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Effectiveness of stretching and bracing for the treatment of osteoarthritis-associated joint contractures prior to joint replacement: a systematic review protocol

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ABSTRACT

Introduction Many patients with osteoarthritis (OA) develop restrictions in passive range of motion (ROM) of their affected joints (called contractures), leading to increased pain and reduced function. Effective treatment to reverse OA-associated contractures is lacking. Our aim is to evaluate the effectiveness of stretching and bracing on native (non-operated) joint contractures in people with radiographically diagnosed OA.

Methods and analysis We will search the following databases without time restriction: Cochrane Library (CENTRAL, Database of Abstracts of Reviews of Effects, Health Technology Assessment Database), MEDLINE, Embase, CINAHL, SCI-EXPANDED (ISI Web of Knowledge) and PEDro. Other sources will include WHO International Clinical Trials Registry Platform, reference lists of included studies, relevant systematic reviews and textbooks. We will include randomised controlled trials (RCTs), controlled clinical trials, controlled before-and-after studies, cohort studies and case–control studies that include participants ≥18 years of age with radiographic evidence of OA. Participants with inflammatory arthropathies or those that have undergone joint arthroplasty will be excluded. Interventions will include therapist-administered or patient-administered stretching, use of an orthosis (static or dynamic), use of serial casting and/or adjunctive modalities. Outcomes will include joint ROM (active and passive), pain (rest and/or activity related), stiffness, activity limitations, participation restrictions, quality of life and adverse events. Studies will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Study inclusion, data extraction and quality assessment will be performed independently by two reviewers. Risk of bias will be assessed using appropriate tools for each study design. Data synthesis will be performed using Cochrane Review Manager software. If sufficient data are available, meta-analysis will be conducted. We will summarise the quality of evidence using Grading of Recommendations Assessment, and the effect size of interventions for RCT and non-RCT studies.

Ethics and dissemination Ethics approval not required because individual patient data are not included. Findings will be disseminated in a peer-reviewed journal.

PROSPERO registration number CRD42019127244

Strengths and limitations of this study

- This systematic review will search multiple databases, the reference lists of included studies and selected sources from the grey literature to assess the effectiveness of stretching and bracing for treating osteoarthritis (OA)-associated joint contractures prior to joint arthroplasty.
- This protocol design is consistent with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols statement and the Cochrane handbook for systematic reviews of interventions.
- Different types of stretching and bracing methods, as well as varying severity of OA in different joints may result in heterogeneity in the outcomes presented by included studies which may in turn make it difficult to perform meta-analysis.
- A lack of high-quality trials that meet our inclusion criteria might make it difficult to draw conclusions supported by high-quality evidence with low risk of bias.

BACKGROUND

Osteoarthritis (OA) is by far the most common arthritis, the most prevalent musculoskeletal pathology and ranks fifth among all forms of disability worldwide.[1–5] Individuals with OA suffer from numerous symptoms associated with the degenerative joint changes, including pain, stiffness and loss of joint function.[6] OA can affect any joint, but commonly affects the knees, hips, first carpometacarpal joint, distal and proximal interphalangeal joints, and inter-vertebral disks and zygapophyseal joints of the cervical and lumbar spine.[5 6] Many patients with OA develop contractures of their affected joints, characterised by a restriction in the joint's passive range of motion (ROM).[7–12] One-third to half of patients with knee OA will develop a contracture in the OA-affected joint,[7–13] as will up to

40% of patients with hip OA.[13] Restricted mobility due to joint contractures compounds OA-associated symptoms such as pain and stiffness, and interferes with activities of daily living.[14–20] In the lower limbs, contractures limit ambulation, increase energy expenditure, increase the risk of falls and increase mechanical stress on proximal joints.[9 14 21 22] The combination of joint contractures and OA therefore leads to significant morbidity beyond that of OA alone and contractures may accelerate the OA disease process.[13] In addition, a preoperative joint contracture is a major risk factor for poor outcomes postarthroplasty.[12] While OA-associated contractures likely share elements of their pathophysiology with other conditions leading to lost joint ROM (eg, immobility, neurological disorders, burns) pathognomonic features of the OA-affected joint may be unique. Changes such as proliferation of synovial tissue, bone deformity, osteophytes, capsular and ligamentous alterations and joint effusions likely also contribute, suggesting the possibility that response to stretching in OA-affected joints may differ from other conditions.[6 11 23–25]

Stretching is a movement applied either by an internal (ie, by the patient) or external force (eg, therapist, brace) with the goal of maintaining or increasing a joint's ROM.[26] Stretch parameters affect the outcome of the intervention when using a static approach and include intensity, frequency, duration and stretch position.[26 27] Intensity is often described as low, moderate or high, the definitions of which may depend on the population being studied. Frequency may range from several times daily to once weekly, duration from minutes (eg, if performed by the patient) to days (eg, if due to stretch from a brace) and position may affect the tolerability and effectiveness of the stretch.[26 27] Static bracing maintains the joint in one position for a defined period of time, while static progressive bracing and serial casting aim to gradually increase the joint ROM by positioning the joint at the end ROM for up to days or weeks.[28]

The effects of stretching depends on the tension of the muscle, the musculotendinous unit (MTU), the proprioceptors of the musculoskeletal system, the muscle spindles and the Golgi tendon organs.[26] Repeated stretching of the MTU to a constant length is believed to increase joint ROM due to gradual reduction in peak MTU tension and stiffness.[29–31] In addition, proprioceptive input is fed back to the central nervous system through the muscle spindles and Golgi tendon organs which respond to changes in length and tension, respectively.[32]

During static stretching, the MTU is held at a constant length. Over time, the passive force required to maintain that length gradually declines resulting in a phenomenon known as stress relaxation.[29] Little is known regarding the effects of stretching on osteophytes; however, early osteophyte formation may be characterised by the development of gelatinous cysts that may be amenable to stretch treatment prior to ossification.[33] Similarly, the effects of stretching on OA-related joint effusions and synovitis has not been well studied, though aggressive stretching on a joint with a large, acute effusion may cause pain and injury by excessively stretching the joint capsule. Initiating stretching prior to large effusion development may therefore be more beneficial.

Muscle-related tension may be classified as active (the contractile effects or the force generated by the interaction of actin and myosin filaments) or passive (arises from the connective tissue components of skeletal muscle when elongated beyond their resting length).[34]

Given the high prevalence of joint contractures in the OA population as well as their clinical implications, early detection, monitoring and therapeutic measures should be instituted to optimise the care of patients with OA developing this condition. Unfortunately, contractures are notoriously difficult to treat,[28 35 36] and evidence-based recommendations for their treatment in patients with OA is lacking. A previous high-quality systematic review showed no benefit from stretching for the prevention and treatment of contractures in musculoskeletal or neurological conditions. This review however included only two studies with OA patients (both randomised controlled trials, RCTs), only one of which evaluated preoperative treatment, and which also included patients with rheumatoid arthritis.[28] We believe this review is important for clarifying whether stretching to maintain joint ROM is beneficial in the setting of OA. The aim of this review is to determine the effects of stretch on contractures in people with radiographically diagnosed OA who have not undergone arthroplasty. It is our hypothesis that the evidence evaluating the effectiveness of stretching for the treatment of OA-related contractures will be heterogeneous in nature and of variable quality.

METHODS

Patient and public involvement

We initiated collaboration with our patient partner prior to the writing of this protocol. Our patient partner assisted in developing the research question, selecting outcome measures and with editing of this manuscript. We will share the results of our systematic review with our patient partner and will request her involvement during the drafting of our final manuscript prior to publication. At our patient partner's request, we have included a glossary of terms to assist the reader (online supplementary table 1).

Criteria for considering studies for this review

Types of studies

This systematic review will include RCTs, controlled clinical trials (CCTs), controlled before-and-after (CBA) studies, cohort studies and case–control studies. Studies using parallel-group designs, within-subject designs or cross-over designs will all be included. We will include studies published in the English language.

Types of participants

We will include adult participants (18 years of age or older) who have radiographic evidence of OA of any

joint. Studies including participants with inflammatory arthropathies (eg, seropositive arthropathies such as rheumatoid arthritis or systemic lupus erythematosus, seronegative arthropathies such as psoriatic arthritis or ankylosing spondylitis, or crystal arthropathies such as gout) for which the treatment effect on primary OA-affected participants cannot be isolated will be excluded. To maintain our focus on preoperative OA contracture treatment, participants that receive treatment after joint arthroplasty will also be excluded.

Types of interventions

Types of interventions will include therapist-administered stretch, patient-administered stretch, use of orthosis (static or dynamic), use of serial casting and adjunctive treatment with modalities of any duration (eg, ultrasound, inferential therapy, thermal and so on).

Comparisons

We will include all studies for which the effects of the intervention can be isolated. That is, we will include studies if they compared a stretching or bracing intervention alone or in combination to any other treatment (eg, stretching plus ultrasound, vs ultrasound only) or placebo, such that differences between the groups can be attributed solely to the stretching intervention.

Types of outcome measures

The major (primary) outcomes will include both passive and active joint ROM (eg, measured using a goniometer or other reliable measurement device), pain at rest or with activity (eg, visual analogue scale,[37] Western Ontario McMaster University Osteoarthritis Index (WOMAC),[38] Knee injury and Osteoarthritis Outcome Score (KOOS)[39 40]) and number of patients experiencing any adverse event (eg, increased pain or injury due to stretching or bracing). Minor (secondary) outcomes will include stiffness (eg, the WOMAC,[38] KOOS,[39 40]) functional performance (eg, 6 min walk test,[41] timed up and go test,[42]) activity limitation or participation restriction (eg, the Oswestry Disability Index,[43]) quality of life (eg, the Short Form 36[44] and the Assessment of Quality of Life,[45]) patient satisfaction (eg, the Quebec User Evaluation of Satisfaction with Assistive Technology,[46]) radiographic changes, postarthroplasty outcomes (if stretching was performed preoperatively, then participants underwent arthroplasty), risk of x-ray exposure and patients who withdrew because of adverse events. Outcome assessment can be measured at any time following intervention. We will group outcomes by three main timing categories: short-term intervention (less than 3 months), intermediate-term (3–6 months) and long-term intervention (>6 months).

Search methods for identification of studies

We will search the following electronic databases from inception to March 2019: Cochrane Central Register of Controlled Trials (CENTRAL), The Database of Abstracts of Reviews of Effects and the Health Technology Assessment Database; MEDLINE (Ovid); Embase (Ovid); CINAHL (Ovid); SCI-EXPANDED (ISI Web of Knowledge); and PEDro (www.pedro.org.au). We will also search the WHO International Clinical Trials Registry Platform (www.who.int/trialsearch) and clinicaltrials.gov/to identify unpublished and ongoing trials. The electronic searches will be complemented with a search of the reference lists of included studies, relevant systematic reviews and textbooks. Regarding grey literature, we will search the Abstract archives from the American College of Rheumatology/Association of Rheumatology Health Professionals, European League Against Rheumatism, Canadian Physiotherapy Association and American Physical Therapy Association conferences from 2012 to 2018. We will contact authors of included studies for additional studies and unpublished data. See online supplementary table 2 for the MEDLINE full search strategy.

Data collection and analysis

Selection of studies

Two review authors (BG and EG) will independently screen the titles and abstracts of the search output to identify potentially relevant studies. We will obtain full reports of all potentially relevant studies that appear to meet the inclusion criteria. The two review authors will resolve any disagreements by discussion and, when necessary, a third author (TMC) will arbitrate. We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in the review. We will record the selection process in sufficient detail to complete a Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram[45] (http://prisma-statement.org/PRISMAStatement/Default.aspx) and 'Characteristics of excluded studies' table. The study selection procedure is shown in figure 1.

Data extraction and management

We will use a data collection form for study characteristics and outcome data, which has been piloted on at least one study in the review. One review author (BG) will extract study characteristics from included studies. A second review author (TMC) will spot-check study characteristics for accuracy against the trial report. We will extract the following study characteristics:

- Methods: study design, total duration of study, details of any 'run-in' period, number of study Centres and location, study setting, withdrawals and date of study.
- Participants: N, mean age, age range, sex, disease duration, severity of condition, diagnostic criteria, important baseline data, inclusion criteria and exclusion criteria.
- Interventions: following the recommendations outlined in the Consensus on Exercise Reporting Template,[47] we will record characteristics of the intervention and comparison including details of treatment and control interventions, duration of intervention, frequency of intervention, stages of

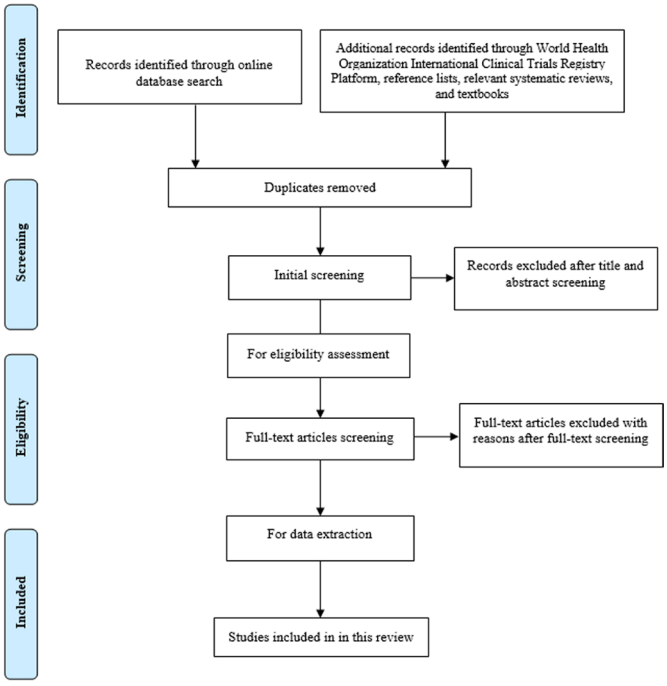

Figure 1 Flow diagram illustrates the study selection process following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement.

intervention, details of co-interventions and their effects on stretched tissue (eg, temperature), compliance with and adherence to treatment.

- Outcomes: details of the major and minor outcomes—methods used to measure outcomes, mean scores and SD of outcomes direction of effect for each outcome.
- Adverse events.
- Characteristics of the design of the trial as outlined below in the 'Assessment of risk of bias in included studies' section.
- Notes: funding for trial, and notable declarations of interest of trial authors.

Two review authors (BG and TMC) will independently extract outcome data from included studies. We will extract the number of events and number of participants per treatment group for dichotomous outcomes, and means and SD and number of participants per treatment group for continuous outcomes. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a third person (eg,). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. Differences in the data extracted by the two review authors will be resolved by discussion and, when necessary, arbitrated by a third author (eg,).

Assessment of risk of bias in included studies

Randomised controlled trials

Two review authors (BG and EG) will independently assess the risk of bias of the included studies. We will assess the following methodological domains: sequence generation, allocation sequence concealment, blinding of participants and treating clinicians, blinding of outcome assessors for objective outcomes, blinding of outcome assessors for self-report outcomes, incomplete outcome data, selective outcome reporting and other potential threats to validity.[48] We will judge these domains explicitly using the following criteria: 'Yes'=low risk of bias; 'No'=high risk of bias; 'Unclear'=either lack of information or uncertainty over the potential for bias. When studies report incomplete data in more than 15% of participants, we will deem them as having high risk of bias from incomplete outcome data. We will summarise the 'Risk of bias' judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (eg, for unblinded outcome assessment, risk of bias for all-cause mortality may be different than for a patient-reported pain scale). We will resolve disagreements by discussion or, if necessary, a third (VW) will arbitrate. We will present the figures generated by the 'Risk of bias' tool to provide summary assessments of the risk of bias. For RCTs, we will use the Cochrane risk of bias tool to assess the for sources of bias.[48]

Non-randomised studies

Two review authors (BG and EG) will independently assess the risk of bias of the included studies. We will present the risk of bias for non-randomised studies in a separate table from RCTs. For CCTs and CBAs we will assess the risk of bias according to the domains outlined in the Cochrane Effective Practice and Organisation of Care data collection checklist. We will judge these domains explicitly using the following criteria: 'Yes'=low risk of bias; 'No'=high risk of bias; 'Unclear'=either lack of information or uncertainty over the potential for bias. When studies report incomplete data in more than 15% of participants, we will deem them as having high risk of bias from incomplete outcome data. We will resolve disagreements by discussion or, if necessary, a third (VW) will arbitrate.

For observational and case–control study designs, study quality will be assessed using the appropriate National Institute of Health/National Heart Lung and Blood Institute (NIH/NHLBI) Study Quality Assessment Tools, and associated criteria.[49] These assessment tools were selected as we anticipate that the types of study designs included in our review will be broad. Rather than use tools from multiple sources (making comparison of quality assessment across studies difficult), the NIH/NHLBI provides a specific evaluation tool for each of the non-randomised, non-controlled study designs listed in our inclusion criteria.

Measures of treatment effect

For continuous outcomes we will report the mean differences (MDs) for each study to provide a summary estimate of the effectiveness of stretch treatment. For continuous outcomes with the same units, we will express effects as MDs and 95% CIs. For continuous outcomes

with different units, we will express effects as standardised MD (SMD) and 95% CI. SMD will be back-translated to a typical scale (eg, 0 to 10 for pain) by multiplying the SMD by a typical among-person standard deviation (eg, the SD of the control group at baseline from the most representative trial, as per the Cochrane Handbook for Systematic Reviews of Interventions.[50]

For dichotomous outcomes, such as adverse event occurrence, the risk difference will be calculated from the treatment group event rate minus control group event rate and will include 95% CIs. The number needed to treat (NNT) for continuous measures will be calculated using the Wells calculator (available at the Cochrane Musculoskeletal Group Editorial office).

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible. This will be noted in the 'Characteristics of included studies' table. Where this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis. Any assumptions and imputations to handle missing data will be clearly described and the effect of imputation will be explored by sensitivity analyses. For dichotomous outcomes (eg, number of withdrawals due to adverse events), the withdrawal rate will be calculated using the number of patients randomised in the group as the denominator. For continuous outcomes (eg, mean change in pain score), we will calculate the MD or SMD based on the number of patients analysed at that time point. If the number of patients analysed is not presented for each time point, the number of randomised patients in each group at baseline will be used. Where possible, missing SD will be computed from other statistics such as standard errors, CIs or p values.[51]

Assessment of heterogeneity

When there are at least two clinically homogeneous studies (studies that investigated the effect of similar interventions on similar populations, reported similar outcomes and similar intervention duration), we will consider meta-analysis. In the absence of such circumstances, we will assess heterogeneity by visual inspection of forest plots and use the I^2 statistic to quantify the heterogeneity of outcomes and to inform decisions about whether to pool data.[52] Where heterogeneity is substantial (I^2 >50%), we will explore the possible causes of heterogeneity in sensitivity analyses, in which individual studies are omitted one at a time or stratified by particular characteristics or, where appropriate, with meta-regression.[53]

Assessment of reporting biases

We will use funnel plots to examine the possibility of small sample bias in the estimates of the short-term effects of stretching and bracing for OA-associated contractures. If we are able to pool more than 10 trials, we will undertake formal statistical tests to investigate funnel plot asymmetry using the Egger's test.[54] To assess outcome reporting bias, we will check trial protocols against published reports. For studies published after 1 July 2005, we will screen the Clinical Trial Register at the International Clinical Trials Registry Platform of the World Health Organisation (http://apps.who.int/trialssearch) for the a priori trial protocol. We will evaluate whether selective reporting of outcomes is present.

Data synthesis

We will undertake meta-analyses only where this is meaningful, that is, if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense. For data that can be pooled, we will use a random-effects model to conduct meta-analyses and analyse data. For other data that can't be pooled due to either study design or outcome measure heterogeneity, we will present a summary of available results for the included studies. For dichotomous outcomes, the number of participants that experienced improvement (or adverse event), as well as the total number of participants, will be reported. For continuous outcomes, we will analyse mean differences with SD. We will report the range of effect sizes across studies for each outcome. We will provide clinical context to our results including the minimal clinically important difference and reference values for our outcome measures, as available. We will analyse non-RCTs separately from RCTs.

Subgroup analysis and investigation of heterogeneity

We will conduct planned subgroup analyses to determine the following effects of stretching and bracing interventions:

- Compare the effects of short-term intervention (<3 months' treatment) with intermediate (3–6 months' treatment) and long-term (>6 months' treatment).
- Evaluate the effects of important OA-associated demographic factors such as sex (male vs female) and age (age<65 years vs age≥65 years).
- Evaluate the effect of radiographic OA severity (Kellgren and Lawrence stages 1–2 vs Kellgren and Lawrence stages 3–4).[55]
- Evaluate the effects of stretching or bracing treatment to different OA-affected joints (eg, axial vs limb joints, large vs small joints and individual joints).
- Determine the effects of different methods of stretching.
- Determine the effects of different methods of bracing or casting.
- Determine the effects of adherence to the stretch protocol.
- Determine the effects of the use of adjunctive treatments on the above.

We will use a formal test for subgroup interactions to aid in the interpretation of subgroup analyses. We will compare the magnitude of the effects between the

subgroups by assessing the overlap of the CIs of the summary estimates. CIs that do not overlap will indicate statistical significance. For studies that contribute data to more than one subgroup (eg, short-term intermediate-term and long-term treatment arms in the same study) but do not provide subgroup population data, formal pooling and statistical testing for subgroup interactions will not be performed; however, data may be presented graphically for visual interpretation.

Sensitivity analysis

To examine the robustness of the findings to potential selection, detection and attrition biases, we will conduct sensitivity analyses. The sensitivity analyses will examine the effects of randomisation, allocation concealment, blinding of assessors (if not a self-reported measure) and completeness of outcome data on ROM, pain, stiffness and functional outcomes.

Summary of evidence

Two authors (BG, TMC) will independently assess the quality of the evidence. We will use the five Grading of Recommendations, Assessment, Development and Evaluations (GRADE) considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies which contribute data to the meta-analyses for the prespecified outcomes, and report the quality of evidence as high, moderate, low or very low.[56–59] We will compile 'Summary of findings' tables using GRADEpro software (GRADEpro GDT 2015). We will summarise the effects of stretching and bracing separately for the major outcomes described above. For both stretching and bracing, we will also separately present tables for RCT and non-RCT summary of findings. We will justify all decisions to down-grade or up-grade the quality of studies using footnotes and we will make comments to aid reader's understanding of the review where necessary.[60]

Ethics and dissemination

Ethics approval will not be needed because data from individual patients will not be included and no privacy will be involved. The final results of this systematic review will be published in peer-reviewed journal, will be disseminated at relevant conference presentations and through plain language summaries targeting relevant clinical and patient audiences.

DISCUSSION

Contractures are common among patients with OA affected joints, have a negative impact on patient outcomes, accelerate OA progression and increase the likelihood of requiring joint replacement.[12 13 61] Established contractures are notoriously difficult to treat and maintaining joint ROM in OA-affected joint is important for patient-centred outcomes.[12 13 28 61] This systematic review will provide an assessment of the effectiveness of stretching and bracing for the treatment of contractures of OA-affected joints. This review has some potential limitations: different types of stretching and bracing methods, varying OA severity and a variety of OA-affected joints may cause heterogeneity. A lack of high-quality trials could reduce the strength of the evidence on this topic. Nonetheless, stretching is an accessible and relatively inexpensive treatment with potentially large positive benefits. Conclusions drawn from this review may benefit patients living with OA, as well as clinicians and policy-makers trying to reduce the health-related burden of this disease.

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Collaborators Doug Salzwedel, Alfretta Vanderheyden.

Contributors TMC conceptualised the study, assisted in study design and methodology, drafted the manuscript and edited the final version. BBG assisted in developing study methodology, drafting the manuscript and editing the final version. MW assisted in developing study design and methodology, drafting the manuscript and editing the final version. ETG and VAW assisted in developing study design and methodology and editing the final version.

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