Life in transition: Improving health outcomes for care leavers: a cluster-randomised feasibility trial

Protocol

Version 0.1, 04 April-2022

Approvals and IDs	Reference
Protocol version	0.1
IRAS project ID	N/A
Research Ethics Committee (REC)	School for Policy Studies, Reference number: SPSREC/21-22/227
Sponsor	University of Bristol
ISRCTN	
Funder	NIHR Health Services and Delivery Research
NIHR CRN CPMS	

This protocol has regard for the HRA guidance

KEY TRIAL CONTACTS

Chief Investigator	Professor Geraldine Macdonald
Co-investigators (applicants for funding)	Dr Patricia Lucas Professor Julie Selwyn Dr Fiona Lynn Professor Chris Metcalfe
Lead Statistician	Professor Chris Metcalfe, Professor in Medical Statistics, University of Bristol Email: chris.metcalfe@bristol.ac.uk
Study website	N/A
Trial Manager (UK)	Jacqueline Hammond

FUNDING AND SUPPORT IN KIND

Funder(s)	Financial and non-financial support given
National Institute for Health Research Clinical Commissioning Group	Grant funding (United Kingdom
Bristol Trials Centre Bristol Medical School, Department of Population Health Sciences, University of Bristol 1-5 Whiteladies Road Bristol, BS8 1NU	Methodological expertise
	Sponsor
BSSNG Clinical Commissioning Group	Host

LIST OF CONTENTS

At the 48 weeks interview we will also ask care leavers about their experiences of participating in the trial, and what their advice would be to a research team wanting to conduct a larger study. A particular focus of

LIST OF ABBREVIATIONS

AE	Adverse Event
BTC	Bristol Trials Centre
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CRN	Clinical Research Network
CSO	Clinical Study Officer
DMC	Data Monitoring Committee
EU	European Union
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
IAPT	Improving Access to Psychological Therapies
GCP	Good Clinical Practice
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
ITT	Intention-to-treat
NHS	National Health Service
NHS R&D/R&I	National Health Service Research & Development/Research & Innovation
NICE	National Institute for Health and Care Excellence
NIHR CRN	National Institute for Health Research Clinical Research Network
NIHR HTA	National Institute for Health Research Health Technology Assessment
PI	Principal Investigator
PICs	Patient Identification Centres
PIL	Participant Information Leaflet
PPE	Personal Protective Equipment
PPI	Patient and Public Involvement
PROM	Patient reported outcome measure
QALY	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SLA	Service Level Agreement
SOP	Standard Operating Procedure
SQL	Structured Query Language
TAU	Treatment As Usual
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UK	United Kingdom
UKCRC	UK Clinical Research Collaboration

TRIAL SUMMARY

Trial title	Promoting good health in Care Leavers (CLs) through training for Personal Advisors (PAs)	
Short title	Life In Transition: Improving Health Outcomes for Care Leavers	
Acronym	LIFT	
Chief Investigator	Professor Geraldine Macdonald	
Sponsor	University of Bristol	
Funder	National Institute for Health Research (NIHR)	
Trial design	Cluster-randomised feasibility trial	
Planned sample size	6 clusters (teams of Personal Advisors); circa 30 Personal Advisors; 60 care leavers	
Inclusion criteria	Care Leavers i) Aged over 16 years at baseline ii) Allocated to the Leaving Care team **for the first time,** in a four-month period beginning 2 months prior to baseline data collection iii) Not simultaneously on the caseload of a social worker.	
Exclusion criteria	Care Leavers • living in foster care (other than 'Staying Put' foster care) or in a residential or secure setting of any kind, including custody, remand, or hospital; or • they are simultaneously allocated to the caseload of a qualified social worker (for example, as a result of being a parent themselves); or • deemed by the local authority to present a risk to themselves or to research staff.	
Number of study centres	3	
Treatment duration	Training intervention delivered over a three-month period	
	Objectives	**Outcome Measures**
Primary	Feasibility of Study Design	The recruitment and retention rates of personal advisors and care leavers, the completion of training by personal advisors in the intervention group, the proportion of care leavers and personal advisors who complete the study assessments, the ability to blind outcome assessors and the potential floor/ceiling effects in our proposed outcomes measures at baseline, post training (for intervention PAs) and 24- and 48-weeks post intervention.
Secondary (Intervention outcomes and measures_	**i)** Impact on Care Leavers' Health and Wellbeing	Qualitative interviews
	a) Wellbeing	4 x ONS questions
	b) Physical Health	3 x Census Questions

	c) Quality of Life	ReQoL20 OR eQoL10 OR EQ-5D-5L
	d) Confidence in health professionals	Revised Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI-10)
	e) Perceptions of physician empathy	Questions regarding Care Leavers' Perceptions of Physician Empathy
	f) Psychological coping (Mastery)	Pearlin Mastery Scale
	ii) Cost-effectiveness	
	a. Health Service Usage	Health Service Use Questionnaire
	b. Quality of Life	ReQoL20 OR eQoL10 OR EQ-5D-5L
	iii) Increased knowledge, skills and confidence of Personal Advisors	Online survey
		Individual interview
Study duration	• 24 months	

TRIAL FLOW CHART

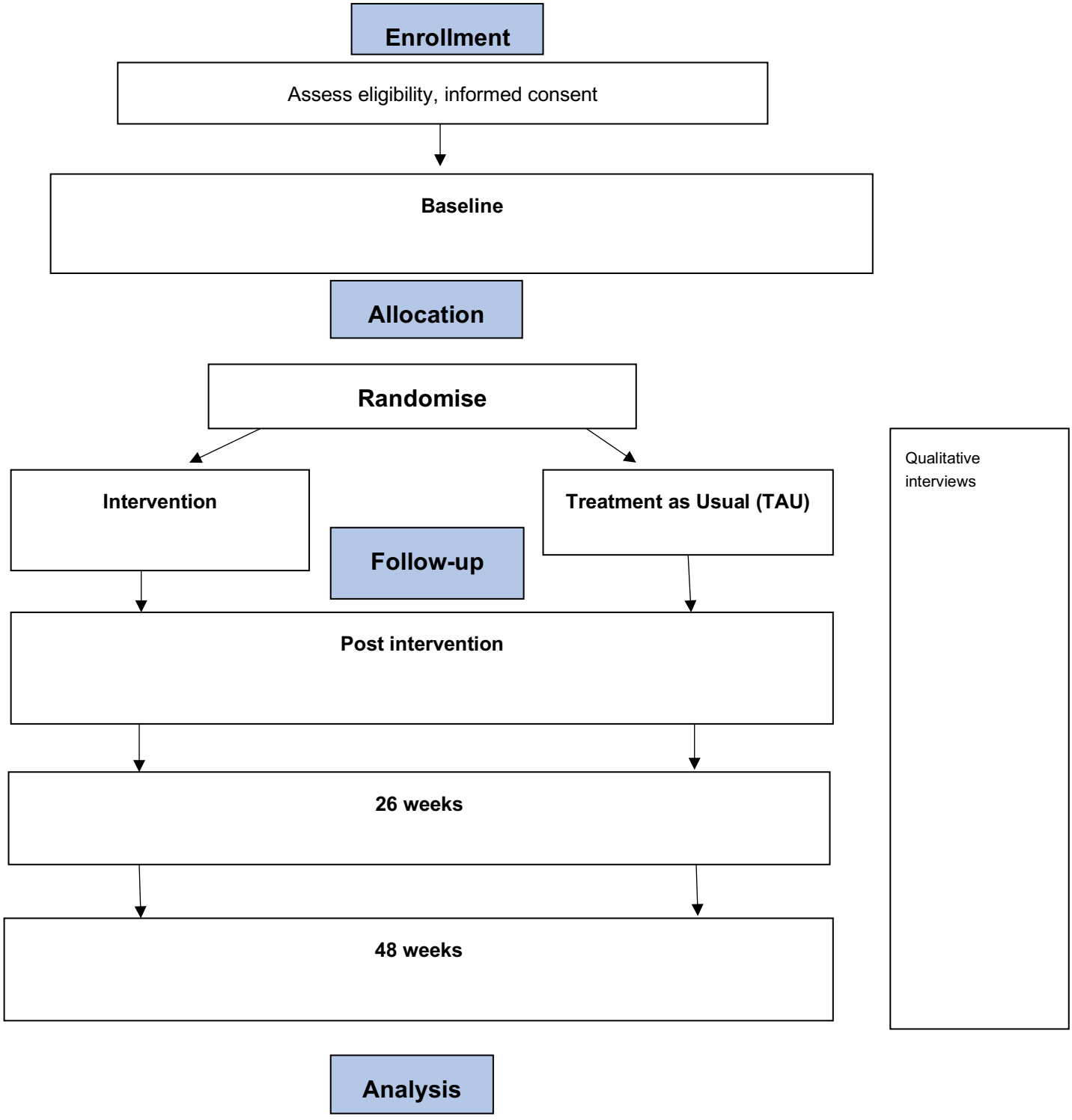


Figure 1 Trial flowchart

1 BACKGROUND AND RATIONALE

1.1 Children looked after and inequalities in health

The number of children being looked after by local authorities has increased year-on-year since 2009. In March 2017 there were 72,670 children looked after in England, of whom 50,470 were in care under a care order, and of whom 4,560 were unaccompanied asylum-seeking children. Looked after and formerly looked after children experience significant health disadvantage during and after their time in care. In 2016, the Care Quality Commission reported that 'support for care leavers was unacceptably poor, with health services failing to cater for their needs or help to prepare them for the next stage in their life ..[with most lacking] adequate health support as they left the care system'.(1 p.36) Inequalities in health amongst looked after children and young people (LACYP) encompass their physical health, sexual and reproductive health, and mental health and wellbeing.

Compared with those living at home, looked after children and young people (LACYP) often have poorer physical and mental health.(2-7) Despite recent improvements (and recognising the difficulties in comparisons with the general population(8)) they remain less likely to have received all routine immunizations,(8, 9) with lowest rates amongst older LACYP and unaccompanied asylum-seeking children.(10, 11) In 2003 Meltzer et al. reported that two thirds of LACYP had at least one physical complaint.(12) The number of LACYP with disabilities is unknown, but ongoing work by Selwyn finds higher numbers than in the general population.

Compared with those in the general population, LACYP and those leaving care, are at greater risk of early sexual initiation(13) and of sexual exploitation.(14) Barnardo's estimates that one third of those children who experience sexual exploitation are looked-after children. Compared with children living with their families, female LACYP are more likely to become pregnant and LACYP are more likely to become parents at an early age.(15-18) Care experienced young women are more likely to smoke during pregnancy, to have symptoms of depression and deliver a low birthweight baby.(19) They may be at increased risk for pre-term birth(20, 21) and are more likely to have an elevated risk of their own children being taken into care,(22) with a significant number experiencing 'recurrent care proceedings.(23)

Many LACYP enter care with existing mental health problems, often associated with trauma.(24-26) The Departments of Education and Health estimate that almost a half of LACYP have a diagnosable mental health disorder.(27) In a study comparing LAC to children who were otherwise deprived in Britain, Ford et al found that looked-after status was an independent correlate of psychiatric disorders (other than autistic spectrum disorders and generalized anxiety disorder) after adjusting for potential confounders.(25) In a study of the files of 274 UK care leavers, Smith found that, in the opinion of their PAs, 46% had mental health needs, of whom 65% were not receiving any statutory service.(28) Because they are especially prone to isolation and loneliness, CLs may be less likely to seek help, and instead resort to ways of coping that cause further harm e.g. self-harm, drug and alcohol misuse.

The National Service Framework for Children, Young People and Maternity Services recognised LACYP as a particularly vulnerable group.(29) Various policy initiatives have sought to improve their physical, sexual and mental health. The introduction of the LAC named nurse represented a significant investment in promoting the health of children whilst in care, but that responsibility ceases when young people leave care.

1.2 Care leavers

Every year, some 10,000 children aged 16-18 years leave local authority (LA) care in England(18) and many start to lead independent lives. Most make these transitions against a background of significant adversity and trauma, having been removed from the care of their parents due to abuse and neglect.(30, 31) Transition to adult services and responsibility for their own health care takes place much earlier than it does for most young people, and for those in care it can happen very suddenly.(32) When they move to independent living care leavers (CLs) have to negotiate the transition from the familiar (place and people) to

the unfamiliar and, at age 18, from children's to adult services. The age at which young people have to move from children's services to adult services also comes 'at a time of marked risk to ongoing psychosocial development and wellbeing' (p.1(33)). Those with mental health needs are likely to find themselves without support at a time they need it most, and CLs are likely to face loneliness and isolation. In this arrangement of service provision, young people are faced with a system that is 'weakest where it needs to be strongest'.(34) Despite initiatives designed to improve the transition to adulthood, research reports that care leavers are often inadequately prepared for, or supported during, the multiple transitions entailed in leaving care.(35, 36) In their 2016 study(1) the Care Quality Commission cited one care leaver as saying:

> 'I don't know why the system thinks a 16-year-old is an adult. Kids in care haven't even had a childhood. How can we be an adult at 16?'

This study seeks to improve health outcomes for CLs by better equipping the staff responsible for them with appropriate knowledge and skills.(37)

1.3 Care Leavers' experiences of transition

Research with care leavers(38, 39) makes clear that the transition from care can, in and of itself, be highly stressful, as young people may be: living on their own, away from familiar environments, having suddenly to budget and care for themselves, and may be trying to re-connect with birth family members. A health survey completed by 418 care leavers found that 44% stated they regularly drank alcohol to excess and 29% had self-harmed.(40) Care leavers (CLs) felt that their health needs were not understood and they had found it difficult to access adult services. Many complained of misdiagnosis, a problem that other research has confirmed.(41) The most common theme reported in all studies of care leavers' views are feelings of isolation and loneliness.

Research into the subjective wellbeing of 474 care leavers, conducted at the University of Bristol in partnership with CORAM Voice, found that 22% said they had a disability or long term health condition affecting day to day activities; 20% were lonely 'all of the time', and 24% rated their anxiety as high (in comparison with17% of young people in the general population (see ONS 2017(42)). Care leavers commented:

> 'At 16, I was left to live in a half independent house …. miles from the school I attended and where my friends live. This left me isolated, unable to afford transport to see my friends. Which led to my relationships with my friends drifting apart.'
>
> Leaving care for me was a bad experience at the start, had no support and was very vulnerable.'

1.4 Leaving care and the role of the Personal Advisor

In the Children and Social Work Act 2017, the Government introduced the requirement for local authorities (LAs) to publish a 'Care Leaver Offer', which outlines the services to support this transition for care leavers within the local authority area. LAs are mandated to provide a Personal Advisor (PA) to support CLs up to the age of 25 (at the time of the initial proposal only those CLs in education or training were eligible for support beyond age 21). The PA's role is to ensure a CL has the correct level of support and to coordinate and review the services needed to implement the CL's 'Pathway Plan', to take reasonable steps to ensure that the young person makes use of these, and to remain informed about their progress and wellbeing.(43) The Pathway Plan is required for all care leavers; it is designed to facilitate successful transition(44) and covers 8 eight areas of their lives, including their 'health and development' and 'emotional and behavioural development'. The Pathway Plan should include details of a young person's health needs and how these should be met, and the development of this plan should be supported by annual Health Assessments undertaken while in care. CLs themselves should be provided with a Health Passport when they leave care, summarizing their health history and needs for their own future reference.

The expectations of the PA is set out in the Children and Social Work Act 2017 and in the description of the 'named worker' in NICE guideline NG43.(45) NG43 covers a range of transitional situations, and those

deemed particularly relevant to the responsibilities of PAs are asterisked in the following extract from Sections 1.27 and 1.28.

‘1.27 The named worker should:

- oversee, coordinate or deliver transition support, depending on the nature of their role;*
- be the link between the young person and the various practitioners involved in their support, including the named GP*
- arrange appointments with the GP where needed as part of transition*
- help the young person to navigate services, bearing in mind that many may be using a complex mix of care and support*
- support the young person’s family, if appropriate
- ensure that young people who are also carers can access support
- act as a representative for the young person, if needed (that is to say, someone who can provide support or advocate for them)*

1.28 The named worker should ensure that the young person is offered support with the following aspect of transition if relevant for them (which may include directing them to other services)

- education and employment
- community inclusion*
- health and wellbeing, including emotional health*
- independent living and housing options.’

1.5 importance of improving the health and wellbeing of care leavers

Few data are routinely collected on the health and wellbeing of CLs, but evidence suggests that, compared with the general population of young adults, they fare less well.(25, 46-49) Most have poorer educational qualifications and socio-economic life chances,(50, 51) and poorer physical, emotional and mental health than comparable peers.(26, 37, 52-55) They are more likely than those who have not been in care to engage in risky behaviours, such as smoking, substance use and misuse, and unprotected sex. They are over-represented amongst the homeless,(56, 57) among young women who become teenage parents,(58) those who self-harm,(59, 60) and those involved with the criminal justice system.(57)

As well as the personal costs to young people, there are significant societal costs. For example, mothers who are CLs are at increased risk of parenting problems and unstable housing arrangements,(19, 61) and their children are more likely to be taken into care,(22) leading some women to avoid involvement with services.(62, 63) Using the costs to young people of not being in education, employment and training (NEET), the NAO estimated lifetime cost of the 2015 cohort of 19-year old care leavers to be around £240 million - £150 million more than if they had the same NEET rate as 19 year old young people who had not been in care.(64p7)

1.6 Why this research is needed now

LAs, Clinical Commissioning Groups and NHS England are required to ensure that effective plans are in place to enable children leaving care to continue to obtain the healthcare they need.(27) Research and guidance emphasise the importance of a named person who can develop a good relationship with a CL and ensure that s/he receives support and advice. For most CLs, the named person is the Personal Adviser (PA) who should be implementing their Pathway Plan, including supporting their health needs. By definition, most will meet the criteria for the ‘named worker’ in the relevant NICE Guideline (NG43, see previous). Statutory guidance(27) makes clear that PAs ‘should have access to information and training about how to promote

physical and mental health' (p.26), to work in partnership with CLs and those health professionals involved in their health assessments, and to ensure that CLs have all the information they need to manage their own health. For those with complex needs, including disabilities, who do not meet the criteria for support by adult services, the PA should ensure that all possible forms of support are identified and made available.

Despite the statutory force of the guidance, health is rarely a major focus for PAs, who are primarily concerned with basic provision of housing and money.(65, 66) Whilst appropriate accommodation is essential for mental and physical health and wellbeing, many care leavers report that insufficient attention is given to their health needs, particularly their mental health needs and as the Care Quality Commission noted, most lack adequate health support.(1 p.36) This was confirmed in our discussions with care leavers whilst developing this proposal.

As adults with whom CLs have (ideally) already formed a supportive relationship, the PA is well placed to promote their health and wellbeing, and their use of health services. However, PA provision varies considerably across LAs,(58) and there is currently no prescribed professional qualification for PAs, other than to have a working knowledge of the issues a care leaver might face as they make their transition into adulthood, and the legal framework in relation to this. Little is known about in-service training provided by LAs, or the supervisory arrangements in place to support them in executing their role.

Without an explicit curriculum to equip PAs to address issues of health and wellbeing, it is unsurprising that these issues are seldom addressed. In preparing their transition Guideline(45) NICE was unable to identify any studies on the effectiveness of 'transition training' for practitioners responsible for supporting young people using children's health or social care services 'before, during and after transition' (2.9) The Care Leavers Association has recommended better training for PA, particularly in relation to mental health. This study will address this gap by developing a brief training intervention designed to equip PAs to better promote and facilitate the health and wellbeing of the care leavers.

2 AIMS AND OBJECTIVES

2.1 Aim

The study has two main aims, the first of which was to develop a training programme that will help PAs to identify and act on the health and wellbeing needs of care leavers. This has been completed. The second aim is to assess the feasibility of evaluating the effectiveness of the training programme in a definitive trial. The remainder of this protocol addresses this second aim.

2.2 Primary objective

To ascertain the feasibility of key procedural elements that would need to form part of an experimental evaluation of the effectiveness of the training intervention, including:

- Whether it is possible to recruit, train and retain all PAs in each participating authority.
- Whether it is possible to recruit and retain a sample of CLs in each arm of the study to a 12 month follow up.
- Whether it is possible to secure blinding of outcome assessors.

2.3 Secondary objectives

Secondary objectives are to:

- Establish the acceptability and feasibility (data burden and cost), and the factors influencing the completion of measures at baseline (PAs and CLs), post training (PAs) and follow up (PAs and CLs).
- To collect outcome measures and assess their performance and quality with this population (acceptability, completeness, means, variability and distribution of scores).
- To use the data collected to estimate the Intra-cluster Correlation Coefficient (ICC) to inform the sample size require for the main trial.
- Determine the feasibility + cost of accessing and using administrative data, if available
- Ascertain the acceptability to LAs and PAs of randomization
- Consider the implications of any contamination between the two arms of the trial e.g. PAs moving between teams in different trial groups.
- Identify barriers + facilitators to implementation of, and fidelity to, the intervention.
- To use the information gathered to inform the design of a pragmatic trial, if this seems feasible.

Outcome and outcome measures - Feasibility

Outcome 1: Recruitment of care leavers to the study

- Measurement: Count of care leavers randomised
- Timepoint: Feasibility study recruitment period for care leavers

Outcome 2: Retention of care leavers

- Measurement: Proportion of recruited care leavers who complete the study assessments
- Timepoints: 16, 32 and 48 post intervention

Outcome 3: Blinded assessment

- Measurement: Ask assessors to record whether the interviewee has an intervention or control PA - best guess if don't know (two-alternative forced choice).

- Timepoints: 16, 32 and 48 weeks post intervention

Outcome 4: Recruitment of personal assistants

- Measurement: Count of personal assistants recruited
- Timepoint: Feasibility study recruitment period for personal advisors

Outcome 5: Fidelity to allocation

- Measurement: Proportion of recruited personal advisors in intervention group who complete the training
- Timepoint: Feasibility study training period for personal advisors

Outcome 6: Retention of personal advisors

- Measurement: Proportion of recruited personal advisors who complete the study assessments
- Timepoints: post-training, 24 and 48 weeks

Intervention outcomes

2.4 Primary endpoint/outcome

Health promoting practices by Personal Advisors

2.5 Secondary endpoints/outcomes

- Impact on Care Leavers' Health and Wellbeing
- Costs and benefits

Intervention outcome measures

2.6 Intervention outcome measures – Personal Advisors

- Health promoting practices by Personal Advisors – data from semi-structured interviews

2.7 Intervention outcome measures – Care Leavers

- Wellbeing – 3 questions about Personal Wellbeing based on those used in the ONS Survey
- Physical Health –3 questions about Physical Health from the Census
- Quality of Life – one of the following: the ReQOL20; the ReQOL10 or the EQ-5D-5L
- Confidence in health professionals - 10-item questionnaire: Revised Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI-10)
- Perceptions of physician empathy – 5-item questionnaire concerning perceptions of the PA's empathic qualities in relation to health
- Psychological Coping (Mastery) 7-item questionnaire: Pearlin Mastery Scale
- Health service usage – Health Service Use Questions

3 TRIAL DESIGN

The LIFT study is designed as a single-blinded, cluster-randomised trial in which up to 12 groups of Personal Advisors will be randomly allocated to one of two trial arms.

Groups may be teams, local authorities, or groups within a team, depending on the organisational structure of the participating local authorities. We aim to randomise groups of comparable sizes.

Those allocated to the intervention group will receive the training intervention designed in Phase 1. Those allocated to the control arm will not receive the training and will continue to work with Care Leavers 'as usual'.

Prior to randomization, PAs will complete a survey covering the main focus of their work with PAs, their knowledge about public health issues relevant to CLs, and their knowledge of relevant local services.

At 24- and 48-weeks post-training of personal advisors in the experimental arm, follow up data will be collected by researchers unaware of the allocation status of care leavers and personal advisors.

Health service usage data will be collected at two-months intervals from baseline to 52-weeks

3.1 Project timetable

Month	Project activity
1	Briefing of site personnel
	Identification of Skills Workshop Facilitators
2	Recruitment of Personal Advisors (PAs)
2-6	Recruitment of Care Leavers (CLs)
	Baseline data collection from PAs and CLs
5-6	Randomisation of PA groups
5-7	Training of PAs in the Experimental Arm
	Post-Training Survey of PAs in the Experimental Arm
7-17	Bimonthly resource use data collection
10-12	24-week data collection from Care Leavers (Outcome data) 24-week data collection from Personal Advisors (Process and Implementation data)
17-19	48-week data collection from Care Leavers (Outcome data) 24-week data collection from Personal Advisors (Process and Implementation data)
14-20	Data analyses
18-22	Drafting of the report
22	Consultation on findings
22-24	Finalising report

3.3 Planned recruitment rate

Personal Advisors

Participant personal advisors will be recruited from each of the participating local authorities. Whilst the local authority can require their staff to participate, and our aim is to recruit all PAs employed in the local authority, we intend to give personal advisors the option to withhold their consent to participate. In this feasibility study we are aiming to recruit from three groups of PAs at each of three local authorities.

Care Leavers

Participating care leavers will be recruited from each local authority until the target sample is reached (60 care leavers).

Recruitment will be proportionate to the size of the local authority and the flow of eligible care leavers and drawn equally from both arms of the study. We have not conducted a formal sample size calculation but are aiming to demonstrate the feasibility of a definitive RCT by recruiting around 20 care leavers at each of the three local authorities.

4 TRIAL SETTING

English local authority departments of Children's Social Care:

- **Bristol City Council**
- **South Gloucestershire Council**
- **Nottinghamshire County Council**

Between them, these three councils represent both urban and rural settings, and small and large departments. Bristol and Nottinghamshire have particularly diverse populations.

5 ELIGIBILITY CRITERIA

5.1 Subject population

The intervention is directed at Personal Advisors, but the intended beneficiaries are young people leaving care. The legal definition of a care leaver is someone who has been in the care of the Local Authority for a period of 13 weeks or more spanning their 16th birthday [The Children (Leaving Care) Act 2000].

5.2 Inclusion criteria – Care Leavers

Care leavers aged over 16 years at baseline, allocated to the Leaving Care team for the first time, in a four-month period beginning 2 months prior to baseline data collection

5.3 Exclusion criteria – Care Leavers

Care leavers will be excluded if they are:

- living in foster care (other than 'Staying Put' foster care) or in a residential or secure setting of any kind, including custody, remand or hospital; or
- they are simultaneously on the caseload of a qualified social worker for reasons other than being a care leaver, for example, as a result of being a parent themselves; or
- deemed by the local authority to present a risk to themselves or to research staff.

6 TRIAL PROCEDURES

The study aims to recruit all Personal Advisors employed by the participating local authorities, and 60 Care Leavers, 30 from each arm of the trial. This section outlines the key trial procedures from identification of potential participants through to end of trial.

6.1 Schedule of trial assessments and outcomes (overview)

Tables 1 and 2 (next page) depicts the key assessments/outcome measures and participant-related procedures scheduled at various trial timepoints. To summarise, participants in the trial will undergo:

- Identification and screening contact; detailed in Sections 6.2 - 6.6.
- Consent and randomisation (enrolment); detailed in Section 6.7.
- Assessments at baseline (0-weeks) and follow up at 24- and 48-weeks post-intervention; detailed in Section 6.8.2.

Study data will be collected from i) Personal Advisors, ii) their managers, and iii) care leavers.

6.2 Identification and screening of potential participants (overview)

Participating Local Authorities will be provided with a clear explanation of the purpose and design of the study, and ensure, as far as possible, that the concerns of individual PAs, line managers and other key stakeholders in the LA are addressed.

Personal Advisors will receive notification of the study from the local authority and be invited to attend a briefing session (face to face or online, depending on circumstances.

Eligible care leavers will be identified by the local authority and invited to participate in the study.

6.3 STEP 1: Participant identification and invitation to participate

Personal Advisors will be accessed via their line managers, who will distribute a Participant Information Leaflet designed for local authority staff. Whilst Personal Advisors may be expected by their employer to participate in the trial, we will nonetheless require their informed consent to do so.

All information provided, both written and verbal, will emphasise that the study is testing the effectiveness of a training intervention rather than the practice of individual PAs or teams.

No Personal Advisor will be pressured to participate, and their voluntary participation will be made clear in our recruitment/consent process.

Care Leavers will be notified of the study through their Local Authority, who will forward an invitation to participate from the research team, together with a Participant Information Leaflet (PIL) designed for Care Leavers. The invitation and PIL will make it clear that the decision to take part or not to take part, is entirely voluntary and will have no effect on the services they receive. Details of the research team will be included on the invitation so potential participants can contact the team directly, should they wish to do so.

In addition, a member of the Research Team will attend drop-in sessions (or similar) organised by the Leaving Care team (with their permission) to talk to care leavers about the study. Drop-in sessions usually take place on Local Authority premises, and we will ensure that we can speak to Care Leavers in confidence if they wish. We will reassure young people that they are not obliged to take part.

6.2 STEP 2: Preliminary (eligibility) screening (Care Leavers) and expression of interest

Following an expression of interest from a care leaver, a member of the Research Team will arrange to meet with them to ascertain eligibility, ensure that they fully understand what they study will entail, that they are willing to proceed, and understand that they can withdraw at any time without giving any reason, and without

prejudice to the services they receive. This meeting may be online or in person, depending on circumstances.

The recruitment of Care Leavers will extend beyond the randomisation of PA groups until the training of PAs in the experimental group has been completed.

6.3 STEP 3: Informed consent

Following discussion with a member of the research team, both personal advisors and care leavers who wish to participate will be asked to sign a form indicating their informed consent.

6.4 STEP 4: Baseline (first study) appointment (for those potentially eligible in Step 3)

Baseline data will be collected once informed consent has been obtained from PAs and CLs.

As with recruitment, the collection of baseline data from Care Leavers will continue beyond the allocation of PA groups to the trial up to the completion of the training by PAs in the experimental group, but will not continue beyond that point.

6.5 STEP 5: Randomisation

Once baseline data have been obtained from all relevant Personal Advisors randomisation will be undertaken by Professor Chris Metcalfe at the Bristol Trials Centre and communicated to the local authority groups by a member of the Study Team.

6.6 Follow-up assessments

Follow-up assessments of Personal Advisors and Care Leavers will be conducted by members of the study team at 24 and 48 weeks following the completion of PA training. Wherever possible, peer researchers will be responsible for follow-up assessments with Care Leavers, supported by Coram Voice.

6.7 Qualitative assessments

Care Leavers: At 24- and 48 weeks following the completion of training by PAs, we will collect qualitative data from our sample of care leavers on the extent to which they feel their health needs (including emotional health and wellbeing) have been recognized and addressed by their PAs in the previous six months. The interviews will explore how often they have seen their PA; whether PAs have brought up topics covered in training modules (including help seeking, smoking, alcohol and substance use, sexual health, nutrition and exercise); what their own health and wellbeing concerns are and whether or not they have felt able to bring these to the attention of their PA; what the response was, and how helpful their PA has been more generally in helping them to address their health issues. We will also enquire how the CL feels about health issues being raised by the PA, and whether or not they subsequently took any steps to address them.

At the 48 weeks interview we will also ask care leavers about their experiences of participating in the trial, and what their advice would be to a research team wanting to conduct a larger study. A particular focus of this conversation will be their views on the use of peer researchers, the incentives offered; what information they would want to know about the findings of the trial, and in what format.

All interviews with Care Leavers will be conducted via a conference facility or via Smartphone facility, unless and until circumstances change and face-to-face meetings are judged safe and appropriate.

Personal Advisors: At the 24- and 48- week follow up points we will re-interview the same PAs to explore:

- Frequency and content of contacts with CL, with particular focus on module topics;
- which modules have been most, and least, useful; how or why;
- what factors beyond the training have helped them to develop and implement a focus on health promotion activities with care leavers, and what factors have impeded this (factors to be explored

include organisational factors such as supervision, workload, follow-up support; personal factors such as lack of confidence, adverse experiences, and care leaver attributed factors such as lack of interest, refusal to discuss).

Throughout the interviews we will ask for *specific* examples, using these to probe further into the processes underpinning the ways that the training has, or has not, been effective in influencing practice. At 48-weeks we will also ask PAs about their experiences of participating in the trial.

File analysis It will not be possible to observe PAs in action, but we will seek permission from LAs (and CLs) to review the health assessments, pathway plans, and PA records of the care leavers we interview, in both arms of the trial. We will use the files as an additional source of evidence of impact, and to triangulate the data from interviews with PAs.

6.8 Thanking participants for their involvement (payments)

Personal Advisors will not receive any payment for participation. Care Leavers will be offered a £20 voucher at each of the three data collection points, plus travel expenses that might be incurred.

6.10 Emergency contact procedure for participants

We do not anticipate any emergencies arising as a result of this study. However, all participants have either a line manager (in the case of Personal Advisors) or an allocated worker (in the case of Care Leavers) and the Participant Information Leaflets will make clear that any concerns about the study should be addressed to these individuals in the first instance.

6.11 Blinding

Peer researchers will not be told the allocation of the care leavers they interview.

6.13 Withdrawal from the trial (or change of permissions)

Participants can change their permissions of fully withdraw for any reason at any time during their involvement in the trial. Participants can stop: (a) attending the training (in the case of Personal Advisors); and (b) providing questionnaire data to the trial (both Personal Advisors and Care Leavers), at any time for any reason without affecting their employment (Personal Advisors) or service entitlement (Care Leavers).

In all cases, efforts will made to report the reason(s) for the change of permissions in a LIFT Change of permissions/Withdrawal form. The study would also retain, confidentially, any data collected up to the point of withdrawal for analysis, as advised in the PIL.

6.14 End of trial

Participant: The participant ends their involvement with the trial when their last assessment is completed (or they have withdrawn from the study).

6.15 Early termination of the study

The trial may be prematurely discontinued by the Sponsor, Chief Investigator (CI), ethics committee or Funder based on new safety information or for other reasons given by the TSC or ethics committee concerned.

7 INTEGRATED QUALITATIVE RESEARCH

7.1 Integrated qualitative research – experiences and acceptability of study and treatment

Embedded within this feasibility c-RCT is a mixed-method process and implementation study of the training intervention, its use by PAs and the experiences of CLs. This information will aid the interpretation of trial findings (albeit these will only be exploratory) and inform any further adjustments to the intervention or methodology that might be required for a successful Phase III trial.

To address key issues of process and implementation we will observe the training provide in each local authority and to collect the following data from PAs and CLs.

Personal Advisors

After the training we will ask all participants in the experimental arm to complete a questionnaire designed to elicit their perceptions of the value of the training, whether it addressed issues of perceived significance, whether there were any gaps, and how their knowledge has changed, if at all. We will also ask questions about the experience of engaging in a blended learning approach to training, as opposed to face-to-face training in the topics covered.

We will ask Personal Advisors about their perceptions of:

- the relevance of the training to the CLs with whom they work and whether it has given them sufficient knowledge to identify, raise and address the health issues covered (i.e. 'content, 'dose' and 'level');
- the extent to which they think organizational factors are likely to support or impede changes to their practice, including, for example, internal factors such as caseloads; administrative systems, line management support, and external factors such as the availability, capacity and responsiveness of other services;
- what impact they think it might have on their practice, and
- how it might benefit the young people with whom they work.

At the 24- and 48- week follow up points we will re-interview the same PAs to explore:

- Frequency and content of contacts with CL, with particular focus on module topics;
- which parts of the training have been most, and least, useful; how or why;
- what factors beyond the training have helped them to develop and implement a focus on health promotion activities with care leavers, and what factors have impeded this (factors to be explored include organisational factors such as supervision, workload, follow-up support; personal factors such as lack of confidence, adverse experiences, and care leaver attributed factors such as lack of interest, refusal to discuss).

Throughout the interviews we will ask for *specific* examples, using these to probe further into the processes underpinning the ways that the training has, or has not, been effective in influencing practice. At 52-weeks we will also ask PAs about their experiences of participating in the trial.

Care leavers

At 24- and 48-weeks, we will collect qualitative data from our sample of care leavers on the extent to which they feel their health needs (including emotional health and wellbeing) have been recognized and addressed by their PAs in the previous six months. The interviews will explore how often they have seen their PA; whether PAs have brought up topics covered in training modules (including help seeking, smoking, alcohol and substance use, sexual health, nutrition and exercise); what their own health and wellbeing concerns are and whether or not they have felt able to bring these to the attention of their PA; what the response was, and how helpful their PA has been more generally in helping them to address their health issues. We will also

enquire how the CL feels about health issues being raised by the PA, and whether or not they subsequently took any steps to address them.

At the 48 weeks interview we will also ask care leavers about their experiences of participating in the trial, and what their advice would be to a research team wanting to conduct a larger study. A particular focus of this conversation will be their views on the use of peer researchers, the incentives offered; what information they would want to know about the findings of the trial, and in what format.

All interviews will be conducted via a conference facility or via Smartphone facility, unless and until circumstances change and face-to-face meetings are judged safe and appropriate.

7.2 Participant consent

Consent for this part of the study will be obtained at the same time as consent to the trial as a whole.

7.3 Analysis of integrated qualitative research data

Information from the process and implementation study include qualitative data that are essential to interpreting the findings of the feasibility study, and in particular to inform the deliberations of the Trial Steering Committee regarding the appropriateness of proceeding to seek funding for a Phase III trial.

The analysis of interview data will be analysed using Framework (Ritchie et al, forthcoming; Ritchie et al, 2003), a comprehensive and systematic approach to the analysis qualitative data. Using Framework, we will summarise and categorise data according to a series of thematic matrices that are grounded in the C-RCT objectives. Each matrix represents a core theme linked to the study objectives, with additional column for sub-topics and a row for each participant. Interview data are placed in the relevant cell, which makes organising and summarising the data very amenable to in-depth descriptive as well as explanatory analysis. Framework will enable us to describe the range of PA and CL experiences and views, to identify areas of similarity and difference between personal advisors and care leavers in each arm of the trial and in each LA. It will also enable us to explore associations within individual accounts and groups of accounts and to see how these relate to hypotheses about the causal mechanisms of the training, its implementation and its link with the clinical outcomes. We will look for similarities and difficulties *within* and *between* local authorities and groups of PAs. Overall this will result in a rich picture of how personal and organisational factors influence the translation and implementation of the training by PAs, and its impact on care leavers.

7.4 Data management, protection and patient confidentiality in relation to the qualitative research data

Recordings of interviews will be held on an encrypted digital recorder (or alternative secure device/mechanism) and regularly transferred to the University of Bristol through approved secure data transfer facilities and/or encrypted memory card/flash drives that adhere to the Sponsor's policies. If a video-conference platform is used to record discussions, only the audio file will be downloaded and retained for analysis. Interview data captured on audio-recorder will be transferred to a secure server hosted by the University of Bristol as soon as possible after each interview.

Recordings will be transcribed by University of Bristol employees or University approved transcription services. The transfer of recordings and transcripts will adhere to the secure transfer of recordings/transcripts procedure specified by the University. Transcripts will be labelled with a study I.D number, edited to ensure anonymity of respondents and stored securely adhering to the University's data storage policies. With consent, anonymised quotations and parts of voice modified recordings may be used for training, teaching, research and publication purposes for this and future studies. As this is a feasibility study we will not make data available to other research teams.

7.5 Safeguarding participants during qualitative research

We will ensure that participants are not subjected to undue distress during the qualitative component of the trial. To mitigate this, and the possibility that participants may disclose information to provoke concern about risk, the interviewer will be an experienced qualitative researcher who will adhere to the following:

Participants will be informed that the interview is strictly confidential, but should they disclose information to suggest that they or others are at significant risk of harm, the interviewer will discuss this with a clinical advisor and may need to disclose these details to the designated safeguarding authority. Should participants become upset or distressed during the interview the researchers will follow a distress protocol (see Appendix 2). The interview will only continue if participants are happy to proceed and engage with the interview topic. If the researcher feels a participant becoming distressed, they will ask the participant if they wish to have a break or discontinue the interview and will offer support. Participants will also be offered a leaflet with the contact details of support networks.

8 INTERVENTION

8.1 General information

To date there has been relatively little bespoke training provided for Personal Advisors. The LIFT study is designed to address this gap.

8.2 Background

Since 2015, statutory guidance has required local authorities, clinical commissioning groups and NHS England to ensure that effective plans are in place to enable children leaving care to continue to obtain the healthcare they need. The guidance makes clear that Personal Advisors 'should have access to information and training about how to promote physical and mental health' (p.26). Personal Advisors (PAs) are expected to work in partnership with care leavers and health professionals to ensure that care experienced young people have all the information they need to manage their own health.

However, health outcomes for care leavers remain poorer than those of non-care experienced peers. The Care Leavers Association (CLA) has called for more be done to understand why this is and what we can do about it (CLA 2017[1])

Amongst many recommendations, the CLA emphasises the pivotal role of the Personal Advisor, recommending that the status of that role should be increased, and training and support provided to all PAs. See also Section 1 above.

8.3 LIFT Intervention

The training programme outlined above has been developed by a multidisciplinary team comprising health specialists, social workers, personal advisors, local authority managers and care experienced young people. The programme was informed by:

- an international review of what we know about the health of care experienced young people,
- a national survey of personal advisors and their managers about what training is needed,
- consultations with care experienced young people, personal advisors, and other stakeholders from health and other sectors.

The training comprises a blend of webinars, online modules (hosted on NIHR Learn), and a skills workshop facilitated by two health professionals including one who is familiar with either looked after children. A 'homework' assignment, in which each PA sets themselves a practice-development goal forms an important part of the training and reflecting on these forms the basis of the final group session. The training is designed to be delivered as set out in Table 1 below.

Table 1: Overview of Training for Personal Advisors

Component	**Delivery**	**Time required of participants**
Introduction to the training	Webinar	1 hour maximum
Six Online Modules	NIHR LEARN	3-hours (4 hours if participants use the accompanying audio files.
Identifying key issues	Webinar	1.5 hours.
Workshop	Face to Face	One day
Action Plan Implementation	Day to day practice	Three weeks, part of routine practice
Final Group Session	Webinar or Face to Face	2 hours

8.3.1 Measuring fidelity

We will run reports on participants' completion of the of the online modules and attendance at webinars and the Skills Workshop. The facilitators of the Skills Workshop will work to a prescribed manual and information will be collected on the extent to which the schedule was adhered to. Some workshops will be observed by a member of the research team.

9 SAFETY REPORTING

9.1 Operational definitions

An Adverse Event is any unfavourable and unintended sign or symptom that develops or worsens during trial participation, whether or not it is considered to be related to the trial intervention

The LIFT study is evaluating the effects of practice of a training intervention for Personal Advisors, and no adverse events are anticipated in relation to professional staff member. Nor is it anticipated that the training will result in any changes in the practice of professionals that might adversely impact on young people/care leavers. However, we recognise that some care leavers are quite vulnerable, and a protocol is in place for reporting any concerns, to the CI in the first instance, and the relevant local Authority manager. For example, participating care leavers may get upset while completing standardised measures, or responding to interview questions, and we will ensure both that young people are alerted to this possibility in the Participant Information Leaflets and at the start of each data collection point. We will also provide participant care leavers with information as to what to do if they have any concerns about their own safety or the safety of someone else.

In developing the Terms of Reference for the Trial Steering Committee it was agreed that any event that adversely effects the wellbeing of a care leaver (e.g. distress reported to a social care practitioner or other professional; self-harm attributable to participating in the research) or actions by the study team that results in a complaint, would be reported to the Trial Steering Committee and the study sponsor, the University of Bristol.

9.6 Recording and reporting AEs

The following information will be recorded for any adverse event identified or reported to the study team:

- participant ID
- event number
- description of the event
- date (and time where known) that it started and stopped
- outcome of the event (including details about sequelae, where relevant)
- relatedness of the event to the intervention (if relevant)
- details of any actions taken in response to the event.

Reporting requirements for serious adverse events will be agreed with the sponsor and the Trial Steering Committee.

10 STATISTICS AND HEALTH ECONOMICS ANALYSIS

10.1 Sample size calculation

No sample size calculation was conducted for this feasibility study. We will recruit sufficient numbers of Personal Advisors and Care Leavers to provide us with information about the feasibility of the main trial, as described in Section 3.3.

10.2 Statistical analysis

Appropriate summary statistics and a CONSORT flowchart will be presented to inform the decision about the feasibility of the definitive trial.

10.3 Economic evaluation

The aim of the economic component is to inform the design of a full economic evaluation to be conducted alongside a future Phase III randomised trial. The focus will be to estimate set up and delivery costs for the intervention for a precise estimate of the costs that would be incurred in mounting a Phase III trial. The economic analysis will also assess the acceptability and validity of economic data collection methods used to identify additional resource use by CLs.

Cost of the intervention The aim is to develop a framework for assessing costs. Costing the intervention will include estimates of non-recurrent costs, such as set up costs and costs of initial training and materials for PAs, as well as recurrent costs associated with delivering the service, and ongoing support of PAs For recurrent costs, we will use bimonthly telephone interviews to estimate delivery costs, with the number, type and duration of contacts between CLs and PAs. As part of the analysis, we will perform a sensitivity analysis to address the uncertainty in intervention costs.

Resource use Service use by CLs will be examined from a NHS (payer) perspective. This perspective enables the inclusion of direct costs to the NHS, allowing for an assessment of potential cost savings and providing a better understanding of the impact of the intervention up to 52 weeks' post-training. To achieve this, data on resource use will be derived from CLs during bi-monthly telephone calls using a modified version of the CRSI, which is a reliable and valid resource use measurement tool. The tool was modified to collect data on health service use only. As planned, acceptability of this self-report questionnaire will be assessed based on completeness of data. Nationally applicable unit costs will be applied to all contacts. The perspective will help identify the capacity for cost savings to the NHS and capture the potential impact of the intervention.

Development of an economic model The structure of an economic decision model will be developed to illustrate the pathway for CLs, covering the time period of transition from care, the training intervention for PAs, and the costs and consequences of subsequent outcomes. This modelling exercise will help ascertain parameters required for a cost-effectiveness analysis. A review of economic literature will be conducted to identify best available sources of evidence to parameterise the economic model. This will include the probabilities required to estimate the likelihood of key events in the model, such as receiving statutory services.

Economic analysis In estimating the cost of the intervention, a micro-costing analysis will be conducted. The data on resource use for recurrent costs will be assessing in terms of completeness of data to help to inform a decision about how best to estimate this in a full trial and provide a suitable framework for assessing costs. Subtotals for each category of cost will be calculated and a total cost estimate presented, along with the mean cost per care leaver. Sensitivity analysis will be conducted to test the impact of key assumptions on the cost of the intervention.

These costs of setting up and delivering the programme will also be included in an estimate of the costs that will be incurred in mounting a Phase III trial. Additional costs in this estimate will include the support costs

needed within the research context, for example, training of staff, recruitment of participants, data collection and reimbursement for participation.

With data on costs and effects on CLs' quality-of-life (EQ-5D-5L) from the feasibility study, the development of the economic model, and additional sources of evidence derived from the economic review, we will explore the cost-effectiveness of the training intervention compared to practice as usual. However, it is expected that, with the small sample and data on costs likely to be skewed, it will not be appropriate to conduct a cost-effectiveness analysis. It is anticipated that this exercise will guide what data are needed within a large-scale cluster-randomised trial and, thus, increase the economic efficiency of further research.

11 DATA MANAGEMENT

11.1 Source data and documents

Source data for this trial will by default consist of electronic versions of preliminary screening and expression of interest forms, consent form(s), participant and completed questionnaires and other records designed specifically for the study. However, where electronic data collection is not possible, equivalent paper documents will become the source data. Data obtained by paper will be entered onto the database as soon as practical by the centre/site research teams, and where applicable or required, by the central research team. Any paper documents containing identifiable information will be stored in a locked filing cabinet at the centre/site, which only members of the local research team have access to.

11.2 Data Handling

Data from all participants will be collected and retained in accordance with the UK Data Protection Act 2018 and UK General Data Protection Regulation 2018 (GDPR). All trial participants will be allocated a unique study I.D number during the screening process, which will remain assigned to them.

Participants will be asked to consent to their personal information and research data being stored by the University of Bristol during the trial and their research data stored by the University of Bristol at the end of the trial. Data will be managed in accordance with the University of Bristol's Standard Operating Procedure (SOP) for the Management of Data, in particular, electronic data. This details how data are to be captured, in particular, with the informed consent of the research participant and giving details as to the purpose for which the information is to be used, the period of time it is to be retained and to whom it is likely to be disclosed. It is ICH GCP 1996 compliant.

Standardised outcome instruments will be used throughout the trial; the components and timing of follow-up measures are detailed in Section 2 (Aims and Objectives) and shown in Tables 1 and 2.

All participant data will be entered into and stored on password-protected Structured Query Language (SQL) databases maintained by the University of Bristol. Secure access to the internet is required for all appointments conducted remotely. For face-to-face appointments, if internet access is not available, paper documents will be available, where feasible and entered on to the database at a later stage when internet access is available. Any data stored on laptops will be encrypted.

Data will be managed in accordance with the University of Bristol's Standard Operating Procedure (SOP) for the Management of Data, in particular, electronic data. This details how data are to be captured, in particular with the informed consent of the research participant and giving details as to the purpose for which the information is to be used, the period of time it is to be retained and to whom it is likely to be disclosed. It is ICH GCP 1996 compliant.

Prior to data entry, each measure will be checked for incomplete or missing information and any inconsistencies checked with the relevant researcher. A record will be kept of all queries raised and the response received. Each participant will be anonymised through the unique identifier assigned by the BRTC. This will be used on the Trial Database. Anonymised data will be stored securely on the University secure

server, separately from any information that could identify participants. Paper forms will be stored in numerical order in a secure place and maintained for three years following study completion.

Access to study data will be limited to named individuals, and access will be password protected. Those individuals with permission to make data changes will be listed in the study Master File, and all changes will be logged, with no deletion of entered data. Data will be stored as csv and Stat data files (.data) on the University's secure servers, which provide automatic back-up. Back-up files will be kept securely on a server separate from the server hosting the master copy. All data held on portable equipment, such as laptops, memory sticks or digital audio-recorders will be risk assessed, encrypted and password protected. All such data will be moved onto the secure server within an agreed number of hours, and the data deleted form the portable equipment.

11.3 Database platform(s)

All administrative and 'clinical' study data will be stored in separate REDCap instances. REDCap is a secure, web-based electronic data capture (EDC) system designed for the collection of research data. The system has been developed and supported by Vanderbilt University. BRTC at the University of Bristol (UniBristol) has set up its own infrastructure so that all systems are hosted at and supported by UniBristol.

A Relational Database Management System will be used to provide integration services between administrative and clinical databases. These data will be stored here, to support the workflow of the study team. These data will not be made available for analysis. These data are stored in a SQL Server system maintained by the UniBristol.

The central research team will manage user-access rights to the database. This includes managing access to participant data according to the centre/site they are recruited from, and restricting access to any information that may identify the treatment received by the participant to staff who are not blinded to the allocation.

11.3.1 Administrative Data

The administrative data will be kept in a secure database that is only accessible from within the University of Bristol firewall. All users will require (at least honorary) contracts with UniBristol to access it.

11.4 Storage and access to data

The University of Bristol is the data controllers for the LIFT trial. Data will be held at the University of Bristol and will conform to the University of Bristol Data Security Policy and in compliance with the UK GDPR, alongside the Data Protection Act 2018.

For monitoring purposes, the CI will allow monitors from the Sponsor (or delegate), persons responsible for the audit, and representatives of the REC to have direct access to source data/documents.

The Trial, and Data, Manager (in collaboration with the CI) will manage access rights to the data set. Prospective new users must demonstrate compliance with legal, data protection and ethical guidelines before any data are released.

12 TRIAL MANAGEMENT

12.1 Trial management group (TMG)

The TMG has responsibility for the day-to-day management of the trial and will report to the TSC. The TMG will meet on a regular basis (monthly) with a core working group of staff having frequent progress meetings. They will link to the network of site research teams to facilitate continuous feedback and early troubleshooting of local site issues that arise. Meetings will be in person and/or by teleconference to maximise attendance.

12.2 Trial Steering Committee (TSC)

A TSC has been established in conjunction with a TMG. Membership, responsibilities and reporting mechanisms of the TSC will be formalised in a TSC charter.

The TSC will make recommendations/key decisions during the trial to the TMG and minutes will be sent to the funder. The terms of reference for the TSC can be found in Appendix 1.

12.3 Data monitoring Committee (DMC)

Given the nature of the study (intervention development + feasibility study) there is no separate Data Management Committee – see Appendix 1.

12.4 Patient and Public Involvement (PPI)

The views of young people are central to this study and have played a significant role in its development. The research team include peer researchers who are full members of the Trial Management Group (known in this study as the Programme Management Group). The peer researchers are supported by Coram Voice, and they have been involved in developing all aspects of the training intervention, the development of Participant information Leaflets and Consent Forms, and the choice of outcomes and outcome measures. They will collect outcome data at the two follow-up points from care leavers and contribute to the interpretation of the data analyses and drafting of the final report and other papers (see Publications Policy Section 15).

12.5 Sponsor and funding

This trial is sponsored by the University of Bristol

This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (Reference 132343). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

13 MONITORING, AUDIT and INSPECTION

13.1 Monitoring

The trial will be monitored and audited in accordance with the Sponsor's policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor, the relevant Research Ethics Committee (REC) and other licensing bodies.

A Trial Monitoring Plan will be developed by the Sponsors and agreed by the TMG and CI based on the trial risk assessment which may include on-site monitoring. This will be dependent on a documented risk assessment of the trial.

The sponsor usually delegates some of the monitoring to the central research team. The following checks would be typical:

- that written informed consent has been properly documented
- that data collected are consistent with adherence to the trial protocol
- that CRFs are only being completed by authorised persons
- that S/AE recording and reporting procedures are being followed correctly
- that no key data are missing
- that data are valid
- review of recruitment rates, withdrawals and losses to follow up.

To inform the development of a Phase II Trial we will monitor the percentage of study participants that meet the eligibility criteria and report the percentage of participants who consent; the available characteristics of consenting participants and non-consenting will be compared. We will report any SAE events to the TSC. If asked to do so, we will also report to the TSC any preliminary data on dropout rates.

13.2 Protocol compliance

There will be no prospective, planned deviations or waivers to the protocol. Any protocol breaches will be documented and reported to the Trial Manager, CI and Sponsor immediately (see Key Trial Contact for contact details). Information about protocol breaches will also be included in routine reports to the DMC and TSC. Protocol breaches identified by the central research team will be reported to the relevant local PI, site team, local NHS R&I and Sponsor as soon as possible. The Sponsor will determine the seriousness of the breach.

In the event of systematic protocol breaches, investigation and remedial action will be taken in liaison with the CI, DMC and the TMG.

13.3 Notification of Serious Breaches to GCP and / or the Protocol

A "serious breach" is a breach which is likely to effect to a significant degree:

- the safety or physical or mental integrity of the subjects of the trial; or
- the scientific value of the trial

The Sponsor will be notified immediately by the central research team of any breaches; they will determine the seriousness of the breach. The Sponsor (or authorised delegate) will report Serious Breaches to the RECs within 7-days of the Sponsor becoming aware of them.

14 ETHICAL AND REGULATORY CONSIDERATIONS

14.1 Governance and legislation

This trial will be conducted in accordance with:

- Conditions and principles of Good Clinical Practice (GCP)
- UK Policy Framework for Health and Social Care Research
- Data Protection Act 2018
- General Data Protection Regulation (GDPR)

Any amendments to the trial must be assessed and approved by the Sponsor prior to submission to the REC.

All recruitment will be undertaken by a member of the research team based in the University of Bristol.

This research trial will be conducted in accordance with conditions and principles of GCP. GCP is the international ethical, scientific, and practical standard to which all clinical research is conducted. Compliance with GCP provides public assurance that the rights, safety, and well-being of people taking part (trial participants) are protected and that research data are reliable.

14.2 Research Ethics Committee (REC) review and reports

Ethics review of the protocol for this trial and other trial-related participant facing documents (e.g. PIL and consent forms) will be carried out by the Research Ethics Committee of the School for Policy Studies (SPS). Any amendments to these documents, after a favourable opinion from the SPS REC has been given, will be submitted to the SPS REC for approval prior to implementation.

All correspondence with the REC will be retained in the Trial Master File (TMF). An annual progress report will be submitted to the REC within 30-days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended. The CI will notify the REC of the end of the trial and if the trial is ended prematurely (including the reasons for the premature termination). Within one year after the end of the trial, the CI will submit a final report with the results, including any publications/abstracts, to the REC.

GCP training will be carried out by certain staff members depending on their delegated responsibilities within the trial, the level of training required will be determined according to the NIHR Delegation and Training Decision Aid. Informed consent to participate in the trial will be sought and obtained according to GCP guidelines.

LIFT

14.5 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

N/A

LIFT

14.6 Indemnity

The University of Bristol is the Sponsor for the LIFT study.

15 DISSEMINATION POLICY

Academic outputs

In addition to the Final Report for the NIHR, a report of the feasibility trial will be submitted to the journal 'Pilot and Feasibility Trials' or equivalent.

We will also seek to publish a report on the views and experiences of those the trial participants, and a paper on the involvement of peer researchers throughout the study.

If the trial progression criteria are met, we may develop a protocol for a Phase III trial (as a basis for a further funding application).

Wider dissemination

An important component in preparing the report of this study and in developing the protocol for a Phase III trial (if indicated) is engagement with our key stakeholders, in this case local authority staff (personal advisors, line manager and senior managers), NHS staff (LAC doctors and nurses) and care leavers.

We will present our findings to those who have collaborated with us in developing the training and participating in it, and incorporate their feedback into the final report and any future research proposal. We will prepare a short, accessible briefing for staff and young people - something the team does well. The highly accessed CoramVoice website will support our dissemination activities by publicizing our outcome and linking to their other activities e.g. national seminars CoramVoice participate in as co-chair of the 'Alliance of children in care and care leavers'.

We will ensure that organisations that it will be important to engage in a Phase III trial are informed of the research and its findings. These include Association of Directors of Children's Services, Public Health England, SCIE, Making Research Count, and Research in Practice.

Publications Policy

The LIFT study agreed a publications policy in May 2021. This document sets out in plain English how decisions will be made as to who is named as an author and who will be named as someone who helped in another way.

The LIFT Study Team

At the time of publication of this protocol (v1), the following researchers from three universities and CoramVOICE are involved in the LIFT study. As personnel change the policy will be updated to reflect this:

At the University of Bristol

- Geraldine Macdonald, Principal Investigator
- Patricia Lucas, Co-Investigator
- Chris Metcalfe, Co-Investigator
- Jaqueline Hammondr, Senior Research Associate

At CoramVoice (currently)

- Thuy Li-Chambers, Peer Researcher
- Sarah Beth Harber, Peer Researcher
- Kiri Scamp, Peer Researcher
- Linda Briheim-Crookall, Head of Policy and Practice Development
- Jenny Humphreys, Participation Manager

At Oxford University

- Julie Selwyn, Co-Investigator

At Queen's University Belfast

- Fiona Lynn, Co-Investigator

The four organisations have signed an agreement to work together.

Publication Policy

We want all members of the LIFT study team to help to write about the study and to talk about it at conferences or other meetings. This is what this publication policy is about. It sets out the 'ground rules' for deciding how we do this.

The policy will help to make sure that everyone's contribution is properly recognised. People write about studies in blogs, in books and in journals: in this policy we will refer to all of these as 'papers'. The policy also sets out who can use data from the study.

Ground rules on writing about the LIFT study

Who can be an author?

There are some conditions that team members have to meet to become an author. These are set out in Appendix 1.

How we will work together on papers

- Ideas for writing a paper about the project need to be agreed by Geraldine Macdonald. This is because she is in overall charge of the project.
- Geraldine will agree who should take the lead on each paper (known as the lead author)
- Geraldine and the lead author on each paper will decide the order in which names should appear on the paper.
- Geraldine will make sure that everyone on the LIFT team will have the opportunity to be a named author.

How we will work together on talks about the LIFT Study

- Anyone wanting to talk about the LIFT study at a conference or other meeting will need to submit a short summary - called an abstract - to the organisers. Sometimes this can be an abstract for a poster presentation.
- Abstracts must be agreed in advance with Geraldine and Patricia, who will consult with the other people who helped develop the proposal (Chris, Julie and Fiona).
- Geraldine and Patricia will need at least 14 days to consult with other team members and make a decision.
- If someone sends an abstract to Geraldine and Patricia and they don't hear back from them in 14 days, they can send the abstract to the conference organisers.
- The study team must have the opportunity to comment on the presentation before it is given, so this also needs to be sent to the team 14 days in advance.

Keeping to our agreements with the funder (NIHR)

- There are some things we have to do because they are part of the contract with NIHR. These including telling them about our publications, our talks and presentations.
- Geraldine has to tell the NIHR about these. The NIHR wants to see copies of all press releases and papers at least three days before they are published.
- Until 5 years after the project has ended, Geraldine has to submit a record of all of all of our activities every year, using something called *ResearchFish*.
- The NIHR has agreed to pay for one journal article that anyone can read (open access). If we need funding for other publications, we have to find it somewhere else.
- All manuscripts/abstracts should acknowledge the funder using the EXACT text below:

'The LIFT Study was funded by the National Institute for Health Research' [***HS&DR Project: 17/108/06]***

Where appropriate, for example on poster or oral presentations, the logos of the following organisations should be included: the National Institute for Health Research (NIHR), the Life in Transition study (LIFT), the University of Bristol, CoramVoice, Queen's University, Belfast, the Rees Centre, Oxford University. These are available from the Bristol Team.

Access to/use of study data

- Anyone who is not a member of the LIFT team must seek permission from Geraldine to use LIFT study data for their own purposes.
- Requests must be made in writing and clearly describe the purpose for which the data are required and how they will be used.
- All publications or presentation using our data must acknowledge the study and the LIFT team (see Appendix 1).
- Anyone using our data must ensure that the use is consistent with ethical and governance approval (either existing or subsequently sought).

LIFT Publications Policy: APPENDIX 1: Authors and Contributors

To be named as an author

To be an author, team members must have:

- Made a substantial contribution to the paper concerned.
- Approved the final version (draft) of the paper
- Accepted responsibility for ensuring that they are familiar with its contents
- Agreed to be accountable for their contribution. In other words, be prepared to ensure that any questions raised about the accuracy of the work are properly investigated and resolved.

What is a substantial contribution?

What is a 'substantial contribution'? Normally, this would include anyone who:

1. Made an important contribution to the design of the study. This could include:
   - Having the idea for the study or helping to design it, or
   - Helping to collect, analyse or interpret the data from the study.

   AND/OR
2. Helped to write the paper or reviewed a draft and made significant contributions at that point.

Helping to get funding for the study or helping to collect study data do not, on their own, justify authorship.

Describing author contributions

The contribution of named authors is usually described in a statement like this one:

'GM was guarantor of the study. GM and PL were responsible for developing the research question and study design …'

The description of the contribution of named authors will be drafted by the lead author and included in the final draft of the paper. Contributors then have the opportunity to correct any errors.

Acknowledging other contributions

We shall acknowledge all others who have played a part in the study but do not fulfil the criteria for contributors. Examples might be the members of the Programme Management Group, local authority colleagues, the Trial Steering Group, and administrative staff.

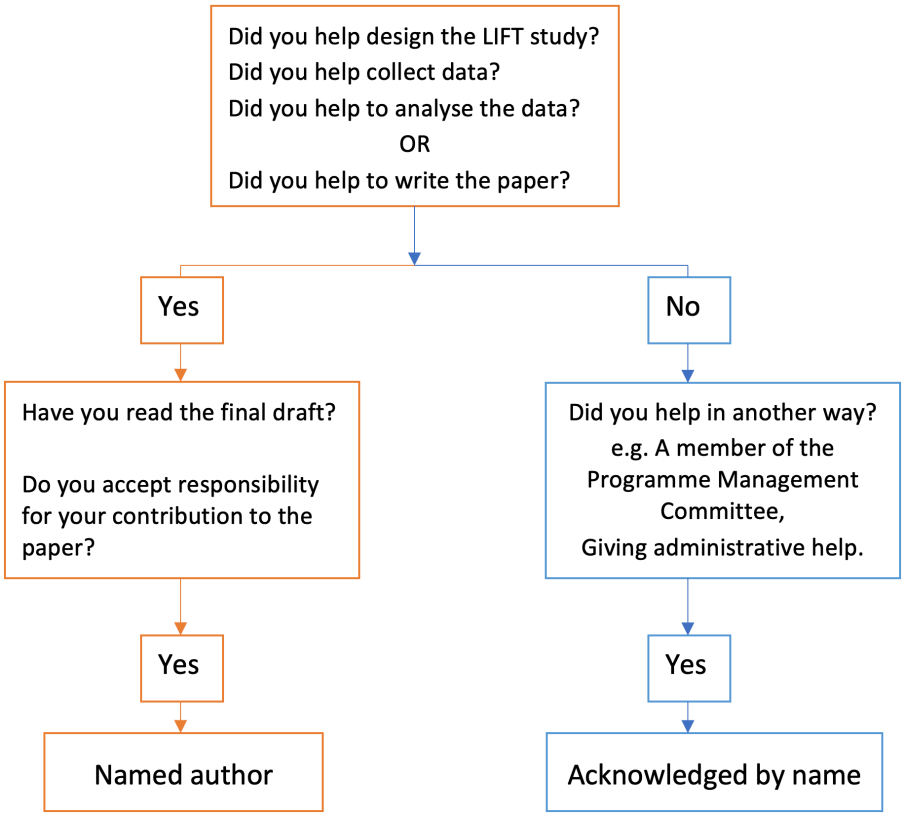
Other people, who do not meet the criteria for authorship, often make a significant contribution to the implementation of the study e.g. administrative staff, external advisory group. They should also be included in the acknowledgements.

Overall responsibility for a paper

The lead author of a paper (see Policy) and the Principal Investigator (Geraldine) will accept overall responsibility for papers and the conduct of the study. That is to say, they will be identified as the 'guarantors' of the study and papers, including the decision to publish.

Overview

This diagram gives an overview of when someone can be named as an author, and when their contribution is acknowledged in another way.



16 SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in UK Policy Framework for Health and Social Care Research, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

..... Date: .06../..01/ 2023

Name (please print): Geraldine Macdonald

.....

Senior Statistician:

Signature:

..... Date: 06/01/2023

Name (please print): Chris Metcalfe

.....

17 REFERENCES

1. CQC. Not Seen, Not Heard: A review of the arrangements for child safeguarding and health care for looked after children in England. In: Commission CQ, editor. London2016.

2. Mooney A SJ, Monck E, Chambers H. Promoting the Health of Looked After Children A Study to Inform Revision of the 2002 Guidance. London: Department for Children, Schools and Families; 2009.

3. Statistics DfEN. Children Looked After in England (Including Adoption and Care Leavers) Year Ending 31 March 2011. Department for Education London; 2011.

4. Tourigny M, Hebert M. Comparison of open versus closed group interventions for sexually abused adolescent girls. Violence and Victims. 2007;22(3):334-49.

5. McMahon AD, Elliott L, Macpherson LM, Sharpe KH, Connelly G, Milligan I, et al. Inequalities in the dental health needs and access to dental services among looked after children in Scotland: a population data linkage study. Archives of disease in childhood. 2017:archdischild-2016-312389.

6. Ward H, Jones H, Lynch M, Skuse T. Issues concerning the health of looked after children. Adoption & Fostering. 2002;26(4):8-18.

7. Scott S, Hattie R, Tannahill C. Looked after children in Glasgow and Scotland: A health needs assessment. Glasgow: Scot PHN. 2013.

8. Walton S, Bedford H. Immunization of looked-after children and young people: a review of the literature. Child: care, health and development. 2017.

9. Ashton-Key M, Jorge E. Does providing social services with information and advice on immunisation status of “looked after children” improve uptake? Archives of disease in childhood. 2003;88(4):299-301.

10. Hill CM, Mather M, Goddard J. Cross sectional survey of meningococcal C immunisation in children looked after by local authorities and those living at home. Bmj. 2003;326(7385):364-5.

11. Garry S, John-Legere S. G426 Evaluating mmr vaccination coverage of looked after children (lac), are we comparing apples with oranges if we consider this population as one group? : BMJ Publishing Group Ltd; 2015.

12. Meltzer H, Gatward R, Corbin T, Goodman R, Ford T. The mental health of young people looked after by local authorities in England. London: The Stationery Office. 2003.

13. Carpenter SC, Clyman RB, Davidson AJ, Steiner JF. The association of foster care or kinship care with adolescent sexual behavior and first pregnancy. Pediatrics. 2001;108(3):e46-e.

14. Jay A. Independent Inquiry into Child Sexual Exploitation in Rotherham 1997–2013, Rotherham. Metropolitan Borough Council; 2014.

15. Oshima KMM, Narendorf SC, McMillen JC. Pregnancy risk among older youth transitioning out of foster care. Children and Youth Services Review. 2013;35(10):1760-5.

16. Craine N, Midgley C, Zou L, Evans H, Whitaker R, Lyons M. Elevated teenage conception risk amongst looked after children; a national audit. Public health. 2014;128(7):668-70.

17. Boonstra HD. Teen pregnancy among young women in foster care: A primer. Guttmacher Policy Review. 2011;14(2):8-19.

18. National Audit Office. Care leavers’ transitions to adulthood: report by the Comptroller and Auditor General. London: NAO; 2015.

19. Botchway SK, Quigley MA, Gray R. Pregnancy-associated outcomes in women who spent some of their childhood looked after by local authorities: findings from the UK Millennium Cohort Study. BMJ open. 2014;4(12):e005468.

20. Bublitz MH, Rodriguez D, Gobin AP, Waldemore M, Magee S, Stroud LR. Maternal history of adoption or foster care placement in childhood: a risk factor for preterm birth. American Journal of Obstetrics & Gynecology. 2014;211(4):397. e1-. e6.

21. Goldenberg RL, Culhane JF. Adoption and foster care placement as a risk factor for preterm birth. American Journal of Obstetrics & Gynecology. 2014;211(4):317-8.

22. Roberts R MS, Forrester D, Smith A, Shelton K. Care-leavers and their children placed for adoption. Children and Youth Services Review. 2017;79:355-61.

23. Broadhurst K, Bedston S. Women in recurrent care proceedings in England (2007-2016): Continuity and change in care demand over time. Family Law. 2017;47:412-5.

24. Sempik J, Ward H, Darker I. Emotional and behavioural difficulties of children and young people at entry into care. Clinical child psychology and psychiatry. 2008;13(2):221-33.

25. Ford T, Vostanis P, Meltzer H, Goodman R. Psychiatric disorder among British children looked after by local authorities: comparison with children living in private households. The British Journal of Psychiatry. 2007;190(4):319-25.

26. Tarren-Sweeney M. It's time to re-think mental health services for children in care, and those adopted from care. Clinical child psychology and psychiatry. 2010;15(4):613-26.

27. Department for Education. Promoting the health and well-being of looked-after children: Statutory guidance for local authorities, clinical commissioning groups and NHS England. London: Department for Education; 2015.

28. Smith N. Neglected Minds. A report on mental health support for young people leaving care. Barkingside: Barnardo's; 2017.

29. Health Do. National service framework for children, young people and maternity services. HMSO London; 2004.

30. Shonkoff JP, Garner AS, Siegel BS, Dobbins MI, Earls MF, McGuinn L, et al. The lifelong effects of early childhood adversity and toxic stress. Pediatrics. 2012;129(1):e232-e46.

31. Department for Education and Department of Health. Promoting the health and wellbeing of looked-after-children. In: Statutory Guidance for local authorities ccgaNE, editor. 2015.

32. Stein M. Research review: Young people leaving care. Child & family social work. 2006;11(3):273-9.

33. Memarzia J, St Clair MC, Owens M, Goodyer IM, Dunn VJ. Adolescents leaving mental health or social care services: predictors of mental health and psychosocial outcomes one year later. BMC health services research. 2015;15(1):185.

34. Robinson J, Cotton S, Conus P, Graf Schimmelmann B, McGorry P, Lambert M. Prevalence and predictors of suicide attempt in an incidence cohort of 661 young people with first-episode psychosis. Australian & New Zealand Journal of Psychiatry. 2009;43(2):149-57.

35. Dixon J, Lee J, Stein M, Guhirwa H, Bowley S, Catch22 N. Corporate parenting for young people in care:: making the difference? 2015.

36. Golding KS. Multi-agency and specialist working to meet the mental health needs of children in care and adopted. Clincial Child Psychology. 2010;15(4):573-87.

37. Rees G SM. Children and young people in care and leaving care. In: J B, editor. The well-being of children in the UK. Bristol: The Policy Press; 2016.

38. Dixon JaB, D. New Belongings: an evaluation. London: Department for Education; 2016 October

39. Stein M. Young people leaving care: Supporting pathways to adulthood: Jessica Kingsley Publishers; 2012.

40. Braden J GJ, Graham D, . Caring for Better Health: An investigation into the health needs of Care LEvaers. London: Care Leavers Associaion and Department of Health.; 2017.

41. Woolgar M, Baldock E. Attachment disorders versus more common problems in looked after and adopted children: comparing community and expert assessments. Child and Adolescent Mental Health. 2015;20(1):34-40.

42. Shenton C ED. Young people's well-being measures: Office for National Statistics; 2017 [Available from: https://www.ons.gov.uk/peoplepopulationandcommunity/wellbeing/datasets/youngpeopleswellbeingmeasures.

43. Children and Social Work Act, (2017).

44. Department for Education. The Children Act 1989 Guidance and Regulations Volume 3: Planning Transition to Adulthood for Care Leavers. London: Department for Education; 2010.

45. NICE. Transition from children's to adults' services for young people using health or social care services. London: National Institute for Health and Care Excellence; 2016.

46. Goodman A, Goodman R. Strengths and Difficulties Questionnaire scores and mental health in looked after children. The British Journal of Psychiatry. 2012;200(5):426-7.

47. Martin A, Ford T, Goodman R, Meltzer H, Logan S. Physical illness in looked-after children: a cross-sectional study. Archives of disease in childhood. 2013:archdischild-2013-303993.

48. McSherry D, Fargas Malet M, McLaughlin K, Adams C, O'Neill N, Cole J, et al. Mind your health: The physical and mental health of looked after children and young people in Northern Ireland. Queen's University Belfast, Office of the First Minister and Deputy First Minister. 2015.

49. Matthews S, Sykes S. Exploring health priorities for young people leaving care. Child Care in Practice. 2012;18(4):393-407.

50. Department for Education. Children looked after by local authorities in England: guide to the SSDA903 collection - 1 April 2017 to 31 March 2018. In: Education Df, editor. London: Department for Education; 2017.

51. Department for Education. Outcomes for Children Looked After by Local Authorities in England as at 31 March 2014, Issued 10 December 2014. London: DfE/National Statisticis; 2014.

52. Hamilton DJ, Taylor B, Killick C, Bickerstaff D. Suicidal Ideation and beahviour among Young People Leaving Care. Child Care in Practice. 2015;21(2):160-76.

53. Viner RM, Taylor B. Adult health and social outcomes of children who have been in public care: population-based study. Pediatrics. 2005;115(4):894-9.

54. Broad B. Improving the health of children and young people leaving care. Adoption and Fostering. 1999;23(1):40-8.

55. Rees P. The mental health, emotional literacy, cognitive ability, literacy attainment and ‘resilience’of ‘looked after children’: A multidimensional, multiple-rater population based study. British Journal of Clinical Psychology. 2013;52(2):183-98.

56. Reeve K BE. The hidden truth about homelessness: Experiences of single homelessness in England. 2011.

57. Centre for Social Justice. Couldn't care less. A policy report from the Children in Care Working Group. The Centre for Social Justice; 2008.

58. Centre for Social Justice. Finding their Feet, Equipping care leavers to reach their potential London: The Centre for Social Justice

59. Department of Health DfEaE, Home Office. Preventing suicide in England. A cross-government outcomes strategy to save lives. London: Department for Health; 2012.

60. Rivara FP. Physical abuse in children under two: a study of therapeutic outcomes. Child Abuse and Neglect. 1985;9(1):6.

61. Dowdney L, Skuse D, Rutter M, Quinton D, Mrazek D. The nature and qualities of parenting provided by women raised in institutions. Journal of Child Psychology and Psychiatry. 1985;26(4):599-625.

62. Chase E MC, Knight A, Aggleton P. Pregnancy and parenthood among young people inand leaving care: what are the influencing factors, and what makes a difference in providing sup-port? Journal of Adolescence. 2006;29:437-51.

63. Connolly J HM, Bohr Y. Pregnancy and motherhood among adolescent girls in child protective services: a meta-synthesis of qualitative research. Journal of Public Child Welfare. 2012;6:614-35.

64. NAO. Care leavers' transition to adulthood. Report by the Comptroller and Auditor General. London: National Audit Office; 2015.

65. Broad B. Young People Leaving Care: Implementing the Children (Leaving Care) Act 2000. Children and Society. 2005;19:371-284.

66. Sims-Schouten W HC. Mental health and wellbeing of care leavers: Makig sense of their perspectives. Child and Family Social Work. 2016;22:1480-7.

APPENDIX 1: **Trial Steering Committee Terms of Reference**[1]

The role of the LIFT TSC

The role of the LIFT SSC is to provide overall supervision for the project on behalf of the Project Sponsor (University of Bristol) and Project Funder (NIHR) and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The main features of the LIFT SSC are as follows:

- To provide advice, through its Chair, to the Study Funder, the Study Sponsor, the Chief Investigator, the Host Institution (the Clinical Commissioning Group) on all appropriate aspects of the project
- To concentrate on progress of the trial/project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society.
- Given the nature of the study (intervention development + feasibility study) there is no provision for a separate Data Management Committee and the LIFT TSC therefore has responsibility for monitoring significant events amongst participants. For the LIFT study, a significant event would be anything that adversely effects the wellbeing of a care leaver (e.g. distress reported to a social care practitioner or other professional; self-harm attributable to participating in the research) or actions by the study team that results in a complaint.
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the trial/project.

LIFT TSC membership

The Constitution of Trial Steering Committee is determined by the NIHR, and the process of nomination and approval is set out at the end in Appendix 1. The NIHR has approved the following membership for the LIFT TSC, and roles and/or expertise are as follows:

- Dr Kristin Liabo (University of Exeter) - Chair:
- Professor Helen Roberts (UCL): Medical Sociologist
- Dr Jane Schulte (ICCS Adoption): Care Leavers, Adoption, Fostering
- Professor Mike Clarke (MRC methodology Hub, Centre for Public Health, NI and Director of the NI Clinical Trials Unit): Statistical advice and trials expertise
- Annie Hudson (London Borough of Lambeth): Children's Social Care
- Ms Christa Laird: PPI, Social Work and Social Work Training

---

*For further information see *https://www.nihr.ac.uk/documents/research-governance-guidelines/12154*

The LIFT TSC will meet once in the first year, and then twice yearly. Minutes will be sent to all members, the sponsor and the funder, and copies will be retained in the study master file.

As Chief Investigator, Professor Macdonald has the responsibility for calling and organising LIFT TSC meetings, in association with the Chair.

NOTE: The NIHR reserves the right to attend any meeting therefore should be included in relevant invitations and reserves the right to convene a meeting of the SSC in exceptional circumstances.

APPENDIX 1

Appointment and constitution of NIHR Study Steering Groups

- The relevant NIHR Programme Director (Ms Donna White) will review the nominees and appoint the Chair and members
- Independent[2] members must make up a minimum of 75% of the SSC membership
- The minimum quoracy for any SSC meeting to conduct business is 67% (two thirds) of the appointed membership.
- Only appointed members will be entitled to vote, and the Chair will have a casting vote
- The Chair and members to sign and maintain a log of potential conflicts and/or interests
- Attendance at SSC meetings by non-members is at the discretion of the Chair
- The primary SSC reporting line is via the Chair to the relevant NIHR Programme Director; however, communication is likely to be between the Chair and the NIHR Research Manager who has day to day responsibility for the project.

** Independence is defined as follows:*

- Not part of the same institution as any of the applicants or members of the project team.

- Not part of the same institution that is acting as a recruitment or investigative centre, identifying and referring patients to a recruitment or investigative centre. (In both cases 'not part of the same institution' means holding neither a substantive or honorary contract with said institution).

- Not related to any of the applicants or project team members.

- It is recognised that independence status may change during the duration of the trial.