The effectiveness of cycling-specific transport infrastructure at reducing the risk of cycling injuries in cyclists: a Cochrane review.
Protocol

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Sponsor University of Nottingham

Funder NIHR Public Health Research programme

Cochrane review INJ0156

1. Background

1.1 Physical activity levels

Physical activity has many benefits for health including a reduced risk of cardiovascular disease (Schnohr 2006; Oja, 2011), cancer (Schnohr, 2006; Inuoe, 2008), type 2 diabetes (Hu, 1999) and other causes of mortality (Andersen 2000; Matthews, 2007; Savela, 2010). A lack of physical activity is a dominant factor in the rise in obesity levels (Prentice, 1995). Yet data from England suggests that fewer than half of all adults and less than a third of children meet the recommended guidelines of physical activity levels (DH, 2011). Inequalities exist in terms of the amount of physical activity undertaken resulting in inequity in the consequent health benefits attained. For both sexes, participation in exercise decreases with increasing age, with women and girls being less likely to be active than men and boys, respectively (DH, 2011). People from ethnic minorities and low income families are less likely to take part in exercise than other ethnic and socioeconomic groups (NHS, 2006).

Previous and current UK governments have stated their commitment to increasing the nation's physical activity levels, and thus its health, evidenced by the number of published consultation documents and action plans over the last decade (for example, "Choosing activity: a physical activity action plan' (DH 2005); "Be active, be healthy" (DH, 2009); "Healthy weight. Healthy lives" (DH 2008); "Start Active, Stay Active" (2011)). This commitment is no doubt fuelled by the estimated annual costs to the NHS for treating obesity related disease which are expected to rise to £10 billion by 2050 while the costs to the wider society are expected to rise to £49.9 billion per year (McCormack, 2007). The economic benefit of decreased morbidity and mortality from a 1% unit reduction in the percentage of sedentary people in the UK is estimated at £1.44bn (mean of £2,423 per additional active person per year)(CJC Consulting, 2005).

1.2 Benefits of cycling

Cycling is a physical activity that confers multiple benefits. It is a readily accessible form of physical activity that can fit more readily into an individual's daily routine than other activities (Cavill, 2008; Hillsdon 1996). It has additional wider public health benefits gained as a result of fewer car journeys in terms of reducing emissions (Lindsay 2011) and improving the local environment through reduced congestion and community severance (McClintock, 2002). Cycling also offers a cheaper form of transport for those who are socially disadvantaged and are less likely to have access to a car than those less socially disadvantaged. Thus, the benefits from increased cycling rates are clearly wide ranging.

1.3 Cyclists as vulnerable road users

The physical environment is known to play a key role in impacting physical activity such as cycling (NICE 2008; Fraser, 2010). A barrier to increased cycling rates is the fear of injury (Rivara, 2011; TfL,2008). Cyclists are vulnerable road users who are frequently in close proximity to larger and faster motorized vehicles which offer the occupants some protection if

an accident occurs, unlike the cyclist. Cyclists report fear of injury from lack of segregated cycling routes, volume and speed of traffic, and driver behaviour (TfL, 2008). In 2008 in England there were 115 pedal cyclist fatalities and 2,450 reported seriously injured casualties (DfT, 2009). There are many more cycle related injuries that are not reported to the police and thus do not appear on the police databases but nevertheless require medical attention (Amoros, 2011; Cross, 1977). Indeed, it is estimated that two thirds of cycle-motor collisions are unreported to the police (Amoros, 2011; Cross, 1977) and half of these result in injury (Cross, 1977). Inequalities exist in cyclist injuries with a risk of cyclist injury 20-30% higher in lower socio-economic groups than higher socio-economic groups (Hasselberg, 2001; Engström, 2002). In 2008 cyclist casualty rates were around 29 per 100000 in the most deprived 10% of areas of England compared to 20 per 100000 in the least deprived (DfT, 2010a). Thus to maximise the public health benefits of increased cycling rates it is necessary to minimize the risk of cycling injuries and people's fear of cycling.

1.4 Cycling infrastructure

One key approach to reducing the fear and risk of injury for vulnerable road users such as cyclists is through engineering and in particular, through transport infrastructure. Transport infrastructure refers to those physical measures within the built environment which are in place to enable traffic to flow safely and thus allow society to function fully. Transportation infrastructure generally develops over time and is frequently designed with the needs of the motorized vehicle user of most importance (Peden, 2004). Within this, infrastructure specific to cycling includes measures to manage cycle traffic and motorized traffic to varying degrees in mixed traffic conditions and generally takes one of three main forms. Firstly, there is cycling infrastructure that manages the road space for shared use by both motor vehicles and cyclists and includes cycle lanes. Secondly, there is cycling infrastructure which separates cycle traffic from motorized traffic. This may include special routes for use exclusively by cyclists but which may also be shared with pedestrians. Thirdly, management of the traffic network represents a third form of cycling infrastructure and includes traffic regulations that ban certain types of traffic from making particular turns and speed management.

The role of infrastructure in reducing the fear of cycling is evidenced by research that has found that changes in infrastructure can positively influence cycling rates (Winters, 2010; Yang 2010; Garrard, 2007) with cyclists choosing to use routes serviced by bicycle facilities. In terms of injury prevention, research also indicates that infrastructure is effective at reducing injuries (Lusk, 2011, Rodgers, 1997, Moritz, 1998). Reducing the risk of cycling injury may also reduce the social inequalities seen in cycle injuries. As an injury prevention strategy, cycling infrastructure is particularly potent for several reasons: firstly it is population based and thus can reach large numbers of the population, secondly its passive mode requires no actions from individuals and thirdly, changes are made only once, thus requiring no reinforcement (Reynolds, 2009).

There has been one previous review of cycling infrastructure and its impact on cycling crashes and injuries. This review identified a number of features that alter the risk of a crash and injury (Reynolds 2009), with on-road "clearly-marked, bike-specific facilities" providing greater protection to cyclists than on-road cycling with traffic or off-road cycling with pedestrians. The promotion of cycling and walking in this country is highly topical with many recent reports on schemes to promote cycling (TfL, 2008; Sloman, 2009; DfT, 2010b) and with much on-going research in this area new results are frequently being published. The current review of measures to promote cycling and walking by NICE will not assess infrastructure (NICE, 2011). There is therefore, an urgent public health need for a review to assess the effectiveness of cycling infrastructure on cycling injuries and to identify those structures which are most effective at reducing injuries.

We propose to perform this literature review as a Cochrane review. There is no Cochrane review of this topic: previous cycling-related Cochrane reviews have focused on the use of cycle helmets (Thompson, 1999; Macpherson, 2008) and cyclist visibility (Kwan 2006). Both the protocol and final report from a Cochrane review are assessed by independent reviewers thus promoting the quality of the final review and its findings. In addition use of the computer package RevMan facilitates meta-analysis of available data, where appropriate. Authors of a Cochrane review are expected to update the review every two years to take account of the most recently published studies and to ensure that the review findings reflects these latest studies.

2. Research objectives

The objectives of this review are to:

1. evaluate the effectiveness of different types of cycling infrastructure at reducing cycling injuries in cyclists by type of infrastructure

2. evaluate the effectiveness of cycling infrastructure at reducing the severity of cycling injuries in cyclists.

3. evaluate the effectiveness of cycling infrastructure at reducing cycling injuries in cyclists with respect to age, sex and social group.

3. Research design

3a. Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials, cluster randomised controlled trials, controlled before-and-after studies and non randomised controlled trials.

Types of participants

We will include studies which include adult or child cyclists or both.

Types of intervention

We will include studies that evaluate the effectiveness of at least one form of cycling infrastructure. Cycling infrastructure generally takes one of three main forms.

1. Firstly, there is cycling infrastructure that aims to manage the shared use of the road space for both motor vehicles and cyclists and include:

    i) cycle lanes - these are part of the road and are indicated, often by a white line and a bicycle icon painted on the lane and appropriate signage. These are to be used exclusively by cyclists. This includes contraflow cycle lanes where two-way cycling is allowed on a street that allows motorized traffic to travel only one way. Cycle lanes may be advisory or mandatory. If the latter, motor traffic is excluded by regulation.

    ii) shared use of a bus lane - these are similarly defined by appropriate markings and signage.

    iii) advanced stop lines - these are marked as a box at a junction and, extending across the width of the road, they allow cyclists to wait in front of the queuing traffic while the signal is red and to leave the intersection ahead of the motorized traffic when the signal turns green.

    iv) bicycle routes - cyclists share the road with motorized vehicles but the route is signed as a preferred route and may avoid particular busy roads.

    v) any of the above where the lanes and stop lines have been painted in colour to make it more noticeable to other road users.

2. Secondly, there is cycling infrastructure which separates cycle traffic from motorized traffic and may include special routes exclusively for cycle traffic, but which may be shared with pedestrians, either in mixed or segregated conditions. These include:

i) cycle tracks - these lie alongside a road but cyclists are separated from motorized vehicles perhaps by a kerb or other physical barrier such as bollards. They may be one-way or, more, frequently two-way.
ii) cycle paths - these are paths which are separate from the road and, significantly, they may be marked to segregate cycle traffic from pedestrian traffic, or they may be shared with pedestrians.

3. Thirdly, management of the network represents a third form of cycling infrastructure. This includes:

i) separation of traffic movements - through direction signage differentiated by vehicle type, or through regulatory means, for example traffic regulations that ban certain types of traffic from making particular turns.
ii) bicycle phases at traffic signals - these operate at a junction and allow cyclists to cross an intersection at a separate time from motorized vehicles.
iii) speed management - achieved either by physical measures such as the use of narrowed roads or speed bumps, or by the imposition of speed limits.

Examples of cycling infrastructure may be placed on continuous roads or at intersections. In some situations there will be more than one infrastructure feature in place and the effect of individual features will be determined where possible.

We will include studies which have evaluated cycling infrastructure in urban or rural environments, or both. We will only include those studies from developed countries because the transport environment for cyclists in non-developed countries will be very different to the UK context and it will be difficult to generalise findings from the non-developed countries to the UK. Findings from non-UK studies will be considered for their generalisability to the UK.

Those studies that describe cycling infrastructure that is not associated with the movement of cyclists, for example, end of trip facilities such as parking or shower facilities, features of the built environment such as green spaces or topography of the environment such as steep road gradients will be excluded.

Types of comparators

Comparators will either be:
a) routes or intersections used by cyclists that do not have cycling infrastructure in place, and thus comparisons may be made of a site either before and after the infrastructure was put in place, or between two or more different sites, some of which have the infrastructure in place and some which do not.
b) routes or intersections which have different types of infrastructure in place.

Types of outcome measures

Primary outcomes

Studies for inclusion must include a measure of cycling injuries sustained as a result of cycling. This will be:

- self-reported injuries
- medically attended injuries.

Secondary outcomes will be:

- crash rates for cyclists.
- cycling rates, as cycling infrastructure may increase cycling rates, thus benefiting the wider public health while having no impact on injury rates,

To account for variations in exposure, we will express self reported or medically attended injuries as injuries per million bike-km, where sufficient data is provided. Alternatively, we will

report number of injuries per hours of cycle use or number of injuries per cyclist, depending on how injuries are reported in the included studies. Where there is sufficient information, we will include a differentiation of injury rates by severity, where possible, according to fatal, serious injury and slightly injured. We will also differentiate between injuries sustained as a result of a collision with other traffic, for example motor vehicles, other bicycles or pedestrians, and injuries relating to having 'fallen off' due to collision with obstacles both within the road and adjacent to the road.

We will include injuries sustained as a result of maintenance issues of infrastructure, such as, poor surfaces. We will not include studies that report only injuries sustained while racing, mountain biking or playing.

3b. Search strategy

Search strategies will be developed iteratively. Results from the search will be assessed to determine whether the strategy is identifying relevant papers and adjusted as required. It is anticipated that the following terms will be included in a MEDLINE search:
exp Accidents, Traffic/ or Accidents/ AND exp "Wounds and Injuries"/ AND cycl*.mp.
The terms will be adjusted as necessary for each database.

The proposed review will search the following databases:

- MEDLINE (Ovid) (1946 to present)
- EMBASE (Ovid) (1974 to present)
- OpenSIGLE (System for Information on Grey Literature in Europe) (http://opensigle.inist.fr/)
- PubMed [www.ncbi.nim.nih.gov/sites/entrez] (to present)
- TRANSPORT (Ovid SP) (includes databases from: Transportation Research Information Services (TRIS); International Transport Research Documentation (ITRD); TRANSDOC (1988 to present)
- GEOBASE
- Index to Theses
- SafetyLit
- TRANweb
- TRID
- Cochrane Injuries Group Specialised Register (to latest version)
- Cochrane Central Register of Controlled Trials (The Cochrane Library)
- Transport Research Laboratory database.

We will search the following relevant websites:

- the National Bicycle Safety Network
- Cycling Embassy of Great Britain
- AAA Foundation for Traffic Safety
- Australian Road Research Board
- Swedish National Road and Transport Research Institute
- Transport Canada
- Transportation Research Board (US)
- International Control Resource Information Network (US)
- Harborview Injury Prevention and Research Center (US)
- CTC (UK).

We will use the search engine Goggle Scholar to help identify relevant research and will systematically search the internet, recording details of websites searched, date, search terms used and results.

We will hand search abstracts of the following relevant conferences:

- World Conference on Injury Prevention and Safety Promotion
- Australian Cycling Conference
- NZ Cycling Conference
- European Transport Conference.

Hand searching will be completed by two reviewers. We will also search the reference lists of included studies, previously published reviews and other relevant material for further studies. We will contact key individuals. Such as those who have previously published relevant work to ask if they can identify any unpublished or ongoing research.

3c. Data collection

Selection of studies

A two stage screening process will be undertaken. Potentially relevant papers will be imported into an Endnote library and duplicates removed. Two reviewers will independently scan titles and abstracts of articles for relevance according to the pre-determined criteria for study inclusion. For those articles retained at this stage the full article will be retrieved. This may require contacting the author, particularly for those papers identified in conference proceedings. It may also be necessary to obtain papers through inter library loans and through the purchase of reports. The full papers will then be reviewed independently once again by two reviewers for relevance according to the inclusion criteria. Papers retained at this second review stage will be included in the final review. Disagreement at either stage will be dealt with by deferment to a third reviewer. Reasons for exclusion of a paper will be saved. Details of all papers retained at the full article stage will be inputted into a Microsoft Access file to aid monitoring of data.

Data extraction

Two authors will independently extract data. We will use a data extraction form which will be designed specifically for this review and will be pre-tested. Reviewers will extract data on:

- study design
- date of study
- country of origin
- characteristics of the study population such as age, sex, socioeconomic group
- characteristics of the intervention and control areas such as urban/rural environment, residential/commercial/industrial/educational, higher/lower capacity roads
- nature of the intervention such as length of cycle lane, position at an intersection/continuous road
- length of follow up/data collection
- data on outcomes/measures of interest.

If data is not available we will contact authors in an effort to obtain relevant data. Any disagreements on data will be deferred to a third reviewer. If sufficient data is available we will comment on its quality using Cycle Infrastructure Design (Department for Transport, 2008) as a guide.

Critical appraisal and quality assessment

Two authors will undertake critical appraisal of the included studies to assess their quality. The following sources of bias will be considered for RCTs:

- random sequence generation (selection bias)
- allocation concealment (selection bias)
- blinding (performance bias and detection bias)
- blinding of participants and personnel (performance bias)

- blinding of outcome assessment (detection bias)
- incomplete outcome data (attrition bias)
- selective reporting (reporting bias)
- other bias.

It is anticipated that due to the nature of the intervention the majority of the studies will be non RCT and thus quality assessment will consider selection bias based on the degree of similarity between the control and intervention areas, performance and detection bias will be based on an assessment of whether data collection and analyses were performed by a researcher blind to location/time of data collection and attrition bias will consider length of time of data collection before and after installation of intervention. We will also assess reporting bias, that is, whether authors appeared to be selective in terms of the results they reported. Reviewers will give a brief description of possible sources of each type of bias and tae the risk as high risk, low risk or risk unclear or unknown. Once again, the findings of the two reviewers will be examined for discrepancies and discrepancies resolved by deferment to a third reviewer.

3d. Data analysis

Data analysis and synthesis

Where there are 3 or more studies reporting the same outcomes we will perform meta-analyses. We will estimate pooled rate ratios and 95% confidence intervals for injury rates, pooled relative risk and 95% confidence intervals for dichotomous outcomes and pooled mean differences and 95% confidence intervals for continuous outcomes. Random-effects models will be used to allow for and to quantify the degree of heterogeneity between studies. If the review includes both randomised and non-randomised studies the primary analyses will be based on randomised studies with secondary analyses including both randomised and non-randomised studies.

If there are insufficient studies to undertake a meta-analysis the results from individual studies will be combined in a narrative review. For those studies included in a narrative review, the key characteristics and findings of the studies will be presented. Difference and similarities between studies will be examined.

Assessment of heterogeneity

For those studies that have been combined in a meta analyses, we will assess heterogeneity of studies by observation of the forest plot, and in particular confidence intervals of the individual studies, and statistical tests of heterogeneity will be undertaken using chi-square tests, with significance defined as a P value of <0.1, and the I^2 statistic. I^2 values above 30% suggest that moderate heterogeneity exists. In such cases, findings will be interpreted with caution. Subgroup analyses will be undertaken to explore possible reasons for heterogeneity.

Assessment of reporting biases

We will assess publication bias by generating funnel plots and observing for symmetry. For those meta-analyses using 10 or more studies, we will test for asymmetry using Egger's test. We will perform this calculation using Stata version 11.

Subgroup analysis

If there is sufficient data we plan to undertake several subgroup analyses. Firstly we aim to consider the effectiveness of the infrastructure at reducing severity of injuries. Thus we will undertake a subgroup analysis according to fatal, serious injury and slightly injured. In addition we will undertake subgroup analyses comparing effect sizes between countries with and without cycle helmet legislation as compulsory wearing of a cycle helmet may affect severity of injuries sustained. Secondly we aim to evaluate the effectiveness of cycling

infrastructure at reducing cycling injuries in cyclists with respect to age, sex and social group. Thus we will undertake subgroup analyses based on age (child vs. adult), sex (male vs. female) and social group (disadvantaged by non-disadvantaged).

Sensitivity analysis

Sensitivity analyses will be undertaken by rerunning the analyses and including only RCTs considered to be at low risk of selection bias in terms of adequate allocation concealment, detection bias in terms of blinded outcome assessment and attrition bias due to follow up of fewer than 80% of participants in each arm.

Dealing with missing data

We will asses the number of dropouts for each included study and will report the number of participants who are included in the final analysis as a proportion of the number of participants who started the study. We will also assess the extent to which studies conformed to an intention-to-treat analysis. Where data is missing we will attempt to obtain this from the authors.

3e. Expected outputs

Findings from the review will be presented in a report which will include detailed background, methods, results and conclusions sections and will consider strengths and weaknesses of the review, of the included papers and implications for practice and research. We will disseminate the findings through presentations at conferences and through peer reviewed publications. We aim to ensure that the findings of the study reach those to whom they are of most use, that is, Road Safety Officers and engineers in local government who have the power to act upon the findings. Findings will be reported in alternative form, as required, that are suitable for a variety of audiences.

4. Ethical arrangements

This review will use published data and we do not intend to seek individual patient level data and therefore we do not need to seek ethical approval.

5. Research Governance

The University of Nottingham have agreed to act as sponsor for this research.

6. Project timetable and milestones

The proposed research will commence on 1st January 2013 and will be completed in 15 months, finishing 31st March 2014. The aim of this proposal is to carry out a Cochrane review. Prior to starting the review it is necessary firstly to register the title of the proposed review with the Cochrane Injuries Group. Checks are performed to ensure that the title has not been registered previously and it is a suitable topic for the Injuries Group. It is then necessary to submit a protocol which is reviewed. This takes approximately four months. Thus to ensure that the proposed research can be completed in 15 months it is necessary to do some work before finding starts. This is reflected in the proposed timetable below.

Pre-funded study

Month -4: Register title of review to Cochrane Injuries Group

Month -4: Submit protocol to Cochrane Injuries Group for review, make any necessary changes

Funded study

Month 1: Devising bibliographical database search strategies, adjusting search strategies to ensure sensitivity, obtaining copies of relevant journals and conference proceedings for hand searching. Commencing search of bibliographic databases.

Month 2: Running database search strategies, organising search of Transport Research

Laboratory database.

Month 3: Commence systematic searching of internet and relevant websites. Commence hand searching of journals and conference proceedings. Inputting potentially relevant studies into Endnote.

Month 4: Commence initial review of titles and abstracts by two reviewers, comparison of findings from two reviewers and resolvement of any disagreements

Month 5: Inputting details of relevant studies into Microsoft Access database, designing data extraction forms.

Month 6: Obtaining copies of full papers, downloading pdfs of full papers where available, contacting authors for copies of full papers, sending off for inter library loans, purchase of reports where necessary. Testing data extraction forms.

Month 7: Commence assessment of full papers for inclusion in the study.

Month 8: Continuing assessment of papers for inclusion, searching reference lists of papers included at this stage.

Month 9: Data extraction, contacting authors for further details.

Month 10: Commence critical appraisal of studies.

Month 11: Inputting data into RevMan, data analyses including subgroup analysis, sensitivity analyses and assessing risk of bias.

Month 12: Analysis of data not included in meta-analysis.

Month 13: Initiate drafting of final report.

Month 14: Writing first draft of report for NIHR, responding to comments from co-applicants and public members, writing final draft report.

Month 15: Dissemination of findings, drafting papers for publication, draft Cochrane review, summarising findings into alternative forms suitable for other audiences.

Milestones:

1 to 6 months:

- completion of searches
- completion of initial review of titles and abstract
- draft data extraction form.

7 to 12 months:

- final papers for inclusion selected
- data extraction complete
- meta-analysis complete.

Month 14:

- first draft of report.

7. Project management

A Study Management Group will be set up to oversee the running and progress of the study. The group will be chaired by the Chief Investigator and will include other co-applicants, the appointed Research Associate/Fellow and Service Users representatives as necessary. The group will meet monthly or as required.

8. Public involvement/service users

Two members of the public are involved in this research: firstly, a member of PEDALS and a retired academic with research interests in safe cycling who has published widely on the topic, and secondly, a Facilitator at PEDALS. PEDALS is a Nottingham based group which campaigns for cyclists in the East Midlands. In addition the study has the support of two further service users, one a representative from Sustrans and the other representing CTC (The national cycling charity). Together they will bring the views of ordinary cyclists to the study. They have agreed to comment on the draft report and advise on dissemination: their experience of working with, and the links they have with local government transport teams

will be invaluable when advising the research team on dissemination of findings for greatest impact.

In addition, Mr Miller, a co-applicant, is a member of PEDALS and was a founder member and chair of BUG (Bicycle Users Group) at Nottingham University Hospitals (NUH) NHS Trust. Mr. Miller acted as a liaison between BUG and NUH NHS Trust Transport Strategy Group and latterly the Steering Group for the Ucycle Nottingham project. Ucycle Nottingham is a project that works with Sustrans and in partnership with Nottingham City Council to increase levels of cycling among staff and students at the University of Nottingham, Nottingham Trent University and Nottingham University Hospitals NHS Trust.

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