

FULL/LONG TITLE OF THE TRIAL:

DISCOVER "Getting the Life You Want" Workshop Programme for Care Experienced young people aged 16-19: A feasibility and acceptability pilot study

SHORT TRIAL TITLE / ACRONYM:

DISCOVER Workshop Programme for Care Experienced young people

DELETE AS APPROPRIATE:

- This protocol has regard for the HRA guidance and order of content; OR
- ~~This protocol has regard for the HRA guidance; OR~~
- ~~This protocol does not have regard to the HRA guidance and order of content~~

RESEARCH REFERENCE NUMBERS:

IRAS Project ID: 303093

TRIAL REGISTRY NUMBER AND DATE:

N/A

PROTOCOL VERSION NUMBER AND DATE:

Version 2.0: 12/10/2022

OTHER RESEARCH REFERENCE NUMBERS

N/A

SPONSOR / CO-SPONSORS / JOINT-SPONSORS

This study is sponsored by South London & Maudsley NHS Foundation Trust (SLaM). Our DISCOVER team is part of National & Specialist CAMHS, within SLaM

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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

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

For and on behalf of the Study Sponsor:

Signature:

Date:/...../.....

.....

Name (please print):

.....

Position:

Chief Investigator:

Signature:

Date:/...../.....

Name: (please print):

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KEY STUDY CONTACTS

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Sponsor	South London & Maudsley NHS Foundation Trust (SLaM) NB: Our DISCOVER team is part of National & Specialist CAMHS, within SLaM
Joint-sponsor(s)/co-sponsor(s)	N/A
Funder(s)	Maudsley Charity Maudsley Charity at ORTUS London SE5 8SN
Key Protocol Contributors	DISCOVER team, as above
Committees	

STUDY SUMMARY

Study Title	DISCOVER "Getting the Life You Want" Workshop Programme for Care Experienced young people aged 16-19: A feasibility and acceptability pilot study
Internal ref. no. (or short title)	DISCOVER Workshop Programme for Care Experienced young people
Study Design	Case series, feasibility pilot
Study Participants	Care Experienced young people, aged 16-19yrs
Planned Size of Sample (if applicable)	N = 40
Follow up duration (if applicable)	2-3 months
Planned Study Period	11 months
Research Question/Aim(s)	<u>Aim 1:</u> To explore the acceptability of the new intervention based on take-up of and retention within the workshop programme, as well as participant feedback. <u>Aim 2:</u> To conduct an initial exploration of the efficacy of the intervention by analysing change in participant scores when comparing mental health emotional well-being scores at the pre- as compared with post-workshop 1:1 meeting

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
Maudsley Charity	This study is funded by an "Innovation and Improvement" Grant from the Maudsley Charity. Our grant number is: G2247 and we have been awarded £180,000 over a 2-year period

ROLE OF STUDY SPONSOR AND FUNDER

This study is sponsored by South London & Maudsley NHS Foundation Trust (SLaM) will be run entirely by our DISCOVER NHS team as part of SLaM.

This study is funded by the Maudsley Charity. We submit quarterly update reports to the funder on project progress. All other Terms & Conditions are outlined in the Award Letter (provided as supporting document in this application for R&D approval).

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

- (1) Medway-DISCOVER Working Group** – early in the planning stages of the project, we formed a working group with Children's Social Care professionals from within Medway Children's Social Services, the site where this pilot study will be carried out. The working group comprises of: five Team Leads, two Social Workers and two Personal Advisors. The goal here was to ensure that the design of the intervention was informed by the expertise of Children's Social Care professionals who engage with our target population on a daily basis. Through these working group meetings, we have gained richer insight into the day-to-day practical as well as emotional challenges CE YP face and that should be considered in our intervention design and study protocol.
- (2) DISCOVER Young People's Advisory Group (i.e. Patient & Public Involvement Group)** – we have formed a young people's advisory group of three 16-18yr olds who are in or have recently left the Care system. We have had four advisory group meetings together via Teams to-date so that the voice of CE YP is at the centre of intervention design and planning. In these meetings, we seek their ideas about how we can develop a group workshop programme that feels relevant, accessible and acceptable for CE YP. More recently, we have sought their feedback on ideas our team has developed for intervention content

PROTOCOL CONTRIBUTORS

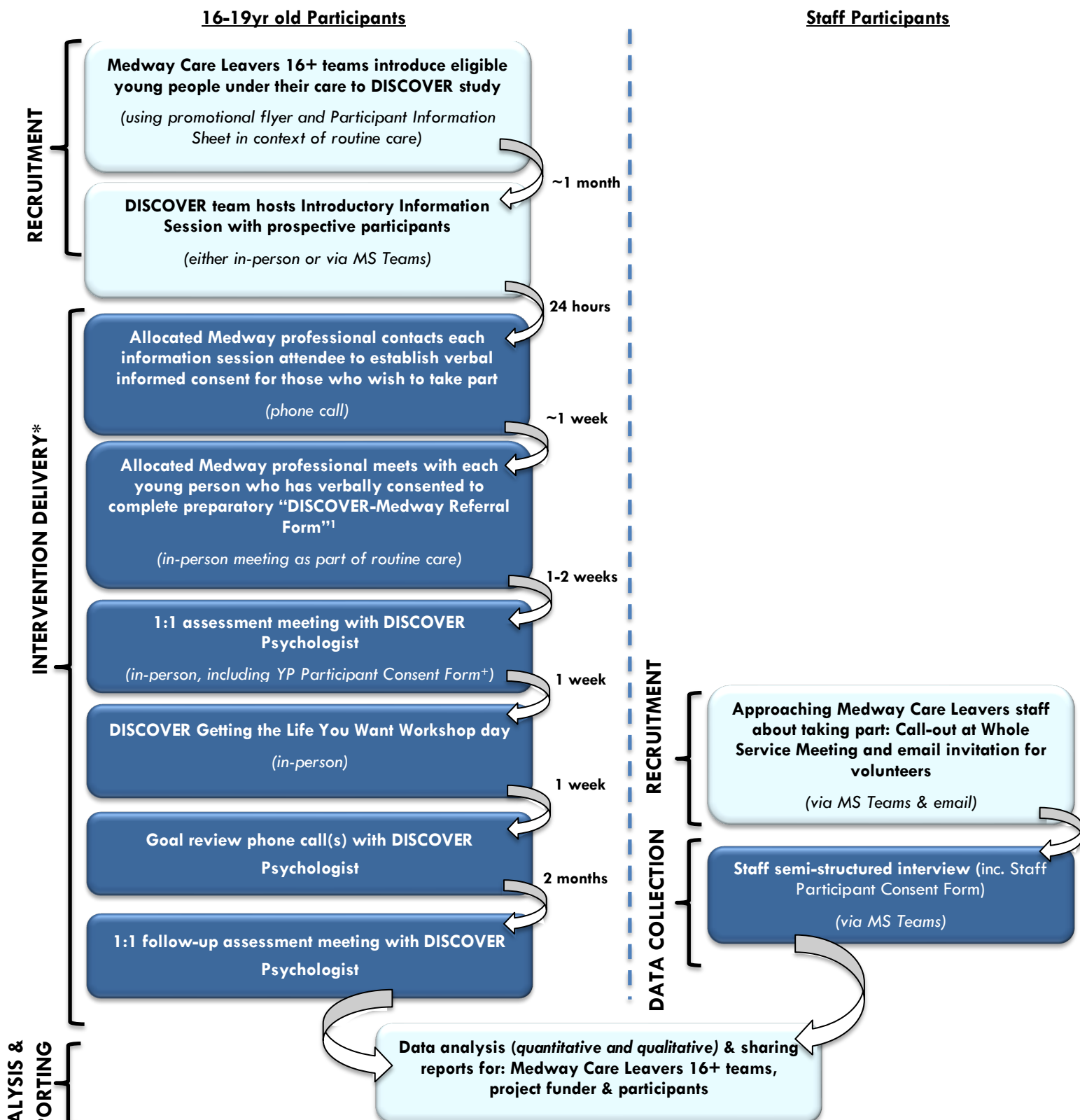
This study protocol was primarily designed by the DISCOVER team, namely Dr Emilie Bourke (Clinical Psychologist) and Dr Irene Sclare (Consultant Clinical Psychologist & DISCOVER Team Lead).

The protocol was designed through consultation with the DISCOVER-Medway Working Group (from Medway Care Leavers 16+ Service) – Debbie Taylor (Group Manager), Joanne Kavanagh (Team Lead), Helen King (Team Lead), Shem Topliss (Personal Advisor), Lauren Dyer (Social Worker), Joanne Blake (Social Worker) & Bernadette Bradley (Personal Advisor)

KEY WORDS:

CARE LEAVERS; LOOKED AFTER CHILDREN; PSYCHOLOGICAL INTERVENTION; WORKSHOP PROGRAMME; ADAPTATION

STUDY FLOW CHART:



*Throughout Intervention Delivery phase: DISCOVER team liaison with Medway Care Leavers 16+ teams re. care planning and risk management as necessary inc. actions to integrate support for participants (e.g. signposting to additional services)

¹DISCOVER-Medway Referral Form will be shared with the DISCOVER team only if the young person goes on to attend their 1:1 pre-workshop meeting and signs the written study consent form. The form will be destroyed by the Medway team using confidential shredding if the young person changes their mind and decides not to participate in the study.

⁺Young person's Participant Consent Form will be completed at the outset of the 1:1 pre-workshop assessment meeting. Allocated Medway professional obtains verbal informed consent over the phone prior to this meeting.

STUDY PROTOCOL

DISCOVER "Getting the Life You Want" Workshop Programme for Care Experienced young people aged 16-19:
A feasibility and acceptability pilot study

1 & 2 BACKGROUND & RATIONALE

Brief Study Overview:

The DISCOVER team has secured 2-year funding from the Maudsley Charity to tailor the workshop programme we deliver in Sixth Forms to meet the specific needs of CE YP. We are planning to complete a pilot of this adapted workshop programme within Medway Children's Social Services.

We will recruit CE YP aged 16-19yrs who are currently known to the Care Leavers 16+ teams within Medway Children's Social Care. The study will be conducted at Medway Local Authority sites (e.g. the main group room in the office building for the Care Leavers 16+ teams), with the option of some stages being completed remotely via Microsoft Teams if needed in the context of the ongoing COVID-19 pandemic.

Public Health & Scientific Justification for the Research:

- In England and Wales, a young person's care order ends at 18 when the Local Authority is no longer their corporate parent and some young people become Care Leavers as early as age 16.
- The statistics for Care Experienced young people's (CE YP) mental health, emotional well-being and life chances are shocking and historically they are under-supported with the transition out of Care.
- ~45% of Looked After young people aged 5-17yrs meet criteria for a diagnosable mental health condition (compared with 13% of peers in the general population; Department of Health, 2016).

We have conducted a review of the literature around the: (1) challenges faced by CE YP specifically, (2) the importance of mental health and emotional well-being interventions to support this group and (3) existing interventions that have been offered to support them. The below bullet points offer a summary of our findings and support the scientific justification of our proposed DISCOVER project:

- CE YP as a highly vulnerable group face barriers to accessing CAMHS when mental health problems are detected.
- These include: the inherent limitations of clinic-based appointments, difficulties attending regular appointments, the perceived stigma of specialist mental health service provision, very high service thresholds and the "cliff edge" they face when trying to access mental health care after their 18th birthday (Become Charity, 2021).
- There is an urgent need for new and flexible community-based interventions that promote emotional well-being and resilience in CE YP (NSPCC, 2015). There is a pressing need for the development of innovative, acceptable and sustainable community mental health programmes to provide early intervention, and thus augment existing CAMHS provision and with sensitivity to the risk of a "cliff edge" in mental health care at 18.
- It is essential that CE YP are actively involved in the development of the service innovations that are designed to meet their needs (NSPCC 2015).

In sum, completing a study that assesses the feasibility, acceptability and accessibility of a new intervention that is designed in collaboration with CE YP themselves, specifically to support CE YP aged 16-19 is highly warranted.

3 THEORETICAL FRAMEWORK

The original DISCOVER programme for Sixth Form students (“How to Handle Stress & Worry”) is an innovative evidence-based mental health intervention which has been designed to reach adolescents who NHS psychology services would otherwise struggle to reach. The approach draws on Cognitive Behaviour Therapy (CBT) and mindfulness frameworks to help young people to manage anxiety and low mood difficulties and build their capacity to handle life stresses. The programme includes individual and group-based methods. Evaluation is inbuilt to our programmes as is user participation in service development. The proposed study will evaluate an adapted version of this DISCOVER manualised intervention (“Getting the Life You Want”); designed to enrich the existing support available for Care Experienced YP as part of their local Children’s Social Services provision. This programme sets out to meet the specific emotional well-being needs of adolescents who are Care Experienced, with the goal of improving their mental health and building their resilience.

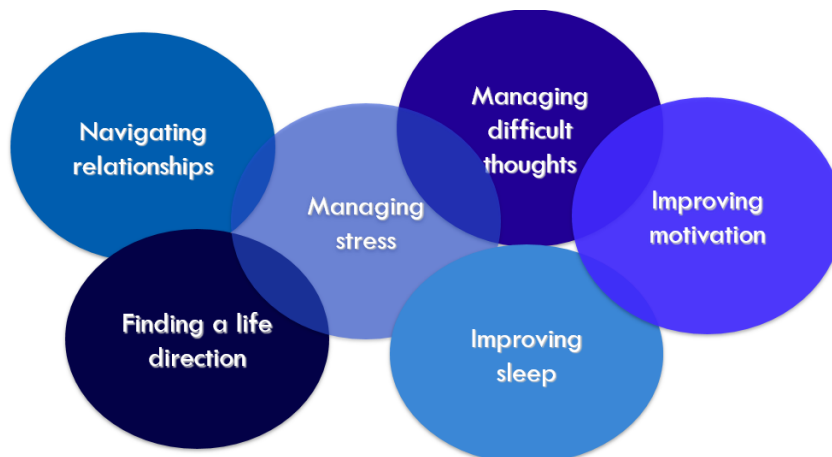
The literature around well-being interventions for Care Experienced young people to-date highlights that some young people leave Care early because, based on past experiences of relationships with family as well as professionals, they believe that they should practice “Survivalist Self-Reliance” (Samuels & Pryce, 2008). This is the belief that they must navigate the world independently without need for outside help to become a “successful” adult. Often mental health and Social Care interventions for CE YP have risked reinforcing this message at the expense of emphasising the protective impact of connectedness to supportive figures.

The version of DISCOVER that will be evaluated in the proposed study has been designed with this theme in mind as well as building on the proven effectiveness of the DISCOVER model in schools (Brown et al., 2019). In addition to CBT and mindfulness, it will draw on core concepts from Acceptance and Commitment Therapy (ACT). ACT is a “third wave” CBT approach. It aims to support service users to create a rich, personally-meaningful life, whilst accepting the pain that is an inevitable part of life (Hayes, Strosahl, & Wilson, 2011). We believe that this offers a strong fit for the emotional needs of Care Experienced young people; they should be supported to manage present stress and pursue future life goals, with sensitivity to the adverse experiences there are likely to have had from early in life. The six core processes within ACT are as follows:

Contact with the present moment

- (1) Acceptance
- (2) Cognitive defusion
- (3) Self-as-context
- (4) Values
- (5) Committed action

These ACT core processes have directly informed the content of the DISCOVER Getting the Life You Want workshop manual as well as the outcome measures that will be used to evaluate its effectiveness. See below visual representation of the modules covered on the workshop day itself:



4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

Our principal research objective is to complete a pilot of the full DISCOVER workshop programme for Care Experienced young people (CE YP) to evaluate its acceptability, accessibility and feasibility within a Children's Social Care setting.

A key aspect of this overarching objective will be whether sufficient young people come forward to take part and remain in the programme to attend all meetings involved (participant retention). As part of this objective, we also aim to gather qualitative feedback from CE YP and Social Care professionals who take part in the pilot intervention.

We also plan to gather self-report data from CE YP who take part in the DISCOVER programme using mental health and emotional well-being focused outcome measures at both the initial 1:1 meeting before the DISCOVER workshop day and the follow-up 1:1 meeting afterwards. Therefore, **our secondary research objective is to complete an initial examination of any change in young people's scores over the course of the DISCOVER programme** (i.e. to gauge any potential benefits of the intervention).

4.2 Outcome

As per the overview offered in the above Section 4.1, the study outcomes will be as follows:

Primary Research Outcome:

- Number of young people who come forward for to express an interest in and ultimately take part in the new DISCOVER workshop programme.
- Participant retention throughout all stages of the programme.
- Participant feedback about the programme during their final 1:1 follow-up meeting (qualitative data).
- Semi-structured staff feedback interview- Social Care professionals' feedback on their experience of referring participants to the programme as well as any other observations about engagement, content and impact (qualitative data).

Secondary Research Outcome:

Change will be assessed by comparing participant self-reported scores on the following validated measures at their pre- and post-workshop meetings (quantitative data):

- Mood and Feelings Questionnaire (MFQ; Angold et al., 1995 – Validated Measure)- the MFQ asks young people to rate statements such as 'I felt miserable or unhappy' to gain assess the extent to which they are experiencing symptoms commonly associated with depression. The cut off score of >27 is indicative of low mood within clinical threshold for diagnosis of depression. A score of 27 or above will be one basis for completion of a full psychological risk assessment.
- Screen for Child Anxiety Related Disorders – Child Version (SCARED; Birmaher et al, 1999 – Validated Measure) – young people rate statements such as 'When I feel frightened, it is hard to breathe' as a measure of the presence and intensity of anxiety symptoms. A total score of ≥ 25 may indicate the presence of an anxiety disorder.
- Child & Adolescent Mindfulness Measure (CAMM; Greco et al., 2011 – Validated Measure) – enables assessment of mindfulness, emotional avoidance and cognitive (de)fusion; core aspects of the Acceptance and Commitment Therapy (ACT) model that we aim to tap within our intervention.

- Warwick & Edinburgh Mental Well-Being Scale (WEMWBS; Tennant et al., 2007 – Validated Measure) – The WEMWBS is a measure of wellbeing and resilience. Young people rate 14 positively worded statements, such as 'I've been feeling optimistic about the future', 'I've been feeling good about myself' and 'I've been feeling confident'. Total scores range from 14-70.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

Study Design:

The design of this proposed study is a case series because our goal is to explore the feasibility, acceptability, accessibility and initial pre-post outcome comparison among young people offered the intervention (as per above outline of research aims). We have not included a comparison/control group because this study represents the first pilot of the DISCOVER Getting the Life You Want workshop programme.

Data Collection Methods:

Mental health and emotional well-being data will be collected from participants using validated self-report questionnaires. These measures will be administered during the two 1:1 meetings with a DISCOVER Clinical Psychologist that each participant will be offered; once before the workshop day and again 2 months afterwards (see Procedures Section 7.3.3. below for specific measures that we will use). During these two 1:1 meetings, we will also gather information from participants about their current stress levels and overall well-being using an unvalidated, DISCOVER semi-structured interview format. In the post-workshop 1:1, we will also use a semi-structured interview to gather feedback from these young people about their experience of taking part in the workshop programme.

These data collection methods are already in regular use as part of the main DISCOVER programme in London Sixth Forms and have simply been adapted to be administered outside of a school setting and within a Children's Social Care context.

A separate semi-structured interview schedule has been designed to elicit feedback on DISCOVER Getting the Life You Want from Team Leads, Social Workers and Personal Advisors within the Medway Care Leavers 16+ service. These interviews will be audio-recorded, with staff participants' consent.

It is our hope that all stages of this programme (aside from the goal review phone calls) can be carried out with participants in-person, however we are able to collect data in remote 1:1 meetings via Teams if necessary in the context of the COVID-19 pandemic.

Data Analysis:

We will analyse the qualitative data gathered from the audio-recorded staff interviews to distil their perspectives and feedback into salient themes. We will also conduct an initial quantitative exploration of the efficacy of the intervention by analysing change in participant scores when comparing outcome measure scores at the pre- as compared with post-workshop 1:1 meeting (i.e. t-tests). As an additional analysis step, we will look at the reliable change index within this pre-post data to capture whether young people's scores have changed over time to a reliable degree (independent of whether they remain within clinical threshold for symptoms for depression/anxiety). We will analyse change score data only where participants have a complete data set (i.e. paired outcome data). This is in keeping with our DISCOVER team's standard analysis strategy where there are missing data points.

Data analysis will be carried out exclusively by members of the DISCOVER team allocated to work on the proposed study. Our team's standard software for such analyses is Microsoft Excel. The Excel database will be stored on our DISCOVER team's secure OneDrive. On advice from the Trust R&D department, we will take the following steps for confidentiality and auditing purposes:

To ensure confidentiality of the data, the Excel database will be:

- Backed-up
- Password-protected
- Access will be restricted to a small number of individuals within the NHS DISCOVER team, all of whom have an Enhanced DBS Certificate and have a professional responsibility to maintain confidentiality.

For audit purposes:

- A front sheet will be used for minuting activity in the database.
- Periodic screenshots will be taken of the database.

6 STUDY SETTING

This study including all data collection will be conducted at Medway Children's Social Services (CSS) and specifically, their Care Leavers 16+ service. This setting is ideal in allowing us to address our research questions and overall aims given that the young people supporting by this service are on the verge of leaving or have recently left the Care system. Thus, this target population are a group who stand to benefit from the DISCOVER programme given the vulnerability to adverse outcomes and struggle to access NHS mental health interventions, as identified in the literature.

Research activity will be carried out by the SLaM DISCOVER team at Medway Children's Social Care (e.g. the main group room in the office building for the Care Leavers 16+ teams or, if needed, young people's semi-independent accommodation) or remotely via Microsoft Teams should this be necessary as government regulations regarding COVID-19 pandemic progress.

As outlined in the study flowchart above, initial contact with eligible participants will be completed by existing Medway CSS professionals who are already in these young people's care team. Therefore, this initial recruitment phase will be conducted in the context of routine care (e.g. meetings at Medway CSS sites and home/accommodation visits by Social Workers and Personal Advisors from these teams).

We have agreed upon a set of considerations related to gaining informed consent from participants and ensuring that safeguarding is our utmost priority with senior Medway CSS professionals, and this documents is included by email together with this protocol document (DISCOVER-Medway Consent & Governance Agreement Letter).

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

Care Experienced young people who are eligible to take part in this DISCOVER research project will be:

- Young people aged 16-19 years who have experience of being in Care and are currently under one of the Medway Children's Social Care, Care Leavers 16+ teams. This means that they are either currently a Looked After young person or a Care Leaver (i.e. they are no longer Looked After but they remain under the care of a Medway Care Leavers team).
- Able to work within a group setting over the course of a day workshop.
- Able to communicate and read in English.

Staff who are eligible to take part in the semi-structured interviews as part of the DISCOVER research project will be:

- Employed within the Medway Care Leavers 16+ service.

- Have been working within this service throughout the period that DISCOVER was promoting, recruiting to and delivering the Getting the Life You Want programme to young people.

7.1.2 Exclusion criteria

We will not be able to recruit young people to the project if they are:

- Acutely psychotic or actively suicidal.
- Currently taking part in other research project(s).
- Under the influence of alcohol or any other substances during DISCOVER programme meetings - this is essential as a safety consideration for all participants and staff. Struggles with alcohol/substance use in themselves are not necessarily a grounds for exclusion; we will discuss with the allocated member of the young person's Care Leavers 16+ team on a case-by-case basis where relevant.
- Unable to communicate and read in English - as we are at an early stage in developing this DISCOVER workshop programme for CE YP, we must exclude these young people. However, we are eager to review this criterion in future to enhance the accessibility of the intervention, once the initial feasibility and acceptability of the workshop programme has been established.

7.2 Sampling

7.2.1 Size of sample

Care Experienced young people: $N = 40$

As this is a feasibility trial, power calculations for intervention effects are not applicable. Sample size was calculated pragmatically based on the size of workshop group that this intervention has been designed for and allowing scope for up to four cycles of the workshop programme within Medway Children's Social Care - see below for rationale for this decision.

The original DISCOVER How to Handle Stress and Worry programme delivered in schools includes 16 young people per group. Through discussion as a team and consultation with our working group of Medway Children's Social Care professionals, we agreed that a smaller number of 8-10 young people would be more appropriate for the Getting the Life You Want programme due to the more complex lives and emotional needs of CE YP.

The final figure of 40 participants therefore represents our aim to complete up to four cycles of the proposed workshop programme, each with an upper limit of 10 young people taking part.

Medway Care Leavers 16+ service staff: $N = 12$

This figure of 12 staff participants reflects a number that would allow the study to complete the 1:1 semi-structured interview with staff across the roles represented in the service: Team Leads, Social Workers and Personal Advisors. This participant number reflects the research team's aim to capture rich and diverse views about the intervention, as balanced with the time required to transcribe, consolidate and analyse qualitative data.

7.2.2 Sampling technique

Eligible young people will be offered the opportunity to take part in this study in the context of routine care from their Social Worker/Personal Advisor. Those who take part will ultimately be a self-selected sample from among this target population of 16-19yr olds who are currently under the care of the Medway Care Leavers 16+ teams.

Eligible staff will be recruited as an opportunity volunteer sample based on their availability to take part in the semi-structured interview which lasts approximately 45 mins, within their usual working hours.

7.3 Recruitment

7.3.1 Sample identification

Care Experienced young people - Care Experienced young people who are eligible to take part will be approached about this project first by their existing Social Worker or Personal Advisor to explore their initial interest in taking part. If the young person states that they are interested to learn more about the project, this Medway professional will give them the one-page summary flyer as well as the DISCOVER Participant Information Sheet. This initial information about the study will be provided by Medway professionals in the context of routine care i.e. during home visits, meetings at a Medway Children's Social Care site and/or over the phone, as relevant to their usual format of contact with the young person.

Children's Social Care staff – all Medway Care Leavers 16+ staff who have been working within the service throughout the period that DISCOVER is promoting, recruiting to and delivering the Getting the Life You Want programme to young people. As such, we will invite staff to come forward as volunteers in response to a general announcement in their weekly Whole Service Meeting, that will also be circulated via email afterwards. We will also recruit volunteers via targeted contact with members of staff who have referred young people to the study. These different channels of communication are designed to enable recruitment of staff who supported a young person on their caseload to take part in the DISCOVER programme as well as those who did not i.e. allowing staff feedback to explore the feasibility, accessibility and acceptability of the intervention with greater validity.

7.3.2 Consent

Care Experienced young people - if, after hearing about the project and reading the information sheet and flyer, a young person is still interested in taking part, they will be invited to attend a 30-minute DISCOVER information meeting. Attendance at this DISCOVER information meeting is contingent on the young person's verbal consent. Ideally, this meeting will be held at a Medway Children's Social Services community site; if this is not possible in the context of the COVID-19 pandemic, we will hold the meeting remotely via Microsoft Teams.

Two members of the DISCOVER team will facilitate this meeting for the group of young people as an opportunity to: (1) learn about what the DISCOVER team does, (2) hear detail about what taking part in the project involves (consistent with the written description in the information sheet), (3) have a "taster" of the kind of activities included in the workshop day itself e.g. group discussion about different words for 'stress' and interactive games (no outcome data will be gathered and no young person will be asked to share any personal information) and (4) ask any questions they may have about taking part. It will be stated clearly that attending this information meeting does not equate to informed consent in itself and does not involve any obligation to proceed further and take part.

Young people who attend the information meeting will be given at least 24 hours to consider whether they would want to take part independently. After this time, they will be contacted over the phone by their allocated Social Worker/Personal Advisor to clarify the decision they have come to. If they do decide to take part, they will meet with their Social Worker/Personal Advisor to complete the DISCOVER-Medway Referral Form which supports them to consider their current difficulties and strengths as well as potential goals for the workshop programme. This process prepares them to engage with a member of the DISCOVER team directly in their subsequent 1:1 pre-workshop assessment session. They will be invited to complete a written consent form only at this final stage of the recruitment process (see below).

Children's Social Care staff – the specific version of the Participant Information Sheet designed for the semi-structured interview aspect of the study will be shared with staff who express an interest in taking part following the announcement at their Whole Service Meeting. Once they confirm that they have read the PIS and if they state that they wish to continue into the study, the DISCOVER team will schedule their interview. The interview will be scheduled a minimum of 24 hours after they have confirmed that they have read the PIS. The staff version of the written consent form will be completed during the interview session, before their interview begins. Both young people and staff who take part will be given a copy of the completed consent form and PIS to keep for their records.

7.3.3. Procedures

1:1 pre-workshop assessment meeting - approximately 1-2 weeks after the information meeting, those young people who give their verbal informed consent to take part will meet with a DISCOVER Clinical Psychologist in a 1:1 confidential meeting before the workshop day itself. During this 1-hour meeting, the young person will be asked about their current mood, stress levels and strategies for coping. They will also complete a written consent for as well as a short battery of outcome measures that assess their mental health and emotional well-being:

- i) Mood & Feelings Questionnaire
- ii) Screen for Child Anxiety Related Disorders
- iii) Warwick-Edinburgh Mental Well-Being Scale
- iv) Child & Adolescent Mindfulness Measure

Where clinically indicated, we will complete a risk assessment and liaise with their Medway Care Leavers 16+ team members as needed to share any risk or safeguarding-related concerns. This meeting will take place at a Medway Local Authority site or, if this is not possible for a young person for some reason, at a safe, private community site of the young person's choosing (subject to Medway CSC & DISCOVER SLaM risk assessment and agreement). A SLaM NHS electronic record will be opened for each participant after this 1:1 pre-workshop meeting, specifically to document their participation in the DISCOVER study (see Section 8.7, Data protection, data storage and patient confidentiality for further detail).

Workshop day - approximately 1-2 weeks after the pre-workshop 1:1 meeting for each participant, two DISCOVER Clinical Psychologists will meet with the participating young people as a group to deliver the DISCOVER workshop over the course of a full day. The workshop day will include psychoeducational content, group discussion, video material and activities with a group of 8-10 participants. At the end of the workshop day, each participant will be supported to set a DISCOVER goal for themselves to work on over the coming weeks (see Goal review phone calls section below). They will also complete a single outcome measure – an anonymous workshop feedback form. This workshop day will be carried out at a Medway Local Authority site.

7.3.4. Follow-up

Goal review phone calls - 1 week after the workshop day, each participant will be offered a 20-minute support call with a member of the DISCOVER team. This optional call is designed to support them as they begin working on the therapeutic goal(s) they set for themselves at the end of the workshop. At the end of this call, they are offered the option of arranging further follow-up calls if they decide this would be helpful for their continued goal progress.

1:1 post-workshop meeting - 2 months after the workshop day, each participant will meet again with a DISCOVER Clinical Psychologist for a 1:1 confidential meeting. During this 1-hour meeting, they will repeat the same short battery of outcome measures (as listed above). The DISCOVER clinician will check in on their current mood, stress levels and strategies for coping, as well as asking for their feedback about their experience of taking part in the workshop programme. This meeting brings their participation in the DISCOVER study to a close. As stated above for the pre-workshop meeting, this closing contact for each participant will take place at a Medway Local Authority site or, if this is not possible for a young person for some reason, at a safe, private community site of the young person's choosing (subject to Medway CSC & DISCOVER SLaM risk assessment and agreement).

Staff semi-structured interview – staff interviews will be completed during the final months of the research study, as DISCOVER team members are also completing the post-workshop follow-up meetings with the young people who completed the workshop programme. These interviews will be completed via Microsoft Teams which has the capacity to record the conversation as a video file, whilst also generating a transcript.

7.3.5. End of trial

Each young person's participation in the study comes to an end after their closing 1:1 post-workshop meeting has been completed. Therefore, the overall DISCOVER trial will come to an end when the last participant has completed this 1:1 post-workshop meeting. At this stage, the remaining data entry into the study database will be completed, the complete database will be 'locked' and we will notify the REC of the end of the study. After this notification, we will complete data analysis and produce the study reports as per plan outlined in Section 9 below.

8 ETHICAL AND REGULATORY COMPLIANCE

8.1 Assessment & management of risk

The included DISCOVER-Medway Consent & Governance Agreement Letter outlines the mutually agreed steps between our NHS SLaM team and the Medway Care Leavers 16+ teams, should risk-related or Safeguarding issues arise for any participant during this study. Through consultation with senior Medway professionals, this document is informed by anticipation of the following potential risks/burdens for participants:

Participants could fear that the content of the workshop day may be inadvertently distressing, for example reminding them of past and/or current adverse experiences. With this issue in mind, we have deliberately designed the workshop content to be present day and future-focused. Content also places emphasis on resilience and skill building within a workshop (rather than group therapy) context. Consequently, no young person will be called upon to share personal information or past traumatic experiences in this group context. Each participant will have pre-workshop 1:1 meeting with a DISCOVER team member. This meeting is an opportunity for a trained clinician to screen for past, current and potential risk issues within a confidential setting.

Even if the Getting the Life You Want intervention is not distressing/harmful, there remains a potential risk for participants that is not an effective intervention, especially as this will be the first full pilot of the programme. However, this can be balanced against the potential benefits of these young people accessing psychological support when they would not otherwise (see the inclusion/exclusion criteria). Participation offers them the opportunity to be supported over 3-4 months by trained mental health professionals who are specialist in engaging with older adolescents.

The intervention being studied is time-limited and relatively brief which means that some participants could become distressed when the programme comes to an end after placing trust in new DISCOVER professionals, especially if in the context of past traumatic experiences. We have taken steps to mitigate this risk by involving their long-term Care Leavers 16+ team at each stage of the programme. These consistent professionals can then be in a position to support their young person to continue working on their DISCOVER goals even after the workshop programme comes to an end.

It could be a burden on some young people that they will be required to attend the workshop for a whole day (~9am-3.30pm), including the associated burdens of travel time, travel expense and time away from full/part-time employment. In an effort to reduce these burdens, we have not pre-set a specific date only after discussion with Medway Social Care professionals, to identify a day that minimises disruption for the group of young people who come forward to take part. We will schedule regular breaks throughout the day so that participants are never expected to focus and engage for longer than 1.5 hours without time for a break.

Similarly, it could be a burden on Children's Social Care staff to complete a semi-structured interview as part of the study; both in terms of their time and any anxieties about their interview being recorded. We will schedule staff interviews during working hours in a time slot that suits them best around their other commitments. Participants will be given the option of turning their camera off before the interview starts if they wish, so that the recording captures only their voice if this leaves them feeling more at ease.

8.2 Stopping criteria

We would consider stopping this proposed DISCOVER feasibility pilot study earlier than planned in any of the following scenarios:

- If no young people come forward for the study, despite recruitment efforts within Medway Children's Social Services.
- If there is an adverse traumatic event affecting several participants' attendance.
- If the COVID-19 pandemic (including any DISCOVER team illness) and associated government restrictions mean that continuing the project becomes untenable. With this said, and as we have stated elsewhere in our responses, we are prepared to run elements of the workshop programme remotely via Microsoft Teams if necessary.
- If the Medway Care Leavers 16+ service (where we will be recruiting our participants) shuts down, or otherwise removes consent for the study.

8.3 Research Ethics Committee (REC) and other Regulatory review & reports

This study protocol will only be initiated once it has received a favourable opinion from an NHS REC and the HRA, including approval of all final versions of the study documents.

As per the HRA guidance, we will ensure that the following criteria are fulfilled:

- Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
- All correspondence with the REC will be retained.
- The Chief Investigator with support from colleagues in the DISCOVER team will produce annual reports as required; within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- The Chief Investigator will notify the REC of the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Regulatory Review & Compliance

As per the HRA guidance, we will ensure that the following criteria are fulfilled/have already been fulfilled:

- We have already ensured that agreements are in place with the single site participating in this study; Medway Children's Social Services. See attached agreed and signed Consent & Governance Agreement Letter.
- For any amendment to the study, our DISCOVER team for this study, in agreement with the sponsor will submit information to the appropriate body in order for them to issue approval for the amendment. DISCOVER will ensure that we collaborate with the Medway site (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

Amendments

As per the HRA guidance, we include the below as confirmation that we have read and understand the necessary steps for applying for an amendment to the study protocol:

- We will submit a valid notice of amendment to the REC for consideration, if we wish to make a substantial amendment to the REC application or the supporting documents. We understand that it is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.
- We will ensure that other relevant review bodies are given the opportunity to review and approve the proposed amendment(s) – in our study's case, this could include our funder the Maudsley Charity, as well as the CAMHS Research Committee within our NHS Trust (SLaM) and the joint R&D Office for SLaM and IoPPN.
- Any such substantive changes to the study protocol and/or study documents will be tracked internally, using our protected DISCOVER team OneDrive system (e.g. retaining all documentation and labelling clearly by version number and date submitted)

8.4 Peer review

The original proposal for development of this adapted DISCOVER intervention for Care Experienced young people was reviewed favourably by the Maudsley Charity and they decided to grant the funding requested (Decision Letter dated 02/12/2019 uploaded with this application).

The Lead Clinician for National & Specialist Outpatient Services within the SLaM NHS Trust has specifically reviewed and approved the Consent & Governance Agreement Letter between Medway Children's Social Services and our DISCOVER team.

We have been advised that the CAMHS Research Committee within our SLaM NHS Trust will review our protocol and documents before commencement of the study. They complete this review once a project has been granted NHS ethical approval.

8.5 Patient & Public Involvement

DESIGN OF THE RESEARCH:

Our DISCOVER team has actively involved Care Experienced young people (CE YP) as well as Children's Social Care professionals in the planning phase of this research project.

Through our team's partnership with the First Star Academy at St. Mary's University, we have formed a young people's advisory group of three 16-18yr olds who are in or have recently left the Care system. We have had four advisory group meetings together via Teams to-date so that the voice of CE YP is at the centre of intervention design and planning. In these meetings, we seek their ideas about how we can develop a group workshop programme that feels relevant, accessible and acceptable for CE YP. More recently, we have sought their feedback on ideas our team has developed for intervention content. To set the correct context for this collaborative advisory work, these young people are paid for their time and expertise in e-vouchers.

We consulted with a Sixth Form student during the design of all participant documents (Participant Information Sheet, Participant Consent Form, Recruitment Flyer, DISCOVER-Medway Referral Form) to ensure that the language used is as young-person friendly as possible.

We have also involved partners from the Medway Care Leavers 16+ teams in the management of this research. Early in the planning stages of the project, we formed a DISCOVER-Medway working group comprising of: five Team Leads, two Social Workers and two Personal Advisors. The goal here was to ensure that the design of the intervention was informed by the expertise of Children's Social Care professionals who engage with our target

population on a daily basis. Through these working group meetings, we have gained richer insight into the day-to-day practical as well as emotional challenges CE YP face and that should be considered in our intervention design.

MANAGEMENT OF THE RESEARCH:

As well as informing intervention content, our multi-disciplinary working group meetings have focused on how to ensure that DISCOVER and Medway Children's Social Care have a shared risk and Safeguarding protocol throughout the implementation of the workshop programme. For example, Social Workers and Personal Advisors have shared the insight that many of the young people from our target population will be living in semi-independent accommodation and, therefore, we should collect contact details for accommodation managers during our initial meeting with project participants. In this way, we will be able to notify these key external professionals (in addition to Medway colleagues) if a young person were to become distressed during any stage of the DISCOVER intervention.

UNDERTAKING THE RESEARCH:

One of the key themes that our CE YP advisory group has emphasised to us is the importance of relationship building with our target population. Firstly, their entry into and experiences within Care have often undermined their ability to trust new people and, secondly, they are likely to have met with numerous and often-changing professionals during their time in the Care system. We have drawn on this feedback to inform how we will implement our project and, in particular, the recruitment phase. We have agreed with our Medway Social Care colleagues that we will provide their Care Leavers 16+ teams with DISCOVER materials (e.g. promotional flyer, information sheet) so that they feel confident to introduce their young people to the workshop programme and weigh up the pros and cons of taking part. Further, after young people have given informed consent to take part, we will adapt our initial DISCOVER 1:1 meeting so that they can invite their carer, allocated Social Worker or Personal Advisor to join them if this would help them to feel more comfortable with a new professional (i.e. DISCOVER Clinical Psychologist). Thus, we have drawn on feedback from our young people's advisory group as well as our DISCOVER-Medway working group to ensure that intervention delivery is rooted within existing trusted relationships for CE YP.

DISSEMINATION OF FINDINGS:

We will develop a young person-facing report to summarise the key findings from the pilot (in addition to the versions for our charity funder, NHS Trust and Social Care colleagues). This report will be designed to share with study participants and we will seek feedback from our CE YP advisory group to ensure that the presentation and language used for this report is as appealing and accessible as possible.

We will approach the Drive Forward Foundation - who we originally consulted at the outset of the project - to offer to present our findings at their CE young adult forum. This organisation aims to enable CE YP to achieve their full potential through sustainable and fulfilling employment. They have expressed an interest in us doing so, especially as their key campaign for this year is CE YP's mental health.

For any formal presentations of our study findings, we will invite participants and/or members of our CE YP advisory group to co-present with the DISCOVER team so that their voice is at the centre of dissemination to key stakeholders.

We will explore the transferability of core Getting the Life You Want workshop content to design: (1) training sessions for social care professionals and (2) a brief supportive intervention for carers. These aspects of dissemination will be subject to the findings from the proposed pilot and ongoing discussions with our Medway Children's Social Care partners.

8.6 Protocol compliance

Protocol compliance will be continually monitored by Dr Irene Sclare (Chief Investigator) and Dr Emilie Bourke (Co-Investigator); the DISCOVER team members currently allocated to work on this study. This protocol document will be used in the induction of any new staff who are employed in future to work on this Getting the Life You Want study.

As per the HRA guidance, we also understand the following:

- Protocol deviations, non-compliances, or breaches are departures from the approved protocol.
- Accidental protocol deviations can happen at any time. We will ensure that any such deviations are adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

South London and Maudsley NHS Foundation Trust will take responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting are adhered to.

8.7 Data protection, data storage and patient confidentiality

All investigators and study site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The overall data custodian will be the Chief Investigator and DISCOVER Team Lead, Dr Irene Sclare.

As our NHS SLAM DISCOVER team will be providing a mental health and emotional well-being intervention that participants would not otherwise be receiving, it is our responsibility to document their participation in the study on the SLAM electronic Patient Journey System (ePJS). As stated in the Participant Information Sheet and Consent Form, we will open an ePJS record for each participant specifically for the duration of their involvement in the study (~3 months).

This record will be opened after their pre-workshop one-to-one meeting with a member of the DISCOVER team and closed again after the follow-up one-to-one meeting at the end of the study. A brief progress note will be added to their record at each stage of the workshop programme and their ePJS care plan and risk assessment will be updated accordingly (and after any relevant discussions with their Medway 16+ Care Leavers team). The infrastructure for this use of ePJS is already in place; as part of their routine clinical practice, all members of the DISCOVER study team have an account and the necessary access to the SLAM system via VPN when in the community.

As this clinical intervention will be delivered in the community, DISCOVER team members will need to record notes from their 1:1 meetings on NHS-owned SLAM Trust laptops. These laptops are password protected. As soon as is possible, these notes will be transferred to ePJS and deleted from these individual NHS laptops.

DISCOVER is a paperless service as far as possible and, therefore, there will be no personal data collected that needs a physical storage space. We have a password-protected team OneDrive - which is located on the SLAM Sharepoint system - where we can store data longer term for reference as needed after the study ends. Only members of the DISCOVER team have access to this OneDrive system. There are specific forms that will be completed by participants in paper format: the Medway-DISCOVER Referral Form, the consent form and the anonymous workshop feedback form. These forms will be scanned, uploaded to the team OneDrive and SLAM confidential shredding used for the original paper copy.

Aside from the workshop feedback form (which will be anonymous), all data will be pseudonymised in the DISCOVER study database on Microsoft Excel. Each participant will be allocated a participant number (e.g. 1-10, depending on number of young people in their workshop programme cycle). The link back document which indicates the participant number by participant name will be stored on the DISCOVER team OneDrive, separately from the main dataset.

Staff semi-structured interviews will be recorded and transcribed via Microsoft Teams. This recording and transcript will be uploaded to the DISCOVER team OneDrive after the interview. Participants will be given the option of turning their camera off before the interview starts if they wish, so that the recording captures their voice only. Each interview will be set up via a dedicated Teams meeting invite, shared only with the specific member of staff taking part; meaning that only the participant and the DISCOVER interviewer will be able to access the meeting and the associated Teams “chat”. As with the young people who take part, staff participants will be allocated a participant number and the recording as well as their quotes will be labelled using this number, rather than their name. Staff quotes used in the final study reports will be anonymised. Any wording that means identifiable information could be inferred from these quotes will be deleted/edited so quotes cannot be linked back to specific staff.

8.8 Indemnity

As DISCOVER is an NHS CAMHS service, the team has been advised that their indemnity arrangements for this study are covered by the NHS Trust; South London & Maudsley NHS Trust.

8.9 Access to the final study dataset

Data will be analysed at the DISCOVER team base - the Michael Rutter Centre which is part of SLaM - or at team member(s) office at home using a SLaM laptop if working remotely. If the latter, all precautions will be taken to ensure that analysis is completed in private to avoid the potential risk of any confidentiality breach. As detailed in Section 8.7 above, all study data will be stored securely on the DISCOVER team OneDrive system; only members of the DISCOVER team have access permissions for this electronic storage system.

9 DISSEMINATION POLICY

9.1 Dissemination policy

The data arising from this study will be owned by the DISCOVER team, together with the workshop programme manual content.

On completion of this study, DISCOVER team members will analyse the data and prepare a Final Study Report. Versions of this report will be prepared as appropriate for senior Medway Children’s Social Services professionals, our funder the Maudsley Charity, the young people who take part in the study and the young people who have advised on the development of intervention content (i.e. those who have contributed through our PPI work to prepare for this project). All participants will receive a young-person friendly copy of the Final Study Report which will summarise findings at the group level, if they indicate that they consent to this follow-up contact from the study team on their Participant Consent Form. In addition, if they wish, they can request their own individual change scores on the outcome measures after the study analysis is complete.

The Maudsley Charity will be explicitly acknowledged as the project funder in all versions of the Final Study Report as well as any formal publication of our findings in a peer-reviewed journal. Summary of the study findings at the group level as well as anonymised feedback quotes from participants (if they have consented to this) will be featured on the DISCOVER team website as well as the Maudsley Charity website.

Our DISCOVER team intends and will have rights to publish our final study data in a peer-reviewed journal and/or present them at academic conferences, after the above process for sharing the Final Study Report with key study stakeholders is complete.

9.2 Authorship eligibility guidelines and any intended use of professional writers

In addition to the above essential reports for stakeholders in this study, our DISCOVER team does intend to prepare a manuscript of our intervention design and findings for submission to a peer-reviewed journal(s). Therefore, authorship for any such academic papers would be within the DISCOVER team and in particular, those team members allocated to work substantively on the proposed Getting the Life You Want study; as it stands, namely Dr Emilie Bourke and Dr Irene Sclare.

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11. APPENDIX

Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	V2	12/10/22	Dr Emilie Bourke	<ol style="list-style-type: none"> 1. Study sampling and design extended to include Children's Social Care staff (as well as the young people already included in the study sample). 2. Staff semi-structured interview schedule and associated PIS and Consent Form were designed to gather qualitative evaluation data that fits within the original research objectives. 3. Edits were made throughout the Study Protocol to reflect this more systematic way of gathering staff feedback about the intervention (indicated in tracked changes).

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.