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Feasibility pilot study of refinement of the Learning Together intervention to promote better mental health and wellbeing amongst young people (Learning Together for Mental Health)

Submission date
01/04/2022

Recruitment status
No longer recruiting

Registration date
20/07/2022

Overall study status
Completed

Last Edited
19/11/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Mental health problems such as depression and anxiety now affect about 1 in 6 to 8 young people. The UK government is increasing funding for services to improve young people's mental health. Most of this funding is for services for those with existing problems rather than to prevent such problems in the first place. Making schools more supportive and inclusive is one way to promote mental health and this is the focus of this study.
The researchers have previously evaluated Learning Together (LT), a programme which aimed to reduce bullying in secondary schools. Learning Together provided the following for schools: a report on student needs; training for teachers; an external facilitator who helped schools form an action group of students and staff to make decisions; and social and emotional skills lessons for students. Learning Together was effective in reducing bullying and improving students' mental health. The researchers now aim to modify this programme to increase its focus on mental health, calling it 'LearningTogether for Mental Health' (LT-MH). They will pilot LT-MH for 1 year in four secondary schools in England to see if it is feasible to deliver and acceptable to students and staff. This would help them to decide whether it would be useful to then do a larger study of LT-MH's impacts on mental health.

Who can participate?
Students in years 7-11 (age 11-16 years) at four secondary schools in southern/central England

What does the study involve?
LT-MH will focus on emotional issues, self-esteem, body image, eating problems and self-harm. The researchers will refine the LT programme in collaboration with Place2Be (the charity who will deliver the new programme) and teachers, students and other participants so that:
1. The student needs report focuses on mental health to help schools set priorities
2. The Action Groups focuses on changing school systems and policies to promote mental health

3. The curriculum focuses on mental heath and emotional learning
All four recruited schools will receive the intervention. The duration of the intervention is one school year i.e. 9 months (September 2022 to July 2023). The students will be assessed before the intervention (June 2022) and at follow-up (June-July 2023). There is no additional follow-up.

What are the possible benefits and risks of participating?
Possible benefits to schools and students are improved mental health and wellbeing across the school. Possible risks include the burden on students and staff of participating in the research.

Where is the study run from?
The UCL Great Ormond St. Institute of Child Health (UK)

When is the study starting and how long is it expected to run for?
November 2021 to September 2023

Who is funding the study?
The National Institute of Health and Care Research (NIHR) (UK)

Who is the main contact?
Prof. Russell Viner, r.viner@ucl.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Integrated Research Application System (IRAS)
315114

Central Portfolio Management System (CPMS)
52593

National Institute for Health and Care Research (NIHR)
131594

Study information

Scientific Title
Refinement and feasibility study of the Learning Together to promote mental health and wellbeing in English secondary schools

Study objectives
Refinement phase:
Is it possible to refine Learning Together (LT) to promote mental health wellbeing (to develop Learning Together - Mental Health [LT-MH])?

Feasibility study:
1. What is the feasibility and acceptability of delivery of LT-MH in secondary schools in England?
2. Is progression to a Phase III trial justified in terms of pre-specified criteria?
3. What level of student awareness does the intervention achieve among year-10 students at follow-up?
4. What do qualitative data suggest in terms of intervention mechanisms and refinements to programme theory and theory of change?
5. How do contextual factors appear to influence implementation, receipt and mechanisms of action?
6. Are any potential harms suggested and how might these be reduced?
7. Is an economic evaluation feasible?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/05/2022, UCL Research Ethics Committee (Office of the Vice Provost Research, 2 Taviton Street, University College London, London, UK; +44 (0)20 7679 8717; ethics@ucl.ac.uk), ref: 21179/001

Primary study design
Interventional

Study design
Intervention refinement involving patient and public involvement and engagement and feasibility study

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental health and well-being among children in English secondary schools

Interventions
The present study will be a refinement of the LT trial, that had been previously implemented, and the feasibility of the study will be tested in four secondary schools. In more detail, the LT-MH intervention will include:
1. A needs assessment survey that will focus on mental health and well-being and will produce a guide for schools to assess the prevalence of mental health problems and identify local needs

2. An Action Group that will focus on reviewing and revising school policies and systems to promote mental health and wellbeing, choosing options from a new menu of actions that have previously been shown to work in schools
3. The curriculum element that will be modified to focus on social and emotional learning using an updated curriculum.

There is only one study arm i.e. all four recruited schools will receive the intervention. There is no randomisation. The duration of the intervention is one school year i.e. 9 months (September 2022 to July 2023). The students will be studied at baseline (June 2022; i.e. before intervention) and at follow-up (June-July 2023). There is no additional follow-up.

Intervention Type
Behavioural

Primary outcome(s)
Feasibility and acceptability will be assessed by data collected from the process evaluation (interviews, focus groups, Action Group minutes) across the 1 school year of the intervention, collated at the end of the study (1 year). Lack of feasibility or acceptability will be defined by meeting any one of the following criteria:

1. Intervention feasibility:
1.1. Three or more schools had a response rate lower than 60% in the baseline (needs) survey
1.2. Three or more schools did not have at least three meetings of action groups regardless of quoracy
1.3. Three or more schools had fewer than two staff complete the in-depth training
1.4. Three or more schools completed no locally decided actions
1.5. Three or more schools had fewer than two staff trained in-depth in restorative practice regularly implementing restorative practice
1.6. Three or more schools implemented the curriculum with lower than 50% fidelity
1.7. Three or more schools did not choose any actions from a menu of evidence-based options
2. Intervention acceptability
2.1. Three or more schools had less than half of senior leadership and action group members finding the intervention acceptable
3. Trial feasibility:
3.1. Three or more schools achieved a response rate of less than 60% at follow-up

Key secondary outcome(s)
Secondary outcome measures will include:
1. Indicative primary outcome for a future full trial: Mental health problems will be measured using the total difficulties score of the Strengths and Difficulties Questionnaire (SDQ) at baseline and at 1 year.

Indicative secondary outcomes will include:
1. Subscales of the SDQ including emotional difficulties, conduct problems, peer problems hyperactivity and prosocial score, each measured at baseline and 1 year
2. Wellbeing, measured by the Warwick-Edinburgh Mental Well-being Scale (WEMWBS) at baseline and 1 year
3. Depressive symptoms, measured using the Short Moods and Feelings Questionnaire (SMFQ) at baseline and 1 year
4. Anxiety, measured using the 7-item Generalized Anxiety Disorder (GAD7) scale, at baseline and 1 year

5. Eating behaviour including disordered eating and body image, measured using the Eating Disorders Examination Questionnaire (EDEQ), at baseline and 1 year
6. Self-harm assessed using one question derived from the Health Behaviour in School-aged Children (HBSC) study at baseline and 1 year
7. Bullying (victimization) measured using the Gatehouse Bullying Scale, measured at baseline and 1 year
8. Cyberbullying, assessed using two items adapted from the DAPHNE II questionnaire asking whether the participant was bullied (victim) and/or bullied someone else (perpetrator) through mobile phone use or the internet, at baseline and 1 year
9. Substance use assessed using questions on habitual smoking, drinking and drug use, as used in the original Learning Together Trial, at baseline and 1 year
10. Student report of school climate, assessed using the Beyond Blue school climate scale, at baseline and 1 year
11. Outcomes for the economic analysis will include the following:
11.1. Health-related quality of life assessed using the Child Health Utility (CHU) 9D at baseline and 1 year
11.2. Health service use focusing on mental health service use assessed using the CASUS questionnaire at baseline and 1 year
11.3. Data on the costs of the intervention in terms of staff and facilitator time will be estimated from process evaluation data undertaken across the school year of the intervention (September 2022 to June 2023) including Action Group minutes and interviews with school staff

Completion date
30/09/2023

Eligibility

Key inclusion criteria
Students in years 7-11 (age 11-16 years) in southern/central England

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
11 Years

Upper age limit
16 Years

Sex
All

Total final enrolment
1206

Key exclusion criteria
1. Any students younger than 11 or older than 16 years
2. Schools in any other regions than southern/central England

Date of first enrolment
20/04/2022

Date of final enrolment
31/07/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UCL Great Ormond Street Institute of Child Health
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Sponsor information

Organisation
UCL Great Ormond Street Institute of Child Health

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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 because this is a feasibility study and not powered to identify changes in outcomes.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		15/11/2024	19/11/2024	Yes	No
Protocol file	version 1.2	23/06/2022	26/09/2023	No	No
Statistical Analysis Plan			26/09/2023	No	No