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Protocol contributors

The study design was developed by the applicants who all made important contributions to the study design and will play key roles in the study conduct.

- Prof Jago takes overall responsibility for the study and all aspects of the protocol with the support of the Project Manager.
- Prof Hollingworth will guide the health economic analysis.
- Prof Foster will lead on stakeholder and policy maker engagement
- Prof de Vocht will guide the quantitative project analyses
- Jo Williams will support the dissemination of work to practice based colleagues
- Dr Salway will lead on all statistical issues.
- Dr Katie Breheny will conduct the health economic analysis
- Dr Emm-Collison will lead on the qualitative component of the study.
- Danielle House will manage the project.

Declaration of interests

The **ACTIVE-6** study was developed by the applicants. There are no other conflicts of interest to declare.

1. TITLE: Assessing the impact of COVID-19 on the physical activity of Year 6 children and their parents: Identifying scalable actions to mitigate adverse impacts and provide rapid evidence to policy makers

2. BACKGROUND AND SCIENTIFIC RATIONALE

2.1: Overview and study summary: Physical activity is important for health among children and their parents. The COVID-19 pandemic and the associated social changes, such as the lockdown, have had a marked impact on physical activity patterns but without data it is impossible to know the magnitude of these effects, how they may differ by demographic variables or the possible solutions for those challenges. **The aim of this project is to examine the impact of changes that have resulted from COVID-19 on the physical activity of Year 6 children and their parents. Specifically, we want to know if there is an acute change in physical activity and if that change is maintained, thereby indicating a chronic impact.** In the sections below we have briefly outlined the rationale for the study and the study design.

2.2: Benefits of physical activity: Physical activity is associated with improved physical and mental health across the life course. Among adults, physical activity is associated with reduced risk of heart disease, type 2 diabetes, many forms of cancer as well as reduced risk of depression and improved psychological well-being (1). The current guidance is that all adults should engage in 150 minutes of moderate intensity physical activity per week and aim to do activities that strengthen bones at least twice per week (1). Analysis of 2006 NHS cost data indicated that physical *inactivity* cost the NHS £1.06 billion per year in direct costs, with a further £6.5 billion in lost productivity (2). These costs are likely to be much higher today. Thus, inactivity is a major drain on the physical, mental, and economic health of the UK and ensuring that all adults are active is essential for population health.

Among children, physical activity is associated with lower levels of cholesterol and blood lipids, favourable blood pressure and body composition (3). These cardiovascular disease risk factors are more prevalent in children residing in households that have a lower socioeconomic position (4). Physical activity is also associated with improved well-being and self-esteem among children as well as improved academic performance (5). The UK Chief Medical Officers recommend that all children and young people should engage in an average of an hour of moderate to vigorous intensity physical activity per day and that this should be accumulated across the day. Moderate to vigorous intensity physical activity (**MVPA**), is activity that raises the heart rate and is most clearly identified when children are slightly hot, sweating and out of breath. Physical activity tends to track from childhood into adulthood. Ensuring that children engage in regular physical activity is important for their current and future health.

2.3: Potential role of COVID-19 on physical activity: COVID-19 has had marked impacts on all aspects of society including physical activity opportunities. This has included removal of a range of options including physical education, travel to school and work, leisure, sports, outdoor play, and playgrounds for both children and adults. While some of these changes are planned to be reversed once the current outbreak ends, any changes to reinstate provision will be slow, gradual and may not be uniform for all groups. For example, physical activity providers may have ceased trading and the way that schools adapt to deliver physical education may range from none, to socially distanced, to full provision. It is also possible (and perhaps probable) that some schools may reallocate physical activity time to “catch-up” on lost learning. Further, the proposed catch-up tutoring provision may differently target those children who are also at risk of lower physical activity. Again, provision is unlikely to be uniform and will depend on decisions taken by each school. **It is therefore essential to identify the variation in provision and assess the impact of different policies on physical activity. Once differences have been identified solutions can be found and widely shared to maximise physical activity opportunities for all children.**

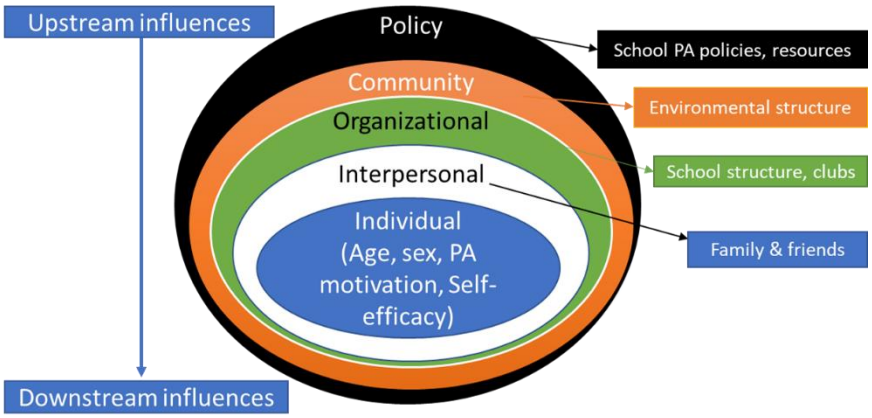
There is considerable potential for changes in physical activity provision to exacerbate existing health inequalities. Children and families from more deprived communities, who had fewer physical activity opportunities prior to lockdown, are likely to be more affected as activity providers in these areas face greater financial challenges and may cease to trade. It is unclear what these impacts

are and how they can be mitigated and so this information is urgently needed to guide future policies. Any effective strategies to increase physical activity are likely to be a complex interaction of changes in structural provision **(upstream)** and the motivation and behaviour of families **(downstream).** Thus, we need to know what schools and families are doing to identify policies and local actions that may be helpful. This will require both quantitative data on any changes in physical activity post COVID-19 as well as qualitative data on what policies schools put in place.

2.4: Factors that impact on physical activity in children and adults (pre and post COVID-19)

Physical activity is a complex behaviour influenced by a variety of factors at multiple levels of influence (6). Most evidence shows individual factors, such as sex, age and motivation to be active are consistently associated with physical activity levels in children and adults (7). There is also a growing body of evidence showing that social factors, such as parental support, socio-economic status, and peer-behaviours (8, 9) and wider environmental and policy factors, such as school physical activity facilities and policies (10) are also associated with child activity. There is a need to capture these influences and how they form part of a complex system that interacts to promote or hinder physical activity. These multiple and varied factors are consistent with the socio-ecological framework that proposes that behaviour occurs due to a mix of direct, indirect and interactive influences acting at different levels (11). In the context of physical activity, these influences can be broadly categorized as either intrapersonal/individual (e.g. age, sex), interpersonal (e.g. family and friends), organizational (e.g. clubs or schools), community (e.g. environment structure such as transport infrastructure) and policy level (e.g. school physical activity policies) factors. The socio-ecological model has strengths in accounting for the wider factors which influence the physical activity opportunities that individuals are afforded. However, previous applications of the framework have been criticised as they do not consider individual psychological variation which is of particular concern as evidence indicates that most variation in child physical activity resides at the individual level (12). It has recently been suggested that, in order to inform the development of more effective intervention a more integrated theoretical approach (13) should be used. This project takes an approach to physical activity in children and adults that integrates the multiple levels within the socio-ecological framework (e.g. school physical activity policies, school physical environment, home environment, parental support, child age) with psychological variables that have been shown to be key to physical activity (e.g. motivation, self-efficacy) as shown in **Figure 1**.

Figure 1: Adapted Socio-ecological model



2.6: Identifying means of assessing the impact of COVID-19 and possible solutions

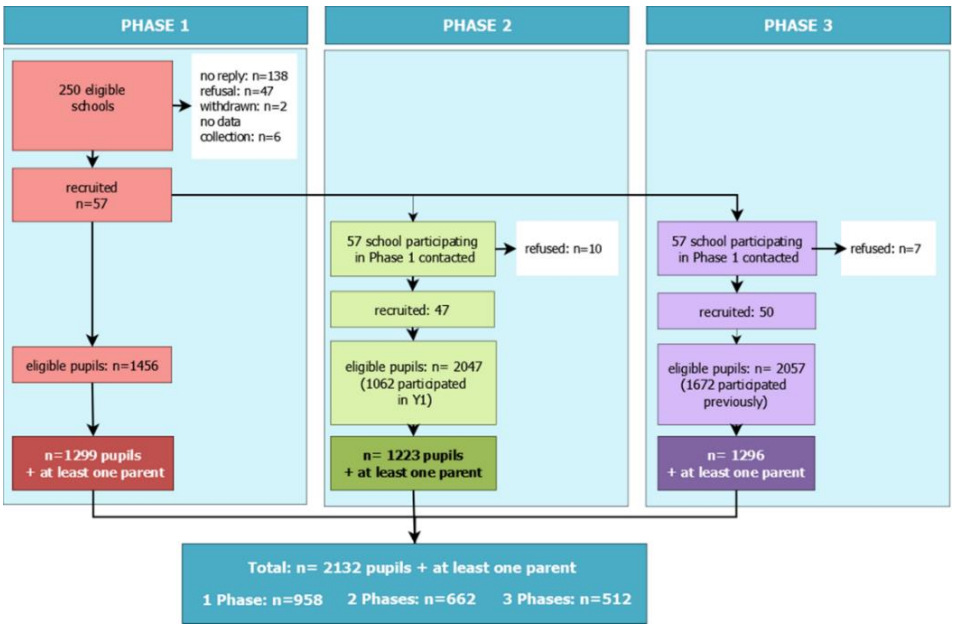
The challenge in understanding the impact of the lockdown and associated adaptations that schools and families have made is in identifying appropriate comparator groups to assess levels of physical activity pre and post lockdown. The impacts of the lockdown and the subsequent changes to the structure of physical activity will likely change over time as the nation adapts to a "new normal" and changes as vaccine provision increases over time. How this impacts on physical activity provision over time is unclear. Thus, there is a need to provide data on what happens and how that varies over time. This represents a challenge as in an ideal world we would examine in depth each of these impacts, model them over time and then write a comprehensive report that captures all the available evidence and shares it with key stakeholders. However, while this remains very important, **there is a pressing need to provide data on what is happening quickly so that schools, parents, and policy makers are aware of the challenge and can implement strategies to mitigate adverse impacts. While these data will be imperfect, they**

will be very useful. As such, a design that compares to an existing reference group while also providing rapid data is needed.

While it is possible to conduct a descriptive study, without a comparator it is hard to know if levels of physical activity are different from before the lockdown. Thus, a study is needed that uses a similar methodology and includes data from comparable groups before and after lockdown. Ideally this would be a cohort of individuals with data pre and post lockdown, but no such dataset exists. We therefore propose to collect new data and compare it to an existing, pre-COVID dataset, the B-**B-Proact1V** study (14-16), using the same sampling scheme and methodology and recruiting from the same schools.(Please note that we are not attempting to collect data from the same children who are now dispersed to secondary schools with different provisions.) Building on the existing survey, we will also examine the causes of any differences and how they could be mitigated. We also seek to understand the implications of COVID-19 on schools' time and financial resources allocated to physical activity. The impact on household finances, inequalities, and association with health-related quality of life and capability wellbeing in parents and children will also be explored. Results will be proactively provided to the government and policy makers so that they are aware of the nature and scale of any problems and associated solutions to problems. This approach will empower leaders to implement solutions at pace and scale.

3. FORMATIVE WORK CONDUCTED BY THE APPLICANTS

3.1: B-Proact1V Study: B-Proact1V was a longitudinal study that aimed to examine the physical activity and sedentary behaviours of primary school children aged 5-11 years and their parents (14-16). As shown opposite, in Phase 1 (data collected between January 2012 and July 2013), all children in Year 1 of primary school (aged 5-6 years) from 57 schools in and around Bristol were invited to participate. In Phases 2 and 3, when the children were in Year 4 (aged 8-9, data collected between March 2015 and July 2016) and Year 6 (aged 10-11; data collected between March 2017 and May 2018), all schools from Phase 1 were invited to participate, and all children within participating schools were eligible in Phases 2 and 3, regardless of whether they had participated in Phase 1. A total of 47 schools participated in Phase 2 and 50 schools in Phase 3. Across the three time points, data were collected for 2132 children with 1299 children in Year 1 (age 6), 1223 children in Year 4 (age 9), and 1296 in Year 6 (age 11). In addition to the quantitative measures we also conducted extensive qualitative work with 50 parents of participants in Year 1, 51 in Year 4 and 42 in Year 6 to provide rich contextual data on the factors that affected the physical activity patterns of this group. **The current study will use the most recent data from B-Proact1V, when the children were in Year 6, as the pre lockdown comparator.**



4. PROJECT RATIONALE

Physical activity is important for health among children and their parents. The lockdown and subsequent phased release from the lockdown will have marked impact on physical activity patterns. The goal of this project is to provide information on how physical activity has changed in Year 6 children and their parents because of the COVID-19 pandemic. We propose to conduct rigorous in-depth analysis of the changes in physical activity in children and parents **and provide**

rapid feedback to policy makers on the nature and scale of the challenge. Due to the challenges with assessing physical activity in children via self-reports we will make the assessment of children's physical activity via accelerometer the primary focus. We aim to provide information on the factors that may account for differences in physical activity when compared to a comparator group and what could be done to mitigate those impacts. Essentially, we seek to provide evidence on how to help families to be active post lockdown.

5. RESEARCH OBJECTIVES: We have seven inter-liked objectives (**A-G**) that are outlined below. The objectives will be met by collecting new data at two time points. **Time 1** (T1) will be during 2021 and provide data on acute effects. **Time 2** (T2) will in 2022 and will provide information on the chronic impacts. Year 6 data from the B-Proact1v cohort (2018 school year) will be the **Time 0** (T0) comparator group.

A) To assess the **acute** effect of the COVID-19 pandemic on the Weekday MVPA of Year 6 children by comparing new data (T1) to T0 data sampled from the same schools 3 years earlier. We will also assess whether effects differ by socioeconomic position and/or gender.

B) To determine if there are differences between the physical activity and sedentary behaviour of Year 6 children and their parents when compared to T0 data sampled from the same schools 3 years earlier for the following secondary outcomes at the Time 1 assessment:

i. Parent accelerometer measured weekday minutes of weekday MVPA
ii. Child accelerometer measured weekend minutes of MVPA
iii. Parent accelerometer measured weekend minutes of MVPA
iv. Child accelerometer measured weekday sedentary minutes
v. Child accelerometer measured weekend sedentary minutes
vi. Parent accelerometer measured weekday sedentary minutes
vii. Parent accelerometer measured weekend sedentary minutes

C) To assess the **chronic** effects of the COVID-19 pandemic on primary and secondary outcomes when data are sampled from the same schools for the T2 assessment.

D) To examine the extent to which differences in total volume of physical activity and sedentary time at both T1 and T2 are explained by the variation in the frequency that the child is active, child physical activity enjoyment and motivation, mode of travel to school, child screen-time, after-school club attendance, parent physical activity motivation and self-efficacy.
i. Examine the specific impact of school walking, cycling and play provision, curriculum physical activity, school grounds and school physical activity policies on differences in physical activity.

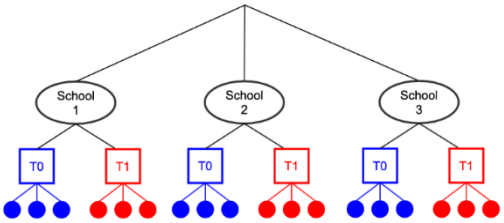
E) To produce rapid interim reports from the project to UK policy makers to inform the development of effective strategies to increase physical activity in groups who may have been disproportionately affected by changes due to COVID-19.

F) To understand the implications of COVID-19 on the time and resources allocated to physical activity by schools and households by addressing four sub-aims:
i. To describe the implications of COVID-19 on household finances and spending on extracurricular physical activities.
ii. To describe changes in the allocation of school budgets to physical activity before and after COVID-19 and explore the reallocation of time between academic activities and physical activity.
iii. To assess the economic implications and affordability of potential mitigation strategies for schools and families.
iv. To explore the associations between preference-based measures (PBMs) of health-related quality of life (HRQL) and capabilities in children and adults and examine the possible impact of inequalities.

G) To use qualitative methods to further explore changes in physical activity during COVID-19, including factors that influenced activity during this time, and potential solutions to mitigate long-term negative impact on physical activity.

6. RESEARCH PLAN AND METHODS

6.1: Overview: **The proposed study is a repeated cross-sectional design with a linked qualitative study**. For the quantitative data (aims A-F) we will collect data in two waves (T1 and T2). The first wave will be between May 2021 and December 2021 and will provide data on the acute impacts on physical activity and associated behaviours. The second wave will assess the same measures with a new sample of Year 6 children, recruited from the same schools the following year between January 2022 and July 2022 to understand chronic impacts. Data from these groups will be compared with the 1296 child and parent pairs who took part in the third phase of the **B-Proact1V** study between March 2017 and June 2018 recruited from the same 50 primary schools in the Southwest of England (14).



6.2: Study design: Repeated cross-sectional design comparing data. Data will be collected at two new time points: T1 during 2021, and T2 during 2022. T0 will be the Year 6 wave of the B-Proact1V study.

6.3: Sample size: This is an unbalanced cluster design, where the baseline numbers are known and fixed, and the clusters are matched across time-points. We used a simulation-based approach (17) to calculate the sample size required to detect a 5-minute difference in child Weekday MVPA, comparing new data collected to the known T0 data. A 5-minute difference has been suggested as the smallest difference that is likely to have a meaningful impact on health and is slightly higher than the average 4-minute impact of accelerometer based physical activity interventions (18).

Simulations were performed using 10,000 iterations based on the known baseline T0 accelerometer data (complete data on 1125 pupils across 50 schools, mean weekday MVPA = 61mins, SD=23.1 mins) and simulated follow-up data for a mean weekday MVPA of 56 mins, based on a between school intra-cluster correlation of 0.15, total SD of 23.1, and within-school variability (school-level random effect) all estimated from the baseline data.

No. of schools	School response rate	Alpha	Power	Mean no. pupils in schools	Pupil response rate	Minimum sample size
50	100%	0.05	98%	13.7	33%	686
45	90%	0.05	97%	13.7	33%	617
40	80%	0.05	95%	13.7	33%	549
30	60%	0.05	90%	16.6	40%	498
30	60%	0.05	84%	13.7	33%	412
25	50%	0.05	89%	20.2	48%	505
25	50%	0.05	81%	15.8	38%	394
20	40%	0.05	82%	21.2	50%	422

The table shows estimates based on between 20 and 50 schools taking part in the study and gives the response rates, minimum number of pupils in each school and corresponding overall sample size to provide at least the specified power to detect a difference at the 0.05 level. For all scenarios, the overall number of children in schools is assumed to be lower than the average of 23 recruited in the T0 data, with the reduction in sample size proportionate across schools. The data in the table show that even if only 50% of schools (25) take part with 16 pupils per school recruited (a response rate of 38% compared to 53% achieved at T0) for a sample size of 394 we would still have 80% power to detect a meaningful difference. These estimates are intentionally very conservative to allow for the possibility of lower numbers of schools and pupils taking part because of COVID-19.The power depends primarily on the school response rate, with pupil response rate to

a lesser extent; if more schools participate this will increase the power (for example, an extra 5 schools with similar pupil response rate will achieve approximately 90% power).

6.4: Time 0 data: The T0 group will be the Year 6 data from the B-Proact1v study. These participants were recruited from 50 schools with a consent rate of 63% of children within schools. There was a considerable variation in both parent and child physical activity showing that we recruited participants from across the physical activity spectrum and not just the active families. For example, for children the mean weekday minutes of MVPA was 60.6 (SD = 23.1) with a mean of 54.7 for parents (SD = 28.5). There was also variation in SEP with 20% within the household with 20% of parents having GCSE as the highest education, 26% having an A-level, 37% having a degree and 1% having a higher degree.

6.5: Setting: Data will be collected in the same 50 primary schools that took part in the Year 6 wave of the B-Proact1v study. All schools are located within the greater Bristol area. During the consent process for the B-Proat1V project, all schools agreed to be re-contacted in relation to future waves of the project. Schools that take part will be asked to sign a school study agreement in which they provide approval to join the study. As noted in other areas of the application, the schools have considerable variation in terms of SEP with the percentage of children eligible for free school meals ranging from 2 to 42%. There is also variation in school size ranging from 105 to 1410 and in the location with a mix of urban, suburban, and rural schools. This diversity in schools will increase the generalisability of results to areas outside the Southwest.

6.6: Study population: Participants will be Year 6 children and one parent per family. Written informed parental consent to take part will be obtained prior to data collection.

6.7: Sampling: All Year 6 children and their parents will be invited to join the study. In families where there are two or more Year 6 children, all willing children will be invited and eligible to take part (at T0 there were 17 such families). Only one parent per family will be asked to provide data.

7. OUTCOME MEASURES

i. **Primary outcome**: The primary outcome will be child accelerometer-measured weekday minutes of moderate to vigorous physical activity (MVPA) at T1.

ii. **Secondary outcomes**: There are 7 secondary outcomes for the T1 assessment:

- **a.** Parent weekday minutes of weekday MVPA (Accelerometer)
- **b.** Child weekend minutes of MVPA (Accelerometer)
- **c.** Parent weekend minutes of MVPA (Accelerometer)
- **d.** Child weekday sedentary minutes (Accelerometer)
- **e.** Child weekend sedentary minutes (Accelerometer)
- **f.** Parent weekday sedentary minutes (Accelerometer)
- **g.** Parent weekend sedentary minutes (Accelerometer)

All these variables (plus the primary weekday child MVPA) will also be assessed at T2 and these will also be treated as secondary outcomes.

i. **Exposures:** In addition to the primary and secondary outcomes we will collect data on a number of quantitative variables that may help to explain changes in physical activity and sedentary time using the same processes that were used in the B-Proact1V study (14, 15). These will include the frequency with which that the child is active in different settings, child physical activity enjoyment, mode of travel to school, child screen-time, after-school club attendance, parent physical activity motivation and self-efficacy, school walking, cycling and play provision, curriculum physical activity, school environment audit and school physical activity policies (12). We will also specifically ask the school about COVID-19-related changes such as restructured physical education and after-school provision. Based on the formative findings, we will collect additional data on child physical activity motivation. In addition, we will collect data on any COVID restrictions in place at the time of data collection (national and/or local), whether children are defined as

clinically vulnerable or extremely vulnerable, and the numbers of staff and children in the year group who absent due to COVID-19 or self-isolating.

ii. **Descriptive variables:** For descriptive purposes we will ask all parents to report the highest level of education in the household and their home postcode to derive the index of multiple deprivation (19) for the home address. Parents will be asked to report the gender of their child as well as their own gender along with the parental relationship to child. (We will also assess whether the child attended key worker school and will keep this as a potential explanatory variable if there are further waves of lockdown and differences in provision from key worker vs non key worker parents). Parent height and weight will be self-reported to calculate body mass index. *(We hope to be able to measure child height and weight in school to calculate child body mass index z-score. This will not be possible until the prevalence of COVID-19 is reduced and therefore these data may only be provided for a sub-set of participants.)*

iii. Economic variables: Parent and child data will be collected at T1 and T2. Parents will be asked to report their HRQL and capability wellbeing using validated questionnaires, the EQ-5D-5L and ICECAP-A PBMs, respectively. Children will be asked to self-report their health-related quality of life (HRQoL) using the CHU9D and the impact of COVID-19 on their capability wellbeing will be assessed using questions currently being employed in the Birmingham CONTRAST study which examines the impact of COVID-19 in children and young people. Data regarding school and parent spending on after school physical activity provision and other extra-curricular activities (e.g. community activities and academic tutoring) will be collected using a questionnaire used in a previous study (20). The Family Economic Strain Scale (21) will be used to collect data on the impact on household finances. Schools will be asked at T1 to report spending on physical activity provision from historical school budgets and their Sports Premium allocation and to report further expenditure at T2. Data from the B-Proact1V school context questionnaire (administered at T0) will provide insights into the pre-COVID-19 allocation of time between academic activities and physical activity. These brief questions will be expanded upon in T1 and T2 to provide a more detailed understanding of the reallocation of time.

iv. Qualitative study: We will use in-depth interviews with parents and school staff to identify the perceived impact of COVID-19 on child and parent physical activity. The interviews will also examine in more detail what different approaches schools have taken to promote physical activity and the opportunities and challenges of those methods. Focus groups with children will also be used to explore their individual experiences during and after the COVID-19 lockdown and the subsequent impact on their engagement in physical activity. These data will be used to compile a list of possible options that could form part of a policy response to the crisis.

8. METHODS FOR DATA COLLECTION

14.01.2022: change to data collection protocol to reflect the need to be responsive to general and local covid fluctuations in regards to in-person data collection.

30.09.2021: change to data collection protocol to include some in-person measures (recruitment briefing, accelerometer hand out, child height and weight measurement) following guidance from Study Steering Committee on 21.09.2021.

8.1: Physical activity assessment: Children and parents will be asked to wear an ActiGraph wGT3X-BT accelerometer for 7 days. These devices will be sent home from the school in family-specific packs that also include details on how to complete the parent survey (see below). Resulting data will be processed using the same processing protocols as used in the B-Proact1V study. Specifically, a valid day of data will be defined as at least 500 minutes of data, after excluding intervals of ≥60 minutes of zero counts allowing up to two minutes of interruptions (22). Child data will be characterised as sedentary, light or MVPA using Evenson population-specific cut points for children (23). Mean minutes of weekday and weekend MVPA will then be derived as well as mean minutes of sedentary time per day. A comparable process will be undertaken for the parents, but the data will be analysed using the Troiano adult accelerometer cut points (24).

8.2: Body mass index: Child height and weight will be measured in schools by a trained researcher from the study team. When study team researchers are in schools, they will wear a FF3/N95 CE certified face mask while in close proximity to any research participant and employ social distancing whenever possible. Child height and weight will be recorded to the nearest 0.1 cm and 0.1 kg, using a Seca digital scale and a Seca stadiometer. Participants will have their height and weight measured wearing their normal school uniform but no shoes. Equipment will be cleaned using clinical grade alcohol wipes between participants. Child body mass index (BMI) will then calculated and converted to an age- and sex-specific standard deviation score (25, 26). Parents will be asked to self-report their height and weight and BMI (kg/m^2) will be calculated*. (We recognise that the COVID situation can change rapidly, and it may be the case that face to face data collection cannot take place at certain time points do to the number of cases, school staff absences etc. In this scenario we would a) attempt to collect the data a few weeks later when the situation changes, or b) not collect the height and weight data in that school).*

8.3: Child survey: Children will be asked to complete all survey items online using a unique link sent via email to their parents after consent has been obtained. The questionnaire will be administered via REDCap online and data will be automatically uploaded to a central University of Bristol server. (*When it is possible to collect data in schools, children may be asked to complete the survey on a tablet. All tablets were used in a previously funded PHR project and have encryption software. If data collection reverts to this method, the survey will be completed in school in a classroom setting with project staff available to answer any questions.)*

8.4: Parent survey: All parents will be asked to complete an online REDCap survey. Using the processes developed in the previous phases of the B-Proact1v project all parents will be sent a unique link to complete the survey online after informed consent has been obtained and asked to complete the survey within one week. Parents will be sent up to three reminders via email to complete the survey. If parents express a preference for a paper option, we will send them a form along with the accelerometers, but we expect less than 20% of families to select this option.

8.5: School audit: The school physical activity environment will be assessed using two measures. A member of the research team will complete a validated school physical activity environment measure (27, 28) during a normal school day. This measure provides an objective estimate of six domains that are pertinent to children's physical activity including provision for different physical activities, the design of the school grounds and aesthetics. The key contact from the school will be asked to complete the School Physical Activity Policy Assessment (S-PAPA), exploring how the school policies and curriculum support physical activity (27). We will also ask the key contact at the school about physical activity changes that they have made because of COVID-19 such as closed or restructured physical education and after-school provision.

8.6: Qualitative study: For the Time 1 assessment, we will conduct interviews with key contacts at approximately 18 schools (n=18). These schools will be purposively chosen based on school characteristics (IMD and size). We will also conduct interviews with approximately 24 parents of Year 6 pupils to ask how COVID-19 has impacted on their family's physical activity. These interviews will focus on comparing activity at the time of the interview with 12 months prior to identify changes in provision, attitudes and motivation for both children and parents and also how they may have changed over time (immediately after lockdown, semi-lockdown, later etc). The interviews will also examine the broader factors that could impact on physical activity at the time of assessment including COVID restrictions, social and local environmental factors in the school and the surrounding community. We will conduct the interviews on a rolling basis during the study and conduct rapid synthesis of findings at regular intervals (after 6 school contacts or 8 parents). We will also conduct focus groups in 6 schools to gain insight from the children on their perceptions of how their physical activity patterns have changed because of COVID-19. We will include approximately 8 participants in each focus group with an equal mix of boys and girls.

This process will then be repeated in the same schools for the T2 assessment where we will also ask the key contacts in the schools what has changed over the previous 12 months in relation to

school policies and what key lessons the school has learnt from the process. Parents and children will also be asked to reflect on changes to physical activity provision over the past 12 months and how things may have adapted or changed either for the better or worse.

8.7: Health economic evaluation: Economic outcome measures will include parents' and children's HRQoL and capability wellbeing. The implications of COVID-19 on household finances will be collected using the Family Economic Strain scale (21) along with an assessment of family spending on after-school physical activity and other extra-curricular activities. Schools' present and historical school expenditure on physical activity resources will be captured via the school audit and the allocation of time to physical activity and academic activities will also be reported.

8.8: Assessment and follow-up: As noted above we will collect data at two timepoints.

- Time 1 will be May 2021 to December 2021.
- Time 2 will be January 2022 to July 2022.

9. ANALYSIS PLANS: In the sections below, we have provided detail on all aspects of the analysis. We will develop more detailed analysis plans for each aim that will be approved by our Independent Study Steering Committee (SSC) prior to any analyses being conducted.

9.1 Main quantitative analysis (Aims A-D): We will employ a repeated cross-sectional analysis, matched on schools, comparing the T1 data with the T0 data, using linear multilevel models with children nested within time periods (0,1 or 2) nested within schools. The difference in average daily weekday MVPA following COVID-19 will be estimated as the regression coefficient for an indicator variable for time period. All models will be adjusted for variables known to be associated with children's physical activity (gender, household education and parent age for parent models), and accelerometer wear time. We will compare these to models additionally adjusted for child zBMI, both for the subset of children with BMI measurements and for imputed data (see below). As data collection is at different times of the year, we will include hours of daylight as a covariate and use harmonic sine/cosine functions (29) to capture any residual background seasonal variation as we have previously done with this dataset. From previous analyses, the primary and secondary outcomes (minutes of MVPA and sedentary time) are continuous and approximately normally distributed and so linear models are likely to suitable, but if necessary, we will consider appropriate transformations. For the main analyses comparing primary and secondary outcomes before and after COVID-19, we will conduct two-sided hypothesis tests for the difference, at a 5% significance level and report the p-value as well as the estimate and 95% confidence interval. This process will be repeated for the T2 data.

The multilevel approach means we can include data from all schools even if they do not participate in the current study. The main source of missing data will child zBMI due to not being able to measure height/weight for some participants due to COVID restrictions. These data will be missing at school level rather than due to individual characteristics. To maximise information and reduce school-level bias, we will use multiple imputation to impute missing zBMI (and any other missing covariate data on children and parents), using child, parent and school data and retaining the multilevel structure (30). Sensitivity analyses will be conducted to compare results from imputed data with complete case analyses.

We will initially compare characteristics between T0, T1 and T2 data. As each wave of the dataset is matched on school and child age, and since Year 6 school-level distributions of key demographics are unlikely to change substantially over three years, we do not expect large differences between the waves. As such, rebalancing the post-COVID-19 samples (e.g. propensity scoring) should not be necessary. However, if there is evidence of imbalance we will use regression adjustment to include any variables that differ notably between the time-points. We will also report response rates by gender and socio-economic status.

Aim A: To determine if there is a difference in average daily MVPA following COVID-19, we will use a linear multilevel model for child weekday MVPA, adjusting for confounders (gender, household

education, zBMI). To identify subgroups particularly at risk following COVID-19, we will extend this model to determine whether any changes in MVPA differ by gender and household education, by including interaction terms between these variables. We will also look at subgroups of child zBMI, using the subset of children with zBMI measurements, and the imputed dataset. We will include COVID restrictions, self-isolating etc at the time of measurement at the individual level.

Aim B: We will apply similar models for the secondary outcomes, adjusting parent models additionally for parent age. The same parent may appear in T0 and either T1 or T2 (or both). For example, analysis of the B-Proact1v data shows that 9% of participating children have a sibling three years younger. For analysis of parent outcomes, we will investigate the extent of this, and if necessary, use robust standard errors to account for the dependence.

Aim C: We will repeat the cross-sectional analysis and models described above to compare the T2 data with the T0 data, to assess longer-term change in physical activity following COVID-19. In addition, we will combine data from all three time-points to explore how MVPA changes over time within a multilevel model framework. Due to the timings of data collection, some of the children in T1 may also be repeated in T2. The multilevel model will thus be cross-classified by child and time period. As data collection following COVID-19 will occur at different times between May 2021 and July 2022, we will explore how outcomes change over time since the end of lockdown by including the time since the end of restrictions in a generalised additive mixed model which allows for a nonlinear relationship with time. Our model is flexible and will include national and local COVID restrictions at different times as well as be able to include additional infection-control measures or future COVID-19 waves if necessary, to estimate their effect on physical activity.

Aim D: To understand the extent to which differences in MVPA between T0 and T2 can be explained by other factors we will undertake a mediation analysis. We will investigate individual factors (physical activity enjoyment and motivation, mode of travel to school, screen-time and after-school club attendance), parental factors (parent physical activity, motivation) and school factors (school walking, cycling and play provision, curriculum physical activity and extra-curricular programs) and include individual and school-level confounders such as school size, deprivation, and location. While the main focus will be on T0-T2 differences, we will also investigate whether similar patterns are evidence in T0-T1 differences using the smaller subset of children for whom zBMI measurements are available.

Formal mediation tests can be problematic and introduce confounding in multilevel models as mediators may act at different levels (31, 32). We will therefore fit models for the individual steps and use a combination of statistical significance of individual terms and Akaike/Bayesian Information Criteria to assess overall model fit to interpret these models in the context of a mediation study. In addition, we will explore school and wave-level random effects to explore how much of the total between-wave variability in MVPA is explained by individual and school-level factors. We will combine evidence from these sources to assess the extent to which mediating factors are present.

9.2: Rapid interim quantitative analysis (Aim E): To provide timely evidence to policy makers, we will conduct rapid interim analyses whereby part way through each wave and at the end of each Wave (December 2021 and July 2022) we will produce a 2-page comparison sheet describing the levels of physical activity in children and parents (mean and standard deviation of minutes of sedentary, light and MVPA and the percentage meeting CMO physical activity guidelines) in the schools and the comparable data for the same schools at T0. Data will be aggregated across schools and presented for all participants and by gender and socio-economic sub-groups. These data will be shared with schools and policy makers at strategic intervals (approximately every 3-4 months or at a natural transition point, such as the summer or Easter break) with the amount of data shared becoming greater over time. (We appreciate that data from the first set of schools will be limited, but we think that policy makers will find these data useful and we will ensure that all users are aware of the limitations and caveats). To preserve data confidentiality, we will not report data for any subgroups with sample sizes less than 10.

9.3: Health economics (Aim F): The B-Proact1V study was not designed to conduct formal economic analyses, therefore there is a lack of pre-COVID economic data. Consequently, the planned analyses will be mostly descriptive. Expenditure on physical activity will be summarised and presented for each wave. HRQL and capability wellbeing utility indices will be calculated and associations with socio-demographic data explored. Finally, the affordability and economic implications of any proposed mitigation strategies will be explored.

9.4: Qualitative analysis (Aim G): Interview and focus group recordings will be transcribed verbatim and analysed using the framework method in which thematic content analysis is conducted and themes are developed, both inductively from the accounts of participants and deductively from existing literature utilising QSR NVivo. Analysis will involve familiarisation, coding, developing a framework, applying the framework, charting data into the framework matrix, and interpretation. Hierarchies of categories will be created and brief summaries, mind maps, and representative quotes for each category will be abstracted. Responses across parents, children and key stakeholders will then be compared. We will examine divergence and similarities across sources to develop a comprehensive understanding of how COVID-19 has impacted on physical activity and the key strategies that could be used to mitigate impacts. When the analyses are repeated at T2, we will conduct a sub-analysis that examines how the school's policies may have changed since T1 and the rationale for those changes.

10. ASSESSMENT OF UNANTICIPATED OUTCOMES:

As the proposed study includes two waves of data collection and comparison to an existing study the likelihood of any unanticipated outcomes is very low. We will however implement an adverse event process modelled on the methods employed in the PHR funded Action 3:30R study (20) which was conducted in 12 Bristol primary schools. Using this process, all adverse events were to be recorded in detail along with subsequent preventive actions and then reported to the chair of the approving ethics committee, the chair of the Study Steering Committee and the funder. (No adverse events were reported). At the time of writing, the UK is still facing COVID-19 challenges. If any staff catch COVID-19 in the process of conducting data collection in schools this would constitute an unexpected adverse event and would be reported. Research staff will assess their own individual risk of hospitalisation (and death) if they catch COVID-19 - if any team individual's personal risk is high, the study team will cease to collect height and weight data in person from children in the study and revert to a fully remote data collection protocol.

11. PROJECT MANAGEMENT AND GOVERNANCE:

Professor Jago will take overall responsibility for all aspects of the project including the liaison with the co-applicants, funder, sponsor and Study Steering Committee. Danielle House (DH), will be the Project Manager. DH will run the project on a day to day basis, supervised by Professor Jago. Dr Emm-Collison will lead the qualitative aspects of the study, supervised by Prof Jago and also lead on the interpretation of all psychosocial variables. Dr Salway will be the statistician. Dr Breheny will be the Health Economics Research Associate, supervised by Prof Hollingworth.

We will convene three groups to support the guidance and management of the study.

- A **Project Management Group (PMG)**, chaired by Prof Jago, will meet monthly. The PMG will include all co-applicants, the Project Manager, Qualitative lead, health economist and statistician, and discuss progress, study design, problems and solutions and ethical issues. Two PPI members, a parent and a teacher will attend four PMG meetings per year.
- An independent **Study Steering Advisory (SSC)** will be established consisting of an independent chair plus three independent members, a PPI representative, and senior members of the study team. The members will have experience in school-based research, physical activity, and statistics. We envisage that there will be three SSC meetings over the course of the project: in the first six months of the project, after the completion of T1 data collection where study progress will be reviewed, and towards the end of the project when final findings will be discussed and interpreted.

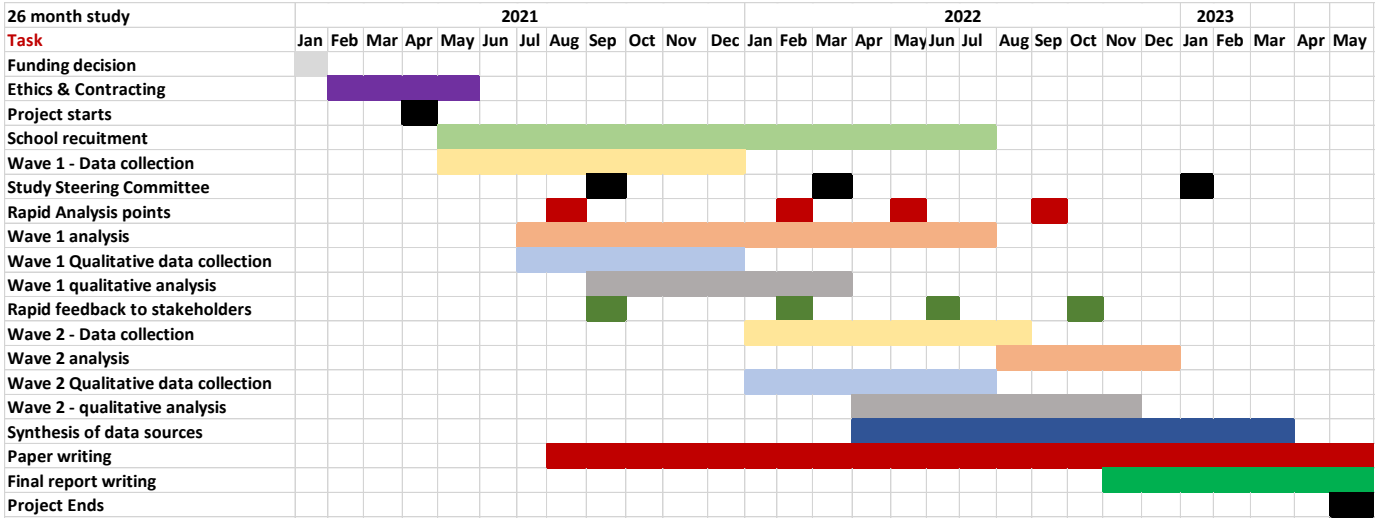
Sponsorship & Trial registration: The University of Bristol has agreed to act as the sponsor for this study. The study is registered on ResearchRegistry.com -

https://www.researchregistry.com/browse-the-registry#home/registrationdetails/604b4760d539c90020642be6/

12. **ETHICAL ISSUES:** Ethical approval for this study has been granted by the University of Bristol's School for Policy Studies ethics committee (SPSREC/20-21/150) which approved the T0 data collection. Specifically, we will seek informed written parental consent for both the child and parent participation. We will also provide all children with a verbal overview of the project and seek their active consent to take part in the project. Children will only take part in the project if they provide both parental consent and child assent. All staff will work in accordance with school and University safeguarding policies.

13. **PROJECT TIMETABLE:** The Gantt chart below provides an overview of the key tasks that will be completed in this 26-month study based on an April 2021 start date, recruiting schools May 2021 and pupils from late May early June 2021 onwards.

03.05.2022: change to Gantt chart to slightly push back T2 rapid analysis and rapid feedback points, to allow for appropriate time for data collection and analysis.



14. PUBLIC INVOLVEMENT

14.1: PPI plan for the current project: We view PPI as critical to the success of the project. We will recruit a parent and teacher to join the Project Management Group as PPI representatives. We have also recruited a parent to sit on the Study Steering Committee. We have requested funds to cover the PPI input into the PMG and Study Steering Committee based on local INVOLVE guidelines.

We have not suggested adding children to the PMG or SSC as our experience suggests that many children feel uncomfortable in these settings and they prefer to provide feedback independently. Instead we will form a virtual child PPI group who will meet annually during the project to provide input on study procedures and feedback mechanisms. Dr Emm-Collison who has extensive experience of working with children, will lead these and we will also invite the PPI representatives from the PMG to attend so that they can represent the child's views at PMG meetings. We will provide all children who attend these sessions with £10 gift cards as a thank you for their support.

15. **TEAM EXPERTISE:** We have put together a team that has all the expertise to deliver the project. The team has been selected to cover all aspects of the study design with a balance of experience. Moreover, given the short notice, the team are in post and ready to start.

Dr Russ Jago is Professor of Paediatric Physical Activity and Public Health at the University of Bristol. Prof Jago's research focusses on understanding the key influences on children and young people's physical activity behaviours and developing strategies to change those behaviours. Prof Jago will lead the project and manage the Project Manager, Dr Emm-Collison and Dr Salway.

Dr Charlie Foster (OBE) is Professor in Adult Physical Activity at the University of Bristol. Dr Foster is Chair of the Chief Medical Officers' physical activity advisory group, where he provides strategic advice to the four Chief Medical Officers and works in partnership with Sport England, PHE and agencies in the other devolved nations to support physical activity across the lifespan from a policy perspective. Dr Foster will lead on all engagement with policy makers, national agencies and the third sector to ensure the maximum impact from the work.

Dr Frank de Vocht is Professor in Epidemiology and Public Health at the University of Bristol. Dr de Vocht is an expert in the analysis of non-randomized epidemiological studies, including natural experiments. Dr de Vocht will guide the project quantitative analyses**.**

Dr William Hollingworth is Professor of Health Economics at the University of Bristol**.** Prof Hollingworth has expertise on the economic evaluation of a wide range of public health interventions in children and adolescents including promoting physical activity, weight management services, smoking prevention and improving mental health. Prof Hollingworth will lead the health economic analyses.

Dr Jo Williams is Consultant in Public Health at Bristol City Council. Dr Williams leads on all child public health childhood work at the council including the healthy schools and physical activity. Dr Williams will provide key insight into the practice based public health challenges of the project, help to recruit schools, and liaise with council education colleagues. Dr Williams will also support the dissemination of work to practice based colleagues through local, regional, and national networks.

Dr Lydia Emm-Collison is a Senior Research Associate at the University of Bristol with expertise in physical activity motivation, qualitative research methods and stakeholder engagement. Dr Emm-Collison was also the project manager for the B-Proact1V project so has extensive knowledge of the data collection processes and has excellent links with the schools and original parents

Danielle House will be the Project Manager. Danielle will lead the recruitment of all schools and participants, data collection, manage the Fieldworkers and assist with the qualitative analysis of the project.

Dr Ruth Salway is a Senior Research Associate in Epidemiology and Statistics at the University of Bristol and will be the project statistician.

Dr Katie Breheny is a Research Associate in Health Economics and NIHR School for Public Health Research (SPHR) Post-doctoral Launching Fellow at the University of Bristol. Dr Breheny's PhD explored the economic evaluation of school based public health interventions, using a physical activity intervention (The Daily Mile) as a case study. Dr Breheny will conduct the economic analyses.

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