ISRCTN18083947 https://doi.org/10.1186/ISRCTN18083947

Investigating implementation support for the Connect Personal, Social, Health and Economic (PSHE) Programme

Submission date
09/12/2021

Recruitment status
No longer recruiting

Registration date
04/01/2022

Overall study status
Completed

Last Edited
17/12/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Connect PSHE is a well-being programme for primary school pupils, delivered to pupils by their teachers. Connect uses an Acceptance and Commitment Therapy (ACT) model, which is a mindfulness-based behaviour therapy. The programme builds pupils' emotional resilience by engaging them with six key well-being behaviours: connecting with others, challenging oneself, giving to others, exercising, embracing the moment and self-care.
This study aims to find out the best way to support teachers to deliver Connect PSHE for Key Stage 2 (KS2) pupils. This will be done by comparing pupils' well-being outcomes before and after receiving the Connect programme, for two groups. In the first group, teachers delivering the programme will receive the usual level of support. In the second group, teachers delivering the programme will receive additional support from a Connect-trained researcher. Participating schools will be randomly assigned to one of the two groups.

Who can participate?
Pupils from KS2 classes in mainstream, primary schools in North Wales can take part in the study.

What does the study involve?
In January 2022, class teachers will be trained in the delivery of Connect PSHE, who will then deliver the Connect programme to all pupils in the class. The lessons will be delivered every week for two terms. Researchers from the University of Warwick will visit each school twice to collect information from learners – at the beginning and end of the Connect programme. Parents /carers of pupils will be contacted in advance of data collection to gain informed consent.
The first research visit will take place in January/February 2022 and the follow-up visit will take place in June/July 2022. The study will be explained to pupils and they will be informed that they do not have to take part if they don't want to, and they can stop at any time without providing a reason. Pupils will complete two questionnaires, asking about how they feel at school and their general well-being. This will take around 20 minutes. Class teachers will be asked to complete a questionnaire, called the Strengths & Difficulties Questionnaire, about the well-being and behaviour of each of the pupils in their class.

What are the possible benefits and risks of participating?
A benefit of participation is that all pupils will receive Connect PSHE, a well-being curriculum designed to improve pupils' emotional resilience. There are no anticipated risks of participating in this study.

Where is the study run from?
The Centre for Educational Development, Appraisal and Research (CEDAR) at the University of Warwick (UK)

When is the study starting and how long is it expected to run for?
From November 2021 to December 2022.

Who is funding the study?
The Regional School Effectiveness and Improvement Service for North Wales (GwE) (UK).
Connect PSHE will be providing the intervention and training to schools free of charge.

Who is the main contact?
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Contact information

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Study information

Scientific Title
The Connect Personal, Social, Health and Economic (PSHE) programme: a feasibility randomised controlled trial investigating implementation support

Acronym
Connect PSHE

Study objectives
To evaluate pupils' well-being outcomes following the delivery of Connect PSHE with standard training against Connect PSHE delivered with additional support for teachers.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/10/2021, Humanities and Social Sciences Research Ethics Committee (HSSREC) (Research & Impact Services, University House, University of Warwick, Coventry, CV4 8UW UK; +44(024) 765 75732; HSSREC@warwick.ac.uk), ref: 21/21-22

Primary study design
Interventional

Study design
Interventional, parallel-group two-arm cluster-randomized control trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental well-being in primary school pupils

Interventions
Connect PSHE, is a health and well-being programme for primary school pupils, informed by psychological theory and research. The programme is manualised and delivered to pupils by teachers through weekly lessons. Connect is built on the Discover, Noticer, Advisor and Values (DNA-V) model, which is an Acceptance and Commitment Therapy (ACT) model for children. ACT is a mindfulness-based behaviour therapy which seeks to enhance psychological flexibility. The curriculum focuses on building skills in four key areas, to facilitate the development of pupils' psychological flexibility and subsequently improve their well-being outcomes. This is achieved through engaging pupils with six key well-being behaviours: connecting with others, challenging oneself, giving to others, exercising, embracing the moment and self-care.

This feasibility study will evaluate pupils' well-being outcomes following the delivery of Connect with standard training versus Connect delivered with additional support for teachers. Implementation fidelity will also be monitored, as this is established as a key factor for the success of interventions in improving outcomes.

All schools participating in the trial will receive the basic set up training for Connect PSHE (1.5 days). This will constitute:
1. 1 day of online ACT training for teachers. These sessions will be experiential and focused on helping teachers develop personal psychological flexibility
2. A 3 h live webinar on the Connect curriculum and the DNA-V model

All schools will also be able to access the standard level of support for Connect PSHE, which is the online support forum and resources toolbox. Half of the schools in the trial will receive additional support for implementing Connect PSHE. This support will constitute four, half-termly visits of 2 h for each school from a Connect-trained researcher. These visits will involve observations and feedback for teachers and will be conducted in schools. Teachers will also receive two half termly online supervision sessions from the researcher.

Schools will be randomised on a 1:1 basis to deliver the Connect intervention as standard or Connect with additional implementation support to their pupils, for a period of 6 months. Minimisation will be used balance schools between the two arms of the trial based on area /school deprivation (as indicated by the percentage of pupils receiving free school meals), and school size. Randomisation will take place after baseline data collection.

Researchers will visit schools to conduct baseline and follow-up data collection. The data collection will take place in the pupils' classroom, during the school day. Pupils will complete the two well-being measures (Me and My Feelings Questionnaire and How I Feel About My School Questionnaire) on paper, which will take approximately 20 min. Teachers will complete a well-being measure, the Teacher-Strengths and Difficulties Questionnaire, for all pupils in their class; this will be done in advance of the data collection visits, and completed questionnaires will collected on the day by researchers. Teacher-report of intervention fidelity will also be assessed via an implementation checklist.

Intervention Type
Behavioural

Primary outcome(s)
1. Self-reported pupil well-being measured using the Me and My Feelings/Me and My School Questionnaire (Anna Freud Centre) at baseline and follow-up

Key secondary outcome(s)
1. Self-reported pupil well-being measured using the How I Feel About My School (HIFAMS) Questionnaire (Allen et al, 2017) at baseline and follow-up
2. Teacher-reported pupil well-being measured using the Teacher Strengths and Difficulties Questionnaire (T-SDQ) at baseline and follow-up
3. Intervention fidelity measured using a 7-item session checklist completed by teachers after delivering each session of Connect PSHE over the 6 month intervention period

Completion date
01/12/2022

Eligibility

Key inclusion criteria
Key Stage 2 pupils (aged 7-11) at mainstream primary schools in North Wales

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
7 Years

Upper age limit
11 Years

Sex
All

Key exclusion criteria
1. Schools for pupils with special education needs and disabilities (SEND)
2. Schools currently implementing another named health and well-being curriculum or intervention at class or school level

Date of first enrolment
15/11/2021

Date of final enrolment
11/02/2022

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
CEDAR
New Education Building
Westwood Campus
University of Warwick
Coventry
United Kingdom
CV4 7AL

Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Gwegogledd Cymru (GwE) - North Wales Regional School Improvement Service

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the sensitive nature of the data. The data will be entered into an electronic database and stored securely on the University of Warwick M Drive.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	For parents and carers version 1	14/09/2021	17/12/2021	No	Yes