



PINE Progression Fund: Research Protocol Feasibility Evaluation of Sleep, Eat, Move, Repeat (SEMoRe) project

Evaluator (institution): Centre for Evidence and Implementation

Principal investigator(s): E. Ott

SEMoRe (Sleep, Eat, Move, Repeat) project

| Intervention Developer | Coram |
|---|--|
| Delivery Organisations | Coram and Redbridge London Borough Council |
| Evaluator | Centre for Evidence and Implementation |
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| Feasibility Study Participants | SEMoRe staff members, Redbridge London Borough Council staff members, foster carers and children in care who are taking part in the SEMoRe programme |
| Number of Participating Sites | 1 |
| Protocol Date | 31/07/2023 |
| Version | 1 |

Summary

This document outlines the feasibility evaluation of the SEMoRe (Sleep, Eat, Move, Repeat) project. SEMoRe is an intervention aimed at young people in care that focuses on improving their sleep, diet, and exercise levels with the goal of improving their mental health and wellbeing. The SEMoRe project was developed by Coram and is based on their previous work with unaccompanied asylum-seeking children in Kent and the City of London. Sleep, diet, and exercise are three important correlates of mental health difficulties, and evidence suggests that improvements to the quality of sleep, diet, and exercise lead to improvements in wellbeing. Through improving the quality and quantity of sleep, a more nutritious ('Mediterranean') diet, and increased physical activity, SEMoRe hopes to be able to support young people and children in care to increase their own mental health, wellbeing, and physical fitness in a holistic way, whilst empowering them to make and sustain this in the longer-term.

The intervention is delivered by a systemic psychotherapist over a year. The intervention involves the following elements, all delivered by the psychotherapist: three 90-minute core training sessions to professionals (including foster carers and local authority staff), workshops focused on topics around sleep, diet and exercise, up to 12 direct sessions with young people and their carers around increasing knowledge and equipping them with tools and strategies to take proactive steps to improve their own health and wellbeing, and individual short-term support and tailored interventions for children where needed. The psychotherapist will also feed into discussions and plans around the child with information on sleep, diet, and exercise in order to support the improvement of their wellbeing. In total, 48 young people are planned to be worked with directly (12 in each of 4 intervention cycles).

The evaluation aims to establish the feasibility of delivering SEMoRe as intended within the service system, and whether the programme is seen as appropriate and acceptable to foster carers and local authority staff. The evaluation will also assess whether the data collection procedures are seen as feasible and lay the groundwork for further evaluation and scale-up of the model. The evaluation will also test and refine the programme theory as is set out in the logic model (see Appendix).

Participants will be SEMoRe staff members, Redbridge London Borough Council staff members and children and foster carers taking part in the SEMoRe programme. Foster carers whose child is taking part in the SEMoRe programme will be involved in collecting outcomes data about the wellbeing of their children (via the Strengths and Difficulties Questionnaire (SDQ) and Child Behaviour Checklist (CBCL)) and the Fitbit data from Fitbits that children will wear throughout the intervention. These measures will provide the outcomes data, which will be used to investigate the changes over time with SEMoRe has on children's wellbeing, sleep, and activity levels. Sixteen interviews will also be conducted with foster carers (n = 8), and SEMoRe and local authority staff (n = 8). The findings will help to clarify whether the model can be feasibly implemented on a larger scale. The evaluation will generate understandings around how this model may be improved and adapted to suit the population best, as well as assessing the feasibility of conducting a future impact evaluation.

Programme delivery will run from September 2023 to September 2024, and the report will be finalised by November 2024.

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Background and problem statement

Children and young people in care have higher rates of mental health difficulties compared to their peers who are not in care. Half of children in care¹ have a diagnosable mental illness (Oakley et al., 2018; Social Market Foundation, 2018), and DfE outcomes data (2019) shows that for children in care, 48% of mainstream primary educated, and 52% of mainstream secondary educated school children have identified social, emotional, and mental health needs.

Services are struggling to meet demand, and very few children and adolescents receive any mental health services. When young people do receive services, they are generally prioritised to the most 'high need' and the primary offer to children and young people is standardised talking therapy. Not all young people engage with this, and the majority will face a significant wait to receive even a short-term intervention (Eastman, 2014; Ott et al., 2023). Children and young people experiencing poor mental health are more likely to have difficulties sleeping (Reigstad et al., 2010; Baddam et al., 2019), have an unhealthy diet (O'Neil et al., 2014) and lack the motivation to exercise (Harvey et al., 2010; Mangerud et al., 2014). There is a significant body of research that has already demonstrated the links between sleep, diet, exercise, and wellbeing (Firth, Firth, et al., 2020; Firth, Solmi, et al., 2020; Hosker et al., 2019).

The SEMoRe project aims to break this cycle and support children, young people, and professionals to offer them the skills, tools, and knowledge to proactively improve wellbeing. SEMoRe fits in a niche between 'universal' provision (e.g., training given to all carers at a school or training given to all foster carers) and more specialist provision, such as that provided by specialist children in care child and adolescent mental health service (CAMHS) teams. The feasibility evaluation of the SEMoRe (Sleep, Eat, Move, Repeat) programme provides a critical opportunity to lay the groundwork for a full-scale evaluation and scale-up of the model while examining the implementation and adaption of the model's new eligibility criteria within the children in care population.

The SEMoRe project has developed from Coram's innovative work with unaccompanied asylum-seeking children in Kent and the City of London. Through improved quality and quantity of sleep, a more nutritious ('Mediterranean') diet, and increased physical activity, SEMoRe hopes to be able to support young people and children in care to increase their mental health, wellbeing, and physical fitness. The project anticipates that when young people feel more confident about themselves, in relation to exercise and eating healthily, they will not only build resilience and a sense of well-being, but also their 'soft skills', and so their social capital, and increase their opportunities for community connection (joining sports clubs, etc.).

The project is underpinned by a salutogenic orientation that organises and orientates everyone supporting a young person to a hopeful and optimistic approach (Mittelmark et al., 2022). Salutogenesis, as set out by Mittelmark and colleagues (2022) proposes that individuals recover from traumatic experiences, such as Adverse Childhood Experiences

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¹ Children in care are often called looked after children (LAC) or sometimes 'children we care for' by some local authorities. We have chosen to use the term 'children in care' this protocol.

(ACEs), when three components are in place: comprehensibility, manageability, and meaningfulness.

- 1. Comprehensibility: a dynamic confidence that experiences, externally and internally, are structured, predictable, and explicable (e.g., 'it is normal to have certain thoughts, feelings and attitudes after experiencing trauma').
- 2. Manageability: confidence that one has access to internal and/or external resources needed to meet the demands and challenges posed by events (e.g., 'carers and others will support me in understanding my feelings and developing ways of coping with them').
- 3. Meaningfulness: events can be seen as challenges that are worthwhile engaging with (e.g. 'things will get better and learning the life skills to help me cope with my feelings will stand me in good stead for the—future now is a good time to develop those skills').

These components help an individual develop a 'sense of coherence' about their lived experience, and their future, and are the key to developing resilience and to recovery. SEMoRe plans to use all three components, supporting young people to develop the behaviours and habits that make current experience manageable, and will support their meaningful engagement with life's challenges in the future and across their lifespan.

Intervention overview

The SEMoRe (Sleep, Eat, Move, Repeat) project aims to work directly with children and young people who are in care, their carers, and other professionals, to give them a better understanding of the impact of sleep, diet² and exercise on mental and physical wellbeing, as well as practical and positive steps to improve these. The SEMoRe project will be delivered primarily by a systemic psychotherapist who is also a trained mental health nurse, who will work closely with the local authority fostering team, and lead on sleep, diet, and exercise (SDE) linking with local expertise as required. The project is led by Thomas Coram Foundation for Children ('Coram') working in partnership with the local authority fostering services. The main activities of the intervention include:

- Training sessions for professionals (including foster carers, Children's Social Workers, Independent Review Officers (IROs), Supervising Social Workers, and Children's Social Care managers) on the importance of sleep, diet, and exercise, and how to support children and young people with lifestyle behaviours. The core training offer is based on three 90-minute sessions for professionals, previously developed and delivered by Coram and offered in Kent and the City of London.
- Direct sessions and workshops for children and young people and their carers around increasing knowledge and equipping them with tools and strategies to take proactive steps to improve their own health and wellbeing.
- Offering individual short-term support and tailored interventions to children and young people who would benefit from additional individual planning. This work will be with foster carers, and parents, as appropriate.
- Providing input to discussions such as Child in Care Reviews, and highlight issues and plans for Sleep, Diet and Exercise, improving wellbeing and mental health.

SEMoRe will run for 12 months, with the core training course for professionals delivered as three 90-minute sessions. The project and delivery roles will be inherently flexible – allowing the practitioner to share their expertise and adapt to the local context, and to allow tailored responses to children and young people within the programme. The initial focus will be on delivering the core training to professionals, and after children have been referred to SEMoRe, to then begin offering more support directly to children and young people engaging their carers and linked professionals.

As noted above, the main provider of the intervention will be a mental health practitioner who will offer and/or coordinate short interventions (up to 12 sessions) to young people and their carers. Some sessions (both online and face-to-face) will focus on psychoeducation and motivational enhancement in relation to behavioural change Some sessions may be practical and hands-on, the young person and/or carer working with a personal trainer or nutritionist on the making practical changes in behaviour in keeping with their own goals setting. Programme sessional personal trainers and nutritionists will work with young people and foster carers. Personal trainers will offer guidance and motivation, while the nutritionist will offer support to children and young people with particular food related needs where this is part of the goals set by the children and young people. Selection of children and young

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² By diet, we mean the definition of the food that a person habitually eats. The programme does not encourage the losing of weight by restricting food.

people to the programme will be in cooperation with fostering social work service teams, inclusion criteria will involve children and young people aged 9-15 years with low mood/anxiety and sleep disruption, and or low motivations or interest in self-care. Children and young people where there is a significant and acute mental health need including self-harm, social phobia and or severe depression are out of scope of the programme and will be referred by the social work teams and or receiving more intensive support from CAMHS or other services.

Participants

Redbridge Council is the only participating local authority, and have been recruited already by Coram based on an existing relationship and sufficient numbers of children in care. Young people who are in care in Redbridge local authority will be recruited to take part in SEMoRe. This will be done by SEMoRe's mental health practitioner, who will work closely with Redbridge Council's staff members to identify eligible children and young people to participate in the programme. Since it is no longer possible for Coram to be co-located in Redbridge council, the practitioner will not have access to the council's relevant case notes. Therefore, they are developing a referral form, which allows them to record details about the children who may be recruited to SEMoRe to determine whether they are in scope to take part in the programme. The practitioner will assess whether children meet the programme's criteria and if they are interested in taking part in SEMoRe.

Those taking part in SEMoRe must meet the following criteria:

- In care in Redbridge London Borough Council
- Aged 9 to 15 years
- Will be viewed by the practitioner as needing support to develop healthy SDE behaviours and habits. This may include having low mood and/or anxiety, some disruption to sleep, low motivation/interest in exercising, poor, unbalanced, and/or restricted diet. The criterion is intentionally kept open.
- Will not have significant and acute mental health needs and will not meet the CAMHS threshold for deliberate self-harm, evidence of emerging psychosis, severe depression, significant social phobia, OCD, or other clinical issues.
- The young person must be willing to take part in the programme therefore those that decline to take part will not be included.

Research questions

The research questions are outlined below.

| Research question | Data sources |
|--|---|
| Feasibility: Can SEMoRe feasibly be delivered as intended, and does it fit with the service system? | Logic model workshop Interviews with staff Interviews with carers Monitoring data on reach and completion |
| Acceptability and appropriateness: Is SEMoRe viewed as appropriate and acceptable by carers and practitioners? | Interviews with staff Interviews with carers |
| Readiness for trial and process evaluation: How feasible are data collection procedures (e.g., collection of Fitbit data, child self-report, adult report, data from LA management information services) and what might trial processes look like? | Monitoring data Outcome data Interviews with staff Interviews with carers Workshop with programme and Foundations |

Methods

Sample and recruitment

Participants in the study will include: SEMoRe staff members (including a full-time psychotherapist employed by Coram, and programme team members from Coram who are overseeing the programme delivery), Redbridge London Borough Council staff members and children and foster carers taking part in the SEMoRe programme. Children and young people in care will be involved in the research indirectly, with data collected about them provided by the other participants, and through Fitbits.

SEMoRe and Redbridge local authority staff members

SEMoRe staff have been involved in the initial set-up phase of the research and have taken part in the initial logic model workshop. SEMoRe and local authority staff will also be invited to take part in semi-structured interviews to assess feasibility. Staff members from the local authority involved in this research will be those involved in the delivery of SEMoRe (we expect that these interviews may involve professionals such as core embedded therapists, personal trainers, fostering managers, and/or social workers). SEMoRe and local authority staff will be interviewed at two time points, and an approximate total of eight interviews will be undertaken with these staff members (4 staff from SEMoRe and LA, interviewed at two different time points).

For those invited to take part in interviews, the purpose of the study will be explicitly stated and contact details of the research team will be provided on participant information sheets. Informed consent will be obtained and documented prior to interviews being conducted (either on paper in person, verbally on the recorder, or returned via email before the interviews). These consent forms will be securely stored by the research team. If a consent form has not been returned prior to the interview beginning, the researcher conducting the interview will confirm that the participant has read the participant information sheet, will go over it with them, and will obtain verbal consent for the interview over the phone. The researcher will record the evidence of this consent.

As part of the consent procedures before interviews, we will also obtain explicit permission to record the interviews. We will explain to participants that these recordings will only be accessible to the research team and stored securely. Participants will be asked at the end of the interviews whether they are still happy for us to use the information that they have provided in our research and remind them that if they change their mind any time up until the write up of our findings, that they are able to withdraw their consent. All requests for consent include information on how research data will be stored and disseminated/published and destroyed or retained.

Foster carers and young people in care

All young people who are taking part in the SEMoRe programme and their foster carers will be invited to take part in our feasibility evaluation by SEMoRe's mental health practitioner at the programme orientation session. Young people and foster carers will be provided with information sheets (in accessible language) explaining the evaluation and detailing the

research procedures. After they have had the chance to read the information, foster carers will be provided with a consent form that will ask whether they consent to be involved in the research, and to provide outcomes data about their child's wellbeing and sleep and movement.

All foster carers participating in the evaluation will be asked by the research team to complete the questionnaires, including the Strength and Difficulties Questionnaire (SDQ) and the Child Behaviour Checklist (CBCL) before the intervention and again as a follow-up after 12 weeks, at which point they will also be asked to provide their child's Fitbit data.

We are not proposing empirical data collection with children beyond the collection of data about them, but it will be made clear to them via the information sheet and through conversation with the practitioner that they are able to opt-out of having this data collected or used, and they are able to withdraw their participation in the research at any point. We are not undertaking any qualitative research with young people at this stage. The voices and perspectives of young people, and the acceptability of SEMoRe approach to them, are important. However, they will have experienced difficulties leading up to the referral, will be living in a foster carer, will be maintaining relationships with a number of adults (including SEMoRe team, foster carers, the child's social worker, the supervising social worker, the IRO, designated teacher, and likely birth family), and may be experiencing mental health concerns. We think this is too challenging a time to be asked to engage with a member of our team for a one-off interview, unlikely to a depth of data beyond interviews with carers.

Foster carers that are involved in the evaluation will also be invited by the research team to complete measures and express interest in taking part in one of eight semi-structured interviews to understand the acceptability and feasibility of the programme and of the study methods. The foster carers will be approached with the help of the practitioner that is supporting the family in question, and they will pass on information sheets. If we receive more than eight volunteers for the interviews, however, we will select interviewees using both purposive and random sampling methods. In order to reflect the views of a diverse group of foster carer participants, we will purposively over-sample those who are from ethnic minority backgrounds. We will then select from any remaining participants randomly using random number generation in excel. When they are invited to take part in interviews, foster carers will be given information sheets that explicitly state the purpose of the study and the contact details of the research team, and informed consent will be obtained and documented prior to interviews being conducted. Consent procedures will follow those outlined in the section above.

Accessibility and risks to data collection

As all participants to the data collection will be adults who are staff at a local authority, on the SEMoRe programme, or have completed the process to become foster carers, we anticipate that all participants will have capacity to consent for research. Additionally, we anticipate that all participants have high levels of English and comprehension. Information, consent, survey, and interview questions will be made simple reading level, and if participants do not understand then the consent process will be ended, and we will not continue on with the research. We will provide accommodations where feasible and reasonable when carrying out the research (e.g., interpreters for interviews for English as an additional language,

phone, or online interviews for those with digital poverty), but again, all participants must have the capacity to consent to the research. Some children and young people may be unable to consent to the use of their Fitbit Data used due to their age or disabilities, but we will gather explicit consent from their carers and will provide them the opportunity to opt-out directly.

We do not anticipate any risks to participants from the research. However, although we are not probing care histories, mental health challenges, or sensitive topic matter, discussing participation in SEMoRe may raise sensitive topic matters. At the end of the foster carer data collection (the SDQ and CBCL), we will include links to other services and resources for support in case completing the data collection has raised any issues or concerns for foster carers. We have included these links in the information sheet for interviews as well.

There may be some risks to participants from the project itself. We have carefully discussed some of these risks, and each participant will have discussed these with the therapist/practitioner. We do not anticipate any risks to the researchers. We do not anticipate that any research collected will be distressing in nature. However, prior to the data collection, researchers will meet to discuss potential safeguarding issues or distressing information that could arise from the research and will debrief in the event of any distressing data. They will be supported by their line managers in the case of any distressing data arising and have contractually access to independent therapeutic support.

Data collection

Outcomes data

The primary outcome measures we will use are the Strengths and Difficulties Questionnaire (SDQ) and the Child Behaviour Checklist (CBCL) as completed by the foster carers. These measures are described below. Foster carers will complete the SDQ and CBCL questionnaires at two time points: before the intervention begins and after the scheduled 12 weeks of delivery. Foster carers will be contacted by the research team to complete the questionnaires, which will be provided via an online questionnaire that will be hosted on Qualtrics, and that will take approximately 30 minutes to complete.

Additionally, we will use data on children's total and deep sleep and minutes of activity from Fitbits worn by the children in evaluation of SEMoRe. We will collect the data on physical activity in weeks 11 and 12. Fitbit data will be collected via the foster carers of the children and young people that are involved in the programme. These data will allow us to investigate the impact that SEMoRe has on children's sleep and activity levels. We have avoided using measures for changes in diet due to the sensitivity of the data and the data collection burden, but we will explore perceived impacts in interviews.

SDQ: This questionnaire consists of 25 items and takes 5 minutes to complete and is designed to assess behaviours, emotions and relationships in children and young people aged 4–17 years. This will allow us to investigate what the changes are that are seen over time in the wellbeing of children enrolled in SEMoRe. The SDQ has five subscales: conduct problems, emotional symptoms, hyperactivity, peer problems and prosocial behaviour. Foster carers will be asked to mark whether 25 statements provided are 'Not true',

'Somewhat true', or 'Certainly true' on a 3-point Likert scale. The SDQ is a sensitive, valid, and reliable measure.

CBCL: The Child Behaviour Checklist (CBCL) will be used to investigate what changes over time are seen in the behavioural and emotional problems of children. The CBCL is valid and reliable, and more sensitive than the SDQ, so is a complementary Outcome. Is a 113-item parent report measure that assesses behavioural and emotional problems in those aged 6–18 years and takes approximately 15 minutes to complete. The checklist comprises of two main scales" a problem behaviour scale and a social competence scale. Three-point Likert scales are also used in this tool, where 0 = "Absent", 1 = "Occurs sometimes", 2 = "Occurs often".

Monitoring data

Administrative data will be collected by the programme team on the attendance of young people with SEMoRe. This will allow for an estimate to be made of the percentage who complete the programme, and the patterns of attendance. This estimate will be used in the interpretation of the statistical findings and to give insight into the engagement of children in care in SEMoRe as part of the implementation and process evaluation (please see next section for details). We will also work with the programme team to collect monitoring data on the training and staff activities to better understand the intervention.

Implementation and process evaluation data collection

In order to answer the research questions around the feasibility of implementing SEMoRe, researchers from CEI will conduct up to 8 semi-structured interviews with core SEMoRe and/or Local Authority staff and up to 8 interviews with foster carers whose child has received or been offered the intervention. Interview guides have been developed by the research team and are based on the research questions set out in this research project and were designed to understand the acceptability and feasibility of the programme and of the study methods. The interviews will be conducted either on the phone or via a video call (e.g. Zoom or Teams), depending on the interviewee's preference, and they will last between 40 to 60 minutes. Interviews will be recorded using dictaphones and then transcribed using an external transcription service.

| Method | Sample size | Time point |
|-----------------------------------|--------------------------|--------------------------------------|
| Survey (SDQ) | Approx. 48 foster carers | Weeks 0 and 12 of programme delivery |
| Survey (CBCL) | Approx. 48 foster carers | Weeks 0 and 12 of programme delivery |
| Admin data (Fitbits) | Approx. 48 children | Data collected at weeks 11 and 12 |
| Admin data (Programme attendance) | Approx. 48 children | Weeks 1-12 of programme delivery |

| Semi-structured interviews (SEMoRe and LA staff) | 8 | Four interviews in October – November 2023, and 4 in May – June 2024 |
|---|---|--|
| Semi-structured interviews (Foster carers of children that have used the programme) | 8 | May – July 2024 |

Project management

Personnel

Delivery team

Cathrine Clarke, Coram, will lead and manage the delivery of SEMoRe, and Rebecca Clarke, SEMoRe mental health practitioner, will deliver programme training and sessions, and manage the programme and the relationship with Redbridge Council.

Evaluation team

Dr Ellie Ott, Senior Advisor, Centre for Evidence and Implementation, principal investigator and project lead, and Emma Wills, Advisor, Centre for Evidence and Implementation, coinvestigator, and co-lead for outcome analysis.

Timeline

| Dates | Activity | Staff Responsible/ Leading |
|-----------------------------------|--|-------------------------------|
| 03/2023-06/2023 | Kick off-meeting, research governance, engagement and DSAs | EO |
| 04/2023-05/2023 | Review theory of change | EO & EW |
| 04/2023-06/2023 | Phase 1 work to finalise research design and processes (engagement with programme) | EO & EW |
| 08/2023 | Protocol, data collection instruments finalised, ethics | EW |
| 09/2023 | Protocol & programme launch | EO |
| 09/2023-06/2024 | Baseline data collection | EW |
| 12/2023-09/2024 | Follow-up data collection | EW |
| 10/2023-11/2023 & 05/2024-06/2024 | Interviews with SEMoRe and LA staff | EW |
| 05/2023-07/2023 | Interviews with foster carers | EW |
| 08/2024-10/2024 | Analysis (interviews, synthesis) | EW & EO |
| 05/2024-11/2024 | Final report | EO & EW |

| 01/2025-02/2025 | Revisions | EO & EW |
|-----------------|------------------------|---------|
| 02/2025 | Final report published | EO & EW |

Risks

| Risk | Possible impact of risk | Mitigation |
|---|---|---|
| Difficulty in LAs recruiting children meeting eligibility criteria | Low sample size—would require a longer time period for trial set up or require that the study focus more on feasibility and adaptation. | Phase 1 to ensure there are sufficient numbers to meet sample sizes. Coram has looked for a LA with sufficient number of children in care, and Redbridge has assured that there will be sufficient intake. Coram may be able to expand to a nearby LA. |
| Reluctance of children to engage in sessions, early termination of participation | Analysis is on an 'intention to treat' basis so reluctance or attrition would not affect analysis. However, it may affect the ability of this intervention to assess whether the programme is promising as a whole. | Not a direct evaluation issue. Implementation will take account of difficulties in scheduling session times. |
| Low response rate in follow up | Affects the ability to detect changes over time. | Research instruments will be piloted. SEMoRe and local authority staff who will have developed personal relationships with participants will support the research team in gathering data if necessary. |
| Low participation in interviews by carers and staff | Given past evaluation experience, we think this is highly unlikely but could affect the confidence in the findings. | Realistic sample sizes proposed. Clear, concise information sheets. Incentives are offered for carers. Flexibility in timing and close working with the delivery team for contact permissions. |
| Low quality of data | Would make it difficult to detect changes over time. | CEI are highly experienced. Data will be delivered at regular intervals to identify any issues quickly. Feasibility evaluation allows for further refinement in a large-scale trial. |
| Evaluation staff absences (e.g., illness, periods of leave, staff turnover) | Could lead to delays in the evaluation. | CEI has a stable staff. Additionally, we have over 40 staff members plus associates and consultants and use state of the art project management system. Multiple team members work together and stay updated on the evaluation for unexpected absences. |

Compliance

Registration

After approval of this protocol, we will register the project with the OSF.

Ethics

Ethical approval has been sought through Foundation's ethical review panel. Initial feedback from the panel's review was positive, and was described as clear and comprehensive, and that mitigated most of the risks. Some points were highlighted for clarification, and the research team are currently waiting on the final feedback and judgement from the panel after providing those clarification.

The consent procedures for participant's participation in this evaluation are described above. Further ethical issues are outlined below:

Confidentiality

All possible steps will be taken to ensure confidentiality and anonymity for participants. Nothing will be said or written that enables any individual to be identified. Participants will be reassured that data collected are for research purposes only; except only when the risk of serious harm to an individual emerges through what has been witnessed or disclosed, in which case the designated safeguarding manager will be informed (see below). CEI has in place appropriate technical and organisational measures to protect personal data and/or special category data, in accordance with Section 5 of the Data Protection Act and the General Data Protection Regulation (GDPR). All information gathered about individuals will be pseudonymised and kept completely confidential and no information about individual study participants will be made available to anyone outside of the research teams at CEI. Data will be securely destroyed 2 years after the completion of the final report of the project. For the data analysis of the results of the Strengths and Difficulties Questionnaire, the Child Behaviour Checklist, and Fitbit data, we will ensure that all data is transferred to us securely.

Procedures for dealing with information arising in the course of fieldwork that is a cause for concern

If participants disclose information about child protection concerns or why their children or vulnerable adults are in need or at significant risk of harm to themselves or others, then disclosure procedures will be followed (attached is our safeguarding protocol). If there are concerns about immediate serious danger for a child or adult, these will be reported to the police urgently. This information will be explained clearly in non-technical language in the information sheets and on the consent forms so that everyone is fully aware. The information will be repeated at the beginning of any interviews conducted to make sure that participants are aware that their information will not be kept confidential in the case of any circumstances involving safeguarding issues or if someone is at risk of serious harm, relevant professionals will need to be notified. The research team are all trained in safeguarding issues, and what to do in cases where reporting information is necessary, and this knowledge will be

refreshed before data collection through a team safeguarding meeting. We also have a project log in case any further referrals or notifications need to happen.

Conflict of interest (Any financial or non-financial conflicts of interest)

There are no financial conflicts of interest. E Ott is a foster carer, and she will remain reflexive on her positionality and maintain the independence of findings

Further identified ethical issues

Respect for the time of participants and staff: We have designed the evaluation activities to minimize the burden for participants. The data collection methods were chosen, and interviews are designed, to be short and held at a time that is convenient for participants. Interviews with professionals will be arranged at a time that is convenient for participants and may occur over the phone in order to minimise the burden on participants.

Voluntary participation: In addition to the consent procedures discussed above, each participant will be made aware that they have a right not to take part or to withdraw at any time before the submission of the report without giving a reason, and that their decision will have no detrimental impact on their employment, their relationship with their social workers or fostering agency. Voluntary participation and the ability to not take part or to skip questions will be reiterated when setting up interviews, before interviews begin, and during interviews. It will also be explicitly stated in data collection for the CBCL and SDQ as well.

How will ethical issues be monitored during the course of the research: The research team will consider ethics as an ongoing process to be discussed at weekly and then fortnightly team meetings. The team is very experienced in the process of ethics and aware of the ethical issues that can arise in research. As the programme has been run before with a different population of children in care and has carefully considered ethical implications (such as for young people with disordered eating), we do not anticipate that participating in the programme will cause harm to participants, but we would share data early if clear evidence of harm is emerging through data input or qualitative interviews. All relevant staff are trained in safeguarding and will follow safeguarding policy and procedures. All CEI staff have had extensive safeguarding training through the NSPCC and extensive background checks. The PI has advanced safeguarding training and a designated lead for safeguarding at CEI. Additionally, we will have a protocol agreed with SEMoRe and with the LA staff for how we will respond to any disclosure of harm to children or adults. We will keep a log of any issues that arise during the course of the research and discuss within the team how best to approach these issues and take all appropriate steps to ensure that these issues are resolved.

How the principles of equality, diversity, inclusion, and equity will be applied to the research: CEI specialises in addressing and working to promote equity, diversity, and inclusion in evaluation and implementation. We will be using CEI's equity in evaluation framework to ensure that we are applying principles of EDIE to the research. In our initial phase of the research, we will identify how we can address equity and inclusion and ensure that we continue to approach the research addressing these issues. In the data collection, we will consider the reach of the programme (including if it reaches the most vulnerable and

considerations of intersectionality), include data on who is reached, and sample for interviews for a diverse group of foster carers.

In the analysis, we will use an equity in implementation science lens to examine the factors, processes, and strategies at different levels that influence the take-up, acceptability, and appropriateness of SEMoRe (Baumann & Cabassa, 2020). We will also reflect on our own positionality and biases, stay close to participants' language, and as far as feasible, we will come together to offer different perspectives.

In disseminating findings, we will consider equity including working with the funder to think about who we need to reach, work with, and influence for the learning to be used to address inequity and any risks in dissemination (e.g., distortion of messages, perceptions of mental health being addressed by SEMoRe only and not also an issue of structural issues and need along the spectrum of mental health) and how we mitigate them. We will encourage the funder to think about plans for a public-facing and a local authority facing summary of findings in addition to the report as a first step to thinking about addressing power in dissemination of findings.

Data protection

Our overarching 'Research Data Protection Statement' is available here. The below is specifically relevant to the project to which this document applies. Any questions about this section can be submitted to dpo@foundations.org.uk with a reference to the Data Protection Identifier (DPID) found in the table below.

We are presuming that Foundations will complete the table below.

| Regulatory framework | | | |
|------------------------------------|--|--|--|
| Relevant legislation | UK Data Protection Act 2018 (DPA) UK General Data Protection Regulation (GDPR) | | |
| Data Protection Identifier (DPID) | #3046 | | |
| DPIA outcome/ risk level | Low | | |
| Type of data processing | Use (and share) | | |
| Categories of data subjects | Children (under 13 and over 13), Parents / Legal Guardians, Carers, Professionals | | |
| Privacy notice | Privacy noticed developed. | | |
| Personal data | | | |
| Lawful basis | Consent (children's data), Public task, and legitimate interests | | |
| Justification for the lawful basis | Our ethical practices require ethical consent (often called "informed consent") to be gathered for the | | |

Data Subject's participation in the feasibility study although this is not considered GDPR consent. We are unable to adhere to the criteria required for GDPR consent to be admissible. This is because GDPR consent requires that personal data is no longer used and is deleted when GDPR consent is withdrawn. When analysing data, it is difficult, time consuming and sometimes expensive to stop using the data because we may need to begin our entire analysis again, and when an analysis is complete it would be very difficult to remove the use of the data from the outputs.

If someone does withdraw their ethical consent, we will remove and delete their personal data as much as possible which may be after the analysis is complete.

Foundations is able to use "Public Task" as the lawful basis for processing Personal Data which is admissible for all Joint Controllers because it is acting upon the instructions from the UK Department for Education in accordance with Annex K of the Grant Offer Letter to Foundations, where it is stated that Foundations is acting as a Processor on behalf of the DfE as Data Controller, and the subject matter of the processing "is needed in order that the Processor Foundations can effectively deliver the grant to provide a service to the "Children's Social Care sector".

Foundations is therefore acting under the authority vested upon it by the DfE as its funder which appropriately corresponds to Foundations conducting its research under Article 6.1(e) of the UK GDPR:

"Processing is necessary for the performance of a task carried out in the public interest."

Children's data will be processed on the basis of consent gained from their parent or legal guardian.

Special category data

Lawful basis

Archiving, research, and statistics (with a basis in the law)

Justification for the lawful basis

Special category personal data being processed for research purposes is under GDPR Article 9.2(j)

| | and DPA18 Schedule 1 Part 1.4(a), (b)&(c) for special category data including data considered to be a protected characteristic under the UK Equality Act 2010. | |
|---|--|--|
| Roles | | |
| Data controller(s) | CEI, Foundations, Coram, and the LA | |
| Data processor(s) | TBC | |
| Data sharing mode | A secure portal and/or encrypted email and/or secure access to other organisations' technical systems | |
| | Archiving | |
| Archiving | N | |
| Archive used for this project | N/A | |
| Linking to NPD and use of SRS | | |
| Organisation(s) submitting data to the NPD team | N/A | |
| Organisation(s) accessing the matched NPD data | List organisations | |
| Retention and Destruction | | |
| Expected date of report publication | September 2024 | |
| Expected date of data destruction | September 2026 | |

If you are looking for further clarification regarding our data protection notification requirements, they will either be found in the project specific Data Privacy Notice and/or our Privacy Policy on our website. If you have any further questions around either of these please submit them to dpo@wweicsc.org.uk with a reference to the Data Protection Identifier (DPID) found in the above table.

References

Achenbach, T., & Rescoral, L.A. (2001). Manual for the ASEBA School-Age Forms & Profiles. Burlington, VT: ASEBA, University of Vermont.

Baddam, S. K., Olvera, R. L., Canapari, C. A., Crowley, M. J., & Williamson, D. E. (2019). Childhood trauma and stressful life events are independently associated with sleep disturbances in adolescents. *Behavioral Sciences*, *9*(10), 108.

Eastman, A. (2014). ENOUGH IS ENOUGH A report on child protection and mental health services for children and young people A policy report for the Centre for Social Justice.

Firth, J., Firth, J., Gangwisch, J. E., Gangwisch, J. E., Borisini, A., Wootton, R. E., Wootton, R. E., Wootton, R. E., Wootton, R. E., Mayer, E. A. (2020). Food and mood: how do diet and nutrition affect mental wellbeing? *BMJ*, 369. https://doi.org/10.1136/BMJ.M2382

Firth, J., Solmi, M., Wootton, R. E., Vancampfort, D., Schuch, F. B., Hoare, E., Gilbody, S., Torous, J., Teasdale, S. B., Jackson, S. E., Smith, L., Eaton, M., Jacka, F. N., Veronese, N., Marx, W., Ashdown-Franks, G., Siskind, D., Sarris, J., Rosenbaum, S., ... Stubbs, B. (2020). A meta-review of "lifestyle psychiatry": the role of exercise, smoking, diet and sleep in the prevention and treatment of mental disorders. *World Psychiatry: Official Journal of the World Psychiatric Association (WPA)*, 19(3), 360–380. https://doi.org/10.1002/WPS.20773

Goodman, R. (1997). The Strengths and Difficulties Questionnaire: A research note. Journal of Child Psychology and Psychiatry, 38(5), 581–586. https://doi.org/10.1111/j.1469-7610.1997.tb01545.x

Harvey, S. B., Hotopf, M., Øverland, S., & Mykletun, A. (2010). Physical activity and common mental disorders. *The British journal of psychiatry*, 197(5), 357-364.

Hosker, D. K., Elkins, R. M., & Potter, M. P. (2019). Promoting mental health and wellness in youth through physical activity, nutrition, and sleep. *Child and Adolescent Psychiatric Clinics*, *28*(2), 171-193.

Mangerud, W. L., Bjerkeset, O., Lydersen, S., & Indredavik, M. S. (2014). Physical activity in adolescents with psychiatric disorders and in the general population. *Child and adolescent psychiatry and mental health*, 8(1), 1-10.

Mittelmark, M. B., Bauer, G. F., Vaandrager, L., Pelikan, J. M., Sagy, S., Eriksson, M., Lindström, B., Magistretti, C. M., & Barry, M. M. (2022). The Handbook of Salutogenesis: Second Edition. *The Handbook of Salutogenesis: Second Edition*, 1–651. https://doi.org/10.1007/978-3-030-79515-3/COVER

Oakley, M., Miscampbell, G., & Gregorian, R. (2018). Looked-after Children: The Silent Crisis.

O'neil, A., Quirk, S. E., Housden, S., Brennan, S. L., Williams, L. J., Pasco, J. A., ... & Jacka, F. N. (2014). Relationship between diet and mental health in children and adolescents: a systematic review. *American journal of public health*, *104*(10), e31-e42.

Ott, E., Wills, E., & Taylor, D. (2023). Reviews of Mental Health Services for Care-Experienced Young People Implementation. www.whatworks-csc.org.uk Reigstad, B., Jørgensen, K., Sund, A. M., & Wichstrøm, L. (2010). Prevalences and correlates of sleep problems among adolescents in specialty mental health services and in the community: what differs?. *Nordic Journal of Psychiatry*, *64*(3), 172-180.

Appendix: Theory of Change for Coram's Sleep, Eat, Move, Repeat (SEMoRe) Project

Context

Increasing numbers of children and young people are struggling with poor mental health and wellbeing.

Children and young people who are in care experience higher levels of poor mental health, and score lower on measures of wellbeing.

Services are struggling to meet demand, and the primary offer to children and young people is standardised talking therapy. Not all young people engage with this, and the majority will face a significant wait to receive even a short-term intervention.

There are significant correlations between sleep, diet and exercise (SDE) and mental health and wellbeing (Firth et al, 2020).

Children and young people can often experience the compounding effects of struggling with poor mental health leading to lower quality sleep, poorer diet and limited physical activity, which then further impacts on their wellbeing.

The SEMoRe project aims to break this cycle and support children, young people and professionals to offer them the skills, tools and knowledge to proactively improve mental and physical health and wellbeing.

