The Olympic Regeneration in East London Study (ORiEL): protocol for a prospective controlled quasi-experiment to evaluate the impact of urban regeneration on young people and their families.

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**Complete List of Authors:**
- Smith, Neil; Queen Mary University of London, Centre for Psychiatry
- Clark, Charlotte; Queen Mary University of London, Centre for Psychiatry
- Fahy, Amanda; Queen Mary University of London, Centre for Psychiatry
- Tharmaratnam, Vanathi; Queen Mary University of London, Centre for Psychiatry
- Lewis, Daniel; Queen Mary University of London, School of Geography
- Thompson, Claire; Queen Mary University of London, School of Geography
- Renton, Adrian; University of East London, Institute for Health and Human Development
- Moore, Derek; University of East London, Institute for Research in Child Development
- bhui, kamaldeep; Queen Mary University of London, Centre for Psychiatry
- Taylor, Stephanie; Queen Mary University of London, Centre for Health Sciences
- Eldridge, Sandra; Queen Mary University of London, Centre for Primary Care and Public Health
- Petticrew, Mark; London School of Hygiene and Tropical Medicine, Department of Social and Environmental Health Research
- Greenhalgh, Trisha; Queen Mary University of London, Centre for Primary Care and Public Health
- Stansfeld, Stephen; Queen Mary University of London, Centre for Psychiatry
- Cummins, Steven; Queen Mary University of London, School of Geography

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The Olympic Regeneration in East London Study (ORiEL): protocol for a prospective controlled quasi-experiment to evaluate the impact of urban regeneration on young people and their families

Neil R. Smith¹, Charlotte Clark¹, Amanda E. Fahy¹, Vanathi Tharmaratnam¹, Daniel J. Lewis², Claire Thompson², Adrian Renton³, Derek G. Moore⁴, Kamaldeep S. Bhui¹, Stephanie J.C. Taylor⁵, Sandra Eldridge⁵, Mark Petticrew⁶, Tricia Greenhalgh⁵, Stephen A. Stansfeld¹, Steven Cummins²*

*Corresponding author:
s.c.j.cummins@qmul.ac.uk
Abstract

Introduction: Recent systematic reviews suggest that there is a dearth of evidence on the effectiveness of large-scale urban regeneration programmes in improving health and wellbeing and alleviating health inequalities. The development of the Olympic Park in Stratford for the London 2012 Olympic and Paralympic Games provides the opportunity to take advantage of a natural experiment to examine the impact of large scale urban regeneration on the health and wellbeing of young people and their families.

Design and methods: A prospective school-based survey of adolescents (11-12 years) with parent data collected through face-to-face interviews at home. Adolescents will be recruited from 6 randomly selected schools in an area receiving large-scale urban regeneration (London Borough of Newham) and compared with adolescents in 18 schools in 3 comparison areas with no equivalent regeneration (London Boroughs of Tower Hamlets, Hackney and Barking & Dagenham). Baseline data will be completed prior to the start of the London Olympics (July 2012) with follow-up at 6 months and 18 months post-intervention. Primary outcomes are: pre-post change in adolescent and parent mental health and wellbeing, physical activity and parental employment status. Secondary outcomes include: pre-post change in social cohesion, smoking, alcohol use, diet and body mass index. The study will account for individual and environmental contextual effects in evaluating changes to identified outcomes. A nested longitudinal qualitative study will explore families’ experiences of regeneration in order to unpack the process by which regeneration impacts on health and wellbeing.

Ethics and dissemination: The study has approval from Queen Mary University of London Ethics Committee (QMREC2011/40), the Association of Directors of Children’s Services (RGE110927) and the London Boroughs Research Governance Framework (CERGF113). Fieldworkers have had advanced Criminal Records Bureau clearance. Findings will be disseminated through peer-reviewed publications, national and international conferences, through participating schools and the study website (http://www.orielproject.co.uk).
Introduction

Health follows a social gradient, with the more socioeconomically advantaged scoring higher on numerous measures of health status\(^1\, ^2\). In the United Kingdom (UK), health inequalities have persisted over many decades with the mortality gap between the most advantaged and disadvantaged groups currently standing at around 8 years\(^3\). Policies and interventions that tackle the wider socio-economic and environmental determinants of poor health have been promoted by successive UK governments to help improve health and wellbeing and reduce health inequalities\(^2\, ^4\). In recent years large-scale programmes that tackle entrenched social and environmental deprivation through improvements in living conditions have become a persistent feature of the policy landscape. Such programmes have usually taken the form of large-scale urban regeneration and neighbourhood renewal programmes which have good potential to tackle health inequalities as they directly influence the wider social, economic and environmental determinants of physical and mental health, such as employment, housing, education, income and welfare\(^5\). In the last 20 years spending on such schemes in the UK has reached over £11 billion\(^6\).

Many of these schemes are area-based, and involve targeting places that are considered to be in the greatest social and economic need, though health improvement is not usually the primary motivation for these programmes\(^6\). Regeneration primarily occurs through infrastructural improvements to the built environment such as better transport links, provision and upgrading of retail space, creation of green space, parks and public areas and improvements in housing\(^7\). General improvements in aesthetics, security and safety via neighbourhood re-design through lighting, furniture, public art, pedestrian zones and the amelioration of environmental stressors such as graffiti, litter and noise are also common components of regeneration programmes.

Despite continuing large-scale public investment, recent systematic reviews identify a dearth of evidence of the effectiveness of urban regeneration programmes in improving health and wellbeing and alleviating health inequalities\(^6\, ^8\, ^9\). The evidence that does exist is weak with mixed findings. In the UK, studies investigating the health impacts of urban regeneration are rare and highly variable in
terms of study quality and reported outcomes, and are located primarily in the grey literature.

Although some studies have reported improvements in health (e.g. mortality rates)\textsuperscript{10} previous research also suggests the possibility of negative effects\textsuperscript{11}. Evaluations have tended to focus on short-term socio-economic outcomes (such as impacts on employment, education, income and housing quality) and have failed to investigate the links to health outcomes. These socioeconomic evaluations have also produced mixed findings, making it difficult to speculate as to the direction and nature of plausible health impacts\textsuperscript{11-13}. Most published studies to date have focused on adults: evaluations of the impact of urban regeneration on young people and their families are needed, since adolescence is likely to be a critical point for the emergence of health inequalities in later life\textsuperscript{14}.

The proposed study focuses on urban regeneration specifically associated with the London 2012 Olympic and Paralympic Games. The components of the proposed regeneration are common to most urban regeneration programmes (e.g. improvements in facilities, services, housing and built infrastructure). This provides an opportunity to generate evidence about the range and nature of positive and negative impacts on health and the social determinants of health and begin to elucidate their causal pathways and the specific components of regeneration which influence health. In this study we propose to assess the impact of urban regeneration on health and health inequalities in a sample of young people and their families in the immediate vicinity of the London 2012 Olympic site.
Aims and objectives

1. What is the impact of a multifaceted urban regeneration programme linked to the 2012 Olympic Games on the social determinants of health (employment), health behaviours (physical activity) and health outcomes (mental health and wellbeing) of adolescents and their parents?

Underpinning this objective are the following secondary research questions:

2. What are the wider socio-environmental and health impacts of urban regeneration in terms of receipt of welfare benefits, educational attainment, social cohesion/capital, diet, smoking, alcohol use and obesity?

3. How are socio-economic and health impacts of the urban regeneration programme distributed by age, gender and ethnicity and interactions between these variables?

4. How, and to what extent, do specific components of the regeneration programme influence health and health behaviours?

5. To what extent are socio-economic and health impacts of urban regeneration sustained over time?
Design and methods

Study design

The study comprises two main elements:

1. A **longitudinal controlled quasi-experimental study** examining changes in socio-economic status (SES), health behaviour and health outcomes in a cohort of adolescent school pupils in year 7 (aged 11-12) and their parents or primary carers (parent/carer). Residents in the intervention area receiving urban regeneration will be compared with those who live in adjacent areas not receiving urban regeneration of this magnitude. Adolescent and parent/carers survey data will be collected in three waves: wave one (baseline pre-intervention, 2012), wave two (six months post-intervention, 2013) and wave three (18 months post-intervention, 2014) in intervention and comparison areas.

2. An **in-depth longitudinal qualitative study** of family experiences of and attitudes towards regeneration in the intervention area and influences on socio-economic status, health behaviours and health outcomes. The initial investigation will comprise of a sub-group of approximately 20 families that reflects the diversity of the survey sample. The qualitative study sample will be drawn from wave one participants and will be repeated at wave two.

Setting

The study will take place in four London Boroughs: Newham (intervention site), Barking & Dagenham, Tower Hamlets and Hackney (comparison sites). The boroughs have an estimated combined population of 1.25 million and are significantly more disadvantaged than the London average. For example, unemployment rates are 35.8% (vs. 29.6% in London), incidents of violent crime are at 29 offences per 1000 population (vs. 24 in London) and the proportion of the population with no educational qualifications is 17.6% (vs. 11.6% in London). This setting is suitable for research of this type as area-based urban regeneration programmes which influence the socio-
economic and environmental determinants of health may be particularly beneficial for relatively
disadvantaged communities with degraded infrastructure.

Participants

Inclusion and exclusion criteria

Participants will be pupils aged 11-12 (school year 7) attending randomly selected schools in the
intervention and comparison boroughs, and their parents/carers. Special-needs schools and Pupil
Referral Units will be excluded, as will pupils attending the index school who reside outside the
school’s borough.

Figure 1 here

The total number of eligible schools in each borough is as follows: Newham, N=14; Tower Hamlets,
N=14; Hackney, N=11; and Barking & Dagenham, N=9. Schools will be selected using simple
randomisation. Refusals will be replaced by eligible schools within the same borough selected by
simple randomisation. In order to reduce recruitment biases we will recruit and use local fieldworkers
with appropriate language skills, working with schools to identify the languages needed.

Sample size

Quantitative study

The study is powered to detect differences in our primary outcome measures of employment, mental
wellbeing and physical activity. In the only high quality controlled prospective study of
neighbourhood change with related outcomes to those proposed here (The Moving to Opportunity
Study) the proportion of people employed increased by 13% amongst minority groups, and mental
wellbeing scores, on a range of scales, improved by 8-33% for adults, and up to 25% for children.

Based on this, a plausible conservative minimum change in our primary outcomes (employment,
mental wellbeing and physical activity) would be 8%. Given the finite number of schools available in
the intervention area (N=14) compared to comparison areas (N=34) we assumed a 1:3 ratio in the number of participants in intervention and comparison arms respectively.

Therefore, a total sample size of 712 adolescents and 712 parents/carers would be required to detect a difference of 8% with 80% power at a significance level of 5%. To take account of clustering by school we assumed an intra-cluster correlation coefficient (ICC) of 0.02 (given that our primary outcome is health related we expect a smaller ICC than that usually seen for measures such as educational attainment which will be more highly school related). This results in a design effect of 2.48 and a total required sample size at second follow-up (wave three) of 1,766 children (24 schools, 74 per school) and 1,766 parents (one parent per pupil with data on the parent, and the wider household, collected through interview). This achieved sample size would therefore have 80% power to detect the minimum difference of 8% we have postulated, at the 5% significance level. Data will be required from a minimum of 6 secondary schools in the intervention site (Newham, minimum n=6) and a total of 18 secondary schools from the comparison sites (Tower Hamlets, n=6; Barking & Dagenham, n=6; Hackney, n=6). A recent school-based study in East London (Research with East London Adolescents; Community Health Survey - RELACHS) achieved response rates of 84% at baseline and 75% at follow-up\(^1^9\). Using these response rates at baseline (wave one) we require a sample size of 3,140 children and 3,140 parents/carers.

**Qualitative study**

The sample size for the qualitative component is based on our previous experience in terms of the key themes to be explored, and the practical considerations of time and resourcing. The aims of the sampling strategy are to recruit a maximum variation sample as far as is possible along our hypothesised axes of difference (family composition, ethnicity and employment status), amending the sampling strategy as needed in the light of new themes identified in emerging data. We will sample to the point of saturation where additional data adds little to emerging themes arising from on-going analysis.
An appropriate sample size for a qualitative study cannot be stipulated precisely in advance. The number of required participants usually becomes clear as the study progresses and as new categories and explanations stop emerging from the data\textsuperscript{20}. We estimate, based on qualitative studies of similar scope\textsuperscript{21-23}, that approximately 20 families will be sufficient, with no more than 70 semi-structured interviews collected over the course of the study.

**Recruitment**

Participants will be recruited through secondary schools in two ways; (i) school-based enrolment of adolescents aged 11-12 in year 7 and (ii) recruitment of parents/carers through the surveyed adolescents. Recruitment through schools is a robust method of conducting a survey of this nature, maximising the response rate to the study for both pupils and parents/carers. Other methods, such as telephone and postal surveys have shown declining response rates in recent years, especially in disadvantaged areas\textsuperscript{24}. We will invite randomly selected secondary schools in each of the intervention and comparison sites to participate by letter, telephone and a site visit (if requested). As the adolescent survey will be undertaken in school settings during school hours, it is anticipated that this will reduce threats to the power of the study, such as response bias, compared to population-based survey methods.

Efforts will be made to retain links with the schools in the periods between data collections in order to reduce loss to follow up. As well as a payment of a £1,000 incentive, schools will be sent personalised thank you cards, receive regular project newsletters and will be presented with a ‘Bronze’ certificate of involvement at the year end. This will be followed by a ‘Silver’ and ‘Gold’ certificate after each successive sweep of data collection. Research team members will also deliver lessons on research methods to older age groups as well as give year group assemblies to explain the project to participants and highlight general aspects of emerging findings that are likely to interest the pupils. Attrition risks will be minimised further by obtaining consent to follow up adolescents if they move to a neighbouring school within the same borough.
Survey protocol

A pilot study will be conducted on a subsample within a participating school to determine the appropriate length of the adolescent questionnaire, identify language or comprehension difficulties with the use of standard scales, and refine elements of the survey protocol focused on school and parental consent, and adolescent assent.

In the adolescent survey, after obtaining the headteacher’s consent, the schools will be provided with an adolescent information sheet and parental information sheet one week prior to the study team’s visit. These materials are then distributed to the pupils in a formal school setting. Parents may opt their child out of the study. All information sheets contain the names and contact details of two members of the study team. Additionally, adolescents will be visited by fieldworkers in a school setting during the week preceding the survey to informally discuss the project. Adolescents will receive a verbal explanation of the study with opportunities for questions immediately prior to starting the questionnaire. Adolescents may withdraw during or at any point after the questionnaire’s completion. Survey questionnaires are anonymous; individuals are linked to responses by a unique identification number.

Parents/carers will be surveyed at the home address provided by the adolescent completing the questionnaire. The quality of first contact and initial interview with the parent/carer is thus very important to ensure successful follow-up at waves two and three. An external market research agency, with extensive fieldwork experience in East London, will administer the 35 minute face-to-face computer assisted personal interview (CAPI) to parents/carers who consent to their participation. Parents/carers receive a postal invitation and information sheet and are given two weeks to opt-out. Thereafter the field team will make eight attempts to arrange an interview before assigning a non-response outcome. To overcome any potential language problems, the parent/carer survey will be translated to two of the most common non-English languages within the local area of study, namely Urdu and Bengali. Interviewers with particular skills can be requested for specific participants, where required. Parents/carers will be given the opportunity to refuse participation when first
contacted by the market research fieldworkers and at any point during or after completion of the
interview. The interview is anonymous and parents/carers are linked to their surveyed child by the
same identification number.

Primary outcome measures and survey instruments

Adolescent questionnaire

A questionnaire will be designed, based on validated items and instruments listed below, to assess
individual and household socio-demographic characteristics, mental health and wellbeing and
physical activity.

There is a difficulty in accurately assigning socioeconomic circumstances to adolescents. Questions
about material items must be verifiable, comprehensible and meaningful to young people. Therefore
household socioeconomic circumstances will be measured using the family affluence scale\(^25\). This
four item questionnaire has been validated in adolescents cross-nationally\(^25\) and is predictive of
physical activity, self reported health and mental wellbeing and dietary outcomes\(^26\). A variation of this
was used in the Well London study also with a similar sample\(^27\).

Wellbeing, mental health and social support will be assessed using three self-completed scales. First,
the Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) is a recently developed scale for
assessing positive mental health\(^28\). It has 14 positively worded item scales with five response
categories (ranging from “none of the time” to “all of the time”) and covers most aspects of positive
mental health (positive thoughts and feelings) currently in the literature, including both hedonic and
eudaimonic perspectives. The scale has been validated in adolescents\(^29\) and cross-culturally within
Pakistani and Chinese subgroups\(^30\). It has been used as a core module in the Scottish Health Survey
since 2008\(^31\) and was introduced to the Health Survey for England in 2010\(^32\). Second, the Moods and
Feelings Questionnaire (MFQ) is a 32-item questionnaire for depressive symptoms based on DSM-
III-R criteria for depression\(^33\). The 13 item short form (SMFQ), based on the discriminating ability
between the depressed and non-depressed, will be completed by each adolescent. Each item is rated
on a three point scale: "true", "sometimes true", and "not true" with respect to the events of the past two weeks. Third, the Multidimensional Scale of Perceived Social Support (MSPSS) is a reliable and validated 12-item instrument designed to assess perceptions about support from family, friends and a significant other. It is rated on a seven point scale ranging from “very strongly agree” to “very strongly disagree”. This scale was used in the previous RELACHS and Well London surveys with a similar sample.

Physical activity and behaviour will be assessed using the self-completed Youth Physical Activity Questionnaire (Y-PAQ). This instrument was developed by the MRC Epidemiology Unit in Cambridge. The validated questionnaire assesses accumulated time spent physically active and taking part in sedentary behaviours. Estimates of total physical activity are comparable with previous population-based studies in a similar age group in Britain and other European countries.

Perceptions of the local cycling and walking environment will be assessed from relevant items adapted from the ALPHA (Assessing Levels of Physical Activity and Fitness) environmental questionnaire. Fifteen items are rated on a five point scale (strongly agree to disagree) with an additional item asking participants to rate in minutes how near they live to a range of services, facilities or businesses.

A range of sociodemographic, health-related and environmental variables will also be collected. Participants will be asked their age, gender, home address and postcode, ethnicity, religion, cultural identity, country of birth, perceptions of neighbourhood environment, self-reported health, any longstanding illnesses or mobility problems, smoking, drinking and dietary behaviours, parental interest in schooling, life events and education or employment expectations on reaching age 16. The height and weight of participants will be recorded by the study team (seca 899 scale, seca 217 stadiometer; seca Ltd, UK), with the exception of those individuals declining or where an accurate reading is not possible, e.g. wheelchair users. Finally, attitudes to the Olympic and Paralympic Games
will be investigated using an adapted version of the Department for Education’s questionnaire for evaluating schools’ engagement with the Games via the national Get Set initiative\cite{42}.

\textit{Parent/carer questionnaire}

The content of the parent/carer questionnaire is similar to that of the adolescent questionnaire. The three primary outcomes (employment, mental health, and physical activity and behaviour) are identical, but use different instruments more applicable to a face-to-face interview with adults.

Parental employment status will be assessed using the standardised questions posed at the 2011 Census for England and Wales\cite{43}. Individual occupations are coded to SOC2010 classifications which may be further coded to the standard National Statistics Socioeconomic Classification System (NS-SEC)\cite{44}.

In addition to the WEMWBS assessment of positive wellbeing, respondents will complete the Hospital Anxiety and Depression Scale (HADS). This is a validated 14 item questionnaire which detects depression and anxiety\cite{45}, with each item rated on a 4 point scale with respect to the last week.

Parents/carers are also asked to rate their child’s behaviour according to the Strengths and Difficulties questionnaire\cite{46}. This instrument is validated for completion by teachers or parents and uses 25 items to assess emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and pro-social behaviour in 4 to 16 year olds. Parenting styles will also be investigated using the positive parenting and poor monitoring components of the Alabama Parenting Questionnaire\cite{47}. This enables the detection of links between parenting styles and child behaviours reported by the child and the parent. Lastly, experiences of job strain will be reported using a validated questionnaire assessing psychosocial job demands, decision latitude and social support at work\cite{48}. Job characteristics are indicative of the quality of employment as well as being directly associated with mental health and cardiovascular outcomes\cite{49}. 

\textit{For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml}
Physical activities and behaviours will be measured using the Recent Physical Activity Questionnaire (R-PAQ). The scale, developed by the MRC Epidemiology Unit, describes the extent of physical activity around the house, travel to work patterns, and determines recreational physical activity energy expenditure over the previous four weeks. This instrument has demonstrated validity for ranking individuals according to their time spent at vigorous-intensity activity and overall energy expenditure\textsuperscript{50}.

Parent/carers' sociodemographic factors include age, gender, relationship with the surveyed adolescent, ethnicity, religion and their country of birth and that of their parents. Socioeconomic indicators vary in their importance and meaning across the ethnic minority groups predominant in this East London sample\textsuperscript{51,52}. Therefore socioeconomic circumstances will be captured using a wide range of measures available from the authors on request.

A summary measure of physical and mental health will be measured by the Short Form Health Survey-12 questionnaire (SF-12)\textsuperscript{53}. This is a shorter version of the Short Form-36 health questionnaire designed for use in clinical practice and research, health policy evaluations and general population surveys\textsuperscript{54}. The SF12 generates a mental component and physical component summary score and has been validated cross-culturally\textsuperscript{55}. Adults additionally report any specific physical or mental health conditions from a list provided and describe patterns of alcohol consumption, smoking and eating habits.

Neighbourhood perceptions will be assessed by scales developed within the Multi-Ethnic Study of Atherosclerosis (MESA)\textsuperscript{56}. The six item scale describes perceived aesthetic quality of the area, walkability of the environment, the availability of healthy foods, and levels of safety, violence and social cohesion within the neighbourhood.

Experiences and perceptions of discrimination will be investigated by a seven item questionnaire adapted from the Ethnic Minority Psychiatric Illness Rates in the Community survey (EMPIRIC)\textsuperscript{57,58}.
Respondents will be asked a series of questions examining the extent of their participation and general attitudes towards the Olympic or Paralympic Games in 2012 adapted from wave four of the Understanding Society UK longitudinal study. These questions distinguish between active participation, such as spectating, volunteering or being in paid employment at the Games, and passive engagement, namely, watching events on television, listening on the radio or reading about it at home.

**Qualitative Data Collection**

Qualitative data collection will comprise three stages. First, narrative interviews will be conducted with a sub-sample of the parents/carers and the adolescent who completed the questionnaire. This approach is informed by theories of social construction. Self-narratives serve as forms of social accounting and public discourse. The aim is to allow participants to recount and reflect in a relatively unstructured and unrestrictive way. The interview will focus on: biographical narratives; perceptions and experiences of the local area and how participants position themselves within the local community; routine individual and family behaviours, especially health related behaviours such as exercise, transport, leisure activities and food shopping; experiences of the spectacle of the Games and the associated regeneration activities; and how participants anticipate the changes and legacy of the Games may impact on them, their families and their neighbourhood.

Second, approximately half of the families from the narrative interview will be invited to participate in a ‘go-along interview’. This is a qualitative semi-structured interview for which the researcher accompanies the participant on a routine activity or journey. Suitable activities and journeys for the go-along interview will be emergent from the narrative interviews (for example, if a participant describes a favourite regular activity as going to the local shopping mall, the researcher will ask to go along on such a trip). We will emphasise clearly that any go-along activity is voluntary and the participant should select something they would like to show the researcher. Go-alongs will be audio recorded - subject to consent, and a photographic log generated. The interviews will investigate environmental and spatial perceptions in the context of sites where participants take part in health
related behaviours. Additionally, the go-along will examine how participants experience these sites and how they relate them to their own lives and narratives of health.

Lastly, video workshops will be conducted with adolescents in schools in the intervention borough. These workshops will elicit adolescents’ own views independently of teacher or parent/carer based accounts. Adolescents will use a video camera to film each other talking about: the availability of extra-curricular activities at school; neighbourhood perceptions focused on crime and safety; leisure and recreation practices with a specific interest in whether these take place within the local area; and the level of active and passive engagements with the Olympic Games and whether the Games are perceived as a positive or negative event in relation to their local area.

**Geographic Information Systems Data Collection**

Using Geographic Information Systems (GIS) and the spatial analysis of secondary environmental data, individual exposure to neighbourhood structural and environmental risks will be captured and quantified. Representative data will be gathered at the finest available spatial level varying from lower super output area (LSOA) to address-level by availability. Secondary data on neighbourhood structural amenities will include the location of food premises, off-licences, civic buildings (e.g. churches, schools and libraries) leisure facilities, walking routes and cycle paths. Routinely collected environmental information will be sought, such as traffic congestion data and information on noise and air pollution. Spatial analysis of land use will be explored using the presence of green or blue (rivers, canals and lakes) spaces, brownfield sites and public and civic space. Further data on the built environment will describe topology such as building heights and surface types. Lastly, area-based socioeconomic measures will be generated using Citizens’ Advice Bureau data, a source rich in contextual information surrounding employment, debt and benefit levels. All data will undergo cleaning and validation to assure its quality.
Data analysis plan

Quantitative study

Questionnaire data will be double-entered and cleaned using range, consistency and logic checks. In cross-sectional analysis of baseline data we will assess the impact of self-reported demographic, socio-economic and environmental correlates of physical activity and mental wellbeing in adolescents and parents, using multi-level regression models that account for the clustered nature of our sample by including school as a random effect. We will compare (i) differences in associations between intervention and comparison sites and schools and (ii) differences in the factors influencing outcomes (i.e. SMFQ, WEMWBS, MSPSS for mental wellbeing and physical activity energy expenditure, time spent in moderate to vigorous physical activity, general physical activity). We will also investigate whether accessibility (density and distance) to health promoting environmental resources (e.g. green space) from either home (adolescents and parents) or school (adolescents) is related to specific health behaviours. For distance metrics we will calculate network distance from the street address of each respondents’ home or school, according to Ordnance Survey Address Layer 2 data, to the nearest relevant environmental resource in a geographic information system.

The main aim of the longitudinal analysis will be to assess the effect of regeneration on primary outcomes (employment, physical activity and mental wellbeing). This will be done by investigating pre-post changes in outcomes between baseline (wave one) and follow-up (wave two). Change is defined as within-individual change in a specific outcome in the intervention area minus the within-individual change in the outcome in the comparison areas. In non-randomized studies such as this there may be differences between the intervention and comparison groups at baseline. If differences are observed we can adjust for these differences by using appropriate baseline individual sociodemographic confounders. We will also consider propensity score and difference-in-difference analyses. Primary outcomes will be assessed at wave three to investigate whether changes at wave two have been sustained. To investigate effects on health inequalities we will undertake a stratified analysis to assess whether any impacts on primary outcomes are socially patterned by sub-groups of individuals. We will assess whether the differences in the social patterning outcomes have changed
over time compared to baseline. Finally, we will also map and describe individual changes in
objective and subjective accessibility to regeneration-related physical and social environmental
resources over time (e.g. access to cycle paths, green space, food retailing, sport and recreation
facilities, crime, social capital/cohesion) and assess whether this is related to individual changes in
physical activity and mental wellbeing. Analysis of secondary outcomes (benefit status, educational
attainment, social capital/cohesion, diet, smoking, alcohol use) will be undertaken in a similar
manner.

**Qualitative study**

The aim of qualitative longitudinal research is to do more than compare two snapshots over time. Analysis of qualitative data for accounts of change over time will help identify the processes and experiences of those changes. Interviews will be transcribed and managed on NVivo software (QSR International Pty Ltd. Version 9, 2010). We will use framework methodology to aid data management, gain familiarity with the data and identify themes and categories to explore further. Our analytical technique will be inductive (going from observed instances to the development of a model or interpretation). Data analysis will be developed along principles outlined by Harding and Gantley. Specifically, the data will be managed in the first instance by mapping key concepts derived from the transcripts (‘charting’) and extracting emergent themes from the transcripts. Transcripts will be analysed iteratively and emergent themes and concepts revisited and refined. Particular attention will be paid to discordant voices or dissonant cases, i.e. elements of the data that do not fit the emerging model and which generate hypotheses for refining or challenging it. Longitudinal qualitative data will be analysed by taking each successive data item (such as an interview) and linking it to previous items on the same participant, with additional re-analysis of past data in the light of subsequent events. For example, if a participant decided to apply to a sports college at age 16 and links this decision in their account to an inspiring encounter during the Olympics, we will look back at the near-contemporaneous interview and look for what, if anything, was said about this at the time. We anticipate that the theoretical and analytic approach to qualitative data will be developed further as qualitative data emerge.
Synthesis of quantitative and qualitative data

The data generated from both elements of the project will be subject to an interpretative synthesis using a narrative summary approach. Narrative summary involves the ‘selection, chronicling and ordering of evidence to produce an account of the evidence’. This may include both straightforward description of findings and the addition of a reflexive commentary on them. Complex narratives can explore dynamic processes, offering explanations that emphasise the temporal and dependent nature of events – essential in a longitudinal study. Such an approach is flexible and theory-led, can deal effectively with large amounts of data and can potentially triangulate different types of evidence.

Narrative summary can integrate qualitative and quantitative data through juxtaposing diverse and seemingly contradictory findings side-by-side and can generate higher-order data and focus attention on critical nuances and tensions.
Ethics and dissemination

The study has been granted approval from Queen Mary University of London Ethics Committee (QMREC2011/40) and permission given from the appropriate boroughs to enter schools through the London Boroughs Research Governance Framework (CERGF113). Further approval has been granted by the Association of Directors of Children’s Services (RGE110927). Written consent has been obtained from each school to survey their pupils and to contact the parent/carer of participating pupils. A Criminal Records Bureau enhanced disclosure check has been carried out on field staff.

Findings will be disseminated through peer-reviewed publications and national and international conference presentations and the study website (http://www.orielproject.co.uk). Schools will be provided with summary statistics at borough level at the end of each wave of data collection. Presentations of aggregate data will be given to adolescent and parent study members via the participating schools.
Discussion

The ORiEL study is a uniquely placed natural experiment equipped to assess the impact of urban regeneration on socioeconomic circumstances, mental and physical health and physical activities and behaviours at an individual, family and environmental level.

The Olympic regeneration programme provides the study with two key strengths. First, the Olympic Games were awarded to London in July 2005, giving this project approximately six years of lead time in which the design of a thorough prospective evaluation of the regenerative impact could be realised, utilising conceptual frameworks from a range of disciplines. This unusual opportunity contributed significantly to the quality of the study design and the creation of a refined study protocol. Previous evaluations of mega-events, especially sporting, have tended to be retrospective and sometimes based around routinely available data on tourism, retail and business and hotel bookings, rather than information gathered specifically for evaluative purposes. Furthermore, many studies have very short post-event evaluation periods. A recent systematic review by McCartney et al (2010) found little evidence of mega-events influencing health or its socioeconomic determinants within the host population, but warned that this may be due to a lack of appropriate data of sufficiently high quality. Thus the ORiEL study will be one of the first studies to address the shortcomings of previous evaluations; the study described is not only a prospective controlled evaluation of a natural experiment with baseline data collected before the intervention, but it will continue to collect data up to three years post-intervention. Lastly, the study encompasses a range of health outcomes, their social determinants and a large number of a priori confounders to enable us to test specifically a range of hypothesised causal pathways.

Second, the Olympic regeneration programme has worked to a fixed timetable. Any changes to the intervention are widely publicised and consulted on with changes to the intervention being readily identifiable. Therefore the study’s conceptual basis, the design and protocols have not undergone major revisions due to external events. In the context of a natural experiment, these are unusual...
circumstances and have provided a unique opportunity to produce and deliver a robust interdisciplinary framework for assessing an intervention.

Despite these advantages, one of the major difficulties of any longitudinal study is minimising sample attrition. This is a particular challenge for the ORiEL study given that the intervention itself (regeneration) may contribute to increased mobility within the sample area. Large scale regeneration may directly promote movement of people between boroughs due to disturbances in the local labour market, such as the need to seek work elsewhere, and changes in housing costs and supply. Indirectly, intervention-led gentrification of the boroughs by those from outside may push out the original dwellers. Such unintended consequences were evident in the redevelopment of Canary Wharf by the London Docklands Development Corporation. This study attempts to minimise attrition by gaining consent from all participants at baseline to permit the study to trace adolescents who change school, but who remain within the same borough. Long term security of the cohort is further strengthened by financial incentives to participate, alongside the formation of academic partnerships with schools, incorporating members of the research team into the schools’ teaching timetable. Lastly, follow up at 6 and 18 months post-intervention represents a trade off between the detection of long term effects and the minimisation of attrition.

Current study status July 2012

We have recruited three post-doctoral workers (quantitative, qualitative and GIS specialists) and two fieldworkers. Invitations to participate were sent to the Headteachers and heads of year at 41 of the 48 eligible schools between 6th October 2011 and 23rd May 2012. We have successfully recruited 25 schools (Newham=6; Tower Hamlets=7; Hackney=6 and Barking & Dagenham=6). Schools that refused participation cited time constraints, school policies against participating in research and research fatigue from multiple requests. Schools refusing did not differ significantly from participating schools in terms of size, school type, catchment area or ethnic and religious composition. Baseline assessments have been completed on pupils from all 25 of the recruited schools. The average sample size per school is 149 in Newham (intervention area) and 116 across all comparison boroughs.
The external market research team entered the field in April 2012 and data collection from parents/carers is ongoing.
Authors' information

1 Centre for Psychiatry, Wolfson Institute of Preventive Medicine, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, Charterhouse Square, EC1M 6BQ, UK

2 School of Geography, Queen Mary University of London, Mile End Road, E1 4NS, UK

3 Institute for Health and Human Development, University of East London, University House, Romford Road, London, E15 4LZ, UK

4 Institute for Research in Child Development, School of Psychology, University of East London, Stratford Campus, Water Lane Stratford, London, E15 4NO, UK

5 Centre for Primary Care and Public Health, Barts and The London School of Medicine and Dentistry, Queen Mary University of London, 4 Newark Street, London, E1 2AT, UK

6 Department of Social and Environmental Health Research, London School of Hygiene and Tropical Medicine, 15-17 Tavistock Place, London, WC1H 9SH, UK

Authors' contributions

All authors contributed to the development of the study protocol and core survey instruments. NS wrote the first draft of the paper. All authors contributed to the critical revision of the paper and approved the final version. The authors had ultimate authority over study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication. The views expressed are those of the authors and do not necessarily reflect those of the funder (National Institute for Health Research).
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Competing interests

SC and TG will be working as volunteers at the London 2012 Olympics.
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