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Camden Active Spaces: Does the Construction of Active School Playgrounds Influence Children's Physical Activity Levels? A Longitudinal Quasi-Experiment Protocol

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Key words: physical activity/ active play/ children/ school/ environment

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INTRODUCTION

Physical activity is essential for every facet of children's health. However, physical activity levels in British children are low. The school environment is a promising setting to increase children's physical activity but limited empirical evidence exists on how a change in the outdoor physical school environment influences physical activity behaviour. London Borough of Camden is re-designing seven existing school playgrounds to engage children to become more physically active. The primary aim of this project is to evaluate how the use of bespoke and innovative design of 'space' can influence physical activity levels in young people.

METHOD AND ANALYSIS

This project will use a longitudinal quasi-experimental design with one baseline data collection session and two follow-ups. Between baseline and follow-up the school playgrounds will be re-designed. At baseline, a series of fitness tests, anthropometric and questionnaire measurements, and 7 day objective physical activity monitoring will be carried out on children. This will be repeated at follow-up. Multilevel regression modelling will be used to analyse the data.

ETHICS AND DISSEMINATION

The results of this study will be disseminated through peer-review publications and scientific presentations. Ethical approval was obtained through the University College London Research Ethics Committee (Reference number: 4400/002).

Strengths and Limitations of this Study

- Camden Active Spaces presents a unique opportunity to evaluate the impact of the construction of school "active playgrounds" on children's physical activity, health, and wellbeing.
- The use of objective measures of physical activity over seven consecutive days is strength of the present study.
- The present study uses a longitudinal quasi-experimental design without control groups.

INTRODUCTION

Physical activity is essential for every facet of children's (aged 5 to 16 years) health. For example, higher levels of physical activity in children are associated with more favourable cardiovascular disease risk factors whereas excessive levels of sedentary behaviour have the reverse effect.[1,2] Physical activity can also benefit psychological health by aiding in the prevention of anxiety and depressive symptoms and contributing to the improvement of self-esteem.[3] Importantly, rather than detracting from learning, more physical activity and breaks from sitting in school are thought to enhance cognitive function and academic performance.[4] It is also more likely that active children will become active adults, since some tracking of physical activity behaviour has been observed from childhood to adulthood.[5] However, in westernised countries current levels of physical activity in children are low as there are increasing opportunities to participate in sedentary activities.[6,7] For example, it is recommended that children engage in physical activity of moderate intensity for at least one hour a day, to maintain good health.[8] However, just 24% of British girls and 32% of boys achieve this recommendation.[7] Physical inactivity is estimated to cost the NHS approximately £8 billion per year in health care costs alone.[8] Encouraging physically active lifestyles in children is therefore crucial in nurturing a healthy future generation of adults.

A recent meta-analysis found that the effects of interventions to increase physical activity in children have been, at best, modest, and concluded that alternative approaches are required.[9] Children spend approximately 60% of their weekday in school where physical activity levels are at their lowest.[10,11] Therefore, the school environment is a promising setting for intervention. The majority of school-based interventions have focused on

physical education (delivered once or twice a week) and have found only small effects.[12] Environments both facilitate and provide the arena for physical activity [13] although there is little robust empirical evidence concerning the effect of changing the physical environment on activity levels in children. Emerging data has suggested that a positive perception of the school play environment was associated with higher levels of moderate-vigorous physical activity (MVPA) during playtime.[14] In a 12 month intervention where the playground environment was redesigned with markings and physical structures, children's morning and lunchtime activity levels were increased 6 months post-intervention, although effects were not sustained at 12 months.[15] Previous studies have collected physical activity data during one school day only therefore it is questionable whether this data is reflective of habitual behaviour and so limits the ability to examine carry over effects outside the school environment (ie, at weekends and during evenings). Taken together, the emerging evidence suggests that the physical environment could play an important role in children's physical activity behaviour, but more robust evidence is required.

SETTING

Camden Borough Council is re-designing seven existing school playgrounds (five primary schools and two secondary schools), that are thought *not* to be conducive to physical activity/ active play, with exciting bespoke features to engage children to become more active. Example features include climbing frames, trampolines, monkey bars, and outdoor gyms, which have been designed based on themes emerging from qualitative work in each school. Camden Council's underlying goal is to encourage participation by creating opportunities for physical activity outside of traditional sports or team competition. This

presents a unique opportunity to evaluate the impact of these structures on children's physical activity, health and wellbeing outcomes while addressing previous limitations in the literature (ie collecting activity data for a period >1day).

AIMS

The *Camden Active Spaces* project encompasses two key elements; 1) redesign of the school playgrounds; 2) evaluation of the hypothesised benefits. In the present paper we focus on the evaluation only. Thus, the primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, engagement, and physical function/fitness.

METHOD AND ANALYSES

The evaluation of *Camden Active Spaces* will use a longitudinal quasi-experimental design. Baseline data collection will take place in the Spring/Summer term 2014, follow-up I data collection will take place during the Autumn term 2014, and follow-up II during the Summer term of 2015 (see Figure 1). Between baseline and follow-up I (school summer holidays) the school playgrounds will be re-designed. A second follow-up will allow us to investigate if short-term effects of the intervention (if they exist) are sustained over a longer period. This evaluation has been funded by the Economic and Social Research Council, UK (ES/M003795/1), whilst the core project (playground redesign) has been funded by Camden Clinical Commissioning Group and London Borough of Camden. Ethical approval was granted by the University College London Research Ethics Committee (4400/002).

Inclusion criteria

School inclusion criteria

Seven schools located in the London Borough of Camden have been selected to receive the re-designed playgrounds and all seven schools have agreed to take part in the study.

Participant Inclusion criteria

We aim to randomly select approximately 100 children (see below power calculation) evenly distributed across school year groups (aged 5 to 11 years in primary school and aged 11 to 16 years in secondary school) from each of the seven schools (total sample size 700). Children aged 17 to 18 years or any school leavers in 2014 will not be asked to participate in the current project, owing to time table restrictions due to final exams and potential loss to follow up. Students whose parents have not opted them out of the study will be eligible to participate (see section Ethics and Dissemination for details on obtaining consent).

Recruitment

The seven schools who will be receiving the redesigned playgrounds have previously been recruited into the study. To recruit children into the study presentations will be given to each year group within each school, during assemblies. The presentations will disseminate information on *Camden Active Spaces,* what would be involved if children were to take part in the study and benefits of the study to children and the school. At the end of the

presentations children will be given participant study information sheets. In order to make parents aware of the study a parent information sheet will be emailed to all parents (translated into different languages where required), posted on the school webpage, in addition to hard copies being made available at the school. In an attempt to maximise response rates and adherence to protocol, each child who completes the wear protocol will be awarded a one-month free swimming voucher and entered into a prize draw to win an iPod Touch (one iPod Touch will be awarded per school). All schools taking part in the study will be entered into a separate prize draw to win one of two Nintendo Wiis.

Procedures

Data collection procedures will take place over a period of 18 months. A team of trained researchers will collect data from each school on a date and time that is convenient for the school. Children will be invited to take part in data collection. Data collection sessions will last approximately 30 minutes. A series of fitness tests and anthropometric measurements will be carried out on children, in an appropriate room in the school (e.g. sports or assembly hall). Once fitness tests and anthropometric measurements have been completed objective devices (accelerometers) will be given to children to monitor their physical activity behaviour. Between four and seven days of accelerometer data are needed to provide a reliable estimate of habitual physical activity.[16] Thus participants will be asked to wear accelerometers for 7 consecutive days. On day seven participants will return the device to research staff at the school where they will then complete a questionnaire on their physical activity behaviour. This exact process will be repeated at follow-up I and follow-up II.

Measurement and instruments

Accelerometer

It is now recognised that accelerometers provide the most reliable and valid measurement of activity in children [17] and are considered the gold standard approach. These wearable motion sensors measure movement across three dimensions, thus providing minute-by-minute time-stamped data on activity intensity, duration, and patterns across the day. Objective physical activity monitoring has been successfully used in similar study settings to the present project.[14,15,17,18]

The present evaluation will use the Actigraph GT3X accelerometer. This device is validated and has been used in other studies with primary and high school children (see for example: www.iconnect.co.uk and http://www.cedar.iph.cam.ac.uk/research/directory/speedy/). The Actigraph GT3X is worn on a belt around the waist with the device itself positioned above the right hip either over or under clothing. Children will be asked to wear the device during waking hours every day for seven consecutive days, but not during water-based activities or sleep.

Fitness Tests

A series of fitness tests will be carried out, following Standard Operating Procedure Forms, on all children taking part in the study. Four fitness tests will be carried out to measure aspects of general fitness: participants will be asked to perform the hand held

Dynamometer test to assess grip strength, the standing horizontal jump test to assess leg power, the peak flow test to assess lung function, and the sit-and-reach test to assess flexibility. Participants' weight and body composition will be measured using the Tanita SC-330 Body Composition Analyser (Tanita Inc, IL, USA) and height will be measured using the Leicester Height Measure, from which BMI will be calculated kg/m^2.

Questionnaires

All children taking part in the study will be asked to complete a questionnaire. The questionnaire will take approximately ten minutes to complete and includes questions on standard demographics and physical activity, as well as potentially important correlates of physical activity.

The Girls Health Enrichment Multi-Studies (GEMS) physical activity survey has been embedded within the questionnaire to give a subjective measure of physical activity. GEMS has validity and reliability equivalent to other self-report measures of physical activity [19] and was deemed suitable for both primary and high school boys and girls by those who designed the present study, owing to its simplicity.

The questionnaire also includes items on travel mode (as used in the iConnect Study; www.iconnect.co.uk), diet, parents health (as used in the DASH study; http://dash.sphsu.mrc.ac.uk/), and health related quality of life (Child Health Utility 9D;[20] to allow for a cost evaluation of the project).

Teachers will be asked to complete the validated Strengths and Difficulties questionnaire;[21] this questionnaire provides a measure of children's behaviour and

mental health and takes approximately five minutes to complete per child. Head Teachers will also be asked to complete a questionnaire to allow for an understanding of differences between schools on "playground policy." Example questions include, "If it is raining are children allowed to go outside and play?" And "How long do schools provide for recess?"

ANALYSIS

Outcome

The primary outcome for this study will be change in average daily time spent in MVPA as recorded by the Actigraph accelerometer. In addition the study has been designed to collect the following secondary outcomes using participant questionnaires and objective measures (1) change in average daily time spent sedentary, (2) change in average daily time spent in light and vigorous activity at different times of the day (playtimes at school, leisure time at home), (3) change in peak flow, sit-and-reach, grip strength, standing horizontal jump, and body mass index (BMI)/body composition, (4) change in other intra-personal variables recorded by questionnaires (e.g. Strength and Difficulties scores).

Quantitative analysis

Raw data files will be extracted from each Actigraph device and processed using bespoke software (Actilife) to quantify a range of features that will directly contribute to the determination of active and sedentary time. Standard criteria will be employed in the analysis and cleaning of accelerometry data, including the use of conventional guidelines to

identify minimum wear time, differentiate non-wear time from prolonged periods of inactivity, and selecting valid cut-points for the identification of different activity intensity bands. Multilevel modelling will be used to analyse the data. This approach offers several advantages over simple regression models. We will be able to model changes in activity over the three assessment periods accounting for the inter-individual as well as intra-individual differences.

Sample size

A previous school based intervention to examine the effects of changes in playground structure on physical activity [17] demonstrated a small effect size (d =0.10). Thus, based on these data, a sample size of N=458 would provide us with 80% power at 5% significance level to detect small differences in moderate intensity physical activity using a repeated measures design (calculated using G-Power). We will aim to recruit 100 children from each school to allow for dropout and incomplete Actigraph data.

ETHICAL CONSIDERATION AND DISSEMINATION

Firstly, head teachers from each school will be asked to provide explicit written consent for their schools and school children to take part in the study. Next, if parents do not want their child(ren) to take part in the study they will be given the option to "opt-out" their child(ren), instructions to parents on how to opt-out their child(ren) are provided in the parent study information sheet. Prior to data collection all high school (not primary school) children will be asked to provide explicit written assent.

The findings from this study will be disseminated to academic researchers and to policymakers through several mechanisms. First, we will employ the usual avenues for dissemination of academic research, including conference presentations and journal articles. Second, we will disseminate this research via social media outlets such as the University College London – Physical Activity Research Group Twitter account. Third, with Camden Council, we will include this physical activity study within the regular programme of briefings that are presented to government departments interested in physical activity, including the Department of Health, the Department for Communities and Local Government, etc.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

LS, CK, and MH designed the study. All authors contributed to the development of the study protocol. LS and MH drafted the manuscript. All authors assisted in drafting the manuscript. All authors read and approved the final manuscript.

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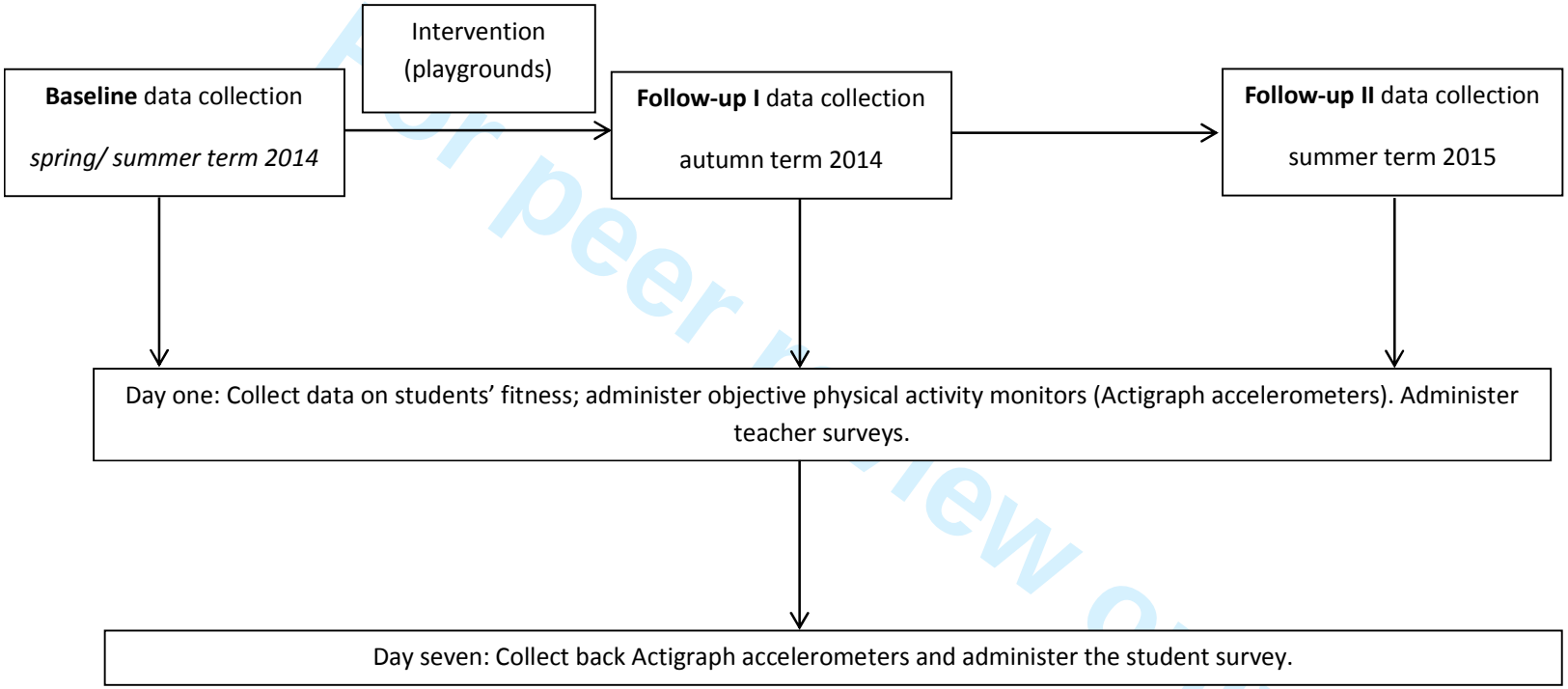
Figure one: Overview of Study Design



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **YES**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **YES**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **YES**
Objectives	3	State specific objectives, including any prespecified hypotheses **YES**
Methods		
Study design	4	Present key elements of study design early in the paper **YES**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **YES**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **YES** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case **NA**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **YES**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **YES**
Bias	9	Describe any efforts to address potential sources of bias **YES**
Study size	10	Explain how the study size was arrived at **YES**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **YES**

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **YES**
		(*b*) Describe any methods used to examine subgroups and interactions **NA**
		(*c*) Explain how missing data were addressed **NA**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **NA**
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **NA**
		(b) Give reasons for non-participation at each stage **NA**
		(c) Consider use of a flow diagram **NA**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **NA**
		(b) Indicate number of participants with missing data for each variable of interest **NA**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **YES**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **NA**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **NA**
		Cross-sectional study—Report numbers of outcome events or summary measures **NA**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **NA**
		(*b*) Report category boundaries when continuous variables were categorized **NA**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **NA**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **NA**
Discussion		
Key results	18	Summarise key results with reference to study objectives **NA**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **YES**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **NA**
Generalisability	21	Discuss the generalisability (external validity) of the study results **NA**

Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **YES**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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A recent meta-analysis found that the effects of interventions to increase physical activity in children have been, at best, modest, and concluded that alternative approaches are required.[9] In the UK, children spend approximately 60% of their weekday in school where physical activity levels, particularly in girls, are low.[10,11] Environments both facilitate and provide the arena for physical activity [12]. Interventions that target the school environment

may offer great opportunity to increase physical activity levels. However, there is little robust empirical evidence concerning the effect of changing the physical environment on activity levels in children. Emerging data has suggested that a positive perception of the school play environment was associated with higher levels of moderate-vigorous physical activity (MVPA) during playtime.[13] Moreover, the number of permanent play facilities in school playgrounds has been found to be associated with higher physical activity levels.[14] A recent review [15] on the value of playgrounds for children's physical activity identified 13 experimental studies, which have produced mixed findings, likely owing to differences in intervention design. For example, the review identified that reducing playground density increased physical activity levels, but the provision of play equipment produced mixed effects, whereas no effects were found on the provision of playground markings and promotion of physical activity by teachers. Just one study investigated the impact of "major" playground reconstruction on children's physical activity behaviour [16] and concluded renovated schoolyards to promote physical activity may increase the number of children who are physically active and may reduce sedentary behaviours. However, physical activity data was collected using direct observation during the school day, only. This limits the ability to examine carry over effects outside the school environment (ie, at weekends and during evenings). Taken together, the emerging evidence suggests that the physical environment could play an important role in children's physical activity behaviour, but more robust evidence is required.

SETTING

Camden Borough Council is re-designing seven existing school playgrounds (five primary schools and two secondary schools), that are thought not to be conducive to physical activity/ active play, with exciting bespoke features to engage children to become more active. Each school will receive a unique playground design, for example displayed in Figure 1. Example features include new Astroturf games pitches, climbing frames, trampolines, monkey bars, and outdoor gyms, which have been designed based on themes (eg, ancient ruins, volcanoes, clouds etc.) emerging from qualitative work with children and teachers in each school. The research team did not carry out the qualitative work nor did they provide input into the design of the playgrounds. Camden Council's underlying goal is to encourage participation by creating opportunities for physical activity outside of traditional sports or team competition. This presents a unique opportunity to evaluate the impact of these structures on children's physical activity, health and wellbeing outcomes while addressing previous limitations in the literature (ie, collecting activity only in school).

We hypothesise that the new play grounds will increase young peoples' time spent in both light and moderate-to-vigorous physical activity and reduce sedentary behaviour during break time, and consequently improve levels of general fitness (eg, grip and leg strength, peak flow and adiposity).

AIMS

The *Camden Active Spaces* project consists of two key elements; 1) redesign of the school playgrounds; 2) evaluation of the hypothesised benefits. In the present paper we focus on the evaluation only. Thus, the primary aim of this project is to evaluate the impact of the re-

designed playgrounds on children's physical activity, wellbeing, engagement, and physical function/fitness.

METHOD AND ANALYSES

The evaluation of *Camden Active Spaces* will use a longitudinal quasi-experimental design. Baseline data collection will take place in the Spring/Summer term 2014, follow-up I data collection will take place during the Autumn term 2014, and follow-up II during the Summer term of 2015 (see Figure 2). Between baseline and follow-up I (school summer holidays) the school playgrounds will be re-designed. A second follow-up will allow us to investigate if short-term effects of the intervention (if they exist) are sustained over a longer period. This evaluation has been funded by the Economic and Social Research Council, UK (ES/M003795/1), whilst the core project (playground redesign) has been funded by Camden Clinical Commissioning Group and London Borough of Camden. Ethical approval was granted by the University College London Research Ethics Committee (4400/002).

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In addition to the seven experimental schools one control school will be recruited into the study. This school will be located in the London Borough of Camden and it will not be receiving a new playground design, moreover, it will not differ from experimental schools based on student demographics or school policy. Owing to resources it is only feasible to collect data from a single control school. The authors acknowledge that an equal number of controls to experimental schools would allow for a more robust experimental design.

Participant Inclusion criteria

We aim to randomly select approximately 100 children (see below power calculation) evenly distributed across school year groups (aged 5 to 11 years in primary school and aged 11 to 16 years in secondary school) from each of the eight schools (total sample size 800). Children aged 17 to 18 years or any school leavers in 2014 will not be asked to participate in the current project, owing to time table restrictions due to final exams and potential loss to follow up. Students whose parents have not opted them out of the study will be eligible to participate (see section Ethics and Dissemination for details on obtaining consent).

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The seven schools who will be receiving the redesigned playgrounds have previously been recruited into the study by Camden Borough Council. To recruit children into the study presentations will be given to each year group within each school, during assemblies. The presentations will disseminate information on *Camden Active Spaces,* what would be involved if children were to take part in the study and benefits of the study to children and the school. At the end of the presentations children will be given participant study information sheets. In order to make parents aware of the study a parent information sheet

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Data collection procedures will take place over a period of 12 months. A team of trained researchers will collect data from each school on a date and time that is convenient for the school. Children will be invited to take part in data collection. Data collection sessions will last approximately 30 minutes. A series of fitness tests and anthropometric measurements will be carried out on children, in an appropriate room in the school (e.g. sports or assembly hall). Once fitness tests and anthropometric measurements have been completed objective devices (accelerometers) will be given to children to monitor their physical activity behaviour. Between four and seven days of accelerometer data are needed to provide a reliable estimate of habitual physical activity.[17] Thus participants will be asked to wear objective devices for 7 consecutive days. On day seven participants will return the device to research staff at the school where they will then complete a questionnaire on their physical activity behaviour. This exact process will be repeated at follow-up I and follow-up II.

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Accelerometer

It is now recognised that accelerometers provide the most reliable and valid measurement of activity in children [16] and are considered the gold standard approach. These wearable motion sensors measure movement across three dimensions, thus providing minute-by-minute time-stamped data on activity intensity, duration, and patterns across the day. Objective physical activity monitoring has been successfully used in similar study settings to the present project.[14,18, 19]

The present evaluation will use the Actigraph GT3X accelerometer. This device is validated and has been used in other studies with primary and high school children (see for example: www.iconnect.co.uk and http://www.cedar.iph.cam.ac.uk/research/directory/speedy/). The Actigraph GT3X is worn on a belt around the waist with the device itself positioned above the right hip either over or under clothing. We will employ a sampling frequency of 30 hz. Children will be asked to wear the device during waking hours every day for seven consecutive days, but not during water-based activities or sleep.

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ANALYSIS

Outcome

The primary outcome for this study will be change in average daily time spent in MVPA as recorded by the Actigraph accelerometer. In addition the study has been designed to collect the following secondary outcomes using participant questionnaires and objective measures (1) change in average daily time spent sedentary, (2) change in average daily time spent in light and vigorous activity at different times of the day (playtimes at school, leisure time at home), (3) change in peak flow, sit-and-reach, grip strength, standing horizontal jump, and body mass index (BMI)/body composition, (4) change in Strength and Difficulties scores.

Quantitative analysis

Raw data files will be extracted from each Actigraph device and processed using bespoke software (Actilife) to quantify a range of features that will directly contribute to the determination of active and sedentary time. We intend to follow methods used in the International Children's Accelerometry Database study that incorporated children aged 4-18 yrs old [2]. Briefly, data files will be reintegrated to a 60-second epoch and non-wear time defined as 60 minutes of consecutive zeros, allowing for 2 minutes of non-zero interruptions. All children with at least 1 day with at least 500 minutes of measured monitor wear time between 7 AM and midnight will be included. Total physical activity will be expressed as total counts, including sedentary minutes, divided by measured time per day (counts/min, cpm). Time spent sedentary will be defined as all minutes showing less than 100 cpm and MVPA time as minutes showing more than 3000 cpm. Multilevel modelling will be used to analyse the data. This approach offers several advantages over simple regression models. We will be able to model changes in activity over the three assessment periods accounting for the inter-individual as well as intra-individual differences.

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measures design (calculated using G-Power). We will aim to recruit 100 children from each school to allow for dropout and incomplete Actigraph data.

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Firstly, head teachers from each school will be asked to provide explicit written consent for their schools and school children to take part in the study. Next, if parents (of primary and secondary school children) do not want their child(ren) to take part in the study they will be given the option to "opt-out" their child(ren), instructions to parents on how to opt-out their child(ren) are provided in the parent study information sheet. Prior to data collection all high school (not primary school) children will be asked to provide explicit written assent.

The findings from this study will be disseminated to academic researchers and to policymakers through several mechanisms. First, we will employ the usual avenues for dissemination of academic research, including conference presentations and journal articles. Second, we will disseminate this research via social media outlets such as the University College London – Physical Activity Research Group Twitter account. Third, with Camden Council, we will include this physical activity study within the regular programme of briefings that are presented to government departments interested in physical activity, including the Department of Health, the Department for Communities and Local Government, etc.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer made substantial contribution to the concept and design of the study. Lee Smith drafted the manuscript and Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer revised it critically for important intellectual content. Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer approved the final version of the manuscript to be published.

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Figure Legends

Figure 1: Example of new playground designs

Figure 2: Overview of study design

Camden Active Spaces: Does the Construction of Active School Playgrounds Influence Children's Physical Activity Levels? A Longitudinal Quasi-Experiment Protocol

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Key words: physical activity/ active play/ children/ school/ environment

Word count: 2317

INTRODUCTION

Physical activity is essential for every facet of children's health. However, physical activity levels in British children are low. The school environment is a promising setting to increase children's physical activity but limited empirical evidence exists on how a change in the outdoor physical school environment influences physical activity behaviour. London Borough of Camden is re-designing seven existing school playgrounds to engage children to become more physically active.

The primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, engagement, and physical function/fitness.

METHOD AND ANALYSIS

This project will use a longitudinal quasi-experimental design. Seven experimental schools and one control school will take part. One baseline data collection session and two follow-ups will be carried out. Between baseline and follow-up the experimental school playgrounds will be re-designed. At baseline, a series of fitness tests, anthropometric and questionnaire measurements, and 7 day objective physical activity monitoring (Actigraph accelerometer) will be carried out on children (aged 5 to 16 years). This will be repeated at follow-up. Changes in overall physical activity levels and levels during different times of the day (eg, school breaks) will be examined. Multilevel regression modelling will be used to analyse the data.

ETHICS AND DISSEMINATION

The results of this study will be disseminated through peer-review publications and scientific presentations. Ethical approval was obtained through the University College London Research Ethics Committee (Reference number: 4400/002).

INTRODUCTION

Physical activity is essential for every facet of children's (aged 5 to 16 years) health. For example, higher levels of physical activity in children are associated with more favourable cardiovascular disease risk factors whereas excessive levels of sedentary behaviour have the reverse effect.[1,2] Physical activity can also benefit psychological health by aiding in the prevention of anxiety and depressive symptoms and contributing to the improvement of self-esteem.[3] Importantly, rather than detracting from learning, more physical activity and breaks from sitting in school are thought to enhance cognitive function and academic performance.[4] It is also more likely that active children will become active adults, since some tracking of physical activity behaviour has been observed from childhood to adulthood.[5] However, in westernised countries current levels of physical activity in children are low as there are increasing opportunities to participate in sedentary activities.[6,7] For example, it is recommended that children engage in physical activity of moderate intensity for at least one hour a day, to maintain good health.[8] However, just 24% of British girls and 32% of boys achieve this recommendation.[7] Physical inactivity is estimated to cost the NHS approximately £8 billion per year in health care costs alone.[8] Encouraging physically active lifestyles in children is therefore crucial in nurturing a healthy future generation of adults.

A recent meta-analysis found that the effects of interventions to increase physical activity in children have been, at best, modest, and concluded that alternative approaches are required.[9] In the UK, children spend approximately 60% of their weekday in school where physical activity levels, particularly in girls, are low.[10,11] Environments both facilitate and provide the arena for physical activity [12]. Interventions that target the

school environment may offer great opportunity to increase physical activity levels. However, there is little robust empirical evidence concerning the effect of changing the physical environment on activity levels in children. Emerging data has suggested that a positive perception of the school play environment was associated with higher levels of moderate-vigorous physical activity (MVPA) during playtime.[13] Moreover, the number of permanent play facilities in school playgrounds has been found to be associated with higher physical activity levels.[14] A recent review [15] on the value of playgrounds for children's physical activity identified 13 experimental studies, which have produced mixed findings, likely owing to differences in intervention design. For example, the review identified that reducing playground density increased physical activity levels, but the provision of play equipment produced mixed effects, whereas no effects were found on the provision of playground markings and promotion of physical activity by teachers. Just one study investigated the impact of "major" playground reconstruction on children's physical activity behaviour [16] and concluded renovated schoolyards to promote physical activity may increase the number of children who are physically active and may reduce sedentary behaviours. However, physical activity data was collected using direct observation during the school day, only. This limits the ability to examine carry over effects outside the school environment (ie, at weekends and during evenings). Taken together, the emerging evidence suggests that the physical environment could play an important role in children's physical activity behaviour, but more robust evidence is required.

SETTING

Camden Borough Council is re-designing seven existing school playgrounds (five primary schools and two secondary schools), that are thought not to be conducive to physical activity/ active play, with exciting bespoke features to engage children to become more active. Each school will receive a unique playground design, for example displayed in Figure 1. Example features include new Astroturf games pitches, climbing frames, trampolines, monkey bars, and outdoor gyms, which have been designed based on themes (eg, ancient ruins, volcanoes, clouds etc.) emerging from qualitative work with children and teachers in each school. The research team did not carry out the qualitative work nor did they provide input into the design of the playgrounds. Camden Council's underlying goal is to encourage participation by creating opportunities for physical activity outside of traditional sports or team competition. This presents a unique opportunity to evaluate the impact of these structures on children's physical activity, health and wellbeing outcomes while addressing previous limitations in the literature (ie, collecting activity only in school).

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The findings from this study will be disseminated to academic researchers and to policymakers through several mechanisms. First, we will employ the usual avenues for dissemination of academic research, including conference presentations and journal articles. Second, we will disseminate this research via social media outlets such as the University College London – Physical Activity Research Group Twitter account. Third, with Camden Council, we will include this physical activity study within the regular programme of briefings that are presented to government departments interested in physical activity, including the Department of Health, the Department for Communities and Local Government, etc.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer made substantial contribution to the concept and design of the study. Lee Smith drafted the manuscript and Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer revised it critically for important intellectual content. Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer approved the final version of the manuscript to be published.

Figure Legends

Figure 1: Example of new playground designs

Figure 2: Overview of study design

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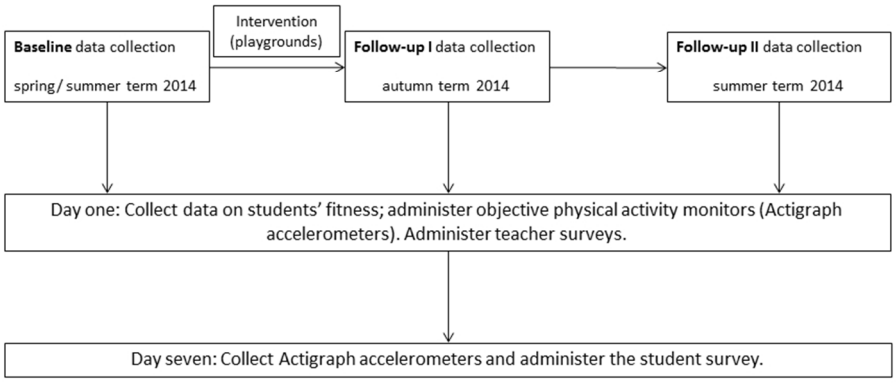
Figure 1: Example of new playground designs

254x190mm (96 x 96 DPI)

Figure Two: Overview of study design



254x190mm (96 x 96 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **YES**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **YES**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **YES**
Objectives	3	State specific objectives, including any prespecified hypotheses **YES**
Methods		
Study design	4	Present key elements of study design early in the paper **YES**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **YES**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **YES** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case **NA**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **YES**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **YES**
Bias	9	Describe any efforts to address potential sources of bias **YES**
Study size	10	Explain how the study size was arrived at **YES**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **YES**

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **YES**
		(*b*) Describe any methods used to examine subgroups and interactions **NA**
		(*c*) Explain how missing data were addressed **NA**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **NA**
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **NA**
		(b) Give reasons for non-participation at each stage **NA**
		(c) Consider use of a flow diagram **NA**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **NA**
		(b) Indicate number of participants with missing data for each variable of interest **NA**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **YES**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **NA**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **NA**
		Cross-sectional study—Report numbers of outcome events or summary measures **NA**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **NA**
		(*b*) Report category boundaries when continuous variables were categorized **NA**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **NA**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **NA**
Discussion		
Key results	18	Summarise key results with reference to study objectives **NA**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **YES**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **NA**
Generalisability	21	Discuss the generalisability (external validity) of the study results **NA**

Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **YES**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Camden Active Spaces: Does the Construction of Active School Playgrounds Influence Children's Physical Activity Levels? A Longitudinal Quasi-Experiment Protocol

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Camden Active Spaces: Does the Construction of Active School Playgrounds Influence Children's Physical Activity Levels? A Longitudinal Quasi-Experiment Protocol

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Key words: physical activity/ active play/ children/ school/ environment

Word count: 2317

INTRODUCTION

Physical activity is essential for every facet of children's health. However, physical activity levels in British children are low. The school environment is a promising setting to increase children's physical activity but limited empirical evidence exists on how a change in the outdoor physical school environment influences physical activity behaviour. London Borough of Camden is re-designing seven existing school playgrounds to engage children to become more physically active.

The primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, and physical function/fitness.

METHOD AND ANALYSIS

This project will use a longitudinal quasi-experimental design. Seven experimental schools and one control school will take part. One baseline data collection session and two follow-ups will be carried out. Between baseline and follow-up the experimental school playgrounds will be re-designed. At baseline, a series of fitness tests, anthropometric and questionnaire measurements, and 7 day objective physical activity monitoring (Actigraph accelerometer) will be carried out on children (aged 5 to 16 years). This will be repeated at follow-up. Changes in overall physical activity levels and levels during different times of the day (eg, school breaks) will be examined. Multilevel regression modelling will be used to analyse the data.

ETHICS AND DISSEMINATION

The results of this study will be disseminated through peer-review publications and scientific presentations. Ethical approval was obtained through the University College London Research Ethics Committee (Reference number: 4400/002).

INTRODUCTION

Physical activity is essential for every facet of children's (aged 5 to 16 years) health. For example, higher levels of physical activity in children are associated with more favourable cardiovascular disease risk factors whereas excessive levels of sedentary behaviour have the reverse effect.[1,2] Physical activity can also benefit psychological health by aiding in the prevention of anxiety and depressive symptoms and contributing to the improvement of self-esteem.[3] Importantly, rather than detracting from learning, more physical activity and breaks from sitting in school are thought to enhance cognitive function and academic performance.[4] It is also more likely that active children will become active adults, since some tracking of physical activity behaviour has been observed from childhood to adulthood.[5] However, in westernised countries current levels of physical activity in children are low as there are increasing opportunities to participate in sedentary activities.[6,7] For example, it is recommended that children engage in physical activity of moderate intensity for at least one hour a day, to maintain good health.[8] However, just 24% of British girls and 32% of boys achieve this recommendation.[7] Physical inactivity is estimated to cost the NHS approximately £8 billion per year in health care costs alone.[8] Encouraging physically active lifestyles in children is therefore crucial in nurturing a healthy future generation of adults.

A recent meta-analysis found that the effects of interventions to increase physical activity in children have been, at best, modest, and concluded that alternative approaches are required.[9] In the UK, children spend approximately 60% of their weekday in school where physical activity levels, particularly in girls, are low.[10,11] Environments both facilitate and

provide the arena for physical activity [12]. Interventions that target the school environment may offer great opportunity to increase physical activity levels. However, there is little robust empirical evidence concerning the effect of changing the physical environment on activity levels in children. Emerging data has suggested that a positive perception of the school play environment was associated with higher levels of moderate-vigorous physical activity (MVPA) during playtime.[13] Moreover, the number of permanent play facilities in school playgrounds has been found to be associated with higher physical activity levels.[14] A recent review [15] on the value of playgrounds for children's physical activity identified 13 experimental studies, which have produced mixed findings, likely owing to differences in intervention design. For example, the review identified that reducing playground density increased physical activity levels, but the provision of play equipment produced mixed effects, whereas no effects were found on the provision of playground markings and promotion of physical activity by teachers. Just one study investigated the impact of "major" playground reconstruction on children's physical activity behaviour [16] and concluded renovated schoolyards to promote physical activity may increase the number of children who are physically active and may reduce sedentary behaviours. However, physical activity data was collected using direct observation during the school day, only. This limits the ability to examine carry over effects outside the school environment (ie, at weekends and during evenings). Taken together, the emerging evidence suggests that the physical environment could play an important role in children's physical activity behaviour, but more robust evidence is required.

Increasing physical activity levels is well established as a way to improve fitness and health outcomes in young people. Strong's et al. [1] review identified 17 experimental studies that aimed to increase levels of physical activity, and these all found improvements in aerobic fitness. Two experimental studies implemented programs of moderately intense exercise 30 to 60 minutes in duration, 3 to 7 days per week, and this led to a reduction in total body adiposity in overweight young people. Interestingly, the review also identified three longitudinal and two experimental studies in young people that showed physical activity or strength training improved muscular strength and endurance. It is plausible to assume that an increase in movement and a decrease in sedentary behaviour may result in an increase in hamstring flexibility. This is important as maintaining hamstring flexibility may prevent acute and chronic musculoskeletal injuries.[17] There is also evidence that physical activity is associated with scores on a scale (The Strengths and Difficulties Questionnaire) measuring mental wellbeing (eg, happiness, behaviour, concentration, self-esteem etc).[18] On this basis we hypothesise that a change in the physical school playground environment which increases levels of physical activity or reduces sedentary behaviour should subsequently improve fitness and health outcomes.

A recent study found that engaging in 40% of moderate-intensity physical activity during school playtime equated to 34 minutes of daily MVPA.[19] This exceeds the *minimum* recommendation of 30 minutes of at least moderate-intensity physical activity for children's good health.[20] It has been suggested that this guideline is a realistic target for children to achieve during school playtime,[21] especially if a playground has been modified to encourage physical activity.

SETTING

Camden Borough Council is re-designing seven existing school playgrounds (five primary schools and two secondary schools), that are thought not to be conducive to physical activity/ active play, with exciting bespoke features to engage children to become more active. Each school will receive a unique playground design, for example displayed in Figure 1. Example features include new Astroturf games pitches, climbing frames, trampolines, monkey bars, and outdoor gyms, which have been designed based on themes (eg, ancient ruins, volcanoes, clouds etc.) emerging from qualitative work with children and teachers in each school. The research team did not carry out the qualitative work nor did they provide input into the design of the playgrounds. The qualitative work and the design of the playgrounds were carried out by two private organisations specialising in playground design. Camden Council's underlying goal is to encourage participation by creating opportunities for physical activity outside of traditional sports or team competition. This presents a unique opportunity to evaluate the impact of these structures on children's physical activity, health and wellbeing outcomes while addressing previous limitations in the literature (ie, collecting activity only in school).

We hypothesise that the new play grounds will increase young peoples' time spent in both light and moderate-to-vigorous physical activity and reduce sedentary behaviour during break time, and consequently improve levels of general fitness (eg, grip and leg strength, peak flow and adiposity).

AIMS

The *Camden Active Spaces* project consists of two key elements; 1) redesign of the school playgrounds; 2) evaluation of the hypothesised benefits. In the present paper we focus on the evaluation only. Thus, the primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, and physical function/fitness.

METHOD AND ANALYSES

The evaluation of *Camden Active Spaces* will use a longitudinal quasi-experimental design. Baseline data collection will take place in the Spring/Summer term 2014, follow-up I data collection will take place during the Autumn term 2014, and follow-up II during the Summer term of 2015 (see Figure 2). Between baseline and follow-up I (school summer holidays) the school playgrounds will be re-designed. A second follow-up will allow us to investigate if short-term effects of the intervention (if they exist) are sustained over a longer period. This evaluation has been funded by the Economic and Social Research Council, UK (ES/M003795/1), whilst the core project (playground redesign) has been funded by Camden Clinical Commissioning Group and London Borough of Camden. Ethical approval was granted by the University College London Research Ethics Committee (4400/002).

Inclusion criteria

School inclusion criteria

Seven schools located in the London Borough of Camden have been selected to receive the re-designed playgrounds and all seven schools have agreed to take part in the study.

In addition to the seven experimental schools one control school will be recruited into the study. This school will be located in the London Borough of Camden and it will not be receiving a new playground design, moreover, it will not differ from experimental schools based on student demographics or school policy. Owing to resources it is only feasible to collect data from a single control school. The authors acknowledge that an equal number of controls to experimental schools would allow for a more robust experimental design.

Participant Inclusion criteria

We aim to randomly select approximately 100 children (see below power calculation) evenly distributed across school year groups (aged 5 to 11 years in primary school and aged 11 to 16 years in secondary school) from each of the eight schools (total sample size 800). Children aged 17 to 18 years or any school leavers in 2014 will not be asked to participate in the current project, owing to time table restrictions due to final exams and potential loss to follow up. Students whose parents have not opted them out of the study will be eligible to participate (see section Ethics and Dissemination for details on obtaining consent).

Recruitment

The seven schools who will be receiving the redesigned playgrounds have previously been recruited into the study by Camden Borough Council. To recruit children into the study presentations will be given to each year group within each school, during assemblies. The

presentations will disseminate information on *Camden Active Spaces,* what would be involved if children were to take part in the study and benefits of the study to children and the school. At the end of the presentations children will be given participant study information sheets. In order to make parents aware of the study a parent information sheet will be emailed to all parents (translated into different languages where required), posted on the school webpage, in addition to hard copies being made available at the school. In an attempt to maximise response rates and adherence to protocol, each child who completes the wear protocol will be awarded a one-month free swimming voucher and entered into a prize draw to win an iPod Touch (one iPod Touch will be awarded per school). All schools taking part in the study will be entered into a separate prize draw to win one of two Nintendo Wiis.

Procedures

Data collection procedures will take place over a period of 12 months. A team of trained researchers will collect data from each school on a date and time that is convenient for the school. Children will be invited to take part in data collection. Data collection sessions will last approximately 30 minutes. A series of fitness tests and anthropometric measurements will be carried out on children, in an appropriate room in the school (e.g. sports or assembly hall). Once fitness tests and anthropometric measurements have been completed objective devices (accelerometers) will be given to children to monitor their physical activity behaviour. Between four and seven days of accelerometer data are needed to provide a reliable estimate of habitual physical activity.[22] Thus participants will be asked to wear objective devices for 7 consecutive days. On day seven participants will return the device to

research staff at the school where they will then complete a questionnaire on their physical activity behaviour. This exact process will be repeated at follow-up I and follow-up II.

Measurement and instruments

Accelerometer

It is now recognised that accelerometers provide the most reliable and valid measurement of activity in children [16] and are considered the gold standard approach. These wearable motion sensors measure movement across three dimensions, thus providing minute-by-minute time-stamped data on activity intensity, duration, and patterns across the day. Objective physical activity monitoring has been successfully used in similar study settings to the present project.[14,23, 24]

The present evaluation will use the Actigraph GT3X accelerometer. This device is validated and has been used in other studies with primary and high school children (see for example: www.iconnect.co.uk and http://www.cedar.iph.cam.ac.uk/research/directory/speedy/). The Actigraph GT3X is worn on a belt around the waist with the device itself positioned above the right hip either over or under clothing. We will employ a sampling frequency of 30 hz. Children will be asked to wear the device during waking hours every day for seven consecutive days, but not during water-based activities or sleep.

Fitness Tests

A series of fitness tests will be carried out, following Standard Operating Procedure Forms, on all children taking part in the study. Four fitness tests will be carried out to measure aspects of general fitness: participants will be asked to perform the hand held Dynamometer test to assess grip strength, the standing horizontal jump test to assess leg power, the peak flow test to assess lung function, and the sit-and-reach test to assess flexibility. Participants' weight and body composition will be measured using the Tanita SC-330 Body Composition Analyser (Tanita Inc, IL, USA) and height will be measured using the Leicester Height Measure, from which BMI will be calculated kg/m^2. These tests have been extensively used in previous cohort studies of young people (eg, http://www.chasestudy.ac.uk/study-measurement) and have shown good validity and reliability in young people across broad age groups (http://www.chasestudy.ac.uk/study-measurement). [25-27]

Questionnaires

All children taking part in the study will be asked to complete a questionnaire. The questionnaire will take approximately ten minutes to complete and includes questions on standard demographics and physical activity, as well as potentially important correlates of physical activity. Teaching assistants and research staff will assist all children in completing questionnaires.

The Girls Health Enrichment Multi-Studies (GEMS) physical activity survey has been embedded within the questionnaire to give a subjective measure of physical activity and provide an understanding of which specific physical activity behaviours are influenced by

the playground redesign, if any. GEMS has validity and reliability equivalent to other self-report measures of physical activity [28] and was deemed suitable for both primary and high school boys and girls by those who designed the present study, owing to its simplicity. The questionnaire also includes items on travel mode (as used in the iConnect Study; www.iconnect.co.uk).

Teachers will be asked to complete the validated Strengths and Difficulties questionnaire;[29] this questionnaire provides a measure of children's behaviour, mental health, engagement and well-being and takes approximately five minutes to complete per child.

Each school has one Head Teacher. Head Teachers (n=8) will be asked to complete a questionnaire to allow for an understanding of differences between schools on "playground policy." Questions include, "During what type of weather are children not allowed to go outside during scheduled breaks (i.e. rain/ snow)?" "Are any sections of the current playground out of use during bad weather (i.e. school field when raining), if yes please specify?" "When children cannot go outside on scheduled breaks, owing to bad weather, where do they spend their break?" and "Are there any current initiatives/programs to promote physical activity and/or healthy lifestyles in your school, if yes please specify?" Head teachers will be asked to complete an identical survey at follow-up to allow for the assessment of changes in "playground policy" between each time point.

ANALYSIS

Outcome

The primary outcome for this study will be change in average daily time spent in MVPA as recorded by the Actigraph accelerometer. In addition the study has been designed to collect the following secondary outcomes using participant questionnaires and objective measures (1) change in average daily time spent sedentary, (2) change in average daily time spent in light and vigorous activity at different times of the day (playtimes at school, leisure time at home), (3) change in peak flow, sit-and-reach, grip strength, standing horizontal jump, and body mass index (BMI)/body composition, (4) change in Strength and Difficulties scores.

Quantitative analysis

Raw data files will be extracted from each Actigraph device and processed using bespoke software (Actilife) to quantify a range of features that will directly contribute to the determination of active and sedentary time. We intend to follow methods used in the International Children's Accelerometry Database study that incorporated children aged 4-18 yrs old [2]. Briefly, data files will be reintegrated to a 60-second epoch and non-wear time defined as 60 minutes of consecutive zeros, allowing for 2 minutes of non-zero interruptions. All children with at least 1 day with at least 500 minutes of measured monitor wear time between 7 AM and midnight will be included. Total physical activity will be expressed as total counts, including sedentary minutes, divided by measured time per day (counts/min, cpm). Time spent sedentary will be defined as all minutes showing less than 100 cpm and MVPA time as minutes showing more than 3000 cpm. Multilevel modelling will be used to analyse the data. This approach offers several advantages over simple regression models. We will be able to model changes in activity over the three assessment periods accounting for the inter-individual as well as intra-individual differences.

Sample size

A previous school based intervention to examine the effects of changes in playground structure on physical activity [23] demonstrated a small effect size (d =0.10). Thus, based on these data, a sample size of N=458 would provide us with 80% power at 5% significance level to detect small differences in moderate intensity physical activity using a repeated measures design (calculated using G-Power). We will aim to recruit 100 children from each school to allow for dropout and incomplete Actigraph data.

LIMITATIONS

It is not possible to carry out a multicentre cluster randomised-controlled-trial. Key limitations of this study include a quasi-experimental design with non-randomly selected control participants and the recruitment of one control school.

ETHICAL CONSIDERATION AND DISSEMINATION

Firstly, head teachers from each school will be asked to provide explicit written consent for their schools and school children to take part in the study. Next, if parents (of primary and secondary school children) do not want their child(ren) to take part in the study they will be given the option to “opt-out” their child(ren), instructions to parents on how to opt-out their child(ren) are provided in the parent study information sheet. Prior to data collection all high school (not primary school) children will be asked to provide explicit written assent.

The findings from this study will be disseminated to academic researchers and to policymakers through several mechanisms. First, we will employ the usual avenues for dissemination of academic research, including conference presentations and journal articles. Second, we will disseminate this research via social media outlets such as the University College London – Physical Activity Research Group Twitter account. Third, with Camden Council, we will include this physical activity study within the regular programme of briefings that are presented to government departments interested in physical activity, including the Department of Health, the Department for Communities and Local Government, etc.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer made substantial contribution to the concept and design of the study. Lee Smith drafted the manuscript and Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer revised it critically for important intellectual content. Lee Smith, Courtney Kipps, Daniel

Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer approved the final version of the manuscript to be published.

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Figure Legends

Figure 1: Example of new playground designs

Figure 2: Overview of study design

Camden Active Spaces: Does the Construction of Active School Playgrounds Influence Children's Physical Activity Levels? A Longitudinal Quasi-Experiment Protocol

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Key words: physical activity/ active play/ children/ school/ environment

Word count: 2317

INTRODUCTION

Physical activity is essential for every facet of children's health. However, physical activity levels in British children are low. The school environment is a promising setting to increase children's physical activity but limited empirical evidence exists on how a change in the outdoor physical school environment influences physical activity behaviour. London Borough of Camden is re-designing seven existing school playgrounds to engage children to become more physically active.

The primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, and physical function/fitness.

METHOD AND ANALYSIS

This project will use a longitudinal quasi-experimental design. Seven experimental schools and one control school will take part. One baseline data collection session and two follow-ups will be carried out. Between baseline and follow-up the experimental school playgrounds will be re-designed. At baseline, a series of fitness tests, anthropometric and questionnaire measurements, and 7 day objective physical activity monitoring (Actigraph accelerometer) will be carried out on children (aged 5 to 16 years). This will be repeated at follow-up. Changes in overall physical activity levels and levels during different times of the day (eg, school breaks) will be examined. Multilevel regression modelling will be used to analyse the data.

ETHICS AND DISSEMINATION

The results of this study will be disseminated through peer-review publications and scientific presentations. Ethical approval was obtained through the University College London Research Ethics Committee (Reference number: 4400/002).

INTRODUCTION

Physical activity is essential for every facet of children's (aged 5 to 16 years) health. For example, higher levels of physical activity in children are associated with more favourable cardiovascular disease risk factors whereas excessive levels of sedentary behaviour have the reverse effect.[1,2] Physical activity can also benefit psychological health by aiding in the prevention of anxiety and depressive symptoms and contributing to the improvement of self-esteem.[3] Importantly, rather than detracting from learning, more physical activity and breaks from sitting in school are thought to enhance cognitive function and academic performance.[4] It is also more likely that active children will become active adults, since some tracking of physical activity behaviour has been observed from childhood to adulthood.[5] However, in westernised countries current levels of physical activity in children are low as there are increasing opportunities to participate in sedentary activities.[6,7] For example, it is recommended that children engage in physical activity of moderate intensity for at least one hour a day, to maintain good health.[8] However, just 24% of British girls and 32% of boys achieve this recommendation.[7] Physical inactivity is estimated to cost the NHS approximately £8 billion per year in health care costs alone.[8] Encouraging physically active lifestyles in children is therefore crucial in nurturing a healthy future generation of adults.

A recent meta-analysis found that the effects of interventions to increase physical activity in children have been, at best, modest, and concluded that alternative approaches are required.[9] In the UK, children spend approximately 60% of their weekday in school where physical activity levels, particularly in girls, are low.[10,11] Environments both facilitate and provide the arena for physical activity [12]. Interventions that target the school environment

may offer great opportunity to increase physical activity levels. However, there is little robust empirical evidence concerning the effect of changing the physical environment on activity levels in children. Emerging data has suggested that a positive perception of the school play environment was associated with higher levels of moderate-vigorous physical activity (MVPA) during playtime.[13] Moreover, the number of permanent play facilities in school playgrounds has been found to be associated with higher physical activity levels.[14] A recent review [15] on the value of playgrounds for children's physical activity identified 13 experimental studies, which have produced mixed findings, likely owing to differences in intervention design. For example, the review identified that reducing playground density increased physical activity levels, but the provision of play equipment produced mixed effects, whereas no effects were found on the provision of playground markings and promotion of physical activity by teachers. Just one study investigated the impact of "major" playground reconstruction on children's physical activity behaviour [16] and concluded renovated schoolyards to promote physical activity may increase the number of children who are physically active and may reduce sedentary behaviours. However, physical activity data was collected using direct observation during the school day, only. This limits the ability to examine carry over effects outside the school environment (ie, at weekends and during evenings). Taken together, the emerging evidence suggests that the physical environment could play an important role in children's physical activity behaviour, but more robust evidence is required.

Increasing physical activity levels is well established as a way to improve fitness and health outcomes in young people. Strong's et al. [1] review identified 17 experimental studies that

aimed to increase levels of physical activity, and these all found improvements in aerobic fitness. Two experimental studies implemented programs of moderately intense exercise 30 to 60 minutes in duration, 3 to 7 days per week, and this led to a reduction in total body adiposity in overweight young people. Interestingly, the review also identified three longitudinal and two experimental studies in young people that showed physical activity or strength training improved muscular strength and endurance. It is plausible to assume that an increase in movement and a decrease in sedentary behaviour may result in an increase in hamstring flexibility. This is important as maintaining hamstring flexibility may prevent acute and chronic musculoskeletal injuries.[17] There is also evidence that physical activity is associated with scores on a scale (The Strengths and Difficulties Questionnaire) measuring mental wellbeing (eg, happiness, behaviour, concentration, self-esteem etc).[18] On this basis we hypothesise that a change in the physical school playground environment which increases levels of physical activity or reduces sedentary behaviour should subsequently improve fitness and health outcomes.

A recent study found that engaging in 40% of moderate-intensity physical activity during school playtime equated to 34 minutes of daily MVPA.[19] This exceeds the *minimum* recommendation of 30 minutes of at least moderate-intensity physical activity for children's good health.[20] It has been suggested that this guideline is a realistic target for children to achieve during school playtime,[21] especially if a playground has been modified to encourage physical activity.

SETTING

Camden Borough Council is re-designing seven existing school playgrounds (five primary schools and two secondary schools), that are thought not to be conducive to physical activity/ active play, with exciting bespoke features to engage children to become more active. Each school will receive a unique playground design, for example displayed in Figure 1. Example features include new Astroturf games pitches, climbing frames, trampolines, monkey bars, and outdoor gyms, which have been designed based on themes (eg, ancient ruins, volcanoes, clouds etc.) emerging from qualitative work with children and teachers in each school. The research team did not carry out the qualitative work nor did they provide input into the design of the playgrounds. The qualitative work and the design of the playgrounds were carried out by two private organisations specialising in playground design. Camden Council's underlying goal is to encourage participation by creating opportunities for physical activity outside of traditional sports or team competition. This presents a unique opportunity to evaluate the impact of these structures on children's physical activity, health and wellbeing outcomes while addressing previous limitations in the literature (ie, collecting activity only in school).

We hypothesise that the new play grounds will increase young peoples' time spent in both light and moderate-to-vigorous physical activity and reduce sedentary behaviour during break time, and consequently improve levels of general fitness (eg, grip and leg strength, peak flow and adiposity).

AIMS

The *Camden Active Spaces* project consists of two key elements; 1) redesign of the school playgrounds; 2) evaluation of the hypothesised benefits. In the present paper we focus on

the evaluation only. Thus, the primary aim of this project is to evaluate the impact of the re-designed playgrounds on children's physical activity, wellbeing, and physical function/fitness.

METHOD AND ANALYSES

The evaluation of *Camden Active Spaces* will use a longitudinal quasi-experimental design. Baseline data collection will take place in the Spring/Summer term 2014, follow-up I data collection will take place during the Autumn term 2014, and follow-up II during the Summer term of 2015 (see Figure 2). Between baseline and follow-up I (school summer holidays) the school playgrounds will be re-designed. A second follow-up will allow us to investigate if short-term effects of the intervention (if they exist) are sustained over a longer period. This evaluation has been funded by the Economic and Social Research Council, UK (ES/M003795/1), whilst the core project (playground redesign) has been funded by Camden Clinical Commissioning Group and London Borough of Camden. Ethical approval was granted by the University College London Research Ethics Committee (4400/002).

Inclusion criteria

School inclusion criteria

Seven schools located in the London Borough of Camden have been selected to receive the re-designed playgrounds and all seven schools have agreed to take part in the study.

In addition to the seven experimental schools one control school will be recruited into the study. This school will be located in the London Borough of Camden and it will not be receiving a new playground design, moreover, it will not differ from experimental schools based on student demographics or school policy. Owing to resources it is only feasible to collect data from a single control school. The authors acknowledge that an equal number of controls to experimental schools would allow for a more robust experimental design.

Participant Inclusion criteria

We aim to randomly select approximately 100 children (see below power calculation) evenly distributed across school year groups (aged 5 to 11 years in primary school and aged 11 to 16 years in secondary school) from each of the eight schools (total sample size 800). Children aged 17 to 18 years or any school leavers in 2014 will not be asked to participate in the current project, owing to time table restrictions due to final exams and potential loss to follow up. Students whose parents have not opted them out of the study will be eligible to participate (see section Ethics and Dissemination for details on obtaining consent).

Recruitment

The seven schools who will be receiving the redesigned playgrounds have previously been recruited into the study by Camden Borough Council. To recruit children into the study presentations will be given to each year group within each school, during assemblies. The presentations will disseminate information on *Camden Active Spaces,* what would be involved if children were to take part in the study and benefits of the study to children and the school. At the end of the presentations children will be given participant study information sheets. In order to make parents aware of the study a parent information sheet

will be emailed to all parents (translated into different languages where required), posted on the school webpage, in addition to hard copies being made available at the school. In an attempt to maximise response rates and adherence to protocol, each child who completes the wear protocol will be awarded a one-month free swimming voucher and entered into a prize draw to win an iPod Touch (one iPod Touch will be awarded per school). All schools taking part in the study will be entered into a separate prize draw to win one of two Nintendo Wiis.

Procedures

Data collection procedures will take place over a period of 12 months. A team of trained researchers will collect data from each school on a date and time that is convenient for the school. Children will be invited to take part in data collection. Data collection sessions will last approximately 30 minutes. A series of fitness tests and anthropometric measurements will be carried out on children, in an appropriate room in the school (e.g. sports or assembly hall). Once fitness tests and anthropometric measurements have been completed objective devices (accelerometers) will be given to children to monitor their physical activity behaviour. Between four and seven days of accelerometer data are needed to provide a reliable estimate of habitual physical activity.[22] Thus participants will be asked to wear objective devices for 7 consecutive days. On day seven participants will return the device to research staff at the school where they will then complete a questionnaire on their physical activity behaviour. This exact process will be repeated at follow-up I and follow-up II.

Measurement and instruments

Accelerometer

It is now recognised that accelerometers provide the most reliable and valid measurement of activity in children [16] and are considered the gold standard approach. These wearable motion sensors measure movement across three dimensions, thus providing minute-by-minute time-stamped data on activity intensity, duration, and patterns across the day. Objective physical activity monitoring has been successfully used in similar study settings to the present project.[14,23, 24]

The present evaluation will use the Actigraph GT3X accelerometer. This device is validated and has been used in other studies with primary and high school children (see for example: www.iconnect.co.uk and http://www.cedar.iph.cam.ac.uk/research/directory/speedy/). The Actigraph GT3X is worn on a belt around the waist with the device itself positioned above the right hip either over or under clothing. We will employ a sampling frequency of 30 hz. Children will be asked to wear the device during waking hours every day for seven consecutive days, but not during water-based activities or sleep.

Fitness Tests

A series of fitness tests will be carried out, following Standard Operating Procedure Forms, on all children taking part in the study. Four fitness tests will be carried out to measure aspects of general fitness: participants will be asked to perform the hand held Dynamometer test to assess grip strength, the standing horizontal jump test to assess leg power, the peak flow test to assess lung function, and the sit-and-reach test to assess

flexibility. Participants' weight and body composition will be measured using the Tanita SC-330 Body Composition Analyser (Tanita Inc, IL, USA) and height will be measured using the Leicester Height Measure, from which BMI will be calculated kg/m^2. These tests have been extensively used in previous cohort studies of young people (eg, http://www.chasestudy.ac.uk/study-measurement) and have shown good validity and reliability in young people across broad age groups (http://www.chasestudy.ac.uk/study-measurement). [25-27]

Questionnaires

All children taking part in the study will be asked to complete a questionnaire. The questionnaire will take approximately ten minutes to complete and includes questions on standard demographics and physical activity, as well as potentially important correlates of physical activity. Teaching assistants and research staff will assist all children in completing questionnaires.

The Girls Health Enrichment Multi-Studies (GEMS) physical activity survey has been embedded within the questionnaire to give a subjective measure of physical activity and provide an understanding of which specific physical activity behaviours are influenced by the playground redesign, if any. GEMS has validity and reliability equivalent to other self-report measures of physical activity [28] and was deemed suitable for both primary and high school boys and girls by those who designed the present study, owing to its simplicity. The questionnaire also includes items on travel mode (as used in the iConnect Study; www.iconnect.co.uk).

Teachers will be asked to complete the validated Strengths and Difficulties questionnaire;[29] this questionnaire provides a measure of children's behaviour, mental health, engagement and well-being and takes approximately five minutes to complete per child.

Each school has one Head Teacher. Head Teachers (n=8) will be asked to complete a questionnaire to allow for an understanding of differences between schools on "playground policy." Questions include, "During what type of weather are children not allowed to go outside during scheduled breaks (i.e. rain/ snow)?" "Are any sections of the current playground out of use during bad weather (i.e. school field when raining), if yes please specify?" "When children cannot go outside on scheduled breaks, owing to bad weather, where do they spend their break?" and "Are there any current initiatives/programs to promote physical activity and/or healthy lifestyles in your school, if yes please specify?" Head teachers will be asked to complete an identical survey at follow-up to allow for the assessment of changes in "playground policy" between each time point.

ANALYSIS

Outcome

The primary outcome for this study will be change in average daily time spent in MVPA as recorded by the Actigraph accelerometer. In addition the study has been designed to collect the following secondary outcomes using participant questionnaires and objective measures (1) change in average daily time spent sedentary, (2) change in average daily time spent in light and vigorous activity at different times of the day (playtimes at school, leisure time at

home), (3) change in peak flow, sit-and-reach, grip strength, standing horizontal jump, and body mass index (BMI)/body composition, (4) change in Strength and Difficulties scores.

Quantitative analysis

Raw data files will be extracted from each Actigraph device and processed using bespoke software (Actilife) to quantify a range of features that will directly contribute to the determination of active and sedentary time. We intend to follow methods used in the International Children's Accelerometry Database study that incorporated children aged 4-18 yrs old [2]. Briefly, data files will be reintegrated to a 60-second epoch and non-wear time defined as 60 minutes of consecutive zeros, allowing for 2 minutes of non-zero interruptions. All children with at least 1 day with at least 500 minutes of measured monitor wear time between 7 AM and midnight will be included. Total physical activity will be expressed as total counts, including sedentary minutes, divided by measured time per day (counts/min, cpm). Time spent sedentary will be defined as all minutes showing less than 100 cpm and MVPA time as minutes showing more than 3000 cpm. Multilevel modelling will be used to analyse the data. This approach offers several advantages over simple regression models. We will be able to model changes in activity over the three assessment periods accounting for the inter-individual as well as intra-individual differences.

Sample size

A previous school based intervention to examine the effects of changes in playground structure on physical activity [23] demonstrated a small effect size (d =0.10). Thus, based on

these data, a sample size of N=458 would provide us with 80% power at 5% significance level to detect small differences in moderate intensity physical activity using a repeated measures design (calculated using G-Power). We will aim to recruit 100 children from each school to allow for dropout and incomplete Actigraph data.

LIMITATIONS

It is not possible to carry out a multicentre cluster randomised-controlled-trial. Key limitations of this study include a quasi-experimental design with non-randomly selected control participants and the recruitment of one control school.

ETHICAL CONSIDERATION AND DISSEMINATION

Firstly, head teachers from each school will be asked to provide explicit written consent for their schools and school children to take part in the study. Next, if parents (of primary and secondary school children) do not want their child(ren) to take part in the study they will be given the option to “opt-out” their child(ren), instructions to parents on how to opt-out their child(ren) are provided in the parent study information sheet. Prior to data collection all high school (not primary school) children will be asked to provide explicit written assent.

The findings from this study will be disseminated to academic researchers and to policymakers through several mechanisms. First, we will employ the usual avenues for dissemination of academic research, including conference presentations and journal articles. Second, we will disseminate this research via social media outlets such as the

University College London – Physical Activity Research Group Twitter account. Third, with Camden Council, we will include this physical activity study within the regular programme of briefings that are presented to government departments interested in physical activity, including the Department of Health, the Department for Communities and Local Government, etc.

Competing interests

The authors declare that they have no competing interests.

Funding

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Authors' contributions

Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer made substantial contribution to the concept and design of the study. Lee Smith drafted the manuscript and Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer revised it critically for important intellectual content. Lee Smith, Courtney Kipps, Daniel Aggio, Paul Fox, Nigel Robinson, Verena Trend, Suzie Munnery, Barry Kelly, and Mark Hamer approved the final version of the manuscript to be published.

Figure Legends

Figure 1: Example of new playground designs

Figure 2: Overview of study design

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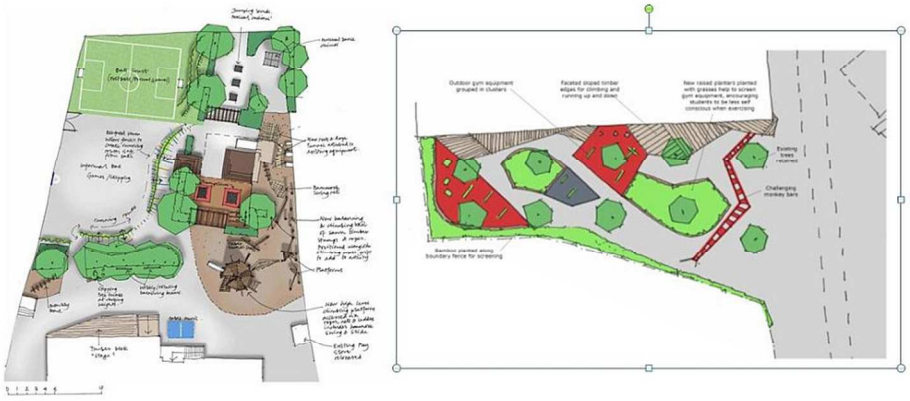
Figure 1: Example of new playground designs



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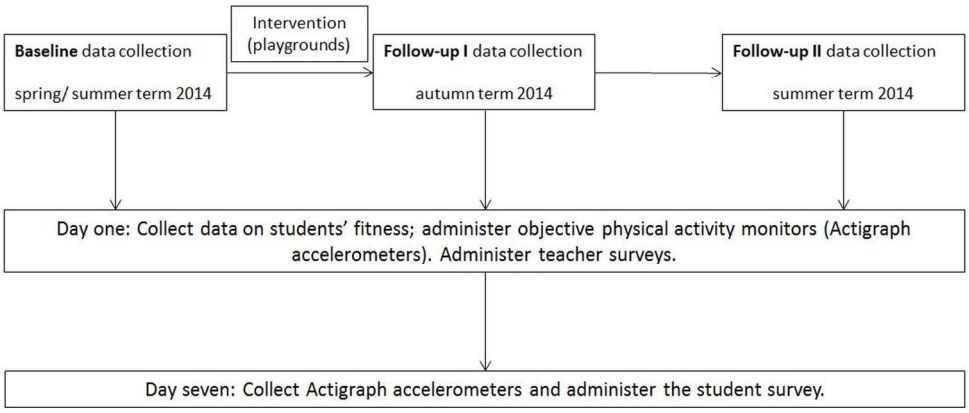

193x90mm (300 x 300 DPI)

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract **YES**
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found **YES**
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported **YES**
Objectives	3	State specific objectives, including any prespecified hypotheses **YES**
Methods		
Study design	4	Present key elements of study design early in the paper **YES**
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection **YES**
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up **YES** *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case **NA**
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable **YES**
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group **YES**
Bias	9	Describe any efforts to address potential sources of bias **YES**
Study size	10	Explain how the study size was arrived at **YES**
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why **YES**

Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding **YES**
		(*b*) Describe any methods used to examine subgroups and interactions **NA**
		(*c*) Explain how missing data were addressed **NA**
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy **NA**
		(*e*) Describe any sensitivity analyses

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed **NA**
		(b) Give reasons for non-participation at each stage **NA**
		(c) Consider use of a flow diagram **NA**
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders **NA**
		(b) Indicate number of participants with missing data for each variable of interest **NA**
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) **YES**
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time **NA**
		Case-control study—Report numbers in each exposure category, or summary measures of exposure **NA**
		Cross-sectional study—Report numbers of outcome events or summary measures **NA**
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included **NA**
		(*b*) Report category boundaries when continuous variables were categorized **NA**
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period **NA**
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses **NA**
Discussion		
Key results	18	Summarise key results with reference to study objectives **NA**
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias **YES**
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence **NA**
Generalisability	21	Discuss the generalisability (external validity) of the study results **NA**

Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based **YES**

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.