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Study of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities

Submission date
29/04/2021

Recruitment status
No longer recruiting

Registration date
24/05/2021

Overall study status
Completed

Last Edited
18/11/2026

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
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). Zippy's Friends (ZF) is a programme that is already used widely (and is shown to be effective) in mainstream schools. The study 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. 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. The researchers 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.

Who can participate?
9-11-year-old children in SEND schools

What does the study involve?
The researchers 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 two 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.

What are the possible benefits and risks of participating?
Participants will be helping the researchers to determine the feasibility of delivering Zippy's Friends to children aged 9-11 in SEND schools, which may result in better care for children in this environment in the future. Taking part in the study will mean giving up some time to answer study questionnaires. The researchers do not anticipate any risks in taking part but if a parent or child experiences any problems with the study, they should contact the Study Manager.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
January 2020 to January 2023

Who is funding the study?
National Institute for Health Research Public Health Programme (NIHR PHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

National Institute for Health and Care Research (NIHR)
129064

Protocol serial number
v1.0

Study information

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

Acronym
Zippy's Friends

Study objectives
To determine the feasibility of conducting a future controlled study to establish the impact of a school-based emotional literacy programme (Zippy's Friends) for children with intellectual disabilities (ZF-SEND) on mental health, behaviour/emotional/social functioning and quality of life, and its cost-effectiveness (economic evaluation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/03/2021, University of Birmingham Science, Technology, Engineering and Mathematics Ethical Review Committee (Research Support Group, C Block Dome, Aston Webb Building, University of Birmingham, Edgbaston, B15 2TT, UK; +44 (0)121 414 8825; s.l.cottam@bham.ac.uk), ref: ERN_20-0262

Primary study design
Interventional

Study design
Two-arm cluster-randomized feasibility study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Children attending special educational needs schools aged 9 – 11 years and their parents

Interventions
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 six modules: Feelings, Communication, Making and Breaking Relationships, Conflict Resolution, Dealing with Change and Loss, and Coping. It will be delivered as 24 45-minute sessions at a rate of twice per week during school term time.

The method of randomisation is random permuted blocks. Six schools will be asked to use ZF in at least one of their classes over a school year and at least two classroom teachers per school will be trained and supported to run the ZF programme. Six schools will provide their standard teaching programmes only (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.

The intervention is delivered during routine classroom time over a 24-week period with 45-minute weekly sessions. Follow up is 12 months post-randomisation.

Intervention Type
Behavioural

Primary outcome(s)
1. Recruitment of schools/teachers/children/parents: recruitment rates for schools, teachers, parents and children as recorded by the number who consent to take part by 12 months
2. Acceptability of research design: willingness to be randomised within the context of an RCT measured using interview at 12 months
3. Fidelity of implementation: fidelity to the programme manual measured using a self-rated checklist during the intervention period
4. Adherence: proportion of children with ID in the intervention arm schools completing the ZF SEND programme at 12 months
5. Retention: proportion of schools, children and parents/carers retained in the research study up to the 12-month post-randomisation follow-up
6. Usual practice: definition of usual practice using interviews at 12 months
7. Estimation of parameters needed for definitive sample size calculation: estimated standard deviation, intracluster correlation coefficient, average cluster size, and coefficient of variation of cluster size for the Strengths and Difficulties Questionnaire (SDQ) calculated at 12-months post-randomisation
8. Feasibility of outcome measures: completion of study outcome measures assessed at 12 months
9. Evidence of harm: no evidence on the basis of the outcome measures that the ZF SEND programme results in harm at 12 months
10. Design and methods for health economic analysis: collection of resource use and health-related quality of life data using EQ-5D-Y and CHU-9D for parents and the child with ID at 12 months

Key secondary outcome(s)
Behavioural and emotional problems measured using the Strengths and Difficulties Questionnaire (SDQ) Total Difficulties score reported by teachers and parents at 12 months

Completion date
31/01/2023

Eligibility

Key inclusion criteria
SEND schools:
1. 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
2. They should have pupils with ID
3. Be able to identify two teachers who consent to take 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:
1. Administratively defined with ID (learning disability/difficulty in UK services terminology) by virtue of attending a SEND school/unit in England or Scotland
2. Schools will identify prior to randomisation at least one class of children in the age range 9-11 years to receive intervention

Parent participants:
1. 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
2. Having a level of English language enabling (verbal) completion of outcome measures

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
53

Key exclusion criteria
SEND schools:
1. Delivering other manualised classroom interventions designed to address mental health, well-being, or emotional literacy

Child participants:
1. No parental assent to participate in the research (although this would not exclude the child from the intervention)
2. 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:
1. 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
2. Insufficient command of the (spoken) English language to complete the outcome measures or lacking capacity to give informed consent

Date of first enrolment
01/06/2021

Date of final enrolment
01/08/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Birmingham
Edgbaston
Birmingham
England
B15 2TT

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
Public Health Research Programme

Alternative Name(s)
NIHR Public Health Research Programme, The Public Health Research (PHR), PHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/12/2024	11/12/2024	Yes	No
Basic results			14/03/2024	No	No
Protocol (other)	V1.1	15/07/2020	18/11/2026	No	No
Study website			18/11/2026	No	No
Study website			18/11/2026	No	No