

## Shared Training and Assessment of Well-Being (STrAWB): Feasibility trial of a joint training and assessment package for foster carers and teachers of looked-after children

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1	13.08.20	v2.0 Outlines move from in-person to online training and adjusted timeline
2	14.12.20	V3.0 Removal of one child self-report measure (BERS-2) and adds online interview option

This study will be performed according to the UK Policy Framework for Health and Social Care Research v3.3 (2017), and following ethical guidelines laid down by the British Psychological Society and British Educational Research Association.

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## **Shared Training and Assessment of Well-Being (STrAWB): Feasibility trial of a joint training and assessment package for foster carers and teachers of looked-after children**

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## List of Abbreviations

AE	Adverse Event
BERS	Behavioural and Emotional Rating Scale
CLA	Children who are Looked-After
CSRI	Client Service Receipt Inventory
CTU	Clinical Trials Unit
DfE	Department for Education
DoH	Department of Health
DT	Designated Teacher
FC	Foster Carer
LA	Local Authority
PAG	Project Advisory Group
PedsQL	Paediatric Quality of Life Scale
PEP	Personal Education Plan
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
SAE	Serious Adverse Event
SDQ	Strengths and Difficulties Questionnaire
SIS	Service Information Schedule
SSC	Study Steering Committee
STrAWB	Shared Training and Assessment of Well-Being
VSH	Virtual School Headteacher

## **1. Study Summary**

### **1.1 Title**

Shared Training and Assessment of Well-Being (STrAWB): Feasibility trial of a joint training and assessment package for foster carers and teachers of looked-after children.

### **1.2 Aim**

This is a feasibility study of an innovative training and assessment package for foster carers and schools. The aim of the study is to determine the feasibility, and to inform the design, of a randomised controlled trial (RCT) evaluating the STrAWB intervention for children in foster and kinship care. It will test the components of any larger RCT with a smaller sample, and address uncertainties around key parts of the process.

### **1.3 Sample**

70 children who are looked-after (CLA) aged 8-11 years (in school years 4-6), and their foster/kinship carers (FC) and designated teachers (DTs).

### **1.4 Randomisation**

Children will be randomly allocated to either the STrAWB intervention or the control arm, stratified by local authority. Allocation to the study arms will be on a 1:1 basis. Where there is more than one child per school, both children will be in the same condition (i.e. cluster randomised by school), because one DT will be responsible for both; this should avoid possible contamination between study arms.

### **1.5 Intervention**

Half the sample will receive the Shared Training and Assessment of Well-Being (STrAWB) package, which consists of:

- a) A training course for FCs and DTs to increase knowledge and confidence to identify potential mental health problems and to provide guidance on completing well-being assessments
- b) A package of measures completed by the FC, DT, and the child to provide a multi-informant assessment of well-being across the home and school contexts
- c) A mental health expert's review of all assessment measures, to create individual CLA profiles of strengths and needs for feedback to FCs, DTs, and children's social workers

### **1.6 Study objectives**

1. To test the procedure of randomisation, and its acceptability to local authorities, schools, and individual participants
2. To determine the consent rate from those approached to take part, and the length of time taken for recruitment



3. To test the acceptability of the intervention to participants
4. To select from two options the most appropriate primary outcome measure for a main trial
5. To provide data on the measures that will inform a sample size calculation for a main trial

### **1.7 Outcomes**

In line with our study objectives, we will assess the following outcomes:

- Acceptability of the randomisation procedure
- Recruitment and retention rates, including reasons for exclusion and drop-out
- Intervention fidelity
- Acceptability of the intervention
- Data completion rates

We will also test two potential primary outcome measures of mental health and well-being, in the intervention and control groups, to assess which is more comprehensible, developmentally appropriate, and useful for measuring impact (e.g. through sensitivity to change in externalising vs. internalising difficulties):

- The Strengths and Difficulties Questionnaire (SDQ) foster carer, teacher, child self-report versions
- The Paediatric Quality of Life Scale (PedsQL) foster carer and child self-report version

### **1.8 Setting and Timing**

5-6 local authorities in England (as required to obtain the necessary sample), with the intervention being delivered between September 2020 and January 2021. Proposed primary outcomes data will be collected twice: at baseline (prior to randomisation), and at a follow-up 12 months later. Feasibility data will begin to be collected directly following training, and will continue until after the 12-month follow-up.

## **2. Funding**

### ***2.1 Intervention***

The intervention is funded by an anonymous donation to the Rees Centre at the University of Oxford.

Total intervention funding: £42,594.86

The anonymous donor's funding will begin on 1<sup>st</sup> April 2020, for a period of 9 months.

### ***2.2 Feasibility trial***

The feasibility trial is funded by the National Institute for Health Research, Public Health Research programme.

Funder grant reference: PHR NIHR127799

Total research funding: £550,296.12

The NIHR PHR funding will begin on 1<sup>st</sup> April 2020, for a period of 27 months.

### **3. Background and Scientific Rationale**

#### ***3.1 Mental health of looked-after children***

The increased risk of mental health difficulties following childhood abuse or neglect is well documented (e.g., Arseneault et al., 2011). Given that the majority of children and young people looked after by English local authorities entered care due to maltreatment (DfE, 2019a), it is unsurprising that evidence indicates children in care are at higher-than-average risk of mental health issues, with reviews citing the prevalence of mental ill health at up to 45% of those in care (Ford, Vostanis, Meltzer, & Goodman, 2007; NICE, 2010). Looked-after children can also exhibit a range of sub-clinical psychological characteristics that do not individually reach the threshold for clinical diagnoses, but which can nonetheless impact significantly on their daily lives (DeJong, 2010). Maltreated children in care may be at further risk of mental ill health due to elevated rates of family and neighbourhood deprivation in their birth families in relation to the general population (e.g., see Sebba et al., 2015), making them more vulnerable to health inequalities. As a result, they are over-represented as users of child and adolescent mental health services (McAuley & Davis, 2009). However, services struggle to effectively meet this need, as documented in a recent report from the House of Commons Education Committee (2016).

Although adolescence sees the emergence of many mental health disorders in the general population, studies show that the gap between CLA and their peers in the prevalence of diagnosable disorders is even greater for those aged between five and 10 years than for older children (McAuley & Davis, 2009). There is evidence that young people are leaving care with mental health problems likely to compromise their ability to cope in the adult world (Memarzia, St Clair, Owens, Goodyer, & Dunn, 2015). In the shorter term, poorer mental health has been linked to educational difficulties for all children (Green, McGinnity, Meltzer, Ford, & Goodman, 2005; NHS Digital, 2018), and for CLA in particular (Sebba et al., 2015), who continue to lag behind their peers (DfE, 2019b).

Mental ill health is also a risk factor for care placement breakdowns (Tarren-Sweeney, 2008); these are problematic in themselves but can also make it difficult for CLA to access support. A report by the NSPCC (Bazalgette, Rahilly, & Trevelyan, 2015) estimated that £6.4 million could be saved in the UK annually by meeting looked-after children's mental health needs and as a result, maintaining stable placements. Consequently, guidance from the National Institute for Health and Care Excellence (NICE, 2010) recommends early identification and intervention for mental health issues in CLA.

At present, national datasets do not record the support strategies used to promote well-being for individual CLA, meaning that information on effective early interventions to mitigate the risk of mental health problems in this population is limited. Moreover, although government guidance notes that local authorities have a duty to promote children's physical, emotional, and mental health, and to give parity of esteem to physical and mental health (DfE/DoH, 2015), Bazalgette et al. (2015) have observed that the aim to prioritise emotional well-being is not being reflected in local policy. Thus, there is a significant gap in our knowledge about how to identify mental health and well-being needs in CLA, and about what support strategies can be deployed at an early stage in response to identified concerns.

This project represents a feasibility study on an innovative approach to improving the mental health of a particularly vulnerable group of young people. It spans the disciplines of psychology, health, education, social work and social policy, and contains a substantial element of user

engagement throughout the process. The Shared Training and Assessment of Well-Being (STrAWB) package consists of:

- a) A training course for foster carers (2 days) and designated teachers (1 day, shared with FCs) to increase knowledge and confidence to identify potential mental health problems and to provide guidance on completing well-being assessments
- b) A package of measures completed by the foster carer, teacher, and the child, to provide a multi-informant assessment of well-being across the home and school contexts
- c) A mental health expert's review of all assessment measures, to create individual CLA profiles of strengths and needs for feedback to carers, teachers, and children's social workers, including practical recommendations for support.

### **3.2 Interdisciplinary training**

Foster carers value training, seeing it as important in improving the care they offer (Clarke, 2009), and several recent policy and practice publications have recommended that foster carers should be trained to identify mental health difficulties at an early stage (Bazalgette et al., 2015; DoH/DfE, 2016; House of Commons Education Committee, 2016). Yet there is little coverage of mental health content in pre-service training or in training for approved foster carers. The House of Commons Education Committee report (2016) also calls for the inclusion of mental health training in initial teacher education, and for teachers and schools to be better equipped to identify, assess and support children and young people with mental health difficulties. Previous research (e.g., Sebba et al., 2016) shows that foster carers value training in which they are given the opportunity to work together with other professionals; for this reason, our training programme includes joint sessions for FCs and DTs to learn together.

### **3.3 Well-being assessment**

At present, assessments of mental health in looked-after children are restricted to the annual completion of the Strengths and Difficulties Questionnaire (SDQ; Goodman, 2001) by foster carers or residential staff. Our review of other available datasets (e.g., the Millennium Cohort Study and the Avon Longitudinal Study of Parents and Children) shows that there is a gap in recording measures of well-being specifically for CLA. The Department for Education has funded a new mental health assessment pilot across nine sites in England (Research in Practice, 2018), focused on assessing mental health and well-being of young people when first entering care. The proposed project would complement this work by providing ongoing (post-entry) assessments for children in care.

There is a general agreement that objective and subjective approaches are needed in measuring well-being (Hadley/Coram, 2015). However, the National Children's Bureau (Ryder, Edwards, & Clements, 2017) notes the lack of any consistent method for measuring looked-after children's well-being, beyond the SDQ; such consistency could provide not only information to plan services, but an indicator of the effectiveness of the care system. The 'Your Life, Your Care' survey, specifically developed for and with CLA by Coram Voice and the University of Bristol in the Bright Spots Programme (Selwyn, Magnus, & Stuijzand, 2018), is a measure of looked-after children's subjective well-being and their experiences in care; however, to date, this tool has been used primarily to provide a picture of children's experiences at the level of the local authority, in order to inform improvements to services, and has not been used to inform individual support plans.

Luke, Sinclair, Woolgar, and Sebba (2014, p116) point out the need for assessments “to take account of the whole picture to include not just the individual child but also their relationships and environment.” Well-being measurements need to assess the child in their multiple contexts, since an individual might experience difficulties at school but not at home, or vice versa. The combination of different perspectives is likely to more accurately predict mental health issues (Goodman, Ford, Corbin, & Meltzer, 2004; Johnson, Hollis, Marlow, Simms, & Wolke, 2014). Statutory guidance for local authorities (DfE, 2018a) therefore notes that looked-after children might benefit from the triangulation of SDQ scores from all three possible informants, though this is not currently standard practice.

Our proposed set of measures will assess supportive relationships with key adults, social networks and peer relationships, and participation in extra-curricular activities. These are all factors associated with improved resilience in primary-aged children (Sun & Stewart, 2007). Given the centrality of peer relationships to mental health, there is a need for assessments that can identify children’s social and emotional well-being in the school context; yet the assessments currently completed by foster carers and/or health professionals generally focus on children’s functioning outside of school. Moreover, they commonly present only one observer’s perspective. A wide-ranging, multi-informant approach to children’s social-relational and psychological adjustment both at home and at school is needed. Previous research by the applicants with older pupils transitioning from primary to secondary school has shown that relationships at school predict differences in mental health and well-being outcomes, via a variety of psychological dimensions relating to self-perception and empathy (Drew, 2018). Our combination of self-, teacher-, and carer-report data will help us better understand how social and psychological functioning within the school setting is related to mental health and well-being outcomes for CLA.

Overall, our approach to measurement represents a shift away from viewing resilience as an ‘intrinsic’ attribute of the individual (Roisman, Padrón, Sroufe, & Egeland, 2002), and towards a definition that captures the role of external processes and supportive social networks (Hjemdal, Friberg, Stiles, Martinussen, & Rosenvinge, 2006) in fostering the psychological underpinnings of well-being. Government guidance on mental health and behaviour in schools (DfE, 2018b) notes a range of risk and protective factors identified in research on the mental health of children in general, at the level of the individual child, the family, the school, and the community. The proposed project would develop this line of work to examine which factors promote resilience in CLA, enabling them to get back on track to healthy development.

### **3.4 Expert review**

The same mental health expert who reviews the carer-reported well-being profile will also review the quantitative results from the teacher-, and child-reported measures, to create a profile of strengths and needs in the individual young person. As Luke et al. (2014) note, the range of interacting personal and environmental factors at play in maltreated children’s lives means that diversity in responses to adversity can be expected. In turn, the uniqueness of individual responses means that a ‘one size fits all’ approach to intervention is unlikely to be effective with this population. Indeed, Drew and Banerjee (2019) have shown that Virtual Schools engage in a variety of strategies to support mental health and well-being, directed at foster carers, school staff, and the children themselves. Importantly, as noted in the DfE/DoH (2017) Green Paper, the school context can offer a relatively acceptable, non-stigmatising environment for interventions to support mental health and resilience. The feedback will therefore include suggestions for DTs, Virtual Schools and FCs on how they might best support children’s individual needs.

### **3.5 STrAWB pilot study**

In 2017-18, STrAWB was trialled in a small pilot study with 18 children. FCs and DTs gave positive feedback; they particularly valued the opportunities for improved communication and integrated working. Resulting changes to practice included securing counselling sessions on the basis of the evidence provided in one child's profile, and re-locating teaching assistant work within the classroom to maintain peer relationships for another child.

### **3.6 Fit with policy and practice**

All looked-after children in England have a Care Plan. The Care Planning and Case Review (England) Regulations (2010) set out the requirements relating to the reviews of children and young people looked after by local authorities: "The purpose of the review is to ensure that the child's welfare is safeguarded and promoted throughout the time the child or young person is looked after by the local authority. The review meeting will consider the Care Plan, monitor progress, and make decisions to amend the Care Plan in the light of changed knowledge and circumstances." After the first 4 months, reviews are held every 6 months and cover areas such as health, education, placement issues, contact and future plans.

Guidance also specifies a number of duties that must be followed to promote the education of looked-after children (DfE, 2018a). Schools have a statutory duty to promote the mental health and well-being of all pupils, through prevention, early identification of need, early support, and access to specialist support where necessary (DfE, 2018b). For looked-after children, there is also the provision of at least one person employed by the local authority to promote the educational achievement of that authority's looked-after children (the Virtual School Head, or VSH), and the use of Personal Education Plans (PEPs) as a distinct part of the child's care plan which summarises the child's current attainment and progress, and documents what needs to happen for the child to fulfil their educational potential. The guidance also notes that VSHs are responsible for the use of the 'Pupil Premium Plus' additional funding that looked-after children are allocated in order to improve their educational attainment; guidance on the use of this funding is flexible, provided VSHs can provide evidence of impact on education.

The project provides potential for change through the development of an innovative screening tool for mental health difficulties in the school context, which will enable school staff to identify specific social, emotional and cognitive risk factors for the development of mental health issues and to target their resources accordingly. The identification of key factors towards which to target interventions will help Virtual Schools to make the best use of the increased Pupil Premium Plus, in line with the DfE/DoH (2015) statutory guidance on promoting the health and well-being of looked-after children, which states that the VSH and designated teacher should both be aware of any health-related information (physical or mental) that might impact on their learning. It will also offer a more transparent process to ensure that looked-after children access the necessary mental health services in a timely manner. The use of multiple informants on children's well-being will also address the issue of under-identification of internalising problems in vulnerable children.

In 2016 the DfE set up an expert working group on the mental health of CLA, with the aim of ensuring that the emotional and mental health needs of this vulnerable group are better met. Recent policy and practice publications have recommended that foster carers and education professionals should be trained to identify mental health difficulties at an early stage (Bazalgette

et al., 2015; DoH/DfE, 2016; House of Commons Education Committee, 2016). The final report from the expert working group (SCIE, 2017) contained a number of recommendations, including:

- The Strengths and Difficulties Questionnaire should be supported by a broader set of measures which can trigger a comprehensive mental health assessment.
- Assessments should focus on understanding the individual's mental health and emotional wellbeing in the context of their current situation and past experiences, rather than solely focusing on the presenting symptoms. The young person, their caregivers, family (where appropriate) and professionals' viewpoints should be included.
- Everyone working directly with looked-after children should receive training on children and young people's mental health so they are equipped with the appropriate skills.
- Every school should have a designated teacher with the training and competence in identifying and understanding the mental health needs of all their pupils who are looked-after.

The DoH/DfE's (2016) advice for school staff on mental health and behaviour notes the central role that schools can play in observing children's day-to-day wellbeing and supporting their mental health. Yet assessments currently completed by foster carers and/or health professionals generally focus on children's functioning outside of school. The school context therefore represents a relatively under-researched arena for CLA and one in which the early identification of children's mental health issues and social well-being is crucial. The Children and Young People's Mental Health and Wellbeing Taskforce report (DoH/NHS England, 2015) prioritises prevention and early identification as not only being effective but also cost-effective. Key recommendations include: early identification of problems to avoid escalation and long-term impairment; improved joint working; promoting resilience; ensuring the provision of comprehensive assessments and appropriate, timely referrals, for the most vulnerable; and training for professionals in mental health and available support and pathways.

## **4. Research Plan**

### **4.1 Design**

The proposed design is a randomised feasibility trial. The project will primarily test whether the STrAWB package of training, assessment and clinical review for CLA can feasibly be delivered and evaluated in an RCT. The pilot intervention will employ the same design that would be used in a full trial, should this go ahead: namely, a two-arm randomised controlled trial, with two points of data collection (baseline and 12-month follow-up) for our primary and secondary outcomes. The RCT is represented in Appendix A.

### **4.2 Sample**

We will recruit children looked-after (CLA) aged 8-11 years (in school years 4-6) from 5-6 local authorities (LAs), and their foster/kinship carers (FC) and designated teachers (DTs; a dedicated role in each school). All foster carers and kinship carers looking after children who are eligible for the study will initially be invited to participate. Our inclusion criteria are for children who:

- a) are in foster or kinship care at the time of recruitment
- b) have experienced abuse and/or neglect while living with birth families (identified in their Child in Need records)
- c) are under a care order (i.e. excluding those in care under Section 20 of the Children's Act)
- d) are in Year 4, Year 5, or Year 6 of primary school; and
- e) have sufficient communication and literacy skills to complete self-report assessments.

The sample size target for this study will be 70 participants overall, 35 per group, recruited from approximately 60-70 schools. One group of 35 participants will receive the STrAWB intervention and the other group will receive treatment as usual in a 1:1 allocation ratio.

### **4.3 Recruitment**

We will recruit 5-6 local authorities to the study (as necessary to meet our sample size target). Participating local authorities will be asked to approach the professionals working with ALL eligible looked-after children for inclusion in the study. Since consent is required from three sources for each child (local authority, foster carer, and Designated Teacher), we anticipate some attrition at the stage of consent. In order to ensure a sample for randomisation of at least 70 children, we will require local authorities to identify a minimum total of 100 children who meet the inclusion criteria.

Local authorities will be provided with the inclusion criteria as listed above, and will be provided with the initial study recruitment materials for distribution. A letter or email of support will be sent from each local authority to all potential participating schools and foster carers, along with a short leaflet outlining the key points about the study. Local authorities will then be asked to provide the research team with contact information for the key professionals.

We will send all foster carers and schools a full information sheet and consent form, written in clear and accessible language. Carers will also receive an information leaflet for the child and a children's consent form. Children's social workers will receive information about the study, to



keep them informed. The purpose of the study will be explicitly stated and contact details of the research team provided. Assent will also be sought from children.

#### **4.4 Randomisation**

Children whose key adults consent to their participation will be randomly allocated to either the STrAWB intervention or the control arm, stratified by local authority. Allocation to the study arms will be on a 1:1 basis. Where there is more than one child per school, both children will be in the same condition (i.e. cluster randomised by school), because the same DT will be responsible for both; this should avoid possible contamination between study arms. National data suggests that the majority of primary schools that have eligible children for the study will have only 1 or 2 looked-after children on their rolls, and our previous pilot recruited 18 children from 17 schools; therefore, the number of participating schools is likely to be only slightly smaller than the number of participating children.

The 35 children in the intervention condition will receive the full STrAWB package. The control group for our primary and secondary outcome measures will consist of 35 children who meet the same inclusion criteria as the intervention group.

#### **4.5 Planned intervention**

The Shared Training and Assessment of Well-Being (STrAWB) intervention for Looked-After Children is an innovative training and assessment package for foster carers and schools. STrAWB's unique cross-context approach can help with early identification of mental health difficulties and support for children's well-being, and has the potential to reduce the risk of developing or escalating mental health problems and to improve resilience following maltreatment. The logic model for the intervention (which would be tested in a definitive trial) illustrates how the activities are theorised to produce these effects.

The STrAWB package consists of four key elements, each of which will be experienced only by those in the STrAWB intervention arm:

1. integrated training on mental health, well-being and resilience for foster carers and designated teachers
2. home-based assessment completed by trained foster carers, based on observations of key signs and indicators of potential mental health difficulties, children's strengths and an outline of activities, including online and screen time; and by the children themselves involving measures of social and emotional functioning in the home and school contexts
3. school-based assessment by school staff
4. review of the combined baseline measures and STrAWB assessments by a mental health expert, to create individual CLA profiles of strengths and needs, with recommendations for support strategies, allowing key adults to identify and respond to the needs of CLA within the home and school settings

For element (1), foster carers and designated teachers of children in the STrAWB pilot study attended a 2-day face-to-face training course (FCs attending both days, DTs one day), in venues provided by the local authority (such as schools and family centres). Training sessions were delivered in small groups (a maximum of 12 people) and include information-sharing from the trainers (using PowerPoint slides), as well as video, exercises and guided discussion. In the current

context (August 2020), there has been a need to adapt the training to be delivered online. See section 4.5.1 below, for the rationale and further information on this amendment to the mode of delivery.

The final part of the training for all participants introduces them to the STrAWB assessment measures and guides them through how they should be completed. Participants are provided with an accompanying handbook (around 80 pages), the sections of which mirror the content of the training but explore topics in more depth: background and context; well-being, resilience and strengths; social factors; mental health factors; mental health problems; the STrAWB assessments; talking and listening; resources and references. The STrAWB training was originally co-developed with foster carers, social workers, clinicians, and CLA, and has been developed for this project with our Project Advisory Group (PAG) of foster carers, Virtual School and local authority staff, care experienced young people, and mental health experts. Further amendments were made in response to feedback from participants in our recent pilot study.

The team has extensive experience of training for both foster carers and school staff, and have successfully run the training in a small pilot in 2017-18. As part of the study, we will design a set of 'train-the-trainer' materials to facilitate potential scaling-up as part of an RCT, and receive feedback on these from our project advisory group and participating local authorities (a full pilot of these materials is not achievable alongside the existing planned delivery of the intervention).

For elements (2) and (3) of the intervention, in the month directly following the training, information is collected from foster carers, designated teachers and children. The intention of this information is to feed into the creation of an individual child profile by a reviewing mental health expert (element 4). All participants will be able to return information as online or hard-copy options. The information collected at this stage (with information on the informants) is as follows:

- Foster carers will complete the STrAWB 'Well-Being Profile' (WBP), a diary method which involves recording core signs/symptoms in the participating children, with attention to impact and context, over a two-week observation period. Six signs/symptoms which occur across the spectrum of disorders were chosen based on their utility as possible markers for clinical problems and ease of observation: mood, anxiety, focus, sleep, fearfulness, and impact. The WBP also includes a review of the child's strengths, and an overview covers children's personal care, practical skills, speech and language, psychotic symptoms, eating, and head injury. The profile elicits free-text answers with daily context. Questions tested in our previous pilot that capture leisure and social and online activities will also be used.
- Children will be supported by their carers to complete brief self-report measures at home, to provide a broader assessment of interpersonal activities, perceived relationship quality, and self-perceptions across the home and school contexts. Qualities of relationships within the peer context, both in terms of general peer acceptance and dyadic friendships, will be assessed using Ebesutani et al.'s (2012) shortened version of the Loneliness Questionnaire (Asher, Hymel, & Renshaw, 1984) and the Best Friend Index (Kouwenberg, Rieffe, & Banerjee, 2013). We will also assess some of the factors that are established antecedents to mental health difficulties, such as perceived self-efficacy and self-esteem, using items from the Student Resilience Survey (Lereya et al., 2016), the EU Kids Online Survey (Hasebrink, Görzig, Haddon, Kalmus, & Livingstone, 2011), a shortened version of Harter's (1988) Self-Perception Profile for Adolescents (Wichstraum, 1995), and a positively-worded measure of children's emotional and psychological well-being, the Stirling Children's Well-being Scale (Liddle & Carter, 2015).

- Teachers will complete the Mulberry Bush Social and Emotional Development Scale, which was co-created and successfully piloted by members of the research team with expert practitioners at the Mulberry Bush residential school for traumatised children (Drew, 2018). The scale provides measures of children's social regulation of behaviour and emotions in ways that specifically capture the needs of this particular group.

Using templates already created and implemented successfully in our initial pilot, these school, home and self-report assessments will be combined for children in the intervention arm to form individual profiles of each child's strengths and needs. Profiles will be reviewed by a mental health expert (e.g. clinical psychologist) who will identify concerns and signpost appropriate onwards referrals. For the proposed study, the clinical psychiatrist and psychologists who have worked with us on our previous pilot study will continue in this role. Part of the purpose of the feasibility trial will be to establish the most appropriate staff members (e.g. looked-after children's psychologist, psychiatric nurse) to complete these profiles in any larger-scale roll-out of the intervention.

Feedback sessions for each child will bring together foster carers, teachers and social workers to consider the review and decide on next steps. As a result of the previous pilot, we have produced a set of guidelines for feedback sessions, which aim to help attendees to understand the information contained in the profile and expert review/guidance and to take appropriate steps where needed. Feedback packs will be provided to DTs, reiterating what they have learned in the training sessions about the purpose of each measure, and giving guidance on how the mental health expert has produced the individual profile from the responses provided. The pack will include clear suggestions for possible actions in response to the highlighted strengths and support needs, and recommendations for feeding the information into the child's PEP meetings.

The intervention is to some extent tailored to individual participants: for example, depending on experience and knowledge, attendees at the training might choose to spend longer on one discussion activity than another, and not all feedback sessions might be attended by children's social workers if their schedules do not allow for this, although we do encourage their attendance. However, the core content of the training sessions, and all of the measures collected to create the individual profiles, will remain consistent; methods of measuring adherence to these procedures are described below. Modifications to the intervention during the feasibility study are not planned.

We acknowledge the Department of Psychiatry, University of Cambridge and the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research & Care (CLAHRC) East of England who funded the development of the original foster carer training and assessment, now integral to STrAWB. Our thanks also go to Cambridgeshire County Council (CCC) and Cambridgeshire and Peterborough NHS Foundation Trust, for their valuable contributions during the preliminary stages. STrAWB has been developed by the Universities of Oxford and Sussex with the kind permission of the University of Cambridge and NIHR CLAHRC East of England, and with funding from the Sir Halley Stewart Trust and an anonymous donor.

#### *4.5.1 Move to online training*

In light of Covid-19 and the associated social distancing measures, we are adapting the face-to-face group training sessions to be delivered as an online training package. Our ongoing discussions with local authorities confirmed that face-to-face group sessions of the kind used in the STrAWB pilot are highly unlikely to be taking place before January 2021 at the earliest. However, the same discussions have impressed upon us the fact that STrAWB is more important now even than

before: as schools and households emerge from a period of lockdown, carers and teachers are preparing themselves for the anticipated impact on children's social and emotional well-being when they return to the classroom. The push to develop an online version of the STrAWB training that is accessible in the autumn term of 2020/21 was therefore preferable to the alternative (pausing the study until the face-to-face format is possible again).

It was neither possible nor desirable to simply transfer the existing 2-day programme and deliver this online. Educational research stresses the need to adapt course content when transitioning to an online format, in response to the online environment, learners' expectations and engagement (e.g. see review by Kebritchi et al., 2017). In addition to these pedagogical considerations, practical issues relating to the current situation also require adaptations: specifically, the fact that designated teachers will be working in over-stretched schools in the coming term mean that whole-day activities will not be possible, and local authorities requested the training be available as 'bite-size chunks'. We are therefore developing a range of online resources and activities which – combined with a series of live online sessions with the trainers – will enable us to deliver the STrAWB training in an engaging online format. A mix of synchronous and asynchronous activities completed by FCs and DTs together will maintain the joint-working element that is central to STrAWB.

A well-developed online version of STrAWB training has its own benefits: it will enable participation by carers and teachers who would otherwise not have been able to attend in person; it also means they can complete some sessions at a time convenient to themselves, which provides the additional flexibility that carers and teachers might need. In addition, by moving the training to online, the activities and resources will all be available to participating FCs and DTs after the study is concluded, so will bring added value (in terms of legacy). This will also mean a more cost-effective package should the feasibility trial support a larger RCT. The current situation can therefore be seen as having provided an opportunity for us to revisit the format of the STrAWB training and future-proof it. Online training will therefore be the method of delivery for the whole duration of the study.

### **4.6 Primary and secondary outcome measures**

Proposed primary and secondary outcome measures will be collected from both arms at baseline (prior to randomisation), and at a follow-up 12 months later. We will test two potential primary outcome measures of mental health and well-being, in the intervention and control arms, to assess which is more comprehensible, developmentally appropriate, and useful. The people completing each measure are given in parentheses:

- Primary outcome 1: The Strengths and Difficulties Questionnaire (SDQ; Goodman, 2001), a brief behavioural measure, which is currently routinely completed on an annual basis by foster carers in England regarding children in their care (child self-report; foster carer; teacher)
- Primary outcome 2: The Paediatric Quality of Life scale (PedsQL; Varni, Seid, & Kurtin, 2001), which includes some items that overlap substantially with the SDQ, but also physical health and activities (child self-report; foster carer)
- Secondary outcome: The Behavioural and Emotional Rating Scale (BERS; Buckley & Epstein, 2004), which assesses areas of personal strength (foster carer; teacher)

For each measure, participants will have the option of completion online or in hard copy (with return postage to the research team prepaid). Adults will complete measures at a convenient time

and location; foster carers will be asked to support children to complete measures at home. Instructions will be provided to carers so they can support children to complete the measures. Completion of questionnaires should take around 15 minutes for teachers, 20-30 minutes for foster carers and 20-30 minutes for each child. Carers will be advised that children can complete the questionnaires in 1-3 sittings in the same week, depending on attention levels.

Use of the SDQ with looked-after children has been shown to provide a good estimate of the prevalence of mental health conditions (Goodman & Goodman, 2012). The carer version of the SDQ is routinely collected by local authorities on an annual basis, and as such offers a familiar data collection tool, but it only provides one perspective. It is recognised that children and adolescents may exhibit mental health concerns in some contexts but not others, so a multi-informant approach to developing a better assessment of a young person's mental health is vital (De Los Reyes et al., 2015). There is evidence with looked-after children that using multi-informant SDQs to combine different perspectives is a reliable predictor of mental health issues (Goodman et al., 2004), and our proposed research would make full use of different versions of the SDQ as it would be completed by the carer, teacher and young person.

We acknowledge that the self-report version of the SDQ is validated for use by those aged 11 and over. Muris, Meesters, Eijkelenboom, and Vincken (2004, p.446) report that "while most psychometric qualities of the self-report SDQ in 8- to 10-year-old children were comparable to those obtained in children aged 11 years and above, reliability of the scale in the younger children appeared less satisfactory." However, other studies (e.g. Hobbs, Axford, & Jodrell, 2011) have successfully used the SDQ self-report with children as young as 7, and report satisfactory levels of reliability. Moreover, our own piloting of the SDQ with children in this age group (Drew, 2018) has shown acceptable levels of completion and reliability (Total Difficulties Score producing a Cronbach's alpha of .83 for Year 4 and .77 for Year 5 pupils).

In recognition of the aforementioned limitations of the SDQ, we will use the feasibility study to compare this with a second primary outcome measure; the resulting analysis would then form the basis of the choice of primary outcome for any definitive RCT. Alongside the SDQ, therefore, we will collect a second (self-report) measure of mental health and well-being. The Paediatric Quality of Life scale (PedsQL; Varni, Seid, & Kurtin, 2001) includes some items that overlap substantially with the SDQ, but the subscales also include physical health and activities. It has been validated for use with our age group.

Our secondary outcome measure will be the strength-based Behavioural and Emotional Rating Scale (BERS; Buckley & Epstein, 2004). The BERS assesses areas of personal strength not covered by the SDQ or the PedsQL, and thus the primary and secondary measures act to complement each other and provide a more rounded picture of children's mental health. All three measures are currently used by the Child Outcomes Research Consortium (CORC), fitting with the panel's recommendation for "taking advantage of the growing utility of routine data" going forward. Previous versions of this Protocol showed that we intended to use the child self-report version of the BERS as well as the parent/carers and teacher versions. On further consideration, we decided not to use the child self-report version. The wording of the measure is designed for children aged 11+ and would not be easily explained to children of 8 or 9, and the length of the questionnaire would present too much of a burden. It also contains a number of items relating to their relationship with 'family' which would be very difficult to apply to children in care.

Removing the self-report version of the BERS as an outcome measure still leaves the two primary outcome measures (SDQ and PedsQL) in self-report form, and the study retains the multi-informant focus with the carer and teacher measures.

#### **4.7 Measures for economic evaluation**

##### **4.7.1 Cost of the intervention**

To calculate a comprehensive unit cost for the intervention, a Service Information Schedule (SIS) will be developed in collaboration with the research team to collect information on time spent delivering the intervention, staff salaries, on-costs, overheads, training costs and materials.

##### **4.7.2 Service use**

The Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001) is a measure of service use that can be administered as self-report or proxy-report. A short version will be developed and refined with PPI input for use with this study, building on several recent trials and pilot studies in school settings (e.g. Bonin, Beecham, & Brown, forthcoming). At baseline and 12 months later, foster carers and children in both study arms will be asked to provide information about contacts with general and mental health services, social care and education support, as well as informal help received from voluntary organisations, carers and friends.

#### **4.8 Research methods**

A variety of methods will be used to assess whether the processes of recruitment, randomisation, intervention, assessment, clinical review, feedback, and collection of data on outcomes, service use and costs all operate as planned. Specifically, these will incorporate the following:

1. A **brief survey** to collect contextual data on children and carers at baseline. This will cover whether the child has a current mental health diagnosis, any medications or treatment received, history of emotional or behavioural disorders, length of time in care, number of placements and duration of current placement. Questions on foster carers will cover the number of years of fostering experience, and mental health training received to date.
2. **Post-training surveys** for all foster carers and designated teachers attending the training sessions. The surveys will include Likert scale ratings on the quality, usefulness, and delivery of the training sessions, along with open-ended questions (e.g. "How do you intend to use this information in your practice?")
3. At 6 and 12 months after the provision of feedback, we will use **semi-structured interviews** with a sample of the different stakeholders involved in the project: FCs ( $n = 10$ ), DTs ( $n = 10$ ), social workers ( $n = 10$ ), children ( $n = 10$ ), and local authority staff ( $n = 5-6$ ). Interviewees will be selected at a rate of 70% from the intervention arm and 30% from the control arm, to enable the fullest possible information to be gathered on the trial process and the intervention. We anticipate that most of the adult stakeholders will opt for telephone interviews, but have budgeted for 20 trips for face-to-face interviews. All of the child interviews will be face-to-face (subject to any Covid-related regulations; otherwise, they will take place online), and will be conducted by a care-experienced peer researcher (trained and supported by Coram Voice), with the support of one of the team's researchers. The interviews will explore the potential facilitators and barriers to implementation in routine settings as part of a full trial, focusing on the following topics:

- Experience of recruitment (adults only, both arms). In the first interview, we will ask all adult stakeholders about their experiences of recruitment into the study. Questions will explore whether the mode of initial contact from the research team via local authorities (e.g. mail, email) was appropriate, whether recruitment materials (leaflets, full information sheets, and consent forms) were easy to understand and useful in terms of helping them decide to participate, and the ease of contacting the research team with any questions.
- Acceptability of randomisation (adults only, both arms). Also in the first interview, we will explore carers' and teachers' responses to the process of randomisation, and whether their allocation to the intervention or the control arm affected their attitudes to the study and to completing the outcome measures.
- Acceptability of the intervention (adults in the intervention arm only). In the first interview, open questions will be used to elicit stakeholders' thoughts on each element of the STrAWB package, including the experience of training (e.g. whether timing of live sessions was convenient), assessment (e.g. whether they preferred to complete measures online or in hard copy, whether surveys were of an appropriate length to retain engagement from start to end, and whether the phrasing of any questions was unclear or problematic), and feedback (e.g. the clarity of the child's individual profile and how useful it had been in informing subsequent support). Interviewees will be prompted to share both positive and negative opinions, and will be asked about potential changes to the content and delivery of the intervention for a full trial. Participants' opinions on the intervention will be revisited in the follow-up interview, where they will be asked to reflect on the strengths and support needs that were identified and what had happened as a result.
- Acceptability of the intervention (children in the intervention arm only). Questions for children about the intervention will focus on their experience of completing the self-report measures: their ease of understanding, whether any topics or individual items were problematic, whether they felt comfortable completing them in the home environment, and whether they had enlisted the support of their foster carer or another adult to complete the measures and how this might have affected their responses.
- Appropriateness of primary outcome measures (adults and children, both arms). We will ask interviewees to comment on the ease of use and clarity of individual items on the SDQ and the PedsQL, and to compare them as measures of looked-after children's well-being in terms of their comprehensiveness and whether the items are age-appropriate (both chronologically and developmentally).
- We will also gather feedback from the PAG on the 'train-the-trainer' materials we produce.

4. Following completion of all baseline feedback sessions, we will use a **semi-structured interview** with the mental health expert to assess their experience of using the assessments to produce individualised feedback profiles. This will include questions on how informative the measures were in helping them to assess children's strengths and support needs across the home and school contexts; the clarity and usefulness of the guidance provided; and the most appropriately-qualified mental health professionals to fulfil this role in any larger roll-out.

5. We will track the support strategies offered to children in the STrAWB condition in response to the needs identified. We expect professionals to select and implement readily available support to maximise potential scalability, and we will monitor and document their chosen support strategies (e.g. referrals to CAMHS, school counselling service, additional small-group intervention/support in schools) across the 12 months following the provision of feedback. We will use **activity monitoring sheets** and **structured interviews** with stakeholders (at 6 and 12 months after the feedback session) to track the response. We will also record if and how the feedback has been used to feed into routine statutory reviews for looked-after children, including Personalised Education Plans (PEPs).

6. **Case study methodology** will focus on 6-8 children (and adults involved in the study). Drawing on data from the interviews and monitoring sheets, the case studies will investigate the process of participation from the perspectives of foster carers, DTs, and the children themselves, as well as how the STrAWB package has impacted on their ways of working and on the individual child.

All research instruments (surveys, interview schedules, and activity monitoring sheets) will be presented to and discussed with our PAG of foster carers, Virtual School and local authority staff, care experienced young people, and mental health experts, to obtain feedback and suggestions for any amendments or additions. We are grateful to the Young People's Advisory Group for Kent, Surrey and Sussex (YPAG KSS) for the invaluable feedback provided on the materials for children.

#### **4.9 Outcomes**

The outcomes for this study will relate to the feasibility of conducting an RCT. The full range of feasibility outcomes is outlined here; key outcomes determining progression criteria are outlined in Section 4.11.

##### **4.9.1 Recruitment**

- Number of eligible children in each participating local authority
- Percentage consenting from those approached to take part (this was 40% in the previous small-scale pilot study)
- Reasons for non-participation
- Time taken to achieve consent (days from initial communication from LA to signed consent form)

##### **4.9.2 Randomisation**

- Number of participants randomised into the two study arms
- Number of participants refusing to participate due to randomisation
- Attitudes toward randomisation (interview data)
- Documentation of what constitutes 'care as usual' for children in the control arm

##### **4.9.3 Intervention**

- The programme for the live online training sessions will include a checklist of topics, and the trainers will record how many of those topics have been covered in each session and how much time was spent on each one
- Ratings and qualitative comments from post-training surveys
- Production of a 'train the trainer' package, and feedback on this from PAG



- Completion rates for home and school assessments, at the level of measures (to ascertain whether a particular questionnaire is more difficult for participants to complete) and individual items (to assess whether responses are missing at random)
- Sample attrition on the primary and secondary outcome measures (and the related reasons for this) at the 12-month follow-up point will be recorded
- Ratings of expert feedback in terms of comprehensiveness and clarity
- Identification of appropriate mental health expert roles for future production of feedback
- Number and roles of those present at feedback sessions, the duration of the discussion, and how the feedback was used to create an action plan for going forward
- We will assess the key components of programme integrity, as outlined by Dane and Schneider (1998):
  1. adherence to the intervention and responsiveness of participants (training checklists, attendance at training, measure completion rates, completed expert feedback, attendance at feedback session)
  2. exposure (involvement at each stage of the intervention, as measured by attendance at both days of training and completion of measures by all informants)
  3. quality of training (feedback forms following training sessions, interview data)
  4. programme differentiation (identifying challenges through interviews).

#### *4.9.4 RCT outcome measures*

- Determination of which of the two proposed primary outcome measures (SDQ, PedsQL) is most comprehensible, developmentally appropriate, and useful (data from outcome measures, interview data from foster carers, teachers, and children, missing data analysis, review of expert feedback, interview with expert)

#### *4.9.5 Sample size for RCT*

- Estimation of likely rates of recruitment and retention in an RCT
- Calculation of sample size

#### *4.9.6 Economic evaluation*

- Proportion of returned service use questionnaires at baseline and 12 months
- Proportion of completion of individual items on the CSRI
- Proportion of local authorities with sufficient data collected to calculate an intervention cost
- Assessment of change in service use patterns over time as a result of the intervention
- Description of 'treatment as usual'
- Feasibility of estimating unit costs for services used by study participants

### **4.10 Data and statistical analysis**

The results of the trial will be reported in accordance with the CONSORT extension for pilot and feasibility trials (Thabane et al., 2016). The feasibility study will evaluate the interacting roles of context, implementation, and setting, in line with the Context and Implementation of Complex Interventions (CICI) framework (Pfadenhauer et al., 2017). The evaluation will focus on the process, agents, and outcomes of implementation; the geographical, socio-economic, ethical and legal context in which the intervention is implemented; and the specific setting in which the intervention takes place.

The statistical analysis of this trial will be descriptive, focusing on estimation rather than hypothesis testing, to address the trial objectives as laid out above. No formal comparison of the groups will take place. A full analysis plan will be developed prior to the final analysis of the trial. The interpretation of the trial will bring together all of the results from the trial along with the trial team experience, and assessing against the pre-specified progression criteria the team will consider the feasibility of a main definitive trial.

Our analysis will describe the study cohort (by school year group and gender), provide descriptive statistics from their primary and secondary outcome measures, and a thematic analysis of the patterns of support and interventions that children in both groups have accessed from baseline to follow-up. Potential for scalability to a larger sample in an RCT will also be assessed in the study. Using the guidelines proposed by Milat et al. (2016), alongside our feasibility study we will assess the fit of the intervention with the current strategic context (e.g. the DfE mental health pilots), develop a scaling up plan that takes account of potential barriers identified in the feasibility study, and identify (with a view to securing) the resources required for scale-up to an RCT. We will examine the key indicators of the feasibility of undertaking an RCT:

- Recruitment and retention data will be presented in terms of absolute numbers and proportions at each stage (those eligible to participate in the study, those randomised into the two arms, those completing the training, assessment, and feedback elements of the intervention, and those completing the 12-month follow-up outcomes data). Reasons for exclusion and drop-out will be categorised. Drop-out data for the 12-month follow-up will be analysed according to study arm, age group, attendance rates at training and feedback sessions, and completion rates of baseline assessments, as well as by information collected in the brief contextual survey (e.g. carer's number of years fostering, child's length of time in care), in order to identify the extent to which these factors might determine drop-out in an RCT. Acceptability of the randomisation procedure will also be assessed qualitatively, using data from the interviews. Information from the activity monitoring sheets will be presented in order to document any changes to 'treatment as usual' for children not receiving the intervention.
- Intervention fidelity will be presented in terms of number of topics covered and amount of time spent on each topic in the training sessions, and completion rates of profile measures by foster carers, teachers, and children.
- Acceptability of the intervention will be presented using descriptive analysis of attendance rates at training and feedback sessions, and completion rates of profile and outcome measures. A thematic analysis (Braun & Clarke, 2006) of interview data will explore whether particular aspects of the intervention are more or less acceptable. Interview data will also be analysed to outline the experts' perspectives on the most appropriate professionals to produce the individual feedback profiles. This would all inform any adaptations to the STrAWB package ahead of an RCT.
- Data completion rates will be presented at the level of each profile measure, to determine whether completion rates fall below 80%. Any individual items falling below this cut-off will also be presented. Differences by study arm, age group, and informant will be presented.
- Descriptive statistics will also be presented for the two potential primary outcome measures for an RCT, to determine whether they produce responses across the range of response options (i.e. not everyone chooses the same response). Completion rates by age group and informant will be presented, along with any individual items where completion rates fall below

80%, in order to determine whether the measures are comprehensible and developmentally appropriate. A review of baseline and follow-up data, expert feedback profiles, and interview data from foster carers, teachers, and the reviewing expert, will be analysed to determine which of the two measures is more useful in terms of profiling individual children and monitoring their mental health and well-being in the longer term.

- The proportion of returned CSRs and proportion of questions completed at each time point will be assessed to determine whether children and foster carers can and will complete the CSR. The extent of missing responses will be analysed following the baseline assessment to identify any problems with the way questions are phrased or the questionnaire design, which will be revised with PPI input if necessary prior to the follow-up assessment.
- The proportion of study participants reporting contacts with a given service will be reported for each time point to determine whether these young people rely primarily on formal service or informal care for support. The findings will show whether it will be sensible to measure (public sector) costs and cost-effectiveness in a full trial. Costs associated with service use will be calculated by attaching a unit cost to each instance of service use.
- The proportion of local authorities providing sufficient data to calculate an intervention cost will be shown, and a comprehensive intervention cost will be calculated.
- A description of 'treatment as usual' will be provided based on control group data.
- As a feasibility study, we will be unable to determine the (cost-) effectiveness of the intervention for different groups; however, our evaluation will investigate the acceptability of the intervention and potential barriers to participation for those in positions of inequality in line with categories from PROGRESS-Plus (Oliver et al., 2008), for example by questioning access to training for male versus female and kinship versus 'stranger' foster carers, those with additional employment or with no access to childcare for children not of school-age, and those for whom English is not their first language or who have lower levels of literacy.

#### **4.11 Progression criteria**

The full range of quantitative and qualitative data collected in this study will be drawn on in order to assess the feasibility of conducting an RCT. The final report of the study will summarise these data to present a clear decision on whether to proceed to an RCT, and an outline of any changes that are necessary to the study design and the STrAWB intervention. As part of this, the following progression criteria will be used:

1. Recruitment: A sample of 70 children is recruited to the study
2. Randomisation: Children are successfully randomised into the two study conditions, and the ratio of intervention to control participants that is achieved would be sufficient to enable comparisons in a definitive trial
3. Retention: Drop-out from the study is within acceptable limits (30%), or necessary alterations to study procedures are identified that would allow for improved retention in an RCT
4. Intervention: The STrAWB package is delivered to those in the intervention condition as specified in the intervention manual
5. RCT outcome measures: One of the two potential primary outcome measures is identified as being appropriate for an RCT. Analysis of the quantitative and qualitative data relevant to this

decision (as specified in the previous section) is subject to approval by the project advisory group

6. Data completion (primary outcomes): The completion rate is good (at least 80% completion of the primary outcome measures at baseline) and analyses reveal no obvious biases in data completion (e.g. by study arm), or necessary alterations to study procedures are identified that would maximise completion rates in an RCT
7. Data completion (economic evaluation): 80% of the foster carers (with the children) complete the baseline CSRI. Sufficient data on the intervention cost can be collected for at least 50% of intervention locations to allow for an assessment of cost variation
8. Scalability: A 'train the trainer' package is produced, and the most appropriate mental health expert roles to produce the individualised feedback are identified. Both are approved by the project advisory group
9. A sample size calculation for the main trial is possible and results in a sample size that will be feasible to recruit given the rest of the results

Table 1 presents provisional 'traffic light' thresholds for criteria (1), (3), (6) and (7), in which achieving 'green' levels indicates that there appear to be no issues threatening the success of the trial, 'amber' indicates that any issues might be remedied, and 'red' indicates that even with modifications, a full trial is unlikely to succeed.

We anticipate recruitment and retention rates in line with similar trials in the field (e.g. foster carer training programmes by Linares, Montalto, Li, & Oza, 2006; Minnis, Pelosi, Knapp, & Dunn, 2001). Based on the progression criteria set out for retention and baseline data completion the following calculations were carried out using a 95% (two-sided) confidence interval approach. For retention the green criterion states that the retention rate must be at least 75%. With an expected proportion of 75%, a sample size of 70 would allow us to predict the rate to within 10.1%. The red criterion sets out that the retention rate must be at least 50%; with an expected proportion of 50%, a sample size of 70 would allow us to predict the rate to within 11.7%. For baseline data completion (including CSRI) the green criterion is a completion rate of 80% or more. With an expected proportion of 80%, a sample size of 70 would allow us to estimate the rate to within 9.4%. The red criterion of at least 55% and a sample size of 70 would allow us to estimate the rate to within 11.7%. The sample size of 70 means that the half width of the confidence interval around the estimated values will not be greater than 12%. Additionally, we do not have a progression criterion where an estimated confidence interval would contain both the green and red criteria, and therefore indicating to both proceed and stop.

Table 1: Provisional Traffic Light Criteria to inform decision on whether to proceed with a full trial

Criterion	Green	Amber	Red
1) Sample size	70 children and their key adults are recruited	50-69 children and their key adults are recruited	<50 children and their key adults are recruited
3) Retention rates at 12-month follow-up	≥75% return outcomes data at 12 months	<75% but ≥50% return outcomes data at 12 months	<50% return outcomes data at 12 months

## Shared Training and Assessment of Well-Being (STrAWB) for looked-after children

6) Data completion on primary outcomes at baseline	≥80% complete primary outcome measures at baseline	<80% but ≥55% complete primary outcome measures at baseline	<55% complete primary outcome measures at baseline
7a) Data completion on economic evaluation (CSRI)	≥80% of either foster carers or children complete the baseline CSRI	<80% but ≥60% of either foster carers or children complete the baseline CSRI	<60% of either foster carers or children complete the baseline CSRI
7b) Data completion on economic evaluation (intervention cost)	Sufficient data on the intervention cost can be collected for at least 50% of intervention locations	Sufficient data on the intervention cost can be collected for <50% of intervention locations but ≥35%	Sufficient data on the intervention cost can be collected for <35% of intervention locations

## 5. Outputs and Dissemination

The feasibility study would result in a tested training and assessment package (STrAWB), including training materials for FCs and DTs, an accompanying handbook, assessment measures for completion by carers, teachers, and children, and written guidance and templates for mental health experts in producing individual feedback profiles. The STrAWB intervention has been developed through a collaboration between colleagues at the Universities of Oxford and Sussex.

As pilot and feasibility work, it would be inappropriate to engage in wide dissemination of the outputs and results unless the main trial is shown not to be feasible. Should the main trial not be feasible, we will publish the study materials, and ensure the relevant communities know that the main trial is not feasible and why that is the case. Should the main trial be feasible we will submit an outline proposal to deliver that study to the NIHR Public Health Research programme.

Regardless of the results, we will feed back our findings to study participants, schools, and local authorities. We will engage our project advisory group of foster carers, Virtual School and local authority staff, care experienced young people, and mental health experts in this process. We will present the feasibility trial results – making clear that this was not an efficacy trial of the intervention – at appropriate conferences (co-presenting with our care-experienced peer researcher), and via a Rees Centre webinar and submission to an appropriate journal outlet, such as *Child and Family Social Work*, on an open-access basis.

Further outputs from the proposed project would include a peer-reviewed journal article, and collaboration with other projects in this call on a journal special edition. Non-technical articles will also be written for Children & Young People Now and the general media, as well as a short PDF briefing posted on the websites of the Rees Centre and NIHR CLAHRC East of England. Young people, foster carers and teachers who sit on the project advisory group will be invited to work with researchers on these pieces.

### 5.1 Anticipated Impact

The main role of this project is to establish whether the main trial can be done, and investigate parameters which may inform the design of that trial. Any benefits for the public can only follow after that trial has delivered its results.

The key beneficiaries will be: young people in care; foster carers; social workers; designated teachers and other school staff; Virtual School Heads; local authority managers; policy-makers and voluntary organisations. The young people in the study will benefit directly from being involved in a process that: a) identifies earlier, and in their daily contexts, the difficulties they are experiencing and support needed to address them; and b) documents their experiences and perspectives in order to influence future support. Pupils who share a learning environment with these children will also benefit, as they are likely to see a reduction in classroom disruption.

Our assessment package focuses not only on emotional well-being but also children's social relationships with peers. Besides the immediate benefits, existing knowledge about the longer-term benefits of social networks suggests this will therefore have long-term effects on children's life chances. Information will be collected about levels of loneliness, leisure and social activities, and qualities of their best friendships. The feedback provided to key adults on this information will help to identify opportunities for support with building and maintaining peer relationships, which research indicates can help children to develop resilience and self-esteem.

The project provides potential for change by enabling professionals to gather an holistic picture of children's well-being and resilience. Children's individual profiles will inform decision making in care planning and individual educational planning meetings. Early identification of the risk of potential mental health difficulties and the specific factors that might predict their emergence will permit the targeted allocation of resources (for example, using a portion of the Pupil Premium Plus grant to fund low-level interventions that help to develop social skills to improve peer relationships, or specific therapeutic interventions to reduce a perceived need for control).

Finally, this study will benefit academics by providing an holistic picture of maltreated children's well-being across the home and school contexts, as understood by multiple informants. The proposed research provides opportunities to further develop and strengthen the interdisciplinary research networks both within the research team and between the team and other interested researchers nationally and internationally.

### **5.2 Further research**

Subject to meeting the progression criteria in the feasibility study, we will submit an application to NIHR for an RCT of STrAWB. This would involve a larger number of participants (using the sample size calculations from this study), across more local authorities. As part of the RCT, we would plan to describe, evaluate, and ultimately provide guidance on the ways in which the needs identified from the STrAWB assessment can be translated into effective intervention/support approaches.

## **6. Project management and governance**

The principal investigator (PI) will hold overall responsibility for the project, including submission of required progress reports to funders, deliverables, financial statements and the correct use of funds. Co-investigators will provide support to the study in relation to their specific areas of expertise. A study management group, comprised of the PI, Project Manager, and Research Fellows will hold (bi-weekly) conference calls, and will be joined by other members of the project team on a monthly basis.

The Project Advisory Group (PAG; which includes Virtual School staff, foster carers and care-experienced young people) will meet once each school term (in person or virtually, using team meeting software), to discuss the progress and to make plans for the next steps. All study materials (information sheets and consent forms, surveys, interview schedules, and activity monitoring sheets) and outputs (reports and presentations) will require the group's approval.

Progress will also be monitored by a Study Steering Committee (SSC), which provides supervision of the project on behalf of the Sponsor and the Funder. This committee will meet a minimum of 3 times during the course of the study, and will report on the progress of the study and its adherence to the protocol. It will also provide oversight on any ethical issues relating to the study.



## **7. Ethics / Regulatory Approvals**

The project will comply with the Economic and Social Research Council's research ethics framework, and will be conducted according to principles outlined in the British Psychological Society Code of Ethics and Conduct [[www.bps.org.uk/what-we-do/ethics-standards/ethics-standards](http://www.bps.org.uk/what-we-do/ethics-standards/ethics-standards)] and the British Educational Research Association Ethical Guidelines for Educational Research [[www.bera.ac.uk/guidelines](http://www.bera.ac.uk/guidelines)]. It has been reviewed by and receive ethical clearance through the Social Sciences Division Research Ethics Committee at the University of Oxford (approval references R62926/RE001 to R62926/RE003), and will go through any local authority research governance requirements. Since more than three local authorities will be involved, it will also undergo scrutiny from the Association of Directors of Children's Services Research Group, which considers both the ethical issues of the research and the practical implications for its members.

Key stakeholders have been involved in the development of the foster care and school strands of the project, and will continue this input through meetings with the PAG of Virtual Schools, care-experienced young people, foster carers and specialists in the mental health of CLA. Ethical considerations have formed a key part of the team's previous discussions, and will continue to be monitored throughout the project, including through the SSC.

### **7.1 Informed consent**

Participants will be recruited via local authorities and Virtual Schools. The person with parental responsibility for looked-after children within the local authority will give consent for all eligible children to participate, subject to the agreement of their carer and the child themselves. Information sheets and opt-in consent forms for the trial will be distributed to the child's designated teacher and the foster carer(s). Where the local authority deems it necessary, birth parents will also be provided with an information sheet on the study and, as appropriate, a consent form for the child's participation. The purpose of the study will be explicitly stated and contact details of the research team provided. The foster carer and Designated Teacher will give consent for their own participation, and the foster carer will collect additional consent from the child. The information sheets for children explain that they do not have to take part and to tell their key adult(s) if they do not want to. Verbal assent will also be sought from all children taking part before completing the assessments, and all participants (children and adults) will be reminded of their right to ignore individual questions or to withdraw completely from the study at any time.

We acknowledge that children may feel pressured to take part in the study. This may be exacerbated by the knowledge that their carers have opted in on their behalf. Foster carers will be provided with a script to go through with the child, which reiterates (a) their right to decide not to take part, even after starting; and (b) their right to skip any questions they do not want to answer. Similarly, participating adults will also be assured of their right to decline or withdraw from the study. All parties will be assured that no penalty – academic, professional, or otherwise – will result.

### **7.2 Risks to participants**

We will not raise with young people any sensitive issues associated with pre-care experiences or reasons for entry to care. Measures will be completed at their own pace and in the familiar

environment of their home, reducing the likelihood of distress or discomfort. We will ensure that school staff, foster carers and social workers are aware of the content of the assessments and can monitor those young people taking part in the project, so that any indication of distress in young people can be responded to using their standard support strategies (e.g. school counsellor). Participating carers and teachers will be asked to record any such incidences, or any other adverse events related to the trial. Participants will be told that if the risk of serious harm to a young person emerges through what has been disclosed in a questionnaire or during the training, a local authority manager will be informed.

As part of the monitoring process, participating carers and teachers will also be asked to record any adverse events (AEs) or serious adverse events (SAEs) occurring during the study, and whether these are related to the trial. Children's social workers will be made of any AEs and SAEs, and these will be added to the risk register. Any examples of AEs or SAEs will be discussed in the PAG and SSC as they might influence future planning.

### ***7.3 Anonymity and confidentiality***

The project does not permit anonymity, since feedback on the needs of children in the intervention arm is an integral part of the process.

If the information reported in the assessments suggests a clinical need in a child, the reviewing mental health expert will discuss this with the child's foster carer and social worker in order to facilitate an appropriate referral.

All possible steps will be taken to ensure confidentiality for participants, and identifying details will be omitted from reports. Participants will be allocated identification codes on receipt of signed consent forms, and these will be used in place of names on all study measures.

Confidentiality boundaries will be agreed by researcher/trainer and trainees at the beginning of each training session with all trainees. Should details emerge during the training to indicate possible health or safety concerns about individual children, the researcher/trainer will discuss concerns with a designated senior staff member within each local authority at the end of the session.

### ***7.4 Data management***

All processes for the management of data in this study will comply with the requirements of the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, as set out in the University of Oxford's Guidance on Data Protection and Research.

The file showing the link between participants' names/contact details and their identification codes will be stored separately from consent forms and interview data on the University server and will only be accessible by members of the research team.

Feasibility study interviews and a proportion of the feedback sessions will be recorded using an encrypted voice recorder. Paper data will be stored in locked filing cabinets in a lockable room; electronic data will be stored on a secure university server, in a folder that is accessible only to members of the research team. Any transfer of data between institutions in the research team will use only anonymised files, and will be done using an encrypted email, via the secure 'Egress' email service, or using the University of Sussex's cloud-based Box system, which is also GDPR-compliant and allows for secure sharing of data with external collaborators.

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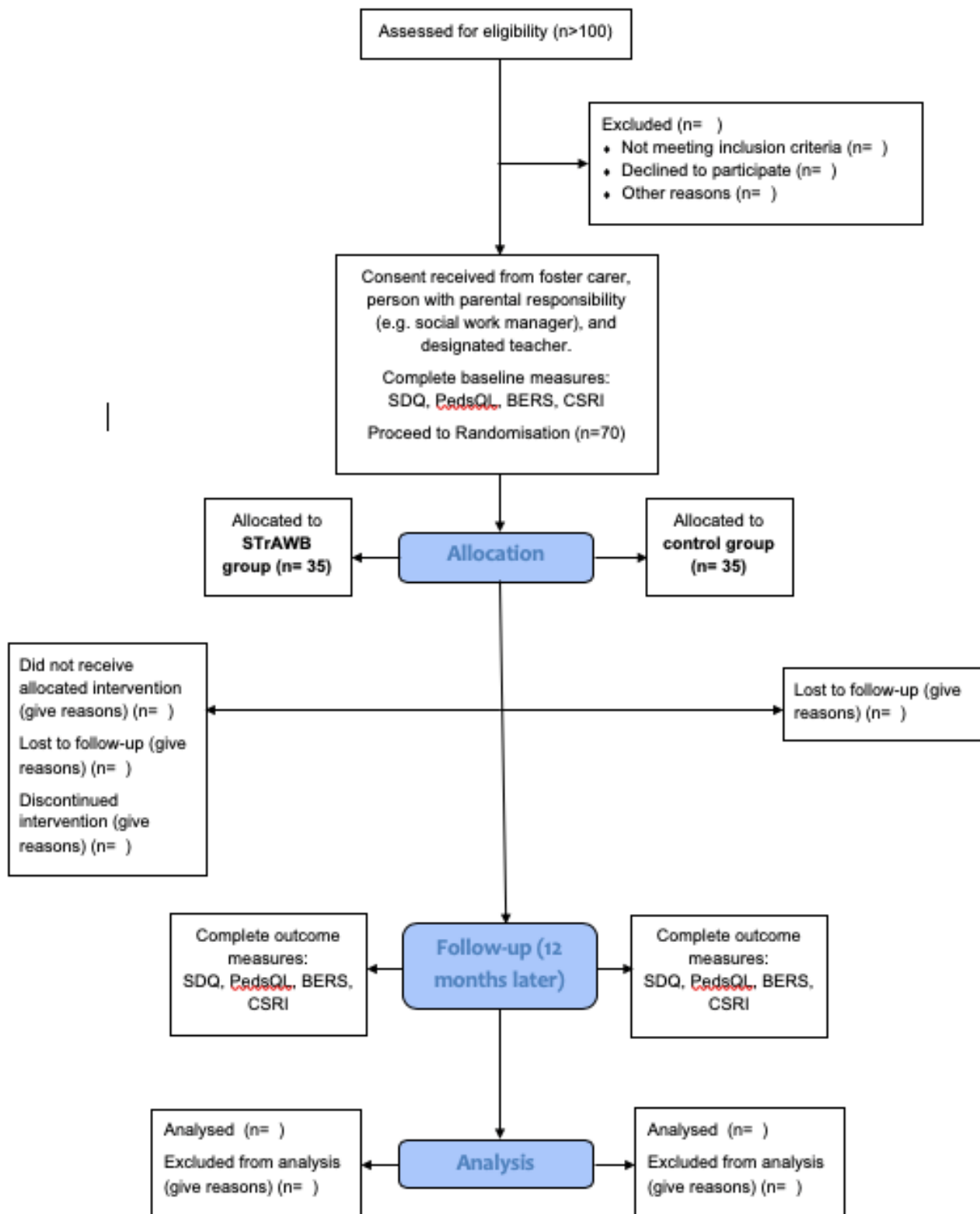
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## Appendix A: STrAWB flow diagram



## Appendix B: STrAWB logic model

