

BMJ Open Effective components of exercise and physical activity-related behaviour-change interventions for chronic non-communicable diseases in Africa: protocol for a systematic mixed studies review with meta-analysis

Chinonso N Igwesi-Chidobe,^{1,2} Emma L Godfrey,^{1,3} Andre P Kengne^{4,5}

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For numbered affiliations see end of article.

Correspondence to

Chinonso N Igwesi-Chidobe; chinonso.igwesi-chidobe@kcl.ac.uk and chinonso.chidobe@unn.edu.ng

ABSTRACT

Introduction: Chronic non-communicable diseases (NCDs) account for a high burden of mortality and morbidity in Africa. Evidence-based clinical guidelines recommend exercise training and promotion of physical activity behaviour changes to control NCDs. Developing such interventions in Africa requires an understanding of the essential components that make them effective in this context. This is a protocol for a systematic mixed studies review that aims to determine the effective components of exercise and physical activity-related behaviour-change interventions for chronic diseases in Africa, by combining quantitative and qualitative research evidence from studies published until July 2015.

Methods and analysis: We will conduct a detailed search to identify all published and unpublished studies that assessed the effects of exercise and physical activity-related interventions or the experiences/perspectives of patients to these interventions for NCDs from bibliographic databases and the grey literature. Bibliographic databases include MEDLINE, EMBASE, CENTRAL (Cochrane Central Register of Controlled Trials), PsycINFO, CINAHL and Web of Science. We will include the following African regional databases: African Index Medicus (AIM) and AFROLIB, which is the WHO's regional office database for Africa. The databases will be searched from inception until 18 July 2015. Appraisal of study quality will be performed after results synthesis. Data synthesis will be performed independently for quantitative and qualitative data using a mixed methods sequential explanatory synthesis for systematic mixed studies reviews. Meta-analysis will be conducted for the quantitative studies, and thematic synthesis for qualitative studies and qualitative results from the non-controlled observational studies. The primary outcome will include exercise adherence and physical activity behaviour changes. This review protocol is reported according to Preferred Reporting Items for Systematic reviews and Meta-Analysis protocols (PRISMA-P) 2015 guidelines.

Ethics and dissemination: There is no ethical requirement for this study, as it utilises published data. This review is expected to inform the development of exercise and physical activity-related behaviour-change interventions in Africa, and will be presented at conferences, and published in peer reviewed journals and a PhD thesis at King's College London.

Protocol registration number: This study was registered with the International Prospective Register of Systematic Reviews (PROSPERO) on 22 January 2015 (registration number: PROSPERO 2015: CRD42015016084).

INTRODUCTION

Rationale

Eighty per cent of worldwide deaths from chronic non-communicable diseases (NCDs) occur in low and middle-income countries, of which 80% occurred in only 23 countries.¹ Nigeria, South Africa, Egypt, Congo and Ethiopia were the African countries among these. The main chronic NCDs in African countries include cardiovascular diseases, diabetes, cancer and chronic respiratory disease.² Bone and joint disorders also contribute significantly to the burden of chronic conditions in the region.³ There have been reports of an interrelation between common NCDs and bone and joint disorders.⁴ For instance, according to the Centres for Disease Control and Prevention,⁵ obesity is a common risk factor for the aforementioned chronic conditions. Furthermore, obesity and chronic pain are believed to have a multifactorial link with no single identifiable causative relationship between the two.⁴ Obesity and chronic pain may arise due to genetic,

metabolic and psychological factors.^{6 7} Obesity is hypothesised to cause pain due to increased mechanical loading while chronic pain may lead to obesity as a result of physical inactivity and increased eating,⁴ further increasing the risk for chronic diseases.

Behaviour-change interventions for chronic conditions often target change in behaviour,⁸ defined as coordinated sets of activities designed to change particular behaviour patterns.^{9 10} A significant component of behaviour change interventions may be non-pharmacological,^{11 12} with exercises to increase physical activity being of utmost importance.¹³ Evidence-based clinical practice guidelines for the treatment of NCDs recommend exercise training to promote physical activity.^{14–18} This is known to improve physiological functioning, cognitive, emotional, social and psychosocial functioning as well as to alter health beliefs and increase acceptance of chronic disease.¹³ Furthermore, systematic reviews and meta-analysis of randomised controlled trials (RCTs) suggest that exercises promoting physical activity may be effective in reducing disability and improving chronic pain.^{19–24}

The challenges presented by chronic diseases in Africa may undermine the development of effective and sustainable primary and secondary interventions.²⁵ Evidence suggests that implementing such non-pharmacological interventions may be difficult in Africa, due to the predominant biomedical model of practice within an acute infective healthcare model.²⁶ Results from a qualitative study that explored treatment adherence among patients with diabetes, hypertension, or both, in a South African community, suggest that factors that may influence adherence to behaviour-change interventions may be multifactorial, including the attribution of the origin of the illness, experiences with the public healthcare system, concerns about the consequences of poor adherence, financial problems, transport problems and social support.²⁷ The intervention in the study, however, was predominantly pharmacological. A recent qualitative exploration of non-specific chronic low back pain in rural Nigeria suggests that patients may view non-pharmacological interventions as illegitimate treatment possibly influenced by the predominant acute infective model of healthcare.²⁸ This suggests that poor treatment adherence may be more pronounced, with interventions having little or no pharmacological component. Therefore, developing potentially effective exercise and physical activity-related behaviour-change interventions for chronic non-communicable conditions in Africa requires an understanding of the components that may increase patients' adherence to these interventions and make them effective in this context. This is especially relevant, as exercise programmes that promote adherence to behaviour change may be underpinned by theories that may be informed by contextual factors irrespective of the chronic condition.¹³ This systematic review aims to determine the effective components of exercise and physical activity-related

behaviour-change interventions for chronic NCDs in Africa, by combining quantitative and qualitative research evidence. This protocol for a systematic mixed studies review with meta-analysis is reported according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses Protocol (PRISMA-P) 2015 guidelines.^{29 30}

Objectives

To conduct a systematic mixed studies review and meta-analysis, to determine the effective components of exercise and physical activity-related behaviour-change interventions for chronic NCDs in Africa, by combining qualitative and quantitative research evidence.

Review questions

The current review will seek to address the following main research question:

What are the effective components of exercise and physical activity-related behaviour-change interventions for common chronic NCDs in adult Africans, based on reports from studies published from inception of databases to July 2015?

To answer the above objective, secondary research questions to be addressed include:

1. What is the effectiveness of exercise and physical activity-related behaviour-change interventions for managing common chronic NCDs in Africa?
2. What are the experiences and perspectives of adult African patients on exercise and physical activity-related behaviour-change interventions for managing common chronic NCDs?

METHODS

A two stage review will be carried out. Studies meeting the listed broad eligibility criteria will be described. Finally, the studies that meet the narrower focus on adherence to the exercise and physical activity-related interventions will be further reviewed.

Eligibility criteria

Eligibility criteria to be considered for selecting studies in the review include:

Inclusion criteria

1. Language: There will be no language restriction.
2. Participants: We will include studies investigating adult African patients (≥ 18 years) diagnosed with chronic NCDs in Africa. Studies in people of African ancestry not residing in Africa will not be included. The targeted chronic diseases will include chronic pain (musculoskeletal pain including degenerative conditions such as osteoarthritis or osteoporosis affecting the back, hip, knee, ankle, shoulder, elbow, wrist, neck; fibromyalgia and chronic fatigue syndrome), hypertension, diabetes or obesity, using standard diagnostic criteria. Chronic pain will be

considered any pain that has duration of at least 3 months. We will use WHO's definitions of the named chronic NCDs.

3. **Interventions:** Exercise and physical activity-related behaviour-change interventions for patients with chronic diseases in Africa. As many such interventions may be complex, comprising of several components, interventions in addition to exercises and physical activity, including medications, nutrition, health education, psychological interventions, social interventions, psychosocial or any form of patient support, will also be included. Interventions might involve contact of patients with lay individual(s) or peer groups, and/or health professional(s) or alternative practitioners. Contact might be face-to-face, telephone-based or web-based.
4. **Study settings:** Health centres, clinics, hospitals or community settings in rural or urban Africa.
5. **Study designs:** RCTs and non-RCTs (quasi-RCTs, controlled clinical trials (cross-over trials), controlled before and after trials and non-controlled before and after studies) that evaluated the effects of these interventions will be included. Observational studies that evaluated the effects of these interventions; or evaluated the factors that influence adherence to the interventions; or explored the factors that influence the effectiveness of the interventions, will be included. Qualitative studies that evaluated experiences or perspectives of patients to these interventions will be included.
6. **Comparators/control:** Any type of control will be included. Intervention studies without control groups will also be included.
7. **Timing:** There will be no restriction based on the length of the administration of the interventions or the follow-up of outcomes.
8. **Outcomes:** The primary outcome will include attendance rate for the exercise and physical activity-related interventions where there was no follow-up period postintervention; or the rate of exercise adherence and physical activity behaviour changes postintervention where there was a follow-up period postintervention. Secondary outcomes will include other clinical outcomes such as disability/physical function, pain and change in blood pressure, body mass index and blood sugar. Psychological outcomes will assess factors such as self-efficacy, and change in knowledge, attitudes, quality of life, confidence, self-esteem, well-being, vitality, social functioning and coping. When clinical outcomes are reported by individual studies, these will be analysed and graded. If a given clinical outcome is not reported on, we will analyse and grade the closest surrogate outcome, if available. All outcomes will be collected as they are reported in individual studies including dichotomous or continuous outcomes. Quality of life measures will be collected only if they are measured with generic validated tools. We will extract definitions of

outcomes as they are reported in the included studies due to the possible changes in disease definitions over time.

Exclusion criteria

1. Studies without an exercise or physical activity component.
2. Narrative reviews, systematic reviews, opinion papers, letters and any publication without primary data and/or explicit description of the methods.
3. Duplicate publications from the same study. For those studies published in more than one journal/conference, the most comprehensive and recent report will be used.

Information sources

Search strategy for identifying relevant studies will comprise two stages including the search of bibliographic databases and the grey literature; and the selection of studies for inclusion. The search strategy was developed and pilot-tested in collaboration with two health information specialists (librarians), at King's College London, with several years of experience in systematic reviews, not associated with the study.

Identifying research evidence through bibliographic databases

1. Studies will be identified using a predefined comprehensive and sensitive strategy (see online supplementary appendix) to search bibliographic databases including MEDLINE (OvidSP, 1946 onwards), EMBASE (OvidSP, 1980 onwards), PsycINFO (OvidSP, 1806 onwards), CENTRAL (Cochrane Central Register of Controlled Trials, current issue), CINAHL (EBSCO) and ISI Web of Science (Science Citation Index, 1900 onwards) until 18 July 2015. We will search the following African regional databases: African Index Medicus (AIM) and AFROLIB, which is the WHO's regional office database for Africa, until 18 July 2015. The search strategy will be informed by the African search filter, reported to have good sensitivity (74% for Medline and 73% for EMBASE), and improved precision from 1.3% to 9.4% in Medline and from 5% to 28% in EMBASE.³¹ The African search filter comprises names of each country in Africa, and truncated terms to capture studies indexed using regional, instead of country-specific, names. While the names of the countries in the filter are primarily in English, names in the relevant official language for each country (if different from the English version) were also included. Similarly, for countries that have changed names over time, both names were included.³¹
2. Trial register and Directory of Open-Access repository websites including <http://www.ClinicalTrials.gov>, <http://www.who.int/trialssearch/> and <http://www.opendoar.org>, respectively, will be searched. In addition, Web of Science Conference Proceedings and

WorldCat Dissertations and theses will be searched to identify the grey literature. Extra evidence will be identified from the reference lists of included articles. Experts in Africa will be contacted to help in identifying other potential sources of information, if required.

The search strategy was developed and pilot-tested following instructions in the Cochrane handbook for systematic reviews of interventions,³² and the Centre for Reviews and Dissemination's guidance for undertaking reviews in healthcare.³³ The search strategy was subsequently critically evaluated, piloted and edited in consultation with the two health information specialists. See the online supplementary appendix for detailed search strategy for all the global databases. This search strategy will be adapted for the African regional databases.

Study records

Data management

Literature search results will be imported into Endnote software for deduplication of records. The deduplicated records will be uploaded to Eppi-Reviewer, an internet based software programme to facilitate collaboration among the reviewers during the process of study selection. The review team will develop and test screening questions and forms for the first and second levels of assessment based on the eligibility criteria. Abstracts, full texts of articles and the screening questions will be uploaded to Eppi-Reviewer. The screening questions will be piloted and refined by the review team prior to the screening exercise.

Selection process

Screening will be performed in two stages: initial screening of titles and abstracts using the inclusion and exclusion criteria to identify potentially relevant articles will be carried out by reviewer 1. Initial screening results will be independently cross-checked by reviewer 2. Initial screening of titles and abstracts will be followed by screening of full articles of these papers by reviewer 1. This will be cross-checked by reviewer 2 and disagreements at this stage will be resolved by consensus or consultation with reviewer 3. We will seek additional information from study authors, if necessary, to resolve questions about eligibility. The reasons for excluding studies will be recorded. A flow chart will be used to trace the overall process.

Appraisal of the quality of included studies

The quality of all included studies will be assessed using the Mixed Methods Appraisal Tool (MMAT).³⁴ The MMAT was developed for systematic reviews that include qualitative, quantitative and mixed methods studies, allowing the simultaneous appraisal of the quality of the most common types of empirical studies including mixed methods primary studies.³⁴ Additionally, the MMAT has been pilot-tested for content validity, efficiency and reliability.³⁵ For the intervention studies,

the following will be assessed: appropriateness of the study design to the research objective, risk of bias in included studies, choice of outcome measures, statistical issues, quality of reporting, quality of the intervention and generalisability of the study results. The risk of bias in included studies will be assessed using the Cochrane Collaboration's risk of bias tool including sequence generation, allocation concealment, blinding, completeness of outcome data, possibility of selective outcome reporting and other potential threats to validity.³⁶

Data collection process

Reviewer 1 will extract the data and these will be confirmed independently by reviewer 2. Inconsistencies will be resolved by consultation with reviewer 3. Quantitative data will be extracted from the quantitative studies using an adaptation of the Cochrane Consumers and Communication Review Group's Data Extraction Template for Cochrane Reviews.³⁷ Qualitative data will be extracted from the included studies using an adaptation of the Supplementary Guidance for Inclusion of Qualitative Research in Cochrane Systematic Reviews of Interventions.³⁸ Some eligible studies may lack some relevant data; we plan to contact the corresponding authors of such studies to request any missing information that is relevant to the review (maximum of three email attempts).

Data items

The variables for which data will be collected include: the country where the study was conducted, the year of publication, the journal and language of publication, context and participants' characteristics (including age range, gender composition, inclusion and exclusion criteria), sample size (including where relevant by intervention group), targeted chronic condition and diagnostic criteria, study design, components of the intervention, the context within which the intervention was administered, who delivered the intervention, the length of the intervention and follow-up, the drop-out rate, outcome(s) measured (including clinical and psychological outcomes), methods for ascertaining/measuring the outcome(s), funding sources, results and comments.

Outcomes and prioritisation

The primary outcome will include attendance rate for the exercise and physical activity-related interventions in studies with no follow-up period postintervention, or the rate of exercise adherence and physical activity behaviour changes postintervention in studies with a follow-up period postintervention. Exercise adherence will be defined by the extent to which a patient acts in accordance with the advised interval, exercise dose and exercise dosing regimen. Physical activity behaviour changes will be defined by changes in patients' bodily movements that result in energy expenditure such as daily routine household, job-related activities or recreational

activities. Attendance or adherence rate is chosen as the primary outcome as this may be relevant across diverse chronic conditions, potentially enabling a meta-analysis. Additionally, this review seeks to identify factors that might increase patients' adherence to exercise and physical activity-related interventions in Africa. Increased adherence might then translate into increased effectiveness of these interventions in Africa. In contrast, some of the secondary outcomes might be more relevant in some chronic conditions than in others.

Secondary outcomes will include other clinical outcomes: disability/physical function, pain, blood pressure, body mass index and blood sugar, using validated measures. Psychological health outcomes (self-efficacy, knowledge, attitudes, quality of life, confidence, self-esteem, well-being, vitality, social functioning, coping) will be assessed using validated measures. Outcome definitions will be based on the definitions used in the included studies. For crossover trials, we will extract data from the first period only, because of potential carry-over effects.

Risk of bias in individual studies

To facilitate the assessment of possible risk of bias for each intervention study, we will collect information using the Cochrane collaboration tool for risk of bias assessment including: sequence generation, allocation concealment, blinding, incomplete outcome data (drop-outs and withdrawals) and selective outcome reporting (table 8.5a in the Cochrane Handbook for Systematic Reviews of Interventions).³² The procedures undertaken to assess each domain for each study will be explicitly described and rated as 'high risk' or 'low risk'. The risk of bias in a study will be reported as unclear if there were insufficient details in the original study. In such instances, the study investigators will be contacted to provide the required details. The judgements for the risk of bias will be made independently by reviewer 1 and 2, based on the criteria for judging the risk of bias (table 8.5c in the Cochrane Handbook for Systematic Reviews of Interventions).³² Disagreements between reviewer 1 and 2 will be resolved by consultation of reviewer 3. We will consider each item in the risk of bias assessment independently, without assigning an overall score, to provide the overall strength of evidence. Appraisal of the quality of the included studies will be performed after study selection during data extraction and synthesis, and the strength of evidence for the findings of this review will be reported.

Data synthesis and analysis, including assessment of heterogeneity

Data will be synthesised in two phases using a mixed studies synthesis design—the sequential explanatory synthesis³⁴—to answer the research questions.

Phase 1 will be used to answer the first research question: "What is the effectiveness of exercise and physical activity-related behaviour-change interventions for

managing common chronic non-communicable diseases in Africa?" In phase 1, the quantitative results of clinical trials and controlled observational studies, and the quantitative results of mixed methods clinical trials and controlled observational studies that assessed the effectiveness of these interventions, will be tabulated, compared and pooled in evidence tables. Effectiveness of exercise and physical activity-related behaviour change interventions in Africa will be determined by assessing the presence of differences in effects calculated statistically using a meta-analysis.³⁴ Narrative synthesis will be used for the data from these quantitative studies that cannot be analysed statistically.

Phase 2 will be used to answer the second research question: "What are the experiences and perspectives of adult African patients on exercise and physical activity-related behaviour-change interventions for managing common chronic non-communicable diseases?" In phase 2, the results of the qualitative studies and the qualitative results of mixed methods studies will be integrated using qualitative thematic analysis. Additionally, patients' perspectives and experiences of the exercise and physical activity-related interventions will be obtained qualitatively from the uncontrolled observational studies using taxonomy of the study results.³⁴ The obtained qualitative data will be analysed thematically together with the results from the qualitative studies. Interpretation of the phase 2 results will be used to determine the useful as well as the unhelpful aspects of the interventions from the patients' perspectives.

Finally, interpretation of phase 1 and phase 2 results will be performed³⁴ to answer the overall objective of the systematic review: "What are the effective components of exercise and physical activity-related behaviour-change interventions for managing common chronic non-communicable diseases in adult Africans." The effective components of the interventions will be ascertained by comparing the effectiveness of the interventions that contained the previously identified useful components identified qualitatively from the qualitative studies and uncontrolled observational studies, with the interventions that did not contain these components of the interventions.

Two tables of characteristics will be designed for included studies and sorted by the year of publication.³⁹ One of the tables will be for the clinical trials and controlled observational studies, and the other table will be for the qualitative and uncontrolled observational studies.

The table for the clinical trials and controlled observational studies will detail authors' references, country, study designs, chronic condition, sample size, gender, age range, socioeconomic status, outcomes measured, scales of measurement, objectives of the intervention, components of the intervention, control arm content, format and provider of intervention, setting (rural vs urban), duration of intervention and duration of follow-up and outcomes.⁴⁰

The table for the qualitative and uncontrolled observational studies will include the authors' references, country, study designs, chronic condition, sample size, gender, age range, socioeconomic status, study objectives, setting (rural vs urban), data collection format, outcomes or themes.^{39 40}

Statistical analysis

For our statistical analysis of the clinical trials and controlled observational studies, the primary outcome will include attendance or adherence rate to the exercise and physical activity-related interventions. Secondary outcomes will include other clinical outcomes: disability/physical function and pain, and change in blood pressure, body mass index and blood sugar, using validated measures. Psychological health outcomes (self-efficacy, knowledge, attitudes, quality of life, confidence, self-esteem, well-being, vitality, social functioning, coping) will be assessed using validated measures. Outcome definitions will be based on the definitions used in the included studies. For crossover trials, we will extract data from the first period only, because of potential carry-over effects. Results will be pooled for meta-analysis for homogenous studies with similar characteristics in terms of design and comparator using a random effects model. Narrative synthesis will be used for the rest of the data to explore the relationship and findings within and between the included studies, in line with the guidance from the Centre for Reviews and Dissemination.³³ Results will be presented in order of primary outcomes followed by additional outcomes.

The statistical strategy will involve finding the absolute change in means from the baseline (and the 95% CIs) in the intervention and control groups where baseline data are available. Relative percentage change between postintervention values in the intervention and control groups will be used where baseline data are not reported. The risk of the outcome in the intervention group will be compared with the control group, with a risk difference calculated from the absolute difference between the treatment and control groups, or the relative risk (or equivalents) for outcome measures that are dichotomous. A record of all adverse effects such as death or worse clinical effects will be documented.

Treatment effects will be assessed where possible using risk ratio (RR) with 95% CI, as RR is more intuitive than OR. Furthermore, clinicians often interpret OR as RR leading to overestimation of effects. Weighted mean differences with 95% CIs will be used for continuous outcomes. Standardised mean differences at 95% CIs will be used if different measurement scales are used. Skewed data and non-quantitative data will be reported descriptively.

Clinical, methodological and statistical heterogeneity might be significant because of diverse conditions, populations and interventions, and study designs, methods and outcomes, respectively. Heterogeneity will be assessed through the Cochran's χ^2 test, based on a 10%

level of significance cut-off. Heterogeneity will further be quantified with the use of I^2 for which values of 25%, 50% and 75% indicate, respectively, low, medium and high heterogeneity.⁴¹ Data analysis will use STATA V.12 statistical software and R statistical software (V.3.0.32014-03-04, the R Foundation for Statistical Computing, Vienna, Austria).

Sensitivity analysis

Subgroup analyses will be used to determine the influence of gender, disease condition and rural versus urban habitation on the results.

Meta-biases

Data from studies published only as abstracts will be added to the meta-analyses to determine if these influenced results. If possible, an investigation of the impact of publication bias will be made via funnel plots and Egger test.⁴²

Qualitative data analysis

For qualitative data analysis of the qualitative studies, mixed methods studies and non-controlled observational studies, thematic synthesis⁴³ will be used to synthesise the qualitative data following these steps:

1. Free line-by-line coding of the findings of primary qualitative studies or qualitative results of mixed methods studies. We will code non-controlled observational studies using a qualitative hybrid deductive-inductive analysis with concept mapping.³⁴ Study findings will be taken as all of the text labelled as results or findings. The non-quantitative data in the entire results section of the included studies will be coded.
2. Organisation of free codes into related areas to construct descriptive themes.
3. Development of analytical themes from the interpretation and abstraction of the descriptive themes into higher order explanations.

Each of these stages of qualitative analysis will be validated by the review team by comparing the generated codes and themes with the results of the primary studies.

Confidence in cumulative evidence

The quality of evidence of the studies will be assessed to determine the confidence in cumulative estimates in the systematic review. This will be judged using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.⁴⁴ The quality of evidence will be assessed across the domains of risk of bias, consistency, directness, precision and publication bias. The quality of a study will be rated as high where further research is unlikely to change the effect estimates, moderate where further research is likely to have an important impact on the effect estimates or change the estimate, low where further research is very likely to have an important impact on the effect estimates and

change the estimate or very low where the estimate of effects is very uncertain.

Reporting of this review

The current systematic review will be reported following the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) Statement.⁴⁵ Where relevant, reporting will be adapted to make sure that all items relevant to the review are included in the report. A PRISMA checklist will be published with the final report.

Potential amendments

We do not intend to make amendments to the quantitative aspects of this systematic mixed studies review protocol based on the findings from the included studies, to avoid the introduction of outcome reporting bias. This is because quantitative studies are more easily influenced by publication bias and the manifestations of these biases are more easily assessed. Any unforeseen amendments will not be influenced by the results of the included studies, and will be approved by the authors of this protocol. Documentation and implementation of probable amendments will be carried out by the first author.

Ethics and dissemination plans

The current systematic review utilises data from published studies, therefore, ethics approval is not a requirement. This review is expected to inform the development of exercise and physical activity-related behaviour-change interventions in Africa. The results from this study will be published in peer-review journals and as a PhD thesis at King's College London. Findings will also be presented at conferences and, where possible, shared with relevant health authorities. We further plan to update the review over time as appropriate.

Author affiliations

¹Faculty of Life Sciences and Medicine, Department of Physiotherapy, Division of Health and Social Care Research, King's College London, London, UK

²Faculty of Health Sciences and Technology, Department of Medical Rehabilitation, College of Medicine, University of Nigeria (Enugu Campus), Enugu, Nigeria

³Department of Psychology, Institute of Psychiatry, Psychology and Neuroscience, King's College London, London, UK

⁴Non-Communicable Diseases Research Unit, South African Medical Research Council, Cape Town, South Africa

⁵Department of Medicine, Groote Schuur Hospital, University of Cape Town, Cape Town, South Africa

Collaborators Professor Sheila Kitchen; Dr Isaac O Sorinola.

Contributors CNI-C conceived of the systematic mixed studies review and designed the protocol, drafted the manuscript, developed the search strategy and pilot searched the databases (assisted by two King's College London health information specialists/librarians). ELG and APK contributed to the development of the review protocol, selection criteria, the risk of bias assessment strategy and data extraction criteria, and provided critical revision of the manuscript. APK provided critical revision of the search strategy and gave statistical advice. All authors read, provided feedback and approved the final version of the manuscript to be published. CNI-C is the guarantor.

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Data sharing statement All necessary information is included in this manuscript.

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