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A randomised feasibility study of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities (ZF-SEND).

PROTOCOL VERSION NUMBER 1.1 15/07/2021

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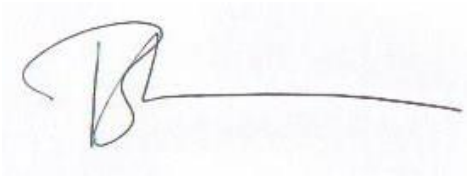
REC ref:	**UOB Ethics: ERN_20-0262**
ISRCTN ref:	**ISRCTN83610691 Study of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities**

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the relevant trial regulations, GCP guidelines, and SOPs.

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

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

Chief Investigator:		
Name: Dr. Biza Stenfert Kroese	**Signature** 	**Date 15/7/21**

General Information This protocol describes the "A randomised feasibility study of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities" clinical trial, and provides information about the procedures for entering participants into the trial. The protocol should not be used as a guide, or as an aide-memoire for the treatment of other participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial. Problems relating to the trial should be referred, in the first instance, to the Chief Investigator.

Contact details – Chief Investigator & Co-Investigators

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Study Co-ordination:

This protocol has been developed by the ZF-SEND Study Management Group (SMG).
For **all queries** please contact the ZF-SEND team through the main study email address. Any clinical queries will be directed through the Study Manager to either the Chief Investigator or Co-Investigators.

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Randomisations:

Randomisation
See Section 14.1.

Serious Adverse Events:

SAE reporting
Where the adverse event meets one of the serious categories, an SAE form should be completed and submitted to Biza Stenfert Kroese within 24 hours of becoming aware of the event (See section 13 for more details). Contact details: B.Stenfert-Kroese@bham.ac.uk

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Glossary of abbreviations

AE	Adverse Event
BILD	British Institute of Learning Disabilities
CA-SUS	Child and Adolescent Service Use Schedule
CF	Consent Form
CHU-9D	Child Health Utilities (9 Dimensions)
CI	Chief Investigator
CRF	Case Report Form
CTR	Centre for Trials Research
CTU	Clinical Trials Unit
CU	Cardiff University
DM	Data Management
EQ-5D-Y	Euro-Qual-5 Dimensions Youth version
GCP	Good Clinical Practice
HE	Health Economics
IC	Informed consent
ICH	International Conference on Harmonization
ID	Intellectual Disability
IEC	Independent Ethics Committee
ISRCTN	International Standard Randomised Controlled Trial Number
MAMS	Me and my School
NASEN	National Association for Special Educational Needs
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality control
QL (QoL)	Quality of Life
QUALY	Quality Adjusted Life Year
R&D	Research and Development
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UoB	University of Birmingham
UP	Usual Practice
ZF	Zippy's Friends

1 Amendment History

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

Amendment No. *(specify substantial/non-substantial)*	**Protocol version no.**	**Date issued**	**Summary of changes made since previous version**

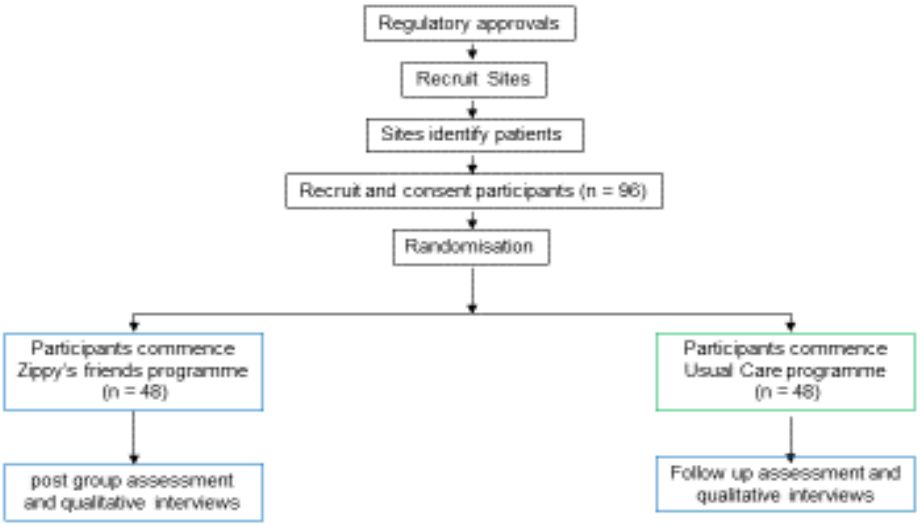
2 Synopsis

Short title	A randomised feasibility study of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities.
Acronym	ZF-SEND
Development phase	Feasibility
Funder and ref.	PHR Project NIHR 129064
Study design	2 arm cluster-randomised feasibility study
Study participants	Children attending special educational needs schools aged 9 – 11 years and their parents.
Planned sample size	96 children (48 per arm).
Planned number of sites	12 schools (8 in England and 4 in Scotland) in total comprising six per arm.
Inclusion criteria	SEND schools: • Firm commitment to the research and have agreed to be randomly allocated to either the intervention or the UP arm (either delayed or no access to ZF SEND) of the study. • They should have pupils with ID. • Be able to identify two teachers who consent to taking part and who are willing to deliver the ZF SEND intervention over one academic year to a group of children with ID. Child research participants: • Administratively defined with ID (learning disability/difficulty in UK services terminology) by virtue of attending a SEND school/unit in England or Scotland. • Schools will identify prior to randomisation at least one class of children in the age range 9-11 years to receive intervention. Parent participants: • Biological, step-, adoptive parent or foster carer or adult family caregiver of the children receiving the ZF SEND intervention or allocated to the UP arm of the research. • Having a level of English language enabling (verbal) completion of outcome measures.
Exclusion criteria	SEND schools: • Delivering other manualised classroom interventions designed to address mental health, well-being, or emotional literacy. Child participants: • No parental assent to participate in the research (although this would not exclude the child from the intervention). • Unable to assent to the MAMS assessment or to communicate using English (and adaptations to meet their communication needs cannot be put in place in the classroom setting). Parent participants:

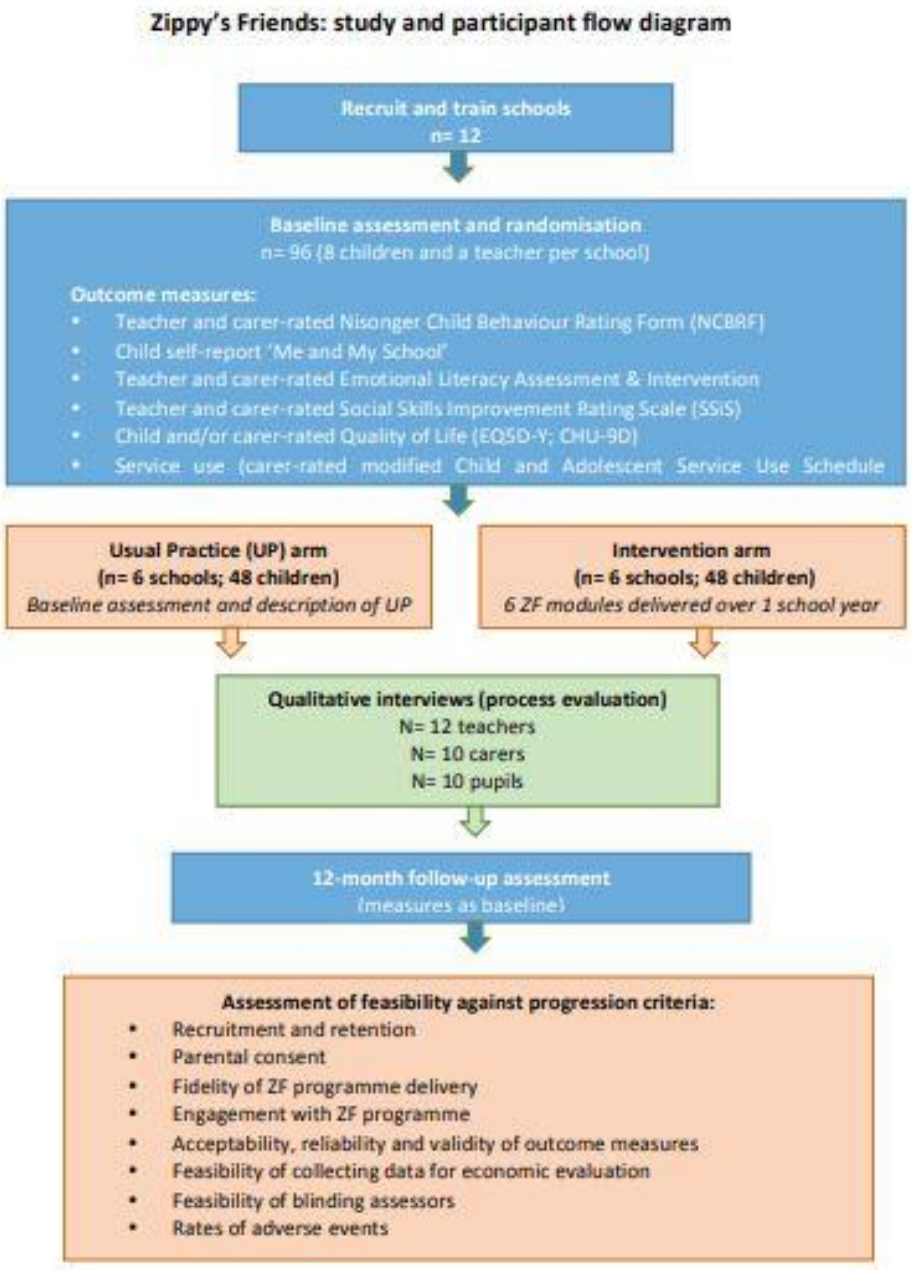
	• Current child protection concerns relating to the child at the point of recruitment or the family are reported by the school to be in a state of current crisis. • Insufficient command of the (spoken) English language to complete the outcome measures or lacking capacity to give informed consent
Intervention duration	Twenty four, 45-minute sessions delivered at a rate of twice per week during school term time.
Follow-up duration	12 months post randomisation
Planned study period	26 months
Primary objective	To determine the feasibility of conducting a future controlled study to establish the impact of ZF SEND on mental health, behaviour/emotional/social functioning and quality of life, and its cost- effectiveness (economic evaluation).
Secondary objectives	i) A process evaluation to consider recruitment and ii) To investigate the validity and reliability of the self-report measure of mental health ('Me and my School' (MAMS).
Primary outcomes	Primary feasibility outcome data on recruitment and retention; fidelity and acceptability of intervention delivery
Secondary outcomes	i) To understand what constitutes education as usual for emotional literacy in special schools for children with ID. ii) The psychometric properties of the MAMS.
Intervention	Zippy's Friends is a manualised, classroom-based programme that aims to develop children's repertoire of coping skills and their ability to adapt those coping skills to various situations. ZF consists of 6 modules: Feelings, Communication, Making and Breaking Relationships, Conflict Resolution, Dealing with Change and Loss, and Coping

3 Study summary & schema

3.1 Study schema



3.2 Participant flow diagram



3.3 Study lay summary

Why this is important:
Children with intellectual disability (ID) have difficulties with learning and coping on their own. They need help with everyday tasks and because of their disability they can become easily stressed and upset and develop long-term mental health problems. Guidelines that have been published recently for people with ID and mental health needs stress the importance of emotional literacy (the ability to understand, express and manage your own feelings) for mental health but as yet there are no suitable

evidence-based programmes to teach emotional literacy to children with ID attending schools for children with special educational needs and disabilities (SEND).

The intervention:

Zippy's Friends (ZF) is a programme that is already used widely (and is shown to be effective) in mainstream schools. Our team has adapted ZF so that it can be taught to 9-11 year old children in SEND schools. ZF is designed to help them deal with social and emotional problems and teach skills to help them cope better with and prevent mental health problems. Parents are sent materials that can be used to prompt the children to use the skills they have learned at school in their own home. The research plan: We plan to include 12 SEND schools/units in our study. Six schools will be asked to use ZF in at least one of their classes over a school year and at least 2 classroom teachers per school will be trained and supported to run the ZF programme. Six schools will provide their standard teaching programmes only; they are called the control group. To allow for a fair test of whether the ZF programme works, chance (rather than researchers or school staff) will decide which schools are put into ZF or the control group. Teachers, parents and children of all the schools will be asked to fill in questionnaires to measure any resulting changes. The most important of these focus on the mental health and behaviour of the children. Other questionnaires are designed to pick up changes in the children's social skills, emotional literacy, quality of life and how they use health, social and education services.

This will be a feasibility study to determine the willingness of schools to take part in ZF or to be in the control group, if ZF is delivered as planned, and if the questionnaires are suitable for measuring the effectiveness of ZF. We will also interview some of the teachers, parents and children and ask them about what encouraged them to take part in the research, and what got in the way of this and about positive and difficult experiences of ZF.

4 Background

Why is this research important?

Intellectual disability (ID) is characterised by an IQ below 70 and associated deficits in adaptive functioning, arising before the age of 18, and is estimated to affect 1.4% to 2% of the UK population [1]. Children with ID are 4-5 times more likely to have a mental health disorder compared to other children and children with ID account for 14% of all children with mental health problems [2]. Their parents, especially mothers, are also more likely to report psychological problems and these health inequalities for children with ID and their parents emerge early in the child's life [2].

Social exclusion and poverty are more likely to be experienced by young people with ID, along with other negative life experiences such as health issues, abuse and bereavement as well as having fewer friends than other children. These biological, psychological, and environmental factors increase their risk of developing mental health difficulties [2]. At least half of children with ID are victimized, rejected or mistreated by peers [3] and 75% of students with ID, compared to typically developing peers, have lower social competence [4] and lower levels of emotional literacy and coping skills which further increases their risk of developing mental health difficulties [5]. These early negative experiences have long-term consequences as young people with mental health difficulties are more likely to have further negative life experiences and unequal life chances as they progress to adulthood [6].

Access to specialist mental health support poses challenges and less than 30% have access to such services [7]. Thus, children with ID and their parents face significant health inequalities and problems gaining access to appropriate and timely services.

There is compelling and consistent empirical evidence that social-emotional competencies can be taught and that these competencies lead to positive and significant improvements in mental health

and well-being, behaviour, and academic achievement [6]. Given this evidence, interventions are needed that aim to protect and improve the mental health and resilience of children with ID. Despite higher prevalence rates of mental health problems in children with ID [2] and research demonstrating a link between emotional literacy and mental health in adults and adolescents in the general population (see page 2 below), there has been limited research that has examined this link between emotional literacy and mental health in children and young people with special educational needs and disability (SEND).

The findings of our early (uncontrolled) pilot work [5] suggest that an adapted school-based intervention (a programme called Zippy's Friends introduced in SEND schools - ZF SEND) is acceptable to and valued by teachers, with some promise of improvements in mental wellbeing, social interactions and problem solving in children with ID. It is therefore important to establish in a controlled and systematic manner whether a school-based emotional literacy intervention such as ZF can be effective in protecting and improving the mental health and resilience of children with ID.

Before such research is conducted, a feasibility study is required to investigate whether ZF SEND can be delivered successfully to small groups of children by SEND teachers in a classroom setting, and whether it would be feasible to conduct a definitive RCT of the effectiveness and cost-effectiveness of ZF SEND.

Conceptualisation of emotional literacy

Emotional literacy has been defined as *'…the ability to perceive accurately, appraise and express emotion, the ability to access and/or generate feelings when they facilitate thought, the ability to understand emotion and emotional knowledge; and the ability to regulate emotions to promote emotional and intellectual growth*' [8]. Bar-On's [9] model of emotional literacy is the most comprehensive and inclusive conceptualisation of this construct, including an array of emotional, personal, and social abilities and skills that influence an individual's ability to cope effectively with environmental demands and pressures. The key factors involved in this model include intra-personal capacity (the ability to be aware and understand one's emotions and to express one's feelings and ideas), interpersonal skills (the ability to be aware of, understand and to appreciate others' feelings as well as to establish and maintain mutually satisfying and responsible relationships with others), adaptability (the ability to verify one's feelings with objective external cues and accurately size up the immediate situation, to alter one's feelings and thoughts with changing situations, and to solve personal and interpersonal problems), stress management strategies (the ability to cope with stress and to control strong emotions such as anger), and motivational and general mood factors (the ability to be optimistic, to enjoy oneself and others, and to feel and express positive feelings).

Evidence for the positive effects of improving emotional literacy on mental health

Emotional literacy skills have been shown to be associated with resilience to mental health problems [10]. When individuals have a broad repertoire of coping skills they are considered to having 'coping flexibility' and recent research [11] has shown that having such flexibility is associated with positive short and long-term outcomes. Studies on coping distinguish between strategies which focus on decreasing the negative feelings a person has after a difficult or stressful situation ('emotion-focused coping') and those which attempt to improve or change the situation ('action-focused coping'). Emotional literacy is associated with (and ZF addresses) both these types of coping strategies.

Research findings suggest that high emotional literacy reduces stress, improves self-esteem and reduces rates of emotional difficulties later in life. A meta-analysis conducted in 2010 [12] which includes adult and adolescent participants (from the general population) found evidence that higher emotional literacy is linked to better mental health. A more recent study [13] also suggests that emotional literacy predicts mental health in adolescents (without intellectual disabilities) and concludes that teaching emotional literacy is an effective preventative intervention, as emotional literacy was a significant predictor of psychological wellbeing and adjustment.

Zippy's Friends, a school-based intervention designed to enhance emotional literacy

Zippy's Friends for mainstream schools has been extensively evaluated in a number of studies in and outside the UK [14-18].

An early (2010) systematic review found support for the effectiveness of ZF for children in mainstream schools, improving coping skills and increasing emotional vocabulary and positive behaviours [19]. The review identified four controlled studies, conducted between 2000 and 2010. Subsequently, research published in 2010 [15] on the effect of ZF on the emotional wellbeing of 523 primary school children in 'disadvantaged' schools in Ireland found a significant positive effect of ZF on emotional literacy, with significant increases in the intervention group's scores for self-awareness, self-regulation, motivation, empathy and social skills. More recently in 2014 [18], the authors reported that the significant increase in emotional literacy in the intervention group was maintained at 12-month follow-up. A large randomised controlled trial with 1483 7-8 year old children in Norway [17] also found ZF to have a significant positive impact on coping and mental health outcomes.

Schools have an important role to play in helping to identify mental health difficulties. Early detection and intervention is key, so that children get the support they need, when they need it [6]. The UK Government's Green Paper 'Transforming Children and Young People's Mental Health Provision' (2017) proposes a new joint working approach between schools and the NHS to help children and young people live fulfilling and happy lives [20]. NICE [21] recommends that priority should be given to those children most at risk of mental health problems.

A systematic review [22] concludes that schools promoting positive mental health and help children to cope with negative life experiences can create psychological resilience. This review shows interventions to have positive effects on outcomes including mental health, social, emotional and educational factors for families, children and communities; with the most effective interventions including skills-teaching, liaison and education of teachers and parents, involvement in the community, continuity of interventions starting with young children, long term whole-school approaches, adaptations to the curriculum and a focus on positive mental health.

However, other than the small pilot study carried out by ourselves [5] (with no control condition and no recording of feasibility outcomes), we could find no trials of whole class or school based mental health interventions for children with ID and/or for special schools. Thus, an evidence inequality exists and research on early school-based interventions designed to improve social/emotional functioning and mental health is needed urgently for children with ID.

Summary

In brief, the research questions (presented in section 5 below) are based on the following:

- The construct of EL has been shown to be a distinct and moderating factor of how life stress affects mental health and wellbeing
- Teaching EL in primary schools is an effective way to promote positive mental health and help children cope with negative life experiences, resulting in better mental health in later life
- EL is underemphasised in the SEND curriculum and mainstream EL programmes (except ZF SEND) do not have SEND adaptations
- NICE recommends help should be given to those most at risk of mental health problems
- Lack of investment in mental health promotion in primary schools, particularly SEND schools, has significant costs for society
- There is an identified need for SEND adapted EL programmes in special schools

4.1 Rationale for current study

We propose to conduct a feasibility study including random allocation of schools, and incorporating a process evaluation and nested study within a trial (SWAT). The overall aim of the proposed feasibility study is to examine whether ZF SEND can be delivered successfully to small groups of children by SEND teachers in a classroom setting, and whether it would be feasible to conduct a later definitive RCT of the effectiveness and cost-effectiveness of ZF SEND. If the Study Steering Committee concludes that it will be feasible to conduct a later definitive trial, the information gathered from the feasibility study will be used to inform a protocol for a definite trial.

5 Study objectives/endpoints and outcome measures

The key aim of this study is to examine whether ZF-SEND can be delivered successfully to class groups of children in educational settings, and in particular whether it would be feasible to conduct a later definitive RCT of the effectiveness and cost-effectiveness of ZF-SEND.

5.1 Primary objectives

To determine the feasibility of conducting a future controlled study to establish the impact of ZF SEND on mental health, behaviour/emotional/social functioning and quality of life, and its cost-effectiveness (economic evaluation).

5.2 Secondary objectives

i) A process evaluation to consider recruitment and retention (schools, child participants and their parents), assess intervention delivery fidelity and examine factors influencing implementation, including fidelity, blinding, mechanisms of impact and context. As part of the process evaluation interviews will be conducted to explore how children, parents and teachers experience the intervention and what constitutes education as usual (usual practice, or 'UP') for emotional literacy in special schools for children with ID. ii) To investigate the validity and reliability of the self-report measure of mental health ('Me and my School' (MAMS);) and its relationship with other (proxy report) measures of mental health and behaviour. iii) To establish what is currently delivered as UP for emotional literacy in SEND schools/units for children with ID. A survey of 20 SEND schools/units (including the 6 control schools/units) will be conducted to describe UP and a sample of teachers, head teachers and parents will be interviewed for this purpose.

5.3 Primary outcomes measure(s)

The feasibility questions to be addressed in the proposed research are the following:

1. ***Recruitment of schools/children/parents***: What are the most effective recruitment pathways to identify SEND schools? What recruitment rate for parents can be achieved? What are the characteristics of schools and families of children with ID approached, screened and recruited?
2. ***Recruitment of schools and teachers***: Can sufficient schools and teachers be recruited to run up the ZF SEND programme over one academic year? What factors influence schools' willingness to take part in the research? Can sufficient teachers be recruited and trained?
3. ***Acceptability of research design***: Are schools and parents willing to be randomised within the context of a RCT? Do they prefer a design with delayed access to ZF SEND in the Usual Practice arm, or will they accept Usual Practice with no access to ZF SEND? How does the offer of delayed access to ZF as part of Usual Practice influence recruitment and retention of schools and pupils?
4. ***Fidelity of implementation***: Can teachers deliver ZF SEND with a high degree of fidelity to the programme manual? What are the key barriers/ facilitators for successful implementation of ZF SEND and how does this vary across different school contexts?
5. ***Adherence***: What proportion of children with ID in the intervention arm schools complete the ZF SEND programme?
6. ***Retention***: What proportion of schools, children and parents/carers are retained in the research study up to the 12-month post-randomisation follow-up?
7. ***Usual practice***: What does usual practice consist of for the support of well-being on a class-wide curriculum basis for children with ID in special schools? How is usual practice different from the programme content of ZF SEND? Does the offer of delayed access to ZF SEND as part of Usual Practice alter what is offered as part of Usual Practice in the year following randomisation?
8. ***Estimation of parameters needed to definitive sample size calculation:*** What are the estimated standard deviation, intracluster correlation coefficient, average cluster size, and coefficient of variation of cluster size for the SDQ at 12-months post-randomisation?
9. ***Feasibility of outcome measures***: Do children, teachers and parents complete the outcome measures for the study?
10. ***Evidence of harm***: Is there evidence on the basis of the outcome measures that the ZF SEND programme results in harm, in which case progression to a full trial would not be recommended.
11. ***Design and methods for health economic analysis***: What is the feasibility of collecting resource use and health related quality of life data for parents and the child with ID? What sources of unit costs for potential resource consequences are appropriate, and how much primary costing research will be required for a later definitive trial? What is the most appropriate approach for measuring and valuing child, family and school outcomes for incorporation into a subsequent trial-based economic evaluation?

A qualitative study will contribute information for many of the above questions and be a part of a mixed methods process evaluation with quantitative data on recruitment, retention and fidelity. The qualitative data will provide information about the experiences of the child participants, their parents and teachers.

5.4 Secondary outcomes measure(s)

Health-related and social outcomes

Proposed outcome measure

The Strengths and Difficulties Questionnaire (SDQ) [24] Total Difficulties score as reported by teachers and parents is planned as the primary outcome for a future main trial. The SDQ total difficulties score includes 20 behavioural and emotional problems items (five each for hyperactivity, conduct problems, emotional problems, peer problems). The SDQ is a mental health screening questionnaire used extensively in UK child mental health settings and in research. The SDQ has also been used in research with children with intellectual disabilities in the UK [25], and maintains good psychometric properties with this population including associations with psychopathology scores from the Developmental Behaviour Checklist (a measure that has four times the number of items, but was developed specifically for children with intellectual disability and validated against clinician-rated psychopathology judgements).

Other outcomes (likely to be secondary outcome measures in a definitive RCT) have been chosen based on: experience in research with children with intellectual disabilities, brevity but with good psychometric properties, and match to the key domains of the Logic Model. Outcomes will include:

- Prosocial behaviour score from the SDQ as reported by teachers and parents – the SDQ also contains five pro-social behaviour items contributing to a pro-social behaviour score

- Me and My School (MAMS) [27], a self-report measure of mental health difficulties for young children. We will use the adapted administration version of this questionnaire [28].

- Emotional Literacy Assessment and Intervention (EL) [29] a proxy report measure (teachers and parents) consisting of 5 sub-scales: Self-awareness; Self-regulation; Motivation; Empathy; Social skills

- Health-related quality of life for children measured using proxy report versions of EQ5D-Y [30] and CHU-9D [31] completed by parents

- Service use as reported by parents using a modified version of the Child and Adolescent Service Use Schedule (CASUS; [32])

- The Nisonger Child Behavior Rating Form teacher version [33]– we will use 30 of the 66 problem items from this rating questionnaire that was adapted for use with children with intellectual disability. Factor analysis of the problem items as rated by teachers led to six sub-scales: conduct problems, insecure/anxious behaviour, hyperactive behaviour, self-injurious/stereotypic behaviour, self-isolated/ritualistic behaviour, and irritable behaviour. We will use three of these sub-scales only as secondary outcomes – those in terms of face validity that do not replicate the domains measured by the SDQ: self-injurious/stereotypic behaviour, self-isolated/ritualistic behaviour, and irritable behaviour

6 Study design and setting

Design

A 2-arm cluster feasibility trial of Zippy's Friends (ZF) programme adapted for SEND schools/units, with clear progression criteria and incorporating a process evaluation. Partnership for Children will train and supervise teachers. A sampling frame of potentially eligible schools will be drawn up and the order in which they will be approached will be determined. Following this, these schools will be allocated at random to information sheets describing a study where Usual Practice either does or does not offer delayed access to ZF SEND. Following recruitment, enrolment of pupils, and collection of baseline data, six special schools will be randomised to receive training in ZF SEND and implement it for one academic year; six schools will be randomised to usual practice (UP).

Blinded researchers will assess school-related well-being by interviewing children; teacher and parent-reported data will not be blinded; the statistician will remain blind to allocation prior to analysis. On-line randomisation will utilise minimisation with a random element, balanced by size of school.

What is currently delivered as UP for emotional literacy in SEND schools/units for children with ID will also be established. A survey of 20 SEND schools/units (including the 6 control schools/units) will be conducted to describe UP and a sample of teachers, head teachers and parents will be interviewed for this purpose. Following the completion of data collection, those schools recruited through the route of delayed access to ZF SEND will be offered the programme as delivered by Partnership for Children.

The nested SWAT will explore the acceptability of two different study designs. One where Usual Practice does not come with the offer of delayed access to ZF SEND, and one where it does. The aim of this SWAT will be to explore the extent to which offer of a 'waitlist' comparator influences recruitment and retention of schools and pupils and modifies what is delivered as Usual Practice during the one-year post-randomisation follow-up period. The findings from this SWAT will be used to inform the design of the subsequent large-scale effectiveness study.

Study setting/context

Twelve SEND schools will be recruited in England (8) and Scotland (4) by the research team. Recruitment will take place directly by contacting SEND schools/units in each Local Authority and through Local Authority and Head Teacher committees and meetings. We will also ask third sector organisations (especially our partner organisations NASEN and BILD) to advise on recruitment strategies. The recruitment methods draw on the successful recruitment routes from the pilot study and also the research team's experience of conducting other research in SEND schools. The intervention will be delivered in schools by the teaching staff.

Recruitment and study duration

It is anticipated that twelve schools will be recruited in the Summer term starting in April 2021 Classes will be identified within those schools and on average 6-10 children and their carers recruited into the study within six weeks of the school electing to take part. Following baseline data collection, those schools allocated to the intervention will deliver it across the 2021/2022 academic year. The study will conclude in 2023.

6.1 Risk assessment

A Study Risk Assessment has been completed to identify the potential hazards associated with the study and to assess the likelihood of those hazards occurring and resulting in harm. This risk assessment includes:

- The known and potential risks and benefits to participants
- How high the risk is compared to normal standard practice
- How the risk will be minimised/managed

This study has been categorised as a low risk, where the level of risk is comparable to the risk of standard care. A copy of the study risk assessment may be requested from the Study Manager. The study risk assessment is used to determine the intensity and focus of monitoring activity.

7 Site and Investigator selection

This study will be carried out at 12 participating sites within the UK. Occasionally during the study, amendments may be made to the study documentation. The Study manager will issue the site with the latest version of the documents as soon as they become available. It is the responsibility of the Study Manager and CI to ensure that they obtain local relevant approval for the new documents.

8 Participant selection

Participants are eligible for the study if they meet all of the following inclusion criteria and none of the exclusion criteria apply. All queries about participant eligibility should be directed to the Study Manager before randomisation/registration.

8.1 Inclusion criteria

The study population will consist of children with ID attending SEND schools in years 5-6 (ages 9-11).

Inclusion criteria for SEND schools:

- The SEND schools to be included in this feasibility study must have firm commitment to the research and have agreed to be randomly allocated to either the intervention or the UP arm (either delayed or no access to ZF SEND) of the study.

- They should have pupils with ID and be able to identify two teachers who consent to taking part and who are willing to deliver the ZF SEND intervention over one academic year to a group of children with ID.
- The teachers must also be willing to complete a 1-day training session, to receive supervision from Partnership for Children and to complete the study records, be video recorded and participate in a qualitative interview post intervention.
- Where teachers consent to participating in the study but not to having ZF SEND sessions video-recorded, alternative ways to assess fidelity will be explored, e.g. self-report or through a member of the research team observing sessions with the head teacher's and teacher's consent.
- The schools which host ZF SEND must have the resources to support the study and must be willing to free up the teachers for training and supervision.

Inclusion criteria for child research participants:

- Administratively defined with ID (learning disability/difficulty in UK services terminology) by virtue of attending a SEND school/unit in England or Scotland.
- Schools will identify prior to randomisation at least one class of children in the age range 9-11 years to receive intervention.
- A member of the research team will initially discuss the study and inclusion criteria with teachers from the SEND schools. They will describe the communication skills required of the children to participate in the study and provide some examples of tasks similar to those used in the ZF intervention and measures to check that potential child participants are likely to have the cognitive and communication skills required to give informed consent, engage with the intervention and complete the outcome measures.
- Teachers will be asked to introduce the intervention to their class as a whole even though some children may not have sufficient communication skills to engage and benefit from a group intervention.

Inclusion criteria for parent research participants:

- Biological, step-, adoptive parent or foster carer or adult family caregiver of the children receiving the ZF SEND intervention or allocated to the UP arm of the research.
- Having a level of English language enabling (verbal) completion of outcome measures. Note that reading skills are not required. Able to provide informed consent.

8.2 Exclusion criteria

Exclusion criteria for SEND schools:

- Delivering other manualised classroom interventions designed to address mental health, well-being, or emotional literacy.

Exclusion criteria for child research participants:

- No parental assent to participate in the research (although this would not exclude the child from the intervention).
- Unable to assent to the MAMS assessment or to communicate using English (and adaptations to meet their communication needs cannot be put in place in the classroom setting).

Exclusion criteria for parent research participants:

- Current child protection concerns relating to the child at the point of recruitment or the family are reported by the school to be in a state of current crisis.
- Insufficient command of the (spoken) English language to complete the outcome measures or lacking capacity to give informed consent to take part in the research.

Specific diagnoses and any comorbid conditions will be recorded but not used as a basis for inclusion/exclusion. This will include the level of ID; the presence of any identifiable genetic syndrome; any physical health, sensory or motor conditions and any behavioural, emotional or mental health conditions (including Autism Spectrum Conditions and ADHD).

9 Recruitment, Screening and registration

9.1 Participant identification

Recruitment of Schools

The initial approach for participation in the study will be to schools, through our partners NASEN, BILD or other contacts through national and local Special Educational needs forums in Scotland and England to advertise and promote the research. Our partners will also use their personal knowledge of head teachers and deputies. Schools will be provided with an information sheet describing the study including the process of randomisation to intervention or a control group. One of two different information sheets will be provided to different schools at random which describes whether they will be offered the chance to participate in the Zippy's Friends programme if they are assigned to the control group or not.

The schools will be provided with the inclusion criteria for the project and will be asked to select class groups that meet the inclusion criteria and teachers who can be trained to provide the intervention within the school. Teachers will be given information about the project, again these will differ depending on whether they are offered the intervention if assigned to the control group or not and asked if they wish to have training in delivering the Zippy's friends programme. If the teachers agree to deliver the programme the schools will then send out information and assent forms to parents on behalf of the research team asking them to **assent to** the research**.** If parents do not assent to their

child taking part in the research then the child will not take part in any of the research processes but they will continue to receive the Zippy's Friends programme as this is considered to be a normal part of the curriculum. As part of the process evaluation, a subgroup of parents who assent to the project will be approached to take part in an interview study for the process evaluation. They will be provided with information and consent forms that relate to this aspect of the project. Children will be provided with information about the project and given the opportunity to assent to the project.

9.2 Screening logs

A screening log of schools will be kept centrally by the research team. Logs of all ineligible and eligible but not consented/not approached will be kept at each site so that any biases from differential recruitment will be detected. Logs should not contain identifiable information.

9.3 Recruitment rates

A total of 12 schools will probably be recruited, exactly when recruitment takes place will depend on the course of the COVID 19 epidemic. Each school will have on average 8 eligible pupils for the study.

9.4 Informed consent

Schools

Schools will be approached via NASEN, BILD or other contacts through national and local Special Educational Needs forums or public lists in Scotland and England. Two different information sheets will be provided to different schools at random which describes the project, process of randomisation and whether they will be offered the chance to participate in the Zippy's Friends after the research programme if they are assigned to the control group or not. Informed consent will be gained from the Head Teacher of each school that wishes to participate in the research.

Teachers

Once Head Teachers have consented to participate, they will ask members of their teaching staff to take part in the project who will also be given information about the project depending on which arm of the study they are in and asked to provide their consent. Teachers will be asked to consent to running the intervention programme, completing assessments, providing reports on teaching

sessions, having sessions observed and recorded on either paper, audio or video and being interviewed by research staff. Teachers will suggest appropriate classes to participate in the study.

Parents

To protect potential participants' (pupils' and parents') privacy, the school will disseminate information sheets, 'right to object' forms and consent forms to parents/carers on the researchers' behalf. Materials will be distributed using the schools' usual communication system. For instance, some schools will use electronic 'parent mail' and others may use paper newsletters. We will request that school uses alternative methods of contact to inform any parents/carers who do not receive information using normal communication systems. We will also ask the school to display trial information on school wide forums e.g. school bulletins to ensure that all parents/carers of KS2 children are informed about the trial and have been provided with an opportunity to complete a 'right to object' form. Potential participants will be able to keep the information sheet which will provide details of who to contact if they require further information about the research or bullying. The right of the potential participant to refuse to participate without giving reasons will be respected.

A subgroup of parents will also be invited to take part in qualitative interviews designed to support the process evaluation. They will be provided with information sheets and consent forms for this specific aspect of the study.

Parental consent for children to receive the "Zippy's Friends" programme is not required as the programme falls within usual curriculum and other institutional activities (BPS, code of human ethics 2010, p.17). Parents will be able to withdraw the collection of their child's data from the trial evaluation by completing an 'opt-out' form'. The opt-out form and accompanying parent information form will detail the aim of the project, the nature of data being collected, how it will be collected, confidentiality, the potential benefits of the research and names and contacts for future inquiries. Opt-out models are standard practice in trials of this nature, as the University is relying on its public task in the public interest to undertake this research (Article 89 of the GDPR and Schedule 2, part 6 of the Data Protection Act 2018). Opt-out forms will be provided at least 2 weeks prior to the baseline survey to allow adequate time to consider the information and be compliant with the new data protection legislation regarding transparency (compliant with GDPR and DPA18 requirements).

Children

Verbal consent and completed assent forms will be gained from all children and young people before they take part. Implicit non-consent of all participants will be tested at every opportunity. Any participant who shows verbal or non-verbal signs of not wanting to take part in the study will be given the opportunity to withdraw from the study and testing will be stopped immediately. It will be made clear to all participants that if any information is disclosed that suggests the child may be at risk of harm from others or may hurt themselves or someone else, then their class teachers and/or safeguarding leads will be informed, and safeguarding procedures undertaken if necessary, to ensure their safety. Teachers will also be notified by the researcher if a child's scores indicate that they may have significant mental health difficulties, and teachers can take appropriate action which may involve informing the child's parents if necessary.

9.5 Registration and Randomisation

9.5.1 Randomisation

A sampling frame of potentially eligible schools will be drawn up and the order in which they will be approached will be determined (focussing on geographical areas nearest the study centres). After the order for approaching schools has been determined, schools will be allocated at random to information sheets describing a study where UP either does or does not offer delayed access to ZF SEND and approached consecutively. This randomisation process will be carried out using random permuted blocks. Following recruitment, enrolment of pupils, and baseline data collection, schools will be randomised to ZF SEND or UP using minimisation, with a random element set at 80% to maintain the integrity of the allocation process. Allocations will be balanced on the basis of school size (fewer than 100 pupils total vs 100 or more pupils - informed by special school sized reported by the DfE [35]), and study site (England/Scotland). An online password protected randomisation system will be developed and implemented by staff in the Centre for Trials Research. Randomisation will be carried out by a member of staff who will not be involved in recruitment, data collection, or analysis.

10 Withdrawal & lost to follow-up

10.1 Withdrawal

Participants and their parents have the right to withdraw consent for participation in any aspect of the study at any time. The participants' care will not be affected at any time by declining to participate or withdrawing from the study.

If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from. These aspects could be:

- Withdrawal from intervention
- Partial withdrawal from further data collection (e.g. some questionnaires/ assessments)
- Complete withdrawal from further data collection
- Withdrawal of permission to use data already collected

If consent for video recording is withdrawn or refused then there are three options. Either no researcher recording/observation takes place, or with consent, a researcher could observe the lesson and audio record it or make notes. If consent is withdrawn during the study then we can provide the teacher in question with the choice as to whether we can use any sessions already recorded or for them to be withdrawn from the project.

The withdrawal of participant consent shall not affect the study activities already carried out and the use of data collected prior to participant withdrawal, unless withdrawal is requested by participants. The use of the data collected prior to withdrawal of consent is based on informed consent before its withdrawal.

10.2 Lost to follow up

Members of the research team will keep record of the number of participants lost to follow up and note the reasons for dropping out of the study using a spreadsheet. This will be done by maintaining close liaison between the research team and the schools and the parents. The intervention is part of the general classroom activities. If pupils withdraw from the lesson or are absent for some lessons, the teachers are asked to record reasons why. All outcome measures will continue to be collected so that attendance/non-attendance can be used as a factor in the data analysis.

11 Study Intervention

11.1 Zippy's Friends

Experimental intervention

Zippy's Friends is a manualised, classroom-based programme that aims to develop children's repertoire of coping skills and their ability to adapt those coping skills to various situations. ZF consists of 6 modules: Feelings, Communication, Making and Breaking Relationships, Conflict Resolution, Dealing with Change and Loss, and Coping (see Table 1 for a brief description of the lesson objectives).

Children who are able to think of a larger number of coping skills are better equipped to use them more often in daily situations. Research has confirmed that children generally like to participate in ZF activities that teach them to cope, and that they experience improvements in their quality of life and relationships after participating in these activities [18]. It is important to note that teaching children how to cope does not mean teaching them that one coping strategy is good and another bad. The goal is rather to use a problem solving approach and to teach children to come up with different ways of dealing with social and emotional problems and to self-evaluate. By seeing how characters in the ZF stories cope in different ways, and by experiencing this for themselves in role-plays and other activities, children become better equipped to choose effective strategies. When they successfully handle one difficult situation, they increase their abilities to adapt to future situations, and this can improve their self-esteem, feelings of competence and general well-being.

In mainstream schools, teachers and teaching assistants deliver the programme during routine classroom time over a 24-week period with 45-minute weekly sessions (4 sessions per module). Whilst the mainstream programme is designed for children aged 5-7yrs, our pilot study [5] indicates that the SEND programme caters best for an older age range (9-11). Teachers are advised to take a flexible approach to make the programme 'age appropriate' (including consideration of mental/emotional age).

The ZF SEND programme closely aligns with the mainstream programme but has additional resources and supplements developed by Partnership for Children in consultation with SEND teachers to cater for children with a wide range of abilities. The SEND programme provides a selection of alternative activities (around five for each of the mainstream activities), and the stories have been adapted at four different ability levels using WIDGIT symbols. The activities include craft sessions, completion of worksheets, role-plays, discussion and use of metaphors.

Completion takes longer owing to the increased complexity of running the programme with SEND pupils and to allow for shorter sessions, repetition of sessions and a range of extra activities. SEND teachers deliver two 45-minute sessions a week to cater for this and to ensure adequate time for completion within one academic year. All children in at least one Year 5/6 class in each school will receive the intervention, or will be present and included whenever possible. One aim of the study is to examine the extent of engagement of children with varying levels of ID in the intervention. Parents will be sent materials throughout the programme that can be used in the home to reinforce and generalise the principles of ZF SEND.

Prior to running the programme, teachers attend a 1-day training course organised by Partnership for Children. Teachers will also receive support and supervision through direct observation of one session and attendance at two support meetings. Additional support is available upon request of the teacher who can contact the Partnership for Children mentor at any time for advice and guidance. The programme materials, training and support are provided by Partnership for Children.

At least two teachers (or a teacher and teaching assistant) in each of the six intervention schools will be selected by their senior management to implement the ZF SEND programme. Each school will identify at least one class to take part in the research– either a Year 5 or Year 6 class (or a combined group of Year 5/6 children in smaller schools). The teachers who are trained to deliver the intervention will typically be the class teachers. All training and support will be provided by Partnership for Children.

Table 1 Lesson objectives for ZF SEND 6 module programme

Module 1 – Feelings To improve children's abilities to recognise different emotions and to identify strategies to cope with them.	
Session 1 **Feeling sad – feeling happy**	To improve children's abilities to recognise feeling sad and to identify ways to cope.
Session 2 **Feeling angry or annoyed**	To improve children's abilities to recognise feelings of anger and annoyance and to identify ways to cope with these feelings.
Session 3 **Feeling jealous**	To improve children's abilities to identify jealousy and to learn ways to cope with this feeling.
Session 4 **Feeling nervous**	To improve children's abilities to recognise feeling nervous and to identify ways to cope with difficult feelings.
Module 2 – Communication To improve children's abilities to communicate their feelings and listen to other people.	
Session 1 **Improving communication**	To improve children's abilities to recognise effective and ineffective ways of expressing how they feel.
Session 2 **Listening**	To improve children's abilities to listen to other people.
Session 3 **Who can help us?**	To improve children's abilities to ask for help.
Session 4 **Saying what we want to say**	To improve children's abilities to communicate their feelings and listen to other people.

Module 3 – Making and breaking relationships To improve children's abilities to make friends and to cope with rejection and loneliness.	
Session 1 **How to keep a friend**	To improve children's abilities to keep their friends.
Session 2 **Dealing with loneliness and rejection**	To improve children's abilities to cope with loneliness and rejection.
Session 3 **How to resolve conflicts with friends**	To improve children's abilities to resolve conflicts with their friends.
Session 4 **How to make friends**	To improve children's abilities to make friends.
Module 4 – Conflict Resolution To improve children's abilities to resolve conflicts.	
Session 1 **How to recognise good solutions**	To increase children's abilities to recognise characteristics of a good solution.
Session 2 **Dealing with bullying**	To improve children's abilities to deal with situations involving bullying.
Session 3 **Solving problems**	To improve children's abilities to resolve conflicts, particularly when they are angry.
Session 4 **Helping others resolve conflicts**	To improve children's abilities to help others resolve conflicts.
Module 5 – Dealing with change and loss To improve children's abilities to cope with change and loss.	
Session 1 **Change and loss are part of life**	To increase children's understanding that change and loss are part of normal everyday experiences.
Session 2 **Coping with death**	To increase children's understanding that death is a normal part of life, and to improve their abilities to cope with situations involving grief and loss.
Session 3 **Visit to a graveyard**	To improve children's abilities to cope with change and loss.

Session 4 **Learning from change and loss**	To improve children's understanding that change an loss can have positive effects.
Module 6 – We cope To improve children's abilities to use a variety of coping strategies in different situations.	
Session 1 **Different ways to cope**	To improve children's abilities to use different coping strategies.
Session 2 **How to help others**	To improve children's abilities to help others cope with different situations.
Session 3 **Adapting to new situations**	To improve children's abilities to apply their coping skills to new situations.
Session 4 **Celebrating together**	To review what we have learned during *Zippy's Friends* and to celebrate together.

Comparator intervention

The comparator intervention will be Usual Practice (UP) - participants will attend their usual classes as well as other services they may be engaged with outside school hours, but without receiving ZF SEND. Because Partnership for Children is the only organisation in the UK offering training in the intervention, there is no possibility of contamination within the control schools during the research. The six schools randomly allocated to the control arm of the study are to receive the same assessment phases as the six intervention schools but will not implement ZF SEND until after 12-month follow-up data collection is completed (whether they are in the 'no access' or 'delayed access' sub-group of the UP arm). Records will be kept to monitor group activities and check for potential overlap between UP and ZF SEND contents. UP may include any services (mainstream and specialised) provided to families and their children with ID as a part of an Education Health and Care Plan in England or equivalent in Scotland. We will not include schools/units already delivering a manualised emotional literacy intervention at time of baseline assessments. All other receipt of psychological support or emotional literacy teaching in both arms of the research will be recorded. This will be done using a summary sheet provided for teachers and parents. This will be further explored in qualitative interviews with control arm teachers and parents (see section 8). In addition, services receipt data (see 6.3) collected at baseline and 12 months will be used to fully describe UP.

11.2 Compliance

School staff who deliver ZF SEND will be trained in its delivery through successful completion of a one day training course. Qualitative interviews with school staff will examine the perceived quality and value of the training, and we will also conduct interviews with two trainers to explore the extent to which the training was delivered as intended. Fidelity of implementation of ZF SEND sessions in the classroom will be evaluated via self-rating by teachers for all sessions using intervention checklists. This will provide data on: the proportion of sessions delivered; whether each activity within a session is completed/partially completed; any factors which disrupted/aided delivery of

activities. In each school we will video record a sample of sessions, which include both children and teachers, this information, the information collected will be coded using the teacher checklist, and an additional tool that covers quality of delivery, any adaptations made to the materials during delivery, class dynamics and contextual issues, with space for free text qualitative observations. Where video recording is not possible (e.g. schools refuse permission) we will use either audio recording or direct observation by a researcher. Rates of agreement to allow video recording, teacher completion of fidelity checklists, and feedback from teachers and research staff will enable us to refine procedures for assessing fidelity within a future definitive trial. Interviews with school staff will be used to explore: adherence to the ZF SEND manual and key influences on implementation; any additions/adaptations made to the manualised content and the reasons for these; engagement in the intervention by pupils and their parents/carers; the perceived value of ZF SEND, and its fit with existing school policies/priorities; staff views on intervention aims and the mechanisms through which it operates. Data on factors affecting implementation across schools, and variations in fidelity/adaptions will enable us to refine the intervention logic model, and to understand key influences on implementation fidelity.

12 Study procedures

12.1 Assessments

Participants will be recruited, assessed at baseline and randomised in the 2021 summer term. The intervention (ZF-SEND) to commence in September of the 2021 Autumn term and continue into the summer term until end the summer term 2022. Post-intervention assessments and qualitative interviews will be completed from May to July 2022. Therefore, all participants (children, teachers and parents/carers) are involved in this study for approx. 12 months.

Children will be seen twice (baseline and post-intervention) for an assessment session with one of the RAs. They will complete the 'Me and My School' questionnaire and two quality of life measures (EQ5D−Y and CHU−9D) with the help of the RA.

Teachers will be asked to complete (for each child participating in the research) three questionnaires: the Nisonger Child Behavior Rating Form (NCBRF), the Strengths and Difficulties Questionnaire (SDQ) and the Emotional Literacy Assessment. They are required to complete these questionnaires during the two assessment periods (baseline and post-intervention) and can choose whether to complete on-line or paper copies. The presence of an RA is not required. Each set of questionnaires (per child) takes approx. 20 minutes to complete and teachers are paid £10 for each set completed.

Parents/carers will be asked during each of the two assessment periods (baseline and post-intervention) to complete one set of questionnaires for their child which consists of 5 questionnaires: the parent/carer-rated Strengths and Difficulties Questionnaire (SDQ), the Emotional Literacy Assessment, the two parent/carer−rated Quality of Life (EQ5D−Y and CHU−9D) measures and the Service use parent/carer−rated modified Child and Adolescent Service Use Schedule (CASUS). Parents will be given various options for how to complete these measures: 1/paper copies sent by post; 2/ on-line; 3/ telephone interview with RA; 4/ face-to-face interview with RA. Each set of questionnaires takes approx. 40 minutes to complete.

A subsample (N=10 -12) of all three participant groups (children, parents/carers and teachers) will be interviewed as part of the process evaluation (see section 12.2 below) during the follow-up assessment phase (autumn term 2021).

Figure 1 presents the schedule of assessments.

RAs will be trained by the project manager and the CI in interviewing skills (for both quantitative and qualitative components of the assessment) and will have an opportunity to practice their skills before the data collection commences. The measures have been used in earlier studies and have been included because they have been shown to be reliable, valid and acceptable for each of the three participant groups.

Compliance with the intervention (Zippy-SEND manual) and attendance rates of each child participant will be part of the process evaluation (see section 12.2 below).

Figure 1. Schedule of enrolment, interventions and assessments[1]

Procedures			**Visits**	
	Screening	**Baseline** **May 2021-July 2021**	**Treatment= 24 sessions** **Sept .2021-June 2022**	**Post Treatment** **May 2022-July 2022**
Informed consent	✓			
Demographics (all groups of participants).		✓		
Eligibility assessment	✓			
Randomisation		✓		
Delivery of intervention			✓	✓
Compliance recording			✓	✓
Teacher and parent/carer-rated Strengths and Difficulties Questionnaire (SDQ)		✓		✓
-Teacher−rated Nisonger Child Behavior Rating Form (NCBRF)		✓		✓

[1] Taken from the HRA CTIMP protocol template (2016).

Teacher and parent/carer−rated Emotional Literacy Assessment		✓		✓
-Service use (parent/carer−rated modified Child and Adolescent Service Use Schedule; CASUS		✓		✓
-Child and parent/carer−rated Quality of Life (EQ5D−Y; CHU−9D)		✓		✓
-Child self−report 'Me and My School'		✓		✓
Qualitative interviews with teachers, parents and pupils				✓
Adverse event assessments				

12.2 Process Evaluation

The process evaluation will examine five key aspects of the feasibility of conducting a definitive trial of ZF SEND: 1) intervention recruitment and adherence; 2) intervention implementation; 3) intervention mechanisms, including receipt and acceptability; and 4) the feasibility of implementing ZF SEND within a definitive RCT; 5) description of what constitutes usual practice for emotional literacy in SEND schools.

We will use recent MRC guidance as a framework for the process evaluation to describe implementation processes, refine the intervention logic model through examining intervention mechanisms, and consider the role of school context in shaping intervention implementation and mechanisms. Data from the process evaluation will address key study questions and aid assessment of trial progression criteria.

A mixed methods approach will be utilised. Quantitative methods will be used to assess recruitment rates/patterns (schools, children and parents/carers) and intervention fidelity. Qualitative interviews with children, school staff, parents/carers in intervention arm schools will examine implementation processes, intervention mechanisms, the role of contextual factors, and interrogate patterns in the quantitative data. Interviews will also explore key aspects of the acceptability and feasibility of a future definitive trial of ZF SEND.

Recruitment of schools and families and intervention adherence

Data on recruitment and retention of schools and families to the study (numbers approached, numbers agreeing to take part, and key patterns) will be examined. In intervention schools, staff delivering ZF SEND will be asked to record attendance of pupils at each session to assess adherence. In each intervention school we will interview at least two members of staff (one class teacher involved in the delivery of ZF SEND and a member of the senior management team) to explore their views on trial recruitment methods (acceptability of randomisation, perceived burden on schools) and factors affecting pupil attendance in ZF SEND sessions. We will also ask a member of the senior management team in each control school to participate in a qualitative interview to explore these issues. Factors affecting recruitment and retention will also be explored in interviews parents and carers (see below).

Intervention implementation (addresses study feasibility Q4)

School staff who deliver ZF SEND will be trained in its delivery through successful completion of a one day training course. Qualitative interviews with school staff will examine the perceived quality and value of the training, and we will also conduct interviews with two trainers to explore the extent to which the training was delivered as intended. Fidelity of implementation of ZF SEND sessions in the classroom will be evaluated via self-rating by teachers for all sessions using intervention checklists. This will provide data on: the proportion of sessions delivered; whether each activity within a session is completed/partially completed; any factors which disrupted/aided delivery of activities. In each school we will video record a sample of sessions, which will be coded using the teacher checklist, and an additional tool that covers quality of delivery, any adaptations made to the materials during delivery, class dynamics and contextual issues, with space for free text qualitative observations. Where video recording is not possible (e.g. schools refuse permission) we will use either audio recording or direct observation by a researcher. Rates of agreement to allow video recording, teacher completion of fidelity checklists, and feedback from teachers and research staff will enable us to refine procedures for assessing fidelity within a future definitive trial.

Interviews with 10 -12 school staff will be used to explore: adherence to the ZF SEND manual and key influences on implementation; any additions/adaptations made to the manualised content and the reasons for these; engagement in the intervention by pupils and their parents/carers; the perceived value of ZF SEND, and its fit with existing school policies/priorities; staff views on intervention aims and the mechanisms through which it operates. Data on factors affecting implementation across schools, and variations in fidelity/adaptions will enable us to refine the intervention logic model, and to understand key influences on implementation fidelity.

Intervention mechanisms, including receipt and acceptability

Interviews will be conducted with: a) about 10 – 12 pupils from intervention schools (two per school); and 10 –12 families from intervention schools (this may include a mix of single and joint interviews if two parents/carers wish to participate together). Interviews with pupils will explore their experience of participating in the intervention, acceptability of intervention content and activities, understanding of key intervention messages, and the extent to which they have used strategies taught. Parents/carers will be asked about whether intervention content taught at school has been used and/or discussed at home with their child, and the extent to which schools have involved them in the intervention (e.g. by sending information home).

Feasibility of implementing ZF SEND within a definitive RCT

Data on school/family recruitment, intervention fidelity and factors shaping implementation processes and intervention mechanisms will be used to help inform assessment of the feasibility of implementing ZF SEND within a definitive trial, including systems and structures needed for recruitment, training and implementation. Qualitative interviews (with school staff in both trial arms, pupils and parents/carers in the trial arm will also explore: a) acceptability of the trial design and randomisation, including preferences regarding the use of a wait list control; b) schools' perception of the burden associated with trial data collection, particularly questionnaire completion by pupils; and c) the acceptability and feasibility of questionnaire measures and fidelity assessment.

Usual Practice

All intervention and control group schools will be asked to complete an interview describing UP in relation to emotional literacy and mental health promotion activities at two time points (prior to baseline data collection and at 12-month follow-up). Qualitative interviews with school staff in intervention and control group schools will explore the provision of usual practice in more detail.

13 Safety reporting

In the unlikely event that any SAEs related to the intervention or research procedures should occur, the CI is responsible for ensuring that all site staff involved in this study are familiar with the content of this section. All SAEs must be reported immediately (and within 24 hours of knowledge of the event) to the study team. SAEs will be assessed at all follow-up time points, and intervention delivery staff will be trained to report these directly to the study team at any point during the study. Rates of SAEs by study arm will be reported to the SSC, and if required, to the REC. Additional information about the potential harm of the intervention will be collected through qualitative interviews with all stakeholders.

Interventions such as Zippy's Friends may have side effects for participants or for the classroom as a whole. This will be investigated in the light of any reports.

13.1 Definitions

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical study participant administered an intervention which are not necessarily caused by or related to the Zippy's Friends programme.
Serious Adverse Event (SAE)	Any adverse event that - • Results in death • Is life-threatening* • Required hospitalisation or prolongation of existing hospitalisation** • Results in persistent or significant disability or incapacity • Consists of a congenital anomaly or birth defect • Other medically important condition***

***Note:** The term 'life-threatening' in the definition of serious refers to an event in which the study participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the participants death; it does not refer to an event which hypothetically might have caused death if it were more severe.

**** Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

***** Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

13.2 Causality

The assessment of whether or not an SAE is a consequence of receiving the intervention will be provided by the CI.

Relationship	Description	Reasonable possibility that the SAE may have been caused by the intervention?
Unrelated	There is no evidence of any causal relationship with the intervention	No
Unlikely	There is little evidence to suggest there is a causal relationship with the intervention (e.g. the event did not occur within a reasonable time after administration of the study medication). There is another reasonable explanation for the event (e.g. the participant's clinical condition, other concomitant treatment).	No
Possible	There is some evidence to suggest a causal relationship with the intervention (e.g. because the event occurs within a reasonable time after administration of the study medication). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other concomitant treatments).	Yes
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.	Yes
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.	Yes

13.3 Reporting procedures

Any queries concerning adverse event reporting should be directed to the Study Manager

All SAEs, whether expected or not, should be recorded on the relevant report form and followed up to resolution wherever possible. The CI (or delegated member of the SMG) should sign and date the SAE reporting form to acknowledge that he/she has performed the seriousness and causality

assessments. SAEs should be reported from time of signature of informed consent, throughout the treatment period.

An SAE form is not considered as complete unless the following details are provided:

- Full participant study number
- A Serious Adverse Event
- A completed assessment of the seriousness, and causality as performed by the CI (or another appropriately medically qualified doctor registered on the delegation log).
- Only reports of related and unexpected SAEs should be submitted to the REC. These should be sent within 15 days of the CI becoming aware of the event.

14 Statistical considerations

14.1 Randomisation

A sampling frame of potentially eligible schools will be drawn up and the order in which they will be approached will be determined (focussing on geographical areas nearest the study centres). Following this, schools will be allocated at random to information sheets describing a study where UP either does or does not offer delayed access to ZF SEND and approached consecutively. This randomisation process will be carried out using random permuted blocks. Following recruitment, enrolment of pupils, and baseline data collection, schools will be randomised to ZF SEND or UP using minimisation, with a random element set at 80% to maintain the integrity of the allocation process. Allocations will be balanced on the basis of school size (fewer than 100 pupils total vs 100 or more pupils - informed by special school sized reported by the DfE [35]), and study site (England/Scotland). An online password protected randomisation system will be developed and implemented by staff in the Centre for Trials Research. Randomisation will be carried out by a member of staff who will not be involved in recruitment, data collection, or analysis.

14.2 Blinding

Researchers who are blind to allocation will assess children's well-being by interviewing child participants according to the MAMS procedure (instances of accidental unblinding will be reported). Teachers, parents and child participants will not be blinded due to the nature of the intervention. The statistician will remain blind to allocation up until the point all analyses are completed.

14.3 Sample size

We aim to randomise 12 schools (8 in England and 4 in Scotland) in total and six per arm. Based on the pilot study, we estimate there will be one class/group per school and an average of eight children per class (and therefore eight children per school). We will therefore recruit 96 children in total (48 per arm). As this is a feasibility study, we seek to provide estimates of key parameters for a future trial and have not conducted a formal a priori power calculation. If two-thirds (66.7%) of

schools approached agree to take part (i.e. 12 out of 18 approached), the 95% CI around the percentage can be estimated within +/- 21.8% (i.e. 44.9% to 88.5%). Assuming that we obtain 12 month follow-up data for 75% of children, randomising 96 will allow the 95% CI for retention, to be estimated within +/- 8.7%.

14.4 Missing, unused & spurious data

All analysis will be performed on complete cases. No imputation of missing data will be carried out.

Further detail will be provided in the Statistical and Health Economics Analysis Plan (SHEAP).

14.5 Termination of the study

here will be no formal 'stopping rules' or 'discontinuation criteria' for individual participants, parts of the trial and entire trial. Any decision to terminate the trial will be reached by the SSC in discussion with the study's funder.

14.6 Inclusion in analysis

All randomised participants' data will be included in the analysis.

15 Analysis

15.1 Main analysis

As this is a feasibility study, the analysis will be descriptive in nature. Continuous data will be reported as means and standard deviations, or medians and interquartile ranges, as appropriate. Categorical data will be reported as frequencies and proportions. All data will be reported both overall, per arm, and by setting type. Outcomes will be estimated with their associated 95% confidence intervals. No formal hypothesis testing will take place.

The study will be reported in accordance with the CONSORT extension for randomised pilot and feasibility studies.

Exploratory analysis of outcome measures to be used in the main trial will be based on the ITT principle, and will compare mean scale scores at 12-months between arms by fitting two-level linear regression models, with pupils nested within schools. The model will adjust for baseline scores, region (England or Scotland), and school size. Results will be reported as adjusted mean differences and 95% confidence intervals, focussing on effect sizes and their precision rather than p-values. Intra-cluster

correlation coefficients will be reported with associated 95% confidence intervals, with sources of variation explored using both quantitative and qualitative data.

We will also fit regression models to explore baseline factors associated with intervention receipt and retention in the study at the 12-month follow-up time points. Findings will be reported and may be used to inform study design modifications required in the main trial.

A detailed Statistical Analysis Plan will be written and signed off prior to undertaking any analysis.

15.1.1 Sub-group & interim analysis

No sub-group or interim analyses will take place.

15.2 Qualitative analysis

With appropriate consent, all interviews will be audio-recorded, transcribed fully, and anonymised for analysis. Computer software (NVivo) will be used to manage the qualitative data and transcripts. Thematic analysis will be used to analyse each of the sub-sets of interviews (school leaders, class teachers, trainers, pupils, parents/carers) separately and independently. We will then also use a thematic analysis approach for a qualitative synthesis across the interview sub-groups. Finally, a triangulation exercise will be conducted combining all of the qualitative results with the quantitative data analysis results including an assessment of potential barriers and facilitating factors (gathered from all data sources) that may need to be taken into account in a future definitive trial, including recruitment strategies, implementation fidelity, intervention mechanisms and their interaction with local context. Data collection across the feasibility study will be designed to maximise the potential for triangulation.

Qualitative analysis will follow three stages. First, we will use a coding framework to thematically analyse each transcript. Second, for each identified theme we will summarise and interpret key findings for each group of interviewees (e.g. all data coded to 'recruitment' within teacher interviews). Third, we will compare main findings from each theme for all interviewee groups (e.g. key findings from teachers, parents and pupils on recruitment). No formal synthesis will take place, rather we will compare findings for each interviewee group, using the written summaries of each theme (for each group of interviewees), and where necessary going back to the coded data. Comparison of findings across the multiple interviewee groups will aid completeness of analysis (e.g. where an issue is only covered in one set of interviews) and understanding the degree of alignment across different groups

of participants. Assessment of feasibility of intervention components/implementation and trial procedures will be aided by understanding the extent to which teachers, parents and pupils share a broadly similar perspective on acceptability/feasibility. Where findings across interviews are divergent this will be important in helping us to incorporate the views of different groups, and to identify where we might make changes to these aspects of the trial.

15.3 Health Economics

The health economic component of this study will include two main elements. The first will involve an estimation of intervention costs, including costs of development, training, supervision, and delivery of Zippy's Friends intervention sessions.

The second component will involve assessing the feasibility of collecting data on broader health service utilisation and health-related quality of life of children with ID. For health service use, this will involve modification and testing of an appropriate version of the child and adolescent service use schedule (CA-SUS) to collect data on health service utilisation. We will assess respondents' understanding of the questions and modify the wording or add explanation if anything is unclear. We will also assess the measure's comprehensiveness in capturing all relevant services as testing may identify items which are redundant or important services that have been omitted. For health-related quality of life, we will assess completion rates and item missingness for proxy report versions of generic paediatric quality of life measures EQ-5D-Y and CHU-9D. These measures allow the calculation of Quality Adjusted Life Years (QALYs) and would be used as the primary outcome measure for cost-effectiveness analysis in a subsequent full RCT.

16 Data Management

Source Data is defined as "All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents." There is only one set of source data at any time for any data element, as defined in site source data agreement.

Study data

	CRF	*Encrypted voice recordings*	*SAE data*
Outcome measures	*X*		
Interviews		*X*	
Adverse events			*X*

16.1 Data collection

All outcome data will be entered into a secure, encrypted bespoke online database developed by the clinical trials unit, based on paper or electronic copies of the measures completed by participants. Fidelity checks and data cleaning will be performed as detailed in the data management plan, and according to CTR SOPs (GCP and GDPR compliant). Electronic data will be stored on Cardiff University servers and access will be password protected (restricted only to those who need direct access, who will be provided with individual log-ins). Paper copy forms will be stored in locked filing cabinets at participating sites and destroyed following data entry.

We will aim to make research data available wherever possible and in line with the NIHR position on sharing data, such that the sharing of research data must: protect the confidentiality and privacy of individuals; respect the terms of consent by individuals who are involved in research; be consistent with relevant legal, ethical and regulatory frameworks; and guard against unreasonable costs.

16.2 Completion of CRFs

All assessments and data collection will be completed using either web-based or paper-based CRFs.

Where possible, assessments should be completed using the web-based CRFs. If paper-based CRFs are used, the research assistant will enter these data on a web-based CRF at the earliest opportunity. All outcome measures are completed by participants at baseline and upon completion of the intervention which will be about 12 months follow up post-randomisation. All CRFs will be administered to participants at site by the RA/s.

In accordance with the principles of GCP, the CI is responsible for ensuring accuracy, completeness, legibility and timeliness of the data reported to the CTR in the CRFs. CRF data will be checked for missing, illegible or unusual values (range checks) and consistency over time.

If missing or questionable data are identified, a data query will be raised on a data clarification form. The data clarification form will be sent to the RA by email. The response to the data query should be completed on the data clarification form. Any paper-based CRFs should not be altered.

All answered data queries and corrections should be signed off and dated by the RA at each site. The completed data clarification form should be scanned and returned to the CTR by email. A copy of the original data clarification form should be retained at the participating site along with the participants' CRFs. The CTR will send reminders for any overdue data. It is the participating site's responsibility to submit complete and accurate data in timely manner.
Detailed plans for data entry and handling are located in the study specific Data Management Plan and will be stored in the TMF.

17 Protocol/GCP non-compliance

The Chief Investigator should report any non-compliance to the study protocol or the conditions and principles of Good Clinical Practice to the CTR in writing as soon as they become aware of it.

18 End of Study definition

The end of study is defined as the completion of the follow-up data collection from the final participant. Once the final report has been approved by the study funder, a copy will be sent to the UoB. A summary report of the study will be provided to the REC within one year of the end of the study.
UoB must notify the main REC of the end of a clinical study within 90 days of its completion or within 15 days if the study is terminated early.

19 Archiving

All data will be kept for 10 years in line with CTR Research Governance Framework Regulations for clinical research. This data will be stored confidentially on password protected servers maintained on the Cardiff University Network. Files will only be accessible to researchers responsible for the running of the study and the CI. All procedures for data storage, processing and management will comply with the General Data Protection Regulation 2016. All paper records will be stored in a locked filing cabinet, with keys available only to researchers and the CI. The Study Statistician will carry out the analyses. All essential documents generated by the study will be kept in the Study Master File.

20 Regulatory Considerations

20.1 Ethical and governance approval

Ethical approval for the study was granted by the University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee as the lead research site. Where necessary, additional approvals will be sought from the management/board of participating organisations.

20.2 Data Protection

UoB and the CTR will act to preserve participant confidentiality and will not disclose or reproduce any information by which participants could be identified, except where specific consent is obtained. Data will be stored in a secure manner and will be registered in accordance with the General Data Protection Regulation 2016. The data custodian and the translational sample custodian for this study is the UoB UoB.

20.3 Indemnity

"The University of Birmingham has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage."

"No provision has been made for indemnity in the event of a claim for non-negligent harm"

20.4 Study management

University of Birmingham (UoB) will act as main partner for study. The UoB has/will be delegating certain responsibilities to Cardiff University Centre for Trials Research (CTR), Investigators, host sites and other stakeholder organisations as appropriate in accordance with the relevant agreement that is informed by regulation and study type.

20.5 Funding

This project was funded by the National Institute for Health Research Public Health Research (NIHR PHR) Programme. Cost associated with training, supervision and support for Zippy's Friends delivery will be met by Partnership for Children.

21 Study management

The study will adhere to NIHR guidelines for research governance (including regarding project steering and data monitoring committees) and will be conducted according to Centre for Studies Research (Cardiff University) Standard Operating Procedures (SOPs), study-specific SOPs will be developed as required. The Study Manager will be responsible for day-to-day running and co-ordination of the study.

The Project Team (PT) will meet fortnightly and will include the CI, Statistician, Senior Study Manager, Study Manager, Data Manager and RA/s. The PT will discuss all day-to-day management issues and will refer any key management decisions to the SMG.

21.1 SMG (Study Management Group)

The Study Management Group (SMG) will meet quarterly and will include all investigators, all employed project staff. Representatives from BILD and NASEN who are co-applicants represent PPI interests and provide a direct link to the PPI Advisory group to discuss study progression and key management issues. SMG members will be required to sign up to the remit and conditions as set out in the SMG Charter.

21.2 SSC (Study Steering Committee)

A Study Steering Committee (SSC) will be established and will meet three times during the study. It will comprise of an independent chair with expertise in ID research and in studies in the ID field, and other independent members: Dr Ailsa Russell and Dr Liz Tilly who are expert in ID and education, a statistician, Louise Marston and Amanda Hilton, a parent of a child with special needs. The CI and Study Manager will attend the SSC as observers. The SSC will review the conduct of the study, provide overall oversight and advice through its independent chair. The SSC will also oversee data monitoring

and ethics. SSC. SSC members will be required to sign up to the remit and conditions as set out in the SSC Charter.

21.3 PPI (Public and Patient Involvement)

This protocol and the initial pilot study were prepared in collaboration with Partnership for Children, an organisation that works in schools and trains teachers to promote mental health in children which brings them in close contact with the setting in which this research is planned and as providers of evidence based interventions, they are on the cutting edge of mental health initiatives for children, including children with ID. Their input has enabled us to be aware of the needs of these children, and those of their parents and teachers. NASEN has agreed to coordinate PPI, to include families and family representative organisations and a teacher panel to advise the researchers. Both panels will feed into the Study Management Group (SMG).

The panels will review research procedures and how these may impact on participants with ID. They will consider the role of the teachers and the support they may need to deliver ZF. They will also be involved in considering the findings and implications of the research as well as dissemination activities. Advisory group members will receive appropriate training and support for all activities. Time will be set aside to prepare the advisers for involvement, through timely and accessible sharing of information. They will receive feedback about how their advice has been taken forward to ensure they can see how their contributions have shaped the project. Where their suggestions are not possible to incorporate, feedback will be provided as to the reasons. All members will be paid for their time, their travel costs will be reimbursed, and refreshments and lunch provided as appropriate to the timing of meetings.

Both Partnership for Children and NASEN have commented on drafts of this protocol, which has significantly improved and shaped up our recruitment plans and design of the intervention protocol. In addition, BILD has agreed to be represented on the TSC. They are all enthusiastic about this project and keen to continue to work with us, considering ZF as an excellent way to address the health inequalities of children with ID. They are uniquely placed to support recruitment and they understand and value the purpose, aims, application and dissemination of the project as third sectors organisations which have the well being children with ID at the heart of their mission statements.

Partner collaboration

Partnership for Children have agreed to be the lead intervention partner for this project. They have already identified and set aside a budget for this project. They will oversee the delivery of the ZF programme, will deliver training for teachers and provide supervision and support for them throughout the project. They will also continue to work with our third sector partners NASEN and BILD (both of whom will be represented on the PPI group).

22 Quality Control and Assurance

22.1 Monitoring

The clinical study risk assessment has been used to determine the intensity and focus of central and on-site monitoring activity in the Zippy's Friends study. Low+ monitoring levels will be employed and are fully documented in the study monitoring plan.

Investigators should agree to allow study related monitoring, including audits and regulatory inspections, by providing direct access to source data/documents as required. Findings generated from on-site and central monitoring will be shared with the UoB, CI and CTR.

22.2 Audits & inspections

The study may be participant to inspection and audit by UoB under their remit as UoB.

23Publication policy

All publications and presentations relating to the study will be authorised by the SMG.

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25 Appendices

25.1 Detailed publication plan

Academic: peer review journal publications including the NIHR PHR Journal, conferences, and social

media audiences. Policy makers/commissioners: with Partnership for Children, NASEN and BILD we will design a campaign strategy to raise awareness of ZF in SEND schools, using the results of the research to inform the campaign and promote the final ZF SEND version to ensure accessibility. Service users: The primary beneficiaries of the research will be children with ID who attend SEND schools and their families. Practitioners: SEND teaching staff/managers will benefit, as they will have suitably adapted manualised teaching materials. We will build on the relationships with educational service providers and practitioners in the UK already forged e.g. email list, social media presence, through the Whole School SEND consortium and at project end a dedicated session at the annual SEND conference, 'NASEN Live', followed up with a webinar/webcast for teachers, parents and practitioners/policy makers.

25.2 Logic Model

See additional document.