Life in transition - Promoting good health in care leavers

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
05/01/2023		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
17/01/2023		Results		
Last Edited		Individual participant data		
30/09/2024	Other	Record updated in last year		

Plain English summary of protocol

Background and study aims

Statutory guidance in the UK requires local authorities to ensure that effective plans are in place to enable children leaving care to continue to obtain the healthcare they need. Personal advisors (PAs) play a key role in the lives of young people leaving care, potentially supporting them for up to seven years from the point at which they leave care. PAs are expected to work in partnership with care leavers and health professionals to ensure that care leavers have the information they need to manage their own health, and the guidance makes clear that PAs 'should have access to information and training about how to promote physical and mental health'. However, at all ages health outcomes for care leavers remain poorer than for those without experience of care. In their 2017 survey, the Care Leavers Association found that whilst many care leavers did not have a diagnosed mental health issue, many had 'serious well-being issues that prevented them from living life fully.' That report emphasised the pivotal role of the PA, recommending that the status of that role should be increased and that training and support should be provided to all PAs. However, to date, there has been little bespoke training provided for Personal advisors (PAs) and what there is has not been rigorously evaluated. The LIFT training programme was developed to assist PAs to support care leavers to better address their physical and mental health and well-being. It was informed by an international review of the evidence, a national survey of PAs and their managers about what training is currently available and what is needed, and consultations with care experienced young people, PAs and other professional stakeholders. The aim of this study is to find out whether or not it is possible to evaluate this training programme using a study design called a randomised controlled trial - an RCT. In an RCT, teams of PAs are randomly allocated to one of two groups, only one of which will receive the training. When well conducted, RCTs are the best way of answering questions about 'what works'. For example, in a large enough RCT of the LIFT training, the only difference between the two groups would be the training itself, and so it is plausible that any differences in outcomes could be attributed to the training. However, RCTs are expensive and can be difficult to implement, so it is sensible to find out if this design is acceptable to participants and can be implemented to a good standard, before seeking funds for a larger study.

Who can participate?

PAs and eligible care leavers in the three participating local authorities

What does the study involve?

PAs in both the intervention (training) and control groups are expected to complete a survey and participate in two interviews over the course of a year. PAs allocated to the intervention group will be expected to complete the training. Care leavers who agree to participate will be asked to complete a range of measures at three-time points: when recruited to the study, and then at two points in the following year. A smaller group of care leavers will be asked to answer bi-monthly questions on their health usage.

What are the possible benefits and risks of participating?

The main benefit of taking part is to help to develop better training for PAs so that they can help other care leavers in the future. We do not believe there are any specific risks to those participating, other than some care leavers might find some of the questions upsetting. In such situations, the young person can stop the interview or choose not to answer the question. Appropriate support will be provided.

Where is the study run from? University of Bristol (UK)

When is the study starting and how long is it expected to run for? September 2022 to August 2024

Who is funding the study? National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact? Prof Geraldine Macdonald, Geraldine Macdonald@Bristol.ac.uk

Contact information

Type(s)

Principal investigator

Contact name

Prof Geraldine Macdonald

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

321282

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

17/108/06, CPMS 54217, IRAS 321282

Study information

Scientific Title

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

Acronym

The LIFT Study

Study objectives

The theory of change underpinning the intervention is that enhancing the knowledge and communication skills of personal advisors in relation to the health and well-being of care leavers will increase the frequency with which health issues are recognised and discussed, which in turn will result in actions by both PAs and care leavers aimed at improving health, ultimately leading to improved health outcomes for care leavers in the longer term

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/03/2022, School for Policy Studies, the University of Bristol (8 Priory Road, Bristol, BS8 1TZ, UK; +44 (0)117 95 46755; sps-ethics@bristol.ac.uk), ref: SPSREC/21-22/227

Study design

Multicenter cluster-randomized feasibility trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Improving the health and well-being of care leavers

Interventions

The LIFT training - overview

The LIFT training is a brief, bespoke programme designed to assist Personal Advisors to support

care leavers to better address their physical and mental health and well-being. The training was informed by:

- 1. An international review of the evidence
- 2. A national survey of personal advisors and their managers about what training is currently provided and what is needed
- 3. Consultations with care experienced young people, personal advisors, and other professional stakeholders

The LIFT training comprises six online modules (taking between 3.5 to 4 four hours to complete), plus a one-day manualized skills workshop facilitated by health professionals familiar with children in care and care leavers, and two webinars, one designed to take questions arising from the modules, the second to review progress on the homework assignment associated with the skills workshop i.e. to identify an area for professional developing in relation to addressing the health issues of care leavers.

The module content covers the following areas:

Module 1 - Care Leavers and Health: The Evidence Base

This first module provides participants with an overview of the range of physical and mental health problems that care leavers can face, how this differs from young people with similar socioeconomic backgrounds, and why this might be. It covers what we know about the impact of their care and pre-care experiences on health, including the latest (2022) evidence of the lifetime impact on their health and well-being. It looks at physical, oral, sexual and mental health and includes evidence from care experienced by young people themselves. It emphasises the extent to which physical and mental health are interlinked and the importance of being alert to how poor health in one area may affect another. It introduces the concepts of trauma and Adverse Childhood Events and identifies some things that they can do to help care leavers improve their health and wellbeing

Module 2 - Care Leavers and Trauma

This module focuses on trauma, its impact on children's development and the ways in which this can make life difficult for care experienced young people. It distinguishes trauma from the impact of trauma (e.g. PTSD, anxiety,) and goes into some detail regarding how the brain deals with trauma and how children and young people adapt, often in ways that are effective 'at the time' but which may not be adaptive as they grow older and find themselves in new situations. This material draws heavily on the work of the UK Trauma Council.

The module describes how trauma can lead to mental health problems and identifies some implications for practice. The module emphasises the importance of:

- 1. Being reliable, ensuring young people have the skills required for various situations helping them to acquire these if needed
- 2. Understanding a young person's behaviour, when this seems to be counterproductive (and how to do this)
- 3. Helping young people to build and maintain social networks
- 4. Promoting resilience, and how to do this

The module teaches to not assume that any problem is attributable to maltreatment but to advocate for appropriate medical assessment if a young person's behaviour suggests there might be another problem, such as autism or ADHD, or learning difficulties.

Module 3 - Health in Every Contact

This module introduces the organisation of the NHS in England, which we know is similar, but not the same in all nations of the UK. It draws out what this means for supporting good health and gives participants examples of how and why it might be useful to think about health in every

contact. The module is heavily focused on case studies and encouraging PAs to think about a range of health issues. It introduces them to the 'wellbeing wheel' - a public health tool that is useful in thinking about health 'in the round' and provides a summary of what we know about young people's unmet needs and the challenges of recognising and responding to help-seeking behaviour.

Module 4 - Culture and Context

This module focuses on 'health and wellbeing in context', introducing participants to theories about how social and environmental contexts shape health, and what this means for individual young people and their individual needs. After presenting the socio-ecological model of health and discussing the cumulative impact of social and environmental influences on health, the module introduces the theory of lifespan development and its implications for young adults, particularly in relation to brain development. The module concludes with a focus on diversity and culture, and why these are important for young people's health and well-being, and for professional practice.

Module 5 - Staying Safe

This module focuses on health issues that young people are concerned about and have said that they want their Personal Advisors to be able to help them with:

- 1. Drug and alcohol use and misuse
- 2. Self-harm, and
- 3. Sexual health

The module begins with a consideration of what we mean by risk and the role that stress plays in risky behaviours. It provides background knowledge about what we know about each of the three issues above and introduces some of the skills that PAs can use to support young people and strategies and skills that can help them to improve these particular aspects of their health, including a brief introduction to motivational interviewing, the core skills of change talk (the OARS, a focus in this workshop) and the role of the Personal Advisors in helping young people who might want to change their behaviour.

Module 6 - The Personal Advisor's Toolkit

This final module suggests how Personal Advisors can use commonly available tools to help guide and support care leavers during their transition to adulthood:

- 1. Local offers
- 2. Health passports
- 3. Pathway plans
- 4. Advocacy and referrals for specialist services
- 5. Knowledge of how health services are organised

In this feasibility trial, participants in the control group continue to work as usual. If their managers wish to make the training available to them at the end of data collection, then this will be arranged.

Method of randomisation

Blocked randomisation (using the random number generator in Stata statistical software) was conducted within each local authority, allocating two of the three teams to intervention and the third to the comparison group.

Intervention Type

Behavioural

Primary outcome(s)

Feasibility measured using 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

Key secondary outcome(s))

- 1. Care Leaver's Well-being status measured using 4 separate questions about personal well-being (not combined into a single scale), based on those used by the ONS at baseline, and 24 and 48 weeks
- 2. Care Leavers' Physical health status measured using 4 questions about physical health from the Census at baseline, and 24 and 48 weeks
- 3. Care Leavers' Quality of life measured using one of the following measures at baseline and again at 24 and 48 weeks (one in each Local Authority in this feasibility study in order to assess which is most acceptable):
- 3.1. Recovering Quality of Life (ReQoL) 20-item questionnaire (ReQoL20)
- 3.2. ReQoL 10-item questionnaire (ReQoL10)
- 3.3. EuroQol Group health-related quality of life in cost-effectiveness analysis comprising five dimensions (EQ-5D-5L)
- 4. Confidence in health professionals measured using the Revised Perceived Efficacy in Patient-Physician Interactions Questionnaire (PEPPI-10) at baseline, 24 and 48 weeks
- 5. Perceptions of PA empathy measured using 5 questions regarding perceptions of the personal advisor's empathic qualities developed for this purpose at baseline, 24 and 48 weeks
- 6. Psychological Coping (Mastery) measured using the Pearlin Mastery Scale questionnaire baseline, 24 and 48 weeks
- 7. Health service usage will be measured using an adapted version of the Client Service Receipt at baseline and at two monthly intervals

Completion date

31/08/2024

Eligibility

Key inclusion criteria

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

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

16 years

Sex

Αll

Total final enrolment

71

Key exclusion criteria

- 1. Care leavers living in foster care (other than 'Staying Put' foster care)
- 2. Care leavers in a residential or secure setting of any kind
- 3. Care leavers with an allocated social worker for reasons other than being a care leaver e.g. as a result of being a parent themselves
- 4. Care leavers deemed by the local authority to present a risk to themselves or to research staff.

Date of first enrolment

23/01/2023

Date of final enrolment

30/08/2024

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Nottinghamshire County Council

Children, Families and Cultural Services
Looked After and Leaving Care
Home Brewery Building
Sir John Robinson Way
Arnold
United Kingdom
NG5 6DB

Study participating centre Bristol City Council

Children's Services B-Bond PO Box 3399 Bristol United Kingdom BS1 9NE

Study participating centre Gloucestershire County Council Children, Young People and Families Shire Hall Westgate Street Gloucester

United Kingdom GL1 2TG

Sponsor information

Organisation

University of Bristol

ROR

https://ror.org/0524sp257

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated or analysed during the current study are not expected to be made available due to the nature of the study design i.e. a feasibility study that is not powered to answer questions of effectiveness.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2.0	12/09/2022	10/01/2023	No	Yes
Participant information sheet	version v2.0	12/09/2022	10/01/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<u>Protocol file</u>	version 0.1	04/04/2022	10/01/2023	No	No