

# BMJ Open Primary care interventions to reduce cardiovascular risk behaviours in adolescents: a protocol for a systematic review

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## ABSTRACT

**Introduction:** Health-compromising behaviours are often acquired in adolescence. Alongside broader public health interventions, preventive interventions within primary care have the potential to encourage long-lasting behaviour change by tailoring messages to each individual. The aim of this study is to determine the effectiveness of primary care interventions in reducing the 3 main cardiovascular risk behaviours (smoking, low physical activity and unhealthy diet) in adolescents aged 10–19 years. It is also to identify successful initiatives and ingredients for such success that could be replicated in primary care.

**Methods and analysis:** This systematic review of the literature and meta-analysis will follow the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) recommendations. The following databases will be searched for articles published between January 1990 and December 2016: MEDLINE, EMBASE, PsychINFO, CINAHL, Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, ISRCTN registry. Our search will focus on randomised and cluster randomised controlled trials of interventions conducted in primary care practices to reduce the 3 main cardiovascular risk behaviours in adolescents aged 10–19 years, compared with active (information leaflet, etc) or passive (usual care, etc) control conditions. The primary outcomes will be smoking, physical activity and diet, measured either objectively or by self-report. Secondary outcomes such as body mass index or insulin resistance will also be examined. 2 reviewers will independently screen articles, extract relevant data and assess study quality using the Cochrane risk of bias tool. A meta-analysis will be considered if the number of studies is sufficient and outcomes are sufficiently homogeneous. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria will be used to assess the quality of the evidence.

**Ethics and dissemination:** This systematic review will add to our knowledge on the prevention of cardiovascular disease early in life and these findings will be disseminated through peer-reviewed publications and presentations at relevant conferences.

**Study registration number:** PROSPERO CRD42016028045.

## Strengths and limitations of this study

- This review will use a systematic and comprehensive approach to add to our knowledge about early prevention of cardiovascular disease in primary care.
- It will help identify successful initiatives as well as ingredients for such success in order to contribute to reducing cardiovascular risk in adolescence.
- Since this is a neglected area of prevention research, the number of high-quality studies included in the review is likely to be limited.
- A high level of heterogeneity both between interventions and outcome measurements could limit the strength of the findings emerging from this review.

## INTRODUCTION

In 2015, 25% of all deaths in the world are to be caused by cardiovascular disorders.<sup>1</sup> These disorders represent the first cause of adult mortality and morbidity in high-income countries and are a growing concern in low-income and middle-income countries as well.<sup>2 3</sup>

Health-compromising behaviours acquired in adolescence and young adulthood are major contributors to the development of cardiovascular disorders in later life.<sup>4</sup> Thus, adolescence represents both a period of risk for the acquisition of such behaviours and a period of opportunity to prevent them. Smoking, low physical activity and unhealthy diet are the most prominent cardiovascular risk behaviours in adolescence.<sup>4 5</sup> Findings from population-based surveys such as the HBSC-2010 survey (Health Behaviours in School-Aged Children, in more than 40 high-income and middle-income countries) show that a significant proportion of adolescents are exposed to these risk factors: at the age of 15, 20% smoke at least once a week

(up from 1% at the age of 11 years), two-thirds of adolescents have sedentary behaviours (watching television 2 or more hours a day on weekdays), more than 80% of them report <1 hour a week of moderate-to-vigorous exercise, less than a third eat fruit daily, and 10% of girls and 20% of boys are overweight or obese.<sup>6</sup>

Population approaches may be successful to improve diet, physical activity and smoking habits.<sup>7</sup> Individual approaches at the healthcare level are also important, however, to individualise public health messages and encourage behaviour change.<sup>7</sup> Within a life-course approach to adolescent health, primary care physicians (PCPs) are ideally placed to promote healthy lifestyles and offer preventive care that may influence young people's health well into adulthood.<sup>8</sup> PCPs' role has been highlighted both in the WHO's report on non-communicable diseases and in national strategies.<sup>9</sup> <sup>10</sup> Despite increased recognition of the added value of preventive care, evidence is needed to support its provision since preventive care is time-consuming and often financially unrewarding for practitioners.<sup>11</sup> Until now, little focus has been placed on the effectiveness of preventive interventions in childhood to ensure ideal cardiovascular health and reduce cardiovascular risk later in life.<sup>12</sup> We found no previous review of the evidence in relation to interventions for the prevention of the three main cardiovascular risk behaviours in adolescents attending primary care.

The aim of this systematic review of the literature is therefore to determine the effectiveness of primary care interventions in reducing the three main cardiovascular risk behaviours in adolescents. Our objectives are to:

1. Identify and summarise the evidence about the effectiveness of interventions in primary care to reduce the three main cardiovascular risk behaviours (smoking, low physical activity and unhealthy diet) in adolescents (aged 10–19 years, according to the WHO definition).
2. Identify the features associated with the effectiveness of interventions, such as communication style (eg, the use of motivational interviewing), mode of delivery (eg, entirely face to face or supported by a web-based tool), duration and frequency.
3. If possible, to measure the effect size of the interventions in reducing each of the three main cardiovascular risk behaviours.

## METHODS AND ANALYSIS

This protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) guidelines.<sup>13</sup> It is registered in the PROSPERO registry (CRD42016028045).

### Eligibility criteria

#### Study characteristics

Inclusion will be limited to randomised controlled trials (RCTs) and cluster RCTs (cRCTs) published in any

language (but with an abstract in English) between January 1990 and December 2015. Completed but yet unpublished trials identified through trial registration platforms will also be eligible for inclusion. Non-RCTs, controlled before-after studies and interrupted time series will, however, also be considered if the number of identified RCTs is low (five or less).

### Population

Studies will be considered if the tested intervention targets adolescents between the ages of 10 and 19 years attending a primary care practice. Studies including participants younger than 10 years will also be included if data in relation to the target age group can be analysed separately. Since young adults are often considered within a developmental continuum from adolescence into adulthood, studies involving participants up to the age of 24 years will also be eligible, as long as they also include adolescents aged between 10 and 19 years and provide data for this age group that can be considered separately.

### Intervention

Interventions that aim to address the three main cardiovascular risk behaviours, either alone or in combination, will be eligible. The aim of the interventions should be to reduce tobacco use, increase physical activity/reduce sedentary behaviour and/or promote a healthy diet (fulfilling criteria for a healthy diet of the American Heart Association).<sup>14</sup> Interventions delivered by the PCP or any other professional working within the primary care practice will be considered, as well as interventions involving multimedia tools targeting patients identified in the primary care practice.

### Comparator or control

Studies comparing the intervention either to an active control (eg, information leaflet, intervention by specialist) or passive control (eg, usual care, waiting list, etc) will be eligible.

### Outcomes

Studies will be included if they assess the effect of the intervention on one or several of the following outcomes:

- ▶ Smoking: objectively measured (cotinine levels) and/or self-reported (subjective);
- ▶ Physical activity/sedentary behaviour assessed either objectively (pedometer, etc) or subjectively, preferably using standardised tools;
- ▶ Diet: objectively measured (biomarkers for dietary habits) and/or self-reported (subjective), preferably using standardised tools.

*Secondary outcomes:* for studies of preventive interventions targeting physical activity and/or dietary habits, outcomes such as body mass index (BMI), blood pressure, blood insulin levels will also be recorded if available.

## Data sources and search

The following databases will be searched for articles published between January 1990 and December 2016: MEDLINE, EMBASE, PsychINFO, CINAHL, Cochrane Central Register of Controlled Trials, ClinicalTrials.gov, ISRCTN registry. We will also search the reference lists of included studies and contact authors of included studies to ask about their knowledge of any additional studies not identified in the initial search.

The search strategy will use a combination of medical subject headings (MeSH) and free-text words for the population, intervention, outcomes and study design, adapted to each database. No limits will be applied. [Table 1](#) presents the initial keywords on which the full search strategy will be developed. A search strategy for PubMed is presented in online supplementary appendix 1.

## Data management

Endnote software will be used for data management. All the results of literature searches will be imported into the program and duplicates removed by the main reviewer.

## Selection process

Selection of relevant studies will follow the PRISMA guidelines, using a three-step process, all carried out by two reviewers, with a third reviewer available to help resolve any disagreement. All identified titles and abstracts will first be screened for inclusion/exclusion criteria, and then the full texts of potentially eligible articles meeting inclusion criteria on the basis of their title/abstract. At each step of the selection process, reasons for inclusion/exclusion will be recorded.

## Data extraction

Using a process similar to the one developed in a previous systematic review by our team, we will develop and

pilot test a data extraction form to record the following data: study authors, country, setting, population and participant sociodemographic characteristics, interventions and their specific features, control condition, outcomes (both subjective and objective, at all follow-up time points) and timing of measurements, and information to be used to assess risk of bias.<sup>15</sup> Two reviewers will independently test the data extraction form on three articles and the form will then be adapted to ensure the reliability of the data extraction process. The two reviewers will then extract data for each included study independently and any disagreement will be resolved through discussion, if needed involving the third reviewer in order to reach consensus.

## Missing data

Attempts will be made to contact study authors via email to obtain clarification if data are incomplete in the study report and we will allow a delay of 6 weeks to receive a response following two email attempts. We do not plan to use imputation to deal with missing data.

## Assessing risk of bias

Two reviewers will independently assess risk of bias for each included study. They will use the tool developed by the Cochrane Collaboration to assess and report risk of bias in the following domains: sequence generation, allocation concealment, blinding of participants and researchers, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias (including conflicts of interest and study sponsorship).<sup>16</sup> Risk of bias will be described as low, unclear or high, and reasons for each assessment will be documented.

## Evidence synthesis

We will produce a narrative synthesis of the data extracted from the included studies and present it in a text and summary tables. In addition to the evidence in relation to the effectiveness of different interventions, a special emphasis will be placed on presenting key components of successful interventions.

## Data analysis

Descriptive statistics will be used to summarise general data in particular in relation to participants and outcomes. If the number and homogeneity of retrieved studies are sufficient, we will pool outcome estimates of intervention effectiveness and conduct meta-analyses using random-effects models. Separate meta-analyses will be conducted for each of the three risk behaviour outcomes. If multiple measures are used to measure an outcome, we will favour meta-analysis of subjective measures as they are likely to be reported in the largest number of studies. However, we also plan to conduct a meta-analysis of outcomes measured objectively if these are reported in more than two studies. Long-term outcomes will be favoured over short-term outcomes for the

**Table 1** Initial keywords on which the literature search will be built

PICOS	Keywords
Population	Adolescents, Teenagers, Youth Primary Health Care, Family practice, General practice General practitioner, Family practitioner, Family doctor, Family physician, Primary Care Physician
Intervention	Intervention, brief intervention, behavior change, counselling
Comparator/ control	NA (no specific control condition will be searched in order to avoid narrowing the search)
Outcome	Smoking, Physical activity, Diet, cardiovascular risk
Study design	Randomized controlled trial, cluster randomized controlled trial

meta-analysis if the number of studies reporting them is sufficient. If length of follow-up is very variable, these data will be introduced as co-variables in the analyses.

Dichotomous outcomes will be presented as risk ratios with 95% CIs. For continuous outcomes, effect sizes will be presented using either weighted mean differences when similar outcome measures have been used or, if possible, standardised mean differences where different measures of a same outcome have been used.

Statistical heterogeneity will be explored using the  $I^2$  statistic. If substantial heterogeneity ( $I^2 > 50\%$ ) is present and the number of included studies is sufficient, we will use subgroup analyses (eg, younger vs older adolescent participants, interventions targeting one vs several risk behaviours, single session vs multiple component intervention, etc) to attempt to identify reasons for heterogeneity. If some studies are at high risk of bias, sensitivity analyses will be conducted excluding these studies to assess the extent to which they influence the findings.

### Assessment of possible reporting bias

If the number of studies included in a meta-analysis is sufficient (~10 studies), we will investigate possible reporting bias using funnel plots.

### Assessment of the strength of the evidence

The quality of the evidence in relation to the effect of interventions on the three main outcomes will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines.<sup>17</sup> The evidence will be assessed across the following domains: design and risk of bias, consistency, directness, precision and publication bias (which includes possible role of sponsor).

## ETHICS AND DISSEMINATION

Ethics approval will not be necessary as no primary patient data will be collected.

Worldwide, the increasing burden of disease due to non-communicable diseases, including cardiovascular diseases, has shed light on the need to place a stronger emphasis on prevention. Interventions targeting adolescents can act at an age when risk behaviours spread their roots and have the potential to influence the health of individuals throughout their adult life. Alongside broader public health interventions, preventive interventions within primary care have the potential to encourage long-lasting behaviour change by better tailoring messages to each individual. This systematic review will add to our knowledge on the prevention of cardiovascular disease. In particular, it will help us identify evidence-based primary care interventions for adolescents for which implementation efforts should be promoted. It will allow us to identify successful initiatives and, hopefully, also ingredients for such success, as well as possible gaps in knowledge in relation to effective interventions opening paths for further research. These

findings will be disseminated through peer-reviewed publications and presentations in relevant conferences. Our review will also serve to define a future research agenda in this as yet much neglected domain of prevention research.

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**Contributors** DMH conceptualised the review and drafted the manuscript. She is the guarantor. EP, BC and J-MG critically revised the protocol. EP developed the search strategy presented in the protocol, together with DMH. All authors approved the final version of the protocol for publication.

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