

COVER PAGE

Evaluating the efficacy of the Promoting Alternative Thinking Strategies (PATHS) curriculum in promoting social and emotional wellbeing among children in primary school: a cluster randomised controlled trial

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TRIAL PERSONNEL

Chief Investigator (CI)

Professor Neil Humphrey
Professor of Psychology of Education
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Co-Investigator (Co-I)

Dr Michael Wigelsworth
Lecturer, Research Methods and Statistics
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Co-Investigator (Co-I)

Dr Ann Lendrum
Lecturer, Psychology
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Co-Investigator (Co-I)

Dr Kevin Woods
Senior Lecturer, Educational and Child Psychology
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Co-Investigator (Co-I)

Dr Gary Squires
Lecturer, Educational and Child Psychology
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Co-Investigator (Co-I)

Professor Rachel Calam
Professor of Child and Family Psychology
School of Psychological Sciences
University of Manchester
Oxford Road
Manchester

Project Manager

Dr Alexandra Barlow
Research Associate
ESI, School of Education
University of Manchester
Oxford Road

Manchester

Sponsor's representative

Professor Colette Fagan
Faculty Associate Dean for Research
Faculty of Humanities
University of Manchester
Oxford Road
Manchester

Statistician

Dr Michael Wigelsworth
Lecturer, Research Methods and Statistics
ESI, School of Education
University of Manchester
Oxford Road
Manchester

Health Economist

Dr Mark Harrison
Research Fellow
Jean McFarlane Building
University of Manchester
Oxford Road
Manchester

Clinical Trials Coordination Unit

Ian Bottomley
Clinical Trial Project Manager
CTCU, Block C Withington Hall
The Christie Hospital NHS Trust
Wilmslow Road
Manchester

SIGNATURES/PROTOCOL APPROVAL

Evaluating the efficacy of the Promoting Alternative Thinking Strategies (PATHS) curriculum in promoting social and emotional wellbeing among children in primary school: a cluster randomised controlled trial.

This document describes the above trial and provides information about procedures for entering participants into it.

The protocol should not be used as a guide for the intervention of participants outside the trial.

Every care was taken in drafting this protocol, but corrections or amendments may be necessary, care must be taken to use the most up to date and approved version.

This trial will adhere to the principles outlined in the ICH Good Clinical Practice guidelines. The trial will be conducted in compliance with the protocol, the Data Protection Act (DPA Z6364106), the Declaration of Helsinki, the Research Governance Framework (2005) and other regulatory requirements as appropriate.

Chief Investigator – Professor Neil Humphrey, University of Manchester.

I, Professor Neil Humphrey, as Principal Investigator for the aforementioned trial to be conducted at the University of Manchester, confirm that I will be responsible to ensure that all members of the local trial team are appropriately trained on the trial protocol and have the relevant qualifications and experience to carry out their role in accordance with the trial protocol.

Signed: Neil Humphrey.

Date: 11/06/12

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LIST OF ABBREVIATIONS

Commonly used abbreviations – add or delete as applicable:

CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
DMC	Data Monitoring Committee
EC	European Commission
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
GAfREC	Governance Arrangements for NHS Research Ethics
GCP	Good Clinical Practice
ICF	Informed Consent Form
ISF	Investigator Site File
ISRCTN	International Standard Randomised Controlled Trial
MS	Member State
Main REC	Main Research Ethics Committee
PI	Principal Investigator
PIS	Participant Information Sheet
QA	Quality Assurance
QC	Quality Control
RCT	Randomised Control Trial
REC	Research Ethics Committee
SDV	Source Document Verification
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMG	Trial Management Group
TSC	Trial Steering Committee

TRIAL SUMMARY

Title: Evaluating the efficacy of the Promoting Alternative Thinking Strategies (PATHS) curriculum in promoting social and emotional wellbeing among children in primary school: a cluster randomised controlled trial

Short title: PATHS to Success

Design: Cluster randomised controlled trial

Objectives: The primary aim of the trial is to examine the impact of the PATHS curriculum on the social and emotional wellbeing of children in primary schools in England, with the following objectives:

Primary Objective:

- To determine the impact of PATHS on a variety of outcomes for children, i.e. social and emotional competence, quality of life, attendance and academic attainment

Secondary Objectives:

- To determine whether the impact of PATHS is sustainable
- To determine the impact of PATHS on children's psychosocial adjustment to secondary school
- To assess the role of implementation variability in mediating the impact of PATHS on outcomes for children
- To assess the validity of the logic model for SEL programmes
- To examine the cost-effectiveness of PATHS

Endpoints:

Primary Endpoint:

- Children in primary schools implementing PATHS will demonstrate significant improvements in social and emotional competence

Secondary Endpoints:

- The sustainability of the effects of PATHS for a 2 year follow up period
- Children in schools implementing PATHS will demonstrate significantly better psychosocial adjustment upon transfer to secondary school, compared to those attending control schools
- Quality of implementation will be associated with improved outcomes in schools implementing PATHS
- Proximal changes in social and emotional competence and the learning environment will be associated with distal improvements in motivation to learn, psychological wellbeing and (reduced) internalising and externalising difficulties, which in turn will impact upon attendance, academic attainment and exclusions
- The PATHS curriculum will demonstrate cost-effectiveness.

Cohorts: Schools allocated to the intervention arm of the trial will implement PATHS, with technical support and assistance from our research team's process group, with children in the three classes detailed below over a two-year period (2012/13 and 2013/14). Schools in the control arm of the trial will continue their usual practice. We will assess outcomes at the beginning (T1), mid-point (T2) and end of the trial (T3) (control/background measures will be taken at T1 and T3). After two years, the main trial will reach its conclusion. At this point, all participating schools will be free to decide whether to continue (or start, in the case of control schools) implementing PATHS. The two-year follow-up phase will begin, during which we will track the cohort of pupils who transferred to secondary school at the end of the main trial (e.g. at the beginning of the 2014/15 school year). Measurement of outcomes for this cohort will follow the pattern established in the main trial (e.g. assessment at the beginning (T3), mid-point (T4) and end (T5) of the phase)

Eligibility: Children in primary school aged 7-11.

Trial Intervention and methods: PATHS comprises 131 lessons across five volumes and one readiness unit that focus upon developing children's self-control, emotional awareness and interpersonal problem-solving. It is designed to be delivered by class teachers for approximately one hour per week throughout the school year. The developmental sequencing of the lessons means that it can be introduced at any age from 4-11. The lessons cover topics including identifying and labelling feelings, expressing feelings, assessing the intensity of feelings, managing feelings, understanding the difference between feelings and behaviours, delaying gratification, controlling impulses, reducing stress, self-talk, reading and interpreting social cues, understanding others' perspectives, using steps for problem-solving and decision-making, self-awareness, nonverbal communication skills, and verbal communication skills.

Trial duration per participant: From consent to last trial assessment.

Estimated total trial duration: 5 years

Total number of participants planned: 50 schools

INTRODUCTION

Background

Experiencing social and emotional wellbeing during childhood is an important outcome in and of itself, but also has implications for public health because of its associations with academic achievement, employment, family and relationship stability and other crucial outcomes later in life. Research indicates a rise in child mental health difficulties in the last several decades, and a recent survey ranked the UK bottom of 21 developed countries in relation to child wellbeing. Current estimates suggest that around 1 in 10 children and young people in England experience clinically significant problems, with higher rates of disorder among adolescents compared to children. This trend is hypothesized to relate to a range of developmental and educational changes that take place around the beginning of adolescence. Research also suggests that certain groups of children and young people are at an increased risk of experiencing inequalities in mental health, both in terms of access to services and likelihood of experiencing difficulties. These include those experiencing socio-economic deprivation, with special educational needs, and from some ethnic minorities.

As one of the most effective agencies for the promotion of health (including mental health), schools have become the main focus of efforts to reverse the trends outlined above. National strategies (such as the Social and Emotional Aspects of Learning (SEAL) programme) have had negligible impact, and as a result there has been increasing interest in the adoption of evidence-based SEL interventions. Systematic reviews and meta-analyses in this area demonstrate that high quality SEL interventions impact on a range of outcomes (including social and emotional competence, mental health difficulties, school attitudes, and academic performance). Universal, preventive interventions are delivered to all children and can be particularly effective, yielding effect sizes in the small-to-medium range that are likely to be of practical significance to schools. Furthermore, the evidence base is stronger when such intervention occurs earlier (primary school) rather than later (secondary school). Multi-component programmes (e.g. curriculum, parenting, ethos/environment) are no more effective than those with a single main component (e.g. curriculum). Interventions carried out by trained school staff (e.g. teachers) are at least as effective (and in some cases, more effective) than those carried out by non-school personnel. Finally, quality of implementation (and in particular, fidelity to treatment protocol) is a crucial mediator of programme impact.

Despite an impressive international research base, rigorous empirical evidence of the impact of the PATHS curriculum in the English educational context is lacking. Although there have been two studies published focusing on the implementation of this intervention in the UK, these were small-scale, exploratory and methodologically limited. The first was a qualitative study of the perceived effects in a single classroom in a primary school in Scotland. The second was a quasi-experimental study carried out in England, which despite benefitting from a control group suffered from a number of methodological flaws (e.g. intervention and control groups not properly matched, no monitoring of treatment fidelity, cluster design unacknowledged, insufficient statistical power). Although the PATHS curriculum is part of an ongoing trial in Birmingham, this focuses on its effects on children in the early stages of primary education (aged 4-6), and does not cover the key objectives of our proposed research (e.g. impact on adjustment to secondary school, sustainability, SEL logic model).

Rationale for the proposed trial

The research will yield insights into the efficacy, effectiveness, cost-effectiveness, durability, and impact on health inequalities of a primary school-based intervention. PATHS has a strong, international evidence base but its effectiveness in England is unproven, making it a perfect candidate for study.

There are also several key gaps in the current literature base. The vast majority of published studies originate in the USA and the efficacy of evidence-based programmes in the English context remains largely unknown. There is also relatively less available evidence on the longer-term (e.g. >6 months) sustainability of programme effects; in particular, it is not known whether involvement in an evidence-based intervention in the primary school years yields subsequent advantages in terms of successful adjustment to and progress in secondary school. Furthermore, the logic model inherent in SEL interventions has not been tested empirically. Published evaluations of the cost-effectiveness of school-

based interventions designed to promote social and emotional wellbeing are lacking. Finally, the extent to which universal SEL interventions might help to address health inequalities experienced by at-risk groups has not been fully explored.

Our proposed research will build upon what is already known in the field and address the specific gaps outlined above. In doing so, it will provide major advances in the theory, research and practice of promoting social and emotional wellbeing in primary education. In response to the commissioned call from the National Institute for Health Research (NIHR), we have selected an intervention that is appropriate to the topic (social and emotional wellbeing) and context (primary school) outlined, and is thoroughly grounded in rigorous research.

Assessment and management of risk

The design of the proposed research minimises the risk of harm to participants. As a failsafe, members of our research team will have reviewed participating schools' health and safety protocols and will act accordingly in the event of such an incident. In terms of emotional harm, in the event of a participant becoming upset or distressed at any point in the research, the researcher will immediately cease data collection and contact an a-priori nominated member of school staff to provide support. Preventive measures will also be in place – for example, contact details of organisations who can provide independent support and advice on social and emotional issues (e.g. Childline) will be made available to all participants.

As the project is school-based and focuses upon pupil outcomes it is inevitable that children under 16 will be sampled. All members of the research team have completed full CRB enhanced disclosure and will be briefed on LA Child Protection protocols. Parental consent will be sought for all participants

TRIAL OBJECTIVES

1. To determine the impact of PATHS on a variety of outcomes for children

Hypothesis 1: Children in primary schools implementing PATHS over a two-year period will demonstrate significant improvements in social and emotional competence (1a), health-related quality of life (1b), exclusions (reduction) (1c), attendance (1d) and academic attainment (1e), when compared to those children attending control schools.

2. To determine whether the impact of PATHS is sustainable

Hypothesis 2: The effects outlined in H1 will be sustained at two-year post-intervention follow-up

3. To determine the impact of PATHS on children's psychosocial adjustment to secondary school

Hypothesis 3: Children in primary schools implementing PATHS over a two-year period will demonstrate significantly better psychosocial adjustment upon transfer to secondary school, when compared to those attending control schools.

4. To assess the role of implementation variability in mediating the impact of PATHS on outcomes for children

Hypothesis 4: Quality of implementation will be associated with improved outcomes in school implementing PATHS

5. To assess the validity of the logic model for SEL programmes

Hypothesis 5: Proximal changes in social and emotional competence and the learning environment will be associated with distal improvements in motivation to learn, psychological wellbeing and (reduced) internalising and externalising difficulties, which in turn will impact upon attendance, academic attainment and exclusions

TRIAL DESIGN

Overall design

The research will utilise a *cluster-randomised controlled trial*. The 'clusters' in this context are individual primary schools. We will randomly allocate a minimum of 50 primary schools from Greater Manchester to an intervention group or comparison group. The random allocation process will be handled independently of the research team by the Christie NHS Foundation Trust.

The 25 intervention schools will be trained to provide the PATHS intervention. Their teachers will then use the intervention materials to deliver lessons three times a week over a two year period to pupils in Years 3, 4 and 5 (the 25 comparison group schools will continue their usual practice during this period). Members of our team will work with and support these schools to ensure that PATHS is implemented properly, and we will record any changes they make to see if this affects later outcomes. We will work very closely with schools on this aspect, collecting data on things like dosage (e.g. do schools deliver the required number of lessons?) and fidelity (e.g. do schools deliver PATHS as it was intended in the intervention manual?) and also talking to teachers, pupils and their parents about their experiences of taking part. At the end of the two year period, schools will be free to continue (or, in the case of control schools, start) to implement PATHS. The children who were in Year 5 at the beginning of the project and transfer to secondary school at the end of the main trial will be followed-up for a further two years to see if the PATHS curriculum impacts upon their adjustment to their new school, and also to see if any intervention effects are sustained over time.

We will take a range of measures at regular intervals to help us find out if PATHS is effective, including social and emotional competence, health related quality of life, school attendance, and academic attainment. We will also perform analyses that will tell us if the intervention provides good value for money. We will assess outcomes at the beginning (T1), mid-point (T2) and end of the trial (T3) (control/background measures will be taken at T1 and T3). After two years, the main trial will reach its conclusion. At this point, all participating schools will be free to decide whether to continue (or start, in the case of control schools) implementing PATHS. The two-year follow-up phase will begin, during which we will track the cohort of pupils who transferred to secondary school at the end of the main trial (e.g. at the beginning of the 2014/15 school year). Measurement of outcomes for this cohort will follow the pattern established in the main trial (e.g. assessment at the beginning (T3), mid-point (T4) and end (T5) of the phase).

SELECTION OF TRIAL PARTICIPANTS

Inclusion Criteria

- Children aged 7-11 attending said primary schools.
- All children who are on a given school's full-time roll in each of the Year 3, 4 and 5 classes at the start of the 2012/13 school year will be considered as potential participants.
- Parental consent will need to be provided for each potential pupil to participate.

Exclusion Criteria

- Any children who do not meet the inclusion criteria specified above will be excluded from the study.

RECRUITMENT OF TRIAL PARTICIPANTS

Geographical Setting

The setting of the trial will be primary schools in England. For reference purposes, 'primary schools' will be restricted to mainstream, state-maintained institutions, providing education for children from the ages of 4-11. We plan to recruit these schools from the 10 LAs that form the Greater Manchester region – Bolton, Bury, Manchester, Oldham, Rochdale, Salford, Stockport, Tameside, Trafford, and Wigan. These LAs provide great diversity in their urbanicity, socio-economic status, ethnicity, and other relevant factors that will help to ensure that our research setting is representative of England.

Identifying Participants

Eligible schools in the areas noted in section 6(i) will be identified using publicly available information on LA websites. Additionally, we will contact school improvement partners and Children's Services Commissioners in each LA with a view to identifying potential participants. Schools will be approached using a range of techniques, including publicity events (e.g. a one day event will be organised that will inform schools of the project), email and post (of project flyers and associated materials), and telephone contact.

Consenting Participants

Schools, parents and their children will be provided with information sheets about the purpose, methods and intended uses of the research, what 'participation' entails, and any anticipated risks and benefits. Different versions will be produced that are appropriate to the different stakeholders. Additionally, a contact number will be provided to enable additional queries to be answered. Consent will be sought at three levels – school, parent and child (assent). In view of the large sample size and measurement protocols (e.g. child surveys filled in online with no direct contact with research team), opt-out will be used for parental consent (however, this will be repeated before each wave of data collection). The only exception to this will be for child interviews, for which we will seek opt-in parental consent in view of the direct contact implied.

Screening for Eligibility

Schools which provide a sufficient number of baseline measures (>85% of teacher and pupil surveys) will be entered into randomisation.

Ineligible and Non-Recruited Participants

Schools which provide do not sufficient number of baseline measures (<85% of teacher and pupil surveys) will not be entered into randomisation.

Registration/Randomisation Procedures

Schools are the unit of randomisation. They will be randomised using a minimisation algorithm that will ensure a balance across the two arms of the trial (intervention and usual practice) in terms of two school level factors: deprivation and English as an additional language

INTERVENTION DETAILS

Intervention Summary

PATHS is a universal, curriculum-based SEL intervention for primary school children. It has an extremely strong international evidence base, including multiple high quality, randomised controlled trials, that demonstrate effects on a range of outcomes including social and emotional competence, mental health difficulties and academic attainment, with effect sizes approaching $d=0.5$ in some instances. PATHS is one of only 12 interventions (in a review of over 800) to have been designated as a 'model program' by the Centre for Study and Prevention of Violence due to clear evidence of its efficacy, sustained effects and multiple site replications. It has also been designated as a 'model program' by the Substance Abuse and Mental Health Services Administration (SAMHSA), and included in their National Registry of Evidence-Based Programs and Practices (SAMHSA also rated it 3.6 out of 4 for 'readiness for dissemination'). Finally, it was recommended to HM Government in the recent Independent Review of Early Intervention.

Details of Trial Intervention

PATHS comprises 131 lessons across five volumes and one readiness unit that focus upon developing children's self-control, emotional awareness and interpersonal problem-solving. It is designed to be delivered by class teachers for approximately one hour per week throughout the school year. The developmental sequencing of the lessons means that it can be introduced at any age from 4-11. The lessons cover topics including identifying and labeling feelings, expressing feelings, assessing the intensity of feelings, managing feelings, understanding the difference between feelings and behaviors, delaying gratification, controlling impulses, reducing stress, self-talk, reading and interpreting social cues, understanding others' perspectives, using steps for problem-solving and decision-making, self-awareness, nonverbal communication skills, and verbal communication skills⁽³⁵⁾. Although PATHS primarily focuses on the school/classroom setting, information and activities for use with parents are also

included in the curriculum package, as are 'extension' activities and tasks to encourage skill generalization.

PATHS is built around the Affective-Behavioural-Cognitive-Dynamic (ABCD) model of development, which focuses on the developmental integration of affect, emotion language, behaviour and cognitive understanding to promote social and emotional competence. There are two key propositions within this model that are directly pertinent to the content and delivery of the PATHS curriculum and the objectives of our research. Firstly, children's behaviour and internal regulation are considered to be functions of their emotional awareness, affective-cognitive control, and social-cognitive understanding. Secondly, the relationship and interaction between different domains of development changes throughout childhood – for example, in early development, emotional development precedes most forms of cognition, meaning that young children experience emotions and react on an emotional level before they are able to fully articulate their experiences. As children get older their behaviour, language, cognition and emotion become more closely integrated. For example, during middle-to-late childhood, children demonstrate an increasing ability to reflect on and plan sequences of action (including consideration of different perspectives on a situation and the variety of consequences that a particular action could yield). The PATHS volumes and lessons are designed to reflect these developmental sequences.

The intended delivery protocol of the PATHS curriculum reflects an 'eco-behavioural systems orientation'. This approach recognises that interventions that focus on the child or the environment alone are not as effective as those that consider both in tandem. Thus, PATHS emphasizes skill building, the development of adaptive relationships (teacher-child and child-child), the teacher's approach to interaction, and complete integration of the intervention at classroom and school levels.

TRIAL METHODOLOGY

Table 1 provides an overview of the various assessments that will be conducted during the course of the trial.

Table 1

Measures		When	Who
School - PATHS coordinator	<u>Usual practice survey</u>	<u>Summer 2012</u> <u>Summer 2013</u>	<u>All schools</u>
	<u>2 day training event</u>	<u>Autumn 2012</u>	<u>PATHS schools</u>
	<u>PATHS school visits</u>	<u>Twice termly - 2012/13,</u> <u>2013/14</u>	<u>PATHS schools</u>
Teachers	<u>Implementer characteristics survey</u>	<u>Autumn 2012 (on training day)</u>	<u>PATHS schools</u>
	<u>Factors affecting implementation: barriers and facilitators survey</u>	<u>Spring 2013</u> <u>Spring 2014</u>	<u>PATHS schools</u> <u>PATHS schools</u>
	<u>Teacher implementation survey</u>	<u>Summer 2013</u> <u>Summer 2014</u>	<u>PATHS schools</u> <u>PATHS schools</u>
	<u>PATHS school visits</u>	<u>Twice termly - 2012/13,</u> <u>2013/14</u>	<u>PATHS schools</u>
	<ul style="list-style-type: none"> • <u>Support/advice with implementation</u> • <u>Interviews with teachers</u> • <u>Observations of PATHS lessons</u> • <u>Completion of above surveys</u> 		
	<u>Pupil outcome survey</u>	<u>Summer 2012</u> <u>Summer 2013</u> <u>Summer 2014</u>	<u>All schools</u> <u>All schools</u> <u>All schools</u>

<u>Parents</u>	<u>Pupil outcome survey</u>	<u>Summer 2012</u>	<u>All schools</u>
		<u>Summer 2013</u>	<u>All schools</u>
		<u>Summer 2014</u>	<u>All schools</u>
<u>Pupils</u>	<u>Pupil outcome survey</u>	<u>Summer 2012</u>	<u>All schools</u>
		<u>Summer 2013</u>	<u>All schools</u>
		<u>Summer 2014</u>	<u>All schools</u>

TRIAL ASSESSMENTS

Assessment of process

We will perform a thorough and detailed ‘process evaluation’ of PATHS throughout the trial. This will comprise in vivo documentation of the treatment arm schools’ operation of the intervention by members of our research team’s process group, who will conduct half-termly visits to each. These visits will include the following:

- Observation of a PATHS lesson* to provide first-hand evidence of quality and fidelity to guidance
- Survey of school PATHS co-ordinator* to monitor ongoing implementation, using seven of Durlak and DuPre’s suggested eight-factor model for the evaluation of implementation:
 - Fidelity – the extent to which the school is adhering to the intended treatment model
 - Dosage – how much of the intervention has been delivered
 - Quality – how well different PATHS components are delivered
 - Participant responsiveness – the degree to which children and their parents engage with the intervention
 - Programme differentiation – the extent to which PATHS activities can be distinguished from other, existing practice
 - Programme reach – rate and scope of participation
 - Adaptation – the nature and extent of changes made to the intervention
- Structured interview protocols with relevant stakeholders (e.g. school PATHS co-ordinator, head teacher, class teachers, children, parents) to provide data on the following:
 - Audit of key processes (e.g. planning, use of resources, difficulties encountered)
 - Focused assessment of emergent or ongoing issues relating to health inequalities (for example, engagement of children and their parents in families affected by poverty)
 - Identification of context specific factors affecting implementation
 - Perceptions of the PATHS curriculum

Primary and secondary analysis

Instrumentation criteria

In selecting our primary and secondary outcome measures we have drawn upon our own and other researchers’ recent systematic reviews of available instruments in relevant domains, including social and emotional competence and mental health. The instruments outlined below were chosen using the following criteria: (i) goodness-of-fit with study parameters (e.g. age of participants, domains of interest), (ii) psychometric properties (iii) brevity, (iv) multiple informant versions (e.g. child, parent, teacher), (v) use in similar or related research published in peer-reviewed journals, and (vi) use in other NIHR-funded trials in this commissioned strand (to allow for direct comparison of treatment effects). Unless otherwise stated, we plan to use online survey software (WorldAPP Key Survey) in the collection of our various measures.

Primary outcome measure

Social and emotional competence

The proximal impact of the PATHS curriculum is on children's social and emotional competence. Recent systematic reviews of measures in this area ^(46, 48) highlighted the *Social Skills Improvement System* (SSIS) rating scales and the *Strengths and Difficulties Questionnaire* (SDQ) as being among the 'gold standard' instruments. The SSIS provides measurement of social skills (including communication, empathy, and self-control), problem behaviours (including internalising and externalising difficulties) and academic competence (including reading and maths achievement¹, and motivation to learn). The measure (previously known as the Social Skills Rating System – SSRS) is well established in the academic literature, having been included in excess of 40 research articles published in peer-reviewed journals. It has child, teacher and parent-rated versions, takes approximately 15-25 minutes to complete, and has been standardised for children and young people aged 3-18 (child-rated version from age 8). The rating scales follow a Likert response format in which raters read a statement (an example from the teacher-rated version is, “[This child] shows concern for others”) and indicate their level of agreement on a four-point scale. The SSIS rating scales have excellent psychometric properties, as detailed below:

- Reliability
 - Internal: co-efficients range from 0.72-0.95
 - Test-retest: co-efficients range from 0.72-0.92
 - Inter-rater: co-efficients range from 0.48-0.69
- Validity
 - Factorial: established through confirmatory factor analysis (CFA)
 - Convergent: correlates with a range of similar instruments (e.g. BASC-2)
 - Discriminative: discriminates between clinical (including children with ADHD, behavioural, emotional and social difficulties, and learning difficulties) and non-clinical samples
- Other
 - Development and subsequent refinement of the SSIS utilized Item Response Theory⁽⁴⁶⁾

The SDQ provides measurement of children's emotional symptoms, conduct problems, hyperactivity/inattention, peer problems and pro-social behaviour. It is the most widely used outcome measure of its type in the UK. Teacher and parent informant-rated versions are available for children under the age of 11, which take approximately 5-10 minutes to complete. The SDQ follows a Likert response format in which raters read a statement (an example from the parent-rated version is, “[This child] often lies or cheats”) and indicate their level of agreement on a three-point scale. The SDQ has strong psychometric properties, as detailed below:

- Reliability
 - Internal: co-efficients range from 0.57-0.87
 - Test-retest: co-efficients range from 0.61-0.80
 - Inter-rater: co-efficients range from 0.27-0.48
- Validity
 - Factorial: established through exploratory factor analysis (EFA)
 - Convergent: correlates with a range of similar instruments (e.g. CBCL)⁽⁵⁴⁾
 - Predictive: strongly predictive of independently diagnosed psychiatric disorders

In view of the overlap between elements of the SSIS and the SDQ and to reduce the data collection burden for respondents, we propose to strategically select subscales from these instruments. So, for example, given that the SSIS externalising difficulties subscale and SDQ conduct problems subscale essentially tap the same domain, we propose to use only the latter in our teacher and parent surveys. Full clarification of the subscales that will be used with each informant (child, teacher, parent) can be found in Table 2 below.

¹ Teacher informant report version only.

Secondary outcome measures

Health-related quality of life

Distal effects of the PATHS curriculum on health-related quality of life will be assessed using the *Kidscreen-27 (KS27)* instrument. A recent systematic review of measures highlighted the KS27 as being among the 'gold standard' instruments in this area. The KS27 provides measurement of health-related quality of life (including physical wellbeing, psychological wellbeing, parent relations and autonomy, social support and peers, and school environment). The KS rating scales are well established in the academic literature, having been included in over 40 research articles in peer-reviewed journals. It has child and proxy-rated (e.g. parent) versions, takes approximately 5-10 minutes to complete, and has been standardised for children and young people aged 8-18. The rating scales follow a Likert response format, in which raters read a statement (an example from the child version is, "Have you felt sad?") and indicate their level of agreement on a five-point scale. The KS27 has excellent psychometric properties, as detailed below:

- Reliability
 - Internal: co-efficients range from 0.78-0.84
 - Test-retest: intra-class correlation co-efficients range from 0.61-0.74
 - Inter-rater: co-efficients range from 0.39-0.52

- Validity
 - Factorial: established through confirmatory factor analysis
 - Convergent: correlates with a range of similar instruments (e.g. PedsQL)
 - Discriminative: discriminates between clinical (e.g. those with chronic health conditions, psychosomatic complaints and mental health difficulties) and non-clinical samples

- Other
 - Development and subsequent refinement of the KS27 utilized IRT

To aid in the cost-effectiveness analysis (see Hypothesis 6), we will supplement the KS27 with the Child Health Utilities 9D (CHU-9D) classification system. This will allow intervention benefits to be accurately mapped onto increases in quality-adjusted-life-years (QALYs).

Attendance, attainment and exclusions

All schools in England record data on attendance, attainment and exclusions for each of their pupils and it is held at both local (e.g. LA) and national (e.g. Department for Education – National Pupil Database (NPD)) levels. We will intercept the data as required at the LA level, reducing the data collection burden on schools involved in the trial. *Attendance* data is recorded as the proportion of half-days missed due to unauthorised absence. Changes in children's *academic attainment* will be assessed in two ways – firstly, via end of Key Stage 2 points scores for Maths and English. These point scores are derived from the National Curriculum levels attained by children in their Key Stage 2 Standard Assessment Tests (SATs), which are completed at the end of Year 6. Secondly, because the former data will only be available for oldest cohort of children who complete Year 6 at the end of the main trial, we will administer InCAS assessments to the whole sample on an annual basis in tandem with our outcome surveys – this will provide indices of their reading, maths and general ability. For *exclusions*, we will record the frequency of both permanent and fixed-term exclusions for each participant during the course of the trial. For the latter we will also record the duration of the exclusion period (number of days).

Psychosocial adjustment to secondary school

Children's adjustment to secondary school will be assessed by utilising key subscales from the KS-27. These are:

- School environment
- Peers and social support
- Psychological wellbeing

Table 2: Summary of outcome measures

Measures		Child	Teacher	Parent
Primary outcome measure	Social and emotional competence	Social skills (SSIS)	Pro-social behaviour, peer relationship problems (SDQ)	Pro-social behaviour, peer relationship problems (SDQ)
			Emotional symptoms (SDQ)	Emotional symptoms (SDQ)
			Conduct problems (SDQ)	Conduct problems (SDQ)
			Hyperactivity/inattention (SDQ)	Hyperactivity/inattention (SDQ)
Secondary outcome measures	Health-related quality of life	CHU-9D		CHU-9D
		Psychological well-being (KS-27)		Psychological well-being (KS-27)
		Social support and peers (KS-27)		Social support and peers (KS-27)
		School environment (KS-27)		School environment (KS-27)
	Psychosocial adjustment to secondary school	Psychological well-being, social support and peers, school environment (KS-27)		
Attendance, attainment and exclusions	Attainment derived from InCAS scores. All other measures to be derived from LA/NPD records.			

STATISTICS AND DATA ANALYSIS

Trial Design

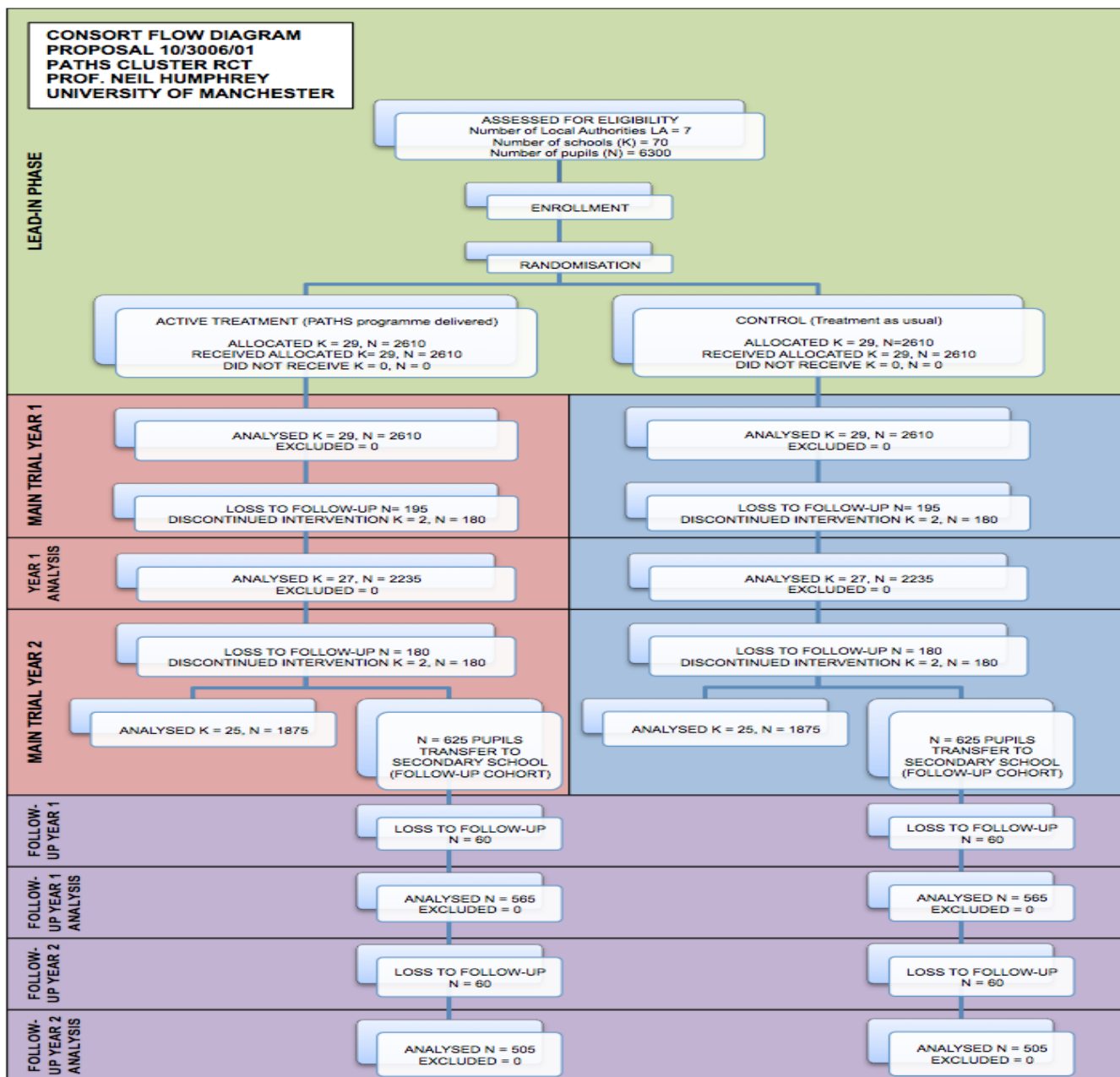
Cluster-randomised controlled trial.

Sample size calculation

Our power and sample size (PASS) calculations are based on previous trials of PATHS, a recent major meta-analysis of universal SEL interventions, and relevant research looking at school effects (e.g. intra-cluster correlations - ICC) for psychosocial outcome variables. In arriving at the various figures that naturally represent professional *estimates* (e.g. the ICC and effect size), we have purposefully been conservative in order to ensure that we will retain appropriate statistical power throughout our various analyses. Thus, we have calculated our required sample size based upon what we expect would be the *upper limit* for the ICC and the *lower limit* for the effect size.

We anticipate an effect size of at least $d=0.2$ for our primary outcome measure. With an estimated ICC of at most 0.05, and an average cluster size of $N=75$ (3 classes x 25 participants), we require 50 clusters (schools) (25 in each arm of the trial) with the standard thresholds of Power at 0.8 and Alpha at 0.05. This would yield a total sample size of 75×50 , $N = 3,750$ (see supporting documentation SD1 CONSORT for flow of participants through the study). As noted above, this is a purposefully conservative estimate; in most published research, the ICC for psychosocial outcome variables in primary schools typically ranges from 0.03 to <0.01 , and the effect sizes for outcome measures in PATHS trials have been close to $d=0.5$ in some cases (26, 25), with most falling into the 0.3-0.4 range. Based on this, we believe that the effect size is most likely to be around $d=0.3$, and the ICC is most likely to be around 0.02. With Power at 0.8 and Alpha at 0.05, and the same cluster size, we would need 12 clusters (6 in each arm of the trial), yielding a total sample size of 75×16 , $N = 900$. However, the larger sample noted above helps to support analyses where the overall dataset will be stratified into sub-groups at school and/or pupil level. As there will be several of these instances in the study (e.g. H3 – adjustment to secondary school, H4 – implementation variability), the retention of a large sample of schools/pupils will optimise power for the ensuing analyses. For example, Hypothesis 3 will be tested using data from the $N=1,250$ children who have transferred to secondary school at the crossover point of the trial (the start of the 2014/15 school year). As a failsafe, in the event of a reduced effect size of <0.3 or inflated ICC of >0.02 , we could of course continue to take outcome measures for the $N=1,250$ children who transfer to secondary school the year after (e.g. at the start of the 2015/16 school year), doubling the sample size for this analysis².

² Although this will shorten the period during which adjustment to secondary school can be measured to one year rather than two (since the trial will conclude at the end of the 2015/16 school year).



TRIAL MANAGEMENT AND OVERSIGHT ARRANGEMENTS

The University of Manchester will be the sponsor of the proposed research. Governance will be provided internally through the existing support systems (e.g. UREC, Research Development Manager, Finances and Accounts, and Research Strategy Group) and independently by the Christie NHS Foundation Trust (UK CRC CTU 9). We will also be held to account by our study Steering Group (made up of senior members of the research team, Christie CTU representative, University of Manchester accountants, NIHR representative, school representatives, relevant charities and voluntary organisations (e.g. Young Minds), parents, young people, and an academic advisor). This group will meet approximately every six months during the course of the study.

Clinical Trials Unit

In general, the CTCU acts as an independent provider of clinical trial services for investigator-led/academic studies undertaken within the Greater Manchester region. These services form part of the research governance that is undertaken on behalf of the (NHS) study sponsor and includes project and grant management, data management, statistical services, trial monitoring and quality assurance. By

providing data management/co-ordination and statistical support of research studies, the CTCU adds value to the programme by means of independent data management oversight, development of the research data record forms/CRFs, provision of a robust database for capture of primary research data and provision of independent QA monitoring of the research studies to ensure compliance with national and international regulations such as DoH Research Governance and Good Clinical Practice.

In this particular study, the CTCU will be providing independent project & trial management to ensure that the study is set up and adheres to compliance with the relevant DH research governance framework. This activity includes preparation of the appropriate study master files and protocols and support for ethics body submissions. Support for the in-study phase of the project will include coordination of relevant IDMC and TMG meetings and a degree of study site monitoring, particularly in respect of consent form process. The CTCU will also be providing the study randomisation service

TRIAL MONITORING

Data Collection

Please see 'Trial Methodology' section

Data will be coordinated by Dr. Alexandra Barlow - Senior Research Associate. Professor Neil Humphrey - Principal Investigator, Mr. Lawrence Wo - Research Associate and Dr. Michael Wigelsworth - Statistician, will also have access to the data for analysis. All of the above members of staff have Criminal Records Bureau clearance at the Enhanced Disclosure level.

Outcome data will be collected via online surveys. Data security for online surveys will be ensured using hypertext transfer protocol secure (HTTPS) data encryption. Data matching will be achieved through the triangulated use of name, date of birth and UPN, but these will be removed prior to analysis. All qualitative data will be anonymised during the transcription process, with pseudonyms given to any personally identifying information. All data will be held safely on secure drives, with the University of Manchester and Microsoft Best Practice guidelines, and adherence to the Data Protection Act 1998 followed. Data will be held behind both internal and external firewalls, and physical transportation (e.g. on flash drives) will be prohibited.

CONFIDENTIALITY AND DATA PROTECTION

Confidentiality

All data will be kept anonymous and confidential except in the event of a child protection issue (for example, a child disclosing details of abuse during an interview), at which point standard safeguarding protocols will be followed. Data security for online surveys will be ensured using hypertext transfer protocol secure (HTTPS) data encryption. Data matching will be achieved through the triangulated use of name, date of birth and UPN, but these will be removed prior to analysis. All qualitative data will be anonymised during the transcription process, with pseudonyms given to any personally identifying information. All data will be held safely on secure drives, with the University of Manchester and Microsoft Best Practice guidelines followed. Data will be held behind both internal and external firewalls, and physical transportation (e.g. on flash drives) will be prohibited.

Data Protection

The research team will use hypertext transfer protocol secure (HTTPS) data encryption – the same technology used in online banking – to ensure the security of the data collected through the project website. Data matching (e.g. matching up a pupil's Time 1 data with their Time 2 data in order to assess the amount of change that has occurred) will be achieved through the triangulated use of name, date of birth and Unique Pupil Numbers, but these will be removed prior to actual analysis.

All qualitative data will be anonymised during the transcription process, with pseudonyms given to any personally identifying information. Since it will obviously be important for the research team to know who a given transcription relates to, we will keep a master list of the real names for each pseudonym on a secure drive at the University of Manchester.

All data are to be held safely on secure drives, with the University of Manchester and Microsoft Best Practice guidelines followed. There will be stringent access policies. Data will be held behind both internal and external firewalls. The physical transportation of data (e.g. on flash drives) will be prohibited.

TRIAL CONDUCT

Protocol Amendments

Any changes in research activity (except those necessary to remove an apparent, immediate hazard to the participant) will be reviewed and approved by the Chief Investigator and submitted in writing to the appropriate REC for approval prior to enrolment into an amended protocol.

TRIAL RECORD RETENTION

Trial records will be retained for approximately five years after the conclusion of the study (this is the period of time during which we expect to still be producing outputs that make use of study data).

END OF TRIAL

The Chief Investigator and/or the trial steering committee have the right at any time to terminate the trial for safety or administrative reasons. The end of the trial will be reported to the REC within the required timeframe if the trial is terminated prematurely. Investigators will inform participants of any premature termination of the trial and ensure that the appropriate follow up is arranged for all involved. A summary report of the trial will be provided to the REC within the required timeframe

PEER REVIEW

Internal review was undertaken by colleagues in the School of Education during the drafting process – this led to minor revisions to the proposal. The proposal has been reviewed by the funder (NIHR), including commissioning panel and expert peer review, on several occasions. Suggested amendments were made, reviewed and approved by the funder.

ETHICAL AND REGULATORY REQUIREMENTS

The sponsor will ensure that the trial protocol, participant information sheet, consent form and submitted supporting documents have been approved by the appropriate research ethics committee, prior to any participant recruitment. The protocol and all agreed substantial protocol amendments, will be documented and submitted for ethical approval prior to implementation.

The CI and sponsor will ensure that the REC and are notified that the trial has finished (either as expected or prematurely) within required timeframes with summary reports to be provided as required