

Supporting looked after children and care leavers in decreasing drugs and alcohol

Submission date 08/04/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/06/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/07/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background

Drug and alcohol (substance) use in young people is a major public health problem. It was estimated in 2013 that alcohol related harm costs the UK £21 billion every year with an additional £15.4 billion estimated to result from drug addiction. If individuals participant in risky substance use as adolescents, they are more likely to continue this behaviour as adults, which increases significantly the risk of them developing mental health disorders, make them more likely to be involved in crime and also more likely to experience poverty. In 2014, one in every 200 children and young people (CYP) in England (a total of 69,000) were looked after by local authority services. Looked after Children and Care Leavers (LAC) are those children and young people up to the age of 21 who have been placed under the legal care of local authorities. About 7% of young people accessing specialist drug and alcohol services have reported that they were in care. Unfortunately, there is limited research, including cost effectiveness data, and, at present no national guidelines, on the most effective way to decrease risky drug and alcohol use in this group. There is evidence that preventative interventions (school based, family based and mixed input) can reduce alcohol use in young people. Recent research has found that that early intervention (or treatment) with Motivational Interviewing (MI) helped in reducing substance use in early substance using young people, especially in studies that delivered multiple sessions of individual MI. There is increasing focus on family and social network therapies as a way of engaging and supporting hard to reach children. Family based therapy, including multidimensional family therapy and brief strategic family therapy, have been shown to be effective in reducing alcohol usage in young people. As LAC are living outside their biological family unit, family-based approaches may not be appropriate, but other approaches involving a person's wider social network could be effective. There is little UK evidence on the best way to identify children in the early 'at risk stage' of substance use or the most effective way to help them, especially when considering the most vulnerable teenagers such as LAC. There is an urgent need for robust evidence to help develop and improve treatment guidelines to decrease substance use in this high risk population of young people. The SOLID study (Supporting Looked After Children and care leavers In Decreasing Drugs and alcohol) aims to reduce drug and alcohol use and improve mental health in Looked After Children aged 12 to 20 years. Two counselling approaches will be adapted for use with these young people called motivational enhancement

therapy (MET) and social behavioural network therapy (SBNT). MET focuses on changing internal thoughts, whilst SBNT focuses on the external or social factors that may affect drug and alcohol use.

Who can participate?

LAC aged 12-20 years identified as being at risk of substance misuse from participating local authorities across the North East.

What does the study involve?

Participants are randomly allocated to one of three groups. The first group receive up to six sessions of SBNT, offered either weekly or fortnightly. Each session lasts 50 minutes. The second group receive up to six sessions of MET, offered either weekly or fortnightly. Each session lasts 50 minutes. The third group receive their usual care. All participants return to usual care after the 6 sessions. They are then followed up to see whether their alcohol and drug use has decreased.

What are the possible benefits and risks of participating?

Although not guaranteed, it is hoped that individuals will benefit directly from this study by giving them the chance to talk openly about their alcohol and drug use. The information that individuals give will be used to help understand how to support Looked after Children and care leavers to change their drinking and/or drug use. No risks have been identified.

Where is the study run from?

Five sites across the North East, inclusive of Newcastle, Durham, Middlesbrough, Stockton and Redcar and Cleveland.

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

March 2016 to February 2018

How long will the trial be recruiting participants for?

National Institute for Health Research (UK)

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

14/183/08

Study information

Scientific Title

SOLID (Supporting Looked After Children and Care Leavers In Decreasing Drugs, and alcohol): a pilot feasibility study of interventions to decrease risky substance use (drugs and alcohol) and improve mental health of looked after children and care leavers aged 12 -20 years

Acronym

SOLID

Study objectives

The SOLID pilot feasibility trial aims to assess the pilot feasibility and acceptability of a definitive three-arm multi-centre randomised controlled trial (two behaviour change interventions and care as usual) to reduce risky substance use (illicit drugs and alcohol), and improve mental health in looked after children and care leavers (LAC aged 12 -20 years).

The study will take place in multiple sites in the North East of England and will have two linked phases:

1. Formative study phase
2. Pilot feasibility randomised controlled trial (RCT)

Ethics approval required

Old ethics approval format

Ethics approval(s)

Newcastle and North Tyneside 1 - Research Ethics Committee, 25/04/2016, ref: 16/NE/0123

Study design

Phase 1: qualitative formative research phase

Phase 2: external pilot feasibility randomised controlled trial (RCT)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Community

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

Risky substance use (drugs and alcohol)

Interventions

Social Behavioural Network Therapy (SBNT) is an approach drawing from family and social interventions in substance use. SBNT has been designed to develop support networks which are wider than just biological family and include peers; it has been found to be effective in reducing substance misuse in adults when delivered through routine services. SBNT uses the external social network of the young person as a catalyst for change.

Motivational Enhancement Therapy (MET) is a form of motivational interviewing which targets an individual's internal thoughts and motivation. The individual's motivation is central to the process. An increase in motivation to change will increase the likelihood of success in decreasing the level of substance use.

The study will use a systematic and person-based approach to intervention adaptation and refinement. Essential therapeutic elements of the interventions (SBNT and MET) will be maintained but aspects of content and delivery for the target group of Looked After Children and Care Leavers will be refined as well as exploring acceptability in an iterative and age appropriate manner. Eliciting the views of the target group (LAC) and tailoring input to their

specific needs is an important part of intervention development; making the intervention more salient and delivery more feasible.

Individuals will be randomised into one of three groups - SBNT treatment group, MET treatment group and control (treatment as usual) group. Randomisation will be stratified by placement type (residential/ non-residential), site and age band (12-14/ over 14).

Individuals randomised into the treatment arms will already be accessing drug and alcohol treatment services. Therefore, the control arm would involve those individuals continuing to receive their usual care.

Individuals will be recruited in the study in October and November 2016 and baseline data collection will occur. Individuals will be randomised into a treatment arm and the treatment sessions will start to be delivered in December 2016 and delivery will be completed by the end of February 2017. Individuals will be offered 6 sessions of treatment, each session will last 50 minutes. The sessions will be offered weekly or fortnightly and will take place within a maximum period of 12 weeks. Following the delivery of the 6 sessions, individuals will revert back to receiving their usual treatment package. Follow up data collection will take place October-December 2017, the outcomes of this round of data collection will be compared to the baseline data collection completed prior to receiving the treatment sessions.

Intervention Type

Behavioural

Primary outcome measure

1. Episodes of heavy episodic drinking (≥ 5 units in 1 day), measured using the Timeline Follow-back Questionnaire, which considers the preceding 7 day and 30 day period
2. Frequency of use of the most problematic classified substance using the Timeline Follow-back questionnaire (7 and 30 day)

Secondary outcome measures

1. Self-reported assessment of mental health and prosocial behaviour over the last 6 months using the Strength and Difficulties Questionnaire
2. An assessment of mental well-being over the last 2 weeks, measured using the Warwick-Edinburgh Mental Well-being scale
3. Self-reported health related quality of life assessing health state on the day of completion, measured using the EQ-5D-5L
4. Self-reported occasions of 'drunkenness' compared against the objective standard-drink unit measure, measured using the Timeline Follow back questionnaire (7 and 30 day)
5. Use of alcohol drinks during the past 12 months, measured using the AUDIT questionnaire.
6. Experiences of using alcohol, tobacco and other drugs within the past three months and throughout whole life, measured using the ASSIST questionnaire
7. Self-reported romantic and intimate behaviour during the past 12 months, measured using items taken from the computer assisted self-interview (CASI) questionnaire used in the Avon Longitudinal Study of Parents and Children (ALSPAC)
8. Self-reported antisocial and criminal behaviour within a lifetime, measured by a questionnaire used in ALSPAC
9. Self-reported use of health and social services during the past 12 months, measured using a bespoke questionnaire
10. Placement stability for the young person during the past 12 months, measured as part of the Health and social services questionnaire

Overall study start date

01/03/2016

Completion date

28/02/2018

Eligibility

Key inclusion criteria

1. Looked Children and Care Leavers aged ≥ 12 and ≤ 20 years
2. Screen positive for being at risk of substance misuse i.e. scoring ≥ 2 on the CRAFFT
3. Informed consent given: LAC under 16 years consent from parent/guardian (local authority) and assent from young person; LAC 16 years and over consent from young person

Participant type(s)

Other

Age group

Mixed

Sex

Both

Target number of participants

150

Key exclusion criteria

1. Already in active treatment with drug and alcohol services
2. Unable to access drug and alcohol services e.g. due to imminent move out of area
3. Unable to give informed consent in English

It should be noted that the intervention is delivered in English. The numbers of young people excluded due to language barriers will be reviewed for the definitive RCT.

Date of first enrolment

01/09/2016

Date of final enrolment

31/03/2017

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Newcastle City Council
United Kingdom
NE1 8QH

Study participating centre
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DH1 5UG

Study participating centre
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Sponsor type
University/education

ROR
<https://ror.org/01kj2bm70>

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

On completion of the study data will be analysed and tabulated and a final study report prepared. This report will be available from the NIHR PHR and FUSE websites. In addition to the NIHR monograph, it is planned to publish this study in peer reviewed 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 websites. Publications will be shared with the TOC and funders. Individuals will not be identified from any study report.

Participants will be informed about their treatment and their contribution to the study at the end of the study, including a lay summary of the results. This will be developed by the study PPI group.

Publication of the results of the study will follow NIHR guidance on communicating research outcomes. NIHR will also receive full citations of research outputs when these become available.

All research reports issued by individual researchers and/or research teams will:

1. Credit the NIHR as a funding organisation
2. Carry the NIHR disclaimer

Only anonymised data will be used when publishing results; no personal identifiers will be used.

Intention to publish date

28/02/2019

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/05/2017		Yes	No

Results article	Phase 1 results	21/02/2019	27/01/2020	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		21/05/2019	10/07/2023	Yes	No
Other publications		19/04/2019	10/07/2023	Yes	No
Results article		08/09/2020	10/07/2023	Yes	No
Results article		01/09/2020	10/07/2023	Yes	No