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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

Submission date
04/09/2016

Recruitment status
No longer recruiting

Registration date
14/09/2016

Overall study status
Completed

Last Edited
31/05/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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
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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?
Protocol article	protocol	11/03/2017		Yes	No
Results article	results	01/03/2023	31/05/2023	Yes	No