

Effectiveness of school mental health and wellbeing promotion

Universal approaches in English primary and secondary schools

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Summary

Funded by the Department for Education, Education for Wellbeing was one of England's largest research programmes for school-based mental health interventions. The aim of the programme was to evaluate pioneering ways of supporting the mental wellbeing of pupils.

The programme was split into two trials: AWARE (Approaches for Wellbeing and Mental Health Literacy: Research in Education), tested in secondary school settings, and INSPIRE (Interventions in Schools for Promoting Wellbeing: Research in Education), tested in both primary and secondary school settings.

This briefing focuses on the results for the INSPIRE trial which explored three initiatives either based around techniques to support mental wellbeing, or approaches to support and encourage help-seeking and allied strategies. These initiatives were delivered in years 4 and 5 in primary schools and 7 and 8 in secondary schools. These approaches were developed specifically for the study and had not been trialled previously. These were: Mindfulness-Based Exercises; Relaxation Techniques and Strategies for Safety and Wellbeing (an 8-lesson mental health literacy programme). Specifically the trial explored the impact of these interventions in the short and longer term on children and young people's self-reported emotional difficulties and intentions to seek help in future if experiencing mental health problems (intended help-seeking). The trial was conducted with 20,489 pupils across 213 schools.

The INSPIRE trial found:

Mindfulness-based exercises

- Mindfulness-based exercises had no overall statistically significant impact on children and young people's emotional difficulties at the short-term follow up (the primary outcome explored in this study) in either primary or secondary schools.
 Nor did it have a statistically significant impact on this outcome at the longer term follow up (9-12 months post intervention);
- However, implementation findings suggest that in secondary schools, mindfulness-based exercises can lead to reduced emotional difficulties if delivered regularly and consistently. In primary schools, however, the opposite was observed with moderate compliance increasing emotional difficulties, which increased further still with high levels of compliance;
- Analysis looking at different subgroups of pupils suggested some groups may benefit from mindfulness-based exercises (e.g. girls in primary schools; those with higher prior emotional difficulties in secondary schools) in the short-term (3-6 months after the start of the intervention);

- However, some groups (e.g., those with Special Educational Needs (SEN) and those with higher levels of prior mental health symptoms in primary schools) may experience higher emotional difficulties 9-12 months post-intervention;
- The economic analysis, based on measures of health-related quality of life, not the outcome measures reported above, found that mindfulness-based exercises had a high probability of being considered cost-effective at both short and long-term follow up in primary schools and at the long-term follow up in secondary schools. However, because in primary schools, the intervention shows no impact on the primary outcome of interest (emotional difficulties) and reveals some negative impacts, cost effectiveness findings are not sufficient to recommend the intervention in primary schools;
- Based on these findings, evidence from this study does not recommend
 mindfulness-based exercises in primary schools due to potential adverse effects
 with some groups of children and young people, and at both moderate and high
 levels of implementation. Evidence from this trial does suggest that mindfulnessbased exercises show promise in secondary school settings when delivered
 consistently and regularly on an ongoing basis.

Relaxation Techniques

- Overall, relaxation techniques had no statistically significant impact on children and young people's emotional difficulties at the short-term follow up (the primary outcome explored in this study) or the longer term follow up (9-12 months postintervention) in either primary or secondary schools.
- Implementation findings suggest relaxation techniques can lead to reduced emotional difficulties if delivered regularly and consistently in primary school settings. However, in secondary schools, more frequent use of relaxation techniques is associated with higher levels of emotional difficulties; an effect that was observed at both moderate and high levels of compliance.
- Analysis looking at different subgroups of pupils suggests particular benefits for certain groups, including those from minority ethnic groups in primary schools, and girls and those with prior mental health difficulties in secondary schools.
- The economic analysis based on health-related quality of life measures, not the
 outcome measures described above, found that relaxation techniques had a high
 probability of being considered cost-effective at the long-term follow up in both
 primary and secondary schools. However, because in secondary schools, the
 intervention shows no impact on the primary outcome of interest (emotional
 difficulties) and reveals some negative impacts with increased compliance, cost
 effectiveness findings are not sufficient to recommend the intervention in
 secondary schools;

• Based on these findings, relaxation shows promise as an intervention in primary schools if it is implemented consistently and regularly on an ongoing basis. It is not a recommended intervention for secondary schools.

Strategies for Safety & Wellbeing (SSW)

- SSW had a statistically significant impact on children and young people's intended help-seeking in primary schools, but not in secondary schools.
- Implementation findings suggest that in secondary schools, SSW can lead to increased intended help-seeking if all sessions are delivered.
- Analysis looking at different subgroups of pupils suggested greater improvements in intended help-seeking for certain groups and young people (e.g., those without SEN and those not eligible for FSM) and in certain settings (e.g., in urban schools).
- The economic analysis, based on health-related quality of life measures, found that SSW had a low probably of being cost effective in the short term but a high probability of being considered cost-effective at the long-term follow up in primary and secondary schools.
- Based on these findings, SSW is a recommended intervention for primary schools, although it may require 'refresher sessions' in subsequent years to sustain effects.
 It also shows promise as an intervention in secondary schools, but only if it is implemented in full.

Other briefings are also available for the research programme which report on:

- Effectiveness of school mental health awareness interventions: Universal approaches in English secondary schools
- School staff perspectives on approaches to mental health promotion: Experiences
 of delivering universal approaches in English primary and secondary schools
- Pupil perspectives on approaches to school wellbeing promotion: Experiences of Mindfulness-based exercises and Relaxation techniques
- Pupil perspectives on school mental health literacy interventions: Experiences of three programmes in English primary and secondary schools

Full technical details of the study are available in the following document:

• Education for Wellbeing: Technical report

These results are also available in the following journal articles:

- School-based intervention study examining universal approaches for well-being and mental health literacy of pupils in Year 9 in England (AWARE): a multi-school, parallel group, cluster-randomised controlled trial.
- Promoting mental health and wellbeing in schools: examining mindfulness-based exercises, relaxation techniques and Strategies for Safety and Wellbeing in English primary and secondary schools (INSPIRE): a multi-school, cluster randomised controlled trial.
- Session delivery completion as a modifier of treatment effects of universal mental health literacy curricula on emotional difficulties and intended help-seeking in primary and secondary schools: complier average causal effect estimation in the AWARE and INSPIRE cluster randomized trials.
- Implementation dosage as a modifier of treatment effects of universal mindfulness and relaxation interventions on emotional difficulties in primary and secondary schools: complier average causal effect estimation in the INSPIRE cluster randomized trial.
- A qualitative study of English school children's experiences of two brief, universal, classroom-based mental health and wellbeing interventions: Mindfulness and Relaxation.
- A qualitative investigation of children and young people's experiences of three universal classroom-based mental health literacy interventions in England.
- A qualitative study of school staff experiences of implementing five universal mental health interventions in England.
- Cost-effectiveness of school-based interventions for well-being and mental health literacy of pupils in Year 9 in England: the AWARE cluster randomised controlled trial.
- Cost-effectiveness of Mindfulness, Relaxation, and Strategies for Safety and Wellbeing in English primary and secondary schools: the INSPIRE cluster randomised controlled trial.

INSPIRE in detail

The aim of the INSPIRE trial was to assess the impact of three interventions, which were developed specifically for this trial and were designed to reflect the mental health support typically rolled out in schools across England. The trial was conducted in three waves between 2018 and 2024. For each wave, baseline data were collected September to October; random allocation occurred post-baseline at the end of October or beginning of November; training of teachers in interventions (where relevant) occurred in November and December and interventions were delivered between January and April. Follow up data were collected at first follow-up (3-6 months after initial delivery) and second follow up (9-12 months post intervention). As part of INSPIRE, schools were randomly allocated to one of the following approaches:

- Training pupils in Mindfulness-Based Exercises embedded into the school day, every day for five minutes.
- Training pupils in Relaxation Techniques embedded into the school day, every day for five minutes.
- A series of eight lessons designed to increase children and young people's skills around personal safety and managing their mental health, as well as helping them to identify their support networks (Strategies for Safety and Wellbeing, SSW).
- Usual practice. Schools that were allocated to usual practice continued as
 usual. They were asked not to implement anything new that resembled the intervention programmes involved in the trial. Existing practice and how this changed
 over time was measured. These schools received free mental health and wellbeing training at the end of the trial.

All three interventions were delivered over a four-month period during the spring term of each wave (January to April) by trained school staff. Prior to the start of the interventions, school staff received a half-day training session in in November or December prior to delivery for whichever intervention they were allocated to, which was led by the Education for Wellbeing intervention development team.

The primary outcomes¹ were tailored to the nature of the intervention. The INSPIRE trial sought to answer the following questions:

 Does participating in mindfulness-based exercises improve emotional difficulties in children and young people, compared to a usual practice group that did not take part in mindfulness-based exercises? (primary outcome)

¹ For Randomised Control Trials, a main outcome of focus must be selected for each intervention. So while many secondary outcomes may be of interest, there is only one primary outcome for each intervention.

- Does participating in relaxation techniques improve emotional difficulties in children and young people, compared to a usual practice group that did not take part in relaxation? (primary outcome)
- Does participating in SSW improve intended help-seeking in children and young people, compared to a usual practice group that did not take part in SSW? (primary outcome)
- To what extent does the impact of each intervention vary due to how it was implemented?
- Does the impact of each intervention vary according to any pupil or school level factors?
- Does participating in mindfulness-based exercises, relaxation techniques or SSW impact on any secondary outcomes?
- Are mindfulness-based exercises, relaxation techniques and SSW cost-effective?

The Study

The Sample

Eligible participants were pupils in primary and secondary schools across England who were in Years 4 and 5 (primary school, aged 8-10 years) or Years 7 and 8 (secondary school, aged 11-13 years) during baseline data collection. 213 schools and 20,489 pupils participated in the trial (INSPIRE primary: 145 schools, 9,731 pupils. INSPIRE secondary: 68 schools, 10,758 pupils). Recruitment was conducted in three waves (2018, 2019, 2022). However, Wave 2 post-intervention data collection was interrupted by Covid-19, therefore, primary findings and implementation findings relate to waves 1 and 3.

After completion of baseline data collection (staff and pupil questionnaires), schools had an equal chance of being allocated to one of three interventions or a usual practice group. Randomisation included a process to ensure the groups were balanced by current mental health provision within the schools, region of England, deprivation and whether the school was located in an urban or rural area. The statistician, quantitative data analyst and economist were blinded to intervention allocation, meaning that they did not know which schools had been allocated to which group.

Measures

Study outcomes were measured at three timepoints: baseline (prior to randomisation), 3-6 months from the start of delivery (first follow up) and 9-12 months from the end of delivery (second follow up). Questionnaires were completed online.

Main impact findings

The primary outcomes were different for each intervention, to best suit the stated intention for the intervention. For mindfulness-based exercises and relaxation, the primary outcome measure was emotional difficulties (Short Mood and Feelings Questionnaire, SMFQ, Angold et al., 1995) at first follow up. For SSW, the primary outcome measure was self-reported intended help-seeking (General Help-Seeking Questionnaire, GHSQ, Wilson et al., 2005) at first follow up.

Secondary outcomes included the same outcome measure as the primary analysis but at the later timepoint (9-12 months post intervention). For all interventions, the following measures were also included as secondary outcomes (measures are included in the associated <u>Technical Report</u>):

• Positive wellbeing (Huebner Life Satisfaction Scale) (Huebner et al. 1991);

 Quality of life (Paediatric Quality of Life, Child Health Utility-9D, CHU9D) (Stevens, 2009) (economic analysis).

Implementation analysis

Baseline behavioural (the Me and My Feelings [M&MF] behavioural subscale; Deighton et al., 2012) and emotional difficulties (SMFQ, as above) were assessed as an indication of levels of need in the classroom.

Baseline mental health provision was determined in two ways. Firstly, whether or not the school had delivered any prior universal mental health programmes to improve mental health literacy or introduce activities to calm and relax pupils before their involvement in the trial. Secondly, using information regarding the extent of mental health training staff members in the school had been offered. These data were collected via the online current mental health provision survey.

In addition to the above measures, pupils' gender (male or female, as recorded in schools administrative data to National Pupil Database specification at the time of the study), percentage of free school meal eligibility at the school level, and the wave of trial pupils participated in were considered.

We also collected information on how much of a given intervention was delivered (dosage) via online teacher surveys. This was measured in different ways depending on the intervention. Specifically, for Mindfulness-based exercises and relaxation techniques this was measured as total minutes delivered; for SSW this was complete (i.e., all sessions delivered) versus incomplete delivery (anything less than the required number of sessions).

Effect modification

To understand whether the impact of the interventions varied according to any pupil or school level factors, the following variables were used:

- Individual level socio-demographic characteristics:
 - a. Gender (male/female)
 - b. Free school meal status of the pupil (no/yes)
 - c. Ethnicity (broad white/ethnic minority groups)
- Individual level difficulties
 - a. Previous mental health (SMFQ above/below cutoff)
 - b. SEN status (SEN/no SEN)
- School level characteristics
 - a. School level deprivation (free school meal status of pupils lowest, medium and highest % categories)
 - b. School setting (urban/rural)

c. Previous implementation of universal mental health programmes before involvement in the trial (prior support/no prior support)

Analysis

Primary and secondary schools were analysed separately due to differences in context. For the main impact findings and secondary outcome findings, the measures were analysed using an intent-to-treat (ITT) approach, where outcomes are analysed for all those allocated to the intervention groups whether or not individuals received an intervention (Gupta, 2011). We used an analytical technique called mixed linear models which compared the scores of young people allocated to mindfulness-based exercises, relaxation and SSW to those allocated to the usual practice group, whilst taking into consideration:

- The impact of emotional difficulties at the start of the project;
- The trial wave;
- Where in the country the school was located (North East, North West, South East, South West);
- Current mental health provision at the school;
- School-level deprivation (measured by percentage of students with free school meal eligibility);
- Whether the school was located in an urban or rural location.

The intervention groups were compared with the usual practice group only, not to each other.

To understand whether the effects of the intervention varied according to pupil- or school-level factors, the same analytic strategy described above was used adding in consideration of a range of different potential moderators of the impact. Each moderator was considered separately:

- Gender (male/female);
- Free school meal status of the pupil;
- Ethnicity (broad White/Ethnic minority groups);
- Previous mental health;
- SEN status;
- School-level deprivation;

- Rural/urban situation of school;
- Previous mental health interventions.

Because research trials are designed to primarily detect the overall effect of the intervention, splitting analysis into subgroups either based on implementation or pupil characteristics reduces the sample size within groups and increases the complexity of the analysis. This means findings for these additional analyses are more exploratory in nature, meaning they can indicate where impact varies but not with the same degree of confidence as the main impact findings.

For the implementation findings, a statistical method called Complier Average Causal Effect (CACE) estimation (Peugh, 2017) was used to test whether intervention dosage changed the impact of the intervention on primary outcomes. CACE categorises pupils as either compliers or non-compliers (see below for how this was defined in each analysis). Statistical techniques are used to estimate which pupils in usual practice schools would have been compliers to the intervention, had they been randomised to receive it. Outcomes are then compared between compliers in the intervention arm and 'would-be' compliers in the control group. The resulting CACE effect therefore tells us the effects of the intervention among only those who complied with the intervention. This contrasts with the main impact findings which tell us the effects for the treatment group as a whole, irrespective of whether they received the intervention in full.

Among those in intervention schools, compliance was derived using dosage information. For SSW, compliance was determined by the completeness of delivery²:

• SSW: compliers received all 8 sessions; (primary schools n = 1,613, 87.6%; secondary schools n = 1,209, 76.4%) non-compliers received fewer than 8 sessions (primary schools n = 228, 12.4%; secondary schools n = 373, 23.6%).

For Mindfulness-Based Exercises and Relaxation techniques, compliance was defined in two ways, moderate and high compliers³, as follows:

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² The compliance figures given below are based on those who were analysed; this amounts to less than the total number of compliers/non-compliers in each intervention, as the software used for analyses (Mplus) removed anyone with missing information on covariates (e.g. pupil gender), and/or missing both compliance *and* outcome information.

³ Moderate compliance was determined using the 50th percentile cut-point and high compliance was determined using the 75th percentile. This means that, for example, in primary schools delivering mindfulness-based exercises, 325 minutes or more is higher than 50% of all reported minutes for this intervention in primary schools, and 393 minutes or more is higher than 75% of all reported minutes for this intervention in primary schools.

- Mindfulness-based exercises in primary schools: moderate compliers received 325+ minutes of mindfulness-based exercises; high compliers received 393+ minutes:
- Mindfulness-based exercises in secondary schools: moderate compliers received 207+ minutes of mindfulness-based exercises; high compliers received 285+ minutes;
- Relaxation techniques in primary schools: moderate compliers received 320+ minutes of relaxation practices; high compliers were those who received 376+ minutes;
- Relaxation techniques in secondary schools: moderate compliers received 180+ minutes of relaxation practices; high compliers received 275+ minutes.

Percentages for each level of compliance are provided in Tables 1-4 below.

Table 1 Proportion of moderate and high compliers across MBE and RT (primary schools)

MBE	Moderate (325+ mins) non-compliers	Moderate (325+ mins) compliers	High (393+ mins) non- compliers	High (393+ mins) compliers
	39.50%	60.50%	74.80%	25.20%
RT	Moderate (320+ mins) non-compliers	Moderate (320+ mins) compliers	High (376+ mins) non- compliers	High (376+ mins) compliers
	42.10%	57.90%	73.90%	26.10%

Table 2 Proportion of non-compliers and compliers for SSW (primary schools)

SSW	Non-compliers (< 8 sessions)	Compliers (8 sessions)
	8.60%	91.40%

Table 3 Proportion of moderate and high compliers across each intervention (secondary schools)

MBE	Moderate	Moderate	High (285+	High (285+
	(207+ mins)	(207+ mins)	mins) non-	mins) compliers
	non-compliers	compliers	compliers	
	49.80%	50.20%	76.60%	23.40%
RT	Moderate	Moderate	High (275+	High (275+
	(180+ mins)	(180+ mins)	mins) non-	mins) compliers
	non-compliers	compliers	compliers	
	42.60%	57.40%	77.40%	22.60%

Table 4 Proportion of non-compliers and compliers for SSW (secondary schools)

SSW	Non-compliers (< 8 sessions)	Compliers (8 sessions)
	12.90%	87.10%

Predictors of compliance are factors that indicate whether someone is more or less likely to comply to the intervention. Having several good predictors of compliance increases the robustness of CACE findings. Where CACE models yield no statistically significant predictors of compliance, results should be interpreted with some degree of caution.

All CACE analyses considered pupils' gender, baseline emotional and behavioural difficulties, free school meal eligibility, whether there had been previous mental health interventions delivered at the school, and each schools' existing level of mental health provision as predictors of compliance. Where the primary outcome was intended help-seeking scores (SSW), models additionally considered the effects of baseline intended help-seeking scores on compliance status and the primary outcome (intended help-seeking at first follow up). Models involving secondary schools additionally included wave of participation in the trial as a predictor of compliance.

To understand whether the interventions are potentially cost-effective, a quality-adjusted life-years (QALY) score was calculated from the CHU9D, using preference weights presented by Stevens (2012). This measure asks about health-related quality of life on a number of areas such as worry, sadness, pain, tiredness, and ability to join activities. The costs of delivering the intervention in each arm of the trial were calculated using data provided by the delivery teams. Participants were also asked to provide information about

contacts with school, health, social and hospital services using a short version of the Client Service Receipt Inventory (CSRI). Costs for services were obtained from publicly available sources. Cost-effectiveness of interventions was determined by the threshold of £20,000 to £30,000 per change in QALY, as accepted by NICE.

Findings

Mindfulness-Based Exercises in primary schools

Does participating in mindfulness-based exercises improve emotional difficulties in children and young people in primary schools, compared to a usual practice group that did not take part in mindfulness-based exercises?

Analyses showed that participating in mindfulness-based exercises had no statistically significant impact on primary school children's emotional difficulties (effect size=0.002, 95%-confidence interval: -0.08, 0.08). This means there were no discernible differences between the usual practice and intervention group in terms of the change in their emotional difficulties from baseline to first follow-up.

To what extent does the impact of mindfulness-based exercises vary due to how it was implemented in primary schools?

Data from 3,630 pupils from 65 Mindfulness-Based Exercises and INSPIRE usual practice primary schools were analysed. 2,095 pupils (58%) were estimated by the CACE model to be *moderate compliers* (i.e. they received 325 minutes or more of mindfulness-based exercises, as opposed to fewer than 325 minutes) while 1,076 pupils (30%) were estimated by the CACE model to be *high compliers*, receiving 393 minutes or more of mindfulness-based exercises (as opposed to receiving fewer than 393 minutes). Moderate compliance led to a **significant increase in emotional difficulties** (an effect that translates to a 13 percentile point increase in symptoms). High compliance led to a **further increase in emotional difficulties** (translating to a 19 percentile point increase). However, none of our considered variables made compliance more or less likely (i.e., there were no significant predictors of compliance), so these findings should be interpreted with some degree of caution.

Does participation in mindfulness-based exercises impact any other outcomes in primary schools?

There were no detected effects of mindfulness-based exercises emotional difficulties at the longer term follow up (9-12 months post intervention), nor did it have an impact on any secondary outcomes at the first or second follow up.

Does the impact of mindfulness-based exercises vary according to any pupil or school level factors in primary schools?

While there was no main effect of mindfulness-based exercises in primary schools, mindfulness improved emotional difficulties more for girls than for boys at the first follow up. At this time point, there was also an interaction with school experience of similar prior interventions such that pupils in schools with prior experience delivering similar interventions had **higher levels of emotional difficulties** at follow up than pupils in schools without this prior experience. At second follow up, although there was no overall long-term effect, those in the intervention group with SEN and higher levels of prior mental health symptoms had **higher levels of emotional difficulties** at follow up than those without SEN or without prior difficulties. There was also an interaction with school location, whereby urban schools had lower emotional difficulties, suggesting the intervention was more effective in schools in urban locations.

Are mindfulness-based exercises cost-effective in primary schools?

The economic analysis found that mindfulness-based exercises in primary schools have a high probability (>50%) of being considered cost-effective, based on the quality of life measures, at both the first and second follow up. That is, while cost savings in terms of service use do not exceed the cost of intervention, the improvements in quality-of-life outcomes indicate that this intervention has a high probability of being considered cost-effective using the standard willingness-to-pay threshold (as used by NICE) of £20,000 to £30,000 per QALY gained.

Mindfulness-Based Exercises in secondary schools

Does participating in mindfulness-based exercises improve emotional difficulties in children and young people in secondary schools, compared to a usual practice group that did not take part in mindfulness-based exercises?

Analyses showed that participating in mindfulness-based exercises had no statistically significant impact on young people's emotional difficulties (effect size=-0.07, 95%-confidence interval: -0.18, 0.05). This means there were no discernible differences between the usual practice and intervention group in terms of the change in their emotional difficulties from baseline to first follow up.

To what extent does the impact of mindfulness-based exercises vary due to how it was implemented in secondary schools?

Data from 3,708 pupils from 29 Mindfulness-Based Exercises and INSPIRE usual practice secondary schools were analysed. 1,109 pupils (30%) were estimated by the CACE model to be *moderate compliers* (i.e., they received 207 minutes or more of mindfulness-based exercises, as opposed to receiving fewer than 207 minutes). 455

pupils (12%) were estimated by the CACE model to be *high compliers* (i.e., they received 285 minutes or more as opposed to fewer than 285 minutes). Moderate compliance led to a significant reduction in emotional difficulties, equivalent to a 38 percentile point decrease. High compliance led to a 42 percentile point reduction in emotional difficulties. Prior implementation of universal mental health programmes was found to be a significant and predictor of moderate compliance whereby those who had not previously been offered a universal mental health programme were more likely to be moderate compliers. None of the considered variables made high compliance more or less likely, meaning some degree of caution should be exercised when interpreting findings.

Does participation in mindfulness-based exercises impact any other outcomes in secondary schools?

There were no detected effects of mindfulness-based exercises emotional difficulties at the second follow up, nor did the intervention show effects on any secondary outcomes at the first or second follow up.

Does the impact of mindfulness-based exercises vary according to any pupil or school level factors in secondary schools?

While there was no main effect of mindfulness-based exercises, at first follow up mindfulness-based exercises improved emotional difficulties more for the young people who had experienced prior emotional difficulties than for those who had not, suggesting there might be a treatment effect in this specific subgroup.

At second follow up, although there was no overall effect, there was an interaction with school deprivation, such that young people in schools scoring in the high and low range of income deprivation had higher emotional difficulties in the intervention group, compared with those in schools with mid-range deprivation scores. In the control group, those in schools scoring in the low range in terms of income deprivation had the lowest emotional difficulties scores.

Are mindfulness-based exercises cost-effective in secondary schools?

Based on the outcomes measured by the health utilities measures, and the data around interventions costs and service utilisation, the economic analysis found that at first follow-up, there is a low probability of mindfulness-based exercises being considered cost-effective, as potential cost savings in terms of service use are exceeded by the cost of intervention, and there is no evidence that students in the intervention group experienced better quality-of-life outcomes compared to those in the control group.

At second follow-up, there is a high probability of mindfulness-based exercises being considered cost effective; while potential cost-savings in terms of service use at the second-follow-up do not exceed the cost of intervention, there is an increase in the quality-

of-life measure over this time, thus increasing the probability that mindfulness-based exercises will be considered cost-effective using the standard willingness-to-pay threshold (as used by NICE) of £20,000 to £30,000 per QALY gained. Although there was no main effect of mindfulness-based exercises in secondary schools, the finding of a high probability of being considered cost-effective due to the fact that cost-effectiveness is calculated based on quality of life (here measured with the CHU9D), whereas the main impact findings are based on emotional difficulties, measured with the SMFQ.

Relaxation Techniques in primary schools

Does participating in Relaxation Techniques improve emotional difficulties in children and young people in primary schools, compared to a usual practice group that did not take part in Relaxation Techniques?

Analyses showed that participating in relaxation techniques had no statistically significant impact on primary school children's emotional difficulties (effect size=-0.01, 95%-confidence interval: -0.10, 0.07). This means there were no discernible differences between the usual practice and intervention group in terms of the change in their emotional difficulties from baseline to first follow up.

To what extent does the impact of relaxation techniques vary due to how it was implemented in primary schools?

Data from 3,800 pupils from 66 Relaxation and INSPIRE usual practice primary schools were analysed. 1,365 pupils (36%) were estimated by the CACE model to be *moderate compliers* (i.e., they received 320 minutes or more of relaxation techniques, as opposed to fewer than 320 minutes). 695 pupils (18%) were estimated by the CACE model to be *high compliers* (i.e., they received 376 minutes or more, as opposed to fewer than 376 minutes). Moderate compliance led to a significant reduction in emotional difficulties. This effect translates to a 44 percentile point decrease. High compliance also reduced emotional difficulties, an effect that translates to a 43 percentile point decrease in symptoms. There were no significant predictors of moderate compliance; however, lower levels of baseline behavioural difficulties significantly predicted high compliance, making high compliance more likely. This means some caution should be exercised in interpreting the moderate compliance findings.

Does participation in relaxation techniques impact any other outcomes in primary schools?

There were no detected effects of relaxation techniques compared with the usual practice group on any secondary outcomes at the first or second follow up. Similarly, there was no longer term impact of the intervention on emotional difficulties at the second follow-up.

Does the impact of relaxation techniques vary according to any pupil or school level factors in primary schools?

While there was no main effect of relaxation techniques in primary schools, the intervention improved emotional difficulties more for children from minoritised ethnic groups than those from a white ethnic group at first follow up.

Are relaxation techniques cost-effective in primary schools?

Based on the outcomes measured by the health utilities measures, and the data around interventions costs and service utilisation, the economic analysis found that relaxation techniques in primary schools has a medium (41%) probability of being considered cost-effective at first follow-up. At second follow-up, relaxation techniques has a high probability of being considered cost-effective. Although there was no main effect of relaxation techniques in primary schools, the finding of a high probability of being considered cost-effective due to the fact that cost-effectiveness is calculated based on quality of life measured with the CHU9D, whereas the main impact findings are based on emotional difficulties, measured with the SMFQ.

Relaxation techniques in secondary schools

Does participating in Relaxation Techniques improve emotional difficulties in children and young people in secondary schools, compared to a usual practice group that did not take part in Relaxation Techniques?

Analyses showed that participating in relaxation techniques had no statistically significant impact on secondary school young people's emotional difficulties (effect size=-0.10, 95%-confidence interval: -0.24, 0.02). This means there were no discernible differences between the usual practice and intervention groups in terms of the change in their emotional difficulties from baseline to first follow up.

To what extent does the impact of relaxation techniques vary due to how it was implemented in secondary schools?

Data from 3,252 pupils from 26 Relaxation and INSPIRE usual practice secondary schools were analysed. 2,261 pupils (70%) were estimated by the CACE model to be *moderate compliers* (i.e., they received 180 minutes or more of relaxation techniques, as opposed to fewer than 180 minutes). 1,565 pupils (48%) were estimated by the CACE model to be *high compliers* (i.e., receiving 275 minutes or more of relaxation techniques, as opposed to receiving fewer than 275 minutes). Both moderate and high compliance **increased emotional difficulties** scores translating to a 25 and 30 percentile point increase, respectively. Lower levels of baseline emotional difficulties significantly predicted moderate compliance (i.e., made moderate compliance more likely). Both baseline emotional difficulties and greater staff training opportunities made high compliance more likely.

Does participation in relaxation techniques impact any other outcomes in secondary schools?

There were no detected effects of relaxation techniques compared with the usual practice group on any secondary outcomes at first follow up. At the second follow up, there was increased intended help-seeking (effect size= 0.12, 95%-confidence interval: 0.05, 0.19) in the relaxation techniques group compared with the usual practice group, but no impact on emotional difficulties at this time point.

Does the impact of relaxation techniques vary according to any pupil or school level factors in secondary schools?

While there was no main effect of relaxation techniques in secondary schools, first follow up relaxation techniques improved emotional difficulties more for young people with prior mental health problems compared with young people without prior mental health problems. At second follow up, although there was no main effect, relaxation techniques improved emotional difficulties more for girls (with a large effect size) and pupils with higher prior mental health difficulties. At second follow up, there was also an interaction with school deprivation, such that those in schools scoring in the mid-range in terms of income deprivation had lower emotional difficulties in the intervention group, compared with those in low- or high-income group schools.

Are relaxation techniques cost-effective in secondary schools?

The economic analysis found that relaxation techniques in secondary schools have a low probability of being considered cost-effective at first follow up, potential cost savings in terms of service use are exceeded by the cost of the intervention, and there is no evidence pupils in the intervention group experienced better quality-of-life outcomes compared to those in the control group.

At second follow up, there is a high probability of relaxation techniques being considered cost effective; while potential cost-savings in terms of service use at the second-follow-up do not exceed the cost of intervention, there is an increase in the quality-of-life measure over this time, thus increasing the probability that relaxation techniques will be considered cost-effective using the standard willingness-to-pay threshold (as used by NICE) of £20,000 to £30,000 per QALY gained.

Strategies for Safety and Wellbeing in primary schools

Does participating in SSW improve intended help-seeking in children and young people in primary schools, compared to a usual practice group that did not take part in SSW?

Analyses showed that participating in SSW had a statistically significant impact on primary school children's intended help-seeking intentions (effect size=0.09, 95%-confidence interval: 0.01, 0.18). This means there was a discernible difference between the usual practice and intervention group, with participation in SSW being linked to greater improvement in intended help-seeking from baseline to first follow up.

To what extent does the impact of SSW vary due to how it was implemented in primary schools?

Data for 3,397 pupils from 64 SSW and INSPIRE usual practice primary schools were analysed; 3,105 pupils (91%) were estimated by the CACE model to be compliers. No effect was observed for compliers (i.e., those who received all of the scheduled sessions compared to those who received anything less than all of the sessions). Gender was found to be a significant predictor of compliance, with males being more likely to be compliers compared to females.

Does participation in SSW impact any other outcomes in primary schools?

In primary schools, there were no detected effects of SSW compared with the usual practice group on any secondary outcomes at first or second follow up, nor was there a discernible impact of the intervention on intended help-seeking at this later timepoint.

Does the impact of SSW vary according to any pupil or school level factors in primary schools?

At first follow up, analyses showed that the impact of SSW on intended help-seeking varied according to pupil SEN status and prior mental health difficulties. We found that for children without prior mental health problems and SEN in the intervention group, their intended help-seeking became higher and, therefore, more similar to those who had experienced prior mental health problems and those with SEN in the SSW group.

At second follow up, although there was no main effect of SSW, there were higher levels of intended help-seeking in urban schools compared with rural schools. There were also higher levels of intended help-seeking in children who were not eligible for free school meals. In the control group, FSM eligible pupils have greater intended help-seeking than pupils who are not eligible for FSM, whereas in the intervention group, intended help-seeking for those not eligible for FSM became higher and, therefore, more similar to those eligible for FSM.

Is SSW cost-effective in primary schools?

The economic analysis found that SSW in primary schools has a low probability of being considered cost-effective at first follow-up and a higher probability of being considered cost-effective at second follow-up.

Strategies for Safety and Wellbeing in secondary schools

Does participating in SSW improve intended help-seeking in children and young people in secondary schools, compared to a usual practice group that did not take part in SSW?

Analyses showed that participating in SSW had no statistically significant impact on young people's intended help-seeking ability at the first follow up (effect size=0.07, 95%-confidence interval: -0.03, 0.18) in secondary schools. This means there was no discernible difference between the usual practice and intervention group.

To what extent does the impact of SSW vary due to how it was implemented in secondary schools?

Data for 3,692 pupils from 29 SSW and INSPIRE usual practice secondary schools were analysed; 3,215 pupils (87%) were estimated by the CACE model to be compliers. Compliance (receiving all scheduled sessions, as opposed to receiving anything less than all sessions), led to a significant increase in intended help seeking, equivalent to a 9 percentile point increase in scores. This contrasts with the lack of a main intervention effect. However, none of our considered variables were significant predictors of compliance so a degree of caution should be exercised when interpreting these findings.

Does participation in SSW impact any other outcomes in secondary schools?

In secondary schools, there were no detected effects of SSW compared with the usual practice group on any secondary outcomes at first or second follow up, nor was there any impact on intended help-seeking at the second follow-up.

Does the impact of SSW vary according to any pupil or school level factors in secondary schools?

At first follow up, there was no evidence that the impact of SSW varied according to any pupil or school level factors. At second follow up, although there was no main effect of SSW, intended help-seeking scores increased more in schools with lower levels of prior implementation of similar universal mental health programmes, compared with the usual practice group.

Is SSW cost-effective in secondary schools?

The economic analysis found that at first follow-up, there is a low probability of SSW being considered cost-effective, as potential cost savings in terms of service use are exceeded by the cost of intervention, and there is no evidence that students in the intervention group experienced better quality-of-life outcomes compared to those in the control group.

At second follow-up, there is a high probability of SSW being considered cost effective; while potential cost-savings in terms of service use at the second-follow-up do not exceed the cost of intervention, there is an increase in the quality-of-life measure over this time, thus increasing the probability that SSW will be considered cost-effective using the standard willingness-to-pay threshold (as used by NICE) of £20,000 to £30,000 per QALY gained.

Conclusions

Recent studies have reported increases in mental health problems in children and young people (Newlove-Delgado et al, 2022). Consequently, there has been growing emphasis on mental health prevention and early intervention, with schools being increasingly highlighted as an important context for provision of universal mental health promotion and prevention initiatives as well as more targeted support (Department of Health and Social Care, 2017). However, the range of school-based approaches evaluated to date vary in effectiveness (Caldwell et al., 2019; Zhang et al, 2023). Furthermore, often mental health support strategies adopted by schools have not been empirically tested, meaning there is a significant need to test whether approaches commonly implemented in schools are effective. This was the rationale behind the INSPIRE trial. A scoping review carried out by the Department for Education consolidated evidence around common school practices (Department for Education, 2017), which informed the selection of the specific interventions within this trial: a light-touch mindfulness-based intervention, a light-touch intervention based on relaxation techniques and an intervention drawing on the 'Protective behaviours' (Fardon, 2011) approach to promote safety and wellbeing (Strategies for Safety and Wellbeing).

Within the INSPIRE trial, Strategies for Safety and Wellbeing is an effective intervention for increasing intended help-seeking in primary school students (main impact findings) but the impacts were not sustained 1 year after the intervention (longer term outcomes). For primary school pupils, the impact of the intervention seems to be particularly concentrated in groups of children without special educational needs and without previous emotional difficulties (effect modification findings). The trial findings cannot unpack why this might be but it is possible that these groups of children have had less need to access support in the past so without the intervention might have been less aware and less inclined to consider seeking support in future. The intervention was found to have a high probability of being considered cost-effective at the long-term follow up in secondary schools. Based on these findings, SSW is a recommended intervention for primary schools, although it may require 'refresher sessions' in subsequent years to sustain effects. It is also shows promise as an intervention in secondary schools, but only if it is implemented in full.

Relaxation techniques showed no overall impact on emotional difficulties (main impact findings). It did lead to increased intended help-seeking at the long term follow up in secondary schools (longer term outcomes). Findings suggest the intervention benefits some students more than others, including minoritised ethnic groups in primary school, girls in the longer term in secondary schools and those with elevated emotional difficulties at the outset in secondary schools (effect modification findings). Implementation findings suggest benefits for emotional difficulties at both moderate and high levels of delivery in primary schools. However, in secondary schools, increased

levels of implementation lead to increases in emotional difficulties. Based on the quality-of-life measure, the intervention was found to have a high probability of being cost-effective in both primary and secondary schools at the long-term follow up. Based on these findings, relaxation techniques shows promise as an intervention in primary schools, but only if it is implemented consistently and regularly on an ongoing basis. It is not a recommended intervention for secondary schools.

Mindfulness-based exercises showed no overall impact in the short or long term (main impact findings) for primary or secondary schools, and there were mixed findings for groups of children and young people with emotional difficulties prior to the intervention, with findings indicating no short term effects but longer term negative outcomes for children in primary schools (effect modification findings). The implementation findings also highlight that mindfulness-based exercises in primary schools may in fact increase emotional difficulties, with difficulties increasing alongside volume of delivery. In secondary schools, there was some indication that it might be a beneficial intervention in settings where there is very little similar existing mental health support on offer (effect modification findings). Implementation findings also suggested that moderate and high levels of implementation in secondary schools led to reductions in emotional difficulties. It was also found to have a high probability of being cost-effective at both short and longterm follow up in primary schools and at the long-term follow up in secondary schools. Given the mixed findings for mindfulness-based exercises in primary schools in this trial. this kind of universal, light touch approach to mindfulness is not recommended for English primary school settings. These primary school findings are consistent with other recent evidence indicating either limited, or possible negative effects for mindfulness with some populations of children and young people (Kuyken 2022; Montero-Marin 2022). However, findings suggest mindfulness-based exercises show promise as an intervention for secondary school settings if it they are delivered frequently and consistently.

On the whole, findings show that different interventions can have different impacts on children and young people, and it is important to ensure that interventions being rolled out in schools are appropriate to the age and characteristics of pupils. When implementing new approaches to support pupils' mental health, monitoring the effect they have is important to understand any benefits and check if any groups were negatively impacted.

Where positive effects were found, the size of these effects tended to be small, with stronger effects relying on extensive implementation. Small effects are common in universal preventative interventions and the effects we observe in these trials are entirely consistent with previous research (Hayes et al., 2024). Nonetheless, small effects amplified to a population level can achieve meaningful impact.

However, even where shown to be effective, universal interventions like those trialled here are unlikely to achieve the larger shift in young people's mental health that is needed based on current prevalence estimates. Rather they should be considered as

part of a wider provision strategy in schools, alongside support embedded within families and communities.

Recommendations

Strategies for safety and wellbeing is a recommended intervention for increasing intended help-seeking in primary school students but may require a repeated dose for the effects to sustain. It also shows promise as an intervention in secondary schools only if it is implemented in full.

Relaxation techniques shows promise as an intervention in primary schools if implemented consistently and regularly but it is not recommended in secondary school settings due to potential unintended consequences when delivered with moderate or high frequency.

Mindfulness-based exercises showed no overall impact in primary schools. Furthermore, in this age range there was evidence of adverse effects for certain groups and at moderate and high levels of implementation. Therefore this intervention cannot be recommended for primary schools. However, if implemented frequently and consistently, it shows promise as an intervention for secondary school settings.

Findings indicate some interventions risk unintended consequences under some conditions or with some populations of pupils. When selecting interventions to be used in schools settings, it is important to check the evidence base to identify interventions that are known to be effective for the specific age and/or stage of education. When implementing new approaches to support pupils' mental health, monitoring is important to understand any benefits and check if any groups were negatively impacted.

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