Passport to Success: can teaching children social and emotional skills improve their mental health?

Submission date 17/11/2022	Recruitment status No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date 24/11/2022	Overall study status Completed	Statistical analysis plan		
		Results		
Last Edited	Condition category	Individual participant data		
02/11/2023	Other	Record updated in last year		

Plain English summary of protocol

Background and study aims.

Around 1 in 6 of children and young people experience mental health difficulties (changes in their thoughts, feelings, and behaviours that impact negatively on their quality of life). The period when children become adolescents (from around age 10 onwards), is important because of the major physical, psychological and social changes that happen. Research has shown that this is a period of particular vulnerability for the emergence of 'internalising symptoms (e.g., feelings of sadness and worry) and associated difficulties (e.g., loneliness). Schools can play a key role in promoting children's mental health. One way this can be done is through universal social and emotional learning (SEL) interventions, which aim to help all children to develop social and emotional skills that can help them to cope better when they face challenges in their lives. One such intervention is called Passport. The main aim of our study is to test whether Passport successfully reduces children's internalizing symptoms.

Who can participate?

The research team will recruit mainstream, non-independent, primary schools from the Greater Manchester city-region that have not previously delivered Passport. In these schools, pupils in Year 5 at the start of the intervention (September 2023) will take part, along with their class teachers.

What does the study involve?

Once school recruitment has finished, all participating pupils will complete online surveys about their internalising symptoms, emotion regulation, wellbeing, loneliness, bullying, peer support, and health related quality of life. After the baseline surveys, half of the schools will be randomly chosen to deliver Passport over 18 sessions, and the other half will continue as normal.

For the schools that deliver the intervention, teachers will deliver 18 weekly lessons across 5 topics (emotions, relationships and helping each other, difficult situations, fairness, justice and what is right, and change and loss) before the first follow up surveys, which will take place

approximately one year after the baseline surveys. Passport lessons are taught in a specific sequence, using a comic book format, and include detailed lesson plans, home activities, posters, comic strips, individual booklets for each child, emotion flashcards, and participation certificates.

What are the possible benefits and risks of participating?

There are no significant risks or disadvantages to completing the surveys and taking part in the intervention. However, all pupils will be informed about sources of support that they can seek out if any of the survey questions/intervention lessons make them feel sad, worried, or upset (e. g., parent/carer, Childline, member of school staff). There is no guaranteed benefit in taking part, but other work by members of the research team has shown that completing well-being surveys can help some children to reflect on their lives.

Where is the study run from?
The Manchester Institute of Education, based at the University of Manchester (UK)

When is the study starting and how long is it expected to run for? January 2021 to July 2025

Who is funding the study? The Kavli Trust (Norway)

Who is the main contact?
Dr Joao Santos, joao.santos@manchester.ac.uk

Study website

https://www.passport2success.co.uk/

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Kavli2021-0000000019

Study information

Scientific Title

Passport to Success: a parallel cluster randomised controlled trial to examine the impact of a universal social and emotional learning intervention on internalising symptoms and other outcomes among children aged 9-11, compared to the usual school curriculum

Acronym

Passport to Success

Study objectives

The trial's research questions (RQs) are classified as confirmatory (C: where research design and /or existing evidence permits hypothesis generation) or exploratory (E: where hypotheses are inappropriate or premature due to insufficient existing evidence and/or research design), drawing on quantitative (QT) data, qualitative (QL) data, or both (QT/QL):

Research Question 1: What is the impact of Passport on children's outcomes? (C, QT)

Hypothesis 1: Children in schools implementing Passport over a one-year period will demonstrate significantly improved outcomes with respect to internalizing symptoms (primary outcome, 1a); emotional regulation (1b); wellbeing (1c); loneliness (1d); bullying (1e); and peer support (1f).

Research Question 2: Are any intervention effects noted in RQ1 sustained (or do they emerge, in the case of null initial effects, or academic attainment, 2g) at 12-month post-intervention follow-up? (C, QT)

Hypothesis 2: The effects noted in H1a-f will be maintained at 12-month post-intervention follow-up (H2a-f); in addition, the emergence of effects on academic attainment are anticipated (H2g).

Research Question 3: Do intervention effects vary by levels of implementation (specifically, intervention dosage)? (E, QT)

Research Question 4: Is Passport cost-effective? (C, QT)

Hypothesis 3: Passport will demonstrate cost-effectiveness.

Research Question 5: Are primary intervention effects mediated by changes in emotional regulation? (E, QT)

Research Question 6: Do low emotional regulation skills at baseline moderate primary intervention effects? (E, QT)

Research Question 7: Is Passport implemented as intended by the developer (7a)? What factors impede or facilitate implementation (7b)? (E, QT/QL)

Research Question 8: What are the perceptions and experiences of school staff and children in delivering and engaging with the Passport? (E, QL)

The primary trial outcome is the difference in children's internalizing symptoms (1a; as measured by our selected instrument and controlled for individual levels and socio-demographic characteristics at baseline) at post-intervention (first follow-up) between schools implementing Passport (intervention) and those continuing usual provision (control). Other outcomes and timepoints are classed as secondary outcomes.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 30/06/2022, University Research Ethics Committee 1, University of Manchester (Research Governance, Ethics and Integrity, 2nd Floor Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, UK; no telephone number provided; research. ethics@manchester.ac.uk), ref: 2022-14050-24401. A minor amendment, ref: 2022-14050-25503, was approved on 04/10/2022

Study design

Parallel cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

See study outputs table

Health condition(s) or problem(s) studied

Prevention of internalizing symptoms in children aged 8-9 (at baseline)

Interventions

We will use a two-group (intervention vs. control) parallel cluster RCT design, with schools as the unit of randomisation. An independent statistician will perform the allocation procedure. Allocation will be at the school level to minimise contamination risk. Schools will be randomly allocated following completion of baseline measures at T0. Minimisation will ensure balance across trial arms in the proportion of children eligible for free school meals (since socio-

economic deprivation will likely co-vary with trial outcomes) and school size (since this will likely impact delivery capacity). This approach confers the benefits of randomisation in terms of rigour and causal inference while also guaranteeing similarity of groups on key observables.

For schools randomly allocated to the intervention arm, there will be one day of training, with a half-day booster session during implementation, for the teachers of children who will be in Year 5 in the academic year 2023/2024. Trained staff will then deliver 18 lessons across 5 modules (emotions, relationships and helping each other, difficult situations, fairness, justice and what is right, and change and loss), designed to be delivered approximately weekly in the period between T0 and T1 when the trial sample is aged 9-10 (Year 5). The developmentally sequenced lessons use an entertaining comic book format, which provides a foundation for activities in which children identify, experiment with, and evaluate the utility of different strategies for dealing with challenging situations. Intervention materials (digital and hard copy) include detailed lesson plans, home activities, posters, comic strips, individual Passport booklets for each child, emotion flashcards, and participation certificates. Adaptation and personalisation that is in line with intervention and session goals are encouraged as a means to improve fit to local needs.

The research team will establish the counterfactual by surveying teachers in participating schools from the usual provision (control) arm, at T0 and T1, regarding their usual practice in promoting social and emotional learning.

Intervention Type

Behavioural

Primary outcome measure

Children's internalizing symptoms (as measured by the KIDSCREEN-52 moods and emotions subscale, and controlled for individual levels and socio-demographic characteristics at baseline /T0 and at post-intervention (T1, approximately 18 weeks)

Secondary outcome measures

Current secondary outcome measures as of 28/04/2023:

Pupil-level data:

- 1. Internalising symptoms at T2, KIDSCREEN-52 moods and emotions subscale;
- 2. Emotion regulation measured using the Coping subscale of the Children's Worry Management Scale at T0 (baseline), T1 (18 weeks), and T2 (1 year);
- 3. Wellbeing measured using the Psychological wellbeing subscale of KIDSCREEN-52 at T0, T1, and T2;
- 4. Loneliness measured using the UCLA 3-item loneliness scale at T0, T1, and T2;
- 5. Bullying measured using the Social acceptance subscale of KIDSCREEN-52 at T0. T1. and T2:
- 6. Peer support measured using the Peer support subscale of KIDSCREEN-27 at T0, T1, and T2;
- 7. Health related quality of life measured using the Child Health Utilities 9D at T0, T1, and T2;

Staff-level data:

- 8. Usual Social emotional learning practice at the school level, measured via a staff online survey adapted from the research team's previous research, at T0 and T1;
- 9. Implementation dosage adaptation measured via an online staff survey adapted from the research team's previous research, at T1 (Intervention arm only);
- 10. Implementation fidelity measured via an online staff survey adapted from the research team's previous research, at T1 (Intervention arm only);
- 11. Implementation adaptation measured via an online staff survey adapted from the research

team's previous research, at T1 (Intervention arm only);

- 12. Teacher perception of SEL culture measured using the Teacher Social and Emotional Learning Beliefs Scale via an online staff survey at T0, T1 and T2 (Intervention and control arms);
- 13. Teacher burnout measured using a brief teacher stress and coping measure (consisting of two items asking about overall ratings of teacher stress and coping) via an online staff survey at T0, T1 and T2 (Intervention and control arms);
- 14. Teacher classroom management measured using the Ohio State Teachers' Sense of Efficacy Scale classroom management subscale via an online staff survey at T0, T1 and T2 (Intervention and control arms);

Pupil and staff-level data:

- 15. Reasons for adaptation of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 16. Reach of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 17. Acceptability of the intervention (whether the intervention is perceived as helpful and appropriate for staff and children), assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 18. Responsiveness to the intervention (how children respond to the intervention), assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 19. Additional factors impacting implementation of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;

Previous secondary outcome measures:

Pupil-level data:

- Internalising symptoms at T2, KIDSCREEN-52 moods and emotions subscale;
- 2. Emotion regulation measured using the Coping subscale of the Children's Worry Management Scale at T0 (baseline), T1 (18 weeks), and T2 (1 year);
- 3. Wellbeing measured using the Psychological wellbeing subscale of KIDSCREEN-52 at T0, T1, and T2;
- 4. Loneliness measured using the UCLA 3-item loneliness scale at T0, T1, and T2;
- 5. Bullying measured using the Social acceptance subscale of KIDSCREEN-52 at T0, T1, and T2;
- 6. Peer support measured using the Peer support subscale of KIDSCREEN-27 at T0, T1, and T2;
- 7. Health related quality of life measured using the Child Health Utilities 9D at T0, T1, and T2;

Staff-level data:

- 8. Usual Social emotional learning practice at the school level, measured via a staff online survey adapted from the research team's previous research, at T0 and T1;
- 9. Implementation dosage adaptation measured via an online staff survey adapted from the research team's previous research, at T1 (Intervention arm only);
- 10. Implementation fidelity measured via an online staff survey adapted from the research team's previous research, at T1 (Intervention arm only);

- 11. Implementation adaptation measured via an online staff survey adapted from the research team's previous research, at T1 (Intervention arm only);
- 12. Teacher perception of SEL culture measured using the Teacher Social and Emotional Learning Beliefs Scale via an online staff survey at T0, T1 and T2 (Intervention and control arms);
- 13. Teacher burnout measured using the Perceived Stress Scale 10 via an online staff survey at T0, T1 and T2 (Intervention and control arms);
- 14. Teacher classroom management measured using the Ohio State Teachers' Sense of Efficacy Scale classroom management subscale via an online staff survey at T0, T1 and T2 (Intervention and control arms);

Pupil and staff-level data:

- 15. Reasons for adaptation of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 16. Reach of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 17. Acceptability of the intervention (whether the intervention is perceived as helpful and appropriate for staff and children), assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 18. Responsiveness to the intervention (how children respond to the intervention), assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;
- 19. Additional factors impacting implementation of the intervention, assessed via qualitative data generation (semi-structured interviews with teachers and other staff, such as members of senior leadership, and focus groups with children) during implementation of the intervention (between T0 and T1) and shortly after intervention delivery;

Overall study start date

01/01/2021

Completion date

25/07/2025

Eligibility

Key inclusion criteria

Recruitment will take place at the school level, meaning most inclusion criteria will apply to schools. These are:

- 1. Must be a mainstream school
- 2. Must be a primary school
- 3. Must be a non-independent school
- 4. Must not have delivered Passport
- 5. Must be in the Greater Manchester city-region or its surrounding areas

Pupil-level inclusion criteria:

6. Pupils must be in Year 4 at the time of baseline surveys (T0)

Participant type(s)

Learner/student

Age group

Child

Sex

Both

Target number of participants

n=60 schools, with n=40 participants per school, meaning a total n=2400. This number already accounts for oversampling, as current power estimates require at least n=52 schools, with n=40 pupils per school, for a total n=2080

Total final enrolment

2242

Key exclusion criteria

Schools and participants that do not meet the inclusion criteria

Date of first enrolment

17/04/2023

Date of final enrolment

30/06/2023

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Manchester Institute of Education

The University of Manchester Ellen Wilkinson Building Oxford Road Manchester United Kingdom M13 9PL

Sponsor information

Organisation

University of Manchester

Sponsor details

Oxford Road Manchester England United Kingdom M13 9PL +44 (0)161 306 6000 seed@manchester.ac.uk

Sponsor type

University/education

Website

https://www.manchester.ac.uk/

ROR

https://ror.org/027m9bs27

Funder(s)

Funder type

Charity

Funder Name

Kavlifondet

Alternative Name(s)

The Kavli Trust, Kavli Trust, O. Kavli og Knut Kavlis Almennyttige Fond

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Norway

Results and Publications

Publication and dissemination plan

Planned publications in high-impact peer-reviewed journals. The trial protocol and the statistical analysis plan are not published or available online and will be made available once signed off by the study statistician.

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The project will adopt open science practices where appropriate and possible. To this end, following trial registration, the trial protocol will be submitted for external review and published. The statistical analysis plan and health economic evaluation plan will be preregistered prior to data collection. An anonymised copy of the project dataset, alongside the project materials, such as the interview schedules and questionnaires, will be securely deposited with the UK Data Service following the completion of the project. The pre-prints of all academic papers and code used in analyses will be deposited in an open repository such as the Open Science Framework (OSF), and per Kavli Trust regulations, all publications will be Gold Open Access. We will also explore publication using the Registered Report approach (e.g. peer review with in-principle acceptance before results are known) with relevant participating journals (e.g. British Journal of Educational Psychology).

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	29/10/2022	17/11/2022	No	Yes
Protocol (other)		26/04/2023	02/05/2023	No	No
Protocol article		02/11/2023	02/11/2023	Yes	No