PILOT STUDY PLAN

Brandon Centre Systemic Integrative Treatment (BC SIT)

University of Hertfordshire

Principal investigator: Professor Joanna Adler

YOUTH ENDOWMENT FUND

Pilot study plan template

The University of Hertfordshire

BRANDON CENTRE (Systemic Integrative Treatment [BC SIT])

Project title	***Brandon Centre Systemic Integrative Treatment (BC SIT)***
Developer (Institution)	Brandon Centre for Counselling and Psychotherapy for Young People
Evaluator (Institution)	*University of Hertfordshire (UH)*
Principal investigator(s)	*Professor Joanna Adler.*
Evaluation plan author(s)	*Professor Brian Littlechild, Dr David Wellsted, Natalie Hall, Amanda Busby*
Evaluation setting	Family homes. The BC-SIT intervention targets the home system, and the interplay between this and school, peer, neighbourhood systems, working collaboratively with other agencies that may be addressing different issues, for example within CAMHS.
Target group	BC SIT works with young people and their families who are offending, have behavioural and emotional problems, and/or are not in school
Number of participants	20 families for the pilot

Study plan version history

Version 1.1 February 2022

Version	Date	Reason for revision
1.2 [*latest*]		
1.1		Responding to feedback from the YEF
1.0 [*original*]		*[leave blank for the original version]*

Any changes to the design need to be discussed with the YEF Evaluation Manager (EM) and the developer team prior to any change(s) being finalised. Describe in the table above any agreed changes made to the evaluation design, research questions and approach, and the rational for these.

Background and rationale

The Brandon Centre for Counselling and Psychotherapy for Young People, known as The Brandon Centre, provides professional services in support of the psychological, social, sexual, and medical problems of young people, aged 8 to 25, across north London boroughs. The Brandon Centre aims to relieve distress, mobilise personal resources and facilitate growth in adolescents towards responsibility and self-fulfilment, and to prevent or alleviate suffering caused by psychological disturbance, maladaptation in adult and family relationships, mental ill health, and unwanted pregnancy.

The Brandon Centre is offering systemic therapy, based on principles of Multi-Systemic Therapy (MST), however it is important to note that they intend to move gradually away from formal MST, whilst still embracing social ecological approaches. Although based on MST, this new intervention, (BC SIT-Brandon Centre Systemic Integrative Treatment), differs significantly. It is longer; 12 rather than 3-5 months. In Phase 2 (in the last 6 months) parents are supported to transition to 'standing on their own' and they work with other agencies to ensure they support this. The Brandon Centre has been providing a precursor to this service since 2017.

MST was originally developed in the USA as an intensive, home and community based therapeutic intervention with young people, their families and wider networks, requiring high levels of staff training and commitment from all parties involved in the process. Evaluations have demonstrated some positive impacts on reoffending when MST is utilised with specific groups of young offenders, including "serious and violent" offenders (Sawyer and Borduin 2011), young people convicted of sexual offences (Borduin et al. 2009) and young offenders with substance misuse problems (Henggeler et al. 2002). This includes one study of serious and violent young people who had offended where reoffending rates by MST participants were significantly lower than those of individuals who had received 'individual therapy', at almost 22 years post-intervention (Sawyer and Borduin ibid).

While not universally favourable in terms of recidivism, findings have been generally positive. There have been fewer robust evaluations of MST beyond the United States, but some exist. A Canadian implementation found that the MST cohort were ten per cent **more** likely to reoffend than the treatment as usual (TAU) group (typically comprising probation supervision) (Leschied and Cunningham 2002, cited in Farrington and Welsh 2005). This has led to discussion on the way in which MST programmes have been implemented elsewhere, raising questions about programme fidelity and transferability. One of the earliest UK tests of MST was run by the Brandon Centre. Here, MST was implemented alongside, rather than in comparison to TAU. Results were favourable leading to support for commissioning (NICE n.d.).

Other evidence considers the variance in outcome and/or impact of MST. One trial concluded that factors including ethnicity, problem severity and certain behaviours, impacted upon both therapist adherence and service user engagement, suggesting that such factors might in turn impact upon programme efficacy (Ryan et al. 2013). It is in part in response to these limitations that Brandon Centre's SIT is now based too on the Social Ecological Theory of Change (CDC 2022), which attests that a young person's behaviour is determined by the functioning of proximal systems in which they are embedded (i.e. family, school, peer and neighbourhood), and the interplay between these. The BC SIT intervention targets the home system, the most enduring for the young person, and the interplay between this and school, peer, neighbourhood systems.

This pilot evaluation will primarily examine outcomes for BC SIT.

Referral process

Referrals are received primarily from NHS Child and Adolescent Mental Health Services (CAMHS), and other agencies in North London.

Screening

All referrals are screened for suitability by Brandon Centre staff using a set of bespoke tools developed for this task, including their own CBCL.

Site contact

Emily Callard, Business Development Manager, Brandon Centre

Prof Brian Littlechild: University of Hertfordshire (UH) contact responsible for the Brandon Centre Systemic Integrative Treatment [BC SIT] (Site contact).

Participant Inclusion criteria

The BC SIT intervention targets the home system, the most enduring for the young person, placement with an imminent plan to return the child home. The young person is living at home or is in a long-term foster care placement, or a short-term placement with an imminent plan to return the child home

- The parent or carer has agreed to an initial assessment
- The young person is regularly absconding, being violent, engaged in substance misuse, offending, defiant or severe oppositional behaviour or harmful sexual behaviour
- Parent or carer has agreed to an initial assessment
- Behaviours to be addressed include at least one of the following; school refusal, regular absconding, violence, substance misuse, offending, defiant or severe oppositional behaviour or harmful sexual behaviour

Exclusion criteria

Not meeting inclusion/referral criteria outlined above.

Sample size

Up to 20 families will engage in the BC SIT programme during the pilot phase of the evaluation

Recruitment and follow up

Following recruitment into the programme, the clients will be followed up at one (t1), three (t2) and six months (t3).

Adherence to Intervention

Adherence to the intervention will be assessed by recording attendance at therapeutic interventions and follow ups assessments.

Service user experience:

Qualitative interviews with families (e.g. parents, carers, guardians and children) to investigate their experience of participating in the intervention will be completed

Analysis – additional measures

BC SIT use individual goal identification and attainment (see Core Measures below) to assess progress in their clients.

Objectives

The BC SIT project has already been through the feasibility phase of the evaluation process and has progressed to a pilot study. The pilot study has a cohort design (N=20 families) and will assess change over time in main outcomes, and continued success of delivery. A further aim is to determine whether it is possible to deliver a large-scale evaluation of the intervention.

Overall aims

The overall aim for the pilot evaluation is to investigate the potential of BC SIT to improve young people and their families' outcomes. The outcomes listed below cover problem behaviour, emotions, trauma, family functioning, and engagement in criminal behaviour.

BC SIT objectives

- The main objective is to assess the improvement in emotion, problem behaviour, and family functioning, distress related to trauma, and reduction in engagement in criminal behaviour by the children involved in the programme.
- Progress to achieving Goals set as part of the BC SIT programme will also be evaluated.
- To assess the potential effect size of the BC SIT intervention.
- To evaluate the methods for recruiting clients from the intervention's target population and retaining clients in the programme once enrolled.
- To evaluate the potential to delivering a larger scale randomised trial.

Core measures

YEF specifies a standard set of measures to be used and compared across a range of commissioned interventions and evaluations. This is referred to as the core measures dataset and are specified below. Additional optional measures have been agreed with individual grantees.

Primary outcomes

Psychological well-being:

- Strength and difficulties Questionnaire (SDQ)
- SCORE 15 Index of Family Functioning and Change
- The Impact of Events Scale (IES) and the Children's Revised Impact of Events Scale-Eight Items (CRIES-8)
- Edinburgh Study of Youth Transitions and Crime (ESYTC) – sweep 3

Adherence to Intervention

- Adherence to the intervention will be assessed by estimating the number of missed appointments and missed follow-up assessments.

Service user experience

- Qualitative interviews will be completed with families (parents, carers and children) to investigate their experiences of participating in the intervention.

BC SIT specific outcomes

- BC SIT use Goal setting as a therapeutic method, and progress on the Goals will form an additional outcome for this programme.

Secondary outcomes

Intermediate outcomes for the child were intended to reduced violence, improved engagement with key individuals, increase in emotional self-management, and improved behaviour.

Intermediate outcomes for parents and family were intended to increased de-escalation skills, reduction in feelings of helplessness, improved confidence, improved community support networks, reduced social isolation, and improved wellbeing.

Long-term outcomes were intended to be reduced offending, improved school attainment, and improved community responses to reducing violence.

These outcomes are outlined in the Theory of Change below, but they cannot be evaluated within the pilot study as most will occur beyond the scope of the evaluation.

Theory of change

BC SIT is based on the Social Ecological Theory of Change, as set out above. Treatment is highly individualised. The BC SIT therapist works with parents on developing strategies and setting boundaries to achieve change in the young person's behaviour. Parental skills develop gradually, with intense support, moving from training to role modelling, enacting with therapist's support, to independent practice. Parental barriers to managing their child are addressed. As parents succeed in the home environment, efforts move on to address contributory factors, such as deviant peers, and reintegration into mainstream education.

Although based on MST, BC SIT however is longer, spanning over 12 rather than a 3-5 month period, supporting parents to transition to 'standing on their own'. The intervention works with other agencies to ensure they support this. It is less rigid and more child-centred, enabling improved collaboration with other services, and draws on the therapists' additional strengths and skills where valuable.

Research objectives

The BC SIT intervention has already been through feasibility testing and has now progressed to a pilot study.

Aim 1: To evaluate improvement in core outcomes over time.

Research questions:

Describe the client sample at baseline.

Describe the magnitude and direction of change in behaviour (SDQ), and Family functioning (SCORE 15) over time (before-after) at 1, 3 and 6 months in comparison to baseline, and describe progress towards achieving Goals at 6 months for clients engaged in the programme.

Describe changes in trauma (IES, CRIES-8) and engagement in crime (ESYTC).

Where possible, describe and evaluate the effect of baseline status on change over time.

Aim 2: Evaluate effect size

Research questions:

To estimate the likely effect size of the BC SIT intervention on behaviour (SDQ) and Family functioning (SCORE 15).

Aim 3: Describe the referral and screening process,

Research questions:

To describe the flow of young people from referral, through evaluation, to engagement on the programme, including reasons for not progressing on the programme (Flow Chart)

To evaluate potential bias in selection, by considering sample characteristics at different points in the referral process and where possible, comparison across subgroups (eg referral sources)

Aim 4: Client retention and data completion

Research Questions

Do more than 75% of clients complete the intervention, and for clients who complete the intervention are more than 80% of the outcome measures completed.

Aim 5: To evaluate the potential to delivering a larger scale randomised trial.

See success Criteria

Aim 6: To assess implementation process

Research Questions:

Has the intervention been implemented with fidelity?

Have service users felt engaged?

How responsive has the intervention been to service user, staff and volunteers (where appropriate)?

Success criteria

The main success criteria for the pilot will be the potential to scale up the intervention to meet a large sample size (eg N > 300). The sample size for a trial to evaluate effectiveness of the intervention will be estimated from evaluation of the potential effect size. Key criteria to assess evidence of promise will be:

1) Referral process: If bias in the referral process is identified, can this bias be addressed?
2) Retention of at least 75% of young people and their families in the intervention once the intervention was started, or evidence that retention can be addressed.
3) Completion of at least 80% of outcome measures at baseline, 3, 6 and 12 months, or evidence that completion can be improved in a larger scale trial
4) Given the likely required sample size for a larger scale trial:
    a. What population size is required to achieve that sample size, and
    b. Can likely delivery centres with a sufficient population be identified?

Methods

Data collection

The BC SIT evaluation draws upon different data sources and methods. These include the use of routine monitoring data collected by the projects, core measures specified by YEF relating to project participants, and qualitative data from interviews and focus groups with project participants and professional stakeholders.

Data collection methods

The majority of quantitative data collected will involve either data routinely collected within the BC SIT programme, or the specified YEF core dataset.

As far as possible all identified data for each grantee programme will be by direct online entry to the REDCap system, stored securely on servers at UH, by members of the grantee team. Staff will receive training on data collection and use of the online system.

Data collection, data entry and queries raised by a member of the grantee team will be conducted in line with the Data Management processes as agreed between the grantees and the evaluation team.

Data will be routinely collected during the referral and screening process (as agreed with each grantee). Once clients are accepted onto the grantee programme the agreed core data will be collected (t0), and follow-ups with the clients will be arranged at 1 (t1), 3 (t2) and 6 (t3) months.

Evaluation data

Routine monitoring data

The evaluation will undertake analysis of aggregated and anonymised data collected by the four family focused grantees relating to information about referrals into the service, the screening and assessment processes, and any formalised reviews. These data will also enable the profile of the source population to be characterised. By monitoring referrals, the evaluation team can assess whether appropriate referrals are being made (as measured against each project's referral criteria), and the extent to which selection bias occurs in accepting clients into the programme.

Key Demographic Data

Each programme will capture key client specific and demographic data, including age, ethnic heritage, gender, relationship to other grantee clients and index of deprivation[1].

Core measures

YEF specifies a standard set of measures to compare across the range of commissioned interventions and evaluations. This is referred to as the core measures dataset. Any additional optional measures have been agreed with individual grantees.

Strengths and Difficulties Questionnaire, SDQ [Family Member and Young Person completed]

https://www.sdqinfo.com/

[1] The particular index of deprivation to be used, and the implications for data processing, are still being discussed at the time of writing.

This is a widely used and well validated measure which has several versions including one for 11 to 17-year-olds, for parents and for teachers. It is used to evaluate antisocial or other behaviour problems.

SCORE 15 Index of Family Functioning and Change [Family member, and Young Person completed]

https://www.aft.org.uk/view/score.htm

A self-report outcome measure, which is widely used in systemic, family-based interventions and has been validated for use by CAMHS. It is well manualised, and has versions for use with younger children and for implementation within families

The Impacts of Events Scale (IES) and the Children's Revised Impact of Event Scale – 8 (CRIES – 8) [Young Person completed]

https://www.ptsd.va.gov/professional/assessment/adult-sr/ies-r.asp

https://www.childrenandwar.org/wp-content/uploads/2019/06/English-CRIES-8-with-instructions.pdf

These are freely available measures of PTSD and trauma. The adult version is a self-report measure that was designed and revised in line with DSM-IV. It is widely used and allows adults to first identify a stressful life event, then report on the level of distress or intrusion ("difficulty") into their lives that the event has been associated with over the preceding week. The children's (CRIES-8) is widely used as a pre-and post intervention measure. It is also self-report, is aimed at children over eight years old who can read independently and is eight items long.

Edinburgh Study of Youth Transitions and Crime – sweep 3 (ESYTC)[2] [Young Person completed]

https://www.edinstudy.law.ed.ac.uk/

The questionnaire used in sweep 3 (when children were aged up to 14) contains the original 15-items with an additional four items on bullying, harming or injuring animals, selling drugs and racial assault or harassment.

[2] We have previously noted concerns with the ESYTC and the general limitations of self-report delinquency data. We thank the YEF for their consideration of these concerns and helpful responses.

Table 1 provides a summary of the data collection schedule.

TABLE 1: SCHEDULE OF PLANNED DATA COLLECTION AND ASSESSMENTS

	Referral	Screening	Baseline (t0)	1 month follow-up (t1)	3 month follow-up (t2)	6 month follow-up t3)
Demographics	X					
Programme Specific process	X	X				
SDQ			X	X	X	X
SCORE 15			X	X	X	X
IES-R			X	X	X	X
CRIES 8			X	X	X	X
ESYTC			X	X	X	X
Goal setting and attainment			x			x
End of intervention, or engagement form			To be completed if a client withdraws, or when they complete the intervention.			

Notes:

- SDQ – Strengths and Difficulties Questionnaire; SCORE 15 — Index of Family Functioning and Change; IES-R — Impact of Events Scale Revised; CRIES 8 — Children's Revised Impact of Event Scale; ESYTC — Edinburgh Study of Youth Transitions and Crime – sweep 3. All scales were agreed as part of initial contracting and are outlined in section 3.
- It may not be possible for clients to be followed up to 12 months for all grantees. Further, it is noted that decisions about whether to move from initial feasibility to pilot will be made before 12 months has elapsed. The expectation is thus that where 12 months data are possible to collate, they will feed into assessment of the pilot phase, not initial feasibility.

DATA SOURCES:

To simplify description of the data we use 'clients' to encompass the young people and, or families being considered for intervention, as appropriate. Data is captured separately for young people and their parents or carers. Please note that each client sub-set will be recorded in both aggregated and dis-aggregated ways to allow the evaluation to capture the different referral routes and their different potential experiences of the grantees' interventions.

The following objectives have been defined as core objectives that will be measured across all four Family Intervention Programmes.

- **Aim 1:** To evaluate the direction and magnitude of change in core outcomes over time, and for BC SIT to assess progress towards achieving Goals.

The key data source will be the data collected on the REDCap database.

The source data for Goal setting and attainment will be the client notes held by ASSIST. Transcription and transfer of anonymised Goal related data for clients from ASSIST to the evaluation team will be an ongoing process on a data format separately specified.

- **Aim 2:** To evaluate effect size.

The effect size will be estimated from the core dataset specified in aim 1.

- **Aim 3:** To describe the referral and screening processfor the BC SIT programme.

Data relating to screening and referral has been identified for each grantee programme, and where possible this has been incorporated into the REDCap database. Where the relevant data cannot be captured in this way, the source data are the records held by the grantee, and transfer of anonymised data will be an ongoing process on a data format separately specified.

- **Aim 4:** Client retention and data completion

Attendance at therapeutic sessions, and the client completion record will allow evaluation of engagement in the BC SIT intervention, and the database record will provide data on data completion.

- **Aim 5:** To evaluate the readiness to delivering a larger scale randomised trial.

Evaluation of this aim will utilise all the data collected in a summary process after all other aims have been evaluated.

Qualitative Interviews: Aim 6

The key focus of our pilot qualitative work will be to better understand the factors that support or interfere with the intervention's delivery; the ongoing Implementation processes of the intervention's recruitment, retention and reach; alongside service users' experiences and views of the intervention. The interviews will help us to further assess acceptability of and engagement with BC SIT by the young people and their families. Interviews with practitioners/referrers will also help us to assess whether and potentially how successfully, processes can be managed and upscaled.

We anticipate inviting up to five children and their parents, carers, or legal guardians from each project to participate in an interview to inform the pilot evaluation, subject to the normal procedure of the therapists on the project discussing this with the parents and young people, as to whether they are willing to be approached or not by the evaluation team. Professional stakeholders (up to five per project), including managers and delivery staff, will

be sampled purposively. Across the full programme of four grantees, we therefore propose to conduct up to a total of 60 qualitative interviews – individually and in focus groups for the pilot study programme of work (up to 15 for BT SIT).

Interviews with the children and their carers may be individual, or as a joint interview depending on the particular context.

The data will be transcribed sufficiently for deductive thematic analysis. In some cases the clients may refuse to be recorded for the interview. In such circumstances a contemporaneous account of the interview will be taken and used for the analysis.

Referral process

Referrals are received primarily from NHS Child and Adolescent Mental Health Services (CAMHS), and other agencies in North London.

Inclusion criteria

Participants will be considered eligible for enrolment in this pilot evaluation if they fulfil at least one of the criteria as defined below.

The BC SIT intervention targets the home system, the most enduring for the young person, placement with an imminent plan to return the child home, and

- Parent or carer has agreed to an initial assessment

Behaviours to be addressed include at least one of the following;

- school refusal,
- regular absconding,
- violence,
- substance misuse,
- offending, defiant or severe oppositional behaviour or harmful sexual behaviour

Exclusion criteria

Not meeting any of the inclusion, or referral criteria outlined above.

Screening

The BC SIT programme completes a proprietary screening process. All referrals are screened for suitability by Brandon Centre staff using a set of bespoke tools developed for this task, including their own CBCL

Sample size

The BC SIT programme has planned to recruit 20 families during the pilot phase, giving a pragmatically determined sample size. Assuming a sample of this magnitude and a two-sided paired test, with 20% drop out, $\alpha=0.05$ and $1-\beta=0.8$, the minimum detectable difference is equivalent to $d=0.75$.

Recruitment and follow up

Once clients have been accepted onto the BC SIT programme baseline assessments (t0) will be collected along with other routine data agreed with the grantee programme and provisioned on the database. The clients will be followed up at one (t1), three (t2) and six months (t3).

Data analysis

Methods overview (adapt as necessary)

Research methods	Data collection methods	Participants/ data sources (type, number)	Data analysis methods	Research questions addressed
Secondary analysis.	Routine monitoring data collected by BC SIT (including core measures).	Those referred, screened, accepted, discharged, AND completing BC SIT services. Includes progress against outcomes, as measured using YEF's core measures.	Descriptive and where appropriate inferential statistics.	Aims 1 through 4.
Primary data collection.	Qualitative interviews.	Purposive sampling of professional stakeholders (N=5) and opportunistic sampling of parents/carers (N=5) and children	Thematic analysis.	Aims 1 through 5

		(N=5) accessing BC SIT services.		

The analysis plan provides a framework that is applicable to all 4 grantees. Each of the referral and screening processes are outlined above. The following measures will be collected and analysed for all projects; SDQ – Strengths and Difficulties Questionnaire; SCORE 15 — Index of Family Functioning and Change; IES-R — Impact of Events Scale Revised; CRIES 8 — Children's Revised Impact of Event Scale; ESYTC — Edinburgh Study of Youth Transitions and Crime – sweep 3.

BC SIT – additional measures

Individual goal identification and attainment

The overall aim for the pilot evaluation is to investigate the potential of BC SIT to improve the outcomes of young people and families referred into the programme. In addition, the data will be used to assess the readiness of this programme to be evaluated in a larger randomised trial designed to evaluate either the efficacy or effectiveness of the intervention.

Objectives

Aim 1 and 2: To assess the direction and magnitude of change in the main outcomes for the families in the programme. To assess the potential effect size of the intervention.

The analysis will consider each of the 4 YEF core measures independently, and progress against the Goals set within the BC SIT programme for each client. The initial analysis will be considered through descriptive statistics for the sample as a whole at all time points, including all demographic and other factors. The analysis will describe change over time as a mean change from baseline, and estimated effect size (with confidence intervals) at 1 (t1), 3 (t2), and 6 (t3) months.

Sensitivity analysis will consider the influence of baseline characteristics, and missing data. As the dataset is small, any models will have to constrain the number of variables included. The analysis will seek to demonstrate gross effects of baseline variability, and missing data (by replacement of missing values) and interpret any influence on the observed change over time.

BC SIT Goal attainment will be characterised as the graded progress against goals for each family. Where there is more than one goal for a client, identification of the main goal will

be used. Progress against the goals will be characterised on the scale in a contingency table and summarised as a median with interquartile range.

Aim 3: Describe the referral and screening process

Analysis of the referral and screening process will be descriptive. A flow chart will be used to show the flow of client from referral through screening to completion of the intervention. Focus will be placed on why clients are not selected for the intervention at each stage. Descriptive analysis will seek to evaluate thought tabulation the extent to which selection of clients is subject to bias, excluding particular groups of clients. Numbers of clients will be small, but where possible analysis will use $\chi 2$ to aid interpretation of the data.

Aim 4: Evaluate client retention and data completion in the programme.

For families starting the programme, retention to the end of the programme is important. Retention is defined as completing at least 66% of treatment sessions. This can be through missing sessions regularly through the treatment period, or by withdrawing from the program early.

The number of families failing to attend scheduled appointments will be estimated, with the number and proportion of missed appointments and assessment sessions at each time point described. To overall adherence to the intervention (appointments) will be estimated as an overall proportion of appointments missed for each family, and the proportion of families attending at least 66% of treatment sessions. Characteristics of families which do, and do not complete the programme will be tabulated and differences highlighted.

Data completion will be tabulated for each outcome.

Aim 5: Evaluation of success criteria

Readiness to progress to a larger scale efficacy or effectiveness trial will be assessed. It is likely that a sample size of 300 clients or more will be required but estimated more precisely following analysis in Aim 2. The progression criteria will consider the potential to deliver a trial of this magnitude.

Progression to a larger scale efficacy or effectiveness trail will consider four main criteria.

1. Bias in the referral process and whether any bias can be addressed.

Bias will be evaluated by highlighting any differences between families which start therapy, compared to those that are referred but are not accepted on to the treatment programme. The reasons for not progressing will be listed.

2. Retention of clients in the intervention.

Retention is an important secondary indicator of bias. Retention will initially be evaluated by determining whether Grantees are successful in retaining at least 75% of families who start the programme. Secondary analysis will consider any apparent differences between families who do and do not complete the programme.

3. Sufficiently robust and unbiased data completion.

Data completion for each of the outcomes will be tabulated. Data will be defined as complete for scales where sufficient data for each outcome has been completed to evaluate a scale score.

4. Whether a trail of sufficient magnitude could be delivered

Analysis will proceed by tabulating the assessed outcomes from analysis of each of the first 3 aims and any mitigations identified in the qualitative analysis. This will provide a summary statement of the success criteria, any bias in selection. and any adjustments that can be made in future studies. The potential number of recruiting centres will be estimated by considering how many young people and families could be recruited from treating centre per year, and the total number of treating centres required to achieve the required sample size.

Please see Aim 6 objectives in the Qualitative interviews section above.

Data management

Data relating to YEF's core measures collected by BC SIT will be entered on to REDCap and securely stored on servers based at UH. The database will be username and password protected and only accessible to members of the YEF evaluation team, members of the grantee team and external regulators if requested.

Access to the evaluation database is controlled and administered by UH Data Management, and access is via end-to-end encryption. The servers are protected by UH firewalls and anti-virus products and are patched and maintained (including back-ups) according to best practice.

The database software (RedCap) provides a number of features to help maintain data quality, including; maintaining an audit trail, allowing custom validations on all data, allowing users to raise data query requests, and search facilities to identify validation failure, and missing

data. Rigorous testing has been carried out on the database, prior to use by grantees, in line with UH SOP's.

After completion of the evaluation the database and associated design documentation will be routinely archived for a period of five years.

Outputs

The UH evaluation team will provide YEF with pilot reports for each of the four grantees for peer review and publication (at YEF's discretion). In consultation with YEF, findings from the research may also be submitted for publication in academic journals and other outlets (e.g. conference presentations).

Ethics and registration and approvals

These studies were not pre-registered. They are a continuation of feasibility evaluations that will not be moving to RCT. The grantees began their interventions before data sharing protocols that are now normative for the YEF were in place and before the evaluators were appointed. As such, referral processes to the interventions and the potential for post evaluation data unmasking, and data linkage will not be possible.

The University's ethics and integrity policies and processes can be seen at: https://www.herts.ac.uk/research/research-management/ethics-and-research-integrity. In accordance with this process, the four pilot studies have full approval from the UH Health, Science, Engineering and Technology Ethics Committee (protocol number: LMS/SF/UH/04697). This approval grants the ability to collate data until 31.03.22

The team are bound by the codes of conducts of our relevant professional and statutory bodies--the British Psychological Society (professional body), Health and Care Professions Council, British Society of Criminology and, or Social Work England. We are all used to working to the DPA, 2018 and GDPR and within trauma informed ethical frameworks where we prioritise participant vulnerability, risks and legislative requirements.

Safeguarding

In line with the process adopted at the feasibility evaluation, within the pilot studies, interview participants will be made aware that there may be situations, under the safeguarding framework, where there is a statutory obligation for members of the evaluation team to break confidentiality and provide information back to the organisation providing the intervention, or other statutory bodies. As outlined above, the research team

would not process identifiable data, but participants need to be clear that for safeguarding reasons, anonymisation is not complete.

The team are used to conducting evaluation and practice with young people and adults who may be vulnerable by the situation in which they find themselves (Care Act, 2014; SVGA, 2006; Sexual Offences Act, 2003). Anyone conducting fieldwork and/or data analysis will be DBS cleared as appropriate and versed in the safeguarding protocol for that evaluation. The initial intention was that we would be following the safeguarding protocols provided by each grantee, working in close liaison with project managers from the grantee. Given the developments and dramatic changes to policy and process, we have now developed our own overarching practice which works in continued consultation with project managers. If a safeguarding concern is raised or identified, then we will enact the following process using common key principles including: if an immediate risk is identified, other work ceases until the police and/or social services are called; once identified, information is passed to the relevant duty safeguarding officer or project manager. Although information is protected by default, all research participants and grantees are aware that data will be shared appropriately to the circumstances of any particular safeguarding risk that may be identified. We will also use a precautionary principle in pre-identified situations of low/medium risk so that children are neither put at further risk, nor unnecessarily criminalised.

Consent

Most of the administrative data being collated for this evaluation is being shared, stored and processed under the principles of legitimate interest. Additionally, there are interviews being undertaken (with service users, stakeholders and service providers) that will proceed on the basis of consent. When providing information and gaining consent from young people, will also ensure that parents, primary caregivers, or legal guardians are informed and provide consent where possible. We are mindful that in some circumstances, parental interests will conflict with young people's rights. In such circumstances, we will prioritise the children's interests. Wherever possible, we will also seek to avoid unnecessary criminalising of children and young people following principles embedded in CPS and policing guidance.

When being invited to participate in interviews specifically for the evaluation, all prospective participants will be provided with an Information Sheet (PIS) and given time to read it fully, before any interview may proceed. Any questions will be satisfactorily answered and if the participant is willing to participate, written informed consent will be obtained. During the consent process it will be made completely and unambiguously clear that the participant is free to refuse to participate in all or any aspect of the pilot evaluation, at any time and for any reason, without incurring any penalty or affecting their continued

involvement in the intervention. We will ensure that: information is provided in accessible, age and cognitively appropriate ways; consent is treated as an ongoing process; that consent and participation can be withdrawn without penalty; that findings and data will be anonymous where possible, confidential throughout and, where appropriate, depersonalised or anonymised as soon as possible according to principles both of the GDPR and UK anonymisation network.

Data protection

Given the sensitive nature of the data, its protection and security are of the utmost importance. UH has well-established procedures relating to confidentiality of information. We are registered and fully compliant with the requirements of the General Data Protection Regulations (GDPR) (Regulation (EU) 2016/679) and the Data Protection Act 2018. UH is certified through Cyber Essentials (the UH Cyber Essentials Certificate number is IASME-A-09513).

For these grantee evaluations data will be transferred to the University of Hertfordshire in pseudonymised form and analyses as specified in the Statistical Analysis Plan. As specified in the DIPA the data will be stored on secure servers and only available to personnel directly involved in the evaluation, or as required by statutory authorities. The data will be electronically archived, and destroyed 5 years after completion of the final evaluation reports.

Access to Data

Access to the evaluation database is controlled and administered by UH Data Management, and access is via end-to-end encryption. The servers are protected by UH firewalls and anti-virus products and are patched and maintained (including back-ups) according to best practice.

Archiving

The pseudonymised evaluation data will be electronically archived on secure servers at the University of Hertfordshire for 5 years after the final evaluation reports have been completed. Access to the data will be managed, and only made available to members of the evaluation team, to YEF personnel, or where necessary for statutory regulatory processes.

Confidentiality

An important principle is to maintain the separation of anonymised client data collected for the pilot evaluation and the client's personal details. This will be achieved by ensuring that all data captured via REDCap is anonymous to the evaluation team. Pseudo anonymity will be achieved by providing each client with a randomly generated study id, used in the dataset that is unrelated to their personal details. All reporting will only provide summary data which avoids the potential to identify individual clients. Where quotes are included from qualitative interviews any identifying material will be removed or modified as appropriate.

By using a random id to protect the identity of the beneficiaries and service users, the projects can provide the data required for the evaluation while maintaining a level of protection against disclosing the clients' identities. We are adopting a relatively routine way to do this, which is for the organisations to retain a key which would allow identification of the clients from the random code. If subsequent data linkage had been possible then this key would also allow longer term follow-up from public and institutional databases. As it has now been agreed that these studies will not be moving beyond RCT (confirmed by the YEF Evaluation Manager via email, 14.09.21), there will be no need to unmask the data as no grantee in these evaluations will be required to collect and share identifiable data for depositing in YEF's data archive.

Central Monitoring

UH staff will review Case Report Form (CRF) data[3] for errors and missing key data points. The pilot evaluation database will also be programmed to generate reports on errors and error rates. Essential study issues, events and outputs, including defined key data points, will monitored and documented.

Direct access to participant records

Participating investigators must agree to allow pilot evaluation related monitoring, including audits and research ethics committee (REC) review, by providing access to source data and other pilot evaluation related documentation as required. Participant consent for this must be obtained as part of the informed consent process for the pilot evaluation.

[3] The data collection process is organised around Case Report Forms, which is a generic description for the data collection forms that are provided at each time point, or to capture other important events (like withdrawal, or the end of evaluation case report forms).

Personnel

Emily Callard, Business Development Manager, Brandon Centre.

Professor Joanna Adler (University of Hertfordshire), Programme leadership including YEF liaison and report oversight.

Professor Brian Littlechild (University of Hertfordshire), Project management, grantee liaison. "Hands on" in all stages of the evaluation including interviews and focus groups. Oversee and conduct ethics, fieldwork, analysis and write up.

Dr Tim McSweeney (University of Hertfordshire), Programme leadership.

Dr David Wellsted (University of Hertfordshire), Programme leadership including YEF liaison and report oversight. Oversight of analysis and evaluation.

Natalie Hall (University of Hertfordshire), Set up of REDCap and training (external and internal). Data Monitoring. Fieldwork (both interviews and focus groups), initial analysis, write up contribution.

Dr Rosemary Davidson (University of Hertfordshire), Fieldwork (both interviews and focus groups), initial analysis, write up contribution.

Amanda Busby (University of Hertfordshire), Statistical support

Declaration of Interests

The investigators named on the protocol have no financial or other competing interests that impact on their responsibilities towards the scientific value or potential publishing activities associated with the pilot evaluation.

The investigators are not aware of any conflicts of interest. None of the co-applicants have raised any issues in relation to any conflicts or potential conflicts of interest, including any facts that, should they come to light at a future date, could lead to a perception of bias. This includes any relevant personal, nonpersonal and commercial interest that could be perceived

as a conflict of interest. There is no commercial sector involvement with the application or the study.

Risks

Risk Assessment

Area	Risks	Likelihood	Impact	Mitigation
Robustness of evaluation	1. Incomplete/inaccurate Data Upload	Medium	Medium	1. Close liaison with grantee data entry personnel. Data Audits and Data Quality Monitoring.
	2. Unreliability of interview data	Low	Medium	2. Checking for internal and ecological validity within interviews. Ensuring participants are secure during interviews.
	3. Idiosyncratic interview analyses	Low	High	3. Inter-rater reliability checks and comparisons within and between projects.
	4. Data breach	Low	Med	4. All administrative data are pseudo-anonymous and there will not be data linkage made. Interview data will be transcribed, redacted and deindividuated. All reports will be based on aggregate or depersonalised data
Safeguarding	1. Immediate participant safeguarding.	Low	High	1. Depending on the risk identified and imminence of threat, interview stopped, police or social services called and grantee protocol invoked.
	2. Retrospective participant safeguarding	Low	High	2. Close reading of comments fields in RedCap and of Interview transcripts to monitor and take prompt, appropriate action, again invoking grantee safeguarding protocols as necessary.
	3. Safeguarding risk to others identified	Low	Low	3. As per 1 above, adopting general safeguarding principles if the identified vulnerable person is not part of a grantee intervention.

Timely Delivery	1. Further lockdowns or other Covid mitigations	Med	Med	1. Most of the pilot evaluation is virtually implemented however, some of the grantee activity is still face to face. We have already extended deadlines to allow for ongoing delays and are hopeful that will be sufficient to keep to the timelines in this document.
	2. Staff sickness	Med	Low	2. We have already dealt with team ill health and if needed, could do so again. Assist have also coped with ill health as needed. Again, we think that the timelines allow sufficient space, assuming that the pandemic does not significantly deteriorate further.
Reputation	1. Mismatch of expectations between the YEF, grantees and/or evaluators	Med	Med	1. Continue to encourage project management and project evaluation teams to liaise more closely with grantees.
	2. Use of findings in unintended ways	Med	Low	2. Reach agreement with the YEF as to how findings may be shared with grantees and with grantees as to how they can be shared more broadly.
	3. Publication management not completed in a timely manner	Med	Med	3. Close ongoing liaison and consultation with the YEF to ensure that findings are open access ideally, and certainly in the public domain.

The Quality Assurance (QA) and Quality Control (QC) considerations for the YEF Project evaluation are based on the formal Risk Assessment performed, that acknowledges the risks associated with the conduct of the evaluation and proposals of how to mitigate them through appropriate QA and QC processes. Risks are defined in terms of their impact on: the rights and safety of participants; project concept including pilot design, reliability of results and institutional risk; project management; and other considerations.

QA is defined as all the planned and systematic actions established to ensure the pilot evaluation is performed and data generated, documented and/or recorded and reported in compliance with the principles of GCP and applicable regulatory requirements. QC is defined

as the operational techniques and activities performed within the QA system to verify that the requirements for quality of the pilot evaluation related activities are fulfilled.

Timeline

Dates	Activity	Staff responsible/ leading
28.02.22	Completion of all qualitative fieldwork	Littlechild
30.04.22	REDCap data , download, cleaning	Wellsted
30.09.22*	Submission of draft final report for BC SIT	Littlechild
30.11.22*	Peer review response and production of final report	Littlechild

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