

# A study to explore whether a multi-component psychosocial intervention can reduce substance use in adolescents who are involved in the criminal justice system in the UK

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<b>Registration date</b> 14/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 31/05/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

There is a body of research that provides clear evidence that young people are more at risk of harm from substance use than adults. The developing brain is more susceptible to the effects of alcohol and drugs and adolescents are more likely to develop harmful and dependent drug use in a shorter time than adults. The impact of alcohol and drug use in adolescence can have lifelong implications, increasing the chances of experiencing physical and mental health issues and social problems. Young people who have committed an offence are far more likely to be using alcohol and drugs than other young people and there is clear evidence that their use of drugs is associated with their criminal activity. Many young offenders are managed in the community and there is evidence that these young people are more at risk of suffering negative consequences of drug and alcohol use. While the youth justice system routinely looks for signs of problematic drug use in this population access to treatment to address their use can be difficult and many of those in need do not receive any treatment. The RISKIT-CJS intervention was developed to address the underlying issues associated with adolescent risk-taking. The aim of this study is to find out whether the RISKIT-CJS intervention is more effective at reducing substance abuse than standard care.

### Who can participate?

Young people aged between 13 and 17 who are engaged with a Youth Offending Team on a community order.

### What does the study involve?

Participants are randomly allocated to one of two groups, where by one third take part in the RISKIT intervention and two thirds receive usual treatment. Those in group one receive treatment as usual for the duration of the study. Those in group two receive usual treatment as well as the RISKIT-CJS intervention. This is delivered over four sessions. The first session involves a face-to-face meeting to discuss substance use and risk taking behavior, to support behavior change and enhance motivation to change. The second session involves a four hour group

session in which participants gain a better understanding of substance use and harms, triggers associated with substance use, minimizing risk, risk diversion and distraction, sexual health. The third session involves another four hour group session in which participants learn communication strategies, assertiveness training, anger management, mindfulness and future planning strategies. The final session is an hour-long individual session in which barriers to change, managing expectancy and enhancing self-efficacy are discussed. Participants in both groups complete a number of questionnaires at the start of the study and then again after six and 12 months to assess substance use and wellbeing.

What are the possible benefits and risks of participating?

Those who participate in the RISKIT programme are more likely to reduce their alcohol and drug use and manage their risk taking behaviour in a more appropriate ways leading to reductions in unprotected sex and criminal activity, all of which have implications for the future wellbeing of young people. There are no known risks involves with participating in this study.

Where is the study run from?

The study is run from the University of Kent with satellite co-ordination centres based at Kings College, London and University of Teesside, and takes place in Youth Offending Teams located in the South East, London and Greater London and North East of England (UK)

When is the study starting and how long is it expected to run for?

September 2016 to August 2019

Who is funding the study?

National Institute for Health Research (UK)

Who is the main contact?

Prof. Simon Coulton

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## Contact information

### Type(s)

Scientific

### Contact name

Prof Simon Coulton

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# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.0

## Study information

### Scientific Title

RISKIT-CJS: Pragmatic randomized 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

RISKIT CJS

### Study objectives

Primary null hypothesis:

The RISKIT CJS intervention is no more effective than treatment as usual in reducing the frequency of substance use 12 months after randomisation as measured using the Time Line Follow Back 28.

Secondary null hypotheses:

1. The RISKIT CJS intervention is no more cost-effective than treatment as usual over 12 months after randomisation
2. The RISKIT CJS intervention is no more effective than treatment as usual in increasing mental health wellbeing 12 months after randomisation as measured Warwick Edinburgh Mental Wellbeing Scale
3. The RISKIT CJS intervention is no more effective than treatment as usual in reducing criminal justice recidivism in the 12 months after randomisation

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics was approved by University of Kent Social Research Ethics Committee, 12/12/2016, ref SRCEA169

### Study design

Multi-centre individually randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Treatment

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Adolescent substance use

### **Interventions**

Participants are randomised to one of two groups using a secure independent randomization service and occurs after completion of the baseline battery. Randomisation employs blocks of unequal size stratified by centre. It is unequal in order to ensure twice as many participants receive the control versus the intervention.

Control condition: Participants receive treatment as usual as provided by the current provider, there is no limit on the intervention or duration of treatment.

RISKIT-CJS intervention: Participants receive treatment as usual augmented with the RISKIT-CJS intervention. RISKIT-CJS is delivered over 4 sessions. Session 1 is an individual face to face session with a trained interventionist lasting 45 minutes; to discuss substance use and risk taking behavior, to support behavior change and enhance motivation to change. Session 2 is a group intervention over a 4-hour period involving both psycho-education and skills development including; understanding substance use and harms, triggers associated with substance use, minimizing risk, risk diversion and distraction, sexual health. Session 3 is a group intervention over 4 hours and involves; communication strategies, assertiveness training, anger management, mindfulness, future planning strategies. Session 4 is an individual face to face session addressing barriers to change, managing expectancy and enhancing self-efficacy delivered over 60 minutes.

All participants are followed up at 6 and 12 months after randomization.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Percent days abstinent from substance use in the 28-days prior to the 12-month follow-up is measured using the Time-Line Follow Back 28 (TLFB28) method 12 months after randomization.

### **Secondary outcome measures**

1. Quantity and type of substances consumed, sexual activity (planned, unplanned and regretted) and incidences of self-harming behaviour in the 28 days prior to the 6 and 12-month follow-up derived from the Time Line Follow-up (TLFB28) method at baseline, 6 and 12 months
2. Mental health and wellbeing assessed using the Warwick-Edinburgh Mental Well-being scale (WEMWBS) at baseline, 6 and 12 months
3. Health, social care, criminal justice, education and employment related units of service

utilisation over the 12-month trial period, assessed using a trial specific Client Receipt Service Inventory (CRSI) at baseline, 6 and 12 months

4. Health Utility assessed using the EQ5D-5L at baseline, 6 and 12 months

5. Process evaluation of the intervention will be assessed using the Therapeutic Alliance Scale for Children (TASC-r) measured after each intervention session and ratings of fidelity of motivational interviews assessed using the Behavioural Change Counselling Index (BECCI)

6. Prognostic analysis will include Demographics, Readiness to change using the RCQ-TV, Self-Efficacy using the Situational Confidence Scale (SCQ) measured at baseline only

7. Qualitative outcomes will involve group and individual interviews with participants, individual interviews with interventionists, criminal justice staff involved in the study and commissioners

**Overall study start date**

01/09/2016

**Completion date**

31/08/2019

## **Eligibility**

**Key inclusion criteria**

1. Aged between 13 and 17 years inclusive

2. Involved with Youth Offending Team on a community order

3. Score of 2 or more on the substance use domain of the ASSET risk profile

4. Willing and able to provide informed consent

**Participant type(s)**

Other

**Age group**

Child

**Lower age limit**

13 Years

**Upper age limit**

17 Years

**Sex**

Both

**Target number of participants**

567

**Total final enrolment**

693

**Key exclusion criteria**

1. Severity of substance use requiring immediate referral for clinical intervention for detoxification.
2. Criminal justice involvement that is likely to lead to incarceration within the follow-up period.
3. Currently on an order that requires substance use abstinence.

**Date of first enrolment**

01/03/2017

**Date of final enrolment**

28/02/2018

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****University of Kent**

Canterbury

United Kingdom

CT2 7NZ

**Study participating centre****University of Teesside**

Borough Road

Tees Valley

Middlesbrough

United Kingdom

TS1 3BX

**Study participating centre****Kings College London**

Denmark Hill

London

United Kingdom

SE5 8BB

## **Sponsor information**

**Organisation**

University of Kent

**Sponsor details**

The Registry  
Canterbury  
England  
United Kingdom  
CT2 7NZ

**Sponsor type**

University/education

**Website**

kent.ac.uk

**ROR**

<https://ror.org/00xkeyj56>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal, conference presentations, and publication of manual and guides for commissioners

## Intention to publish date

31/08/2020

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	11/03/2017		Yes	No
<a href="#">Results article</a>	results	01/03/2023	31/05/2023	Yes	No