1. Project title. The M74 study: longitudinal follow-up of the health effects of a new urban motorway

2. Background

2.1. Existing research. A variety of urban regeneration initiatives have been pursued in recent decades, often driven by a view that promoting economic growth is key to improving the health and prosperity of deprived urban populations. The case for such interventions is consistent with a social ecological model of health in which economic conditions, as well as physical and social environments, are seen as important influences on health. However, there is little robust evidence that urban regeneration initiatives have produced the economic or population health outcomes claimed for them in practice.[1]

One specific approach to improving access to employment, education and other opportunities involves increasing people's mobility. However, the societal costs attributable to traffic congestion, poor air quality, physical inactivity, injuries, noise and other impacts of motor transport in English urban areas have been estimated at £40 billion per annum.[2] Furthermore, the benefits and harms of a pattern of mobility dominated by motor transport are inequitably distributed. Serious injuries to child cyclists and pedestrians are three and four times more frequent respectively in the most deprived areas of England than in the least deprived[3] and people without cars make fewer trips than those with cars, but travel 50% further on foot.[4] Less affluent groups or areas are therefore disadvantaged in terms of overall mobility and injury risk, but may gain benefits from additional physical activity as a result. A population shift towards more sustainable transport offers a potentially winning combination of an increase in physical activity coupled with reductions in traffic congestion and use of fossil fuels, and is therefore increasingly regarded as desirable on public health, environmental and equity grounds.[5] In a series of systematic reviews, however, we have shown a lack of good evidence from intervention studies as to how to achieve this.[6-8] NICE guidance has drawn particular attention to a lack of robust controlled longitudinal studies of the behavioural impacts of environmental changes,[9] and a recent House of Lords report identified a specific need for more evidence on the effects of interventions on car use.[10] One particularly contentious type of intervention is the construction of new major roads. With Egan et al.[11] we previously showed in a systematic review that new major roads in urban areas are associated with noise disturbance and severance effects, whereby residents are separated from amenities they use (e.g. shops, parks) or their interpersonal networks and social contacts are disrupted.[12] However, we found no evidence about effects on physical activity or health inequalities, and little evidence to support a common assertion that new roads reduce the incidence of injuries.

2.2. Rationale for current study. The intersection between transport infrastructure, urban landscape and public health is exemplified in Glasgow, a conurbation characterised by extremes of affluence and deprivation. A longstanding project to extend the 1960s urban motorway network was resurrected by the new Scottish Government following devolution in 1999. An independent public local inquiry in 2003 considered the arguments for and against the construction of a new five-mile section of the M74 motorway. The inquirers concluded that the claimed benefits were likely to be 'ephemeral' and that the new motorway 'would be very likely to have very serious undesirable results' for local communities, and therefore recommended against the proposal.[13] This advice having been overruled by the government of the day, construction began and the motorway was finally completed on 28 June 2011 at a cost of ~£800 million (see section 7.1). It is claimed that the new motorway will relieve congestion, improve conditions for pedestrians and cyclists on local streets, reduce traffic noise and bring new local employment opportunities, helping to regenerate some of the most deprived and least healthy urban communities in Europe. Objectors claim that the new motorway will largely benefit freight traffic and motorists from outside the local area and will encourage car use, degrade the quality of the local environment and reduce the safety and attractiveness of local routes for pedestrians and cyclists. These can be regarded as two sets of competing, testable hypotheses about the effects of the intervention.[14] The developing situation in Glasgow provides an opportunity to study the positive and negative effects of such changes, thereby contributing to greater understanding of key population health impacts of major changes to the urban environment from which more general lessons can be learned for the implementation of future initiatives.

The case for taking advantage of such opportunities for 'natural experimental studies' has been made repeatedly in recent years. New MRC guidance recommends that the case is strongest when (a) there is scientific uncertainty about the effects of the intervention, shown in this case by the syntheses of evidence

cited above; (b) the intervention cannot be introduced in the context of a randomised trial, which would be unrealistic in this case; (c) data are available with which to compare exposed and unexposed groups, which is possible in this case because of our extensive preparatory baseline research (see below); and (d) the principles of the intervention under investigation are generalisable. The last condition is satisfied because rather than treating the intervention as a 'black box' to which people are either exposed or not, we have designed a multilayered study in which all significant alterations in characteristics of the urban environment believed to be important *general* determinants of activity patterns and wellbeing — such as aesthetic quality, perceived safety and pedestrian access to local amenities — will be characterised and geocoded in an environmental audit (see section 4.3) and their specific associations with changes in residents' perceptions and behaviours analysed in detail.

In anticipation of the planned changes to the urban environment, a baseline cross-sectional study was carried out by the principal applicant with some of the current co-applicants in 2005. This study included a postal survey of travel and physical activity behaviour, neighbourhood perceptions, and general health and wellbeing in adult residents of the intervention area and two matched control areas in Glasgow and a preliminary qualitative interview study. Contact has been maintained with the original study participants by means of annual mailings, and the baseline study has produced a PhD thesis,[15] four published papers[14, 16-18] and hypotheses and research methods to inform the follow-up study. Key baseline findings included the observations that access to local amenities was the most significant quantitative local environmental correlate of active travel;[17] that the new motorway could cause inequitable psychological or physical severance of routes to those amenities, for example by reducing the perceived safety of walking routes to local shops;[18] and that people may not use local walking routes or destinations such as parks and shops if these are considered undesirable, unsafe or 'not for them'.[18] The follow-up study proposed here would build on our previously collected baseline data to examine whether and how a major set of changes to the urban environment has affected key aspects of the health and health-related behaviour of the local population, notably those of social inequalities in mobility, access to amenities, active travel, physical activity and wellbeing.

2.3. Risks and benefits. The intervention under scrutiny in this study has already been carried out. Study participants will not be exposed to any further intervention or to any data collection procedure that places them at risk of physical harm. The modest burden of completing a survey and (in some cases) participating in a week of unobtrusive activity monitoring and an interview are justified in view of the original contributions of the proposed study, which will combine a range of disciplinary perspectives, quantitative and qualitative research methods and public engagement in examining the health and distributional impacts of major changes to the urban environment. On 28 November 2011, the Chancellor of the Exchequer announced an intention to increase expenditure on this type of infrastructure project. Given the lack of evaluative evidence available to guide such investment decisions, it is therefore timely to take the opportunity to complete this study which is designed to address evidence gaps and research recommendations identified in the relevant Wanless,[19] Commons[20] and Lords[10] inquiries and recent NICE[9] and MRC[21] guidance.

3. Research objectives

The **purpose** of the project is to address the following **primary research question**:

1. What are the individual, household and population impacts of a major change in the urban built environment on travel and activity patterns, injuries and wellbeing, and how are these impacts distributed between and experienced by different socioeconomic groups?

and the following **secondary research question**:

2. What environmental changes have occurred in practice, how are the effects of the environmental changes experienced by local residents, and how are any changes in behaviour or wellbeing mediated and enacted at individual and household levels?

in a **mixed-method longitudinal study** with the following elements:

Population	Householders living close to the route of a new urban motorway
Intervention	Construction of a new urban motorway
Comparator	Householders not living close to the route of a new urban motorway
Primary outcomes	(a) Walking for transport (b) Cycling for transport (c) Car use (d) Moderate-to-vigorous physical activity within the neighbourhood
Secondary outcomes	(a) Road traffic casualties (b) Perceptions of the neighbourhood environment (c) Wellbeing (d) Overall moderate-to-vigorous physical activity

combined with the analysis of routinely available population data on injuries, travel behaviour and perceptions of the neighbourhood environment.

The **objectives** of the study are as follows:

1. To characterise the context, content and implementation of the intervention by means of an environmental audit
2. To follow up a cohort of residents of the intervention and control areas previously surveyed at baseline in 2005
3. To draw new repeat cross-sectional samples of residents of the intervention and control areas
4. To measure objectively the travel and activity patterns of a subsample of survey participants
5. To estimate changes and differences in the primary and secondary outcome measures between the intervention and control areas, and by level of exposure to environmental changes within those areas
6. To examine the extent to which any changes in the behavioural outcome measures are mediated by changes in perceptions of the neighbourhood environment
7. To examine the extent to which any changes in the behavioural outcome measures are associated with changes in wellbeing
8. To interview a further subsample of participants to elicit how the effects of the environmental changes are experienced by local residents and how any changes in behaviour or wellbeing are mediated and enacted at individual and household level
9. To examine changes in the incidence and sociospatial distribution of injuries on the road network
10. To explore trends and spatial variation in travel behaviour and perceptions of the neighbourhood environment using existing national population datasets
11. To examine the extent to which the results of the different analyses support either of the two competing overall hypotheses regarding the cumulative effects of the intervention (see section 2.2).

The milestones for achieving these objectives are given in section 14 below.

4. Research design

4.1. Overall research design. The study will adopt a mixed-method approach, using a combination of quantitative (cohort, repeat cross-sectional, single cross-sectional and interrupted time-series) and qualitative (documentary analysis and interview) research methods to evaluate both individual- and population-level changes in health and health-related behaviour (primary research question) coupled with achieving an in-depth understanding of how these changes are experienced and brought about (secondary research question) to assess the evidence for the two competing overall hypotheses. The study will comprise three main components (Appendix: Figure A1):

- **Core surveys of local study areas** to compare changes in neighbourhood perceptions, travel behaviour, physical activity and wellbeing in the intervention and control areas by means of combined cohort and repeat cross-sectional follow-up surveys of local residents (objectives 1, 2, 3, 5, 6, 7, 11)
- **A two-tier in-depth study** of a subsample of core survey participants to quantify differences in neighbourhood-specific physical activity between intervention and control areas, and to elucidate

participants' experiences of environmental changes and the mechanisms through which these changes influence behaviour (objectives 4, 5, 6, 8, 11)

- **Analysis of existing national population datasets** to evaluate the impact of the intervention on road traffic casualties and to describe concurrent regional and national trends in travel behaviour and neighbourhood perceptions (objectives 9, 10, 11).

4.2. Recruitment. Participants will comprise adults living at private residential addresses in the local study areas previously surveyed at baseline in 2005,[17] sampled either from our existing database of baseline respondents (cohort study) or from a newly drawn list of private residential addresses randomly selected from the Royal Mail Postcode Address File (PAF) (repeat cross-sectional study). See section 5.1.

4.3. Core surveys of local study areas

Previous baseline survey. The 2005 baseline postal survey included items on demographic and socioeconomic characteristics, health and wellbeing (including the SF-8 scale and self-reported height and weight), perceptions of the neighbourhood environment, travel behaviour and overall physical activity.[17] **Neighbourhood perceptions** were elicited using a scale we developed, tested and published to assess characteristics (aesthetics, green space, access to amenities, convenience of routes, traffic, road safety and personal safety) relevant to the local urban context and the claimed benefits and disbenefits of the intervention (see section 2.2).[22] **Travel behaviour** was assessed using a one-day record of all journeys adapted for postal self-completion from the travel diaries used in the Scottish Household Survey (SHS) and National Travel Survey (NTS) and currently also in use in the Commuting and Health in Cambridge study.[23] **Overall physical activity** was assessed using the International Physical Activity Questionnaire (IPAQ: short form, last seven days).[24]

New surveys. Of the original cohort (n=1322), ~1000 gave written consent to be reapproached and will be invited to take part in a follow-up postal survey. This will comprise a repeat of all the baseline measures coupled with more detailed measures of walking, cycling and other physical activity in the neighbourhood. Assessment of neighbourhood-specific physical activity will be important for understanding the context in which physical activity takes place. In recognition of the time elapsed (and therefore the likely attrition of the cohort) between baseline and follow-up, new cross-sectional samples of residents will also be drawn in each local study area (target total n=3000, minimum required total n=1200; see section 10) and issued with a similar questionnaire. New participants and cohort respondents who have moved home will be asked for their current location and duration of residence and the reasons for moving to explore possible residential selection bias. Survey protocols will include intensive evidence-based measures to maximise response including postal pre-notification and follow-up of non-responders and the offer of a £5 gift voucher for each completed questionnaire.

Environmental audit. To understand the context, content and implementation of the intervention, an environmental audit of the local study areas will be conducted to ascertain whether the intervention was implemented as originally planned, to elucidate the broader environmental impact of the intervention and compare it with the proponents' and objectors' previous predictions (see section 2.2), and to identify any potential area-level confounders. Data will be collected in an iterative three-step process:

- A documentary analysis of the original proposals for the intervention and its environmental impact assessment (EIA)
- Semi-structured interviews with key stakeholders (e.g. councillors, transport planners, NGOs and residents' organisations: see section 16) to identify changes in the built environment resulting either directly from the intervention (e.g. changes in traffic flows on local roads) or indirectly (e.g. new housing developments adjacent to new motorway junctions). Each interview will be recorded using a digital voice recorder and transcribed verbatim
- Targeted site observations to verify and geolocate these changes, collecting data on both community-scale characteristics (e.g. population density, land-use mix and street connectivity) and street-scale characteristics (e.g. traffic volume, traffic speed and indicators of incivilities) hypothesised to influence travel and physical activity, using an adapted version of an existing audit tool.[27]

4.4. Two-tier in-depth study

Objective activity monitoring. From those core survey participants who express a willingness in principle at the time of their survey, we will select a random subsample stratified by age, sex, car ownership and socioeconomic status (n=400: 200 intervention, 2×100 control) to wear an Actigraph GT3X accelerometer and a BT QStarz global positioning system (GPS) data logger. The Actigraph GT3X is a hip-mounted triaxial accelerometer that provides detailed information about the intensity, frequency, and duration of physical activity. Accelerometers of this kind have been extensively validated in laboratory and free-living conditions. The BT QStarz data logger uses signals from satellites to determine the location of the wearer. When worn together these devices collect synchronous data on the location and intensity of activity, thereby allowing more precise estimates of neighbourhood-specific physical activity and greater understanding of participants' movement patterns. We have previously combined GPS with accelerometry for understanding the activity behaviour of children[28] and are currently using them in combination in studies of travel behaviour in adolescents and adults.[23, 29] Adapting protocols we have used successfully in previous studies,[30] participants will be asked to wear the two monitors on an elasticised belt during waking hours for seven days, receiving and returning the devices by post along with written instructions and a logbook supplemented by verbal instructions over the telephone if required. We will apply several strategies to support participants in adhering to the protocol, including sending email or text-message reminders if requested and helping participants identify and overcome any difficulties with wearing the devices. Participants will receive a £5 gift voucher upon return of their devices.

Qualitative interview study. We will identify a further subsample of up to 60 monitoring participants (30 intervention, 2x15 control) — purposively selected to ensure heterogeneity in age, gender, employment, car ownership, household composition and socioeconomic status, and including those who were interviewed at baseline wherever possible — and invite them for a face-to-face semi-structured interview. A semi-structured topic guide will be developed to elucidate how any changes in the environment have been experienced, whether the activity patterns (e.g. routes to work or school) or wellbeing of the participants or their households have changed over time, and the reasons for and mechanisms of those changes. Each interview will be recorded using a digital voice recorder and transcribed verbatim.

4.5. Analysis of existing national population datasets

Interrupted time-series analysis of road traffic casualties. This will be conducted using autoregressive integrated moving average (ARIMA) interrupted time-series (ITS) analysis of the police STATS19 dataset (1997-2013), which contains details of the coordinates, circumstances, vehicles and casualties involved in every road traffic accident notified to the police. ITS analysis will be used to determine whether the completion of the new motorway is associated with a change in the level and slope of the trend in incidence of injuries. ARIMA is considered the strongest ITS design for estimating intervention effects in non-randomised studies.[31, 32]

Repeat cross-sectional analyses of trends in travel behaviour and neighbourhood perceptions. This will be conducted using the main survey and travel diary datasets from the Scottish Household Survey (SHS) (2005–2013). Because SHS is a national survey, the sampling fraction is too small to provide a large absolute sample size in the relatively small geographical area of greatest interest in this study. Nevertheless, preliminary analyses conducted at baseline highlight the utility of SHS data in providing a 'contextual backcloth' for the analysis and interpretation of our more detailed local survey data. By negotiating access to SHS travel data at the level of postcode sector and pooling these across four consecutive cross-sectional survey waves (2001 to 2004), we were able to show that respondents living in the postcode sectors abutting the route of the proposed new motorway were more likely than those living elsewhere in Scotland to be younger, to live in a household with no car or in a lower income band and to have a long-term health problem, and reported spending significantly less time travelling by car and significantly more time travelling by bus, by rail and on foot.[15] We will extend this analysis using subsequent waves of SHS data (2005-2013) to compare trends in these summary travel data between intervention, control and comparator areas (see section 5.2) and to compare patterns and trends in residents' perceptions of their neighbourhoods (aspects of neighbourhood disliked, safety when walking in the neighbourhood after dark, quality of life affected by fear of crime, perception of convenience of services) reported in the main survey.

4.6. Outputs and translation. The lessons from this experiment in reshaping the urban landscape will be used locally through our established interface and networks with the local and regional policy and practitioner community (see below and section 16). It will also inform future policy and planning in other parts of the UK where population growth is anticipated, by contributing to a growing body of evidence on the health impacts of environmental redesign in which general characteristics such as aesthetic quality, perceived safety and pedestrian access to local amenities are altered. Individualised physical activity feedback will be provided to all participants who have taken part in activity monitoring. Emerging research findings will be disseminated to participants in an annual newsletter and on a study website. Research findings will be presented at national and international scientific and professional meetings across the public health and transport spectrum and published in high-quality journals in both scientific disciplines. The applicants have a track record of successfully disseminating the results of previous research in this topic area at international conferences such as the International Congress on Physical Activity and Public Health and the European Transport Conference and in such journals as the American Journal of Preventive Medicine and the British Medical Journal. The Glasgow Centre for Population Health (GCPH) (www.gcph.co.uk) will take lead responsibility for establishing and maintaining links with relevant organisations and stakeholders locally, regionally and nationally, to maximise engagement with the research process and to stimulate discussion and debate regarding findings and implications for policy and practice. GCPH has well-established collaborative relationships with a number of key organisations including local authorities, regional and national transport and planning authorities and the Scottish Government. The research team already have close working links with other relevant bodies such as the UKCRC Centres of Excellence in Public Health Research (Griffin, Humphreys, Jones and Ogilvie), the NIHR School for Public Health Research (Griffin and Ogilvie) and Sustrans (through the iConnect study: Mutrie and Ogilvie) (see section 15). At the wider policy level, the study will contribute to the anticipated revision of NICE guidance on physical activity and the environment in 2014-2015 and to the developing field of quantifying the public health benefits (including the economic benefits) of transport policy and practice.[5]

5. Study population

5.1. Inclusion and exclusion criteria. For the core surveys, the study population will comprise adults aged 16 and over who either (a) responded to a baseline postal survey addressed to their home address in one of the local study areas at baseline (2005) and choose to respond to a subsequent survey pack at follow-up in 2013, or (b) live in one of the local study areas at follow-up (2013) and respond to a postal survey addressed to the householder at their home address. Participants for the in-depth studies will be selected from among those who take part in the core surveys. The study population for the analyses of existing national population datasets will comprise (a) the whole population of road users as reflected in the police STATS19 injury dataset and (b) adults aged 16 and over who took part in the Scottish Household Survey.

5.2. Study areas. For the core surveys, three local study areas will be defined exactly as in the baseline study: the 'M74 corridor' intervention area ('South') and two control areas, one surrounding the existing M8 motorway ('East') and one with no comparable major road infrastructure ('North'). These study areas were carefully and iteratively delineated at baseline using spatially referenced census and transport infrastructure data combined with field visits to ensure similar aggregate socioeconomic characteristics and broadly similar topographical and urban morphological characteristics apart from their proximity to urban motorway infrastructure (Table 1). Further details of this process are given in Ogilvie, pp 251-260.[15] Baseline analysis confirmed no significant differences between the achieved survey samples in these three areas on any socioeconomic or behavioural summary measures apart from a minor difference of borderline statistical significance (p=0.053) in the distribution of housing tenure. All three study areas extend from inner mixed-use districts close to the city centre to residential suburbs, contain major arterial roads other than motorways, and contain a mixture of housing stock including traditional high-density tenements, high-rise flats and new housing developments (Appendix: Figure A2). Analyses of existing national population datasets will be based on intervention and control areas delineated to match as closely as possible those applied in the core surveys, while also using a morphologically-defined Glasgow city (urban footprint) boundary as well as the West of Scotland region and the whole of Scotland as larger comparators. The eastings and northings of STATS19 injury records will be used to assign incidents to datazones, currently the smallest administrative geographical unit in Scotland. A similar approach will be taken with SHS data depending on the level of spatial precision with which the data guardians are willing to release the data (for the baseline analyses, such data were made available at the level of postcode sector).

Table 1. Delineation of local study areas for the core surveys

Study area	Definition
South	A set of OAs encroaching within 500m of the proposed route of the new M74 motorway
East	A set of OAs encroaching within 500m of the routes of the existing M8 and M80 motorways
North	A set of OAs not encroaching within 500m of the route of any existing or proposed motorway

OAs: Census output areas.

6. Socioeconomic position and inequalities. This study is explicitly focused on exploring the effects of an intervention in relatively deprived urban neighbourhoods (see section 7.1). It will therefore make an important contribution to the evidence on physical activity and the environment, a field dominated by research conducted in more affluent and less densely populated settings. Although the local study areas are characterised by high aggregate levels of relative deprivation, the survey samples obtained in these areas at baseline included both more and less affluent groups (e.g. 52% owner-occupiers).[17] The study therefore provides an opportunity to examine the sociospatial patterning of health, behaviour and behaviour change. In addition, the analysis of injury data will specifically test whether an intervention of this kind is associated with a reduction in the well-established socioeconomic gradient in the incidence of road traffic casualties (see section 2.1).

7. Intervention, intervention and control groups and loss to follow-up

7.1. Intervention. The intervention forms part of a wider strategic initiative to regenerate the 'Clyde Gateway' area, and changes in the local built environment are not limited to motorway construction. As introduced in section 2.2, the intervention comprises the construction of a new five-mile section of the M74 motorway in southeastern Glasgow and the associated changes to the urban built environment, which includes the insertion of highly visible viaducts and embankments as well as junctions and slip roads intersecting with local streets in residential areas; the realignment of feeder roads; and the redevelopment of former open space, demolition of old housing stock and construction of a new residential development on a brownfield site adjacent to one of the new motorway junctions. The new motorway runs between Kingston (close to Glasgow city centre) and Cambuslang (on the southeastern edge of the city), passing through or adjacent to several established residential areas such as Govanhill, Toryglen and Rutherglen: some homes are less than 50m from the carriageway. The most affected neighbourhoods are among the most deprived in the UK, reflecting a local history of rapid deindustrialisation in the late twentieth century. Car ownership is low, and part of the route lies in the Shettleston constituency, which has the lowest life expectancy for males in Scotland (68.2 years) — more than seven years below the national average. The intervention has been funded by a public sector partnership comprising Transport Scotland, Glasgow City Council, South Lanarkshire Council and Renfrewshire Council and delivered by Interlink M74 Joint Venture, a consortium of civil engineering contractors. The intervention was completed and opened to traffic on 28 June 2011 at a cost of ~800 million (m74completion.com).

7.2. Allocation of participants to intervention and control groups. This is a natural experimental study in which treatment allocation is determined by place of residence. Participants will be recruited from one of three local study areas (see section 5.2) and assigned to overall 'intervention' or 'control' status based on their area of residence. Within the South (intervention) and East (first control) areas, both of which now contain motorway infrastructure, participants will further be assigned to a graded measure of exposure to the infrastructure based on the proximity of their home address (see section 11.1).

7.3. Anticipated attrition of cohort and target achieved sample size. The MRC Social and Public Health Sciences Unit has a track record of high retention rates in cohort studies.[33] However, we acknowledge that the interval between baseline and follow-up poses challenges for achieving a high follow-up rate within the original cohort. For this reason, while cohort follow-up will be important for characterising individual typologies of response to the intervention and providing a sampling frame for in-depth studies, the sample size estimations for the primary outcome measures are based on repeat cross-sectional analyses which do not depend on securing the follow-up of most of the original cohort.[14] Survey recruitment in areas of relative deprivation is widely acknowledged to be difficult, but this has not prevented the completion and publication of natural experimental studies in similarly deprived communities in Glasgow such as the evaluation of the

opening of a new supermarket in nearby Springburn.[34] We successfully recruited a total of 1322 participants (between 428 and 457 in each of the three local study areas) at baseline, and our sample size estimations for the follow-up study are based on the conservative assumption that we might achieve only 400 repeat cross-sectional responses from each local study area.[17] In practice, with the deployment of additional evidence-based methods for enhancing response, such as the offer of a £5 incentive for each completed questionnaire, we expect to achieve larger repeat cross-sectional samples and therefore commensurately greater power to detect differences over time and between areas.

8. Proposed outcome measures

Primary outcome measures. Changes (in both cohort and repeat cross-sectional studies) in three measures of travel behaviour over an eight-year interval from baseline (2005) to follow up (2013): walking for transport (min·day^{-1}), cycling for transport (min·day^{-1}) and car use (min·day^{-1}). Differences between study areas in time spent in moderate-to-vigorous physical activity within the neighbourhood (nMVPA: min·day^{-1}).

Secondary outcome measures. Changes in the monthly incidence of killed and seriously injured (KSI) road traffic casualties between 1995 and 2013 (204 monthly data points) and in their distribution by type of road user (pedestrian, cyclist, motorist, etc.), class of road (motorway, A road, B road, etc.) and small-area socioeconomic status (Scottish Index of Multiple Deprivation: SIMD) of location of incidents. Changes in neighbourhood perceptions and SF-8 physical and mental summary scores. Differences between study areas in time spent in overall MVPA (min·day^{-1}).

9. Assessment and follow up. Baseline quantitative survey data were collected in 2005 and baseline qualitative interview data in 2006. Follow-up survey data will be collected in 2013 and national population data will be examined for the periods 1997 to 2013 (injuries) and 2005 to 2013 (travel behaviour and neighbourhood perceptions). Subsets of the survey samples will also take part in objective measurement and qualitative interviews in 2014. See section 14.

9.1. Assessment of effectiveness. The effects of the intervention will be assessed by triangulating the results of complementary analyses using a variety of comparisons as appropriate to the different sources of data available. For injuries, the level and slope of the time series of monthly KSI incidence, and the distribution of injuries by type of road user, class of road and SIMD of location, before and after the introduction of the intervention and between intervention, control and comparator areas will be compared. For all other outcomes measured at baseline and again at follow-up, net changes between baseline and follow-up will be computed. For cohort analyses, net change will be defined as the average within-subject change in the intervention group minus the average within-subject change in the control group after adjustment for covariates. For repeat cross-sectional analyses, net change will be defined as the average within-group change in the intervention group minus the average within-group change in the control group after adjustment for covariates. For outcomes measured only at follow-up, differences between intervention and control groups will be computed after adjustment for covariates.

9.2. Assessment of harms. Participants will not, in the course of the research, be offered any intervention or asked to undergo any form of data collection that places them at risk of harm. The main potential harms arising from the intervention itself are an increase in the incidence or severity of injuries or a redistribution of injuries towards more vulnerable road users or more deprived neighbourhoods, and an increase in adverse perceptions or experiences of the neighbourhood environment. These potential harms are all reflected in the primary and secondary outcome measures specified for the various levels of the study. All quantitative hypothesis-testing will use two-tailed statistical tests to ensure that the analysis is equally open to the possibility of an adverse or a beneficial outcome.

10. Proposed sample size. The study is designed around the objective of detecting changes in the key primary outcome measures (changes in travel behaviour and physical activity) and the most important secondary outcome measure (a change in the incidence of injuries).

10.1. Travel behaviour. We have previously published the distributional statistics of the primary travel behaviour outcome measures in the baseline sample (Table 2).[17] Applying these mean values and standard deviations to the simplest situation of a comparison between two groups, a cross-sectional sample of 400 per wave per study area (which we exceeded at baseline) would be expected to allow the detection with 95% confidence and 80% power of an increase of 5 min·day^{-1} in walking for transport from baseline to follow-up within one study area, or a cross-sectional difference of 2 min·day^{-1} in cycling for transport or 5 min·day^{-1} in walking for transport between intervention and control areas at follow-up. These differences are of similar magnitude to the estimated effect sizes for interventions synthesised in previous systematic reviews, the differences in walking observed in comparisons of 'high-' and 'low-walkable' neighbourhoods in observational studies, and the increases in time spent in overall physical activity that are likely to confer health benefits. The availability of two control areas, a larger follow-up sample than the minimum of 400 per study area, and the potential to compare longitudinal changes between study areas using a combination of cohort and repeat cross-sectional analyses will increase the power of the study to detect smaller changes.

Table 2. Distributional statistics for primary outcome measures in baseline sample[17]

Outcome	Mean	SD	Median	IQR	Range
Walking for transport (min·day^{-1})	19.2	27.8	10.0	30.0	0–205
Cycling for transport (min·day^{-1})	0.7	7.3	0.0	0.0	0–130
Car travel (min·day^{-1})	24.4	40.8	0.0	40.0	0–510

10.2. Physical activity. Assuming a baseline (control) mean value for accelerometer-derived MVPA of 10 min·day^{-1} and a standard deviation of 7 min·day^{-1},[35 36] 86 participants per group would be required to detect a difference of 3 min·day^{-1} in nMVPA between intervention and control areas. Our target total achieved sample of 400 participants in objective monitoring would be more than sufficient to achieve this, even allowing for the fact that in our previous studies ~20% of participants have returned an accelerometer file with fewer than the accepted minimum standard of four 10-hour days of recording.

10.3. Injuries. It is not generally considered feasible to perform conventional sample size estimations for interrupted time-series analyses.[37] However, a minimum of 50 time points is recommended for ARIMA ITS models to enable cyclical trends in the pre-intervention series to be adequately modelled.[31] The STATS19 injury dataset from 1997 to 2013 contains 204 monthly data points and therefore easily exceeds this minimum recommendation.

11. Analysis

11.1. Analysis of core survey data. Questionnaire data will be checked and cleaned using a combination of standard range and consistency checks and the data cleaning procedures, algorithms and software already published or developed in-house for the relevant instruments. Distances will be computed from the centroid of the unit postcode for each participant's home address (a) in a straight line to the nearest part of the new motorway infrastructure and (b) by road network to the nearest motorway access point (junction) in a GIS. Unit postcodes (e.g. G12 8RZ) are the smallest available unit of postal geography in the UK; residential unit postcodes cover about 15 delivery points (addresses) on average. The main analyses will comprise multivariable regression analyses of the effect of exposure (as represented by distance) to the new transport infrastructure and other environmental changes (see section 11.2) on changes in neighbourhood perceptions and on travel behaviour — and whether these differ between the study areas — after adjustment for baseline sociodemographic, geographical and health-related correlates; stratified outcome analyses to examine how the effect of exposure to the intervention varies according to sociodemographic characteristics and baseline physical activity; and multivariable regression analyses of the relationship between changes in travel behaviour and changes in overall physical activity and wellbeing.

11.2. Analysis of environmental audit data. A comparative analysis of the notes from the documentary analysis and the transcripts of the recordings from the stakeholder interviews will be undertaken to identify environmental changes in the intervention and control areas. These changes will then be verified by the site

observations, geocoded and used to compute additional environmental exposure measures for the analysis of survey responses (see section 11.1). Any inconsistencies between the three data sources will be identified and resolved using an iterative checking process.

11.3. Analysis of objective activity monitoring data. Actigraph and GPS data will be downloaded, cleaned and merged using a combination of bespoke in-house and third-party software already developed for these instruments. From the Actigraph data measures of compliance, wear time and overall MVPA will be derived and — following standard practice in this field — participants with at least four 10-hour days of recording will be included in analysis. The merged data will then be projected into a GIS. A measure of nMVPA ($min \cdot day^{-1}$) will be derived by identifying all activity that takes place within a neighbourhood (provisionally 800m) buffer around each participant's home address. Adjusted multivariable regression analyses will be used to examine differences in nMVPA and overall MVPA between study areas, using baseline and follow-up survey data on physical activity from the same study areas to weight the analysis if appropriate.

11.4. Qualitative analysis of semi-structured interview data. The transcripts will be checked against the audio recordings. An iterative process of content analysis using NVivo or similar software will then be used to code segments of transcripts, extract related segments, identify and group themes, and identify patterns and negative cases using the method of constant comparison. Higher-order themes will mostly be derived from the topic guide, whereas the lower-order themes are likely to emerge from the data elicited in the interviews and mixed-method analysis of how those are related to participants' spatially-referenced activity data. After an initial batch of interviews, an interim descriptive account based on the content analysis described above will be discussed with the research team in order to validate emerging findings and review the interview recruitment strategy and topic guide before continuing with further recruitment, interviews and analysis.

11.5. Analysis of existing national population datasets. Changes in KSI incidence will be analysed using ARIMA ITS analysis. Candidate ARIMA models that fit the pre-intervention response variable will be identified. An appropriate transfer function will then be identified and applied according to whether the impact of the intervention appears to take the form of an abrupt permanent change, a gradual permanent change or an abrupt temporary change.[38] The ITS analysis will then be stratified by type of road user, class of road and SIMD quantile to examine the sociospatial distribution, and changes in that distribution, of KSI incidents. In addition, the research team will endeavour to identify any local confounding factors that may require to be considered in analysis. Descriptive analysis of SHS data will compare trends in summary measures of travel behaviour, and patterns and trends in residents' perceptions of their neighbourhoods, between intervention, control and comparator areas.

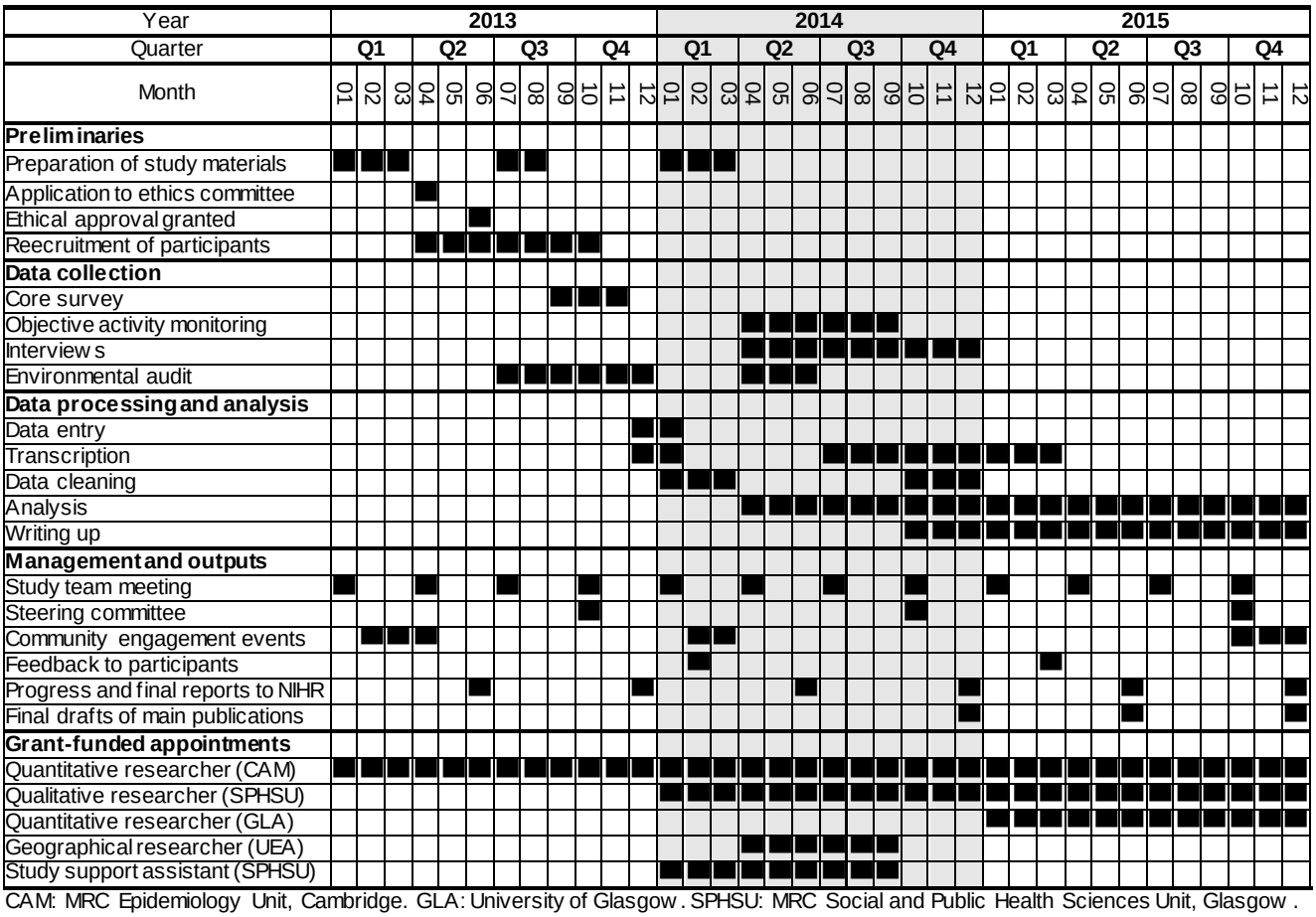
12. Ethical arrangements. The proposed study does not involve NHS patients or staff or the use of NHS data. Ethical approval for the baseline phase of the study was granted by the University of Glasgow Faculty of Medicine Ethics Committee (reference no. FM01304). We will apply to the most appropriate current University ethics committee for approval of the follow-up study in the second quarter of 2013 (the second quarter of the project). Participants will not be exposed to any invasive or intrusive research procedures. They will be recruited from among existing (baseline) participants in the study or by responding to letters addressed to the householder at their home address. They will be offered £5 incentives to return a completed questionnaire and, if applicable, to return their activity monitors. We regard these as appropriate responses to the well documented decline in response rates to questionnaire surveys in health research.

13. Research governance. The study will be sponsored by the University of Cambridge and will be conducted and managed by the MRC Epidemiology Unit in collaboration with the co-applicants from the MRC Social and Public Health Sciences Unit, University of Glasgow and other institutions under the terms of a formal collaboration agreement. The study will be directed by a scientific committee of the principal investigator and the co-applicants that will meet quarterly, to which the survey manager of the MRC Social and Public Health Sciences Unit and the project researchers will report. Data collection and data management will be delegated to and managed by the Survey Room at the MRC Social and Public Health Sciences Unit, which conducted the baseline survey. The study will be conducted in accordance with relevant current MRC and university policies and standard operating procedures including those pertaining to informed consent, indemnity, data protection and data storage. We will convene a study steering

committee (SSC) that will meet annually. The SSC will be chaired by a senior UK public health academic, and will include two other independent academic members, one from public health and one from transport studies.

14. Project timetable and milestones. Jan-Aug 2013: Refine study design and survey instruments; apply for ethical approval; commence documentary stage of environmental audit; prepare for survey data collection. **Sep-Dec 2013:** Collect survey data (initial and reminder waves, successfully completed in two months at baseline); complete documentary stage of environmental audit. **Jan-Mar 2014:** Clean survey data; prepare for objective measurement and qualitative fieldwork. **Apr-Dec 2014:** Analyse survey data; collect objective measurement data (with an issued sample of 30 wk^{-1}, as previously achieved in the Commuting and Health in Cambridge study: see section 15); undertake qualitative environmental audit and interview fieldwork. **Jan-Dec 2015:** Continue analysis of survey and spatial data, analyse existing national population datasets, objective measurement and qualitative data and write up. See Figure 1.

Figure 1. Project timetable



CAM: MRC Epidemiology Unit, Cambridge. GLA: University of Glasgow. SPHSU: MRC Social and Public Health Sciences Unit, Glasgow.

15. Expertise. The **UKCRC Centre for Diet and Activity Research (CEDAR)** (involving both **the MRC Epidemiology Unit** at the University of Cambridge and the **University of East Anglia (UEA)**, which together have considerable experience in population-based studies of travel behaviour and physical activity)[23, 29, 39] will lead on the overall scientific strategy for the study and the analysis of the core survey and objective activity monitoring data. The study will be led by David Ogilvie, who previously designed and carried out the M74 baseline study and now leads on natural experimental studies in CEDAR. He is the PI on a related study of the Cambridgeshire Guided Busway (CGB) (funded by NIHR) and work package leader in the iConnect study (www.iconnect.ac.uk). He will supervise the lead quantitative researcher, supported by the other CEDAR applicants: Simon Griffin (MRC programme leader on the prevention of diabetes and obesity) and Andy Jones (a health geographer with expertise in geographical analysis of physical activity, road traffic accidents and environmental change). Andy Jones will also supervise the geographical researcher based at UEA in year 2. Shannon Sahlqvist and David Humphreys are postdoctoral researchers with experience in objective activity measurement, postal surveys and evaluation

of physical activity interventions (Sahlqvist) and evaluation of area-based interventions (Humphreys) who will further contribute to study design, analysis and interpretation. CEDAR and its constituent institutions also offer wider expertise in physical activity measurement and statistical methods relevant to this study. The **MRC/CSO Social and Public Health Sciences Unit (SPHSU)** at the University of Glasgow contributes expertise in understanding social and neighbourhood effects on health and health inequalities, will be responsible for data collection and data management and will lead on the qualitative studies. Shona Hilton leads the Unit programme on Understandings and Uses of Public Health Research and will supervise the qualitative researcher. Hilary Thomson is a Senior Investigator Scientist in the Unit's Evaluating the Health Effects of Social Interventions programme. The Unit's Survey Room has 20 years' experience of undertaking cohort studies in deprived areas and conducted the M74 baseline study. Also at the **University of Glasgow**, Richard Mitchell, an epidemiologist and geographer, will supervise the researcher leading on the analysis of the existing national population datasets. He is co-founder of the Centre for Research on Environment, Society and Health, and has expertise in the use of secondary and spatial data analysis to explore environmental influences on social and spatial health and inequalities. Nanette Mutrie at the **University of Edinburgh** is director of the Scottish Physical Activity Research Collaboration (www.sparcoll.org.uk), has expertise in evaluating physical activity interventions and chaired the NICE programme development group on physical activity and the environment. She will contribute to the physical activity aspects of study design, analysis and interpretation. The **Glasgow Centre for Population Health (GCPH)** will lead the interface between the research team and the wider stakeholder community (see section 16). Fiona Crawford is a public health programme manager who leads the Centre's research programme on active and sustainable travel and chairs the Centre's transport and health advisory group.

16. Members of the public. The aim of public involvement in this study is to enable local residents and other stakeholders to help shape the research process (particularly the interviews) and respond to relevant emerging findings, including those of the environmental audit. Public involvement will be pursued by directly engaging with representative community groups in the study area through a variety of means which GCPH has previously used with success. In addition to engaging local people through formal mechanisms, we will use methods designed to reach beyond those community members already participating in representative structures. The involvement of more disparate groups and local residents will follow guidelines set out in the National Standards for Community Engagement (www.scdc.org.uk/what/national-standards) produced on behalf of the Scottish Government to ensure that public involvement is open, transparent and effective and will also use the principles set out by INVOLVE (www.invo.org.uk). The Scottish Community Development Centre (SCDC: www.scdc.org.uk) will be employed on a consultancy basis to manage this process and organise a series of events or workshops for local residents close to the inception, middle and end of the study (see project timetable in Figure 1). SCDC will use the VoiCE tool (www.voicescotland.org.uk) to analyse, plan, record and evaluate the process, quality and outcomes of local engagement.

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