**Learning Together to promote mental health and wellbeing (LTMH) feasibility study
Statistical Analysis Plan - 14 March 2023**

Introduction

Mental health problems such as depression and anxiety now affect about 1 in 6 to 8 young people(1). The UK government is increasing funding for services to improve young people's mental health(2). 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(3). 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 'Learning Together 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.

Study design

This will be a feasibility study in four schools to assess the feasibility and acceptability of delivery of LT-MH and data collection in secondary schools in England.

Sample Size

No formal power calculations have been performed as this is a pilot study and the primary aim is to evaluate feasibility and acceptability. Four state secondary schools in southern/central England will participate, purposively recruiting schools from a broad range of backgrounds. All schools will be mixed sex and with an Ofsted inspection rating of 'requires improvement' or higher and with a non-temporary head-teacher. Schools will vary by the proportions of students eligible for free school meal (above and below the national average) and Ofsted rating ('requires improvement' or 'good' versus 'excellent') as proxy measures of need and capacity for implementation. The research evaluation will focus on students in year 7 (age 11-12) at baseline but in year 10 (age 14-15) at 12-month follow-up in order to pilot response rates and measures for a future full trial (where students would be in year 7 at baseline and year 10 at follow up) rather than to estimate intervention effects. We estimate approximately 670 students per wave will complete the surveys (informed by a mean 167 per school in the Learning Together trial).

Randomisation

Schools will not be randomised to the intervention as all schools will receive the intervention in order to assess feasibility and acceptability of implementation across schools varying by need (measured by deprivation level using free school meal eligibility proportions as a proxy) and by school capacity (measured by Ofsted rating as a proxy).

Study flow chart

Data on the four schools and the number of young people surveyed at baseline and follow up will be presented in a flow chart.

Demographic and Other Characteristics

Descriptive summaries of baseline and follow-up data will be tabulated. Descriptive statistics for continuous variables will include the mean, standard deviation, median, inter-quartile range, range and the number of observations. Categorical variables will be presented as numbers and percentages.

School level characteristics will also be tabulated.

Outcomes

Primary outcome

The primary outcomes for the study are feasibility and acceptability.

Feasibility and acceptability of data collection will be assessed by participation rate in the baseline and follow-up survey. Feasibility and acceptability of the intervention will be assessed by data collected from the follow-up survey process evaluation (e.g. 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 overall will be defined by meeting any one of the following criteria:

    a. Intervention feasibility

        1. three or more schools had a response rate lower than 60% in the baseline (needs) survey
        2. three or more schools did not have at least three meetings of action groups regardless of quoracy
        3. three or more schools had fewer than two staff complete the in-depth training
        4. three or more schools completed no locally decided actions
        5. three or more schools had fewer than 2 staff trained in-depth in restorative practice (RP) regularly implementing RP
        6. three or more schools implemented the curriculum with lower than 50% fidelity
        7. three or more schools did not choose any actions from a menu of evidence-based options

b. Intervention acceptability

-   three or more schools had less than half of senior leadership and action group members finding the intervention acceptable assessed by a self-reported binary measure (Appendix 1)

c. Study feasibility

-   three or more schools achieved a response rate of less than 60% at follow-up

Failure on one or more of the intervention (feasibility or acceptability) criteria would imply the intervention was not sufficiently feasible or acceptable to evaluate the intervention in a full study. Failure on the study feasibility criteria would not speak directly to intervention feasibility/acceptability but require reconsideration of study design in any future full study.

Secondary outcomes
Analysis of process – not outcome – data will be the primary focus of this feasibility and acceptance study. However, data from baseline and follow-up student surveys will enable assessment of the indicative primary and secondary outcome measures as below:

a. Indicative Primary outcome

-   Strengths and Difficulties Questionnaire (SDQ)

b. Indicative Secondary outcomes will include:

1. SDQ subscales: including prosocial, conduct problems, peer problems, hyperactivity and impact supplement subscales.
2. Wellbeing: Warwick-Edinburgh Mental Well-being Scale (WEMWBS)
3. Depressive symptoms: Short Moods and Feelings Questionnaire (SMFQ)
4. Anxiety, measured using the 7-item Generalized Anxiety Disorder (GAD7) scale
5. Eating behaviour including disordered eating, measured using the Eating Disorders Examination Questionnaire (EDEQ)
6. Self-harm: using one question derived from the Health Behaviour in School-aged Children (HBSC) study.
7. Bullying (victimization) measured using the Gatehouse Bullying Scale
8. Cyberbullying, assessed using two items adapted from the DAPHNE II questionnaire
9. Substance use
10. Student report of School climate, using the Beyond Blue school climate scale

We will also analyse intervention awareness among year 10 students at follow-up.

Statistical analysis
No assessment of effectiveness will be carried out since the study does not include a control group and is not oriented towards assessing this.

Descriptive summaries of baseline and follow-up data will be tabulated. Descriptive statistics for continuous variables will include the mean, standard deviation, median, inter-quartile range, range and the number of observations. Categorical variables will be presented as numbers and percentages.

Data from this feasibility study will be used identify the most appropriate measures for future studies. We will assess the reliability and completeness of measures to support decision making.

We will assess intervention awareness among year 10 students at follow-up using several binary measures of awareness (of the intervention overall, student participation in decisions, the meaning of restorative practice, staff use of restorative practice and the curriculum) adapted from measures using in the INCLUSIVE trial included in the student questionnaire. We will explore how this varies by student socioeconomic status, gender, ethnicity and sexual orientation (Appendix 2).

Dropouts and Missing Data
Questionnaire completion rates are expected to be high so only a small amount of missing data is expected and it is not thought likely that it will have to be accounted for in any assessment of the indicative primary and secondary outcome measures.

In the event of whole school dropout before the intervention starts, a replacement school will be identified and enrolled. Data from the replacement school will be included in follow up results.

Interim Analysis and Data Monitoring
No interim analysis is planned for this feasibility and acceptability study

Safety Monitoring
An SAE is defined as any situation that results in death, hospitalisation, disability, congenital abnormality or life-threatening risk.

The SAE reporting process is described in full in the reporting SAE SOP.

References

1.   Kessler RC, Berglund P, Demler O, Jin R, Merikangas KR, Walters EE. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication. Arch Gen Psychiatry. 2005;62(6):593-602.
2.   Transforming children and young people's mental health provision: a Green Paper. London: Department of Health and Department for Education, England; 2017.
3.   Bonell C, Allen E, Warren E, McGowan J, Bevilacqua L, Jamal F, et al. Effects of the Learning Together intervention on bullying and aggression in English secondary schools (INCLUSIVE): a cluster randomised controlled trial. Lancet. 2018;392(10163):2452-64.

Appendix 1

Senior leadership and action group acceptability measure

Q. Do you think LEARNING TOGETHER MENTAL HEALTH was a good way to promote students' mental health?

Please ✓ <u>one</u> box

Yes	☐
No	☐

Appendix 2

We want to assess student awareness of LTMH overall and by socioeconomic status, gender, ethnicity and sexual identity. Awareness will be reported in terms of five separate binary measures as follows, all of which are adapted versions of measures used previously in the INCLUSIVE trial:

Awareness of LTMH

Q. This school has recently been taking actions to improve students' mental health

Please ✓ <u>one</u> box only

Yes	☐
No	☐
Not sure	☐

Q. At this school, students were recently involved in deciding how the school should improve students' mental health

Please ✓ one box only

Yes	☐
No	☐
Not sure	☐

Awareness of RP

Q. If there is trouble at this school, staff respond by:

Please ✓ all that apply

Punishing those who did wrong ☐
Meeting with those involved to understand what happened and help them get on better ☐

Q. I understand what is meant by 'restorative practice'

Please ✓ one box only

Yes, definitely ☐
Yes, sort of ☐
No ☐

Awareness of curriculum

Q. This past year in class, we've been learning about our emotions and resilience

Please ✓ one box only

Yes ☐
No ☐
Not sure ☐

Socioeconomic status, gender, ethnicity and sexual identity will be assessed using the following categorical measures previously used in the baseline survey:

Q. Do any of the adults you live with own a car, van or truck?

Please ✓ one box only

No ☐
Yes, one ☐
Yes, two or more ☐

Q. Do you have your own bedroom for yourself at home?

Please ✓ one box only

No ☐
Yes ☐

Q. How many computers do the family members you live with own (including laptops and tablets but not including game consoles or smartphones)?

Please ✓ one box only

None	☐
One	☐
Two	☐
More than two	☐

Q. How many bathrooms (rooms with a bath or shower) are in your home?

Please ✓ one box only

None	☐
One	☐
Two	☐
More than two	☐

Q. Do you have a dishwasher at home?

Please ✓ one box only

Yes	☐
No	☐

 Q. During the past 12 months, how many times did you travel out of the United Kingdom (UK) for a holiday/vacation?

Please ✓ one box only

Not at all	☐
Once	☐
Twice	☐
More than twice	☐

Q. At birth, were you described as:

Please ✓one box

Male	☐
Female	☐

Q. Which of the following best describes how you think of yourself now? (some people's gender identity is not the same as how they were described at birth).

Please ✓ one box

Boy	☐
Girl	☐
Non-binary (neither male or female)	☐
Other	☐

Q. Which ethnicity best describes you?

Please ✓ one box

White	☐
Asian or Asian British	☐
Black or Black British	☐
Mixed or multiple ethnic groups	☐
Other ethnic group	☐

Q. Which of the following do you consider yourself to be?

Please ✓ one box

Straight or heterosexual (girl attracted to boys OR boy attracted to girls)	☐
Gay or lesbian (girl attracted to girls OR boy attracted to boys)	☐
Bisexual (attracted to girls AND boys)	☐
Asexual (not attracted to girls or boys)	☐
Unsure/questioning	☐
Other	