NatCen Social Research (NatCen) proposes to carry out an efficacy trial of Fit to Study, a programme of physical education (PE) provision which aims to encourage pupils to do more physical activity.

The Intervention

The Fit to Study intervention been designed by academics at Oxford University and Oxford Brookes University. The intervention was piloted in a small number of schools and evidence from the evaluation of the pilot, conducted by NatCen, informed the review and redesign of the intervention.

The underlying premise of the Fit to Study intervention is that increasing moderate to vigorous physical activity (MVPA) contributes to improved cognition and concentration. An assumption is that these changes may have a positive effect of classroom behaviour and within one year increase in regular MVPA will lead to improved attainment.

The Fit to Study interventions was developed in two stages:

1. A developmental stage during which the developers explored the most appropriate delivery approaches and design for Fit to Study.
2. A pilot stage involving 8 schools. This was conducted in two phases. 4 schools delivered Fit to Study in the first phase. Emerging findings led to a review of the intervention. The remaining 4 schools delivered the revised Fit to Study intervention during the second pilot phase. Each phase was delivered over one school term.

The intervention has been designed as a whole school intervention that can be incorporated into PE lessons. The trial is focused on year 8 pupils only. Fit to Study is targeted at increasing vigorous physical activity (VPA) during PE lessons instead of MVPA. It is believed that by focusing solely on VPA the threshold of MVPA that is associated with increased cognition is likely to be achieved.
As part of the intervention PE teachers are provided training and guidance so that they can adapt PE lessons to create more opportunities for pupils to achieve MVPA during PE lessons. The intervention consists of two key adaptations:

1. Four minutes of VPA during the warm-up at the start of each PE lesson
2. Three ‘fitness infusions’ which are short intense bursts of VPA lasting 2 minutes each.

This would mean that each PE lesson includes at least 10 minutes of VPA. Assuming that pupils have two PE lessons per week, the Fit to Study hypothesis is that at least 20 minutes of VPA per week will benefit pupil brain function by improving attention and working memory, which in turn will improve learning – resulting in a positive impact on attainment.

The intervention is to be delivered by PE teachers during scheduled PE lessons. The logic of the intervention is set out in the model below:

**Significance**

The role of regular physical activity in people’s lives has been the subject of research in a number of different fields; most obviously in medicine focusing on the benefits of following healthy lifestyles at both the individual and societal level. However, there is increasing focus on the benefits that participation in sport or PE provision that requires moderate to vigorous physical activity can have on other aspects of peoples’ lives including mental well-being, social development (such as, leadership skills, and team working), social interactions, cognition, and educational attainment.

Recent reviews of studies looking at the impact of increasing Moderate to Vigorous Physical Activity (MVPA)¹ in children on academic achievement found that heart rate increases during PE lessons had either a positive relationship with attainment or none at all with virtually no studies reporting a negative effect. ² ³ Evidence from the field of

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¹ An MVPA fact sheet (2009) defines moderate physical activity as activities equivalent in intensity to brisk walking or bicycling. Vigorous physical activity is an activity that produces large increases in breathing or heart rate, such as jogging, aerobic dance or bicycling uphill. http://www.californiaprojectlean.org/docuserfiles/200911_MVPA_FactSheet%5B1%5D.pdf

² Neuroscience and Education: A review of Educational Interventions and Approaches Informed by Neuroscience, Paul Howard-Jones, EEF January 2014.
neuroscience has shown that MVPA increases blood flow and connectivity in the hippocampus (a part of the brain), which may help improve cognitive functions such as working memory and attention. Analysis of longitudinal datasets confirms neuroscience findings in relation to physical activity and improved cognitive function as well as on classroom behaviour which may enhance academic performance. This review suggests that further research is needed to establish the optimal intensity and duration of physical activity (and MVPA) to improve cognitive function.

A three year cluster randomised trial in the USA involving 24 schools tested PAAC, a school based intervention that promoted 90 minutes of MVPA/week in addition to a 60 minute PE lesson found no significant difference in attainment (a secondary outcome measure) among a sub-sample of participants. More recently, a trial based in England that tested two interventions to modify MVPA among Year 7 pupils in 60 secondary schools analysed accelerometer data and assessed level of well-being. It concluded that ‘modest’ classroom initiatives are unlikely to have a meaningful impact on MVPA or feelings of well-being.

The Education Endowment Foundation and the Wellcome Trust are working together to build research expertise and knowledge at the interface between neuroscience and education. The Fit to Study intervention, an EEF and Wellcome Trust collaboration will add to this body of evidence by measuring levels of physical activity and assessing changes in cognitive function and attainment among secondary school pupils.

The policy context

Participation in physical activity has been the focus of policy makers for some time. A 2013 cross-government initiative in the UK set out a priority to increase participation in sport amongst people of all ages, but with a focus on engagement amongst children and young people. The initiative set out funding to improve primary PE and Sport provision through the PE and Sport Premium, to expand the School Games Programme to increase opportunities for young people to play competitive sports. It included a commitment to support Sport England to help 14-15 year olds to keep playing sports throughout their lives. A recent Ofsted review found that whilst there had been an increase in Good and Outstanding PE teaching in schools, there was still significant progress to be made for PE in secondary schools to consistently contribute to pupils’ fitness.

In addition to general concerns about participation in physical activity, the level of activity and engagement during PE lessons may vary by pupil characteristics, such as gender. A

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6 This intensity of physical activity was based on the U.S Department of Health and Human Services guidelines set out in Healthy People 2010.
Government review of participation in sport among girls highlighted low levels of engagement in sport as a concern. The drop in girls’ participation levels begins in in primary school and becomes more pronounced in years 8 and 9 of secondary school (between 12-14 years of age). This trend continues as girls’ experiences of PE and sports at school are likely to affect attitudes and engagement in sport later in life. Moreover, girls’ and women’s participation in sport is significantly lower among lower socio-economic groups. Schools, particularly those in deprived communities, have an important role to play in motivating all pupils to increase participation in PE and sports through effective PE provision and teaching.

Methods – Impact Evaluation

The evaluation comprises of a full efficacy trial with 100 schools during which PE teachers will deliver Fit to Study during all Year 8 PE lessons across three terms (one full school year). An average of 225 Year 8 pupils per school is expected to take part in the intervention. The efficacy trial will aim to answer the following principal research questions:

- What is the impact of Fit to Study intervention on Maths attainment of participating pupils?
- What is the impact of Fit to Study intervention on Maths attainment of participating pupils (a) with low prior attainment and (b) eligible for free school meals?
- What is the impact of Fit to Study intervention on Maths attainment of participating (a) girls and (b) boys?

The sample and design

The intervention will be evaluated using a two-arm cluster (school-level) randomised controlled efficacy trial. The trial will estimate the effect of Fit to Study on Year 8 pupils’ Maths attainment.

A randomised controlled trial (RCT) uses the mechanism of randomisation to assess the causal impact of an intervention. Random assignment of schools to treatment and control groups ensures that, in principle, the two groups have the same baseline characteristics. Any differences at baseline are due to chance and are accounted for in the statistical analysis. As a result, the discrepancy in outcomes at the end of the trial can be attributed to the intervention itself. As an efficacy trial, the evaluation aims to test the effect of the intervention under ideal circumstances, restricting variation in factors that could affect outcomes as much as possible. School-level randomisation was necessary because the intervention is implemented across the whole year group, making pupil- or class-level randomisation impossible.

A total of 100 schools will be recruited for the trial. In treatment schools, all pupils in Year 8 will receive the intervention based on the training delivery plan set out by the developers. Considering the average number of pupils in the eight pilot schools (225), 22,500 pupils are expected to receive the intervention.

School participation will be voluntary and will be incentivised. Both control and treatment schools will receive £500 for taking part in the trial, because the neuro measurements (including MRI scans) to be taken by the intervention developers place a particularly high burden on schools.

Recruitment of schools will be led by NFER with support provided by Oxford University. NatCen will contribute to relevant recruitment materials and ensure that information about the trial and consent are provided.

The aim will be to recruit schools into the trial based on a number of selection criteria:
- The sample will include state schools and free schools but not grammar schools;
- Average proportion of pupils eligible for FSM (Free School Meal) must be at least the average for England (15%);
- Schools can be mixed or single-gender
  - Geographical regions selected by the intervention developers include: greater London; Thames Valley; Southampton and Portsmouth; Bristol and Bath; Birmingham and Coventry; and Cheltenham/Gloucester; Luton, Bedford Milton Keynes

In order to reduce the burden of testing on schools and in consideration of the costs associated with testing, three Year 8 form groups (around 90 pupils) will be randomly selected for outcome testing in each school. This means that approximately 9,000 pupils will be tested as part of the trial.

**Pre-randomisation data collection**

During recruitment schools will provide a list of their current Year 7 pupils (expected to be in Year 8 when the trial starts). Information will also be collected on the expected number of Year 8 form groups and how PE lessons are organised (i.e. by form group, ability, or gender). Pupil data will be gathered and will comprise of data pertinent to matching in the NPD (i.e. first name, last name, date of birth, and name of form group of all Year 7 pupils likely to start Year 8 in September 2017). NFER are recruiting schools for the trial and will collect this data and transfer it securely to NatCen.

During recruitment schools will sign a memorandum of understanding, which formally admits them to the trial and sets out the requirements for participation. The requirements include administering an opt-out consent process for participation in the evaluation (pupil testing and data linkage) by sending a letter to parents/carers, collecting opt-out slips within a two-week timeframe, and informing the Fit to Study team about any parents who have returned slips and opted their child/ren out of the study.

**Randomisation**

School-level stratified randomisation will result in the equal allocation of recruited schools to either:
- Control group (‘Business as Usual’), or
- Treatment group – PE teachers deliver Fit to Study.

Stratification by geographic area and school gender type (whether schools are gender segregated - all girls or all boys - or mixed) will be incorporated in order to ensure that control and treatment groups are as similar as possible. All Year 8 pupils are potentially eligible for treatment conditional to parental consent. The proposed stratification is underpinned by the assumption that PE and after school sporting activity provision varies by school type (gender, segregated or mixed).
NatCen will undertake the random assignment of schools to treatment and control, following schools’ submission of the above data at recruitment.

Whilst the trial includes all Year 8 pupils, in order to reduce test burden and associated costs only three Year 8 forms in each school (around 90 pupils) will be selected to measure change in attainment (see Outcome Measures section below). Following the randomisation of schools, NatCen will use a random number generator to select the three forms in each treatment and control school (this will be based on information on the number of forms and form names provided by schools at recruitment). Prior to testing, schools will be asked to send out information on the testing process and data linkage to the parents/carers of these pupils and to support the opt-out consent process.

**Outcome Measures**

**Pre-treatment baseline**

EEF’s standard guidelines on testing procedures for evaluation of RCTs recommends the use of National Pupil Database records of key stage attainment as a pre-test score where high correlations are observed between key stage scores and tests.\(^{11}\) Therefore, pupil KS2 scores obtained from the NPD will be used as the pre-intervention scores.

**Attainment measure**

Maths attainment, as measured by the raw scores achieved in the Progress Test in Mathematics (PTM), Level 13 will be the primary outcome measure. The test will be administered by NatCen interviewers in schools post-treatment towards the end of the 2017-2018 summer term. The Progress Test in Mathematics is a standardised group test that assesses pupils’ mathematical skills and concepts. PTM Level 13 is suitable for pupils completing Year 8. The test takes approximately 75 minutes to complete.

PTM assesses two dimensions of learning:
- mathematical content knowledge (Curriculum Content Category); and
- understanding and applying mathematical processes through reasoning and problem solving (Process Category).

**Impact Analysis Plan and Statistical Power**

Analysis on primary outcomes will follow EEF’s analysis guidelines. Analysis will be carried out on intent to treat basis whereby all pupils within the randomly selected forms are analysed according to the study arm to which they were initially assigned, regardless of whether they went on to participate in the intervention.

Multivariate regression analysis will be used to obtain effect sizes on the outcomes of interest. This will involve fitting a multi-level linear regression model with random intercepts; the pupil being level one in the model and the school level two. The regression model will control for prior attainment using data on prior performance from the NPD. The model will also control for stratification variables.

Additional analysis will also control for sex and FSM. Separate regression models will be estimated for those who qualify for free school meals and for girls and boys. Finally, the differences in outcomes between segregated and mixed-gender school girls and boys will be explored.

A complier average treatment effect (CACE) will be estimated to show the effect of Fit to Study on pupils in schools that comply with the assignment to their trial status. Compliance will be defined with reference to the proportion of MVPA sessions actually delivered out of the number of sessions that should have been delivered. CACE estimates will be reported for a range of compliance cut-offs, from 90% compliance to zero compliance.

Effect sizes and their respective 95 per cent confidence intervals will be calculated following the procedure set out in Tymms:

\[ ES = \frac{\beta}{\sigma} \]

Where \( \beta \) represents the adjusted difference in outcomes between intervention and control groups obtained from the full regression model and \( \sigma \) the square root of the pupil level variance obtained from fitting an unadjusted multilevel model, following Hedge’s \( g \). The unadjusted model contains a constant, intervention dummy variable, baseline achievement and stratification variables, but no further covariates.

Summary descriptive statistics are produced below along with estimates of ICCs for each regression model estimated.

**Minimum detectable effect sizes**

These power calculations set out minimum detectable effect sizes, measured in standard deviations, that can be estimated with 80% power and a 5% significance at different achieved sample sizes (after attrition). All calculations assume:

- 90 pupils (3 forms) per school are tested
- a two-tailed test
- a significance level of 5% and power of 80%
- baseline covariates explaining 50% of variance at pupil and at school level\(^{13}\)
- no clustering of effects at the class level.

<table>
<thead>
<tr>
<th>ICC(^{14})</th>
<th>Achieved sample size (schools)</th>
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<tr>
<td></td>
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<td>0.10</td>
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<td>0.16</td>
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\(^{13}\) EEF (2013) gives estimates of the correlation between KS2 and GCSE Maths results at 0.76, giving an estimated R\(^2\) of 0.58. Education Endowment Foundation (2013) *Pre-testing in EEF evaluations*. London: Education Endowment Foundation.

\(^{14}\) ICC estimates provided by the Education Endowment Foundation (2015, p.1) for Maths scores at Key Stage 4 range from 0.11 to 0.21 for different English regions. Estimates tend to be lower for younger pupils, so we would expect marginally smaller scores for Year 8 pupils. Education Endowment Foundation (2015) *Intra-cluster correlation coefficients*. London: Education Endowment Foundation.
Methods - Process Evaluation

Alongside the impact evaluation, a process study to test implementation fidelity will be carried out. Exploring implementation fidelity is important for furthering understanding of any contextual and experiential considerations that affect implementation, and to inform analysis of intended primary and secondary outcomes along with any unintended outcomes. The main research questions that will be answered are:

- How is the programme delivered and what factors influence implementation fidelity?
- What type of PE lesson modifications take place in control schools during the treatment period?
- What more generally are the barriers and necessary conditions for success?
- What is PE teachers' level of engagement with available external support and guidance?

The key dimensions of implementation that the process evaluation will assess are: fidelity, dosage, quality, reach, responsiveness, usual practice and adaptation.

Fit to Study Costs

As part of the implementation study cost data will be collected from schools and the intervention developers to

What is the estimated per pupil cost of delivering Fit to Study?

School surveys

Two on-line school surveys will be conducted. The first will take place at the start of the school year in September 2017 when schools will have finalised their Year 8 timetable and the post-intervention survey will take place in June 2018. All schools in the trial will be invited to take part in the survey.

Start of school year survey

This survey will seek confirmation of the pupil lists obtained pre-randomisation and will note any changes to the organisation of Year 8 from groups. It will record any new pupils entering Year 8 and those who have left the school. The survey will gather contextual information on the whole-school approach to PE lessons, PE teachers and their experience, the PE timetable, sports activities covered in PE lessons, and extra-curricular sports activities open to Year 8 pupils. Questions related to pupil testing will be included and schools will be provided with information related to the gathering of cost data.

Post intervention survey

Schools will be invited to take part in this survey prior to pupil testing. We will gather the perceptions of teachers in treatment schools of implementation, key challenges encountered, adaptations made and the perceived benefits of Fit to Study. Cost data will be collected. Control schools will be asked to provide information on delivery of PE lessons and any changes made of lesson plans and activities during the academic year.

In-depth case study research

A pragmatic approach to carrying out a robust process study is proposed. This will be conducted in three phases:

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15 Evans, R, Scourfield, J., and Murphy, S. (December 5 2014) Pragmatic, formative process evaluations of complex interventions and why we need more of them. Journal of Epidemiology and Community Health. Published Online First: doi10.1136/jech-2014-204806
Phase I - early implementation: This phase will start following the completion of the ‘start of school year survey. Interviews with PE teachers who took part in the training provided by the Oxford team and are involved in the delivery of Fit to Study. This phase will take place during the first 3-4 months of Fit to Study delivery during the Autumn term. In control schools, telephone interviews will be carried out with the Year 8 PE leads. We propose to conduct a total of 20 interviews – 15 in treatment schools and 5 in control schools. Schools will be purposively selected using key sampling criteria. The selection process will be informed by responses provided in the survey. Sampling criteria may include:

- School type (girls’, boys’, mixed)
- Proportion of FSM pupils in Year 8, and
- Geographical location.

Phase II – on-going delivery: Data collection will be carried out in the latter part of the spring term at which point the assumption would be that Fit to Study is being delivered in a consistent way and any early implementation issues (identified during Phase I) have been adequately addressed.

One day site visits will be conducted to a sub-sample of treatment and control schools from Phase I. The selection will be based on the early analysis of teacher interviews conducted during Phase I.

In treatment schools, visits will include the observation of 1-2 Fit to Study PE lessons and 1 interview with the PE teacher and/or the Year 8 PE lead. An observation template will be used to note Fit to Study delivery, pupil responsiveness and any observed adaptations.

Visits to control schools will involve the observation of one PE lesson and an interview with a PE teacher.

A purposive sample of 10 schools – 7 treatment and 3 control schools will be selected for site visits using similar selection criteria to those used in Phase I sampling.

Phase III – fidelity and sustainability: Interviews with PE teachers in treatments schools from the Phase I sample will be conducted towards the end of the Summer term. The main purpose will be to understand how delivery of Fit to Study progressed over time, adaptations made and whether Fit to Study will be sustained and scaled up to include other year groups. The post-intervention survey will be administered during this phase.

Fitness test analysis and review of teachers’ logs
Oxford University will collect pre- and post-treatment data on fitness levels. The fitness test will be administered by PE teachers and comprised a standard ‘bleep test’ used by schools. Oxford University will provide a school level aggregated summary of analyses conducted on pupil activity levels any observed changes in level of fitness. This will be used as contextual data to explain any effects.

Fit to Study delivery partners have developed an App to be used by Year 8 teachers to log activity during each PE lesson. Teachers will be asked to log in the following information:

- Date of lesson
- Time of lesson
- Class/form name
- Group size (no. of pupils attending)
- Location of lesson (inside/outside)
- Sport/lesson activity
- Minutes of VPA during warm-up
- Number of 2 minute infusions
- Notes (do not enter pupil or teacher names)

This teacher’s log is a component of the intervention and teachers will be required to submit lesson logs. Lesson log submission will be monitored by the intervention developers and submitted data will be collated and analysed to assess fidelity.

**Costs of Delivering Fit to Study**
An important aspect of the evaluation is the provision of a reasonable estimate of the cost to schools to deliver Fit to Study, should a school wish to implement Fit to Study in the future.

A list of items such as staff time and associated tasks, along with the cost of purchasing any additional PE equipment would be drawn up. At the same time, the academic team delivering the intervention will be asked to provide their cost estimate for the delivery of Fit to Study. The pre- and post-intervention school survey administered to schools will include cost questions. By comparing the costs across treatment schools, a cost estimate to deliver Fit to Study in one school over one academic year will be provided.

**Ethics and Registration**
NatCen’s research information leaflet setting out the requirements for the trial will be sent to schools at recruitment. Schools that sign a MoU will send out a parent information leaflet to parents of all Year 8 pupils. The information leaflet will explain the study; the research activities for the trial, data linkage, the storage of anonymised data in the EEF’s archive and the UK data Archive. Parents/carers will be able to opt their child out of data linkage at any point during the study. The parents/carers of pupils selected for testing will be send information on the testing process and schools will be asked to support an opt-out consent process. NatCen will maintain a database of opt-outs and delete all pupil data as soon as an opt-out is communicated.

Ethical approval for this study has been sought from the University of Oxford Ethics Board and has been communicated to NatCen’s Research Ethics Committee. The NatCen REC will review the study design and consent requirements to confirm compliance with internal ethical standards.

The trial will be registered with the International Standard Randomised Controlled Trial Number (ISRCTN) (register the trial at: www.controlled-trials.com)

**Personnel**
The project will led by the Children, Families and Work Team. The team will work closely with impact evaluation experts in NatCen’s Evaluation Team. Contact with schools as well as testing and data entry processes would be coordinated through NatCen’s Operations Department.

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<tr>
<th>Children, Families and Work Team</th>
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<tr>
<td><strong>Dr Fatima Husain</strong></td>
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<td><strong>Lydia Marshall</strong></td>
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<td><strong>Sandy Chidley</strong></td>
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Risks

The main risks to this project will be low participation in the trial, low take up and compliance with the intervention, risks associated with schools not complying with the random allocation, and low response rates in the post-intervention pupil testing. We will develop a detailed risk register at the start of the project to monitor and manage risks on an on-going basis.

All data will be collected and transferred in compliance with the Data Protection Act and NatCen’s Information Security Management procedures which meet ISO 27001 standards.

Data protection

NatCen has a range of policies and practices in place to ensure secure data handling. We categorise all data and files to 5 different levels, dictating how they are stored, handled and transmitted. The sample data for this study is Level 3 - ‘Respondent Confidential’. Only those who carry out research tasks and those who need to check or process the data will have access to names and addresses. Our confidentiality measures for Level 3 data include:

Encryption

All staff and freelancer laptops that hold Level 3 respondent confidential data have a hard drive encrypted using PGP Whole Disk Encryption by Symantec. This means that should the laptop be lost or stolen, the data contained on the hard drive is inaccessible. The encryption used by PGP is certified to FIPS 140-2 standards. We also use encrypted digital recorders for qualitative interviews,

Password Policy for office based staff

- Complex passwords, change every 30 days
- 10 password history automatically enforced
- Account locked out after 5 wrong attempts

Access control

- Access to project data is managed via compliant segregation
- Strict access control policy, limited to named authorised individuals
- Unique serial numbers assigned to avoid use of personal information.

Data Security Plans

- Project data security plan detailing data security procedures.
- Rights of access recorded before granted.

File Systems Auditing

- File System Auditor used to monitor activities logging what was created, updated, moved, renamed and deleted and when.
NatCen processes for retention and destruction of personal data exceed ISO 20252 requirements on archiving and secure deletion.

**Timeline**

*September – December 2016*
Finalise number of schools to be recruited, finalise protocol, revise theory of change, finalise outcome measures and data collection procedures, seek ethical approval, develop analysis plan

*January 2017- April 2017*
Recruit schools, sign MOU, conduct baseline pen-and paper survey of schools

*April- June 2017*
Oxford conduct baseline assessment of pupils

*July 2017*
Randomisation of schools and Y8 form groups

*July – August 2017*
Oxford delivers Fit to Study training

*September 2017*
Schools start delivering Fit to Study; school survey conducted

*October 2017*
Process study commences

*January 2018*
Application made to NPD to obtain baseline data

*June - Jul 2018*
Post-intervention testing of 9,000 pupils in treatment and control schools; school survey

*September – December 2018*
Analysis and reporting

*January – March 2019*
Peer review, Final report