1. Promoting good health in Care Leavers (CLs) through training for Personal Advisors (PAs)

3. Background and Rationale

3.1 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 disadavantage 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 rourtine 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.

3.2 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]

3.3 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:

> 'A*t 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.'*

3.4 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.'*

3.5 Importance of improving the health and/or 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]

3a 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.

4. Aims and objectives

The study has two main aims: first, to develop a training programme that will help PAs to identify and act on the health and wellbeing needs of care leavers, and secondly, to assess the feasibility of evaluating the effectiveness of the training programme in a definitive trial.

Reflecting good practice in the development and evaluation of complex social interventions,[67,68] the proposed study is organised into two main phases, with the following objectives in each:

Phase 1

1. To scope current training provision for PAs.
2. To determine the appropriate content and mode of delivery of training to assist PAs to address the health and wellbeing of care leavers.
3. To test and refine a manualised training programme and associated logic model.

Phase 2

4. To conduct a feasibility trial (LAs) to inform the development of a protocol for a Phase III randomised trial.

5. To conduct a process and implementation evaluation of factors that facilitate or impede the acquisition and use of PA knowledge and skills, and the perceptions of care leavers and other key stakeholders on the impact of PA training.

5. Research design

Phase 2 will comprise a feasibility trial of the training intervention in 3 LAs in which PAs in half of the teams responsible for Care Leavers will be randomized to receive the training and follow-on support and those in the other half will continue with 'practice as usual'. This trial will include a study of process and implementation. The goal of this phase is to determine whether the findings justify developing a protocol for a Phase III trial and to inform the development of a suitable methodology.

5.1 PHASE 1: Developing the training programme

This phase will bring together relevant data from the existing literature and current practice in social care, to provide the foundation for development of an appropriate training programme. Corresponding to research objectives 1-3 above, in this stage of the research we will:

- Establish current practice in the use of and training of PAs
- Review the evidence to inform the content and mode for a health training module for PAs
- Consult with stakeholders about their views about the content and mode for a health training modules for PAs
- Develop a logic model for PA training to improve care leavers transition to adult health services, establishing inputs, outputs and outcomes within a theoretical model which will guide implementation and evaluation
- Develop, deliver and user-test a short training programme for PAs to support care leavers transition to adult health care.

These aims will be met using a survey of current practice, a rapid review of evidence, consultation and activities designed to ensure that the resultant intervention reflects the needs of all key stakeholders, and a test-run study of the proposed intervention.

5.1.1 Survey of current practice

Building on contacts already made with a range of local authorities, we think it is important to conduct a telephone survey of local authorities in England and Health and Social Care Trusts in Northern Ireland to identify who acts as PA (professional backgrounds); size and organization of each PA workforce; size, composition and turnover of PA caseloads; expectations of the PA role; what training is currently provided to PAs; details of any training provided on health and wellbeing; current use of CLs final health assessments and the Health Passport; and what, if any, data are currently recorded regarding PA activities or care leavers' health. We will use the National Leaving Care Benchmarking Forum which covers 80 LAs (http://www.leavingcare.org/), and with whom we are already in contact, to support the survey in England. Macdonald has contacts with key informants in Northern Ireland (NI).

We have chosen to focus on England and NI as the latter provides information on differences that might result from an integrated system of health and social care. The data collected will be examined against the expectations of role of the PA as defined in the Children and Social Work Act 2017 and NICE guideline NG43[45] (see 3.3 above).

5.1.2 Rapid systematic review

Building on an earlier rapid review 2010,[69] we propose to conduct a systematic review of the evidence about what factors can help lay workers to recognise and facilitate help-seeking behaviour, with particular attention to issues relating to mental health and well-being.

Methods We will follow NICE social care guidance[70] adapted to rapid review methods where our aim will be a broad overview of relevant research.[71]

Search Strategy Searches will be undertaken on electronic databases for i) health and allied health literature (MEDLINE, CINAHL PSYCInfo, EMBASE, Cochrane Central Database of Controlled Trials (CENTRAL), Cochrane Database of Systematic Reviews, Database of Reviews of Effectiveness (DARE), Science Citation Index-expanded, Health Management Information Consortium (HMIC)); ii) social sciences and social welfare (International Bibliography of the Social Sciences (IBSS), Social Services Abstracts, Social Care Online, ChildData, , Sociological Abstracts, Social Science Citation Index, National Criminal Justice Reference Service Abstracts, Campbell Library); iii) education (ERIC, AUEI, BRIE) iv) other evidence-based research repositories (metaRegister of Controlled Trials (mRCT), HSRProj, UK Clinical Research Network Study Portfolio, Database of Promoting Health Effectiveness Reviews (DoPHER), The Trials Register of Promoting Health Interventions (TRoPHI); v) economic databases (the NHS Economic Evaluation database (NHS EED), the Paediatric Economic Evaluation database (PEDE), the Health Economic Evaluations database (HEED), the American Economic Association's electronic bibliography (EconLit) and the IDEAS economics database.

We will search for studies that identify effective strategies for promoting help-seeking amongst young people aged 11 or above, or helping adults to identify indicators of health need, particularly in relation to mental health. We will develop a search strategy to identify relevant reports published since 2011 (the date of the last search), amended as appropriate. The search developed for the previous review will be modified to identify reviews relevant to help-seeking amongst young people with health problems to include {terms for childhood and adolescence} OR {terms for care leavers} AND {terms for health help seeking}.

The MedLine search undertaken in 2011 yielded 1,067 citations published post 2000, of which 81 were reviews, of which only four met the inclusion criteria. This reveals a paucity of evidence concerning 'what works' in achieving help-seeking or early identification of problems at that time. Our search strategy will include help-seeking for physical needs, and search dates will be planned to take advantage of the searches conducted for NICE guidelines NG43 ('Transition from children's to adults' services for young people using health or social care services') and PH29 ('Looked-after children and young people'), i.e. post 2014 and 2008 respectively. Literature will be restricted to OECD countries, but will not be restricted by language.

Double, independent data extraction and study critical appraisal will be completed, using a range of quality appraisal tools appropriate to the literature identified.

We do not anticipate that studies will lend themselves to any meta-analyses, but in the event that this is possible, Macdonald and Lucas have the expertise to do so. It is more likely that we will synthesise the findings in narrative form. As well as informing the development of a training programme for PAs, this work will help the research team and collaborators to develop a theory of the likely mechanisms by which it might bring about improvements in health promoting practices. We will register the review with PROSPERO.

5.1.3 Developing a prototype training intervention

Using the findings from the review and survey of local authorities we will work with care leavers from North Somersest and young people from CORAM Voice, PAs and other stakeholders to develop a prototype training intervention that we will test in North Somerset. With regard to care leavers, we will learn from previous research showing that the meaningful involvement of care leavers requires the research team to ensure that activities are compatible with young people's schedules, that young people are reimbursed for their time, and given feedback about how their ideas have, or and have not been, taken forward to the training programme.[72] This process will also be used to identify the most appropriate outcomes for the feasibility trial.

Methods We will convene a meeting (anticipated duration 10.30 until 15.00) in which we will bring together a group of 12 care leavers, a group of Personal Advisors and a group of other stakeholders such as designated LAC doctors and nurses, GPs, social workers and team leaders. Peer researchers from CORAM Voice will facilitate two groups of six care leavers; other members of the research team will facilitate the professional groups. The aim of these consultations is to clarify what each group sees as the most important health concerns for CLs; the information and help they feel CLs need in relation to their health and wellbeing; the approaches that motivate or deter them from seeking help from their PA and other sources, and the role that after PAs could play in improving their health and wellbeing.

In the morning, we will use Q-Sort methodology, which involves a sorting and ranking exercise designed to elicit views with the aim of developing consensus views. Using the investigators' knowledge of the field and the results of the rapid review, we will produce a set of cards, each labelled with a different health issue identified in the rapid review, along with some blank cards to capture issues that may not have been identified but that are important to CLs. Participants will be asked to review the cards individually and consider where they would place each card on the large Q-SORT pyramidal grid, identifying more and less important topics. They are then asked to discuss their views in a small group and to agree on a single Q-SORT pyramid. During the lunch hour the research team will work with the peer researchers to produce a short presentation that captures the deliberations and priorities of each group. This will be presented in the afternoon session and differences explored. This approach was very effective in engaging CLs and professionals in an earlier project identifying the outcomes they considered important when evaluating interventions to address the consequences of maltreatment.[73] In addition to identifying priority health and wellbeing concerns, we will use these consultations to identify the information and help they consider most important, the major impediments to seeking or accepting health and social care support, and the ways in which PAs could best support them.

These findings will inform the training, including its aims, scope, content, the support materials required and those best placed to deliver the curriculum. We anticipate training delivered in two half days is achievable given pressure on staff, but will confirm in consultation with LA staff and managers.

5.1.4 Identifying possible outcome measures

Having established the content of the training and the ways in which it is expected to improve outcomes for care leavers, we will undertake further consultation with care leavers and other stakeholders to identify best possible measures, both administrative and standardized. Potential measures are discussed below (5.2.10) but we will use these consultations to test the acceptability of a range of measures to care leavers, local authority and NHS staff, including the extent of data burden that each might impose. We plan to do this via three separate consultations with three groups of between 12-15 participants.

5.1.5 Developing a logic model

We will develop a logic model that describes the predicted pathways between the content of the training and improving health outcomes for care leavers. We will use Green and Krueter's Precede/Proceed model for health programme planning and evaluation as a framework to identify the changes required to bring about changes in outcome (http://lgreen.net/precede.htm).[74] This is the most commonly used planning approach in health promotion and has been used by Lucas to design an intervention targetting health professionals' behavior (see https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5745782/).

Precede/Proceed facilitates the identification of those conditions (skills, education, context, resources, policies and organisation) required to bring about changes in environment and behavior which, in turn, will deliver desired changes to health and wellbeing. We will use the results of our survey, rapid review and coproduction work (see 5.1.1.-5.1.4) to identify our primary and secondary outcomes, the behaviours that influence them, and the conditions which enable and reinforce change. Our aim is to identify the functional components of an intervention to achieve this, which could be delivered in a portfolio of modules.

Provisionally, we think that the underpinning theory of change would be that skills, knowledge and tools available to PAs are currently insufficient to support care leavers to seek help for their health and wellbeing. We will increase knowledge of health issues, health resources and the barriers to health care-taking, including social and emotional health. Changes in knowledge will be supported by enhanced skills in talking about health, recognizing unmet health needs, and motivational interviewing. PAs will be provided with tools to enable them to act on new knowledge and skills and to support care leavers to understand their own health needs.This will be augmented by familiarity with available services, access to health promotion resources, and relationships with health colleagues developed during training. These elements (knowledge, skills and tools) will create an environment predisposed to health promotion, reinforcing of health care taking, and enabling of self-care for CLs. PAs who are more sensitive to and more able to support health issues will provide an environment where CLs are more likely to identify, discuss and to respond to their own health needs. We hypothesise that these changes require that PAs consult with the LAC nurse prior to the CL reaching the age of 18 (organizational component), and access appropriate health care services locally (resource component).

5.1.6 Finalising the training intervention

Drawing on the above, we will produce a draft training programme, including a trainers' manual and toolkit, a handbook for PAs, and a strategy for providing post-training support. The training will be developed using the Design and Delivery Framework developed by the MIT Learning Center in Michigan (http://web.mit.edu/training/trainers/guide/framework.html), drawing on the steps outlined above, early consultations and the existing literature indicate the following candidate modules: i) sexual and reproductive health, ii) smoking (cessation), iii) (tackling) drug and alcohol misuse, iv) recognizing signs of trauma, v) establishing and maintaining supportive social networks (avoiding isolation), vi) transition to adult services for those with existing diagnoses, vii) when to see the GP and when to use A&E, viii) maintaining physical and mental health and wellbeing (healthy eating, being physically active) ix) recognising and managing anger x) recognizing and managing anxiety xi) using your Health Passport and health records. To maximize the impact of the training for CLs, the training is likely to include a focus on the skills associated with encouraging positive behaviour change, such as building on strengths and motivational strategies relevant to young people.[75,76] However, we do not want to pre-empt our discussions with professional staff and care experienced young people

In constructing the programme we will also draw on findings from implementation science regarding effective training initiatives. These suggest that, in order to implement new skills and knowledge, practitioners need to be supported within their organizational context. For example, we will involve line managers in the training, to ensure they are confident in their ability to supervise this aspect of PAs' work. We will consider the best way to provide ongoing support e.g. via organizing a follow-up meeting between PAs and a named LAC nurse, and/or providing a consultation service e.g. a monthly half day in which they are available to take phone calls or respond to emails from PAs; or an on-line discussion forum.

Our suggestion is that the training sessions will take be delivered face-to-face, in a venue away from PAs' usually place of work. Training will be provided by LAC doctors and nurses, using a manual of presentations and group work tasks designed during the development phase of the research. We envisage that follow up training will include online additional information and monthly tasks focused on putting learning into practice. We will also provide a question and answer service either via phone or email. Final decisions on how best to provide follow-up support will be finalised after the consultations and rapid review. Current evidence suggests that such support is an essential component of and effective training model.

We will convene three focus groups to gauge stakeholder responses to the draft training programme (including post-training support), comprising care leavers, PAs, and health and social care staff. We will use feedback to revise the programme manual, modules and associated documents/logic model. Using a similar methodology to that described in 5.1.3 we will use this sesson to identify candidate outcomes and measures for the feasibility study.

5.1.7 Test run of the proposed intervention.

Phase 1 will conclude with a ‘test-run’ of the training programme, undertaken in one LA that will not be part of Phase 2. This test-run will establish the resources needed to organize, recruit to, and provide the training; the level of PAs interest and attendance; the delivery requirements such as time of day, location, and length of training sessions. Following the training we will use questionnaires and qualitative interviews with participants to assess its perceived relevance for PAs, whether the content is appropriately ‘pitched’, how useful they find the materials provided; whether they think the training is realistic and how likely it is that they will be able to implement it, based on the training itself and the proposed follow-up support. We anticipate using quizzes within the training to quickly assess and reinforce knowledge gains and we will review these for improvements. The training will be observed by members of the research team to identify strengths and weaknesses in the content as delivered, and dynamic issues between participants and between participants and presenters. The sessions will also be observed by care leavers, who will provide feedback on their perceptions of the extent to which the content and delivery maintain a clear focus on the needs of care leavers, accurately reflects the issues they consider important, and advocates for approache they find acceptable and anticipate being effective.

We will undertake follow-up telephone interviews with PAs who did and did not complete the full training to understand the barriers and faciliitators to this. We will ask whether, and how, they intend to implement the knowledge, skills and tools in their day-to-day work. We will explore whether they feel it will improve their practice. We will also assess the extent to which the follow-up support is ‘working’ as intended, and what factors, if any, have impeded or facilitated the application of newly acquired knowledge and skills.

Feedback on the ‘test run’ will be used to amend the training and follow-on support; revise our draft logic model (if necessary); identify changes needed to facilitate implementation of the intended impacts of training on PA behaviour, and plan fidelity measures to be collected in the feasibility study. We anticipate three months will enable us to plan, recruit to, deliver and follow-up the training sessions.

5.2. PHASE 2: Feasibility trial

5.2.1 Aims and design of the main trial for which this feasibility study is being conducted

The primary aim of the main study which would follow this feasibility trial, will be to determine the effectiveness of the training intervention in improving health promoting practices amongst PAs with the aim of improving the physical and mental health of care leavers. We anticipate that to inform a Phase III trial it would be appropriate to assess:

i) impact on PA practice (process and implementation) via routinely collected data, such as PA involvement prior to leaving care; PA access to final health assessments, and Health Passports issued as a percentage of those that should be completed or issued), and

ii) impact on CLs’ health and wellbeing (outcomes) by recruiting and following up a random sample of CLs from age 16 (when a PA is allocated to them) to age 21.

We anticipate that the main trial would comprise a two-arm cluster randomized trial (c-RCT) in which working groups of PAs are randomly assigned to receive the training designed in Phase 1 or to continue with practice as usual without such training. A c-RCT is the design of choice because social care staff, including PAs, work within established teams, who typically have the same line manager, and who share attitudes and working practices. Cluster randomization therefore provides the only means of minimizing ‘contamination’ between PAs in a LA context. Our Phase 2 feasibility trial will inform the design of the main trial, particularly the feasibility and acceptability of randomisation of teams within LAs.

5.2.2 Aims and design of this feasibility study

Adressing the research objectives 4 and 5 set out above, the focus of this feasibility c-RCT is to ascertain the feasibility of key procedural elements of the main trial, including:

- Whether it is possible to recruit, train and retain all PAs in each participating authority. If there is high staff turnover amongst PAs, this might have implications for the delivery of the intervention f(a need for training at regular intervals to accommodate new staff); it might affect the feasibility of obtaining and using administrative data.
- 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

Specific 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 and variability of scores including interval estimates e.g. 95% confidence intervals).
- To explore the use the data collected to estimate the Intracluster Correlation Coefficient (ICC), to inform the sample size require for the main trial. This will, to some extent, depend on the primary outcome decided in Phase 1.
- Determine the feasibility + cost of accessing and using administrative data, if available
- Ascertain the acceptability to LAs and PAs of randomization
- Consider any contamination between the two arms of the trial e.g. PAs moving between teams in trial groups.
- Assess the impact of alternative incentives for CLs (see below)
- Identify barriers + facilitators to implementation of, and fidelity to, the intervention.
- To apply pre-specified progression criteria to the main c-RCT

5.2.3 Methods/design

The feasibility trial comprises a c-RCT in which 12 PA teams (numbers of LAs dependent on organisational structure) will be randomly allocated to one of two trial arms. 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 CLs ‘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.

5.2.4 Sample

No sample size calculation has been conducted for this feasibility study. We will recruit sufficient numbers of PAs and CLs to provide us with information about the feasibility of the main trial. We aim to randomize 12 *teams* of PAs. The size of the teams vary with the size and organisational structure of LAs, but we anticipate a total sample size of 30 PAs, each responsible for 25 care leavers. Using the strategy outlined below, we will recruit 60 care leavers (30 from each arm of the trial) from whom we will collect data at baseline, 26- and 52 weeks post training. Having determined the primary outcome measure(s), we will estimate i) the proportion of CLs who agree to provide data, ii) the proportion who do not provide outcome data and iii) the variability between respondents and between teams in the outcome measure(s). We will explore the possibilities of using routinely held information to allow inclusion of aggregate data held on all CLs allocated a PA in the participating LAs (e.g. completed health assessments).

Whilst the sample size in this study may not be sufficient to inform the power calculation that will be required for a phase 3 study, we will use the available data to estimate the standard deviation and interval estimates (i.e. 95% confidence intervals) of the outcome measures, as this will help inform those calculations (see NIHR guidance on feasibility studies).

5.2.5 Setting We currently have a commitment from Bristol City Council and South Gloucestershire to participate in the feasibility trial, with interest from two other LAs. Because of the importance of contextual factors in interpreting the findings of any evaluation of a complex intervention like the one proposed, the organisational context in each participating authority will be described in detail and investigated as part of the proposed investigation of process and implementation (see below).

5.2.6 Participants Participants in the feasibility study will be all PAs working within the participating LAs with care leavers eligible for PA support. As indicated above, we will also recruit a sample of 60 care leavers aged 16 or over who fall within one of the four categories eligible for support from a PA. These are set out in the Children Act 1989 and include those who meet the criteria for an ‘eligible child’ (Schedule 2, Para 19B); a ‘relevant child’ (Section 23A and B); and a ‘former relevant child’ (Sections 23C and 23CZA). Given information on the turnover of PA caseloads, new cases allocated two months pre- and post-training of the intervention group will be approached for recruitment (anticipating 60-80% response rate).

5.2.7 Intervention and Control

Intervention – Training PAs in the intervention group will receive the training programme developed in Phase 1 (above) and follow on support. The detail of the training will be captured in a manual and portfolio of resources provided to participants. We will establish training fidelity through observations and trainer records. See Section 5.3.2.

Comparator – Practice as Usual Practice as usual (PAU) within each participating local authority will be described in detail, to identify any significant differences across the participant LAs, and – using survey data from Phase 1 - from PA provision nationally. For the feasibility study, we will provide training to PAs in PAU at the end of the trial period.

5.2.8 Recruitment, ‘hearts and minds’ and informed consent

i) Personal Advisors and other key stakeholders: At the outset the research team will spend time with participating LAs, explaining the purpose and design of the study, and ensuring, as far as possible, that the concerns of individual PAs, line managers and other key stakeholders in the LA are addressed. We will emphasise the fact that the study is testing the effectiveness of a training intervention rather than the practice of individual PAs or teams. PAs will be expected by their employer to participate in the trial, but we will nonetheless seek their informed consent, not least because experience teaches us that it is difficult to successfully conduct a trial when individual staff members are ‘conscripts’ rather than ‘volunteers’. The complexity of the intervention lies in the multi-layered organizational context in which training will be delivered, and the mechanisms of influence/change between the practice of PA and the impact on young people’s health. Reluctant participants would impact on the success of the study and our ability to determine whether or not this intervention is sufficiently promising to merit a Phase III trial.

ii) Care Leavers: We have considerable experience of working with groups of care-experienced young people to develop, test and refine a range of study related tools. Care leavers from North Somerset and CORAMVoice will work with us to develop a user-friendly information sheet. This will explain what the study is trying to do, and what would be involved in participating in it. It will make clear that the research team includes peer researchers who have experience of the care system. Those who express an interest in the study will be contacted by a member of the research team to arrange aconvenient time and place to meet. During this meeting the researcher will answer any questions, and ensure that the young person understands what is being asked of them. If they are happy to proceed the researcher will ask them to sign a consent form. This will cover standard issues such as confidentiality, anonymity, safeguarding, digital recording of any qualitative interviews, the right to withdraw at any time, and – if necessary - permission to access health data contained within their pathway plans or final health assessment. In recognition of their contribution to the study, and to encourage retention, care leaver participants will be given a £20 voucher at each of the three data collection points, plus travel expenses.

5.2.9 Randomisation Randomisation will be at the level of the PA team and will be undertaken a member of the Bristol Randomised Controlled Trials Collaboration who is unaware of the identities of the teams, after baseline data have been collected from Personal Advisors.

5.2.10 Data and data collection

Personal Advisors We will collect information from participating PAs at baseline, 26 weeks and 52 weeks post intervention. Baseline data collection will include information about their qualifications, experience, caseload, and basic socio-demographic. Questionnaires will include knowledge of health issues relevant to CLs, confidence in identifying and raising health issues with CLs; knowledge of available resources and how to facilitate young people's engagement with the support services they need, and frequency and content of recent contacts with CLs.

Care Leavers Whilst the intervention is directed towards PAs, the intended beneficiaries are care leavers. This will be reflected in the choice of outcomes and measures. Whilst these can only be determined once the intervention and underpinning theory of change are agreed, they are (in line with NICE recommendations) *likely* to include some of the following:

Possible primary outcomes: General Health (using the GHQ12[77]), Quality of life and emotional wellbeing (measured using the Lancashire Quality of Life Profile including Cantril's Ladder and the Life Satisfaction Scale,[78] and the four question used in the ONS Survey on Personal Wellbeing[42]), Help-Seeking (using the Help-Seeking Questionnaire[79]) and self-efficacy - young people's ability to act independently in their own health interests (using the Generalised Self-Efficacy Questionnaire[80]).

Possible secondary outcomes: Continuity of care i.e. sustained (loss of) contact with relevant health services; adherence to medical regimen (where appropriate, including attendance at adult health services); sexual health (knowledge + behaviours); decrease in smoking (frequency, cessation advice/how to source), reducuction in alcohol and substance use (knowledge, use); increase in exercise and health eating (knowledge and uptake); enhanced social networks, fewer contacts with police and criminal justice system; numbers in education, employment and training.

As indicated, we will explore all possibilities of using routinely held information to allow inclusion of aggregate data held on all CLs allocated a PA in the participating LAs (e.g. completed health assessments). This will permit comparison with the general population, other LAs and the care leaver population.[79,81] Data only obtainable directly from young people will be obtained from the subsample of recruited CLs. The interview schedule for this group will include some open-ended questions about young people's physical health and their experience of support from their PA (see below – Process and Implementation).

Peer researchers Building on previous experience in using peer researchers as a means of securing high quality information from care experienced young people, we are collaborating with CORAM Voice who will provide, train and support a group of peer researchers to collect data from care leavers at 26- (by telephone) and 52- weeks (face to face) post randomization of the PAs. Using peer-researchers was a key factor in achiving a 60-80% response rate in the six local authorities who participated in the 'Bright Spots' study conducted by Selwyn and colleagues at CORAMVOICE (see below).

5.3 Process and implementation Study

5.3.1 Rationale for the process and implementation study

As indicated in 5.2.8, PAs operate in a complex organisational environment and any behaviour change endeavor is inherently a complex social intervention. The training programme is a short intervention designed to enhance the practice of PAs and, ultimately, to promote the health of care leavers. Evidence from implementation science indicates that the effective implementation of the knowledge and skills covered in the training programme will depend on a wide set of issues. These include the characteristics of the training itself, and of the staff group being asked to implement it, organisational capacity and culture, and the ability of the organisational context to support a new way or working. For example Greenhalgh et al.[82] outline eight constructs relevant to effective implementation including characteristics of the innovation, adopter or staff characteristics, systems readiness, the wider inter-organisational context, and implementation process. Analyses by others draw similar conclusions. For example, Meyers et al.[76] identified the following as essential to effective implementation: capacity-building strategies (organisational capacity, staff training), structural support (implementation teams and plans), and implementation support strategies (coaching, supervision, feedback). In their analysis of what makes programmes work, Blasé and Fixsen[83] point to the importance of staff selection, training, consultation and coaching, performance evaluation, decision-support data systems, facilitative administrative / management supports and systems interventions.

Therefore, drawing on the implementation science literature we will, within this feasibility c-RCT, embed a mixed-method process and implementation study of the training intervention, its use by PAs (which may vary across LAs, across PAs, and from one young person to another) and the experiences of CLs. The information provided 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.

5.3.2 Methods

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.

- **Process and implementation data from Personal Advisors**

Post training After the training we will ask all participants 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. In developing this questionnaire, we will explore the possibility of asking a series of questions that might shed light on knowledge acquisition. If this is not possible, we will rely on respondents' *perceptions* of knowledge acquisition, recognizing that such data need to be treated cautiously. The questionnaire will contain questions on:

- perceptions of the relevance of the modules covered 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 26- and 52- 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 52-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.

- **Data from Care leavers**

At 26- and 52 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 52 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.

5.5 Progression criteria for a Phase III Trial

The aim of the feasibility trial is to determine the appropriateness of proceeding to a Phase III trial. This decision will be made on the basis of the data provided on a range of issues. Provisionally, we consider the following would be appropriate:

☑ Unequivocal '**Go'** criteria would be i) recruitment and course attendance by 70%+ eligible PAs and recruitment of 50%+ of CLs invited, ii) evidence that blinding of outcome assessors is possible; iii) availability of high quality administrative data that are comparable across LAs/LCGs with no evidence of extensive missing data, and iv) qualitative and quantitative data that indicate the acceptability of the trial processes and data collection tools.

☒Unequivocal '**Stop'** criteria would be i) recruitment and training of less than 50% of eligible PAs or recruitment of 40% of CLs invited, and ii) evidence from qualitative data that the trial processes were not acceptable; iii) significant contamination across study arms, and no evidence that the intervention is having any impact.

▣ **Revise and progress**.The feasibility study may identify a number of challenges or problems that can be resolved by changes to the certain aspects other study design e.g. a change of outcome measure; a change in arrangements for data collection; or an amendment to the planned analyses. In circumstances such as these, the findings will be discussed with the Trial Steering Committee, who may judge the most appropriate decision to be 'Revise and progress'.

5.6 Economic analysis

The aim of the economic component of this proposal is to inform the design of a full economic evaluation to be conducted alongside a future Phase III randomised trial. As such, the focus is to estimate preliminary set up and delivery costs for the intervention to provide 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 PAs and CLs.

Cost of the intervention The aim is to develop a framework for assessing costs. Costing the intervention will include non-recurrent costs, such as set up costs and costs of initial training for PAs and providing them with associated materials, as well as recurrent costs associated with delivering the service, ongoing support and supervision of PAs, and an estimate of additional demands on PA time in their work with care leavers. We will ask PAs to estimate any additional direct and indirect time demands relative to their caseloads. For recurrent costs, we will pilot different methods of data collection, including easy-to-complete time sheets, cost diaries, telephone interviews and electronic records. Assessing and comparing the methods in terms of completeness of data will help to inform a decision about how best to estimate this in a full trial and provide a suitable framework for assessing costs. 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 multi-agency public sector perspective, as opposed to a NHS (payer) perspective. This broader perspective enables the inclusion of direct and indirect costs, 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 using The Child and Adolescent Service Use Schedule, which is a reliable and valid resource use measurement tool. The tool will be modified to include service use within the public sector e.g. Social Services Department, Department for Education, Criminal Justice Service. As planned, acceptability of this self-report questionnaire will be assessed based on completeness of data. In addition, validity will be assessed by comparing reported resource use with routine data sources, where feasible. Nationally applicable unit costs will be applied to all contacts, derived from UK publications and, where relevant, data provided directly from study sites. The broader perspective will help identify the capacity for cost savings and capture the wider potential impact of the intervention.

Associated costs of the evaluation In preparing the costs for this study we have made some assumptions about the support costs required for the study itself. These include:

1. The time and resource required of LA staff i.e. time for briefings with researchers, participating in interviews (including providing informed consent) and completing questionnaires, attending training; and recruiting care leavers;
2. The cost of providing relevant data in an anonymized form that can be combined across local authorities. This may require the development of a data sharing agreement with each LA.

In addition, we have incorporated the cost of both reimbursement for all care leaver participants to recognize the time given by care leaver respondents, and additional incentives to aid retention and thank care leavers for their commitment. We will work with our peer researchers to consider alternative incentive arrangements (cash incentives above reimbursement, prizes, non-monetary incentives).

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.

5.7 Data Analyses

5.7.1 Feasibility outcomes

We will report the primary outcomes for the trial descriptively, reporting the number of PAs recruited and retained throughout the trial; training fidelity (proportion of PAs recruited attending all or part of training, knowledge gains assessed during training); the extent of staff turnover; how many CLs approached and recruited; the numbers of care leavers retained throughout the 12 months follow-up; the extent of any contamination between the trial arms, and the extent to which we managed to secure and maintain blinding of outcome assessors. In addition, we will report on the acceptability and feasibility randomization, the outcome measures trialed and the extent to missing data at each time point; determine the cost of accessing and collecting administrative.

5.7.2 Clinical outcome

The clinical outcome measures will be presented as summary statistics. As this is a feasibility study, no significance tests will be conducted.

Values to inform the main trial sample size calculation will be estimated and presented, which may include the intra-cluster correlation coefficient, and the outcome rate in the usual care group, as appropriate to the chosen primary outcome measure.

5.7.3 Qualitative 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.

5.7.4 Economic analysis

In estimating the cost of the intervention, a micro-costing analysis will be conducted. The data on resource use for recurrent costs, collected through the different methods trialed, will be compared and the extent of missing data assessed to determine the most effective method of data collection for a Phase III trial. 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 from the feasibility study, the development of the economic model and additional sources of evidence derived from the economic review, we will plan to 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.

6 Dissemination, Outputs and anticipated impact

All applicants take knowledge transfer and matters of impact seriously and are researchers because we want to make a difference to children’s lives. The study will be carried out in a transparent and inclusive manner with full dissemination of activities and findings. However,

6.1 Anticipated outputs and impact

The status of the study as a feasibility study has some implications for the nature and extent of further outputs and dissemination, but we anticipate the following outputs.

- Final report for NIHR.
- A manualised training intervention for personal Advisors
- A protocol for a Phase III trial If progression criteria for a Phase III are met, a key output will be a protocol for a Phase III trial to accompany a further research proposal.
- Academic publications We will submit a report of the feasibility study to the open access journal ‘Pilot and Feasibility Trials’ or equivalent, another on the systematic review in Phase 1, and a third on the views and experiences of relationships between CLs and the PAs they support.
- Informing and engaging key stakeholders 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’.
- Knowledge brokers 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.
- Further funding If the feasibility study indicates that a Phase III trial is appropriate, we would seek funding from the appropriate NIHR funding board. We anticipate that a Phase III trial would require funding for a further three year period to assess impact in a sufficiently large group of Local Authorities.

6.2 Possible barriers for further research, development, adoption and implementation

We are not expecting or intending local authorities to implement any findings from this study, given its status as a feasibility study. This study, with an embedded assessment of process and implementation, is designed to highlight potential barriers to uptake, with a view to resolving these. A Phase III trial is necessary to comprehensively assess the success of the approach outlined in this feasibility trial. The current study aims to identify issues of acceptability, accessibility and feasibility, and how these might be addressed.

7. Project timetable (months per task in brackets)

Year 1: Development of training: convene study steering group (1); conduct survey of LAs (1-6) and rapid review (1-4), rapid review (1-4), Consultations with Care Leavers, Personal Advisors and other stakeholders (1); finalise draft training programme, manuals and logic model; 'test run' of training intervention (10-11); Draft report from feasibility study (11-12);: Finalised training programme (12); Draft and submit ethics application to SREC (9-12).

Year 1 Milestones Rapid Review Completed (end of month 4); Survey of LAs Completed (End of Month 6); Consultations Completed [End of Month 7]; Training programme, manuals and logic models developed (end of Month 12).

Years 2+3 Feasibility Trial: **Months 9-12**: recruit LAs, prepare the ground for feasibility study; **Months 13-18**: Recruit PAs and collect baseline data collection - PA Knowledge Audit (13-14); Recruit sample of Care Leavers and collect baseline data (15-17); Randomisation of PA teams (18); Training and Post-training knowledge Audit (19-21); Process and Implementation Study, comprising interviews with PAs, CLs and other stakeholders (16-25); Resource data collection and analysis(26-32); Post-Training data collection (22-31); Data management and analysis (13-33); Preparation of report and other outputs (31-36).

Training of peer researchers (4-31);

Milestones Years 2-3: Ethical approval secured (13); Randomisation of PA Teams [14]; Completion of Process and Implementation Study [30]; 52-week Data Colleciton completed [31]; Report Submitted [36].

8. Project management

The study will be lead by Macdonald at the University of Bristol, and project managed by the Trial Manager under her supervision. Macdonald has considerable experience in managing complex projects, including research. The research team will meet monthly in Year 1, and bi-monthly in years 2 and 3, unless more frequent meetings are indicated. Most meetings with include virtual attendance, to reduce travel and time costs, with the exception of the peer researchers who may prefer to attend in person.

A Trial Steering Group will be established with an independent chair, that will meet once towards the end of Year 1, and every six months in Years 2 and 3 with at least one/two face-to-face meetings during this period. As this is a feasibility trial of an intervention, and given the nature of the intervention, we propose integrating the functions of a Data Management Committee into that of the Trial Steering Committee.

Coram Voice is a partner in this project, and their involvement has been fully costed. However, it was not possible to secure a signature from them by the submission date. This can be provided in due course.

9. Ethical Approval

The study will be conducted in accordance with the principles set out it the UK Policy Framework for Health and Social Care Research. The entire project will be subject to ethical committee approval from the research committee of the School for Policy Studies at the University of Bristol, and the Association of Directors of Children's Services. The requirements of individual local authorities and the detail of their research governance arrangements will vary, and we will initiate early conversations with each LA to ensure their requirements are met. Ethical approval fo the Feasibility Study will be sought through the

Integrated Research Application System. The Trial Steering Committee will ensure that the study is conducted to the appropriate standards, and provide advice through the chair, to the NIHR, as required.

9.1 Consent, confidentiality and anonymity

Care will be taken to ensure that all interviews are conducted with freely given, informed and written consent of both care leavers and LA staff. We will use clear, straightforward, accessible, and well-drafted documentation to introduce the study to potential participants, and ensure that all participants know that they can withdraw from the study at any time with having to provide an explanation. Care leavers will be aged 16 or over, and should be able to provide their own consent. All participants will be given an assurance that all information they provide will be treated confidentially, except in relation to safeguarding issues (see next paragraph). They will also be assured that no information will be used in any report that could identify them. Details about individual cases will be forgone or disguised, to comply with this. Where data might identify an individual member of staff (for example a head of service describing something unique to their authority), specific consent from that individual will be obtained. The names of those participating will not be known outside the research team. We will discuss with the trial local authorities whether LAs should be named in any report or subsequent dissemination.

9.2 Disclosure and safeguarding

It is possible that in the course of an interview a respondent may disclose information that indicates a threat to their welfare or that of others. The Participant Information Sheet will make clear that in such circumstances the researcher will be obliged to inform the appropriate authorities.

9.3 Support for peer researchers

The peer researchers will be members of CORAM’s National Voice Team. *A National Voice* is an ambassador program for children and young people in, and leaving, care The service is managed by the Head of Policy and Practice Development who is expert in co-production with care experienced children and young people. The Peer Researchers will managed and supported by the Manager of *A National Voice* who is experienced in working with children and young people.

As members of the National Voice Team, the Peer Researchers will receive 1-1 support from the manager, attend team meetings and receive monthly supervision. In addition, they will be supported in terms of preparation for meetings and the focus group by staff from *A National Voice*, and debriefs after every session.

Induction to Coram Voice and the research This will include meeting the University of Bristol team and training in basic safeguarding, information security, GDPR, equalities and diversity, and health and safety.

The training has been designed to be delivered to young people and will be delivered by staff experienced in training young people in co-production methodology and work with care experienced young people. Following the induction, the young people will be provided with a two-stage training programme, comprised as follows:

Phase one training: – focus group work with care leavers and stakeholders:

- Recap on Who is who
- Understanding the research Project – aims and objectives
- What Peer research is
- Confidentiality/consent and safeguarding
- How to engage young people, designing and delivering group work, ice breakers, facilitating engagement by young people, supporting quieter members, ensuring inclusivity
- Co-production methodology – what it is, how to do it
- Understanding the role of the PA
- Scoping of areas of support young people need

Young peer researchers will input into the design of the training program, which will include working with the researchers from UOB to identify what was important to young people.

Phase two training:

- Understanding aims and objective of second stage
- Listening skills
- Note taking exercise (using extract)
- Prompting and Probing exercise
- Role play with snapshot and feedback
- Interviews role play of good & bad interviews (open ended questions etc.)
- Active listening
- Practice interviews in pairs
- Dealing with difficult interviews – practice and tips
- Safe interviews/managing risk/disclosure/boundaries
- Observation techniques and tips

Staff from Coram Voice to recruit, induct, support, train and be on site in the LAs supporting the delivery of the peer research and supporting the young people in work with UOB in the planning and set up of the peer research.

Study Specific Training

Working with Coram Voice, the Trial Manager and University of Bristol team will provide training regarding the study and its organisational aspects. Two of the three academic members (Macdonald and Selwyn) are qualified and registered social workers, with years of experience of working with LAC. Lucas is a psychologist with comparable experience of working with vulnerable young people, and a good knowledge of care leavers.

As agreed with CORAM, oversight of the allocation of work to peer researchers will sit with the Trial Manager

9.4 Data management

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. A study data base will be established that is designed to ensure completeness, accuracy, reliability and consistency.

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.

10. Patient and Public Involvement

In preparing this proposal we sought the views of young people in two ways. We first undertook a review of existing research on what care leavers have said about their experiences of leaving care, with a particular focus on their perceptions of their health needs and current support with their physical and mental health needs. We then with with a group of care leavers in North Somerset (on 15th May). At this meeting we asked them about their experiences of leaving care, what they saw as their health needs, and how easily they found getting help with their physical and mental health needs. We also asked them about the support they received from their Personal Advisors. This group of care leavers had a particular concern with issues of mental health and wellbeing, arising from a sense of isolation, long waiting times and a lack of local resources, particulalry those they saw as acceptable. They also talked of the struggles they had to accessing appropriate GP care, eye care and exercise. We explained what we were proposing and asked them if i) they thought it was sensible/worthwhile, and ii) whether they would be willing to help us with the research if it was funded. Their response was a definite ‘yes’ to both questions. In collaborating with this group of care leavers, with care leavers at Coram Voice, and with the peer researchers on the project, we aim to ensure that the collaborations are mutually beneficial. We have also met and received support and comments from Health and Social Care staff responsible for the wellbeing of Care Leavers in 3 LAs, including providers commissioners and frontline staff.

As indicated above, care experienced young people will be involved as peer reserachers throughout this project. As such they will be regarded as members of the research team, and attend research meetings, supported by a member of staff from Coram Voice. Whilst colleagues from Queens and U Bristol may join by telephone, we think it is important that young people will find it easier to participate in these meetings in person, rather by means of telephone, SKYPE or WhatsApp, but they will have the opportunity to decide. We will also involve a wider group of care leavers in consultations in Phase 1, both to assist us in determining the content of the training, and the choice of outcomes and outcome measures.

11. Project /research expertise

The academic team includes Macdonald, a registered social worker with experience in conducting trials within children’s social care. Lucas is Reader in Child Health Research and an expert in Health Promotion and mixed methods research. Lynn is a health economist who was worked previously with Macdonald. Selwyn is Director of the Hadley Centre for Fostering and Adoption, and an expert in LAC and their wellbeing. The team will be supported by Metcalfe, Professor of Medical Statistics and Co-Director of the Bristol Randomised Trials Collaboration.

Macdonald, Lucas and Lynn have experience of delivering trials, including within children’s social care. All understand the challenges of evaluating complex social interventions and will work closely with NHS collaborators Emma Bradly and Amanda Cundy (Consultant Paediatricians and Designated LAC Doctors in Bristol and South Gloucestershire respectively); Kathryn Cox and Elizabeth Dando (Designated LAC nurses in Bristol and South Gloucestershire respectively) and CORAM Voice (a children’s rights charity providing advocacy for care leavers) who will provide, train and support peer researchers in developing and testing the intervention (see above).

12. Success criteria and barriers to proposed work

In terms of the success of the project overall, this will be determined by a clear answer to the question of whether or not the intervention appears promising and the feasibility study suggests that it is appropriate to seek funding for a Phase III trial. The main barriers to success are those set out in the feasibility study, namely recruitment and retention of PAs and Care Leavers, and determining the sensitivity of the outcome measures used.

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