Supporting Looked After Children and Care Leavers In Decreasing Drugs, and alcohol (SOLID): a pilot feasibility randomised controlled trial 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.

Key words:

Feasibility study, Pilot randomised controlled trial, Children in care, mental health, substance use, England.

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Conflict of Interest:

Eileen Kaner sat on the PHR- Research funding Board until October 2016.

Denise Howel was a member of NIHR HS&DR Commissioning Board until 2016
Member of NIHR PGfAR subpanel from 2017

Elaine McColl was an Editor for NIHR Journals Library (PGfAR journal) from 2013 to 2016 and was a member of NIHR CTU Standing Advisory Committee until 2016.

Permissions

The protocol for the pilot RCT has been published elsewhere: Alderson, H. McGovern, R. Brown, R. Howel, D. Becker, F. Carr, L. Copello, A. Fouweather, T. Kaner, E. McArdle, P. McColl, E. Shucksmith, J. Steele, A. Vale, L. Lingam, R. (2017) SOLID (Supporting Looked After Children and Care Leavers In Decreasing Drugs, and alcohol): a pilot feasibility randomised controlled trial of interventions to decrease risky substance use (drugs and alcohol) and improve mental health of Looked After Children and Care Leavers aged 12 -20

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The research reported in this 'first look' scientific summary was funded by the PHR programme as project number 14/183/08 For more information visit https://www.journalslibrary.nihr.ac.uk/programmes/phr/1418308/#/

The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PHR editors have tried to ensure the accuracy of the authors' work and would like to thank the reviewers for their constructive comments however; they do not accept liability for damages or losses arising from material published in this scientific summary.

This 'first look' scientific summary presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the PHR programme or the Department of Health and Social Care.

Scientific summary

Background

Looked after children and care leavers (henceforth referred to as children in care) are young people who have been placed under the care of the local authority, in many instances due to a history of abuse and or neglect. Compared to their peers, these young people have a four-fold increased risk of drug and alcohol use and significantly increased risk of mental health disorders. To date there is a lack of robust evidence on the most effective interventions to decrease this risk of substance use in this high risk group of young people.

Aim

The SOLID pilot trial (Supporting Looked After Children and Care Leavers In Decreasing Drugs, and alcohol) aimed to assess the 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 children in care (aged 12 -20 years).

The study had two linked phases: 1. Formative qualitative work followed by 2. An external pilot randomised controlled trial (RCT).

Objectives

Phase 1: Formative Study:

a) To adapt two behaviour change interventions for children in care to help reduce risky substance use: i, Motivational Enhancement Therapy (MET); ii. Social Behavioural Network Therapy (SBNT). The adaptations to the interventions were made with involvement from children in care and drug and alcohol treatment seeking young people, their carers, drug and alcohol workers, and social workers working with children in care to ensure acceptability and feasibility of the intervention packages.

b) To refine and produce manuals for the intervention packages for integration into care pathways for children in care.
c) To conduct a survey with drug and alcohol service leads across England to characterise usual care.

Phase 2: External Pilot RCT

Primary objective:

d) To conduct a three arm pilot RCT (comparing: i. MET, ii. SBNT, and iii. Control – usual care), to determine if rates of eligibility, recruitment and retention of children in care, and acceptability of the interventions are sufficient to recommend a definitive multi-centre randomised controlled trial.

Secondary objectives:

e) To establish data yield, data quality and acceptability of the proposed outcomes measures for self-reported alcohol and drug use, mental health and well-being, sexual behaviour and placement stability 12 months post recruitment, in order to inform a sample size calculation for a definitive multicentre RCT.
f) To assess acceptability and engagement with the adapted MET and SBNT interventions by children in care, their carers and front line drug and alcohol workers.
g) To carry out a process evaluation to include fidelity of intervention delivery and qualitative assessment of the barriers to successful implementation.
h) To develop a core intervention delivery package, potentially of a single optimised intervention, linked to a theory of change model to use in the definitive trial.
i) To develop and assess tools to collect data on costs and health benefits, and carry out a value of information analysis to inform the appropriate sample size in a definitive study.
j) To apply pre-specified 'stop: go' criteria and determine if a definitive multi-centre randomised controlled trial is feasible, and, if so, develop a full trial protocol. Criteria for progression to a definitive trial were recruitment of 60% of children in care identified as eligible, 80% of participants attending 60% of offered sessions and retention of 70% of participants at 12 month follow up.

Methods

Public and patient involvement

PPI was sought at multiple time points throughout the study. PPI representatives included children in care, local authority employees, drug and alcohol practitioners and non-looked after children. Their contributions have influenced the study design and they have co-designed study documentation and the adapted MET and SBNT manuals.

Formative phase:

The formative research consisted of five separate, but interconnected, stages: the selection of two evidence based interventions suitable for adaptation to be used with children in care; development of a theory of change model; conducting qualitative interviews and focus groups with key stakeholders to examine the principles behind the MET and SBNT approaches; analysis of the qualitative data and the co-production of the final interventional manuals.

Participants (children in care, foster carers, residential workers, social workers and drug and alcohol workers) were recruited purposively to ensure maximum diversity.

In-depth 1:1 semi-structured interviews, dyad interviews and focus groups were used to explore the assumptions inherent within our logic models, the principles behind the adapted MET and SBNT approaches, their relevance to children in care and the broader therapeutic approaches, inclusive of the key behavioural and motivational domains that the interventions should address when working with the population of children in care.

Interviews and focus groups were audio recorded and transcribed verbatim. Data was collected until data saturation. Transcripts were anonymised and identifiable participant details removed. Pseudonyms were allocated to each transcript and have been used within all reports and publications to maintain participants' anonymity.

Survey:

A phone/online survey of all drug and alcohol providers was carried out to describe the drug and alcohol treatment services offered in each local authority in England as of 2018. The survey aimed to define usual care for a definitive future study.

RCT:

The three-arm RCT, compared the adapted MET and adapted SBNT interventions developed in the formative phase to usual care. The trial involved children in care across six local authorities in North East England. Trial participants were screened for drug and alcohol use with the validated six question CRAFFT (Car, relax, alone, forget, family, trouble) screening tool administered by their social worker. Children in care, aged 12-20 years, who reported drug or alcohol use within the previous 12 months and who were able to provide assent or informed consent in English, depending on their age were eligible to participate in the trial. Assent was taken from children under 16 years and informed consent for those over 16 years. Those who were currently receiving treatment from drug and alcohol services, were due to move out of the area, or unable to give informed consent (due to acute or severe mental health difficulties, mental capacity or language barriers) were ineligible to participate.

Data were collected at baseline and 12 months post- baseline, using participant completed questionnaires on a tablet computer. The baseline and follow-up questionnaires measured self-reported drug and alcohol use (Alcohol Use Disorder Identification Test, Alcohol, Smoking and Substance Involvement Screening Tool), mental health and wellbeing (Strengths and Difficulties Questionnaire and Warwick-Edinburgh Mental Wellbeing Scale), and health-related quality of life (EQ-5D-5L). The follow-up questionnaire also collect data on placement stability, use of health and social service, self-reported sexual behaviour and anti-social and criminal behaviour. Data using Time Line Follow Back substance use and self-reported occasions of ‘drunkenness’ in the last 30 days was collected.

Individual randomisation was stratified by placement type (residential/non-residential), site and age band (12-14/over 14), to reflect risk profile for substance use. Interventions were delivered by experienced young people’s drug and alcohol practitioners who received two full days’ training in the adapted allocated intervention; either SBNT or MET. Participants

allocated to the control group received usual care, which involved their social worker making a referral along the usual drug and alcohol service pathway as required.

Process evaluation:

A detailed process evaluation, using both qualitative and quantitative methods was conducted, and involved children in care, their foster carers, residential workers, social workers and drug and alcohol practitioners. In-depth 1:1 interviews, dyad interviews and focus groups were used to explore the key lessons learned from implementing SOLID (both the interventions and the trial processes). Quantitative methods (practitioner intervention log, audio files) were used to assess the quality of intervention delivery (treatment fidelity) by applying a validated process rating scale developed in the UKATT trial.

Economic analysis:

The study conducted an exploratory return on investment analysis which aimed to assess the feasibility of a within trial economic analysis in the context of a definitive trial.

Ethics and Consent:

A favourable ethical opinion was granted by Newcastle and North Tyneside 1 NRES Committee (16/NE/0123). Informed consent (assent for those <16 years) was taken from all participants. For children in care aged under 16 informed assent was requested with an accompanying adult (parent, carer, social worker, children's home lead) present. If the accompanying adult did not have parental responsibility (PR) the research team contacted the adult with PR to obtain informed consent prior to the young person taking part in the research.

An adverse events procedure was implemented however, no adverse events were reported throughout the study.

Analysis:

Qualitative data:

The transcripts from the qualitative interviews (formative and process evaluation) were subject to thematic analysis, an iterative process, using the constant comparative method. Qualitative software (NVIVO 10) aided in the organisation of thematic codes and categories. The analysis of drug and alcohol practitioner data within the process evaluation was informed by Normalisation Process Theory.

Quantitative trial data:

The main outcomes were feasibility outcomes to inform the design of a future definitive study. Descriptive statistics were used and no formal comparisons were drawn as the sample size was not powered to detect differences.

Table A: Stop Go Criteria

	Green criteria	Amber criteria	Red criteria	Achieved
%Eligible participants consenting to trial	≥60%	40-60%	<40%	53%
% children attending 60% of offered sessions	≥80%	20-80%	<20%	9%
%of participants retained to 12 months follow-up	≥70%	50-70%	<50%	54%
Were interventions delivered with fidelity	Yes	Unclear	No	Unclear

Were interventions perceived acceptable by children in care and workers	Yes	Unclear	No	Low uptake of intervention by children, but acceptable to workers
Does the Value of information analysis show future research is worthwhile	Worthwhile	Unclear	Not worthwhile	No available data

Results:

Formative:

The manual development incorporated adaptations suggested by key stakeholders (n=65; 24 children in care, 8 non-care young people and 33 professionals). Key adaptations made were: the need to focus on overcoming mistrust and insecure attachments that children in care experience due to their history of abuse and or neglect and their interactions with the care system. Due to the fragmented nature of support networks available to children in care more flexibility is required regarding social network members. There is a need to use creative methods to engage children in care. Finally, children in care are known to have higher rates of co-morbid mental health problems and higher levels of risk-taking behaviour, therefore treatment goals need to be wider than substance misuse alone to accommodate the diverse needs of this population group. The manuals underpinned the training delivered to the drug and alcohol practitioners in preparation for the intervention delivery.

Survey:

In total 122 (82%) of 149 national drug and alcohol services, completed the survey. The survey highlighted the high levels of variation in drug and alcohol service across England with regards to screening and intervention delivery. None of the services reported delivering manualised evidence based interventions. Just over half of the local authorities (67; 55%) said they offered a 'bespoke service' however, this was often not specified in many cases; 35 (29%) reported offering structured work.

RCT:

Of the 1450 eligible children in care, aged 12-20 years, 860 (59%) were screened for drug and alcohol use by social workers over a period of a year. 211 (24.5%) met inclusion criteria for the trial and 112 young people (7.7% of the original eligible cohort) consented and were randomised into the trial arms.

In total, 15 out of the 76 (20%) participants allocated to an intervention arm attended any of the offered MET or SBNT sessions. 60 participants (54%) completed the 12 month follow up questionnaires. The pilot RCT did not meet the pre-specified 'go' criteria demonstrating that a definitive RCT is not feasible. As the primary outcomes were recruitment and retention to 12 month follow-up; no formal comparisons are drawn between groups as the sample size had not been powered to detect group differences.

Process evaluation:

There were 109 stakeholders involved in the process evaluation (37 children in care and 72 professionals). Findings illustrated that the principles of the adapted interventions were acceptable to the different professional groups and the method of collecting data on a tablet worked well. However, the combination of multiple steps in the study process and the time lost between screening and first appointment set up within the current referral pathways, meant that the process was not swift enough to engage participants in the trial and the interventions. Additionally, even though many participants were engaged in risky drug and alcohol use, acknowledgement of risk and the need to reduce their use was rare. The combination of these factors meant that the adapted interventions could not be delivered to a sufficient extent to fully test acceptability in practice.

Cost of intervention delivery:

A log was completed by drug and alcohol practitioners to help the research team calculate the cost of delivering the interventions. The practitioners seemed able and willing to fill out the log. Unfortunately, the sample size was too small to conclude whether or not the tool is acceptable to use in a definitive study.

Fidelity of intervention delivery:

Practitioners uploaded 9 out of a potential 26 audio recordings. The quality of the recordings was variable and due to the limited number we are unable to assess the internal validity of the interventions being delivered.

Economics:

Our exploratory return on investment analysis concluded that a medium to large health effect would need to be demonstrated before the intervention would be considered cost-effective.

Synthesis of findings:

The criteria to determine the feasibility of progressing to a full definitive trial were not met. Major challenges were found, social care staff were overstretched resulting in screening and recruitment being problematic. This compounded with children in care experiencing complex care arrangements and placement instability resulted in intervention delivery being challenging and the fidelity of the intervention could not be assessed due to low uptake. The current format of the intervention pathway was not feasible to deliver.

This is the first UK-based pilot feasibility trial that assessed the feasibility of delivering behaviour change interventions to decrease drug and alcohol use and support mental health of children in care. Several key lessons have been learnt to inform future service delivery and research for children in care.

1. Model of care

The screen and treat, model used in SOLID has been shown to be problematic. Any future trial needs to think about how best to engage children in care. The current model of referring participants on to another service does not work; interventions need to be delivered opportunistically within enhanced social care pathways. .

2. Delivery agent and support

SOLID tried to use the existing drug and alcohol services and standard referral system to deliver novel interventions. Children's services departments are often less research mature and very stretched. Without additional, dedicated 'in service' academic support, potentially in

the form of embedded researchers/academic social workers, research with children in care will prove difficult. An embedded researcher has the potential to be jointly managed by local authorities and universities, facilitating clearance to engage clients; this could significantly change the research culture within units. A new way of working where drug and alcohol workers could be allocated to social care services and residential units would decrease referral times and could be a new way of delivering these interventions. The NIHR Clinical Research Network has now extended support into research taking place in non-NHS settings, such as health and social care and public health, these amendments could facilitate the necessary change as it has within NHS research trials.

Conclusion:

This study found that many children in care do not identify themselves as needing a drug and alcohol intervention despite reporting use of substances and linked risky behaviours. This mismatch between professional and children in care's views justifies further attention. Future ecologically relevant models of care are needed for children in care to improve the outcomes of these potentially vulnerable young people across their life course.

Study registration: ISRCTN80786829 and CRD42018098974

Funding details: This project was funded by the National Institute for Health Research (NIHR) Public Health Research programme. NIHR number 14/183/08.

Word count 2655