

PILOT STUDY PLAN

Level Up!

Evidence Based Practice Unit and The Anna Freud National Centre for Children and Families

Principal investigators: Dr Emily Stapley and Dr Daniel Hayes

Pilot study plan template (no control group)

Evidence Based Practice Unit, The Anna Freud National Centre for Children and Families

Dr Emily Stapley and Dr Daniel Hayes

PROJECT TITLE	Level Up! Safe Steps to Secondary School Evaluation
DEVELOPER (INSTITUTION)	Tavistock and Portman NHS Foundation Trust
EVALUATOR (INSTITUTION)	Evidence Based Practice Unit, The Anna Freud National Centre for Children and Families
PRINCIPAL INVESTIGATOR(S)	Dr Emily Stapley and Dr Daniel Hayes
EVALUATION PLAN AUTHOR(S)	Dr Emily Stapley, Dr Daniel Hayes & Dr Hannah Merrick
EVALUATION SETTING	Online delivery
TARGET GROUP	10-11 year olds, transitioning from primary school to secondary school
NUMBER OF PARTICIPANTS	Up to 150 participants

Study plan version history

VERSION	DATE	REASON FOR REVISION
1.2 [<i>latest</i>]		
1.1		
1.0 [<i>original</i>]	22.03.21	

Intervention

- *Please include a detailed description of the intervention being evaluated, including any training and the model of delivery (this could also be filled by the delivery team).*
- *Also, a full explanation and discussion of the prior evidence, theoretical and scientific background, policy and practice context and rationale for the intervention, including how the prior evidence informs the research questions and need for the pilot study. Please include references to the academic and policy literature as relevant (and a full reference list for any in-text citations).*

- *Wherever possible, please include as much information from Step 1 of EIF's 10 steps to evaluation success as possible, i.e. Outcomes, Why (theory/rationale/ business as usual), Who (recipients, universal/targeted), What (materials, procedures, providers, location, frequency, format, training and quality assurance), and How much (dosage).¹*
- *Please also include information on the logic model for the intervention (see Step 2 of EIF's ten steps to evaluation success), if one has already been developed.*

Background

Conduct disorder affects about 6% of all those aged 5 to 16. Early onset (under age 10) is particularly likely to result in persistent difficulties. Whilst low in prevalence, such difficulties are associated with huge economic, social and psychological costs (Erskine et al, 2016; Rivenbark et al., 2018). Evidence identifies behavioural problems, such as conduct disorder, oppositional disorders and disorders associated with impulsivity, as potential precursors for offending behaviour and contact with youth justice. It is estimated that around 80% of all criminal activity is attributable to people who had conduct problems in childhood and adolescence, including about 30% specifically associated with conduct disorder (Sainsbury Centre for Mental Health, 2009). Likewise, about 90% of severe, recurrent adolescent offenders show marked antisocial behaviour in early childhood (Piquero et al., 2010).

Tackling these precipitating conditions therefore provides scope to intervene early to prevent behaviour escalating to the point of involvement in criminal activity. Working with schools/teachers to identify and assess young people most at-risk whilst at primary school provides an opportunity for targeted early intervention. The Year 6 to Year 7 transition period is also a known worry for children/parents/teachers, as youth crime peaks in summer holidays and children lose the protective factors provided by education (Cordis Bright Consulting, 2015). A direct clinical intervention with at-risk young people will address their needs by providing them with the skills to manage behaviour through improvements to self-control, problem solving, and understanding their own and others' emotions. This will be reinforced through family-focused sessions, providing systemic support to supervise behaviour.

The Tavistock and Portman NHS Foundation Trust have developed a new intervention (Level Up! Safe steps to secondary school) aimed at tackling young people evaluated levels of impulsivity/hyperactivity who may be at risk from violent/disruptive behaviour, which will span pupils and their family's transition from primary to secondary school.

Level Up! Safe Steps to Secondary School

The Level Up! Safe Steps to Secondary School is being delivered online by the Tavistock and Portman NHS Foundation Trust. Young people will complete five sessions, with several planned activities per session. Alongside this, the parents will be provided with online

¹ <https://www.eif.org.uk/resource/10-steps-for-evaluation-success>

videos (Soundclouds) prior to each session, including parenting tips and explaining what the young people will be doing within the session. Each week there will be a group discussion for the young people and a group discussion for the parents via Zoom. Alongside the sessions, there will be the possibility of extra online one-to-one sessions with young people and/or parents who are not engaging in the group format.

The programme is delivered over four weeks during the summer holidays (between primary school and secondary school). Each week young people can access online activities via the Level Up website and then attend a group Zoom call at a set time. The sessions and online activities aim to help young people identify potential strengths and risks over the transition from primary to secondary school. These sessions will also identify struggles that young people may face in the areas of academic achievement (impulsivity/hyperactivity/in class behaviour) and anti-social behaviour in school and in the community. Within the sessions, there will be a focus on building resilience in both settings. Later sessions and activities aim to focus on helping the young people to think about their community, the available support and resources within their community and what they can do to help make their community even better. Following this, the sessions and activities will aim to help the children think about the move to secondary school and how to manage some of the feelings that it might bring up. Again, each session will be ended with a group discussion about the activities led by a clinician.

The final fifth session is delivered during the October half-term once the young people have started secondary school. The final session will review the children's move to secondary school and reflect on possible changes that have occurred since then. The young people will meet on a group call to complete a final activity together, led by a clinician. The final session will let young people have the opportunity to talk through how they are managing, talk through their experiences and highlight any potential concerns.

The clinical team will have regular contact with the parents to help them explore any concerns they may have, build their relationship with their child and help them get more support if they want it.

Art therapy sessions: each week the young people will also be able to join an art therapy session. They will be sent art tutorial videos and an online art group will take place. The young people will be provided with the art materials needed to participate.

Figure 1 shows the Logic Model for Level Up! Safe Steps for Secondary School. The Level Up programme aims to work by improving young people's interpersonal skills and confidence to support improved peer relationships and increase young people's self-awareness and reflective capacity to improve emotion regulation and management of emotion states. With parents, Level Up aims to improve parental monitoring and communication. For both young people and parents, the Level Up programme aims to increase access to support networks and communities, increase safety awareness within their communities and reduce fears and

concerns about transition to secondary school. These mechanisms of change aim to lead to a transition to secondary school with minimal difficulty and having longer term impacts on outcomes, including reduced impulsivity and risky behaviours or decision making, increased access to positive communities/support and peer relationships, improved child and parent relationships and communication.

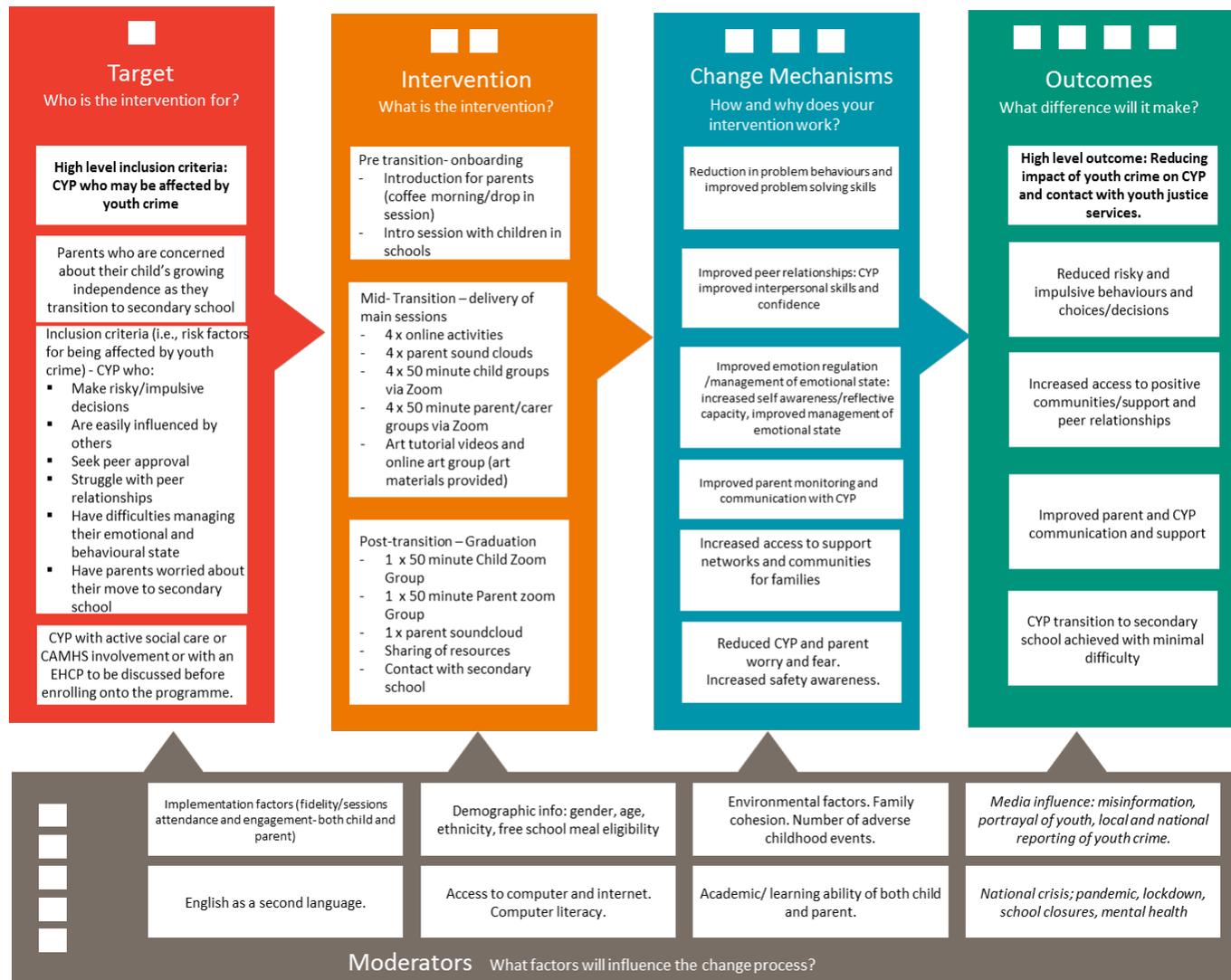


Figure 1. Level Up! Safe Steps to Secondary School Logic Model

Research questions and/or objectives

Objective: To evaluate the Level Up! Safe Steps to Secondary School intervention, a new psychoeducational and therapy-based intervention for young people aged 10 to 12 (and their parents), which aims to reduce risk factors associated with crime.

Research Questions: The pilot strand focuses more on building evidence that would inform the future scale-up to large-scale delivery and evaluation.

1. What are appropriate measures of process, mechanism and impact that reflect the programme's theory of change?
2. What are the best methods for recruitment and retention of participants in the evaluation?
3. Are there early indications that the intervention is associated with positive changes in relevant outcomes?
4. Based on the data available, what would be an adequate sample size for a full trial of the intervention?
5. What challenges does the evaluation encounter, including recruitment and retention issues, and how might these be addressed in a future scaled-up evaluation?

Success criteria and/or targets

Research Criteria				
Method	Indicator	Fully Met	Partially Met	Not Met
Logic model and TiDIER	Agreed by Tavi and AFC	Yes	-	No
Acceptability of data archiving and linkage to participants	Proportion of dropouts recorded due to data archiving	0-35%	36-50%	51-100%
Ability to collect parent baseline measures	Proportion of parents/carers completing baseline questionnaires	55-100%	40-54%	0-39%
Ability to collect YP baseline measures	Proportion of young people completing baseline questionnaires	55-100%	40-54%	0-39%
Ability to collect follow up measures from parents	Proportion of parents/carers completing follow up questionnaires of those with complete baseline questionnaires	55-100%	40-54%	0-39%
Ability to collect follow up measures from young people	Proportion of young people completing baseline questionnaires	55-100%	40-54%	0-39%
Ability to collect school data	Proportion of schools that agree to data sharing	50-100%	40-49%	0-39%
	Proportion of data received for YP and parents who consent to school data being shared	55-100%	40-54%	0-39%

Level Up criteria				
Method	Indicator	Fully Met	Partially Met	Not Met
Ability to engage and enrol schools	Proportion of schools accepting Level Up offer	50 – 100%	40 – 49%	0 – 39%
Ability to receive appropriate referrals from schools	Proportion of referrals that meet the screening criteria	55 – 100%	40 – 54%	0 – 39%
Ability to recruit and retain YP to project	Proportion of YP completing 3 group sessions	55 – 100%	40 – 54%	0 – 39%
Ability to recruit and retain parents to project	Proportion of parents completing 2 group sessions	55 – 100%	40 – 54%	0 – 39%
Ability to collect routine clinical data (SDQ)	Proportion of YP complete baseline and follow-up SDQ	55 – 100%	40 -49%	0 – 39%
Ability to collect routine clinical data (SDQ)	Proportion of parents/carers complete baseline and follow-up SDQ	55 -100%	40 – 49%	0 – 39%

Impact on evaluation outcome measures:

- a. No evidence of substantially negative effects on young people’s or parent’s outcome measures.
- b. Evidence of substantial negative effects on young people’s or parent’s outcome measures.

From Interview/Focus group data:

- 1) Acceptability of the Level Up programme:
 - c. Parents/YP report programme as acceptable and/or how acceptability could be increased.
 - d. Parents/YP report programme as unacceptable but not how acceptability could be increased. Research team/Level Up team identify a plan to increase acceptability.

- e. Parents/YP report programme is unacceptable, and the research team/Level Up team does not identify a plan to increase acceptability.
- 2) Acceptability of evaluation methods:
- a. Parents/YP report evaluation as acceptable and/or how acceptability could be increased.
 - b. Parents/YP report evaluation as unacceptable but not how acceptability could be increased. Research team/Level Up team identify a plan to increase acceptability.
 - c. Parents/YP report evaluation is unacceptable, and the research team/Level Up team does not identify a plan to increase acceptability.
- 3) Perceived impact of intervention on young people and parents
- a. Parents and young people report positive impacts of intervention on themselves (e.g., understanding of emotions, management of emotions, confidence)
 - b. Parents and young people do not report any changes or impacts on themselves from taking part in Level Up.

Methods

Methods and data collection

This study will use a mixed methods evaluation design to answer the research questions.

Young people and their parents/carers who have been selected to participate in Level Up by their schools, and identified as eligible for participation by the clinical team delivering the intervention, will be sent an intervention welcome pack by the clinical team, which will include an invite to participate in the evaluation of Level Up. Participants who consent to participate can complete either or both strands of research activity.

Quantitative research strand:

Young people and their parents/carers will be asked to complete a set of questionnaires online twice: prior to or early in their involvement in Level Up (pre-intervention/baseline) and at post-intervention when they have completed the intervention. The following standardised measures will be collected by the research team:

- Antisocial behaviour, as measured by the child-report Problem Behaviours Frequency Scale (Farrell et al., 2000). This scale measures the frequency of delinquency behaviours. Respondents are asked to indicate how often (0, 1-2, 3-5, 6-9, 10-19, or 20 or more times) in the past month they have been suspended, stolen something or shoplifted, cheated, or damaged the property of others. Item scores are summed, with higher total scores indicating higher levels of delinquency.
- Resilience, as measured by the child-report Student Resilience Scale (SRS; Lereya et al., 2016). The Student Resilience Survey is a 47-item measure comprising 12

subscales measuring students' perceptions of their individual characteristics as well as protective factors embedded in the environment. We will be using three subscales – family connection, problem solving, and goals and aspirations. Each item was rated on a 5-point scale (1 = never to 5 = always). Example items include: “At home, there is an adult who is interested in my school work.”, “When I need help, I find someone to talk to” and “I think I will be successful when I grow up.”

- Difficulties in feelings, behaviours and relationships, as measured by the Strengths and Difficulties Questionnaire (SDQ, parent- and child-report; Goodman, 2001). The SDQ is a 25-item emotional and behavioural screening questionnaire comprising of five subscales: emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problem and prosocial behaviour. An additional supplement provides a score on the impact of difficulties on the child's life.
- Emotion regulation, as measured by the child-report TEIQue emotion regulation subscale (Mikolajczak, et al., 2007). These are six items measured on a scale of 1-7 (disagree to agree). Example items include: “I find it hard to control my feelings” and “I can control my anger when I want to.”
- Parent monitoring, as measured by the Parent Monitoring Scale (Capaldi & Patterson, 1989). This scale consists of 11 items, measured on a scale 1-4, This scale is designed to assess a parent's perception of parental rule-setting, supervision, consequences and monitoring. Example items include: “How much do you know about who your child spends time with?” and “Do you tell your child what time he/she has to be home on school nights?”
- Child-parent relationship quality, as measured by the Child-parent relationship scale (CPRS; Driscoll & Pianta, 2011). Parents are asked to reflect on the degree to which 30-statements currently applies to their relationship with their child. Items are measured on a scale of 1-5 (definitely does not apply to definitely applies). Three subscale scores are obtained: conflicts, positive aspects of relationship, and dependency.
- Child Experience of Care Questionnaire (CHI-ESQ; Brown et al., 2014) - parent- and child-report version completed by young people and parents/carers at post-intervention only. The CHI-ESQ consists of 12 items rated on a scale of 1-3 (Yes/Very well/Comfortable= 3, Only a little/Ok/Maybe =2, not really/Not very well/Uncomfortable =1). Example items include: “Did the people who saw you listen to you?”, “Were you given enough explanation about the help available here” and “If a friend needed this sort of help, do you think they should come here”.

Alongside this, implementation and process data will be collected by the delivery team, consisting of:

- A Template for Intervention Description and Replication (TIDieR), which the research team will provide for the clinical team to complete to describe the structure/content

of the intervention in detail over the course of the intervention, including noting if any adaptations to delivery are made.

- Activity or clinical data collected by the clinical team over the course of the intervention (e.g. number of sessions and activities delivered by the clinical team and completed by young people and parents/carers).

Social and demographic data, including factors which may moderate the effects of the intervention (e.g. age, gender, ethnicity, and free school meal eligibility), will also be collected through the research team accessing, with the young people's and their parents/carers' consent, data routinely collected by the young people's schools.

Qualitative research strand:

A subsample of the overall research sample will be invited to participate in the qualitative strand. Qualitative data collection will be conducted by the research team over the course of the project and will consist of the following data sources:

- Semi-structured interviews with 7-10 young people and 7-10 parents/carers to understand how those receiving the intervention perceive its benefits and outcomes, including exploration of the factors (mechanisms) that participants perceive as improving outcomes, as well as their suggestions for improvement of the intervention.
- Focus groups will be conducted with young people (up to five per group) to ask about any challenges presented for them by the research and data collection process, to ascertain acceptability and feasibility from their perspective of the research design.
- Semi-structured interviews with 7-10 school staff and the intervention delivery staff.

While COVID-19 restrictions still apply, interviews and focus groups will take place over via video call (e.g. MS Teams) or over the phone.

Recruitment

After young people and parents/carers have been identified as suitable for the intervention using the clinical team's screening tool, parents/carers will be sent the study information sheet and an expression of interest form in their intervention welcome pack by the clinical team. Parents/carers will be given sufficient time to read and consider the information, consult partners or family members and ask any questions that they may have before being asked for their consent to participate. The information sheets will include the research team's contact details, which potential participants can use to contact the researchers with any questions prior to giving their consent to take part.

Recruitment of parents/carers and young people for the research study in general:

If parents/carers are interested in taking part in the research (on behalf of themselves and of their child), then they can complete the expression of interest form (used to arrange

research data collection and including their name, address, phone number and email address) and send it back to the research team (e.g. by post or email) or to the clinical team, who will then email it securely to the research team. Upon receipt of the expression of interest form, prior to the first session of the intervention, a member of the research team will then ask participants for their informed consent to take part in the research study – including the completion of questionnaires, the research team accessing data routinely collected by the young person’s school and the clinical team, and to be approached by the research team to potentially participate in an interview/focus group. Once consent has been received, participants will be able to access a link to the online questionnaires, which will be sent to participants by the research team by email at baseline and follow-up.

Recruitment of participants for the qualitative strand of the research study:

For the qualitative strand, following their completion of at least two sessions of the intervention, the research team will send (e.g. by post or email) the parents/carers an information sheet specifically about the interview/focus group strand of the research, and another expression of interest form to complete if they and/or their child are interested in being interviewed by the research team. If affirmative, then parents/carers can complete the expression of interest form and send it back to the research team (e.g. by post or email). When an expression of interest form is received, two informed consent forms (one for the parent to consent on behalf of their child taking part and one for the parent’s own consent to take part) will then be sent to the parent/carer (e.g. by post or email) by the research team. Once the parent/carer has returned their informed consent form(s) (e.g. by post or email) to the research team, the research team will contact them to arrange a date/time for their interview or focus group.

Recruitment of school staff and delivery team

School staff involved in the identification and referral of young people to Level Up! will be contacted by the clinical team, who will forward the research team’s expression of interest form to them. School staff involved in identifying children will be asked to express an interest in participating in an interview. School staff who express interest will be contacted directly by a member of the research team. Intervention delivery staff will also be invited to participate directly by the research team.

Data analysis

The study’s outcome measures and interviews/focus groups will seek to enhance our understanding of the barriers and facilitators to delivery, benefits and drawbacks of the intervention, how engaged stakeholders are with the intervention, how satisfied stakeholders are with the intervention, the appropriateness of questionnaires, the best

methods for recruitment and retention, and whether questionnaires provide any early evidence of intervention effectiveness.

Statistical analysis:

Statistical analysis will focus on pre- and post-measure differences in scores, including analysis of factors that could affect this, e.g. demographics. Where warranted and possible, sub-group analyses will be performed. Implementation and process data (e.g. percentage of sessions completed) will also be reported. A statistical software package (SPSS) will be used to facilitate this.

Qualitative analysis:

The researcher(s) will initially code or assign relevant extracts of the transcripts to broad overarching categories, derived 'top-down' from the research questions (e.g. suggestions for improvement of the intervention). The research team will then break down the data (transcript extracts) coded within these overarching categories into themes and subthemes, derived 'bottom-up' from the data. This process will follow the six stages of a thematic analysis outlined by Braun and Clarke (2006).

We will make use of researcher triangulation and a consensus process in our analysis. The qualitative research lead (Emily Stapley) will re-code 10 to 20% of the transcripts using the themes and subthemes derived from the data by other members of the team. The purpose of this is to help the original researcher(s) to refine and reflect on their themes and subthemes, with the qualitative research lead suggesting edits or additions where necessary. The research team will also discuss the thematic frameworks with each other to reach consensus on the final list of themes and subthemes for each research question.

Our use of the NVivo qualitative data analysis software package will provide a clear audit trail for the analysis process.

We will not be conducting member checks on the data due to the difficulty of arranging additional contact with our participant groups to facilitate this. This type of credibility check has its strengths, such as in terms of enabling participants to provide a check on the research team's interpretations of their own words. However, this type of credibility check also has its challenges, such as in terms of negotiating possible disagreements between the researchers and participants in their interpretations, without inducing a bias in the findings

Outputs

Outputs for the evaluation will include the following:

- A measurement framework to inform future evaluation
- A full report of the evaluation processes and findings to YEF
- A drafted and submitted research paper

- Two lay summaries of the research one for professionals and policy makers and one for CYP and parents
- Slides for disseminating findings and presentation of these at least one network event (e.g., Schools in Mind)

Ethics and registration

Ethics approval has been obtained from University College London Research Ethics Committee (Ethics ID:18633/003 and 18633/002). An amendment has been submitted to add in data archiving and linkage processes to information sheets and research processes for the pilot study phase.

Data protection

All data will be handled in accordance with the General Data Protection Regulation (GDPR) & UK Data Protection Act (2018). The research team has obtained approval from the UCL Data Protection Officer stating that the research project is compliant with the General Data Protection Regulation 2018. The Data Protection Registration Number is: Z6364106/2020/01/113.

Electronic versions of consent/assent forms will be stored on the Anna Freud Centre's secure servers. If we receive any paper versions of consent forms will be stored in a locked filing cabinet to which only the researchers involved in the project will have access. The filing cabinet is in an office which requires a pass to enter each floor. The key to filing cabinet is stored in a password-protected lockbox.

Parents/carers will be asked to give their contact details (e.g. home address, email address, phone number) on paper at the point of expressing their interest and giving their consent to take part in the research (for contact regarding the research, e.g. arranging data collection visits). Electronic versions of this information will be stored in a password-protected spreadsheet on the Anna Freud Centre's secure servers. Any paper versions of the contact details forms will be stored in a locked filing cabinet to which only the researchers involved in the project will have access.

Questionnaires will be administered online using UCL's secure system - REDCap within the UCL Data Safe Haven. The UCL Data Safe Haven "provides a technical solution for storing, handling and analysing identifiable data. It has been certified to the ISO27001 information security standard and conforms to NHS Digital's Information Governance Toolkit. Built using a walled garden approach, where the data is stored, processed and managed within the security of the system, avoiding the complexity of assured end point encryption. A file transfer mechanism enables information to be transferred into the walled garden simply and securely." (<https://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/tech-soln>). Questionnaire data will be stored in a password-protected spreadsheet in the UCL Data Safe Haven.

Encrypted dictaphones will be used to audio record interviews and focus groups. Interviews/focus groups will be anonymised at the point of transcription, with identifying details, e.g. names of people and places, removed. Any external company (Transcription

Centre) commissioned to transcribe interview/focus group data will be approved by the Anna Freud Centre's information governance lead and asked to sign an NDA. Direct quotations will be used in reports of the findings, but they will not identify individuals. Audio files and transcripts will be stored on the Anna Freud Centre's secure servers. An Anna Freud Centre-approved transcription service will be commissioned to transcribe interview data and will sign a data processing agreement guaranteeing confidentiality and GDPR compliance. Other than this, only the research team will have access to the data.

Schools will be asked to sign a data sharing agreement so that they can provide the research team with demographic information about the young people taking part in the study, including name, address, date of birth, unique school pupil reference number, gender, ethnicity, school attendance. This data will be securely transferred to the research team by schools (i.e. encrypted over email). Electronic versions of this information will be stored in a password-protected spreadsheet in the UCL Data Safe Haven.

The Tavistock and Portman NHS Foundation Trust will be asked to provide the research team with routinely collected implementation data relating to the young people and parents' involvement in the intervention, e.g. number of sessions attended. This data will be securely transferred to the research team by the clinical team (i.e. encrypted over email). Electronic versions of this information will be stored in a password-protected spreadsheet in the UCL Data Safe Haven.

The legal basis for processing data for the research project is public interest (Article 6 (1)(e) and Article 9(2)(j) of the GDPR). This means that personal data can be processed where necessary for the performance of a task carried out in the public interest. In this case, it is to carry out research and inform future health provision.

This research project will hold the following types of data on participants:

- Personal data: Names, contact details, gender, age, ethnicity, Unique pupil reference number and free school meal eligibility
- Anonymised questionnaire answers and interview transcripts, and interview audio recordings
- Pseudonymised routine clinical data, including number of sessions attended and questionnaire data

Personnel

Delivery Team:

- Dr Laverne Antrobus, Consultant Child Educational Psychologist, Lead Clinician, Tavistock and Portman NHS Foundation Trust
- Dr Jessica Powell, Child, Community and Educational Psychologist, Tavistock and Portman NHS Foundation Trust
- Rachel Humphries, Specialist Mental Health Nurse, Tavistock and Portman NHS Foundation Trust
- Jamie Williams, Art therapist, Tavistock and Portman NHS Foundation Trust
- (Another member of the delivery team is to be recruited)

Evaluation Team:

- Dr Emily Stapley, Co-Lead, Senior Research Fellow, Evidence Based Practice Unit, The Anna Freud National Centre for Children and Families
- Dr Daniel Hayes, Co-Lead, Senior Research Fellow, Evidence Based Practice Unit, The Anna Freud National Centre for Children and Families
- Dr Hannah Merrick, Project Manager, Research Fellow, Evidence Based Practice Unit, The Anna Freud National Centre for Children and Families

Risks

- 1) Low recruitment of parents and young people to evaluation (high risk): clear procedures are in place to introduce the research to families and clear information sheets provided to families explaining the research process in accessible language. Concerns have been raised about the impact of long-term data archiving and the data linkage on recruitment.
- 2) Safeguarding concerns raised (low risk): to protect both researchers and participants, the safeguarding procedures of the Anna Freud Centre will be adhered to at all times. All researchers will have received safeguarding training. In circumstances of a participant revealing something that indicates that there may be a serious risk to themselves or others, the participant would be immediately informed of the need to discuss this with others and safeguarding protocols implemented. Participants will also be informed of the limits to confidentiality in the information sheets and at the outset of any questionnaire completion and interviews/focus groups.
If a safeguarding issue arises during contact with members of the research team, it will be reported to the clinical safeguarding lead from the Tavistock and Portman NHS Foundation Trust working with that family, who will then take any action as necessary. All safeguarding issues will also be reported to the director of our department (the Evidence Based Practice Unit; EBPU – UCL) for further advice. This procedure will be discussed with participants at the outset of any questionnaire completion and interviews/focus groups.
- 3) Confidentiality breach (low risk): the low risk of breach of confidentiality inherent in all research will be addressed by adhering to the standard regulatory procedures, in accordance with the GDPR and the Data Protection Act (2018). This will be outlined in the participant information sheets. No individual will be identified in any publication arising from this research.
- 4) Burden to participants (low risk): there is a small amount of burden anticipated for participants as a result of being interviewed and completing the surveys, as well as taking part in the intervention. Considerations will be given to the time and length of the interviews/focus groups/questionnaires to minimise this. Young people and parents/carers will also receive a £10 voucher (e.g. Love2Shop) as a thank you for taking part in the interviews/focus groups.
- 5) Content of surveys and interviews/focus groups causing upset/distress (low risk): given the sensitive nature of the intervention, we recognise that a small number of participants may find answering survey or interview questions stressful or upsetting. Information sheets will outline that taking part is voluntary and that participants can withdraw at any

time. If participants become upset during the interviews/focus groups/surveys, this will be managed by the researcher emphasising that it is the participant's choice to raise particular issues, that they are not expected to talk about anything that they are not comfortable discussing, and that they can stop taking part at any time. The researchers are experienced in interviewing children and vulnerable groups and will also receive interview training from the lead researcher (ES) prior to data collection. Parents and young people will also be provided with information in the participant information sheets on who they can contact to get support and discuss any concerns they might have.

Timeline

Dates	Activity	Staff responsible/leading
April/May '21	Set up Data Sharing Agreements with schools referring young people to Level Up programme.	HM/ES/DH
May/June '21	Expression of interest forms for evaluation sent to families consented to take part in the Level Up programme.	Level Up Team
May/June '21	Contact made with families who return an expression an interest and participant information sheets sent.	HM/ES/DH
May/June '21	Consent and assent collected from young people and parents to participate in research.	HM/ES/DH
May/June '21	Pre-intervention Strengths and Difficulties questionnaire collected from young people and parents	Level Up Team
May/June/July '21	School teachers approached and recruited for school staff interviews	HM/ES/DH
June/July '21	Online pre-intervention questionnaire link sent to participants	HM/ES/DH
June/July '21	Demographic data collected from schools, where consent is given and DSAs are in place	HM/ES/DH
July '21	School staff interviews analysed	HM/ES/DH
July/August '21	Level Up! delivered to young people and parents. Attendance and completion data collected.	Level Up team
August '21	Begin to approach young people and parents to participate in interviews	HM/ES/DH
September '21	Recruitment and completion of delivery staff interviews	HM/ES/DH
Oct '21	Following final Level Up session, post-intervention questionnaire link sent to participants	HM/ES/DH
Oct '21	Post-intervention SDQ data collected	Level Up team
Oct/Nov '21	Focus groups with young people	HM/ES/DH
Oct/Nov '21	Implementation data and routine clinical data sent to research team	Level Up team
Nov/Dec '21	Data analysis and drafting of report	HM/ES/DH

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