Study protocol

RISKIT-CJS: Pragmatic randomised controlled trial to evaluate the effectiveness and cost effectiveness of a multi-component intervention to reduce substance use and risk-taking behaviour in adolescents involved in the criminal justice system.

RISKIT-CJS 14/183/02 Version 1.3 12/07/2017

Full Title: Pragmatic randomised controlled trial to evaluate the effectiveness and cost effectiveness of a multi-component intervention to reduce substance use and risk-taking behaviour in adolescents involved in the criminal justice system.

Short title: RISKIT-CJS

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• **Sponsored by:** University of Kent

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2. Principal Investigator signature

I confirm that I have read and understood protocol 1.4 dated 26.04.2015. I agree to comply with the study protocol, the principles of Good Clinical Practice (GCP), research governance, clinical trial regulations and appropriate reporting requirements.

Print Name: Professor Simon Coulton

Signature …… Date: 12 September 2016

3. Glossary of abbreviations

BECCI	Behaviour Change Counselling Index
C.I.	Confidence Interval
CRSI	Client Receipt Service Inventory
CCA	Cost-Consequences Analysis
CEA	Cost-Effectiveness Analysis
CHU-9D	Child Health Utility – 9-dimension questionnaire
CJS	Criminal Justice System
CUA	Cost-Utility Analysis
DMEC	Data Monitoring and Ethics Committee
EQ-5D-5L	EuroQol – 5-dimension questionnaire
GCP	Good Clinical Practice
MRC	Medical Research Council
NHS	National Health Service
NIHR PHR	National Institute of Health Research, Public Health Research
PI	Principal Investigator
PNC	Police National Computer
QALYs	Quality-adjusted life years
RCQ-TV	Readiness to change – treatment version
RCT	Randomised Controlled Trial
SDM	Social Development Model
SCQ	Situational Confidence Questionnaire
TASC	Therapeutic Alliance Scale for Children
TLFB	Time Line Follow Back
TMG	Trial Management Group
TSC	Trial Steering Group
WEMWBS	Warwick Edinburgh Mental Well-Being Scale
YOT	Youth Offending Team
YOT-MIS	Youth Offending Team Management Information Systems

4. **Responsibilities of Sponsor:** University of Kent are the award holders and will act as the sponsor for this study.

Funder: NIHR PHR is funding this study ref: 14/183/02.

Trial management: A Trial Management Group (TMG) will be appointed to manage the strategic progress of the trial. The day-to-day management of the trial will be coordinated by the Senior Trial Manager. A Trial Steering Committee (TSC) will be appointed, both to oversee this trial on behalf of the Funder and Sponsor and to take on the role of Data Monitoring and Ethics Committee (DMEC).

Chief Investigator: The Chief Investigator will have overall responsibility for the trial.

Principal Investigators: The Principal Investigators (PIs) will have overall responsibility for the conduct of the study at a particular trial site.

4.1 Trial management: The following functions falling under the responsibility of the sponsor will be delegated to Professor Simon Coulton [Chief Investigator]

- Ethics Committee Opinion (including application for research ethics committee favourable opinion, notification of protocol amendments and end of trial, site specific assessment and local approval).
- Good Clinical Practice and Trial Conduct (including GCP arrangements, data monitoring, emergency and safety procedures).
- Administration of funding for the study will be carried out by the University of Kent who hold the award. Professor Simon Coulton is the lead for the University of Kent.

4.2 Trial conduct at sites

Site PI responsibilities

- Study conduct and the welfare of study subjects.
- Familiarity with the study conditions.
- Compliance with the protocol, documentation of any protocol deviations and reporting of all serious adverse events.
- Screening and recruitment of subjects.
- Compliance with the Principles of GCP, the Data Protection Act and any other relevant legislation and regulatory guidance.
- Ensuring that no participant is recruited into the study until all relevant regulatory permissions and approvals have been obtained.
- Obtaining written informed assent from participants prior to any study specific procedures.
- The PIs shall be qualified by education, training and experience to take responsibility for the proper conduct of the trial. They shall provide a current curriculum vitae, signed and dated as evidence for the Trial Master File.
- Ensuring Study Site team members are appropriately qualified by education, training and experience to undertake the conduct of the study.
- Availability for TSCs, DMECs, monitoring visits and in the case of an audit.
- Maintaining study documentation and compliance with reporting requests.
- Maintaining a site file, including copies of study approval, list of subjects and their signed informed assent forms.
- Documenting appropriate delegation of tasks to other study personnel e.g. Research Co-ordinators.

- Ensuring data collected is accurate, timely and complete.
- Providing updates on the progress of the trial.
- Ensuring subject confidentiality is maintained during the project and archival period.
- Ensuring archival of study documentation for a minimum of ten years following the end of the study, unless local arrangements require a longer period.

4.3 The Caldicott principles

Principle 1. Justify the purpose(s) for using confidential information: Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian.

How we will abide by Principle 1: Should we need to transfer personal data between research centres, who requested and who executed the transfer, together with the reason for the transfer. This log will be kept on a password protected Excel file.

Principle 2. Don't use personal confidential data unless it is absolutely necessary: Personal confidential data items should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

How we will abide by Principle 2: We will gather personal data in order to follow-up participants only for those who consent for us to do so.

Principle 3. Use the minimum necessary personal confidential data: Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data is transferred or accessible as is necessary for a given function to be carried out.

How we will abide by Principle 3: Personal confidential data will include name, address and contact details for those who consent in order to ensure they can be contacted at the appropriate contact point.

Principle 4. Access to personal confidential data should be on a strict need-to-know basis: Only those individuals who need access to personal confidential data should have access to it, and they should only have access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes.

How we will abide by Principle 4: Only the Study Research Administrator at University of Kent will have access to all of the information to ensure allocation concealment in the trial. The data will be accessed on a need-to-know basis only.

Principle 5. Everyone with access to personal confidential data should be aware of their responsibilities: Action should be taken to ensure that those handling personal confidential data - both clinical and non-clinical staff - are made fully aware of their responsibilities and obligations to respect patient confidentiality.

How we will abide by Principle 5: We will be providing training to all active researchers in the trial to ensure they understand confidentiality principles.

Principle 6. Comply with the law: Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organisation complies with legal requirements.

How we will abide by Principle 6: The research sponsor will ensure that all use of personal data will be lawful.

Principle 7. The duty to share information can be as important as the duty to protect patient confidentiality: Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

How we will abide by Principle 7: We will abide by the policies of participating organisations.

5. Protocol summary

Trial Title: Pragmatic randomised controlled trial to evaluate the effectiveness and cost effectiveness of a multi-component intervention to reduce substance use and risk-taking behaviour in adolescents involved in the criminal justice system.

Acronym (short title): RISKIT- CJS

Protocol version and date: V 1.3 12.07.2017

Summary of Trial Design: Mixed method, prospective, pragmatic randomized controlled trial with individual allocation, combining both quantitative and qualitative evidence. The study will be conducted across three geographical areas; South East England, South London, North East England, covering a diverse socio-economic and ethnic population.

Summary of Participant Population: Adolescents aged between 13 and 17 years currently involved in the criminal justice system (CJS) and engaged with a participating YOT who score 2 or more on the ASSET, ASSET Plus, or equivalent assessment tool for substance use. Identification of participants will be conducted in collaboration with YOT staff and baseline assessment conducted by trained staff from KCA/Addaction. Interventions will be conducted in suitable locations; youth or substance use facilities by KCA/Addaction staff and follow-up conducted by research staff in similar facilities.

Planned Sample Size: We aim to recruit 567 participants over a 12-month period with the aim of assessing at least 396 of these at the 12-month assessment.We estimate a loss to follow-up at the primary end point, 12 months post-randomisation, of 30%. Our sample is designed to identify a clinically important effect size difference of 0.3 in the primary outcome measure, percent days abstinent from all substances, with an alpha of 0.05 and power at 80% using atwo sided test.

Planned Number of Sites: The study will be conducted across three geographical areas; South East England, South London, North East England

Study Intervention: Participants in the intervention group will receive the RISKIT-CJS intervention in addition to any treatment as usual. Groups are delivered in premises managed by KCA/Addaction by trained and experienced specialists in the delivery of therapeutic interventions to young people who are provided with ongoing supervision and support. The mean group size is 6 participants.

Follow Up Duration: Follow up will be conducted at 6 months and 12-months post intervention; completion of a questionnaire.

Planned Trial Period: 01 September 2016 – 30 August 2019

6. Study Protocol

6.1 Background: Adolescence is a critical developmental stage when young people make behavioural and lifestyle choices that have the potential to impact on their health and wellbeing into adulthood. While risk-taking is important for healthy psychological development, for many, inappropriate risk-taking is significantly associated with health and social harm during adolescence and these harms persist well into adulthood [1].

Young people involved in the criminal justice system are a particularly vulnerable group with a greater propensity to take risks that are likely to have long term impact on their future health and wellbeing. This is because young offenders often lead chaotic lives and face complex problems, including substance use [2], unsuitable accommodation and emotional or mental health issues. Literacy levels are unacceptably low and the vast majority have in the past been excluded from school [3]. As a result of the above risk factors, the list of negative consequences that result from substance use by young people is extensive and includes physical, psychological and social problems in both the short and long term.

Epidemiological studies highlight the fact that, in common with other vulnerable groups of young people such as the homeless and those in care, young offenders are a hard to reach group from a health needs perspective, only accessing physical and mental health services in times of crisis and accessing these services is often associated with involvement with other agencies [4-6].

6.2 Rationale for current study: Young people are much more vulnerable than adults to the adverse effects of substance use due to a range of physical and psychological factors that often interact and the differential impact of substances on the developing brain [7]. While the relationship between criminal activity and substance use is complex there is clear evidence that the prevalence of substance use is far higher in the youth offending population than the general youth population and that the two are related in the context of other forms of disinhibitory behaviour, such as aggression and risk-taking. Young people who offend experience a range of complex multiple risks and vulnerabilities including, neglect and abuse [8], substance use and related problems [9, 10] and exclusion from school [11].

The Youth Justice System in England and Wales works to prevent offending and re-offending by those under the age of 18 years. Latest available data indicates that of the 1,235,028 annual arrests in England and Wales 14% were aged 10-17 years [3]. In 2012/2013 there were 27,854 first time entrants (first reprimand, warning of community conviction) to the Youth Justice System [3]. The rate of recidivism in this group is estimated at 36% [3].

Research has shown that young people who offend are more likely to experience a range of inequalities in later life, for example poorer physical health [9], early pregnancy in females [12] and higher rates of tobacco use and drug and alcohol dependence [5, 10, 11], reduced employment chances and economic hardship [13]. Indeed, there is widespread agreement that young people who offend are at increased risk of health and social problems making them one of the most vulnerable and often ‘hard to reach’ populations in the UK [14], which has one of the highest youth custody populations in western Europe [15].

Systematic reviews of interventions for substance using offenders in criminal justice environments have not identified a clear, evidence based intervention strategy [16] but highlight the paucity of good quality research in the area and the lack of UK based studies and no rigorous studies focussing on young offenders.

6.3 Intervention: The development of RISKIT [17] was based on two streams of work; a participative consultation with young people and a review of the current research evidence. The theoretical perspective was informed by the Social Development Model (SDM) [18-20]. This approach suggests that the distal influences of socio-economic status, biology, normative regulation and discipline are mediated through proximal influences on behaviour which are identified as; perceived opportunities for pro- or antisocial behaviour and perceived rewards for this behaviour. The SDM marries the ecological context of young people's behaviour to an explanation of how this ecology influences their behaviour. It suggests that even in the absence of a structural change to their health ecology, the provision of socio-emotional and cognitive skills can help young people prevent or reduce risk-taking behaviour and also suggests that the building of bonds with organisations promoting pro-social learning and opportunities is important in the reduction of risk-taking. The model provides a coherent and empirically validated approach that suggests that intervention approaches should be multi-component and encompass; knowledge and education, cognitive and learning skills, self-efficacy and motivation.

The participatory consultation was adapted from participatory action research [21, 22] and was carried out with a number of groups of young people. The aim of the exercise was to establish, with young people what they perceived as risk-taking behaviour, why they took risks, the consequences of taking risks and how they perceived the problems could be addressed. The main themes in terms of risk-taking behaviour centred around; criminal activity, substance use and sexual activity and these activities considered as being linked. The participants considered prevention programmes, that focus on the negative outcomes of risk, failed to appreciate that risk-taking can be positive and lead to positive outcomes an issue highlighted by other research exploring the processes associated with risk-taking [18, 23]. The young people highlighted the need for some education regarding risks and consequences, but particularly highlighted the preference for interventions that provided skills and strategies to manage risk and the opportunity to discuss these skills with peers and to learn how to implement them. Interestingly parental influences were not considered critical to any intervention and many considered parental involvement would be inappropriate and unacceptable. The primary focus for the young people was not on eradication of risk-taking but rather a focus on how risk could be reduced and the negative consequences minimised.

We consulted a number of existing reviews and research studies [24-29] and found that while there is a growing body of research in the field there is a paucity of rigorously evaluated interventions with the majority of research arising from the US with limited applicability to the UK. Of importance was what has been proven not to work, this includes focusing on negative aspects of risk and risk abstinence. Promising intervention approaches included motivational interviewing and cognitive and socio-emotional life skills training. In addition there was emerging recognition of the importance of providing interventions in a structured manner and with the young people's preference for peer group interventions the importance of managing the potentially negative effects of labelling and peer influence.

Synthesis of the participatory group views, theoretical underpinnings and the review of the evidence was undertaken and the RISKIT intervention model developed as an approach that focuses on those who are vulnerable to the negative consequences of their risk-taking behaviour. The intervention combines individual motivational interviewing sessions, to target motivation and behaviour change with eight group orientated life skills sessions that covered a variety of areas; identifying and managing risk, communication skills, assertiveness training, anger management, preparing for behaviour change, sexual health. In addition, the group sessions focused on identifying resources within the community that could be of benefit for the young people and provided opportunities to access these resources.

An initial feasibility study was undertaken followed by a larger randomized pilot study [17] in adolescents across Kent identified as engaging in excessive risk behaviour. Consent rates in the eligible population were high, 80%, with almost all attending at least part of the intervention and 74% attending all of the intervention sessions. Follow-up rates were high with 82% being followed-up at 6 months. At this point 32% of the intervention group had reduced their risk-taking behaviour to a point where it was of no further concern and the impact of the intervention led to a greater reduction in substance use than the control condition indicating a positive effect on this domain. Participant views were positive with high levels of engagement and satisfaction and a general view that the intervention had been useful in developing new skills, informative and lead to changes in behaviour. Delivery of the model was sustainable but requires the input of specialist, rather than generic staff and a full economic evaluation of cost-effectiveness was not undertaken. Further to our pilot study the RISKIT intervention has been tested for feasibility in both custodial and community criminal justice settings with high levels of satisfaction on the part of the participants. In the community settings consent and engagement was high with 90% consenting and almost 100% attending, in part because the group intervention was provided over two half-day sessions over consecutive weeks, on weekends, rather than the eight weekly one-hour sessions provided in the pilot study.

The proposed study builds on the Medical Research Council guidelines for the development and evaluation of complex interventions. We have conducted research to explore the theoretical validity of the intervention and synthesized this theoretical approach with the current evidence base and the views of potential participants in order to model an appropriate intervention approach. We have tested the feasibility of implementing the intervention in the target population and refined the intervention and its delivery as a result of that feasibility study. We have conducted an appropriately designed pilot study to explore potential effectiveness on the key parameters and found evidence of potential effect in reducing substance use and risk-taking behaviour and high levels of satisfaction and engagement. As the proposal involves a specific population, those engaged with the criminal justice system rather than adolescents per se, we have conducted a second feasibility study in this population to assess feasibility and acceptability and found high levels of engagement and acceptability in this population. The next step is to conduct a rigorous evaluation to address key outcomes in a way that provides valid scientific evidence and is useful to those engaged with this population and commissioners of services. To this end we have proposed a full, multi-centre randomized controlled trial, with an embedded qualitative component, of the intervention versus treatment as usual to explore the effectiveness of the intervention; in reducing substance use, improving mental-wellbeing, reducing criminal activity that is economically viable to implement and acceptable to the target population.

6.4 Intervention process: RISKIT-CJS is delivered in 4 steps consisting of two one-to-one sessions lasting approximately one hour and two half-day group sessions over two consecutive weeks. Groups are delivered in premises managed by KCA/Addaction by trained and experienced specialists in the delivery of therapeutic interventions to young people who are provided with ongoing supervision and support. The mean group size is 6 participants. Details of the intervention are contained in the RISKIT manual, (http://mentor-adepis.org/wp-content/uploads/2013/05/RisKit-Operational-Manual.pdf).

The intervention involves four distinct steps.

Step 1 of the intervention entails a single face-to-face session using motivational interviewing approaches to discuss current substance use, risk-taking behaviour, and support for behaviour change and enhance motivation to engage with the intervention.

Step 2 involves a group session over half a day at a location convenient for the participant. This session addresses a number of key issues involving both psycho-education and skill development including; understanding substance use and associated harms, understanding triggers of substance use behaviour, strategies for managing and minimizing risk, strategies for diversion and distraction and sexual health.

Step 3 is conducted a week later at the same location as step 2 and involves a similar group approach. At this session, issues covered include communication strategies and assertiveness training, managing anger and mindfulness and planning for the future.

Step 4 is a single one-to-one session using a motivational interviewing approach that addresses outstanding barriers to change, managing expectancy and enhancing self-efficacy to change. At this stage, interventionists work with participants to identify local service contacts that may be useful.

Each step of the intervention is delivered on separate days; over a four-week period to allow for any behaviour change may occur to be the focus of step 4.

7. Research aim and objectives

7.1 Primary objective: To conduct a prospective pragmatic randomised controlled trial to evaluate the effectiveness of the RISKIT-CJS intervention compared with treatment as usual for substance using adolescents involved in the criminal justice system.

7.2 Secondary objectives

- To evaluate the cost-effectiveness of the intervention compared with treatment as usual.
- To explore participants and criminal justice staff experience of the intervention and the acceptability of the methods employed.
- To assess the fidelity with which the intervention is conducted and explore the role of fidelity, therapeutic alliance and baseline psychological factors on the outcomes observed.
- If the intervention is shown to be effective within the parameters set to develop a protocol for dissemination and integration of the intervention in current practice.

8. Study design: Mixed method, prospective, pragmatic randomized controlled trial with individual allocation, combining both quantitative and qualitative evidence. The study will be conducted across three geographical areas; South East England, South London, North East England, covering a diverse socio-economic and ethnic population.

9. Outcome trial assessments

9.1 Baseline assessments: Research staff will meet with participants at a pre-arranged appointment. Eligibility will be assessed and those eligible provided with a written and verbal description of the study and invited to consider participating. If a participant is willing to participate consent will be taken for those aged 16 or more or those considered by the YOT staff as being ‘Gillick competent’. For those not considered ‘Gillick competent’ caregivers will be contacted and asked to provide informed consent. Once consent is

received baseline assessment will be undertaken and data recorded on a secure IPad using a specifically designed study application. The baseline assessment consists of a combination of researcher-led and self-completed outcomes with the option of allowing self-completed outcomes to be completed by interview for those who have difficulties in reading English. Baseline assessment is estimated to take 30 minutes and immediately after assessment allocation will occur and the participant informed of their allocation. In addition to providing the allocation the randomization system will allocate the participant to an intervention group with a start date and location. All participants will be thanked for their time and provided with a £10 voucher as compensation for their time and to reduce attrition in the follow-up sample [30]. Confirmation of group and time will be made by phone, email or post after the allocation.

9.2 6 and 12 month assessments: Two weeks prior to the 6 and 12-month follow-up assessment participants will be contacted by phone and post to make an appointment to carry out the follow-up assessment. Location of interviews will be either in Addaction offices or YOT with the option to complete the assessment by phone if no suitable location can be identified. The 6 and 12-month assessment will be similar to the baseline assessment and at participants will be provided with a £10 voucher to compensate for their time. Follow-up assessment will be conducted by trained researchers.

9.3 Primary outcome measure: Our primary outcome measure is percent days abstinent from substance use in the 28-days prior to the 12-month follow-up. This is measured using the Time-Line Follow Back 28 (TLFB28), a valid and reliable tool for assessing the quantity and frequency of substance use over time periods ranging from 1 to 365 days. The outcome has been validated for use in adolescent populations [31] and recent pilot work has indicated high levels of agreement between the shorter, 28-day, and longer 90-day, reference period. In addition to percent days abstinent the tool allows derivation of a number of secondary outcomes over the period; quantity and type of substances consumed, sexual activity (planned, unplanned and regretted) and incidences of self-harming behaviour. The TLFB is completed by a trained member of research staff and takes approximately 20 minutes. The outcome is measured at baseline, 6 and 12 months.

9.4 Secondary (Effectiveness) Outcome Measures: Mental health and wellbeing will be assessed using the Warwick-Edinburgh Mental Well-being scale (WEMWBS). WEMWBS is a 14-item, self-completed scale addressing different aspects of eudemonic and hedonic mental health wellbeing. The scale has established valid reliable psychometric properties in adolescent populations[32] and established sensitivity to change [33], the instrument is highly correlated with other measures of psychological health and well-being including the Strengths and Difficulties Questionnaire and the General Health Questionnaire and measures of adolescent quality of life, Kidscreen. WEMWBS will be measured at baseline and then again at 6 and 12 months.

In order to assess potential prognostic factors, in addition to demographics, that may impact on outcome Readiness to change, measured using the Readiness to change questionnaire, (RCQ-TV), and self-efficacy, measured using the Situational Confidence Questionnaire, (SCQ) will be measured at baseline. Both instruments are relatively short self-completed questionnaires with established psychometric properties in the adolescent population.

The process of delivering the intervention may also play a role in the outcomes observed in the intervention group and we aim to assess this process using two distinct approaches. First, at the end of the intervention we will ask each participant to rate the intervention using the Therapeutic Alliance Scale for Children (TASC-r; [34]) a 12-item self-completed questionnaire with established psychometric properties in the adolescent population. Second a random sample of 20% of individual motivational interventions, stratified by centre, age

and gender, will be recorded and assessed by independent raters using the Behavioural Change Counselling Index (BECCI; [35]) to assess fidelity and quality of interventions delivered.

The economic outcome measures will address the costs of delivering the interventions, changes in health utility in the 12 months after randomization and the costs associated with participants in the 12 months after randomization. Costs associated with delivering the intervention will be derived using a micro-costing approach accounting for the actual costs including associated training, facilities, overheads and management costs. Health utility will be assessed using the self-completed 5-item EQ5D-5L and 9-item CHU-9D assessed at baseline, 6 and 12 months. Service utilization on the part of the participant will be assessed using a specifically designed client receipt service inventory (CRSI, [36]) currently being piloted with the adolescent population. Service use will be assessed from a wide public sector perspective encompassing health and social care; criminal justice, education and employment service utilisation.

Criminal justice outcomes will include arrests, charges and convictions and will be derived from both Police National Computer (PNC) Systems and YOT Management Information Systems (YOT-MIS). Data will be collected for all offence types for the 12 months prior to and 12 months after randomization. In addition, data on offences, court appearances and sentencing occasions.

9.5 Assessment of effectiveness: The proposed trial is the first evaluation of the RISKIT intervention in an adolescent population involved within the criminal justice system. However, the proposal draws upon pilot studies in educational and custodial settings that suggest potential positive effects. Our pilot study in schools indicated high levels of engagement and reduced risk-taking and substance use in the intervention group at 6 months, our work in custodial settings suggests that the intervention is feasible and acceptable to participants. Our proposal addresses the question of whether the intervention yields evidence of effect in real world practice settings, and as such is a study of pragmatic effectiveness rather than a more strictly controlled study of efficacy. The intervention is delivered by a specialist agency rather than offender management staff, mirroring the multi-agency approach advocated within the criminal justice setting and widely generalizable across the United Kingdom.

9.6 Assessment of harms: If the results of our pilot work were replicated in this larger study we would expect a reduction in substance use, risk-taking behaviour and criminal activity and improvements in social functioning and mental wellbeing. In order to quantify these potential benefits, we aim to measure a range of behavioural outcomes as part of the current study.

Our pilot work did not yield any information on potential harms or adverse effects of the intervention. Those potential participants with severe substance use requiring immediate, intensive intervention is excluded from the study and staffs involved in delivering the intervention are trained and experienced specialists. As part of the intervention staff that becomes concerned about welfare of a young person will have established safeguarding and welfare procedures. Any participant who feels coerced or distressed about taking part in the research study will have the opportunity to withdraw from the study at any time and this information will be explicit within the consent procedure.

All adverse events will be recorded and assessed by the site PI, who will seek advice of PI's at other sites if necessary. They will assess seriousness, causality and expectedness of each event. Adverse events will be recorded for 90 days after the end of the intervention period and at each of the follow-up points.

Adverse Event (AE): Any untoward occurrence in a trial participant to whom a study intervention has been administered that does not necessarily have a causal relationship with the intervention. Any AE can therefore be an unintended consequence of the intervention.

Serious Adverse Event (SAE): An adverse event is classified as seruious or non-serious. A SAE is an adverse event that results in the following:

- Death.
- Emergent substance use that requires referral for treatment by a specialist agency.
- Raises safeguarding issues that require disclosure to third parties in accordance with the Addaction Safegurading protocol.
- Changes in the severity offending pattern of concern to YOT staff.
- Any potentially iatrogenic effect of the intervention observed by, or reported to Interventionists
- Any event that is considered significant by research staff or principal investigator.

Relationship of AE to procedure: For each AE the PI must define and record the relationship to the study procedure as either:

- Definite
- Probable
- Possible
- Unlikley
- Not related

All events where the relationship is recorded as possible will be reported to the TSC who will make a decision whether the severity requires investigation by those members delegated to undertake the responsibilities of DMEC.

9.7 Definition of end of study: The end of study will be the last participant's final study contact, at 12 months follow up February 2019.

10. Participants: All adolescents within YOT are routinely screened using the ASSET tool, ASSET Plus or equivalent. Trained researchers will liaise with staff within YOT to identify potential participants scoring 2 or more on the substance use section of ASSET, or equivalent, and arrange to meet with them at a scheduled appointment. ASSET, soon to be replaced with a modified ASSET Plus or equivalent, is a standardized assessment tool, developed within the CJS in England and Wales, which aims to identify the underlying causes of a young person's offending behaviour and to plan appropriate interventions [37]. It is often used on multiple occasions to help measure changes in young offenders' health and social needs and the risk of reoffending over time. ASSET has been used with all young offenders in England and Wales since 2000 and it examines 12 dynamic risk factors; living arrangements, family and personal relationships, education, neighbourhood, lifestyle; substance use, physical health, emotional health, perception of self and others, thinking and behaviour, attitudes to offending, motivation to change. The severity of each section is rated on a 0-4 scale [37]. Data from the Juvenile Cohort Study shows that 32% of young offenders score 2 or more on the ASSET tool for substance use and 12% score 3+ [38]. Substance use is defined as alcohol, established illicit substances (As listed in the Misuse of Drugs Act 1971 and revisions), legal highs and inappropriate use of prescribed medication.

10.1 Socioeconomic context and inequalities

Young offenders often lead chaotic lives and face complex problems, including substance use, unsuitable accommodation and emotional or mental health issues. Literacy levels are unacceptably low and the vast majority has in the past been excluded from school [3]. As a result of the above risk factors, the list of negative consequences that result from substance use by young people is extensive and includes physical, psychological and social problems in both the short and long term. Furthermore, young people who offend experience a range of complex multiple risks and vulnerabilities including, neglect and abuse [8], substance use and related problems [9, 10] and exclusion from school [11]. Research has shown that young people who offend are more likely to experience a range of inequalities in later life, for example poorer physical health [9], early pregnancy in females [12] and higher rates of tobacco use and drug and alcohol dependence [5, 10, 11], reduced employment chances and economic hardship [13]. Indeed, there is widespread agreement that young people who offend are at increased risk of health and social problems making them one of the most vulnerable and often 'hard to reach' populations in the UK [14], which has one of the highest youth custody populations in western Europe [15].

10.2 Inclusion criteria: Young people aged 13 to 17 years inclusive, engaged with the criminal justice system in the youth offending service and on a community order, scoring 2 or more on the ASSET tool, ASSET Plus or equivalent on the substance use domain, able and willing to provide informed consent.

10.3 Exclusion criteria: Severity of substance use requiring immediate referral to specialist services, known criminal justice involvement likely to lead to incarceration during the intervention or follow-up period, currently on an order with substance use abstinence as a pre-requisite.

11. Trial Procedures

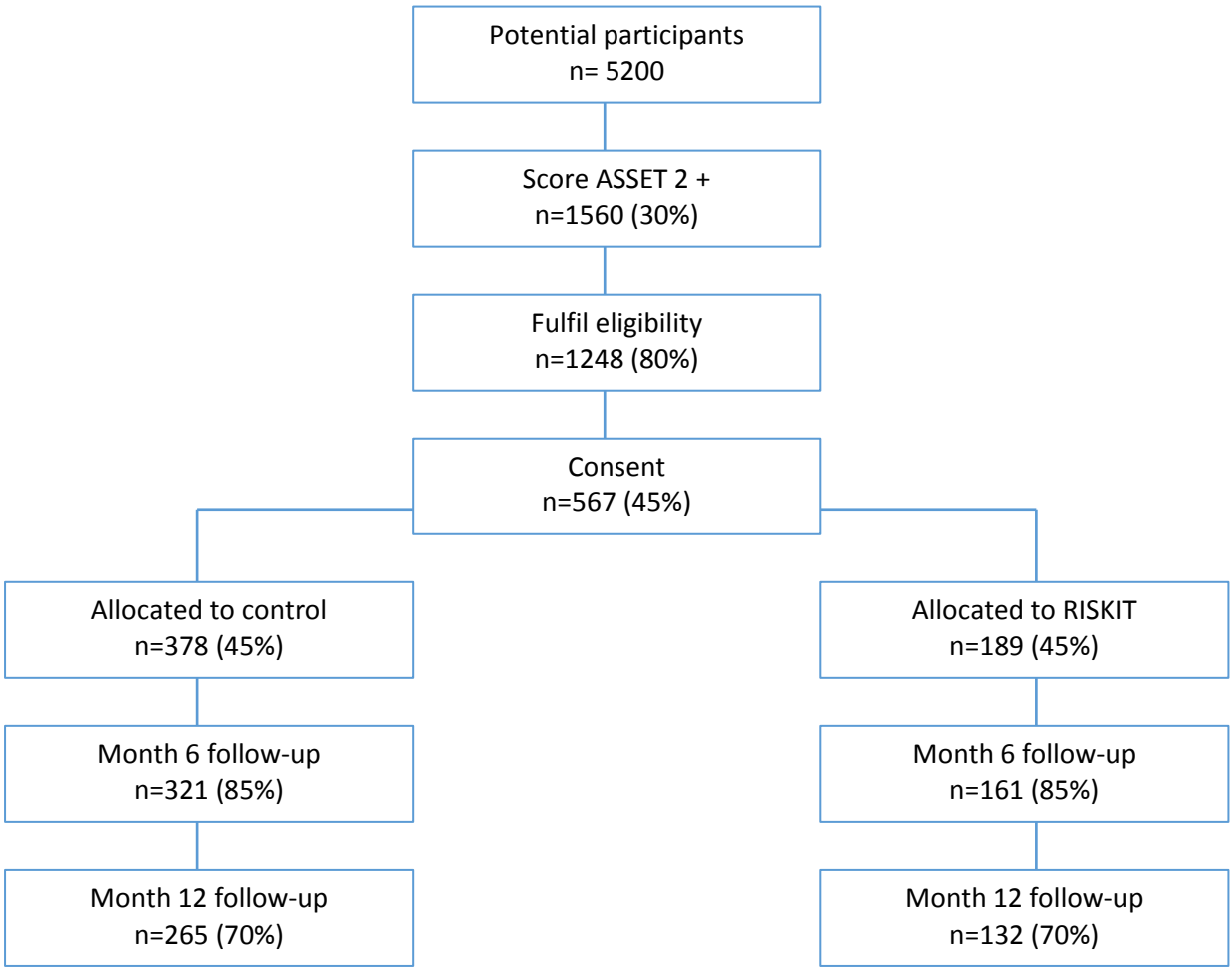
11.1 Training: Existing intervention staff will be augmented with new staff in locations where RISKIT is not currently available, North East England. Existing experienced youth workers, employed by KCA/Addaction, will be trained using an existing training package by training staff from the South East area. The training is provided over two days and covers; theoretical underpinnings, delivering programme elements, managing groups, individual motivational interviews, managing risks and safeguarding. A full intervention manual, covering training and practice, is available for interventionists; senior practitioners will observe practice and deem practitioners as competent prior to embarking on the RISKIT programme. Supervision is provided by senior staff with experience of delivering the intervention throughout the study period. In addition, all interventionists will attend a half-day training session on trial procedures and outcome assessment prior to the start of recruitment.

11.2 Control Intervention: Guidelines suggest that interventions should be provided for adolescents within CJS settings who score 2 or more on ASSET, ASSET Plus or equivalent for substance use. But the reality is that those with no immediate clinical need for treatment, in the form of detoxification or substitution are unlikely to receive an intervention, rather existing services are signposted and rates of engagement are low [6]. When intervention is provided it often takes the form of short duration brief behavioural change interventions with limited evidence of effectiveness in substance using population [39].

12. Randomisation: Allocation conducted at the level of the participant and conducted independent of the research team using random permuted blocks of variable length. Randomisation strings are generated by Codeface Ltd and encrypted and stored within the baseline data collection tool. To allow for the most efficient use of resources differential allocation will be employed with twice as many participants allocated to the control group compared with the intervention group. Power calculations have been adjusted to reflect the allocation ratio. Allocation will include stratification by gender, Youth Offending Team (YOT) and age (13-15 years versus 16-17 years).

12.1 Flowchart of study

14/183/02 RISKIT-CJS Flow chart



13. Screening for the trial: All adolescents within YOT are routinely screened using the ASSET tool. Trained researchers will liaise with staff within YOT to identify potential participants scoring 2 or more on the substance use section of ASSET, ASSET Plus or equivalent and arrange to meet with them at a scheduled appointment.

13.1 Intervention fidelity: The process will be assessed through recording interventions delivered and an assessment of intervention fidelity. Analysis of fidelity will include the proportion of allocated sessions attended and assessment of fidelity to session content analysed independently using the BECCI index.

14. Project timetables and milestones

Months 1 – 6	Initial set-up, recruitment of centres, staff training, ethics
Month 7 – 18	Participant recruitment
Month 9 – 21	Qualitative research interviews
Month 12 – 24	6 month follow-up
Month 18 - 30	Month 12 follow-up
Month 30 – 33	Effectiveness, economic and criminal justice analysis
Month 33 - 36	Writing report and dissemination of results

15. Statistical considerations

15.1 Sample size calculation: For the effectiveness analysis is designed to identify a clinically important difference of 0.3 for the primary outcome measure, percent days abstinent from all substances at 12 months post-randomisation in addition to a clinically important difference of the secondary outcome measure of mental health wellbeing, measured using the WEMWBS. In order to detect an effect size difference of 0.3, with alpha of 0.05 at 80% power using a two-sided test requires 175 analysed at 12 months in each of the two groups, a total of 350. As the intervention is intensive and potentially costly to implement we have increased the efficiency of the study by allocating participants in a 2:1 ratio, with twice as many allocated to the control condition. As differential allocation leads to a loss of power we have maintained the integrity of the sample size calculation by increasing the numbers required; 264 in the control group and 132 in the intervention group, a total of 396. Our previous studies with adolescents and those involved in the criminal justice system (SIPS-CJS, RISKIT) suggests that loss at 12 months is likely to be somewhere in the region of 15 to 30% and we have adjusted the required sample to account for a 30% loss at 12 months. This inflates the required number to 567; 378 in the control group and 189 in the intervention group. Between 2013 and 2014 the mean number of potentially eligible participants across the participating regions was 5200, with a prevalence of ASSET score 2 or more ranging between 32 and 42%, of these we estimate 80% will meet all other eligibility criteria. Based on these estimates we require a consent rate of the order of 40% in order to achieve our estimated sample size estimation over the recruitment period. Our experience in the feasibility study suggests that 60% of those eligible are likely to consent.

The qualitative component of the study will be purposive and include group discussion with participants in the intervention group and individual interviews with staff in participating YOT's. Participants will be chosen purposively in order to provide diversity in terms of site, and age and ensure appropriate participation by gender, social class and ethnicity. The sample size considerations of the qualitative component are driven by the need to achieve data saturation, the point at which no new themes are emerging from the data, and this

needs to be judged in practice. Our previous experience of similar studies estimate the participants needed to be of the order of 12 groups and the number of staff in YOT to be of the order of 24.

15.2 Effectiveness analysis: Effectiveness analysis will be conducted by treatment allocation using a two-sided 5% significance level. Analysis and results will be presented in accordance with CONSORT guidelines. The primary outcome is percent days abstinent from substance use in the 28-days prior to the 12-month follow-up. After checking for distributional assumptions and making any appropriate transformations this will be analysed using an analysis of covariance adjusting for baseline values and stratification values used in the allocation process; age, gender and centre. Results will be presented as mean differences between the groups and the associated 95% confidence intervals. Missing data will be assessed using multiple imputation approaches to model missing data scenarios and sensitivity analysis will be conducted to explore the relative impact of missing data on the observed outcome. Secondary outcomes will be analysed in a similar manner.

Analysis will also be undertaken to model the relationship between pre-randomisation factors and observed outcome at 12-months; demographics, self-efficacy, readiness to change. This analysis will employ a linear regression model including interaction terms for allocated group. To further enhance our understanding, we will additionally incorporate an analysis of process by enhancing the prognostic analysis by including measures of adherence, fidelity, derived from the BECCI ratings, and therapeutic alliance.

Exploratory sub-group analysis will be undertaken to model the relationship between gender, ethnicity and social class measured using index of material deprivation from postcode on observed outcome.

15.3 Cost-effectiveness analysis: The effectiveness analysis will be complemented by an economic evaluation that will evaluate the economic implications of the intervention versus treatment as usual. Substance use generates high costs for the individual, health service and society in general and the economic analysis will be conducted first using a narrow health and social care perspective, to concord with NICE guidelines for the conduct of health economic evaluations and second using a wider public sector perspective incorporating costs associated with employment, training, education and criminal justice.

The costs associated with identifying the eligible population and delivering the interventions will be estimated by prospectively monitoring local costs associated with this activity and micro-costing training, management, supervision, facilities and associated overheads. Data will be extracted from study billing records. Impact on service use on the part of the participant will be estimated using a specifically designed CSRI and units of service use valued using national sources of information.

The economic analysis will comprise cost-consequences analysis (CCA), incremental cost-effectiveness (CEA), and cost-utility analyses (CUA). The CCA will report mean and confidence intervals of: primary and secondary outcomes as described above as well as the quality-adjusted life years (QALYs) gained, costs per participant in each arm, and differences between arms. The CEA will comprise calculation of the incremental cost per incremental day free of substance use, and the CUA, incremental cost per QALY gained. QALYs will be calculated from CHU-9D data converted to health state utilities using preference weights specific to the UK population and integrated over time. A sensitivity analysis calculating EQ5D-5L-based QALYs will also be conducted. All analyses will be conducted over the time horizon of one year. Analysis of uncertainty will comprise reporting of standard errors and/or 95%CIs around increments and calculation of the cost-effectiveness acceptability curve. Non-parametric bootstrapping will be employed to

investigate joint uncertainty in costs and effects and both one-way and multi-way sensitivity analysis will be conducted to explore the impact of our basic assumptions. The study will be conducted and reported in accordance with good practice guidelines for health economic evaluations [40].

15.4 Criminal justice outcomes: Criminal justice outcomes will be analysed using a combination of linear and logistic analysis of covariance to explore changes between groups and associated differences. A secondary analysis of CJS data will incorporate baseline risk assessments to explore the potential intervention effects on participant risk status.

15.5 Qualitative analysis: The aim of the qualitative component of the proposal is to explore participants' and practitioners' experience of the RISKIT-CJS intervention in order to generate information pertaining to the feasibility, acceptability, contextual influences and mechanisms of action. The qualitative design consists of two elements; the first is participatory group work with participants who have experienced the RISKIT-CJS programme and the second telephone interviews with practitioners who work with these participants. Thematic coding of qualitative data will be carried out using specific software (QSR NVIVO) that allows for the coding of both verbal, transcripts and field notes, and visual data. The coding allows for the identification of recurrent and important themes and the generation of a framework of themes relating to the key research questions and objectives. A detailed description of themes will be presented. Emergent themes that may be explored from the quantitative data analysis will be incorporated into the analysis plan as secondary exploratory analyses.

16. Compliance and withdrawal

16.1 Assessment of compliance: Visits to the individual YOT's in the geographical sites will be conducted by research staff to ensure compliance with protocols.

16.2 Withdrawal of participants: Participants have the right to withdraw from the trial at any stage. Reasons for withdrawal will be recorded. Participants can withdraw from the study completely, whereby all trial data previously collected will be deleted. They may withdraw from the study partially whereby no further data collection will be undertaken. They may withdraw from any allocated intervention but agree to adhere to any future follow-ups.

17. Data monitoring, quality control and quality assurance

This is a low risk trial. The University of Kent and the /NIHR PHR Programme have therefore agreed that the TSC will also monitor trial data in place of a separate Data Monitoring and Ethics Committee (DMEC). To this end, independent members may access unblended study data and meet in closed session. The main areas of focus will include informed/consent, recruitment, data quality and completeness of documentation.

Following the initial meeting, the TSC will meet annually. Its role is to oversee the trial to ensure it is conducted to high standards in accordance with the protocol, the principles of Good Clinical Practice (GCP) applied to non-drug trials, and relevant regulations and guidelines. This committee will also take responsibility for the ethical compliance of the trial. The purpose of this committee will be to monitor efficacy and safety endpoints, although only independent members may have access to unblinded study data. Written Terms of Reference will be agreed by the TSC. All monitoring findings will be reported and followed up with the appropriate persons in a timely manner. The study may be subject to inspection and audit by the University of Kent under their remit as sponsor, and other regulatory bodies to

ensure adherence to GCP. The investigators' institutions will permit ethical review, trial-related monitoring and audit, and regulatory inspection(s), and provide direct access to source data and documents.

All monitoring findings will be reported and followed up with the appropriate persons in a timely manner. In case of adverse events deemed a serious, the chair of the TSC will form an extraordinary DMEC, where members who will follow good practice guidelines in assessing the relationship between events and the process of the trial and take any appropriate action. The study may be subject to inspection and audit by the University of Kent under their remit as sponsor, and other regulatory bodies to ensure adherence to GCP. The investigators/ institutions will permit trial-related monitoring, audits, ethical committee review and regulatory inspection(s), providing direct access to source data/documents.

18. Adverse event monitoring and reporting: Due to the nature of the study it is not expected that participants will experience any adverse events/serious adverse events during the study. In the event that the participant reports an event related to the study during a study visit this will be reported on an adverse event form and fully investigated by the CI. Each site principal investigators will assess the adverse even following the CONSORT guidelines[41] (see annexe). All adverse events will be reported to the TSC chair.

19. Ethics and regulatory issues: As participants are not being recruited from the NHS, the proposed research will not require NHS ethical approval but we will seek multi-site ethical approval from the University of Kent ethics committee, which covers all non-NHS studies carried out at the University. Information sheets will be provided to all eligible subjects and written informed assent/consent obtained prior to any study procedures.

20. Research governance: The University of Kent will be the nominated sponsor of the study. A dedicated trial manager under the supervision of the chief investigator will manage the day-to-day conduct of the study. A trial management group consisting of all principal investigators, research staff, named collaborators and at least one lay member will meet monthly to monitor conduct of the trial and address any issues arising. In addition, the study will be overseen by a trial steering committee, with an independent chair, expert and lay members and a separate data monitoring and ethics committee. The study will be conducted in accordance with the Data Protection Act and the Freedom of Information Act and will be conducted in accordance with the Medical Research Councils Guidelines on Good Clinical Practice in Clinical Trials and will include compliance with appropriate ethical approval and the Declaration of Helsinki.

21. Confidentiality: All data generated from the study will be stored in a secure environment and identified only by a unique participant identifier. The master registry, containing the link between personal information and the identifier, will be maintained in a separate secure environment and data linked only for the purpose of follow-up. No personal identifiable information will be kept beyond the 12-month follow-up point unless prior consent for longer-term follow-up has been received. For the purposes of this proposal analytical datasets will not contain any personal information.

22. Insurance and finance: Indemnity in respect of potential liability arising from negligent harm relating to design and conduct of the research is provided by the University

of Kent for those researchers who have their substantive contracts of employment with the University of Kent. Researchers not employed by the University of Kent will be indemnified by their current institution. This is a non-commercial study and there are no arrangements for non-negligent compensation. NIHR Public Health Research Programme is funding the study.

23. Study report/publications: The data will be the property of the Chief Investigator and Co-applicants. Publication will be the responsibility of the Chief Investigator. It is planned to publish this study in peer review articles and to present data at national and international meetings. Results of the study will also be reported to the Sponsor and Funder, and will be available on their web site. All manuscripts, abstracts or other modes of presentation will be reviewed by the TMG prior to submission. Individuals will not be identified from any study report.

During the study we aim to present the design, aims and findings to audiences at a number of subject specific international conferences. We will also plan an end of study forum, organised in collaboration with the University of Kent that brings together all elements of the research team to discuss the interpretation of the study across a variety of stakeholder groups. Throughout, and after the study, we aim to develop and maintain a website, with portals specifically designed for different audiences placing the results of the study in the wider context of intervention work in the fields of youth justice and adolescent health. A full manualised training and intervention package will be developed in collaboration with Addaction and made available to other service providers. Using our experience of implementing RISKIT in school settings we will also provide a matrix of appropriate implementation strategies across the youth justice environment.

A short version of the protocol has been submitted and published in BMC Public Health in 2017[42].

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Appendix 1 CONSORT extension for harms