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### Educational Interventions for Antibiotics Misuse and Self-Medication in Africa: A Systematic Review and Meta-Analysis [Protocol]

*Interventions Éducatives sur le Mauvais Usage des Antibiotiques et l'Automédication en Afrique : Une Revue Systématique et Une Méta-Analyse [Protocole]*

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#### ABSTRACT

**BACKGROUND:** Antibiotics misuse and self-medication remains one of the most serious public health challenges globally. Persistent rise in resistant bacterial infections has been attributed to high prevalence of antibiotics misuse and self-medication. Large volume of literature has emerged describing studies that evaluate the effectiveness of various types and combinations of educational and behavior-modification techniques to reduce antibiotics misuse and self-medication. No previous systemic review has attempted to assess the quality of evidence in public domains on educational strategies aiming to reduce prevalence and improve knowledge, attitude and practice on antibiotics misuse and self-medication in Africa. This study, therefore, intends to assess the quality of evidence presented and determine the effectiveness of health education as an intervention tool for reducing prevalence and improving knowledge and attitude on antibiotics misuse and self-medication among adults in Africa.

**METHODS:** This study will include published papers on effectiveness of health education in reducing antibiotics misuse and self-medication from 2011–2021. Systematic search for literature will be conducted according to the Preferred Reporting Item for Systematic Reviews and Meta-analysis (PRISMA) guidelines to identify published studies based on our predetermined inclusion and exclusion criteria in PubMed, EMBASE, PsychINFO, CINAHL and Web of Sciences. Two independent reviewers will assess all identified studies and another set of reviewers will extract data for analysis and evidence synthesis. **WAJM 2023; 40(1): 114–120.**

**Keywords:** Health Education, Antibiotics misuse, Self-medication, Systematic review and meta-analysis.

#### RÉSUMÉ

**CONTEXTE:** Le mauvais usage des antibiotiques et l'automédication restent l'un des plus graves problèmes de santé publique dans le monde. L'augmentation persistante des infections bactériennes résistantes a été attribuée à la prévalence élevée de l'abus d'antibiotiques et de l'automédication. Un grand nombre de publications décrivent des études qui évaluent l'efficacité de divers types et combinaisons de techniques d'éducation et de modification du comportement pour réduire l'abus d'antibiotiques et l'automédication. Aucun examen systématique antérieur n'a tenté d'évaluer la qualité des preuves dans les domaines publics sur les stratégies éducatives visant à réduire la prévalence et à améliorer les connaissances, l'attitude et la pratique sur le mauvais usage des antibiotiques et l'automédication en Afrique. Cette étude a donc pour but d'évaluer la qualité des preuves présentées et de déterminer l'efficacité de l'éducation à la santé comme outil d'intervention pour réduire la prévalence et améliorer les connaissances et l'attitude sur le mauvais usage des antibiotiques et l'automédication chez les adultes en Afrique.

**MÉTHODES:** Cette étude comprendra les articles publiés sur l'efficacité de l'éducation sanitaire dans la réduction de la mauvaise utilisation des antibiotiques et de l'automédication entre 2011 et 2021. Une recherche systématique de la littérature sera effectuée conformément aux directives PRISMA (Preferred Reporting Item for Systematic Reviews and Meta-analysis) afin d'identifier les études publiées en fonction de nos critères d'inclusion et d'exclusion prédéterminés dans PubMed, EMBASE, PsychINFO, CINAHL et Web of Sciences. Deux examinateurs indépendants évalueront toutes les études identifiées et un autre groupe d'examineurs extraira les données pour l'analyse et la synthèse des preuves. **WAJM 2023; 40(1): 114–120.**

**Mots clés:** Education à la santé, Mauvaise utilisation des antibiotiques, Automédication, Examen systématique et méta-analyse, Systématique et méta-analyse.

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## INTRODUCTION

The discovery of antibiotics by Alexander Fleming in the 19th century marked the turning point in the fight against infectious diseases.<sup>1</sup> Yet, the American Infectious Disease Society recently alerted the world on the epidemic of resistant antibiotic infections<sup>2</sup> with an impending brewing public health crisis. The global surge in the antibacterial drugs resistant infections have persistently been linked with rising trends in antibiotics misuse and self-medication.<sup>3</sup> Thus, antibiotics misuse and self-medication has become one of the most serious global public health challenges and elicited significant interests among public health researchers.<sup>4</sup> Only about 20% of all antibiotics used are prescribed within the healthcare industry.<sup>5</sup> While about 80%–90% of all antibiotics are used in the community, majority of those antibiotics are used without prescription by trained health personnel.<sup>6</sup> Developing countries account for greater proportion of antibiotics misuse and self-medication.<sup>7,8</sup> In Africa, unregulated supply chain<sup>9</sup>, scarce health manpower<sup>10</sup> and lack of funds to purchase prescribed antibiotics<sup>10</sup> have aided and abated antibiotics misuse and self-medication. Reported prevalence of antibiotics misuse and self-medication in African countries ranges from 12.1% to 93.9%.<sup>11,14</sup> In Nigeria, which has the largest unregulated prescription drugs market in the continent, prevalence of antibiotics misuse and self-medication was reported to be higher than most other African countries.<sup>12</sup> In addition, studies within Nigeria have reported poor knowledge about antibiotics use, poor understanding of effective use of antibiotics and poor antibiotics practices.<sup>13,14</sup> Antibiotics misuse and self-medication has been associated with medical, social and economic consequences.<sup>15</sup> Aside from the resistance to common and cheaper antibiotics as widely reported especially in the African countries,<sup>16</sup> delay in presentation for care due to antibiotics misuse and self-medication, prolongs hospital stay and increase the cost of care and adds to financial strain on families.<sup>17</sup> Antibiotic misuse and self-medication also lead to adverse drug

effects with serious negative outcomes as well as exposes higher generations of antibiotics to misuse and abuse.<sup>18</sup> The long-term effects are increased morbidity and mortality because of antibiotics resistance and treatment failures for mostly infectious diseases.<sup>19</sup> Many factors have been reported as causes and associations of antibiotics misuse and self-medication. Significantly, studies have reported socioeconomic status,<sup>20</sup> peer influences, age,<sup>21</sup> gender,<sup>22</sup> literacy level, occupation, previous experiences, government policies among factors contributing to antibiotics misuse and self-medication. However, review of literature is widely used to provide better understanding of what is known and what is not known from the available knowledge in the public domain. Systematic reviews play significant role in public policy development, clinical and in public health interventions. Unlike traditional narrative review, which lack scientific rigors, systematic review methods which have now increasingly gained popularity in medical research entails “replicable, scientific, and transparent process that aims to minimize bias using exhaustive literature search by providing the reviewer’s audit trail of decisions, procedures and conclusions.”<sup>23</sup> Health education strategies are useful tools in the study of health seeking behaviors in communities and societies.<sup>24</sup> Health education interventions guided by health belief model have been used to study sexual abstinence among adolescent girls,<sup>25</sup> physical activity<sup>26</sup> and drugs misuse<sup>27</sup> among many other social and behavioral health problems. Health education interventions using models of health seeking behaviors have also studied self-medication and antibiotics misuse in communities and hospital-based settings.<sup>28</sup> A recent systematic review investigated prevalence and reasons of antibiotics self-medication<sup>11</sup> with focus on African settings. Another systematic review concluded that “lack of attention of the public health researchers regarding not only self-medication but associated important problem like antibiotic resistance and potential adverse events deserves immediate implementation public health programmes for increasing

awareness and importance of this issue”.<sup>12</sup> However, no previous systematic review to the best of our knowledge has attempted to provide a systematic analysis of published papers on cost-effective public health interventions to be implemented to prevent antibiotics misuse and self-medication. Our study will help in providing such explicit objective evidence on what is known and what is not known about health education interventions for antibiotics misuse and self-medication by analyzing data from published studies that meet our sets of inclusion criteria. Findings from this study will have both therapeutic and policy implications at national and global levels.

The aim of this study is therefore to systematically identify all published studies on health education interventions for antibiotics misuse and self-medication, to assess the quality of the evidence presented in the studies and extract data to determine the quantitative effect of health education in reducing antibiotics misuse and self-medication. The study will specifically determine the following objectives:

1. Quantitative effect of health education in reducing prevalence of antibiotics misuse and self-medication.
2. Effect of health education in improving knowledge about antibiotics misuse and self-medication.
3. Effect of health education in improving attitude about antibiotics misuse and self-medication

## METHODOLOGY

### Study Design

The Preferred Reporting Items for Systematic Reviews and Meta-analyses will be used to conduct the systematic review and meta-analysis described in this protocol (PRISMA). This review will combine the recommendations for conducting systematic reviews and meta-analyses from the Cochrane Collaboration with those from the University of York’s Center for Dissemination and Reviews (CRD). An ethical approval is not thought to be necessary for the study because it is a systematic review that will draw on primary studies.

### Inclusion and Exclusion Criteria

Studies must have been done in Africa, be interventional (randomized clinical trial, cluster randomized trial or quasi-experimental trials), and contain individuals aged 18 to 65 as the subjects to be eligible for inclusion in this study. Intervention must be health education of any type of method and length (long, intermediate, or short duration). Comparison to be considered must be a control group not receiving an intervention or a control group receiving an alternative intervention.

All observational and/or interventional research studies conducted outside of Africa, and studies using non-human participants will also not be included. Letters, opinions, case-reports, and other editorial submissions will not be accepted. In addition, studies where interventions are not health education even if within Africa, studies done among caregivers, and whose subjects are considered too sick will not be included.

### Outcome Measurement

The outcomes to be measured in all included studies will be improvement in:

- Prevalence of antibiotics misuse and self-medication
- Knowledge on antibiotics misuse and self-medication
- Attitude on antibiotics misuse and self-medication
- Practice on antibiotics misuse and self-medication.

### Information Sources

To identify all studies that satisfy our inclusion criteria, multiple databases relevant to our research questions will be searched. Multiple databases search has been shown to provide better outputs as compared with a single database search in systematic reviews.<sup>29</sup> In addition, references of identified studies will be assessed to identify other potential studies for inclusion. Multiple databases search combined with reference checking increases inclusion rates of systematic reviews.<sup>30</sup> The following databases will be searched from 2010–2021:

MEDLINE(PubMed), EMBASE, BIOLINE, PsycINFO, CINAHL and Web of Sciences. Other potential sources that

will be searched include conferences and abstracts books.

### Search Strategy

To broaden the search strategy, both keywords and index/subject terms will be used. The Boolean operator “OR” will be used to broaden chances of retrieving more publications rather than “AND”, that will enable greater sensitivity but at the expense of precision which is less favored to enable inclusion of more publications. To increase the precision of our search strategy, we will apply search filters with respect to the following fields:

1. Article /publication type (Primary research articles in academic journal type of publication)
2. Publication dates (From 2011–2021)
3. Language (To include only studies published in English language)
4. Subject
5. Ages (Participant included must be Adults).

### Search for “Grey Literature”

We will attempt to search for all unpublished data on effects of health education intervention on antibiotics misuse and self-medication by searching the following sources:

1. Dissertations /Thesis
2. Conference abstracts, presentations, proceedings
3. Government reports
4. Newsletters /Bulletins

We will limit our search terms to titles[ti] and abstracts[ab] only. We will search google and google scholar for grey literature, Scopus, Web of Sciences, SciFinder, ProQuest Dissertation & Theses, Ethos, NGOs and IGOs websites, OpenGrey and OpenDOAR websites.

### Documenting our Search Strategies

To allow for reproducibility, we will document the following steps/actions taken during our systematic review search.

- Databases searched
- Database time covered
- Search strategies applied
- Date each search was conducted
- Number of results for each search strategy

- Number of results after deduplicating.

### Search Terms

The following keywords search terms will be used as key words and subsequently with MeSH synonyms and respective databases vocabularies. #Antibiotics, #Antimicrobials, #Antibacterial agents, #Self-medication, #Self-prescription, #Misuse, #Nonprescription, #Non-prescription, #Over-the-counter, #Drugs, #Drug misuse, #Inappropriate use, #Antibacterial agents, #Self-medication, #Self prescription, #Misuse, #Inappropriate use, #Health education, #Intervention, #RCT, # Randomized control trial, #Quasi randomized trial, #Non randomized control trial, #Quasi randomized control trial, #adults, #Community based study.

Table 1 below shows detailed search strategies for PubMed search which will be modified to search other databases where there are specific requirements that are different from PubMed database.

### Selection Process

Two reviewers will independently assess titles and abstracts of our search results for possible inclusion or exclusion based on our predetermined set of criteria. Where titles and or abstracts are adjudged for possible inclusion, the full texts of the articles will be retrieved for quality assessments prior to data extraction by a set of two independent reviewers. In a situation where two independent reviewers disagree on a particular article, such disagreement will be resolved by consensus. Where a consensus is not reached, a third reviewer will be used as tiebreaker as it is shown in methods of systematic reviews of prevalence studies.<sup>31</sup>

### Data Collection Process

Two Reviewers will independently extract data from included studies using a Data Abstraction Form (DAF) developed priori (See attached index). The reviewers will extract data on: Corresponding Author, Year of Publication, Country, State, Type of participants, Study settings, Sample size, Sampling design, Number of participants/Response rate, antibiotics

**Table 1: Educational Interventions for Antibiotic Misuse and Self Medication in Africa**

Theme	Search terms
<b>Educational Interventions</b>	1. “Health-communication”[tiab] OR “Health-communications”[tiab] OR “Health Promotion”[tiab] OR Educat*[tiab] OR Campaign*[all] OR Radio[all] OR Video*[all] OR audio[all] OR Train*[all] OR Counsel*[all] OR Pamphlet*[all] OR Poster*[all] OR print*[all] OR leaflet*[all] OR flyer*[all] OR brochure*[all] OR booklet*[all] OR publication*[all] OR card*[all] OR television[all] OR graphic*[all] OR picture*[all] OR pictorial*[all] OR pictogram*[all] OR illustrat*[all] OR Advertis*[all] or advertiz*[all] OR Health education[mh] OR Health Promotion[mh] OR Health Communication[mh] OR Patient education as topic[mh]
<b>Antibiotics misuse/ self-medication</b>	2. (Antibiotic*[tiab] OR “Anti-bacterial-agent”[tiab] OR “Anti-bacterial-agents”[tiab] OR “Antibacterial agent”[tiab] OR “Antibacterial agents”[tiab] OR “Anti-Bacterial-Compound”[tiab] OR “Anti-Bacterial-Compounds”[tiab] OR “Antibacterial Compound”[tiab] OR “Antibacterial Compounds”[tiab] OR Bacteriocid*[tiab] OR antimicrobial*[tiab] OR “anti-microbial”[tiab] OR “anti-microbials”[tiab] OR antibacterial*[tiab] OR “anti-bacterial”[tiab] OR “anti-bacterials”[tiab] OR “Anti-Mycobacterial-Agent”[tiab] OR “Anti-Mycobacterial-Agents”[tiab] OR “AntiMycobacterial Agent”[tiab] OR “AntiMycobacterial Agents”[tiab] OR Anti-Bacterial Agents[mh]) AND (Misuse[tiab] OR Overuse[tiab] OR use[tiab] OR abuse[tiab] OR “Self-Medicat”[tiab] OR “Self-Medication”[tiab] OR “Self Medicate”[tiab] OR “Self Medication”[tiab] OR Self-prescription*[tiab] OR Self-prescrib*[tiab] OR Self medication[mh] OR Non-prescription*[tiab] OR “Inappropriate use”[tiab] OR “over the counter”[tiab] OR Drug misuse[mh])
<b>Africa</b>	3. (“Africa”[MeSH] OR Africa*[tw] OR Algeria*[tw] OR Angola*[tw] OR Benin*[tw] OR Botswana[tw] OR Motswana[tw] OR Batswana[tw] OR “Burkina Faso”[tw] OR Burkinabe*[tw] OR Burundi*[tw] OR Cameroon*[tw] OR “Canary Islands”[tw] OR “Cape Verde”[tw] OR “Cape Verdean”[tw] OR “Central African”[tw] OR “Central Africans”[tw] OR Chad*[tw] OR Comoros[tw] OR Comorian*[tw] OR Congo[tw] OR Congolese[tw] OR “Democratic Republic of Congo”[tw] OR Djibouti*[tw] OR Egypt*[tw] OR “Equatorial Guinea”[tw] OR “Equatorial Guineans”[tw] OR Eritrea*[tw] OR Eswatini[tw] OR Ethiopia*[tw] OR Gabon[tw] OR Gabonese[tw] OR Gabonaise[tw] OR Gambia*[tw] OR Ghana[tw] OR Ghanaian*[tw] OR Guinea[tw] OR Guinean*[tw] OR “Guinea Bissau”[tw] OR “Ivory Coast”[tw] OR “Cote d’Ivoire”[tw] OR Ivorian*[tw] OR Ivoirian*[tw] OR Jamahiriya[tw] OR Jamahiriyia[tw] OR Kenya*[tw] OR Lesotho[tw] OR Mosotho[tw] OR Basotho[tw] OR Liberia*[tw] OR Libya*[tw] OR Libia[tw] OR Madagascar[tw] OR Malagasy*[tw] OR Malawi*[tw] OR Mali[tw] OR Malian*[tw] OR Mauritania*[tw] OR Mauritius[tw] OR Mauritian*[tw] OR Mayote[tw] OR Mahoran*[tw] OR Morocco[tw] OR Moroccan*[tw] OR Mozambique[tw] OR Mocambique[tw] OR Mozambican*[tw] OR Namibia[tw] OR Namibian*[tw] OR Niger[tw] OR Nigerien*[tw] OR Nigeria*[tw] OR Principe[tw] OR Reunion[tw] OR Reuniones[tw] OR Rwanda*[tw] OR “Sao Tome”[tw] OR Santomean*[tw] OR Senegal[tw] OR Senegalese[tw] OR Seychell*[tw] OR “Sierra Leone”[tw] OR “Sierra Leonean”[tw] OR “Sierra Leoneans”[tw] OR Somalia[tw] OR Somali*[tw] OR “South Africa”[tw] OR “South African”[tw] OR “South Africans”[tw] OR “St Helena”[tw] OR Sudan*[tw] OR Swaziland[tw] OR Swazi*[tw] OR Tanzania*[tw] OR Togo[tw] OR Togolese[tw] OR Tunisia*[tw] OR Uganda*[tw] OR “Western Sahara”[tw] OR Sahrawi*[tw] OR Zaire[tw] OR Zairian*[tw] OR Zambia*[tw] OR Zimbabwe*[tw] OR “Central Africa”[tw] OR “Central African”[tw] OR “West Africa”[tw] OR “West African”[tw] OR “Western Africa”[tw] OR “Western African”[tw] OR “East Africa”[tw] OR “East African”[tw] OR “Eastern Africa”[tw] OR “Eastern African”[tw] OR “North Africa”[tw] OR “North African”[tw] OR “Northern Africa”[tw] OR “Northern African”[tw] OR “South African”[tw] OR “Southern Africa”[tw] OR “Southern African”[tw] OR “sub Saharan Africa”[tw] OR “sub Saharan African”[tw] OR “subSaharan African”[tw]) NOT (“guinea pig”[tw] OR “guinea pigs”[tw] OR “aspergillus niger”[tw])
Duration	4. “2010/01/01”[PDAT]: “2022/06/10”[PDAT]
Search-1	5. #1 AND #2 AND #3 AND #4
Search-2	6. animals [mh] NOT humans [mh]
Search-3	7. #5 NOT #6

misuse and self-medication prevalence in experiment group, and prevalence in control group at pre and post intervention, antibiotics misuse and self-medication mean scores in knowledge and mean score in attitude at pre- and post-intervention.

#### Data Items

Variables for which data will be obtained include:

*Design:* Total sample size enrolled, Number allocated to treatment (cases) group, Number allocated to comparison (control) group, Follow-up period, Final number evaluated

*Participants:* Target population, Socio-demographic profiles.

*Study Structure:* Setting, Location, Data Collection Method, Funding.

*Intervention:* Method of health education, Group receiving health education, Duration of training, Incentives, Other interventions.

#### Outcomes for which Data would be sought include:

1. Pooled antibiotics misuse and self-medication prevalence
2. Mean score of knowledge of antibiotics misuse and self-medication across all included studies
3. Mean score of attitudes for antibiotics misuse and self-medication across all included studies
4. Mean score of practice for antibiotics misuse and self-medication across all included studies.

Other variables for which data will be sought include age of participants, sex, place of residence. Where there is missing information, attempts will be made to contact the authors using the address of corresponding authors.

#### Study Risk of Bias Assessment

Assessment of risk of bias is an essential component of systematic reviews. The Revised Cochrane Risk of Bias Assessment Tool (RoB 2) which is the most widely preferred tool available,<sup>32</sup> will be used to evaluate the included studies for possible bias. Bias is assessed in five distinct domains in the RoB 2. Within each domain of RoB 2 there are 1-2 questions that will be responded to as “Yes”, “Partially Yes”, “No”, “Partially No”, “Not Sure”. The answers will lead

to judgments of “low risk of bias,” “some concerns,” or “high risk of bias”.

#### Effect Measures

The primary outcome will be occurrence of event (antibiotics misuse and self-medication). The effect measure will be proportion of the event within the groups. Other outcomes to be measured will be mean scores of knowledges, attitude and practice of antibiotics and reasons for antibiotics misuse.

#### Data Synthesis Methods

The table of characteristics of included studies and the quality assessment will be used to assess whether a study is eligible for inclusion or not. Quantitative variables will be reported using mean and standard deviation and variance while qualitative discrete variables will be reported using median and inter-quartile range. Where there is missing summary statistics, attempt will be made to contact the authors for information or raw data to enable synthesis of the summary statistics. Non-normally distributed variables will be transformed by either Freeman-Turkey transformation<sup>33</sup> or by Logit transformation methods.<sup>34</sup> Results of meta-analysis will be displayed in forest plot. Graphs will be used to display publication bias assessment and heterogeneity. Tables will be used to summarize frequencies and percentages. Results will be synthesized using the following methods:

- *Narrative summary:* This will include summary of types of antibiotics misuse, sources, and reasons of antibiotics misuse.
- *Tables:* This will include frequencies and percentages of types of antibiotics misuse, sources, and reasons of antibiotics misuse.
- *Graphs:* This will include bar graphs and pie charts to summarize types of antibiotics misuse, sources, and reasons of antibiotics misuse.
- *Meta-Analysis:* This will include weighted effects sizes of individual studies as well as pooled summary of effect size combined in a meta-analysis. A fixed effect model will be used for the summary, however, where there is significant heterogeneity, a random effect model will

be used. Also, sub-group analysis based on certain characteristics such as study settings, gender and age will be carried out. Meta regression will be performed using median age of included studies to assess its effects on the primary outcome variable (prevalence of antibiotics misuse and self-medication).

#### Heterogeneity

We will explore presence of heterogeneity to enable us to know whether there are significant variations in the characteristics of our included studies. Clinical heterogeneity will be assessed by examining the table of included studies to assess participants characteristics, study settings, samples sizes and effects sizes. Statistical heterogeneity will be assessed by first examining forest plot of the meta-analysis using “eye-baling” approach. Presence of overlaps in confidence intervals margins of included studies will suggest lack of heterogeneity. Quantitative measurements of heterogeneity will be done by using chi-squared test and I<sup>2</sup> tests. A P-Value >0.05 signifies lack of heterogeneity. I<sup>2</sup> test of 25% will mean low heterogeneity, 50% will mean moderate heterogeneity and 75% will mean high heterogeneity. If there is significant heterogeneity, we will use subgroup analysis (such as subset of studies or subset of participants) and meta-regression to explore sources of heterogeneity across the included studies. Also, we will use random effect model for our meta-analysis if significant heterogeneity exists.

We will assess the robustness of our synthesized results using sensitivity analyses. This will enable us assess our decision on included studies and on the quality of the included studies. We will carry out sensitivity assessment using the following approaches:

- Forest plot by precision
- Egger’s and Begg’s regression
- Finding/removing outliers
- Leave-one-out.

#### Reporting Bias

We will assess presence of bias in reporting results of our included studies using the following methods:

- *Examination of Funnel Plot Appearance:* Absence of asymmetry of the funnel plot by presence of outliers will indicate presence of bias in the reporting of result of our included studies.
- *Egger's Regression Test:* This will test Y-Intercepts with P-Value. If the P-Value is greater than 0.05 it shows lack of reporting bias.
- *Standardized Residual Histogram:* This test will also show a symmetry of included studies when there is no reporting bias.
- Galbraith plot
- Normal Quintile plot
- Rosenthal fail safe test
- Glasser and Olkin fail safe test
- Trim and Fill test.

### Certainty (or Confidence) Assessment

We will assess the methodological quality of our included studies using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.<sup>35</sup> The GRADE has gained momentum as an internationally recognized framework to assess the quality of evidence systematically and transparently.<sup>36</sup> The GRADEPro software will be used to design our Endpoint and Summary of findings tables<sup>37</sup> Two independent reviewers will use the GRADE criteria to evaluate the quality of evidence across studies. The quality of evidence is evaluated based on the type of evidence, quality points, consistency, directness and effect size. The five GRADE criteria summarized according to Victoria Srbely<sup>38</sup>- below:

1. Type of evidence (study design). Scientific evidence derived from randomized control trials begins at a rating of four points; in contrast, evidence from observational studies is assigned a rating of two.<sup>39</sup>
2. Quality points (Limitations). A total of three points can be deducted under this category based on inadequacies in follow-up procedures, sparse data, blinding, allocation concealment, and attrition.<sup>40</sup>
3. Consistency. Heterogeneous studies are evaluated under this category if they all address the same outcomes and interventions. A

quality point is deducted under this category for inconsistent results between studies while, in contrast, a quality point is added if a dose-response effect is observed or if adjustment of confounders increased the effect size.<sup>41</sup>

4. Directness. A maximum of two points can be deducted for issues affecting the generalizability of the results to the population of interest. Examples of issues affecting directness include co-interventions that are being tested alongside the intervention of interest, as well as the use of samples that are either too broad or too restricted.<sup>42</sup>
5. Effect Size. The GRADE criteria add a quality point for an odds ratio (OR) or relative risk (RR) 2 and adds two quality points for an (OR) or RR.

One quality point is added for effect sizes  $> 2$  (or  $< 0.5$ ), while two quality points are added for effect sizes that are  $> 5$  (or  $< 0.2$ ) and are all statistically significant. No quality points are added for effect sizes  $< 2$  or statistically insignificant results. The final score of at least four points indicates high quality of evidence, three points reflects moderate quality of evidence, two points suggests low quality of evidence, and one point represents a very low quality of evidence.<sup>43</sup>

To further assess the robustness of this review, sensitivity analysis will be performed by removing studies with low quality and examine their effects on the pooled aggregate statistic.

### Protocol Registration Number

CRD42022299022 (Prospero).

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