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Physical activity containing behavioural interventions for adults living with modifiable chronic non-communicable diseases in Africa: A systematic mixed-studies review

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Abstract

Background

Physical activity improves physiological, cognitive and psychosocial functioning in chronic non-communicable diseases (NCDs). This study reviewed papers on effects and patients' experiences of physical activity interventions for chronic NCDs in Africa.

Methods

We conducted a systematic review of clinical and qualitative studies by searching eight bibliographic databases and grey literature until April 19, 2017. The mixed-methods appraisal and Cochrane Collaboration's tools were used for quality and risk of bias assessments. Three-stage sequential explanatory syntheses was done.

Results

One randomised controlled trial (RCT), 2 non-controlled before-and-after studies, and 2 qualitative studies of diabetic South African and Reunion patients were included. Exercise and sports unrelated with home and occupational activities were increased in the long term (1 year: moderate quality evidence) and short term immediately after a 4-week intervention (low quality evidence). There was conflicting evidence of intervention effects on home and occupational physical activities. Behaviour change techniques improving chronic disease knowledge, addressing environmental barriers and stimulating/supporting physical activity were important to patients. Procedure-related components – health professional training and adequate health facility were important to patients but were not addressed.

Conclusion

High quality RCTs are needed to confirm the intervention components for improving physical activity for chronic NCD management in Africa.

Key words: Physical activity, Behaviour change, Chronic non-communicable diseases, Diabetes, Africa

Introduction

Eighty percent of chronic non-communicable disease (NCD) mortality occurs in developing countries, particularly in Africa[1]. The commonest NCDs include cardiovascular diseases, diabetes, cancer and chronic respiratory diseases[2], with positive correlation between NCDs and bone and joint disorders[3]. Obesity is a common risk factor for NCDs, and a multifactorial link exists between obesity and chronic pain including genetic, metabolic, psychological and mechanical factors [4-6]. Additionally, chronic pain and exercise incapacity are associated with NCDs [7]; for example people with chronic back pain have a greater risk of all-cause and cardiovascular mortality [8].

Evidence-based treatment guidelines for NCDs recommend physical activity to improve physiological, cognitive, emotional, social and psychosocial functioning, alter health beliefs, increase acceptance of chronic disease, and reduce disability [9-19]. Systematic reviews suggest that specific interventions can increase physical activity [20]. This reverses or reduces chronic disease progression and premature deaths [21], and can reduce the pain and disability associated with chronic musculoskeletal pain [18, 22, 23].

For adults aged 18 to 64 years, the World Health Organisation recommends 150 minutes of moderate-intensity aerobic physical activity or at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week, or an equivalent combination of moderate-intensity and vigorous-intensity physical activity; plus muscle strengthening activities involving major muscle groups done on 2 or more days a week [24]. However, independent of gender, ethnicity and income, more than half of all adults in Africa are inactive [25].

NCDs require ongoing management over years or decades, and need a coordinated health care model centred on patients' circumstances to facilitate self-management skills and behaviour change [26]. However, behaviour patterns are deeply embedded in people's cultural, social and economic characteristics[27], and hence partly controlled by intrapsychic and external factors [28], irrespective of the chronic condition [29].

For the purposes of this study, behaviour-change interventions are coordinated activities designed to change particular behaviours [28]. They are often complex comprising many interacting components [30, 31]. Behaviour change intervention components are the techniques which constitute the active ingredients of the intervention, and the procedures used to deliver those techniques[31]. Behaviour change techniques (BCTs) are replicable components of an intervention designed to alter/redirect causal processes that regulate behaviour with minimum delivery specifications that allow their identification[31, 32]. They are useful for identifying and standardising the reporting of complex interventions in systematic reviews [31, 32]. Procedures include who delivers the intervention, to whom, how often, for how long, in what format, and in what context [31, 33]. Physical activity is any bodily movement resulting from the contraction of skeletal muscles that leads to energy expenditure [34].

No systematic review has examined the effects of behaviour change interventions on physical activity behaviour of people living with chronic NCDs in Africa; patients' experiences of these interventions; and to what extent interventions addressed patients' concerns. These are the objectives of this study.

Methods

Search strategy and selection criteria

This systematic review was registered with the International Prospective Register of Systematic Reviews (CRD42015016084) and the protocol published [35]. Following PRISMA guidelines[36], we searched MEDLINE, EMBASE, PsycINFO, CENTRAL, CINAHL, Web of Science, African Index Medicus (AIM), and AFROLIB (WHO's regional office database for Africa) from their inception dates up to April 19, 2017.

We used a combination of Medical Subject Headings, free text terms and word variants for *hypertension, diabetes, obesity* and *chronic musculoskeletal pain* conditions, *African search filter* [37], word variants for *physical activity related therapies*, and the search filters for three study types – *clinical trials, qualitative and observational studies* (supplemental file). We also searched grey literature as described in the protocol [35]. These conditions were selected because they are the most prevalent in Africa [1, 38], and may be the most easily modified by physical activity. Lung diseases were not included because we envisaged that a significant proportion may be secondary to communicable diseases such as tuberculosis.

The reference lists of relevant systematic reviews were appraised for potentially eligible studies.

There was no restriction by language or intervention settings. Studies were selected if they involved adults (≥18 years) living in Africa with hypertension, diabetes, obesity or chronic musculoskeletal pain.

There were no restrictions on study design, comparators and timing. Clinical studies (Randomised Controlled Trials – RCTs, non-controlled before and after – B/A studies, mixed-methods B/A studies) were included if they investigated the effects of physical activity interventions on physical activity behaviour. Qualitative studies were included if they explored experiences and perspectives of individuals to these interventions. Physical activity behaviour change was the primary outcome evaluated in this review. We excluded studies of African patients not living in Africa; studies without a physical activity intervention, physical activity behavioural assessment or any primary data; and duplicate publications.

We selected studies in two stages. In the first stage, CNI-C (first author) screened titles and abstracts using the eligibility criteria to identify potentially relevant articles. This was cross-checked by ELG (last author), APK (second author) and IOS (third author). In the second stage, screening of full articles was done independently by CNI-C, ELG and IOS. Disagreements were resolved by consultation with APK. Further details are in the review protocol [35] and the flow chart (Figure 1).

Data extraction and quality assessment

This was done by CNI-C, and cross-checked independently by ELG and IOS. Disagreements were resolved by consultation with APK. The data collection process is detailed in the protocol [35]. Intervention descriptions were recorded as described by primary authors and subsequently coded with the taxonomy of hierarchically clustered BCTs [30] using the definition of Michie, Abraham [31] and Whitlock, Orleans [33]. Consensus agreement in coding was achieved via group discussion of the multidisciplinary review team.

We assessed the quality of all studies with the Mixed Methods Appraisal Tool (MMAT) [39] as described in the review protocol [35]. For RCTs, quality criteria included appropriate random sequence generation/clear description of randomisation, allocation concealment or blinding, complete outcome data (≥80%), and low drop-out rate (<20%). For non-controlled B/A studies, the criteria were low selection bias in recruiting participants representative of the population; valid and reliable outcome measures; accounting for confounding and co-variate variables; complete outcome data (≥80%), acceptable response rate (≥60%) and follow-up rate. For mixed-methods B/A studies, the overall quality score is the lowest score of the study components. For qualitative studies, the criteria were adequate/relevant sources of qualitative data; qualitative data analysis addressed research objectives; consideration was given to how results were related to context; and consideration was given to how findings related to researcher's influence [39].

A total score for each study was based on the number of met criteria (Tables 1 and 3).

Data analyses

Three stage analyses were carried out using a mixed studies synthesis design – the sequential explanatory synthesis [40].

First stage: narrative synthesis of clinical studies

Different methods and outcomes employed by studies precluded meta-analysis. There was varied intervention content, objectives, study designs, study quality, chronic condition, sample size, gender, age, outcome measures and contexts. Clinical studies were therefore summarised using narrative synthesis to determine the effects of interventions on physical activity behaviour. For comparability of results from RCTs and B/A studies, within-

group pre-and post-physical activity change score effect sizes were calculated for each clinical study.

The overall strength of evidence was judged using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach as described in the review protocol [35].

Second stage: thematic synthesis of qualitative studies

Qualitative studies were reviewed to explore patients' experiences/perspectives of these interventions (no eligible observational study was identified). NVivo version 10 software (QSR international, Melbourne, Australia) was used.

Thematic synthesis is the method that fits with the aims of this review [41] because it answers questions relating to intervention need, appropriateness, acceptability and effectiveness without compromising on key principles of systematic reviews [42, 43]. We used descriptive line-by-line coding to generate categories. Categories were then organised into related areas to construct descriptive themes. Finally, higher order analytical themes were developed through interpretation and abstraction of descriptive themes. Each stage of qualitative synthesis was validated by the review team comparing generated categories/themes with primary results.

Third stage: comparative analysis of clinical and qualitative studies

A comparative analysis was done to determine to what extent clinical studies addressed patients' needs and concerns identified in the qualitative studies.

Results

Overview of the searches

Figure 1 shows detailed overview of the searches; Table 1 – characteristics of clinical studies and quantitative aspect of mixed-methods studies; Table 2 – characteristics of qualitative studies and qualitative aspect of mixed-methods studies; Table 3 – standardised intervention description (intervention components) provided by the reviewers; Table 4 – comparative analysis of clinical and qualitative results; supplemental table – intervention description and outcomes reported by primary authors.

Five independent articles, all of which involved patients with diabetes mellitus were eligible: 1 RCT= Debussche et al, 2012 [46]; 1 B/A study= Rotheram-Borus et al, 2012 [47]; 1 mixed-methods B/A study= van der Does and Mash, 2013 [44]; 2 qualitative studies= Serfontein and Mash, 2013 [48] and Balcou-Debussche and Debussche, 2009 [49] (Tables 1 and 2). van der Does and Mash [44] included clinical and qualitative arms, and therefore contributed to the number of both clinical and qualitative studies. The reference list of the relevant systematic review [45] did not yield additional studies.

Figure 1: Flow diagram of the selection process of studies for inclusion in the review

Overview and methodological quality of included studies

Identified studies were published between 2009 and 2014 from South Africa (3 studies) and Reunion (2 studies). Reunion is in the African search filter due to its geographical location in Eastern Africa in the Indian ocean, east of Madagascar and southwest of Mauritius [35]. There was a total of 517 participants, ranging between 13 to 398 participants in individual studies.

The proportion of women ranged from 38% to 100%. Settings included rural (n=1), urban (n=2) and mixed (n=2) (Tables 1 and 2).

For the methodological quality of the clinical studies, Debussche et al, 2012 [46] and van der Does and Mash [44] were 75%; whereas quality was 50% in Rotheram-Borus et al, 2012 [47] (Table 1). Debussche et al, 2012 [46] had usual care control group; whereas there were no control groups in van der Does and Mash [44] and Rotheram-Borus et al, 2012 [47] (supplemental table). Debussche et al, 2012 [46] was low risk for bias due to blinding of patients, complete outcome data and non-selective reporting, but it was unclear whether outcome assessors were blinded. van der Does and Mash [44], and Rotheram-Borus et al, 2012 [47] were high risk for bias due to lack of random sequence generation, allocation concealment and blinding of outcome assessment, but they were low risk for bias due to incomplete outcome data and selective reporting. For the methodological quality of the qualitative studies, Serfontein and Mash, 2013 [48] and Balcou-Debussche and Debussche, 2009 [49] were 100% (Table 2). The quality of van der Does and Mash [44] is denoted above.

Interventions in clinical studies

Debussche et al, 2012 [46] combined educational sessions and physical activity performance. van der Does and Mash [44] had interventions only comprising interactive educational sessions. Rotheram-Borus et al, 2012 [47] combined psychoeducational sessions, with mobile phone-based peer support, and was the only study with a theory based intervention: power-to-prevent programme (Supplemental Table).

Table 3 shows a total of 18 BCTs. Intervention providers included peers [47], educators [46], health promoters [44], dieticians [44, 46], nurses [46], exercise physiologists [46], and a medical doctor [44]. The

duration of interventions ranged between 4 weeks and 9 months. Intervention frequency ranged from once every week to once every 3 months. Session duration was around one hour, although it was unspecified in most studies. Interventions were delivered in primary care centres [44, 47]; or tertiary hospital [46] (Table 3).

Outcome measurement

All studies utilised different self-report measures and none used objective or direct measures of physical activity.

In Debussche et al, 2012 [46], physical activity was assessed by the adaptation of a validated questionnaire [50], calculating occupational and home physical activity scores based on the mean of five items dealing with the frequency of sitting, standing, walking, lifting heavy loads and sweating during activity. Additionally, sports activity was measured by combining intensity (millijoules per hour i.e. energy expended during the activity per hour), time spent each week (number of hours doing the physical activity per week), and perseverance (number of months that the activity was performed per year). van der Does and Mash [44] used the Summary of validated Diabetes Self-Care Activities questionnaire that assessed diet, physical activity, medication taking, blood-glucose testing, foot care and smoking [51]. The physical activity subscale included 2 items: *'on how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity)'* and *'on how many of the last SEVEN DAYS did you participate in a specific exercise session other than what you do around the house or as part of your work?'*. Rotheram-Borus et al, 2012 [47] measured physical activity using the number of steps taken per day.

Table 1: Characteristics of clinical studies

Table 2: Characteristics of qualitative and mixed-methods studies

Table 3: Intervention components in the clinical studies

Effects of interventions on physical activity

Mixed effects of interventions on physical activity behaviour were found.

In Debussche et al, 2012 [46] (n=398; quality=75%; validated habitual physical activity questionnaire incorporating home, leisure, occupational and sports measure [50]), the physical activity intervention involving combined interactive educational sessions about diabetes and performance of physical activities during workshops, significantly increased sports activity at one year follow-up (effect size = 0.4). However, occupational and home physical activity did not differ from baseline. Patients were then split into intervention and control groups. A subsequent quarterly outpatients counselling visits provided to the intervention group did not provide additional benefit over the control group (supplemental table).

In van der Does and Mash [44] (n=84; quality=75%; physical activity subscale of validated Diabetes Self-Care Activities questionnaire which assessed housework, work activities and specific exercise [51]), the physical activity intervention only comprising interactive educational sessions about physical activity significantly increased continuous physical activity (at least 30 minutes) outside of home, and occupational activities immediately after the four-week intervention (effect size = 0.6) (supplemental table).

The intervention in Rotheram-Borus et al, 2012 [47] (n=22; quality=50%; physical activity measure= number of steps taken daily), combined psychoeducational sessions about physical activity, with mobile phone-based peer support, and did not increase physical activity, but reduced number of steps from 1931.8 at baseline to 1559.8 at 6 months follow-up (effect size = - 0.2) (supplemental table).

Experiences and perspectives of patients to physical activity interventions

Three themes emerged:

Increasing biomedical understanding of chronic condition – diabetes

Organised, simple and comprehensive structured educational programmes covering all aspects of patients' chronic condition [44] including management strategies [48]were important to participants[48]. Recapping previous educational sessions enhanced recall [48]. Communication styles incorporating motivational interviewing principles such as empathy, liveliness, inclusiveness [48], and collaborative group sessions enhanced understanding [48, 49].

Self-help educational materials such as handouts, flip charts, booklets and posters enhanced understanding and recall, and made the sessions more interesting [44, 48, 49]. Health education delivered within mainstream health care settings bestowed value and legitimacy to self-management recommendations [49].

Addressing physical and social environmental barriers

Adverse environmental conditions and social stressors may limit physical activity despite sufficient biomedical knowledge of a chronic condition [44, 48, 49]. Examples include unsafe environments, poor timing of physical activity [48]; family problems, stressful work conditions [44, 48, 49].

Social support facilitated through the health professional and other patients in group sessions may mitigate stressors (*"…when I sit with other people, I feel better"* [44, 48]). Combined group and individual sessions may be superior to group sessions, due to privacy concerns [44].

Strategies stimulating/supporting physical activity behaviour change

Physical activity behaviour may be influenced by motivational interviewing techniques, such as eliciting talk about change, using enthusiastic communication styles and encouraging group solutions [44, 48]. Emphasising chronic disease complications may further increase the motivation to improve physical activity [44].

Actual performance of the desired physical activity may increase physical activity through increasing self-efficacy[44]. Untrained health professionals operating within a biomedical health care system were more likely to be impatient with patients, damaging patient-health professional relationship [44, 49]. These health professionals undervalue the skills needed for administering behaviour change interventions, lack ownership, doubt effectiveness of programmes and are poorly motivated, which might be alleviated by providing ongoing training and support [44].

Potentially limiting behaviour change were inadequate venues or programmes that were not integrated into routine care [48]. Unintegrated programmes meant that there were conflicting opinions about who should lead interventions [44] and timing problems [48]. Patients wanted ongoing programmes with the possibility of repeat sessions, with specific dates and times that aligned with other hospital appointments/daily activities; and programmes delivered by specifically trained health professionals[44].

The extent to which interventions addressed patients' concerns

Table 4 shows that no clinical study targeted any of the procedure-related intervention components identified in the qualitative studies. All clinical studies [44, 46, 47] adopted techniques

that 'increased patients' biomedical understanding of their chronic condition' (BCT: Shaping knowledge). However, none used self-help educational materials.

Debussche et al, 2012 [46] addressed both physical and social environmental barriers (BCTs: Restructuring the physical and social environments). Rotheram-Borus et al, 2012 [47] addressed only social factors (BCTs: Social support (practical), Social support (general), Social support (emotional), Regulate negative emotions) (Table 4).

In Debussche et al, 2012 [46], there was performance of physical activity during educational sessions (**BCTs:** Behavioral rehearsal/practice and habit formation). In van der Does and Mash [44], complications of the chronic condition was emphasized (BCT: Health consequences) (Table 4).

Table 4: Comparative analysis of clinical and qualitative results

Discussion

Summary of main results

All studies involved patients with type 2 diabetes mellitus, with one patient having type 1 diabetes mellitus in Rotheram-Borus et al, 2012 [47]. No study of patients with hypertension, obesity or chronic musculo-skeletal condition could be included in this review. Therefore, results can only be very tentative based on the limited evidence available to this review.

Moderate quality of evidence suggested that exercises and sports performance not associated with home and occupational activities were increased in the long term – 1 year (in terms of frequency per week, energy expended per hour, number of hours per week and

number of months the activities were performed per year). Low quality of evidence suggested that exercises and sports activities increased in the short term – immediately after a 4-week intervention (in terms of total minutes of continuous activity) [44, 46]. There was conflicting evidence on the effects of interventions on home and occupational physical activities [44, 47].

This review could not confirm the BCTs responsible for improvements in physical activity because primary clinical studies did not investigate this. Despite possible links between engagement with physical activity interventions and physical activity behaviour change [52], no study examined this. Furthermore, it was not possible to undertake a meta-regression to determine the intervention components for improving physical activity due to the limited number and low quality of studies.

A meta-regression of clinical studies in high income countries found that interventions that combined self-monitoring of behaviour with at least one of four other self-regulatory techniques such as prompting intention formation, providing feedback on performance, prompting specific goal setting, and prompting review of behavioural goals were significantly more effective than other interventions in improving physical activity and healthy eating [53]. However, that meta-regression did not thoroughly investigate the impact of procedure-related intervention components [53]. The impact of theoretical constructs on physical activity behaviour could not be ascertained in the current review because only Rotheram-Borus et al, 2012 [47] had a theory-informed intervention and did not measure theoretical constructs [47]. Evidence suggests that no theory is superior in influencing physical activity, although interventions based on the social cognitive theory produced the greatest effect sizes [54]. However, none of the studies was from an African setting.

The BCTs in Debussche et al, 2012 [46] and van der Does and Mash [44] which improved physical activity in the long and short term respectively, included self-monitoring of behaviour and at least one other self-regulatory technique. Providing feedback on behaviour and prompting goal setting were two other self-regulatory techniques in Debussche et al, 2012 [46]. Prompting goal setting was one other self-regulatory technique in van der Does and Mash [44]. The techniques in Rotheram-Borus et al, 2012 [47], which did not improve physical activity, did not include self-monitoring of behaviour but provided feedback on behaviour and prompted goal setting.

In the comparative analysis in Table 4, Debussche et al, 2012 [46] was the only clinical study that reported physical activity changes in the long term (1 year), and used techniques addressing all three themes identified in the qualitative studies. van der Does and Mash [44], which reported increases in physical activity in the short term, addressed two of the three themes but did not tackle environmental and social barriers. Rotheram-Borus et al, 2012 [47], which found no improvements in the number of steps taken daily, utilised BCTs that targeted two of the three themes but did not use BCTs 'stimulating/supporting physical activity' (Table 4).

No intervention addressed any procedure-related intervention component identified as important in the qualitative studies (Table 4). Fidelity was not assessed in any study, and untrained health professionals may have limited the extent to which identified BCTs were delivered with fidelity. Although Debussche et al, 2012 [46] mentioned training health professionals in counselling, there were no details recorded of this training, and no assessment of intervention fidelity [46].

Although some clinical studies on obesity, type 2 diabetes mellitus and hypertension identified during this review included behaviour change intervention components, and measured clinical outcomes such as blood pressure and fasting blood glucose, they were excluded because physical activity was not measured in any of them (Figure 1). This highlights the key emphasis on biomedical rather than behavioural outcomes in Africa which may prevent successful behaviour change. No study on chronic musculoskeletal pain was identified at all, highlighting the limited focus of physical activity behaviour change for chronic musculoskeletal pain in Africa. Systematic reviews of studies conducted in high income countries suggest that exercise supervision, participation in an exercise programme, accuracy of exercise performance, participation in a motivational behaviour change programme, refresher/booster/follow-up sessions, supplementing face-to-face verbal instructions with other audio/visual/written material, reward and punishment strategies, goal setting, feedback, group discussion, problem solving to overcome barriers to adherence, self-monitoring through the use of an exercise plan/exercise contract/exercise logbook, education about pathology and how to manage/cope with symptoms, assessing community resources/social networks, effective communication, reinforcement and feedback, and cognitive behavioural strategies may improve physical activity in patients with chronic musculoskeletal pain [55-58]. Most of these components were identified in this review, suggesting their significance in other chronic conditions.

Measurement of physical activity

Lack of direct or objective physical activity measurement in studies is a potential weakness [34]. Although self-report physical activity measures are the most practical and cost-effective approach to physical activity measurement, including both direct/objective and self-report

measures may account for the weaknesses of both measurement types. For instance, high sensitivity to small errors and measurement of non-physical activity energy expenditure are associated with direct/objective physical activity measures [34]. Greater estimation of high intensity/vigorous physical activity than low to moderate physical activity, plus recall and social desirability bias are associated with self-report physical activity measures [34].

The physical activity measurement in Debussche et al, 2012 [46] acknowledged work activities, housework, sports and leisure activities within the context of frequency, intensity, duration, and overall physical activity over time, concurring with the World Health Organisation recommendations [24]. In van der Does and Mash [44], physical activity was measured within the context of housework, work activities and specific exercise, taking into consideration frequency and duration but not intensity. In Rotheram-Borus et al, 2012 [47], the measurement of physical activity only using the number of steps taken per day, was the least validated of the measures as it did not consider duration, intensity, and physical activity that does not involve taking steps.

Strengths and Limitations

This review combined the strengths inherent in quantitative and qualitative studies thereby compensating for their respective limitations. However, the generalisability of findings is limited by both the quality of evidence and paucity of studies conducted in only a few countries. Only studies of patients with diabetes mellitus in South Africa and Reunion were eligible, limiting generalisability. Although Reunion is classified within Eastern Africa, it is a French overseas territory, also including Europeans, Indians and Chinese, which is a limitation. Many interventions were not physical activity-specific, and were very complex, containing dietary and pharmacological elements, which may have influenced outcomes. Important

intervention components were derived from a few studies. Suboptimal physical activity measurement could have influenced outcomes.

Conclusions

Limited evidence suggested that physical activity unrelated with home and occupational activities were improved; and that self-monitoring of physical activity may be associated with this improvement. Inconclusive evidence was found for home and occupational physical activity. Patients appreciated behaviour change techniques that improved chronic disease knowledge, addressed environmental barriers and supported physical activity. Procedure-related components including health professional training and adequate health facility were not tackled by any study despite being important to patients.

High quality RCTs in Africa should test interventions delivered by trained health professionals, and focusing only on physical activity, assessed with validated measures; and link this to short and long term behavioural/biomedical outcomes. This will improve the evidence for these interventions in Africa. These behaviour change interventions need to be patient-centred by being responsive to patients' concerns, preferences and needs.

Authors' contributions

CNI-C conceived of the study, developed the search strategy, pilot searched the databases, selected studies, and synthesized data. CNI-C, ELG, APK and IOS contributed to further development of the review protocol, selection criteria, quality assessment, the risk of bias assessment, data extraction and analyses. CNI-C prepared the draft manuscript. All authors contributed to a critical revision of the manuscript. CNI-C prepared the final manuscript. All authors approved the final manuscript. CNI-C is the guarantor.

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Competing interests

None declared

Ethical approval

Not required

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Figure Legends

Figure 1: Flow diagram of the selection process of studies for inclusion in the review