlled Trial
SF-12	Short Form 12 questionnaire
SSC	Study Steering Committee
TMG	Trial Management Group
UoS	University of Southampton
UoY	University of York
WEMWBS	Warwick-Edinburgh Mental Wellbeing Scale
YTU	York Trials Unit

6 BACKGROUND AND RATIONALE

6.1 Existing research

Diversion is a process whereby an accused offender is formally moved into a programme in the community, such as an out-of-court community based intervention (OCBI), instead of being moved through the criminal justice system (1). Diversion programmes were initially conceived to minimize the effects of labelling associated with offending (2). Despite the use of diversion programmes in the UK, particularly amongst a younger population (1, 3, 4), the evidence base around diversion is still unclear.

6.1.1 Diversion and recidivism amongst young populations

Literature searches were conducted using CINAHL, EMBASE, Europe PMC, MEDLINE, NIHR Library and Web of Science databases using the search terms: diversion, out of court disposals and court diversion. Studies on diversion have largely been undertaken outside the UK; the majority being conducted in the United States (US), with a few studies in Australia, New Zealand and the rest of Europe. Of the studies found, the majority focussed on younger populations and on family treatment as a therapeutic intervention. For example multi-systemic therapy is a resource intensive programme, which focuses on factors within the offender's social

network that contribute to their offending behaviour (5). Treatment usually takes place within the community, such as at home or at school. A meta-analysis of diversion programmes for juvenile offenders was undertaken in 2012 and identified 28 studies involving 19,301 youths (6). The most common outcome reported amongst the studies was *recidivism* i.e. the tendency of the offender to reoffend. Of the five types of programme included, a statistically significant reduction in recidivism was only observed for family treatment (OR=0.57, 95%CI= 0.40 to 0.82). Overall there was high heterogeneity amongst the studies; in terms of the research and programme design, as well as the quality of programme monitoring and implementation. The mean age of the population in studies identified by the meta-analysis ranged from 12.6 to 15.9 years of age. Despite this, the case for diversion amongst young adults is increasing, due to a growing recognition of their varying levels of maturity and complex needs (7, 8). In the UK a small number of Police Constabularies are exploring the use of out of court disposals amongst 18-24 year olds involved in less serious offending (9). Evidence of the effectiveness of diversion amongst this population group is limited.

6.1.2 Addressing health outcomes

Young adult offenders aged 18-24 represent a third of the prison case load (7) and are at risk of poor mental health outcomes (10, 11); including risk of alcohol misuse, drug abuse, self-harm and suicide (12-16). The literature on diversion therefore calls for a 'systems approach,' integrating the work of multiple agencies to address the wider determinants of reoffending (17). Despite this, the majority of studies have focussed on recidivism as their main outcome. One study conducted in Connecticut identified individuals with co-occurring mental health and substance misuse across sites with and without diversion programmes (18). The study used a quasi-experimental design to examine the effect of diversion on several outcomes, including quality of life, mental health and general satisfaction. Although there was no difference in the quality of life and mental health between the groups, the diversion group was less likely to be re-incarcerated and had significantly greater improvements in general life satisfaction ($p < 0.01$). Similarly, a national multi-site study in the US examined the effects of diversion on adult offenders (n=2000) with co-occurring mental illness and found small differences between diversion and usual care; for measures of mental health symptoms, substance use, criminal justice recidivism, and quality of life. The study concluded that changes in mental health outcomes are dependent on the type of intervention received, rather than diversion itself (19). However, the quasi-experimental design and small sample size affect the validity of any conclusions drawn.

6.1.3 Cost effectiveness of diversion

No studies have investigated the cost effectiveness of an out-of-court community-based intervention amongst 18-24-year-old offenders. Existing economic evaluations have focussed on offenders aged under 18 years, and in particular on family treatment programmes (20, 21). In one such study the net benefit of treatment versus usual care was £1,222 (95% CI -£5,838 to £8,283) per young person. One cost effectiveness study, undertaken in the United States in 2002, compared criminal justice diversion programmes among those with serious mental health and substance misuse (22). However, only one site delivered pre-booking programmes i.e. diverted offenders before being brought to charge. Comparing the pre-booking site to post-booking sites, the overall health costs (treatment) were higher for diversion in the pre-booking site (USD $6,577 higher).

There are theoretical models and some evidence to support the effectiveness of each of the individual components of the Gateway intervention. There is also evidence to suggest that the issues of offending and recidivism in young adults are complex and therefore require a range of interventions. The Gateway intervention brings together different elements in a coordinated approach to identify problems on an individual basis and connect to appropriate support. Undertaking an RCT to evaluate effectiveness will address the identified lack of robust evidence. The outcomes, while including recidivism, focus more on measuring the impact on the wider determinants of health of the offender, while taking account of the effect on the victim.

This takes account of the need for more meaningful outcomes identified from the literature. The planned economic evaluation will fill the existing gap in the evidence and provide vital information currently lacking. As the literature has shown, diversion interventions are being introduced more widely; it is therefore important to understand the cost effectiveness of this intervention.

6.2 Rationale for intervention and current study

The Gateway intervention model was conceived by Hampshire Constabulary as a 'culture changing initiative' that sought to address the complex needs of young adults aged 18-24 years. Central to this is the belief that transitions into adulthood are not linear and that more work is necessary to support desistance amongst this vulnerable population. However, the lack of robust evidence on diversion was recognised as a limitation. Consistent with existing evidence on diversion, initial unpublished evidence from Checkpoint, a Durham Constabulary court diversion programme, found no changes in recidivism. However, there were two important distinctions in this trial: it was an adult service and did not respond to the needs of a particular age group. Furthermore, the study did not evaluate longer term health outcomes and continued engagement with the health services. Hampshire Constabulary therefore wanted to explore the effect of the Gateway Intervention model on a wider set of outcomes, with a particular focus on health and well-being, of both offenders and victims.

Given that one of the main drivers and collaborators for this project is Hampshire Constabulary, who wish to implement the Gateway intervention throughout the Hampshire Constabulary Force Area (HCFA), it is imperative to understand the effectiveness and cost-effectiveness of the intervention. This is particularly important as although each of the three components of the Gateway intervention are underpinned by theory and have been evaluated in isolation (13, 23-29), there has been no previous attempt to evaluate the Gateway intervention in its entirety. The proposed randomised controlled trial (RCT) and economic and qualitative evaluation will address this evidence gap and inform national decision making.

6.3 Gateway intervention: conceptual framework

The Gateway intervention was initially developed as an OCBI for 18-24 year olds in the Southampton Policing District by the Hampshire Constabulary in partnership with the Hampton Trust – a third sector organisation specialising in working with perpetrators of domestic abuse and young people with troubled backgrounds and gangs (further details in Appendices 1 and 2).

Although each of the three components draw on their own underlying theories, the overarching Gateway model draws on the life-course developmental theories of delinquent and anti-social behaviour; and specifically on the interactional theory proposed by Thornberry et al (30). The interactional theory model "offers a broad explanation for the causes and consequences of involvement in antisocial behaviour," and to both the social and personal factors that evolve and influence behaviour over the life-course (31, 32). One of the central premises of the intervention is to support desistance amongst a group of young offenders as they transition into adulthood. Several longitudinal studies have examined the risk and protective factors of delinquent and anti-social behaviour across adolescents and young adulthood. According to interactional theory such factors may include: structural adversities, such as employment/ debt, substance abuse and mental or physical health; as well as neuropsychological deficits, such as antisocial/delinquent beliefs and a lack of guilt or empathy (33). Through the three components of the Gateway: assessing needs and mentoring through referrals; empathy/resilience training; and restorative justice, the programme addresses several risk and protective factors, thereby promoting health and well-being for the individual and supporting desistance.

Although the overall model is novel in its approach, each of the three components have been developed according to underlying theories related to reoffending behaviour and restorative justice:

Component 1: Assessing needs (including wider determinants of health and offending). The offender meets with the Gateway navigator who assesses the need of the offender, particularly the factors that may influence reoffending behaviour; such as drug and alcohol misuse, health and employment issues (13, 23, 25). The navigator may also provide a *mentoring* role. A recent evaluation in Wales showed that mentoring helps offenders to engage meaningfully with agencies, build a more stable lifestyle and move away from crime and substance misuse (26). However there is limited evidence about what forms of mentoring are most effective.

Component 2: The LINX Workshops. Developed by The Hampton Trust, the LINX workshops assist young adults in the development of cognitive and affective empathy. The LINX workshops are rooted in Social Learning Theory, which suggests that behaviour is learned from the environment through the process of observational learning (27); and that 'acting-out' may be a means of establishing status within a subculture, thereby enhancing self-concept (28). The LINX workshops address offending behaviour and its impact on self and victim and personal/protective factors. Preliminary qualitative evidence from the evaluation of LINX workshops indicate their role in enacting positive change and improving self-conduct; as conveyed by the following quote:

"…I have not been so angry and violent and have learnt to control my actions and temper." (24)

A quantitative evaluation was undertaken on a sample population of 100 participants of the LINX programme. Surveys were administered at two intervals, before and after the programme. They found significant improvements ($p<0.05$) in both behaviour and self-concept, using a self-concept and behavioural scale (34).

Component 3: Restorative Justice. This approach offers the chance for all stakeholders affected by criminal activity, such as the accused and victim, to meet, discuss their harms, and bring about a resolution. This usually takes the form of a 'restorative justice conference' run by a trained facilitator (29). Restorative justice will be offered to the offender **only** if requested by the victim. A recent multi-scheme evaluation in the UK found that restorative justice led to high levels of satisfaction among victims who participated in the restorative process (35). A meta-analysis conducted in Canada found that such programmes are more effective at improving victim and offender satisfaction compared to traditional non-restorative approaches ($p < 0.01$). However, it is important to note that these results are limited by the possibility of self-selection bias due to the voluntary nature of restorative justice (36).

7 STUDY METHODS

7.1 Study methodology

We will undertake a pragmatic randomised controlled trial (RCT) of offenders aged 18-24 years within the HCFA, with an internal pilot phase. An RCT provides the most robust method to establish whether the Gateway intervention is effective through a comparison of a group of participants who receive the intervention with a group who receive disposal as usual to a court summons or a different conditional caution (usual care). York Trials Unit (YTU) will lead on the RCT element of this study.

There will also be an economic evaluation, qualitative study and process evaluation. Researchers and health economists based at the University of Southampton (UoS) will lead on these elements of the study.

This mixed-methods approach will ensure the study evaluates the impact of the intervention on participants, the views of victims, assesses the intervention itself, and examines the cost effectiveness of the Gateway programme.

7.2 Aims and objectives

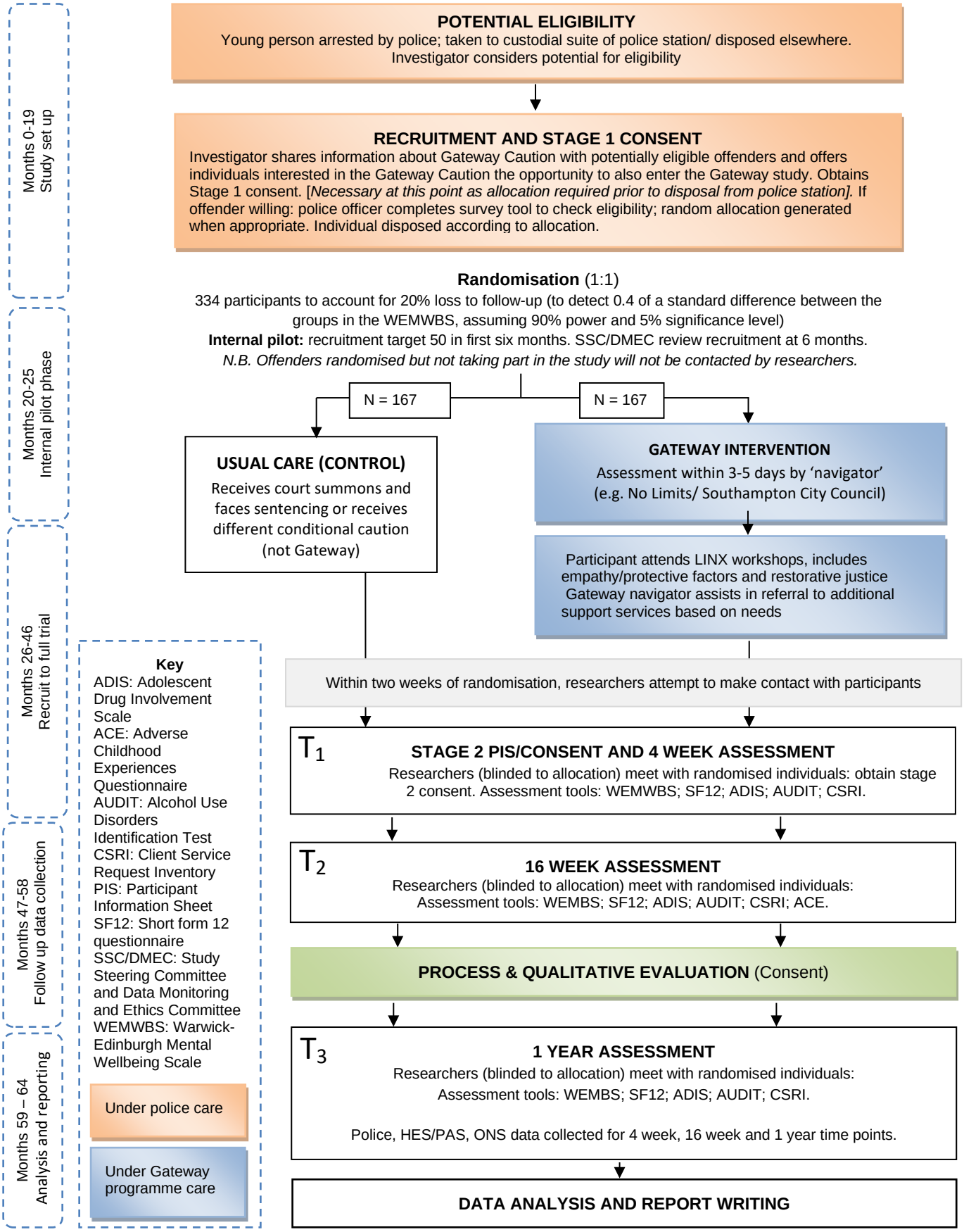
The aim of the study is to evaluate the effectiveness and cost effectiveness of the Gateway programme issued as a conditional caution compared to court summons or a different conditional caution (usual care). The Gateway programme is an out of court community-based intervention for improving the health and wellbeing of young adult offenders (aged 18-24), victim satisfaction and reducing recidivism.

The study objectives are to:

1) Examine the effect of the Gateway intervention on (i) health and wellbeing including, alcohol and substance use (ii) access to and use of health and social services by offenders and (iii) quality of life, amongst young adult offenders
2) Explore the views and experiences of victims
3) Assess the quantity and quality of the Gateway intervention and the generalisability of the findings
4) Identify and measure all relevant consequences, both cost and benefits, of the Gateway intervention compared with usual care
5) Examine the effect of the Gateway intervention on reoffending

Objectives 1 and 5 will be addressed in the RCT; objectives 2 and 3 in the qualitative research and process evaluation and objective 4 in the economic evaluation.

7.3 Study Flow chart



7.4 Quantitative outcomes and measures

7.4.1 Primary outcome measure

The primary outcome measure is the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS). This will be used to measure health and well-being amongst study participants. WEMWBS is a 14-item self-reported questionnaire that addresses mental health and wellbeing and has established valid reliable psychometric properties in adolescent populations (37, 38). Compared to other well-being indices, WEMWBS was tested for response bias and showed low correlation with both subscales of the Balanced Inventory of Desirable Responding: Impression Management ($p=0.18^*$) and self-deception ($p=0.35^{**}$), which make it suitable for self-report (39). Participants will self-report WEMWBS at 4 weeks, 16 weeks and one-year post-randomisation. ($^*p<0.05$ $^{**}p<0.01$)

7.4.2 Secondary outcome measures

The following are the secondary outcome measures:

- The SF-12 will be used to report health status. The 12 items of the SF-12 provide a representative sample of the content of the eight health concepts (40) and the various operational definitions of those concepts, including what respondents are able to do, how they feel, and how they evaluate their health status.
- Risky alcohol use will be measured using the Alcohol Use Disorders Identification Test (AUDIT). The Audit tool is a simple screening tool that is used to identify the early signs of hazardous and harmful drinking and mild dependence. AUDIT has been validated amongst an adolescent population (41, 42).
- Drug use will be measured using the Adolescent Drug Involvement Scale (ADIS). The ADIS was deemed most appropriate, as it captures recent/ current use, and has been validated within this population age group (43).
- Adverse Childhood Experiences (ACE) questionnaire, based on the ACE module of the Behavioural Risk Factor Surveillance System (BRFSS), run by the Centers for Disease Control and Prevention (CDC) in the USA – at 16 weeks only
- Reoffending type and frequency through access to routine data: Hampshire police records will be used to examine the type and frequency of offence.
- Data on resource use, including access to primary and secondary care health services and social care, will primarily be used to inform the cost benefit analysis and cost consequence analysis. Data will be obtained through self-reported responses to questions based on the Client Service Receipt Inventory (CSRI).

7.5 Study setting and population

The four trial recruitment sites are Southampton (including Eastleigh, New Forest and Romsey), Portsmouth, Isle of Wight and Basingstoke Policing Districts, which are all within HCFA.

The study population is 18-24-year-old offenders residing within HCFA. According to police statistics, the five main offence categories for this age group are violence; possession or trafficking of drugs; theft; criminal damage; and public order offences. These young adults represent a vulnerable population with a range of complex needs, such as mental health issues and drug and substance misuse. They are more likely to come into contact with the police both as suspects and victims of crime and are significantly over represented in the formal justice process, accounting for approximately one-third of police, probation and prison caseloads (7). Eligibility will include those dealt with in custody and disposed from police stations, and offenders dealt with through a ‘voluntary interview’ and therefore disposed out-of-custody.

7.6 Intervention

The Gateway intervention is a police-led intervention, which will be delivered over two years using a multi-agency approach. Young adults randomised to the Gateway programme will receive a 16-week conditional contract, known as a conditional caution. The conditions include a requirement to participate in the Gateway intervention and not to re-offend. A breach of the conditions may result in the offender being charged for the original offence.

7.6.1 Content and delivery of Gateway intervention

Part 1: Initial assessment with 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 social workers, provided by third sector organisation, No Limits, and Southampton City Council. The navigators will also mentor the individual through the programme.

Parts 2/3: The LINX workshops and Restorative Justice. 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.

The LINX workshops will take place in a neutral venue as close as possible to where the offender lives. For example, for those living in the Southampton area, workshops will be held at Southampton City West Quay facilities. Delivery will be by the third sector organisation, The Hampton Trust.

The first workshop will be delivered at week three and the second delivered at week ten after randomisation.

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 should 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, and 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 during week 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.'

Running parallel to both days the leaders of the LINX workshops will build on the support that the navigators give to the young adults and reinforce the motivation needed to access other services. If 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.

7.6.2 Provision of Gateway intervention

No Limits is a third sector organisation that provides free advice, counselling, support and advocacy for under 26-year-olds. No Limits will provide the Gateway navigators for the Gateway intervention. Two further navigators will be provided by Southampton City Council, working alongside the navigators at No Limits.

The Hampton Trust is a third sector organisation established in 1996 that has worked with domestic abuse perpetrators within and outside of the Criminal Justice System. It has developed extensive skills and expertise in developing community-based interventions for adults and young people. The Hampton Trust developed the LINX workshops and will deliver the workshops as part of the Gateway intervention.

Restorative Solutions are a not-for- profit community interest company commissioned by the PCC to offer restorative justice options to the local community. Through Restorative Justice, victims can meet with their offenders and communicate the impact their crime has had on them; thereby empowering the victim.

Other agencies accessed through the triaging of needs include The Prince's Trust, Two Saints (housing) and local Community Mental Health Teams.

7.7 Study duration and assessment schedule

	Throughout the project period	Pre-disposal	Immediately post-recruitment	Within one week of randomisation	4 weeks post randomisation	16 weeks post randomisation	1 year post randomisation	End of study
Eligibility screening by investigators at sites in HCFA		X						
Stage 1 initial consent		X						
Randomisation			X					
Stage 2 full consent with researcher					X (and up to week 16)			
Completion of Case Report forms (WEMWBS, SF12, CSRI, ADIS, AUDIT, ACE*)					X (and up to week 16)	X (and up to 1 year) *ACE data collection at week 16 only	X	
Participants assigned to intervention meet with Navigator				X				
Qualitative consent	X							
Qualitative research	X							
Process evaluation	X							
Obtain routine police data on recidivism							X	
Send report to NIHR PHR and carry out dissemination activities								X

7.8 Comparator: usual process

The comparator for this RCT is usual process. Under current guidance, for young adults aged 18-24, where there is enough evidence for prosecution (known as Full Code Test 1) 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.

7.8.1 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, but they are not the same as a criminal conviction.

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.

7.8.2 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 release 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 (see 7.8.3) if the full code test is subsequently met.

7.8.3 Court Summons

This is an out-of-custody process. If it is not necessary to arrest an offender i.e. detain them in custody (see 7.8.2), 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.

7.9 Sample size

Based on 2013/14 data, approximately 1403 young adult offenders were dealt with in the Southampton area over 12 months. Of these some 779 (55%) were dealt with via court-based proceedings (usual process). It is this cohort that the Gateway programme seeks to target and engage. Based on existing splits between offence categories only 3% of offences are serious indictable only offences that would properly be dealt with at Crown Court (and therefore excluded). This provides a potential cohort of around 750 in a year. In order to be eligible for the Gateway programme offenders must admit responsibility for the offence and accept the conditional caution contract. Existing data from the Ministry of Justice, which is consistent with Hampshire Constabulary, indicates that approximately 70% of offenders plead guilty at an initial hearing. However, recruitment to the trial has to be while the offender is being processed immediately before disposal. They cannot be recruited once they get to court as they are then within the Criminal Justice System. Figures produced by Southampton police members of the research team in May and August 2019 show the number of potentially eligible young adult offenders across three trial sites to be 277 per year.

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 (WEMWBS user guide (38)). There is also variation in the standard deviation of the WEMWBS with estimates ranging from 6 to 10.8 (44) 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 are required. Preliminary figures from The Hampton Trust's skills/attitudes workshops for domestic abuse (RADAR intervention) suggests a drop-out rate of approximately 15%. Conservatively, we will account for 20% loss to follow up therefore 334 participants need to be recruited and randomised.

Ideally, and as planned in the original application, we would collect baseline measures of the outcome data to be used in the analysis to improve precision and to gain increases in power. However, this option has now proved to be impossible in this new setting. We are therefore collecting outcome measures at an early time point to recover the gains in power that would have been lost. This will be achieved by including the 4-week measure as an outcome in the repeated measures analyses (alongside the 16 week and 1-year timepoints) rather than including the measure as a covariate in the model. We are still collecting some baseline

characteristics which will be included as covariates in the analysis and are likely to maximise power and precision also. The sample size was conservative, as it did not adjust for the correlation between baseline and follow-up so the sample size remains unaffected. In summary, this change is unlikely to adversely affect the validity of the outcome measures, the sample size, plans for analysis or integrity of the trial.

7.10 Eligibility criteria

7.10.1 Inclusion criteria

- Suspects aged 18-24 years
- Suspect resides within HCFA
- Anticipated guilty plea (i.e. admitted the offence and said nothing which could be used as a defence or has made no admission but has not denied the offence or otherwise indicated it will be contested)
- Full code test 1 met (i.e. there is sufficient evidence and it is in the public interest to charge the suspect)

7.10.2 Exclusion criteria

- Hate crime according to CPS Policy;
- Domestic violence related crime
- Domestic violence related crime referred to CPS;
- Sexual offence as defined by the CPS
- Knife crimes
- Where on conviction the court is more likely to impose a custodial sentence (based on sentencing guides);
- Remand in custody order is sought
- Breach of court or sexual offences orders;
- Any offence involving serious injury or death of another;
- Any serious previous convictions within the last 2 years (i.e. serious violence, grievous bodily harm (GBH) or worse, serious sexual offences, robbery or indictable only offences)
- Summary offences more than 4 months old
- Persons subject to Court bail; Prison Recall, Red IOM (Integrated Offender Management) or currently under Probation
- Indictable only offences;
- All drink/drive or endorsable traffic offences;
- Offender already has a Gateway programme flag
- Offender needs an interpreter

7.11 Randomisation

Individuals will be randomised to either the intervention or control group on a 1:1 basis. To ensure that only those that are willing to participate are randomised, a stage 1 initial interest consent form will be completed *prior* to randomisation. All police officers and investigators (hereafter referred to collectively as investigators) coming into contact with potential participants will undergo rigorous training prior to the start of the study and be given a script for guidance when obtaining consent. Randomisation will be conducted through a web-based eligibility checker and randomisation system. The eligibility tool (SurveyGizmo) has been developed by Hampshire Constabulary in discussion with YTU and uses a randomisation sequence approved by the trial statistician. The system has been 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) (45). This approach to consent and randomisation is 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.

7.12 Internal pilot

The first six months of trial recruitment will be treated as an internal pilot, the aim of which will be to assess whether continued progression into the full trial is appropriate. Recruitment to the trial will continue while a decision is made.

According to police estimates an average of 23 individuals will be eligible to receive the Gateway intervention each month once all the sites are recruiting. Based on these estimates, assuming a take up rate of 60%, and allowing for variations in priorities, and annual/sick leave for recruiting police investigators, we aim to consent and enrol a minimum of 12 individuals per month once all the sites are recruiting. It is anticipated that the Isle of Wight will be open to recruitment on the 1 May 2020 and therefore will not contribute to the internal pilot phase.

During the first six months, taking site set up into account, we will aim to consent and enrol as follows:

Internal pilot month	**Target for recruitment**			**Cumulative total**
	Southampton (inc. Eastleigh, New Forest and Romsey)	**Portsmouth**	**Basingstoke**	
Month 1 (Oct-19)	4	-	-	4
Month 2 (Nov-19)	8	-	-	12
Month 3 (Dec-19)	7	-	-	19
Month 4 (Jan-20)	8	-	-	27
Month 5 (Feb-20)	7	2	-	36
Month 6 (Mar-20)	8	4	2	50
Total (31 Mar 2020)	**42**	**6**	**2**	**50**

The Study Steering Committee (SSC) and Data Monitoring and Ethics Committee (DMEC) will assess trial recruitment at Stage 1 consent based on the following progression criteria:

- If a recruitment rate of 90% or more eligible individuals is met, we will continue to recruit for a further 21 months or until we have reached the required 334 participants.
- If 70% - 90% of the recruitment target is met, then the SSC/DMEC will, taking into account site set up, consider extending the recruitment period by 1-4 months.
- If 60% - 70% of our recruitment target is met then the SSC/DMEC will, taking into account site set up, consider extending the recruitment period by 4-6 months. A request for a further study extension will be discussed with the funders.
- If less than 60% of our recruitment target is met, then the SSC/DMEC will meet and discuss closure of the study, in collaboration with the funders.

7.13 Analysis and reporting of the trial

All analyses will be undertaken in Stata v14 (or later). For both groups, the numbers screened in the eligibility tool, randomly assigned, receiving the intervention or care as usual, completing the study protocol, and providing outcome data will be summarised. The number of participants withdrawing from the intervention and/or the trial and, where available, the reasons for withdrawal, will be summarised by group. The flow of individuals through each stage of the trial

will be presented in a CONSORT flow diagram. Baseline data from the police records will be described by trial arm using appropriate summary statistics. No formal statistical testing will be conducted at baseline. Statistical analyses will be conducted using the principles of intention to treat unless otherwise specified: all participants' data will be analysed as belonging to the group to which they were randomised, irrespective of whether they actually received the complete intervention or withdrew from the study. Statistical significance will be assessed at the 5% level unless otherwise stated, and 95% confidence intervals will be provided as appropriate.

WEMWBS will be summarised descriptively (n, mean, SD, median, minimum and maximum) at each time-point by group and overall. Plots of the mean and 95% CI by time and trial arm will also be presented. A repeated measures mixed model will be used to compare the two groups. The repeated measurements from participants will be modelled by the covariance structure. The outcome modelled will be WEMWBS at 4 weeks, 16 weeks, and 12 months and the model will include covariates (all identified *a priori*), group and time as fixed effects. An interaction term assessing whether the difference between the groups changes over time will also be included in the model. Different covariance patterns for the repeated measurements will be explored and the most appropriate pattern will be used for the final model. Model assumptions will be checked and if they are in doubt the data will be transformed prior to analysis or alternative non-parametric analysis methods will be used. The primary analysis will compare the two groups at 12 months. A secondary analysis will compare the two groups at 4 weeks and 16 weeks. Secondary outcomes will be analysed using similar models as described above. Recidivism, from police data, will also be calculated at 12 months.

We aim to assess social, demographic and economic determinants, and their relationship with health outcomes. This background information will allow us to adjust for potential confounding in statistical analyses essential for examining the potential inequalities within this population. However, it is anticipated that these analyses will necessarily be limited to the data routinely collected and included in police records at baseline. This will include: age, gender, ethnicity, and offending history. Depending on the completeness of data collected we also aim to examine the effects of: educational qualifications; current housing situation; finances (e.g. Benefits, debts); substance misuse (e.g. drugs); and occupation.

The efficacy of the intervention under full compliance will be assessed using Complier-Average Causal Effect Analysis (CACE), using data from attendance registers kept by the Gateway team. The sensitivity of the results to missing data shall be assessed using multiple imputation methods.

Analyses and results will be reported in accordance with the CONSORT statement for trials.

8 ECONOMIC EVALUATION

An impact inventory will provide a structure for the economic evaluation. An impact inventory constitutes a more recent extension to the traditional cost-consequences analysis (CCA), and involves listing all the relevant costs and benefits consequential to the intervention. This approach is particularly useful when sectors other than healthcare are involved. The data provided in such an analysis may be used for estimates of cost effectiveness depending on the data collected. For Gateway, the main consequences are likely to be on offenders, depending on the elements of the intervention to which they are exposed. The primary outcome focuses on the short-term health consequences of the intervention. Longer term health effects might include changes to substance abuse, both current and planned, as well as life planning. Other relevant consequences might include changes in re-offending with knock on effects on putative victims as well as on costs to the criminal justice system of processing offenders. Consequences might also be detected in the educational, employment and housing sectors. A list of the relevant sectors/headings likely to show consequences due to the intervention would be drawn up in the preparatory stage using the recently published impact inventory template (46) creating a distinction between health and societal perspective. Unit costs would be based on best

estimates of the relevant resource use. Any changes in re-offending would be costed using the estimates for the monetary losses attributable to different type of crime (47, 48).

A health economics analysis plan detailing intended analyses will be drafted before the completion of data extraction and agreed with the Trial Management Group (TMG).

9 QUALITATIVE EVALUATION

9.1 Study population

Three of the five main categories of offence (violence, theft and criminal damage) within this population group may involve a victim. According to figures from a study in Birmingham, which examined the effects of deferred prosecution on offending, only 30% of victims were willing to engage with Restorative Justice (49). It is this group that we seek to engage. Given that a small number of victims may be willing to engage in research, a quantitative assessment with victims will likely lead to skewed results. However, given the importance of the victims' perspective, within the broader aims, a qualitative study has been proposed to explore the experiences of victims.

9.2 Qualitative method

In-depth interviews will be undertaken with affected victims within the Gateway study; for victims willing to undertake Restorative Justice and for those who are not. Perceived satisfaction will be informed by the literature, and the factors associated with satisfaction, such as need for 'trust, respect, neutrality and voice,' will be used to inform the topic guide for interview (50).

9.3 Main qualitative outcome

Victim perception of Restorative Justice and the development of a conceptual framework on reported victim satisfaction will be the main outcomes of the qualitative research. It is anticipated that the framework will be used in subsequent research to inform future developments, such as a victim satisfaction questionnaire, necessary for the on-going implementation of out-of-court disposals.

9.4 Inclusion/ exclusion criteria

The main eligibility criteria include victims that have been contacted by Restorative Solutions (RS).

9.5 Sampling

Given that the evaluation of Restorative Justice is likely to be affected by self-selection bias – as victims who are willing to engage may be more likely to be satisfied with it – if possible we will conduct interviews with those contacted by the Police who are unwilling to engage with Restorative Justice. If feasible, the sampling method will be purposively based on those who engaged in Restorative Justice and those who did not; in both control and intervention arms. The exact number of participants is difficult to predict in advance since sampling will continue until data saturation; but we anticipate that between 20 – 30 individuals will need to be interviewed. Interviews will take place at a quiet interview room at a community centre in Southampton, Portsmouth, Isle of Wight or Basingstoke, offered through the collaborative agency partners such as No Limits or Wheatsheaf Trust.

9.6 Qualitative data analysis

The qualitative data will be analysed using thematic analysis; this is more consistent with the pragmatic approach taken, as compared to other methods (51).

10 PROCESS EVALUATION

To evaluate the effectiveness of a complex intervention, the Medical Research Council recommend a Framework approach, which integrates a dynamic view and considers the underlying complexity of the intervention. The MRC framework allows, and supports, the integration of a number of informing theories that relate to its key functions. For example, to evaluate the role of *implementation*, the evaluation draws on the Steckler and Linnan theory, which argues that to effectively capture *implementation* one should consider the effect of fidelity (to what extent the intervention was delivered as had been intended by the researchers), dose delivered and received (amount of intervention offered to participants and extent to which participants engaged) and reach (proportion of targeted participants that engaged in the intervention) (52). Furthermore, it aims to inform policy and practice by capturing not only whether the complex intervention worked, but how it was implemented, its causal mechanisms and how the effects may differ from one context to another. A process evaluation will be conducted within the overall study to assess the quantity and quality of what is being delivered through the Gateway intervention and the generalisability of its effectiveness. To achieve this, the process evaluation will integrate routine quantitative data from the implementing agencies, as well as qualitative work with all stakeholders of the Gateway intervention, including the implementers and the benefactors. It is anticipated that the results from the process evaluation will inform the iterations of the Gateway intervention logical framework (see Appendix 2).

Specific research questions include:

- What are the external barriers to its implementation and effects?
- What is the quantity and quality of what is being delivered?
- What are the mechanisms through which the intervention brings about change?

10.1 Structured observation and qualitative interviews

The interaction between the Gateway navigator and the participant, as well as the LINX facilitator and the group participants, are essential components of the Gateway intervention. Additionally, understanding which components of the intervention are effective, as well as any barriers and facilitators to the intervention, from the perspective of the participants is vital.

10.1.1 Interaction between navigator and participant.

Given that the responsibility of the Gateway navigator is to assess the needs, this will be discharged through verbal, face-to-face interaction with participants. To capture the situational interaction between navigator and participant, video recordings were therefore considered to be more appropriate than audio recordings (53). To assess these interactions, video recordings will be taken at random, with consent from all participants, and in line with good practice for video-based research on healthcare communication (54). In order to adequately distinguish the key components of this interaction, the structured analysis will draw on existing evidence related to effective mentoring, as well as motivational interviewing. Based on the literature these may include, for instance, providing open communication; and noting the importance of goals and expectations (55, 56).

10.1.2 Interaction between LINX facilitator and group participants.

Observations will be undertaken within this study at one time point. The observations will be used to ascertain the context of the LINX workshops and what is really being delivered. A total of three groups will be observed at any time point in their programme. Each group will only be observed once. Combined with other methods, observations provide an understanding of the context, show how what is being described in interviews (e.g. interviews with implementers) is being enacted in practice, and provide potential explanations for apparent inconsistencies in spoken accounts (57). Participant observation will be conducted using the three phase method proposed by Spradley (58, 59). In the first stage, ‘descriptive observation’ will be undertaken – to provide the researcher with an orientation to the field under study and, if necessary, refine the research questions. In the second stage, ‘focused observation’ will be carried out, which involves narrowing the perspective on those processes and problems which are essential for the

research questions. Finally, in the third stage, 'selective observation' will be conducted, which focuses on finding further evidence and examples for the types of practices and processes found through focus observation.

To ensure that researcher blindness is maintained for the main trial, observations of the Gateway intervention will be carried out by researchers that are not involved in the Gateway trial recruitment and follow-up.

10.1.3 Semi-structured interviews with Gateway participants

In-depth interviews will be undertaken within the study. These interviews will be used to explore the barriers, facilitators and perceptions of participants in engaging with the Gateway programme. A sample of up to 15 individuals will be interviewed after they have completed the programme. Recruitment will be supported by collaborative partners. Semi structured interview guides will be used to frame the qualitative interviews.

10.2 Process evaluation methods

In-depth interviews and focus group discussions with stakeholders and participants from Gateway intervention arm: The inclusion and exclusion criteria will differ by type of participant. Implementing agencies and commissioners: as stakeholders of the Gateway, they will have been identified before the study and will include individuals who have been involved in the design, development, implementation and management of the Gateway. It is expected that up to 15 individuals will be sampled. Offenders: both in-depth interviews and focus groups will be undertaken with participants. For focus groups, participant groups will be chosen at random and contacted through the group facilitators of the LINX workshops. The focus group discussions will take place following the LINX workshops. Any client group that is currently enrolled in the treatment programme is eligible for a focus group discussion. Based on feasibility and the necessary resources required to organise and manage the focus group discussions, between 5-10 groups will be feasible within the given time period. A further sample of up to 15 participants, will be recruited for in-depth 1-2-1 interviews, which will be undertaken over the telephone, with verbal consent. Potential participants will first be contacted by a Gateway Navigator, who will request their permission for the research team to make contact by phone and text, and email them a copy of the Gateway process evaluation leaflet at least one day before researchers make contact. Once an interview has been arranged, the PIS will be emailed to the participant at least 24 hours in advance, to allow time to read through. Researchers will go through the PIS and read out the consent form to participants over the phone, and ask to provide verbal consent. Participants will receive an email copy of the consent form as a confirmation. Participants will be able to withdraw at any point.

In-depth interviews with Gateway navigators, key informants and Police in other regions: To explore the process of Gateway, how the effects may differ from one context to another, and the replicability of the Gateway programme beyond Hampshire, in-depth interviews will be undertaken with Senior Police Officials in other Policing Districts; and with national and local policy makers. Suitable participants will be identified through YTU, our Police Partners and through the impact strategy plan. The interviews with Gateway navigators will be conducted face to face at a community centre in Southampton, Portsmouth, Isle of Wight or Basingstoke; interviews with key informants and Police in other regions will be conducted by phone or in-person.

Routine data: Routine data from the main implementing agencies will be used to examine the fidelity, dose and reach of the Gateway intervention. The police data will be used to track and follow-up outcomes of those receiving usual care, such as the outcomes received in court (punitive versus non-punitive). The latter will be used to profile the sample and establish the precise routes taken for the control arm.

To ensure that researcher blindness is maintained for the main trial, the in-depth interviews and focus group discussions with participants from the Gateway intervention arm will be carried out by researchers that are not involved in the Gateway trial recruitment and follow-up.

All stakeholder and navigator participants will be offered a £10 shopping voucher in gratitude for their time. All the young people taking part in the process evaluation interviews and focus groups will be offered a voucher or cash incentive and, where relevant, travel expenses, in line with payments to participants in the quantitative trial element of this project. See section 11.4 Recruitment for full details.

10.3 Data Analysis

For structured observation between navigator and participant, the use of either conversation analysis or thematic analysis will be explored. Due to the unknown nature of the interaction, it is not possible to state which type of analytical approach will be used. Evidence suggests that active listening and an open agenda is the most effective way to ensure that health needs are identified (53, 60); and that the study of talk-in interaction, such as Conversation (or Disclosure) Analysis, would be appropriate. We will, however, explore this further through initial feasibility work. For interviews, focus group discussions, and observed interactions between LINX facilitators and participants, the qualitative data will be analysed using the thematic approach as outlined by Braun and Clark (61). Routine data will be obtained through the implementing agencies over the study period and entered into secure databases. The statistical analysis of the data will be undertaken using Stata version 14. Descriptive statistics including median (IQR), mean (SD) and number (%) will be used to assess fidelity, dose and reach; and profile the cohort of participants.

Standard methods will be used to safeguard rigour, including multiple coding to check the validity and consistency of coding. The lead qualitative researcher will second code a selection of the transcripts and the whole research team will be involved in discussions relating to the interpretation of the data. An audit trail of study procedures will be kept along with a journal to track reflexive practice to maintain transparency (62, 63). Negative case analysis will be used as this involves searching for elements of the data that do not support or appear to contradict patterns or explanations that are emerging from the data analysis (64). All these measures will help avoid premature theme formation and incomplete representation of data.

11 TRIAL PROCEDURES

11.1 Set up of sites

The procedures for recruitment and randomisation of participants as detailed below have been established at Southampton Police Station. All sites will access the same eligibility and randomisation tool, based at Southampton. The system will record which centre police investigators are based at and each centre will have an identifier within the participant unique identifying number.

To allow for training of police investigators at the sites and ensure delivery of the Gateway intervention is possible and consistent with the current model, the following timetable for bringing sites on board is planned.

- Portsmouth: 1 March 2020 (were hoping for 1 February but not feasible)
- Basingstoke: 1 March 2020
- Isle of Wight: 1 May 2020

11.2 Training of Police Investigators to recruit and randomise

The HC Gateway Project Lead and Project Sergeant (the HC Gateway Team) have trained the police investigators at Southampton and will undertake the training of investigators at the additional sites. They will arrange training sessions for all the relevant teams across the Northern (Basingstoke) and Eastern (Portsmouth and Isle of Wight) areas of Hampshire. This

will be face to face training for each team or shift delivered in their own station or office. They will use existing team briefings or meetings, including when some teams have ring-fenced training time. A record of training will be kept and shared with the UoY researchers. Investigators new to sites during the recruitment period will be identified and training delivered as appropriate.

Due to abstractions (e.g. annual leave, sickness, operational commitments) not all relevant staff will receive face-to-face training. Therefore information about Gateway will be cascaded by those trained colleagues (particularly sergeants) when Gateway processes need to be used. Within the main custody centres of Portsmouth, Basingstoke and Newport (Isle of Wight) at least one key individual will be identified as a point of contact to act as an 'ambassador' who will be given some additional training. They will act as local subject matter experts and be able to advise and nudge on behalf of the HC Gateway Team in Southampton. This will not be a formal role and will be in addition to their normal job.

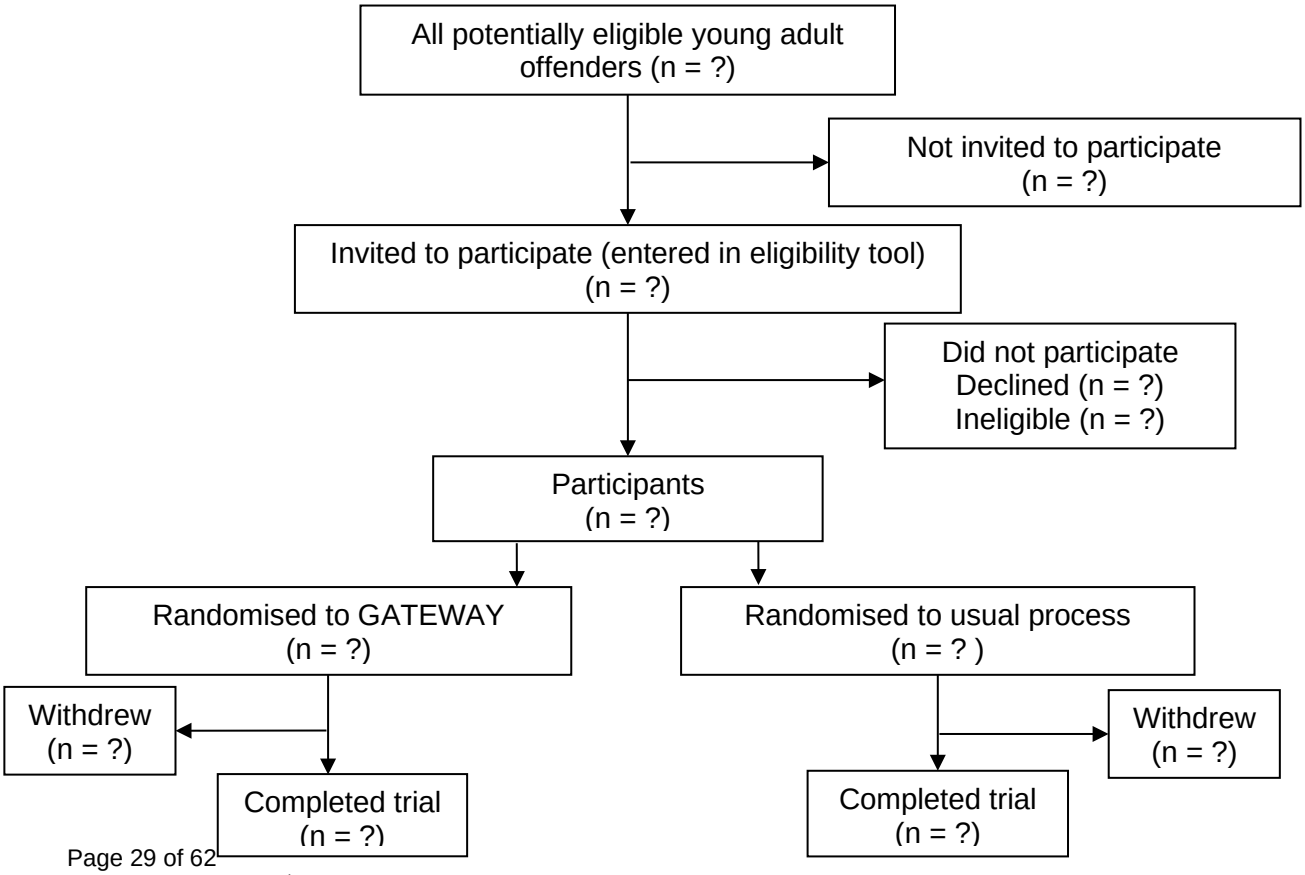
The HC Gateway Team will maintain the HCFA intranet site for the Gateway project. This site contains information including: a copy of the training materials, Gateway study and intervention processes, a short video about the study aimed at potential participants, copies of relevant forms, FAQs and contact details for the HC Gateway Team.

The HC Gateway Team will continue actively scanning the police Records Management System (RMS) to identify potential Gateway participants who are being dealt with in and out of custody. They will prompt relevant investigating officers/staff at sites to use the Gateway process with details of where they may also find more information. Where relevant, additional advice and support will also be given over the phone or in person if that is practical.

This hub and spoke model for the delivery of training will be reviewed by the HC Gateway Team and progress discussed at TMG meetings. Where necessary revisions will be made during the roll out of training to sites.

11.3 Site recruitment flow chart

A breakdown of numbers by site will be provided where this information is available.



11.4 Recruitment

The study population represents a vulnerable group with complex and overlapping health and social needs. Most will be disadvantaged young adults, faced with previous and continuous adversity, such as unemployment, substance misuse, or exposure to abuse. Our process for recruitment acknowledges that engaging this target population is likely to be challenging. Initially, as a thank you for their time, the participants were issued with a high street shopping voucher for £10 following each meeting with a researcher where a Case Report Form (CRF) was completed. An additional £5 voucher was offered to those attending face-to-face meetings as a contribution to travel expenses. Those completing an interview over the telephone were to be sent a £10 voucher via email. However, we have experienced difficulties in getting participation in Week 4 interviews, with the current incentive being ineffective in attracting adequate numbers to attend meetings. Our PPI representative has advised that an increased amount and payment in cash are likely to improve the attendance rate and completion of the CRFs. Some participants will need to travel long distances to a meeting, with associated expenses in excess of £5, whilst others would need to take time off work in order to attend. Members of the TMG have agreed that changing from the voucher format to cash is also likely to increase universal appeal of the incentive. An examination of guidance issued by the Health Research Authority supports the use of payments (Appendix 6: Payments to participants in Gateway: consideration of guidance on ethics by the Health Research Authority). We will therefore be paying £30 in cash for those completing a CRF and an additional £10 if they have attended in person. For those completing an interview over the phone we will email a voucher for £30.

To identify risks in the recruitment process, initial feasibility work was carried out by Inspector Lee Fryatt of Hampshire Constabulary. The overall process of screening for eligibility, randomisation and recruitment in the custody suite was addressed through preliminary data and discussions with Custody Sergeants.

As by law the police have to know the destination for an offender, randomisation has to take place in the police station at disposal. It has now become apparent that for legal and safety reasons, it will not be possible for a researcher to be based in the custody suite.

Investigators dealing with potential participants will be briefed on the study and provided with a script for guidance when enrolling participants. They will also be trained in obtaining stage 1 consent. It will be made clear to participants that they will be provided with more details of the study at a later date by a researcher from the UoS and have the right to withdraw at any time.

The investigators will also be trained to use the web-based eligibility and randomisation tool to ensure accurate recording of selection information. They will use the tool once an offender has expressed an initial interest and signed the stage 1 consent form. Participants will be informed of their random allocation during disposal from the police station.

We will be unable to collect baseline data on the primary or secondary outcomes at the time of or immediately after randomisation, but instead have added a four-week data collection time point to the trial. Permission will be sought from participants for the police to provide the UoS with their contact details and to access their police records for data on variables such as age, gender and ethnicity and offending history, trigger offence and any subsequent re-offending.

11.5 Screening and pre-randomisation procedures

The investigators will be trained to confirm the following prior to using the eligibility tool:

- Suspect is aged 18-24 years
- Suspect lives within the HFCA area where the Gateway programme is being delivered
- Anticipated guilty plea (i.e. admitted the offence and said nothing which could be used as a defence or has made no admission but has not denied the offence or otherwise indicated it will be contested)

- Suspect does not need an interpreter
- Suspect does not already have a Gateway programme flag
- A disposal decision has been made (i.e. full code test 1 has been met)

If the individual meets these criteria, express a willingness to take part in the study and are not disqualified because of the exclusion criteria, the investigator logs in to the electronic eligibility tool (available at all sites) and responds to the following questions:

1) Please enter your collar number (5 digits)
2) Enter 11 digit RMS number
3) Offender RMS ID (7 digits)
4) Has the offender signed a stage 1 consent form stating that they understand the options available to them? Yes = next question. Consent not sought as offender already identified as not eligible for Gateway.(please continue with survey in order to record reason for ineligibility) = exclude
5) Is the disposal decision for a conditional caution? YES = Q7 NO = Q8
6) Has a supervisor identified any reason why a Gateway Caution is not suitable in this case? YES (please indicate reason in comments box) = Exclude NO = Randomisation to Gateway caution or different conditional caution
7) Is the offence;
   Hate crime
   Domestic crime
   Knife crime
   Sexual offence
   Drink/Drive or endorsable traffic offence
   YES to any = Exclude
   None of the above = continue
8) Is this an indictable only offence? YES = exclude
9) Is this a breach of court order or a sexual offences order? YES = exclude
10) Is a remand in custody being sought? YES = exclude
11) Does the offence involve death or serious injury (wounding or GBH) as per CPS charging standards, or serious threat to another person? YES = Exclude
12) Is the offender likely to receive a custodial sentence (if unsure please refer to Sentencing guidelines)? YES = Exclude
13) Does the offender have any serious previous convictions within the last 2 years? (i.e. serious violence, GBH or above, serious sexual offences, robbery, any indictable only offence) YES = Exclude
14) Summary offences must not be more than 4 months old. Please tick one of the following answers: Not a Summary offence = continue; Summary offence less than 4 months old = continue; Summary offence over 4 months old = Exclude
15) Is the person subject to any of the following;
   Court bail
   Prison Recall
   Red IOM (Integrated Offender Management)
   Currently under probation
   YES to any of above = Exclude
   None of the above = continue
16) Has a supervisor directed that due to another reason Gateway is not suitable? (If yes please indicate reason in comments box below) No = Randomisation

Offenders meeting the criteria will be randomised to receive the intervention (Gateway Caution) or be processed as per usual practice (prosecution or different conditional caution).

11.6 Consent process

A staged approach to obtaining consent will be taken to facilitate recruitment at the point of disposal.

Stage 1 consent: During processing, offenders will be identified as potentially eligible by the investigator. For legal reasons, the investigator will tell the offender about the potential option of a Gateway Conditional Caution instead of a court summons or a different conditional caution. If the offender says they are interested in a possible Gateway Caution the investigator then verbally informs the offender about the 'University study' and offers them a Gateway Leaflet Stage 1. A Stage 1 combined investigator script and participant information sheet (PIS) and consent form will be used for consistency. If the offender agrees to take part in the study, the investigator will obtain the offender's signature on the Stage 1 PIS and consent form.

At this point the investigator will check the individual offender's eligibility in the web-based eligibility tool and if confirmed, randomisation will be carried out. The participant will be told their allocation at this point as part of disposal from the police station.

Stage 1 consent will include permission for the police to pass the individuals contact details to the researchers and an understanding that they are being entered into the study. Permission for the researchers to email, telephone and text participants will be explicitly obtained.

A small number of participants recruited through the out-of-custody process (see 11.9), will be contacted by telephone to have the Gateway caution option and study participation explained. They will be asked to give verbal Stage 1 consent to participate. If verbal consent is given, their details will be entered in the eligibility tool and randomisation will be carried out. A note that verbal consent was given will be included in the offender's incident record. Written consent will subsequently be sought prior to any trial related activities for the participant. Anyone declining to confirm their verbal consent in writing will be withdrawn from the trial. This approach is necessary to ensure all potentially eligible participants have the chance to join the study and is in keeping with the pragmatic nature of this trial. (See section 11.9 Enrolment procedure; and 17.3 Consent).

The researchers will attempt to make contact with participants within two weeks of randomisation to provide them with further information about the study and attempt to arrange the first meeting. However, a degree of flexibility will be exercised, for example, where this is dictated by the timing of the receipt of participants' details following randomisation, or researchers' availability.

Stage 2 full PIS and consent: At the week 4 data collection point the researchers will provide participants with a copy of the full Stage 2 PIS. The researchers will go through the individual points on the consent form, providing explanations as required. Participants will be provided with any other information they may need, and any queries will be answered. After time to consider their involvement, and if they decide to proceed, full consent for participation in the trial will be obtained. This consent will relate to the collection of personal information, trial data at three data collection points and permission to access data from police records (recidivism) for up to 10 years from their enrolment in the study. Although the current study will be completed by 30 June 2023, at the suggestion of the funders, long term recidivism data will be assessed as a separate follow up exercise at 10 years.

In order to maximise participation, the week 4 consent and data collection point may occur at any time up to the second data collection point at 16 weeks. Should a participant attend for the week 16 interview having not attended week 4, consent will be taken at that point. Similarly, flexibility around the timing of the week 16 data collection point will be exercised.

Signed Stage 1 consent forms will be retained securely at Southampton, Portsmouth, Isle of Wight and Basingstoke Police Stations. Police study team members will collect completed forms from all sites for secure retention at Southampton Police Station. Scanned copies of completed

Stage 1 consent forms will be uploaded to a secure service (Huddle) accessible to researchers at the Universities of Southampton and York. The researchers in Southampton will retain in a locked filing cabinet in their office, the originals of the signed Stage 2 consent forms. Scanned copies will be uploaded to the secure Huddle platform or sent as encrypted files via a secure service to the research team at the University of York (UoY).

Consent for qualitative interviews, observations and focus groups will be obtained separately from Stage 1 and 2 for the trial. Potential participants in the qualitative research include offenders participating in the Gateway programme (clients), victims, commissioners and those delivering Gateway (e.g. police investigators and case workers).

Qualitative consent may occur at any point between week one or year one post randomisation, depending on the process within the Gateway intervention.

- Consent will be obtained to observe the interaction between navigator and client (video observation) at week 1.
- Consent will be obtained for observation, and focus groups, of those involved in LINX workshops at week 3 or week 10.
- Consent will be obtained for in-depth interviews of victims, clients, navigators and commissioners, between week 16 and up to 1 year.

These signed consent forms, where available, will be stored securely in locked filing cabinets in the researcher's office. Where verbal consent is obtained, this will be recorded on consent forms by the researchers electronically, and the forms will be stored securely on the UoS server. Each potential participant will receive a copy of the PIS for a specific component of the study and be given a minimum of 24 hours to decide. For those on the Gateway intervention, e.g. social workers and participants, the PIS will be given to potential participants through social workers at collaborative agencies e.g. The Hampton Trust (LINX workshop), No Limits and Southampton City Council (Gateway navigators), or emailed directly to them once the interview is arranged. For victims, the PIS will be offered through the supporting victim service (Restorative Justice), and for commissioners, the PIS will be offered via mail and email. A consent form will be signed by participants willing to take part in the interviews, including a separate form for being video recorded. Where written consent is not possible, verbal consent may be taken over the phone and confirmation emailed with the voucher gift.

Details of the PISs described above, who they are intended for and when they will be used are listed in chronological order of first intended use in the table below.

Participant information sheet ID	Participants	Time point of document use
gateway_leaflet_stage1	All potential trial participants	At stage 1 recruitment by police investigators.
Stage 1 script PIS and consent	All potential trial participants	At stage 1 recruitment by police investigators.
gateway_PIS_videoobservation_clients	Clients of Gateway intervention	A minimum of one day before consent to the video observation which will be undertaken at week 1 post randomisation.
gateway_PIS_focusgroups_clients	Clients of Gateway intervention	A minimum of one day before the observations and focus groups, which will be held at week 3 or week 10 post randomisation
gateway_PIS_stage2	Participants who have given Stage 1 study consent	At first data collection interview, usually Week 4 post randomisation, but may be at Week 16 if Week 4 does not take place

gateway_PIS_indepth_clients	Clients of Gateway intervention	A minimum of one day before the interviews, which will be held between week 16 and up to 1 year post randomisation
gateway_PIS_indepth_commissioners_otherpolicingdistricts	Police commissioners and other professionals involved in court diversions	A minimum of one day before the interviews, which will be held between week 16 and up to 1 year post randomisation
gateway_PIS_indepth_commissioners_localagencies	Members of stakeholder agencies involved in delivery of the Gateway intervention	A minimum of one day before the interviews, which will be held between week 16 and up to 1 year post randomisation
gateway_PIS_indepth_gatewaynavigator	Case workers (navigators) involved in delivering Gateway intervention	A minimum of one day before the interviews, which will be held between week 16 and up to 1 year post randomisation
gateway_PIS_indepth_victims	Victims of clients on the Gateway intervention	A minimum of one day before the interviews, which will be held between week 16 and up to 1 year post randomisation
gateway_leaflet_process_evaluation	Clients of Gateway intervention	A minimum of one day before researchers make contact, when first approached to take part by navigators

11.7 Loss of capacity during participation in the study

In the unlikely event that a participant lost mental capacity after consenting to take part, they would be withdrawn from the study. Data collected up to the point of withdrawal would be retained and used in the analysis as per consent obtained.

11.8 Withdrawal from study (Change of Status)

Participants will be free to withdraw from the trial at any point without giving a reason. The initial consent script (Stage 1), the full patient information sheet (stage 2) and all the qualitative interview PISs include information on how a participant can withdraw from the study, including who to contact. Forms for documenting withdrawal and other applicable change of status categories are available for use by the Gateway team and the UoS researchers.

Notice of withdrawal will be accepted face-to-face, in writing by letter or email, by telephone verbal or text message to anyone in the Gateway team or research team at the UoS. Change of status forms will be completed by the Gateway team and/or UoS researchers, uploaded to Huddle and the paper copy sent to YTU in a timely manner so they can record when a participant withdraws from the study.

Participants who withdraw from the study after giving Stage 1 consent but before giving Stage 2 consent will have their records wholly anonymised. For analysis purposes they will be treated as randomised to their allocated groups.

Participants who consent to stage 1, but not to subsequent stage 2 but without withdrawing, will still be treated as randomised to their allocated groups, but will not have any assessments.

For participants who withdraw following Stage 2 consent, the UoS will keep the information about them that has already been obtained up to that point. To safeguard the individual's rights under GDPR only the minimum personally identifiable information will be retained by the Universities.

Participants who decide to withdraw from the study at any stage, will not undergo any further follow-up related to the study. The data collected up to the point of withdrawal for any reason will be retained and used in the analysis as per consent given.

Participants who are randomised to receive the intervention but who breach their Gateway Conditional Caution and are referred back for a court appearance will continue to be approached for data collection and analysis will be on an intention to treat basis. A Change of status form must also be completed for these participants.

11.9 Enrolment procedure

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. Out-of-custody is where suspects attend a voluntary interview, normally at a police station (but not in the custody suite), however in limited circumstances the interview may take place in another location.

In-custody recruitment involves obtaining written consent immediately prior to assessment of eligibility and randomisation. The participant is disposed from the custody suite knowing the conditional caution or that they will be receiving a court summons in the post. The in-custody pathway is set out in Figure 1.

Out-of-custody recruitment (Figure 2) may proceed in one of two different ways:

1. If the investigator ends the voluntary interview knowing or believing that the outcome will be a conditional caution or prosecution (based on the available evidence and prior discussion with the duty Sergeant), they will explain the Gateway study and seek written consent. The suspect then leaves the police station and the investigator gets their Supervisor's final decision (prosecution or caution). This decision may be made immediately or may take days or weeks. The investigator then enters the suspect's details in the eligibility tool and records the randomisation outcome. If the participant is to receive either a Gateway or other conditional caution, they attend an appointment at the Police Station where the caution is issued. If the participant is allocated to prosecution, a summons is issued by post.

2. If the investigator ends the voluntary interview unclear about the outcome decision and/or if the suspect is eligible, no information about Gateway is given and consent is not sought. The suspect leaves the police station. The Supervisor will either immediately or in the following days or weeks, make the decision about whether to proceed. If the suspect is to be prosecuted or issued a caution, Gateway becomes a possible outcome. The Investigator contacts the suspect by phone using the standard police procedure for identification of the individual. The investigator explains the Gateway programme and seeks verbal consent, as it is not practical for the suspect to attend the police station at this point. If verbal consent is given, the investigator records this in the RMS and enters the suspects detail in the eligibility tool and records the randomisation allocation. If the participant is randomised to a Gateway caution or a different conditional caution, the investigator invites the participant to the police station where the relevant caution is administered. The Stage 1 Consent form is then offered for signing; if signed, the participant carries on in the study. If the participant does not provide written Stage 1 consent or refuses to attend the meeting, a change of status form will be completed indicating withdrawal of verbal consent and they will no longer be in the study. If the participant is randomised to prosecution, they will receive their summons by post and have no further Police interaction. In this instance (prosecution), the Investigator or the Gateway team will contact the participant and arrange to meet them to obtain written consent. If written consent is given they continue in the study; if written consent is not given (could include refusal to meet) they will no longer be in the study and a change of status form will be completed accordingly.

Figure 1: Gateway In-custody Recruitment Pathway

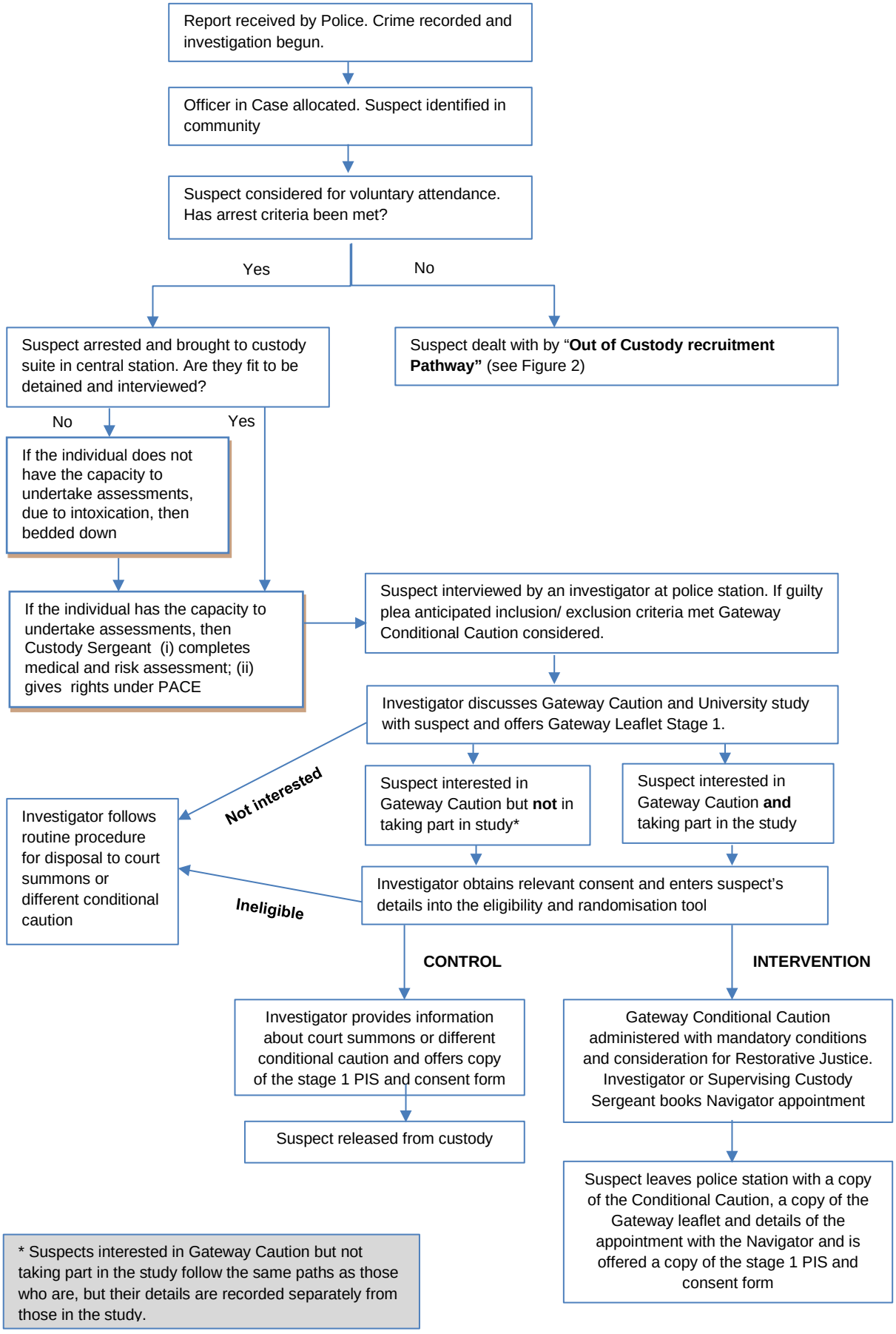
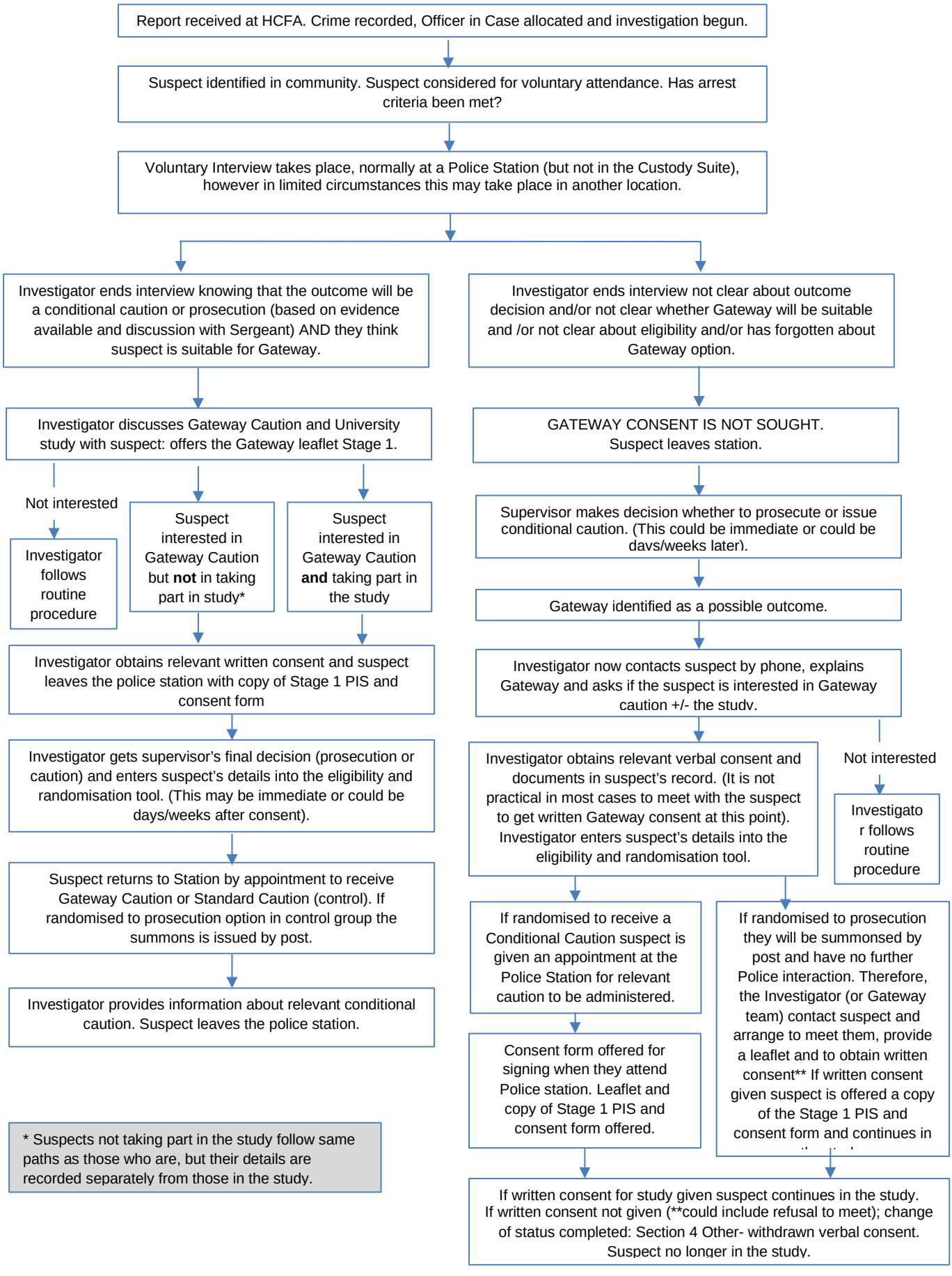


Figure 2: Gateway Out-of-custody Recruitment Pathway



11.10 Data collection time points

Structured interviews with participants allocated to both the intervention and control groups will take place within a community centre (T1 Week 4, T2 Week 16 and T3 1 year) located in central Southampton, Portsmouth, Isle of Wight or Basingstoke. Should participants be unable or unwilling to attend a face-to-face interview, then arrangements for a telephone interview will be made. However, the first interview will be a face to face meeting in order to obtain written informed consent. CRFs will not be sent to participants in the post.

Ahead of each data collection time point, a total of four attempts may 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. A link to a short information video about the study will be included in one of the texts from the researchers. Should these contact attempts be unsuccessful, a letter with a telephone number for the research team will be sent in the post to the participant. Contact attempts, including the letter, until contact is successfully established, i.e. a conversation takes place between a researcher and a particular participant, will be recorded by the researcher actioning these in a central log.

Once an appointment has been booked and the details have been confirmed to the participant, a text reminder will be sent to their mobile number at one week and one day prior to their booked appointment. Discretion will be applied in relation to the reminders, e.g. a one-week reminder may not be required if an arrangement is made and communicated very close to the meeting, or additional reminders may be scheduled if it is felt that the participant may benefit from these.

If the participant cancels an interview or misses it without notice, the researchers will attempt to re-establish contact in order to reschedule this. Up to four attempts will ordinarily be made, and a combination of texts or calls may be used. If these attempts are unsuccessful, ahead of the next time point up to four attempts will be made to re-establish contact and gauge availability.

The number of contact attempts is indicative, rather than prescriptive. Similarly, some flexibility may be required in relation to the timing of data collection points, with the latter influenced by participants' availability.

If no interviews take place at week 4, 16 and/or 1 year the participant will be deemed Lost to Follow up.

11.11 Blinding

Research team members involved in consent and data collection will be blinded as far as possible to participant allocation. Randomisation will be undertaken by investigators who are not involved in data collection for the study. The face-to-face and telephone assessment CRFs include a tick box for the researcher to indicate whether they believe blinding was compromised during assessment and if so, which group they believe the participant to be in.

Members of the study team responsible for statistical analysis of the study will be kept blind to group allocation. The statistical analyses will be performed blind to participant allocation.

11.12 End of study definitions

The end of the study is defined as the date when the last randomised participant has responded to their 1 year follow up questionnaire or been given the required opportunities to do so as outlined in 11.8. The study will be stopped prematurely if:

- The Study Steering Committee (SSC/DMEC) recommends this
- Funding for the study ceases
- It is mandated by the UoS Research Ethics Committee or Hampshire Constabulary Ethics/Senior Management Committee

The sponsor, funders, UoS Research Ethics Committee and Hampshire Constabulary Ethics/Senior Management Committee will be notified in writing when the study has concluded or if it is terminated prematurely.

12 DATA MANAGEMENT

12.1 Quality assurance and quality control

The UoS has agreed to be the lead sponsor for this project and take overall responsibility for the quality of study conduct. This study will be fully compliant with the Research Governance Framework (65). A trial specific data management plan will be produced and enacted by YTU to provide detailed instructions and guidance relevant to the Gateway study database set up, data entry, validation, review, query generation and resolution, quality control processes involving data access and transfer of data to the Sponsor at the end of the study, and archiving.

A rigorous programme of quality control will be undertaken. The day-to-day management of the trial will be the responsibility of the Trial Manager based at YTU. Regular meetings of the TMG will be held to monitor adherence to the trial protocol. Quality assurance checks will be undertaken by YTU where feasible, to ensure integrity of informed consent, randomisation, trial data collection and data entry procedures.

12.2 Data management

Study data will be recorded in a number of files for both the administration of the study and collection of participant data.

A Case Management System (Huddle) will be maintained by Southampton police as a key for linking the various sources of data for individuals together. For the purposes of analysis data will be pseudonymised, and for subsequent reports and publications the data will be wholly anonymised. For the purposes of ongoing data management, once randomised, individual participants will be identified using their unique study identification number.

Trial data will be handled in accordance with the appropriate data management procedures at YTU: e.g. DM01 CRF Design; DM03 Manual Entry of data; DM05 second checking of data. An independent data monitoring and ethics committee (DMEC) will oversee data management.

12.3 Data entry

The data will be collected by Researchers at the UoS using paper CRFs. Completed forms will be posted to YTU using pre-paid, pre-addressed envelopes, to be entered/scanned into a secure system (Teleform). Photocopies will be retained by the researchers at the UoS in a locked filing cabinet in their office.

Electronic data from databases may be sent and received electronically.

All trial data will be stored and transferred following YTU standard operating procedures. The staff involved in the study (both at Southampton and YTU) will be trained on data protection.

Data will be checked according to procedures in the Trial Management File and referenced in the trial specific Data Management Plan.

12.4 Data storage and archiving

Each site will hold data according to the General Data Protection Regulation (GDPR) and Data Protection Act (Great Britain 2018)(66); data storage will be regularly reviewed to ensure compliance with the new requirements. Personal data and special category personal data will now be processed in connection with this study under the legal basis of Article 6(1)(e) and

Article 9(2)(j) of the General Data Protection Regulation (GDPR), respectively for processing for the performance of a task carried out in the public interest, and as necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, with Article 9(2)(j) operating in conjunction with the safeguard requirements set out in Article 89(1) of the GDPR.

Trial data will be collated in CRFs identified by a unique identification number (i.e. the participant identification number). The researchers collecting the data will maintain a log of activity at the site and will list the participant identification numbers and YTU will also maintain a list of participant identification numbers for all participants.

All study data related to the qualitative, health economics and process evaluation elements of the study will be stored in accordance with the UoS Data Management Policy (http://www.calendar.soton.ac.uk/sectionIV/research-data-management.html). This data will be stored on a secure server, accessed via password protected computers at the UoS.

Qualitative data, such as notes, video recordings and audio files, will be securely kept at the UoS in locked cabinets or on password-protected and encrypted electronic devices for a minimum of ten years. All audio files will be deleted after transcription. Access to the data will only be granted to the research team. If any data is shared in any format, it will be transferred securely and with password protection. The secure online University Drop-off service or encrypted memory sticks will be used for electronic data transfer.

All data recorded electronically for the trial analyses will be held in a secure environment at the UoY, with permissions for access as detailed in YTU Data Management Plan. The UoY Department of Health Sciences Information Technology service provides YTU with a backup procedure approved by auditors for disaster recovery. Full data backups are performed nightly using rotational tapes, to provide five years' worth of recoverable data. The tape backup sessions are encrypted, and password protected, with tapes stored in a locked fire-proof safe in a separate secured and alarmed location.

All study files will be stored in accordance with Good Clinical Practice guidelines. Study documents (paper and electronic) held at YTU will be retained in a secure (kept locked when not in use) location for the duration of the study. All essential documents, including source documents, will be retained for a minimum period of ten years after study completion. The separate archival of electronic data will be performed at the end of the study, to safeguard the data for the period(s) established by relevant regulatory requirements. All work will be conducted following the UoY Data Protection Policy which is publicly available (67).

12.5 Source and data to be collected

Source	Data
Consent forms	Consent dates and signatures (Stages 1, 2 and qualitative)
Verbal consent	Recorded in individual's police record
Personal details form	Name, address, DOB, telephone number(s), email address
CRFs	Self-reported data for WEMWBS, SF12, AUDIT, ADIS, ACE, CSRI
Qualitative interviews	Interviews: video recordings and transcripts
Police databases	Recidivism and variables e.g. DOB, gender, ethnicity. Data on participant compliance with allocation.
Training logs and certificates	Training records for police investigators and researchers

13 PATIENT AND PUBLIC INVOLVEMENT

13.1 Pre-study Patient and Public Involvement (PPI)

Patient and Public Involvement (PPI) has driven this proposal from the outset. The LINX workshops, within the Gateway intervention, have been developed by the Hampton Trust – who deliver several interventions for court mandated young perpetrators of domestic abuse. This charity led approach to prioritisation has meant the public have been integral from the earliest stage of conception. Three PPI meetings were held with young adults currently on a Hampton Trust programme: two with adults aged 18-24 (3 attendants); and one for ages 24+ (2 attendants). In March and August 2017, we consulted the groups on various aspects of the study including importance, acceptability and feasibility. The representatives unanimously felt the Gateway programme would have significant benefit, with one older representative stating it, "would have helped me at that age. I was in and out of prison about seven times when I was younger; nothing addressed the root of what was the matter." The groups fed back in detail around the logistics of the study: the process around randomisation and consent; ways to manage challenges following up the control arm; and opinion on assessment forms. These suggestions have been incorporated and shaped the design of the study. Furthermore, a young adult PPI group was consulted during the production of the PIS, providing constructive feedback. These PISs will be again shown to our PPI representatives, representing a group of young adult offenders.

13.2 PPI involvement during the study

There will be two members of the SSC/DMEC who will be Public Representatives.

One is an ex-offender, and currently works for Hampshire Youth Offenders Team (HYOT) as a peer mentor and support worker. The other PPI representative is a victim advocate who works for a victim charity and who will represent victims at the SSC/DMEC.

They represent the voice of the service users at Steering Group meetings, helping the group reflect on the realities of delivering the programme from the user perspective, and reminding the committee of some of the vulnerabilities and needs of this population.

These two representatives will also work closely with the PPI co-ordinator for the study, providing strategic input, advice and guidance throughout, with a particular focus on the logistics of getting the project underway, reviewing and adapting the protocol. The victim advocate will focus on providing input on acceptability from the victim perspective based on different offences, as well as providing guidance and input throughout any victim satisfaction evaluations. Both will be actively consulted throughout the project.

Input from offender representatives:
The PPI co-ordinator will work closely with partners at The Hampton Trust to involve young adult representatives who have been through the Gateway programme, and have a clear understanding of the challenges and benefits that participants might face. We will also work with HYOT to involve young adults with experience of the criminal justice system, but no prior knowledge of Gateway, to help provide a perspective from those not previously familiar with the programme. Young Adult PPI representatives will work with the PPI co-ordinator to develop consent forms, PISs, and initial information leaflets, plan recruitment strategies and consider the most effective ways of arranging interviews and qualitative work.

Widening PPI representation
Additionally, a Public Participation Panel (PPP) will be set up throughout the study, which will be made up of community leaders and representatives from different groups in the city, including a Victim Advocate from a local victim agency and a Reformed Perpetrator. We may also consult with wider stakeholders at key points, such as the Magistrates, defence lawyers, and other representatives from the Criminal Justice System.

We will also invite local community leaders, and members of the public, to the PPP meetings. We will work closely with this group to ensure we understand the concerns and attitudes of the wider community. Our dedicated PPI officer will develop a coordinated plan to support this approach. We have costed in dedicated PPI support to help coordinate this.

14 VALUE TO NHS LOCALLY AND NATIONALLY

Research into the effectiveness of OCBIs and diversion outside of the criminal justice system has mostly been undertaken outside of the UK. A recent study in the US showed that diversion to health services can help to improve life satisfaction and reduce the likelihood of re-incarceration of offenders with mental serious mental illness and co-occurring substance use disorders (13). Despite there being an increased acknowledgement of the role OCBIs and diversion can have in the increased health and well-being for young adult offenders, the evidence base for diversion is still unclear and the consensus around what constitutes an effective model remains under investigated (5,6,14). A quasi experimental study on the effect of a OCBIs for young people under the age of 18 found improved mental health outcomes at the end of the intervention; although the interpretation of the results were limited by the small sample size and methodological design (6). A recent meta-analysis suggests that the outcomes of OCBIs are dependent on the type of intervention used; and that reduced reoffending rates may not be observed for some intervention types (15).There is a need for better evidence-based practice, as well as improved methodologies for this target population.

The 2013 Harris Review on self-inflicted deaths in custody 'Changing Prisons, Saving Lives' calls for more to be done to divert young adults from entering the criminal justice system; increased availability of child and adolescent mental health services; and earlier prevention within the community (12). There is now a growing impetus to address the needs of young adult offenders aged 18-24, who represent a population at risk of poor mental health outcomes, including risk of alcohol misuse, drug abuse, self-harm and suicide (10,16). Furthermore, there is an interest in understanding the potential for cost savings where the current social and economic costs of young offenders is estimated at around £19 billion a year; placing considerable pressure on public finances (10). Evidence from RCTs suggest that community-based interventions for children (aged 13-17) on a court referral order, or a supervision order, can reduce societal costs for young people with severe psychosocial and behavioural problems, and generate cost savings (17).

The Gateway programme responds to and integrates two evidence-based theories related to reoffending behaviour. First, through the integration of the seven pathways, which consider the determinants of reoffending, including health, housing support, education training and employment; drugs and alcohol; families; finance and debt; and attitudes, thinking and behaviour. Second, through the integration of empathy training, which also draws on a restorative justice approach. The seven pathways to reoffending and restorative justice are deemed integral to rehabilitation and improved quality of life and improved victim satisfaction (18). However, there remains knowledge gaps into the effectiveness of interventions that draw on these approaches. This study therefore seeks to add to the knowledge base, by examining the effectiveness of the Gateway programme at improving health and wellbeing for young adult offenders (aged 18-24), reducing recidivism and improving victim satisfaction compared to usual care. By evaluating the potential barriers and facilitators to its implementation (19), the study sets out to assess the potential scalability and replicability outside of the largely urban Police District setting of this study.

15 DELIVERABLES AND IMPACT

The main outputs will be the production of a formal report and a short summary report in plain English (referencing the full report) outlining the key methods, results and implications for policy

and practice. The target audience for this report will primarily be composed of individuals and organisations involved in health, social care and policing. This might include, for instance, volunteers, social care workers, investigators, researchers, and clinicians. As the audience may not be familiar with research, the language will be in plain English, with limited technical language relevant to the research. Further outputs include dissemination within academic and policy making circles. These have been described in the next section.

The potential impact of the study outputs are as follows:

- The research primarily will have an impact on vulnerable population groups (offenders and victims) who are not effectively engaged in research as they are harder to reach. The risk of not engaging this population group, however, will widen health inequalities and its impact on society.
- As the main beneficiaries of the research study, this research will potentially have an impact on an offender's engagement in, knowledge and attitudes of, and improvement in, health and well-being.
- The economic evaluation used in this study will provide key evidence to inform decision making: on the cost-effectiveness of the intervention, the potential to make cost-savings and improve public finances.
- The results of the study will be shared with key parliamentary groups, including the Ministry of Justice, thereby influencing decision-making on the commissioning of services outside of the HCFA. The evidence may support policy decisions or changes to legislations, regulations and guidelines on OCBIs. A few individuals have already been identified and will be contacted; including Lord Harris and Lord Bradley, who produced the Harris Review and the Bradley Report, respectively.
- It is expected that at least five publications will be published in academic journals including open access journals. This will be to maximise the evidence-base and knowledge uptake across academic disciplines; and will benefit the wider academic community in the future.
- By increasing public discourse around OCBIs and increasing public understanding on the evidence, there will be wider impacts to culture and society; contributing towards improved relationships between groups and enhancing community cohesion.
- The multi-agency approach established through the study will enhance collaboration within the community; by working towards shared objectives, for the benefit of the local community and wider society.
- Where the stakeholders of the research are also non-governmental organisations and public services, the research will also increase the effectiveness of public services and policy.
- The study evidence will also be used to enhance the practice of front-line services, such as the Liaison and Diversion scheme; and will therefore have a wider impact on improving services for users and improving the knowledge base of practitioners.

16 COMMUNICATIONS AND DISSEMINATION

The primary output from the study will be the report to the NIHR Public Health Research Programme.

The study has the potential to create a wide impact by influencing and improving: health and welfare; public policy and public services; culture and society. To maximise the impact of the study by informing the wider public involved and interested in the project scope, we will develop a strategy that reaches commissioners, care providers, policy makers and the wider public.

Our dissemination approach will engage the following three groups of beneficiaries:

16.1 Project partners and the wider public (non-academic)

Evidence disseminated through PPI representatives, PPP and SSC/DMEC and (involving all implementing agencies).

- The Hampton Trust will be involved in sharing findings within their own networks; by using face-to-face meetings, social media and email correspondence.
- The Hampshire Constabulary and Police and Crime Commissioner will present final findings at the College of Policing, which includes the What Works Centre for Crime Reduction, alongside the academic partners involved in the project.

16.2 Academic audiences

- Dissemination through the National Institute for Health Research Applied Research Centres (NIHR ARC). The NIHR ARC Communications Officer will be directly involved in publishing research updates bi-yearly through a blog.
- Peer review publications and conference presentations within an academic audience, including public health, criminology and policing. Journals may include the BMJ, BMC Public Health, and Policing and Society, an international journal of research and policy. Abstracts will be submitted for presentation of the results at relevant conferences, such as The Society of Evidence Based Policing Conference, The Society of Social Medicine Conference and The Faculty of Public Health Conference.

16.3 Policy makers

Development of an impact strategy and project plan will be undertaken by the Public Policy Research Facility at the UoS.

17 ETHICAL CONSIDERATIONS AND APPROVAL

17.1 Regulatory compliance

The study will be conducted in compliance with the approved protocol, and the principles of Good Clinical Practice, where applicable. The sites in HCFA will comply with the protocol and applicable national regulations, including Mental Capacity Act (2005).

See also section 18.5 and appendices 3 and 4 for the applicable study approvals required; and appendix 5 for the governance approval required.

17.2 Ethical conduct of the study

The study will be conducted to protect the human rights and dignity of the patient as reflected in the 2013 version of the Helsinki Declaration (68).

17.3 Consent

Our feasibility work indicated that staged consent was the most practical option within the study design (69). In the first stage, all potential participants will be given information initially about the Gateway programme and asked if they are interested in being randomised to the Gateway Conditional Caution or processing as usual for a court summons or a different conditional caution (i.e. not Gateway). If they express an interest in the Gateway Conditional Caution as a potential option, they are then told about the study and asked by the investigator if they are interested in participating in the study. Depending on the response they are asked to sign the relevant sections of the Stage 1 consent form. For a small number of participants who are initially recruited over the telephone, randomisation will take place based on verbal consent,

(See section 11.6 Consent process for full details). Signed Stage 1 consent will subsequently be obtained prior to any information being shared outside HC. If written Stage 1 consent is not obtained, the participant will be withdrawn from the study.

The investigator then enters information in the eligibility tool and, if eligible, the individual is randomly allocated to either the intervention or usual process. Only participants who have consented to take part in the research will have their personal contact details passed to the research team at the UoS.

At the second stage, the UoS researcher will ask participants if they are willing to continue in the study: involving assessment at three time points and for their data in police records to be accessed for up to 10 years, for the purposes of the research. The full patient information sheet (Stage 2 PIS) will include information related to the study's aims and objectives, as well as any risks/benefits of the study, and how to withdraw from the study at any point.

If selected for qualitative interview or for observation, the participants, selected victims and staff delivering Gateway, will be provided with information, given the relevant PIS and asked to consent to be interviewed and/or filmed for research purposes.

At each point of gaining consent, the principles of research ethics will be observed; and participants will be aware they can opt-out at any time without giving a reason.

17.4 Confidentiality

The researchers and investigators will ensure that participants' anonymity is maintained and that their identities are protected from unauthorised parties. Participants will be assigned a unique identification number and this will be used on consent forms, CRFs and other records.

Person-identifying information will only be used when specific consent for its use for research purposes has been given to the investigator by the participants in writing. Details will then be stored securely in the police research Case Management System (Huddle) for sharing only with the research team: a) passing contact details to the researchers to arrange meetings for data collection; b) linking data on recidivism etc.

All records will be kept in locked storage and transferred using secure means. All consent forms will be secured safely in a separate compartment of a locked cabinet: Stage 1 originals at Portsmouth, Isle of Wight and Basingstoke will be transferred to Southampton Police Station and Stage 2 at the UoS. Electronic copies of Stage 1 and Stage 2 will be held securely on Huddle with password protected access. Personal information will not be released, except as necessary for study monitoring purposes.

At the end of the study, data held by the UoS and the UoY will be securely archived for a minimum of ten years.

All information provided for the purposes of this study will be kept strictly confidential. However, if a participant discloses information that may mean the future harm of another individual or relate to an offence for which they have not been charged, then the researchers are required to break that confidence by law. Examples of such disclosures are outlined in the Stage 2 PIS. The research team at the UoY and UoS will be the only individuals with access to study data. Primary data will be pseudonymised using a unique identifier code. A link back to the participant details will be possible through the Case Management System (Huddle).

A police data analyst will ensure that all routinely collected police data is pseudonymised before being transferred. In order to access police data, a confidentiality agreement between the respective parties has been drawn up, agreed and signed. The confidentiality agreement protects an individual's personal information by ensuring that anyone handling the data does not

use or divulge or communicate to any other person; exceptions which will be outlined in the data sharing agreement (e.g. where disclosure of Police Data is ordered by a Court of competent jurisdictions). Confidentiality agreements will also be sought for any other data should this be necessary.

17.5 Research ethics approvals

The outline proposal was submitted to the Hampshire Constabulary Ethics Board, who have agreed to support the study and confirmed that no further Board considerations are needed. Should any ethical issues arise these will be referred for discussion at the Hampshire Constabulary Ethics Board meeting.

In addition, the study protocol and all associated study documents such as information sheets, consent forms, and questionnaires, will be submitted to the UoS Ethics and Research Governance Board for approval. The UoY Health Sciences Research Governance Committee (HSRGC) does not require the study to be submitted to them as approval will be obtained from the UoS. The UoY HSRGC will be provided with copies of approvals once obtained.

External Ethics Boards:

- **HRA Research Ethics Service approval.** As the research study does not involve the NHS, nor participants identified through the NHS, the proposed study does not require NHS research ethics committee approval.

- **Social Care REC approval**. Although the research study is funded through the NIHR Public Health Research Programme, and not the NIHR School of Social Care Research, the study may still be considered as social care research and therefore the remit for the Social Care REC was obtained. The Social Care remit is attached as Appendix 3. According to the remit, the study does not require Social Care REC ethical approval, as sections 1-9 do not apply. It is important to clarify that study participants will have the capacity to give consent in accordance with the Mental Capacity Act (2005).

  According to the Social Care REC, studies do not require review by the Social Care REC if it is reviewed by another committee operating 'in accordance with the ESRC's Framework for Research Ethics.' (See attached letter; Appendix 4) The HEI Ethical Board at the UoS governs in accordance with the ESRC's Framework and is therefore acceptable for social care research operating outside of the Social Care REC remit.

- **Her Majesty Prison Probation Services** (HMPPS, formerly NOMS). Confirmation was sought from the National Research Committee at HMPPS. According to HMPPS, if the research requires accessing prospective participants that are under the care of HMPPS or National Probation services or HMPPS/probation services or facilities are used to identify people then HMPPS /NRC approval would be required. 'As participants are being recruited under the care of the police service and not HMPPS, therefore HMPPS / NRC approval is not required.' (See attached email confirmation as Appendix 5).

17.6 Researcher safety

Primary data collection will be undertaken in accordance with the UoS Primary Care Population Health Department's lone working protocol where appropriate. Researchers have undertaken the safety training offered by Hampshire Constabulary.

17.7 Participant and victim safety

Ethical considerations were discussed with all project stakeholders including our PPI group (young offenders) and advisors from the Police and Crime Commissioner's Office. The main considerations related to the impact of the research on the young offenders, as well as victims,

who represent a vulnerable population. There were concerns about the risk of coercion due to the study recruitment taking place within a police setting. To circumvent this issue, we will:

- inform eligible offenders that they can choose not to enrol in the study and can opt for usual care if preferred
- provide simple information in the verbal and written form about all study components and what it means for them. These materials were tested during our feasibility work in Autumn 2017 and were revised again with our PPI group
- consult the PPI groups (offenders and victims) in the development of any study materials
- receive peer input from PPI representatives, including a victim advocate and a reformed perpetrator within the SSC/DMEC, throughout the study period (see Section 13.2)
- ensure that participants are made aware of the independence of the academic research team

17.8 Indemnity

This study will be sponsored by the UoS. This project is covered under the terms and conditions of their Professional Indemnity and Clinical Trials Insurance, subject to informed consent being obtained from the participating volunteers.

This study falls within the UoY automatic public liability insurance cover as the research is within the UK and limited to questionnaires and interviews with adults. In addition, the YTU has insurance cover for claims for compensation for the trials undertaken by the Unit.

18 PROJECT MANAGEMENT AND GOVERNANCE

18.1 Project management

The governance structure for the study will comprise a Trial Management Group (TMG), and an independent Study Steering Committee (SSC) which will also act as the Data Monitoring and Ethics Committee (DMEC). The Chief Investigator (CI) will have overall responsibility for the study. YTU will be responsible for project management of the trial.

18.2 Trial Management Group (TMG)

The TMG is the executive decision-making body and is responsible for overseeing the day-to-day running and management of the trial. The group will comprise the CI, co-investigators, Gateway Police Officers, Trial Manager, Process Evaluation Lead, Trial Statistician and Trial Coordinator. The TMG will meet regularly, at least once a month during the set up phase of the study, and thereafter according to the needs of the study. Meetings will be via teleconference and/or face-to-face.

18.3 Study Steering Committee (SSC) and Data Monitoring and Ethics Committee (DMEC)

Due to the low risk nature of the data in this study, the SSC will also take on the role normally undertaken separately by a data monitoring and ethics committee (DMEC). The independent members of the committee will be allowed to see unblinded data if required. Ethical issues will be a main focus for the independent members.

The SSC/DMEC will provide overall supervision for the study on behalf of the study sponsor and study funders and to ensure that the study is conducted in accordance with the protocol and 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 of the SSC/DMEC will comprise of an independent Chair and at least two other independent members, a patient representative, the CI and the Trial Statistician. Other study co-investigators and observers (e.g. from NIHR Local Clinical Research Network) may also attend the meeting at the discretion of the Chair. The committee will meet at least four times during the study or more frequently if the committee requests. Meetings will be face-to-face when possible and via teleconference where necessary.

18.4 Quality assurance and quality control

The UoS has agreed to be the lead sponsor for this study and take overall responsibility for the quality of study conduct. This study will be fully compliant with the Research Governance Framework and, where relevant, MRC Good Clinical Practice Guidance.

A rigorous programme of quality control will be undertaken. The day-to-day management of the trial will be the responsibility of the Trial Manager based at YTU. Regular meetings of the TMG will be held and they will monitor adherence to the trial protocol at the trial sites. Quality assurance checks will be undertaken by YTU to ensure integrity of randomisation, informed consent, study entry and data collection procedures.

18.5 Risks and benefits

The main risk for the offenders participating in the study is the nature of the topics discussed during quantitative assessments and qualitative interviews; which include discussions on mental health and drug and substance use, as well as adverse childhood experiences. Offenders, who are allocated to receive the intervention, will also be encouraged to examine their own behaviour and its impact, which may be challenging and distressing for them. All assessments will be supported by experienced social workers, who are experts in discussing these issues.

For victims, their involvement in Gateway is linked to the crime carried out by the offender. If they are willing and consent to take part in a qualitative interview, the discussions may cause some distressing thoughts or emotions to arise. To support victims, we will work closely with trained workers at Restorative Solutions who have experience of working with victims, and will be able to offer both victims and researchers support and advice. Prior to obtaining consent, all victim participants will be made aware that their participation is entirely voluntary and will be aware that they will be able to terminate interviews at any point.

A further risk relates to public perceptions around OCBIs as alternatives to criminal justice. We will therefore engage with a representative group of the public through public participation panel meetings to seek their advice on how the study should be promoted and disseminated.

A related risk is the public perception that offenders are being paid as a result of committing a crime. Against this it is argued that payments are needed to increase collection of the required data, and payments are within the relevant Health Research Authority guidance. In addition, the decision about payments was supported by the study PPI advisor. Payments are confined to those giving up their time to participate in the trial, which is time limited and will only include sufficient participants for conclusions to be reached. A short public resource will be produced which will document the rationale for payments and include the positive results that police diversions have had based on previous studies. This will be used when appropriate.

A major benefit of this study is the provision of a comprehensive assessment of the Gateway intervention exploring whether the intervention is effective at improving outcomes for offenders aged 18-24 years and is cost-effective in comparison to usual care. This is essential for commissioners, policy makers and agencies involved in work with young offenders to enable them to decide the future direction of court diversion within this population group. In addition, this research will help address the evidence gap on the effectiveness of out-of-court community-based interventions, particularly their effectiveness on a wider set of health and well-being outcomes, not just recidivism alone.

The economic evaluation will demonstrate the economic impact and any potential to make cost savings. The Gateway Intervention has not been previously evaluated in its entirety and so the benefits of the intervention are unclear. Instead, previous evaluations have evaluated the individual component parts of the intervention. Based on this evidence there are a number of potential benefits of the Gateway intervention and OCBIs including: improved access to health and social services for young offenders; improved quality of life; improved health and well-being; reduced recidivism and improved cost effectiveness in comparison to usual care.

The qualitative evaluation will provide a greater understanding of victims' views and experiences of the intervention and therefore its acceptability to the wider public.

18.6 Funding

Research funding has been secured from the National Institute of Health Research (NIHR) Public Health Research (PHR) Programme. PHR project reference number: 16/122/20.

Funding for the intervention has been provided by the Hampshire Police and Crime Commissioner up to the end of March 2020. Hampshire Constabulary have stated they will cover the costs of the intervention from 1 April 2020 to end of March 2021, and anticipate looking favourably on requests for further funding thereafter.

Hampshire Constabulary are funding two full time police officers (Inspector Ben Taylor and Sergeant Caroline Chapman) to oversee the Gateway project.

19 PROTOCOL AMENDMENTS

Amendment No.	Protocol Version No.	Date Issued	Authors Name	Details of Changes Made
1	2.2	12 August 2019	Alison Booth Ann Cochrane Sara Morgan Megan Barlow-Pay	**Global changes** ● Research team details have been updated. ● Minor wording corrections and clarifications throughout. ● Clarified that the Gateway programme will be issued as a conditional caution ● Added 'different conditional caution' as an option in the control arm of the trial to reflect usual practice and aid in increasing the number of potential participants in the trial. ● Removed the word 'embedded' throughout to separate out the qualitative research and the economic evaluation from the trial. Participants in the process evaluation are no longer restricted to those recruited to the trial, but may be offenders who have been through the Gateway programme. **7.5 Study setting and population** ● Specified Southampton Policing District (SPD) includes Eastleigh, New Forest and Romsey police stations. **7.8 Comparator: usual process** ● Provided additional information about the usual process here and throughout ● Clarified that participants may be recruited to the study while in custody or out-of-custody **7.10 Eligibility criteria** ● amended and clarified inclusion/exclusion criteria

				9 Qualitative evaluation and 10.2 Process evaluation methods ● Information added to explain that different researchers will undertake the observations to those interviewing the Gateway participants in the observed sessions in order to maintain blinding to allocation. **11.3 Screening and pre-randomisation procedures** ● amended and clarified screening criteria **12.5 Source and data to be collected** ● Police training records added as data collected **13 Patient and public involvement** ● Information about PPI during the study period added including highlighting ethics as a focus for independent members of the SSC/DMEC **18.6 Funding** ● Added information about funding for the intervention **19 Protocol amendments** ● Table of amendments updated.
2	2.3	25th September 2019	Alison Booth Ann Cochrane Sara Morgan Megan Barlow-Pay	**7. Study methods (and throughout)** ● Addition of two recruitment sites: Portsmouth and Basingstoke ● Amendment to internal pilot to reflect change in number of anticipated eligible offenders: extended from 4 to 6 months) ● Amended length of study: 23 month extension to be requested ● Change 2 year follow up of police HES/PAS and ONS data to 1 year ● Clarification throughout that participants may be recruited in custody in a police station or out-of-custody (voluntary interview) ● Added to information about sites for delivery of LINX workshops: neutral place as near where offenders live as possible ● Protocol summary updated to reflect these changes ● Contacts list updated ● CLAHRC replaced with ARC ● Addition of email address to list of personal information to be collected Minor spelling, wording and abbreviation corrections throughout
3	2.5 N.B. v2.4 was submitted and further amendments were requested; these were added, and version revised to 2.5	10th March 2020	Alison Booth Ann Cochrane Sara Morgan Megan Barlow-Pay Inna Walker	2 Protocol summary updated 7.5 Addition of Isle of Wight as fourth recruitment site. 7.10 Additional exclusion criteria of 'Currently under probation' added 7.13 Plan for CACE analysis added 10.1 Clarification about qualitative interviews and their purpose added. 11. Addition of section 11.1 Set up of sites and 11.2 Training of police officers to recruit and randomise. 11.4 Details of increases in payments and payment type been added 11.6 Added information about cases where randomisation will be with verbal consent initially. Summarised the timing and use of the PISs in a table.

				11.9 Addition of detailed explanation about enrolment procedure for in and out of custody. Figure 2 added and 17.3 updated. 11.10 Details of attempts to contact participants added 18.5 Addition of risk of adverse public perceptions of payments to offenders. 18.6 Addition of details about funding for the intervention 19 Protocol amendments table updated. Appendix 6: re payments to participants added. ● Contacts list updated. ● Minor wording corrections throughout
4	n/a	7th April 2020	Alison Booth	No changes to protocol made; status of study in light of COVID-19 pandemic summarised in a letter
5	2.6	8th May 2020	Megan Barlow-Pay Alison Booth Ann Cochrane Inna Walker	10.1.3 Minor amendment to wording to remove stratified sampling 10.2 Interview process changed to telephone instead of face to face. Amendments made to recruitment process to allow for change 11.6 Verbal consent included in process evaluation for telephone interviews

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67. University of York. (2018) Data Protection Legislation: University Policy, Procedures and Guidelines [Available from: https://www.york.ac.uk/records-management/dp/ .]
68. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *Jama* 2013;310:2191-4. 10.1001/jama.2013.281053
69 Health Research Authority. (2018) Applying a proportionate approach to the process of seeking consent UK2017 [Available from: Accessed online at: https://www.hra.nhs.uk/about-us/news-updates/hra-publishes-new-proportionate-consent-guidance/ on 13 May 2018.]

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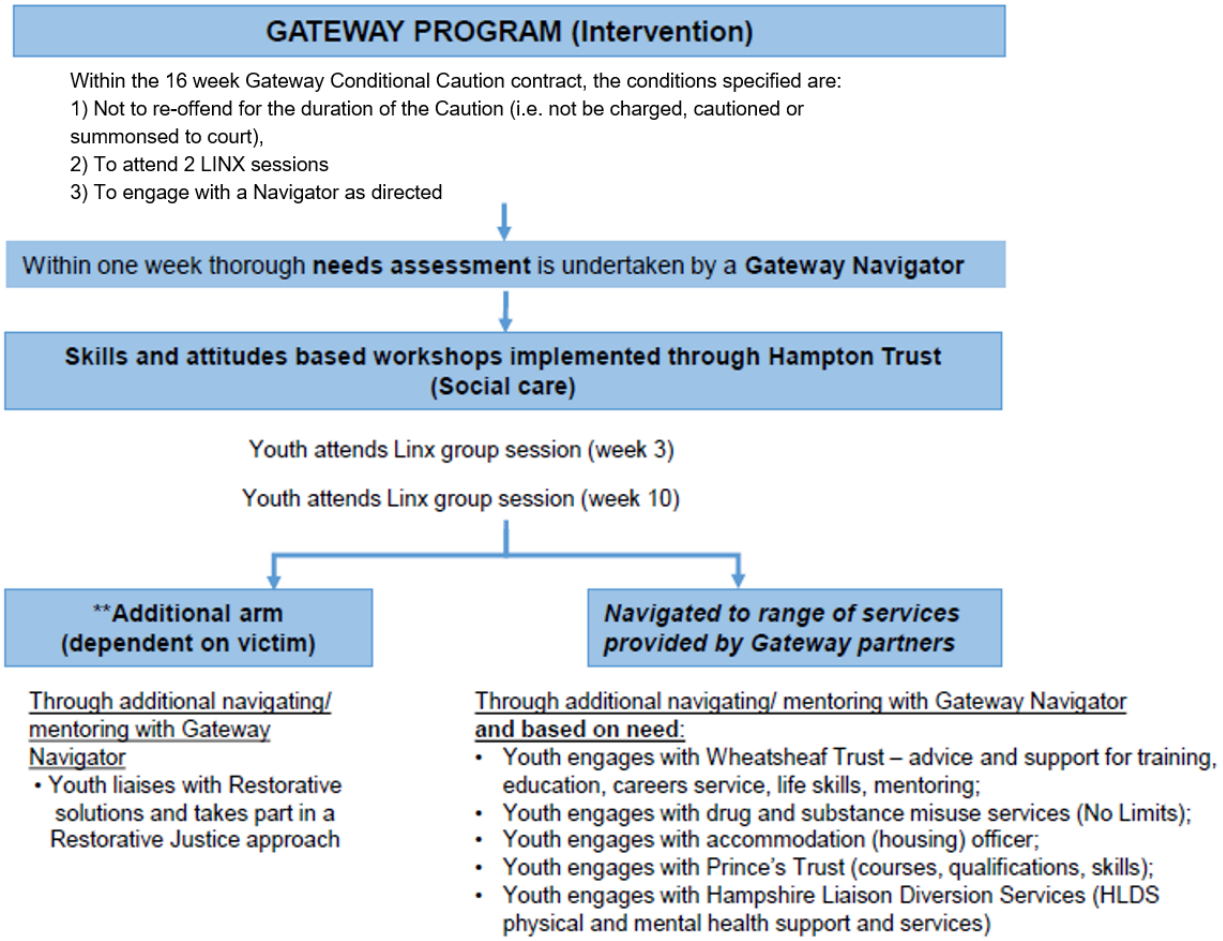
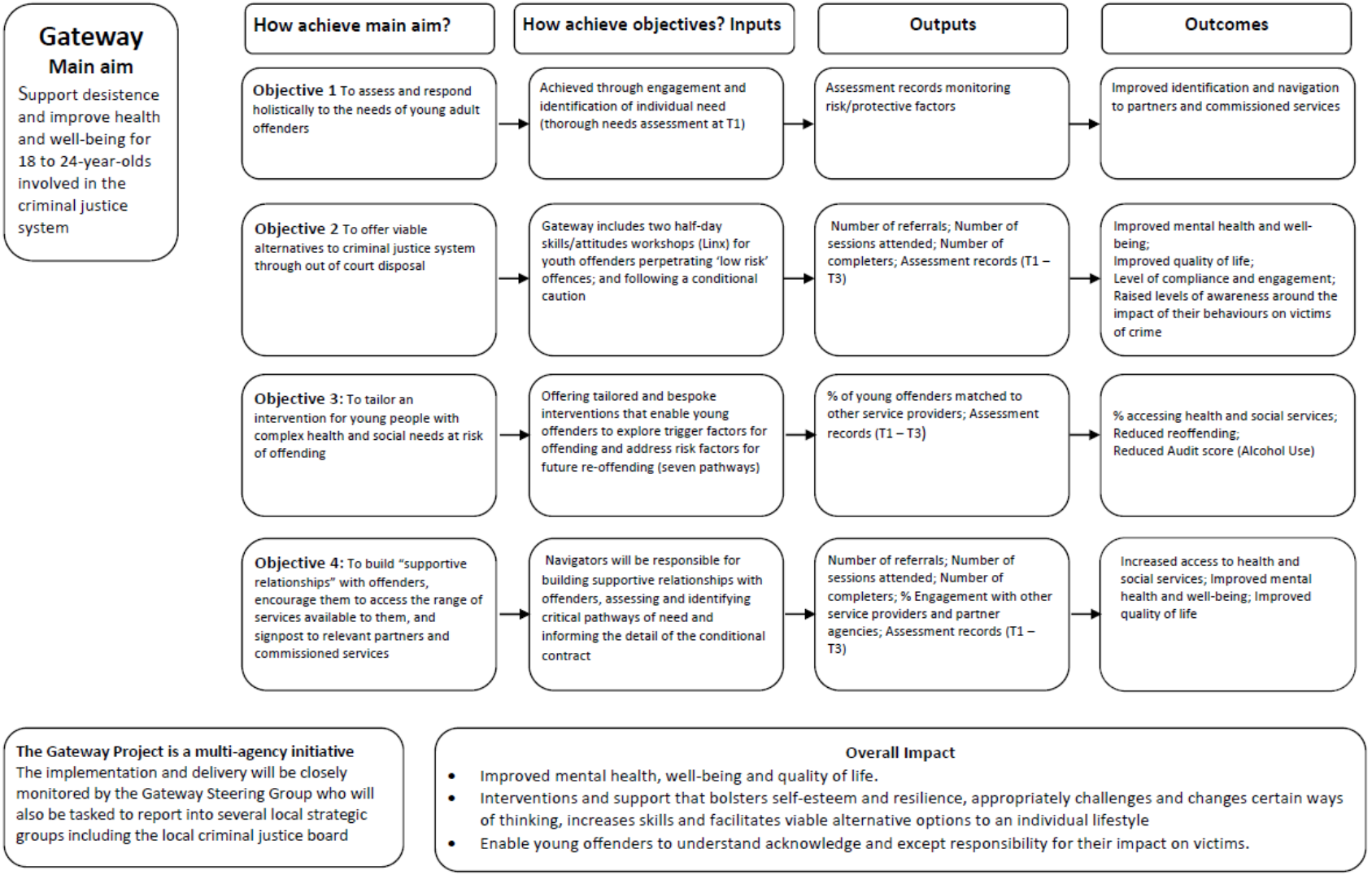
Appendix 1 Outline of Gateway intervention



Appendix 2 Gateway intervention theory of change (logical framework matrix)



Appendix 3 Social care remit letter

Thank you for your query. The remit of the Social Care REC is as follows:

1. Social care studies funded by Department of Health.
    - Research commissioned directly through the Policy Research Programme.
    - Health and Social Care Information Centre (HSCIC) studies (i.e. those to be designed by HSCIC for implementation by Councils with Adult Social Services Responsibilities, who do not then individually need to seek additional review)
    - Studies commissioned by or through National Institute for Health Research (NIHR) School for Social Care Research.
    - Social care studies funded (in rare cases) through NIHR.

2. Social care research that involves people lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005. The Social Care REC is recognised by the Secretary of State as an Appropriate Body for this purpose.

3. Social care research involving sites in England and another United Kingdom country.

4. 'Own account' research undertaken by Councils with social services responsibilities, where the Chief Investigator and/or sponsor feels there are substantial ethical issues.

5. Studies of integrated services (health and social care), provided that there is no clinical intervention involved.

6. Studies taking place in NHS settings with NHS patients where the approach uses social science or qualitative methods, provided that the research does not involve any change in treatment or clinical practice.

7. Intergenerational studies in social care, where both adults and children, or families, are research participants.

8. Other social care studies not suitable for review by other NRES RECs, subject to the capacity of the Social Care REC. This could include service user-led research.

9. Adult social care research involving changes in, or the withdrawal of, standard care.

Social care research does not require review by the Social Care REC if it is reviewed by another committee operating in accordance with the ESRC's Framework for Research Ethics, unless sections 1 or 9 above apply or the research involves NHS patients or service users as research participants. A review is required if there is a legal requirement for REC review e.g. under the Mental Capacity Act. Student research within the field of social care should ordinarily be reviewed by a University REC (UREC). If a UREC review is not available to a student, they can contact the Co-ordinator for advice.

The Social Care REC does not consider any research involving clinical interventions. Such research should be reviewed by another appropriate REC within the NRES.

I have also attached two documents which state which studies need to be reviewed by a REC – Governance Arrangements for RECs (GAfREC) and an algorithm - Does my project require review by a REC? These documents also give details of the exemption for review if studies are reviewed in accordance with the ESRC's Framework for Research Ethics.

Appendix 4 Social care REC letter

Morgan S.A.

From:	SOCIAL-CARE, Nrescommittee (HEALTH RESEARCH AUTHORITY) <nrescommittee.social-care@nhs.net>
Sent:	09 February 2018 11:41
To:	Morgan S.A.
Subject:	Remit of Social Care REC
Attachments:	Remit of Social Care REC.PDF; does-my-project-require-rec-review.pdf; Updated GAfREC 24 February 2012.pdf
Follow Up Flag:	Follow up
Flag Status:	Flagged

As just discussed.

Thank you for your query. I am attaching the remit of the Social Care REC, an algorithm and the Governance Arrangements for RECs so that you can check if your applications falls within the remit of the Social Care REC.

As you will see from our remit and the other documents, social care research does not require review by the Social Care REC if it is reviewed by another committee operating in accordance with the ESRC's Framework for Research Ethics, unless sections 1 or 9 (of the attached document) apply or the research involves NHS patients or service users as research participants. A review is required if there is a legal requirement for REC review e.g. under the Mental Capacity Act. Student research within the field of social care should ordinarily be reviewed by a University REC (UREC). If a UREC review is not available to a student, they can contact the REC Manager for advice.

Please forward any further queries.

Best wishes

Barbara

Barbara Cuddon
REC Manager
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Appendix 5 HMPPS approval not required email

Morgan S.A.

From: National Research [NOMS] <National.Research@noms.gsi.gov.uk>
Sent: 15 February 2018 11:06
To: Morgan S.A.
Subject: RE: RCT in police custody, Southampton

Dear Dr Sara Morgan,

Thank you for your email.

In general, if you are undertaking research that requires accessing prospective participants that are under the care of HMPPS or National Probation services or if you require using HMPPS/probation services or facilities to identify people or if you would like to interview HMPPS / National Probation staff then you will need to get HMPPS /NRC approval.

In your case the participants are under the care of the police service and not HMPPS therefore HMPPS / NRC approval is not required. Thank you.

Kind regards,

Richard,
NRC Co-ordinator

From: Morgan S.A. [mailto:S.A.Morgan@soton.ac.uk]
Sent: 12 February 2018 09:12
To: National Research [NOMS] <National.Research@noms.gsi.gov.uk>
Subject: RCT in police custody, Southampton

Hi,

I am writing to get some advice about applying for ethics with HMPPS.

We are about to undertake an evaluation of a randomised controlled trial at Southampton police station, recruiting 18-24 year olds eligible for a court diversion scheme. Eligible participants will be randomised, and those chosen for the intervention arm will be offered the 'Gateway intervention', which is a community-based intervention funded by Hampshire Constabulary. The routine care arm will be given a court summons, and will be processed as usual.

As recruitment is taking place within police custody, we felt that there may not be a requirement for HMPPS ethics. Further still, the intervention is being offered in the community, by social care services, rather than through any prison or probation services.

However, I wanted to confirm that this would be the case?!

Perhaps it would be easier to discuss this on the phone, if so I would be grateful if you could send a contact telephone number.

I look forward to hearing from you at the earliest opportunity,
All the best,
Sara

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Appendix 6 Payments to participants in Gateway: consideration of guidance on ethics by the Health Research Authority

James Raftery

9th January 2020

Summary

This note takes as background the proposed change in the way participants in Gateway are recompensed. This has arisen from data in the pilot stage showing difficulties in carrying out Week 4 interviews and feedback suggesting that this was at least partly due to low levels of payment for expenses. The current 'thank you' is a standard £10 voucher following each meeting with a researcher where a Case Report Form (CRF) is completed. An additional £5 voucher is offered to those attending face-to-face meetings as a contribution to travel expenses. The proposal is to increase the standard to £30 and travel expenses to £10 and for both to be paid in cash.

This note first reviews the HRA guidance and then considers issues around the level of payment and associated risks.

The HRA has issued guidance for two types of research, that involving patients and healthy people. More safeguards apply to the latter. Gateway involves healthy people as opposed to patients. However since Gateway is funded by the Public Health Research Programme, and the primary outcome is health and wellbeing, the HRA approach to both types of participants is worth summarizing.

Patient volunteers

The ethics of paying patients in medical research are outlined by the Health Research Authority 2014 Ethics Guidance "Payment and Incentives in Research" https://www.bing.com/search?q=hra+payment+clinical+trials&form=EDGSPH&mkt=en-gb&httpsmsn=1&msnews=1&plvar=0&refig=a8a179defb4e4bb5b5e2bd62d65004c4&PC=DCTS&sp=-1&pq=hra+payment+cli&sc=0-15&qs=n&sk=&cvid=a8a179defb4e4bb5b5e2bd62d65004c4. This guidance was largely seen as to Research Ethics Committees (RECs) but applies more widely.

It noted that payments to patients are often seen as controversial for fear of undue influence to participate.

> "Where payment is proposed, the REC should consider whether the payment is proportionate to the "burden" imposed by the research. Such burdens may often be significant without involving excessive risk e.g. number of hospital visits, tissue samples taken, lifestyle restrictions, diaries, questionnaires etc."

However, the HRA was clear that payments play a role:

> "Payments to patients, in addition to reimbursement, for taking part in therapeutic research are permissible."

It also supported payment in cash:

> "Where payment is deemed to be acceptable for taking part in research it is acceptable for that payment to be made in cash. Whilst vouchers (or other non-cash payments) may also be used, a REC should not normally insist upon the use of vouchers (or other non-cash payments) for participants who use drugs where cash payments are proposed by researchers."

Healthy volunteers

Under HRA definitions, Gateway involves healthy volunteers:

> "Where patients are invited to take part in non-therapeutic research as 'patient volunteers' (i.e. they do not have the disease that is a target of the research) they should be treated as "healthy volunteers" with regards payment. "

HRA guidance applies to Phase 1 trials which involve patient volunteers in "Incentives in Phase 1 Trials < https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/phase-1-clinical-trials/>.

> "Payments made to participants in phase I trials must never be related to risk. Payment amounts can be detailed in generic advertisements in the form of a daily rate (in this context the term "daily" refers to a 24-hour period). A minimum daily rate should be used in all generic advertisements and stated as being "from £X". The group recommends that the minimum amount to be stated is £100."

It went on to recommend clarity in use of terms using the example of egg donation in infertility studies:

- "Payment: a generic term covering all kinds of transactions involving money, and goods with monetary value, whether those transactions are understood as recompense, reward or purchases.
- Recompense: payment to a person in recognition of losses they have incurred, material or otherwise. This may take the form of the reimbursement of direct financial expenses incurred in donating bodily material (such as train fares and lost earnings); or compensation for non-financial losses (such as inconvenience, discomfort and time).
- Reward: material advantage gained by a person as a result of donating bodily material, that goes beyond 'recompensing' the person for the losses they incurred in donating. If reward is calculated as a wage or equivalent it becomes remuneration.
- Purchase: payment in direct exchange for a 'thing' (e.g. a certain amount for a kidney, or per egg.)

Conclusions on HRA Ethical guidance

As Gateway involves healthy volunteers, payment is within HRA guidance. Even under the more restrictive guidance, healthy patients can be paid amounts that exceed expenses. And in both instances, payment can be in cash. Given the above, the term payment seems preferable to the others reviewed.

Issues arising

Two issues are briefly considered: the level of payment and the risks involved.

Given that a £10 voucher is seen as inadequate, the question is what higher level might be justified. Although testing different levels might be attractive that would constitute a different study. Two figures were considered: £20 and £50. As the former was considered too low and the latter too high, £30 was agreed as worth trying. As this will need to be agreed formally it was considered important to propose a level that was likely to be successful and did not require to be changed again.

The main risks were perceived as how this might be presented as payment to wrong doers. Against this, it was argued that higher payments were needed to increase collection of the required data, that the proposed payments were within the relevant HRA guidance and was supported by the PPI advisory group. And that payments would be confined to those participating in the trial which will last for a limited time and only include sufficient participants for conclusions to be reached.