STUDY PROTOCOL

Methods

Design

The design of this research will be a systematic review. This systematic review will adopt and follow the reporting guidelines and criteria set in the Preferred Reporting Items for Systematic Review (PRISMA) statement, and standard in systematic review reporting (Moher et al., 2009).

Inclusion and Exclusion Criteria for Considering Studies

In this systematic review we will include peer-reviewed journal articles (published only). We focused on empirical research studies using quantitative study design and research methods. We primarily limited our design to intervention designs (randomize control trials, cluster-randomized trials, quasi-experimental trials), which targeted group-level intervention and park or place-based interventions. While qualitative indicators may be present in the article, if the study used a mixed-methods design, this systematic review will only extract the quantitative data. The inclusion criteria are: (1) article described an intervention conducted at a park; (2) article published in English or Spanish; (3) evaluated physical or mental health outcomes; (4) and program/intervention was conducted in a park accessible to the larger community (i.e., schoolyard only used by school children). Two key considerations are needed to identify park-based interventions. The first are articles that describe interventions that focused on park use after an environmental change at a park or parks (e.g., updating park equipment). The second are articles that describe cohort studies in which groups of people are recruited to a health program that involves a park component. We will exclude abstracts, dissertation/theses, blogs, newsletters, organization documents and government reports, book and book chapters, conference proceedings, studies evaluating Public Open Space, studies primarily assessing neighborhood-level characteristics (sidewalks), and studies conducted in national and state parks.

Populations of Interest and Exposure Measures

This study will review articles that report an empirical analysis that involves the comparison of either groups that receive a health intervention at a park (or prescribes park use) compared to those who do not. We are also comparing studies that have an environmental intervention at a park and comparing park use and related health behaviors or health status before and after park-level intervention. Studies across age groups will be included to characterize interventions in parks for children and adults. There will not be any restrictions for the gender or geographic location of the study participants.

Outcome Measures

Key health behaviors, primarily physical activity (e.g. moderate-to-vigorous physical activity), and health outcomes such as strength, balance, mental well-being, and body mass index (BMI) are all outcomes of interest. We are keeping the outcomes broad to capture the interventions conducted in parks.

Search Strategy

The following databases will be used to search for relevant peer-reviewed publications: Web of Science, Pubmed, and Scopus. Manual hand-searching of reference lists from studies identified as relevant by experts will be conducted to further identify articles of interest. One author will consult with experts int eh field to identify any other relevant articles as well as further fine-tune the search criteria. All searches

will be limited to studies published in the English or Spanish language, as that is the capacity of the authors. The search terms are presented in Appendix 1.

The literature search will be conducted in conjunction with a research librarian who has an expertise in systematic reviews. The authors will work with the research librarian to fine tune the search.

All records will be downloaded and de-duplicated in EndNote (V8). The de-duplicated list of records will be imported into Covidence, an online, systematic review platform that allows for screening of records by multiple users. First, we will conduct the title/abstract screening of records against a list of inclusion/exclusion criteria, then the full-text review in the Covidence system.

Identification and Selection of Studies

Initially, one author experienced in systematic reviews will screen relevant citation (title, abstract, keywords). An author will subsequently screen the full text of articles meeting inclusion criteria at the title/abstract screening phases and a second author will review each decision for quality assurance. Rational for excluding studies will be recorded and reported as part of the screening process. Any discrepancies are to be reviewed by the senior author for reconciliation. The authors will select the studies following the evidence-based checklists developed by the PRISMA statement. Per PRISMA guidelines, a flow diagram will be developed to show the process of study selection at different phases.

Data Extraction and Management

The final list of articles will undergo data abstraction using the Community Guide's *Guide to Community Preventive Services* tool (Zaza et al., 2000). This tool contains 55 questions; however, we will adapt some of the questions to account for the needs of this abstraction for a total of 62 questions. The types of information abstracted included (1) descriptive information (e.g., the purpose of the study, how the intervention was being delivered, geographic location and study site); (2) the study population (e.g., eligibility criteria, demographic characteristics, attrition details); (3) results (estimate, significance, interpretation); and (4) study quality. A full list of questions attached in Appendix 2. These questions will be transcribed to an online survey platform, Qualtrics, and includes both structured interview and open-response options. Once trained on the tool, two co-authors will independently extract study information. After data abstraction is complete, two co-authors will conduct a quality assurance check to ensure all data were accurately extracted.

Methodological Quality Assessment

The quality of each eligible study will be assessed using the validated Guide to Community Preventive Services. The key domains of the GCPS tool used to determine the quality of the studies are: description of the study, sampling type, measurement, analysis, interpretation of results, and other details. Quality for all included studies will be assessed by the first author and for 10% of included studies completeness and accuracy independently by the second author. Differences in quality assessment will be resolved by a discussion of all authors.

Data Analysis and Reporting the Findings

The data synthesis will include a descriptive summary of the study characteristics. A summary table of risk of bias will also be included. A table on empirical outcomes found by intervention type and primary outcome will be presented as relative risks, odds ratios, or risk difference for dichotomous outcomes or mean or mean differences for continuous outcomes. Longitudinal studies will be presented with effect

sizes of the change in the health-related outcomes over time. Significance values in either p-values or confidence intervals will be presented if available.

Meta-analysis will only be considered when the included studies are sufficiently homogenous in terms of study design, participants, interventions and outcomes to provide meaningful summary measures. If meta-analysis is not possible, the data will be synthesized narratively based on a framework for narrative synthesis.

REFERENCES

Moher D., Liberati A., Tetzlaff J., Altman D.G. (2000) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. Annals of Internal Medicine, 151, 264–269.

Zaza, S., Wright-De Agüero, L. K., Briss, P. A., Truman, B. I., Hopkins, D. P., Hennessy, M. H., ... & Pappaioanou, M. (2000). Data collection instrument and procedure for systematic reviews in the guide to community preventive services. *American Journal of Preventive Medicine*, 18(1), 44-74.

Appendix 1.

Starting a Literature Review – Parks and Parishes

Topic: Identify park-based interventions _

Main ideas here and related words and phrases:

1: Park*	*AND*	**2: Physical Activity**	*AND*	**3: Intervention***
Parklet* Built environment* Playfield Recreation center* Green space Fitness zone*		Exercise Moderate to vigorous MVPA Physical health Mental health Sedentary METs Metabolic equivalent task		RTC Randomized controlled trial SOPARC SOPLAY System for Observing Play and Recreation in Communities Experiment Program* Evaluation Direct observation

NOT

- Cattle, cows, elephant*, deer, boar, predator*, leopard*, national park

ADDITONAL KEY WORDS:

DATABASES

- Search database such as (e.g., Pubmed, Web of Science, SCOPUS)

PUBLICATION TYPE

- Interested in intervention or empirical studies but will review editorials and commentaries for background.

LANGUAGES

- English and Spanish

YEARS

- Through current date

Appendix 2.

Data Abstraction Form

This abstraction form is derived from the Guide to Community Preventive Services. Each abstractor should review each paper using this form. This form consists of 3 sections: Part 1 - Classification Information, Part 2 - Descriptive Information about the intervention (evaluation study characteristics, measurement of outcomes, and results), and Part 3 - Study Quality (focused on execution of the study).

On average it takes 2-3 hours to read an article and complete the form. Some questions include text boxes, for these questions please do not limit the amount of information that can be provided.

Part 1. Classification Question

Instructions/Definitions:
1. Study Design
2. Intervention Components -- many studies have multiple components, therefore please select all that apply

a. Provision of information only: These interventions try to change knowledge, attitudes, or norms. Intervention methods might involve instruction (classes, assemblies), small media (brochures, leaflets, posters, letters) or large media (television, radio, newspapers). For these interventions, also note that target population.
b. Behavioral interventions: These interventions try to change behaviors by providing necessary skills or materials. Intervention methods might involve modeling or demonstration, role playing, participatory skill development, individual benchmarking (goal-setting), providing feedback, providing incentives or penalties, or providing materials necessary to perform the desired behavior (condoms, smoking cessation). For these interventions also not the target population.
c. Environmental interventions: These interventions try to change the physical and or social environment to promote health or prevent disease. Interventions in the physical environment might involve adding to (fluoride in water), changing (resilient playground surfaces), or subtracting from (lead from paint) the environment. Interventions in the social environment might include increasing employment opportunities or development of community coalitions to change social systems.
d. Legislation/Regulation/Enforcement: These interventions try to change behaviors or alter risk factors by legislating particular behaviors, regulating risk factors, and enforcing those laws and regulations (tobacco tax, school vaccination laws).
e. Clinical: These interventions aim to increase access to and assurance of clinical care (patient-focused).
f. Public Health or medical care system interventions: These interventions aim to change to change the public health or clinical care systems to increase or improve delivery of systems, such as surveillance systems.

3. Primary outcome measure(s): How was (were) the outcome measure(s) defined? Check all that apply and provide the definition used by authors.
a. Behavior - such as the observed correct use of work site protective equipment
b. Other intermediate or mediating outcome: an outcome that precedes or is correlated with one or more health outcomes and stems from exposure to a determinant
c. Non-fatal health outcome: injury
d. Severity of illness/injury: severity scores for injury outcomes
e. Death: fatal outcomes
f. Surrogate outcome: an outcome that is considered to be a proxy for health or other outcomes of interest

Study Design

- [ ] Randomized trial (experiment) - Individual
- [ ] Randomized trial (experiment) - Group
- [ ] Non-randomized "trial" (with >= 1 comparison group) - Individual
- [ ] Non-randomized "trial" (with >= 1 comparison group) - Group
- [ ] Prospective cohort study
- [ ] Other designs with concurrent comparison groups
- [ ] Retrospective cohort study
- [ ] Place-based study
- [ ] Case-control study
- [ ] Pre-post study
- [ ] Cross-sectional study
- [ ] Non-comparative study
- [ ] Time-series study
- [ ] Not reported

Intervention Components (check all that apply)

- [ ] Provision of information only
- [ ] Behavioral intervention
- [ ] Environmental intervention
- [ ] Legislation/Regulation/Enforcement
- [ ] Clinical
- [ ] Other

If "provision of information only" or "behavioral intervention" was selected, what population was targeted?

- ○ General
- ○ High-risk group
- ○ Professional group

If "environmental intervention" was selected, what type was targeted?

- ○ Physical environment
- ○ Social environment

Was the intervention part of a larger intervention effort?

- ○ Yes (describe in Part 2 - question 1)
- ○ No

Primary outcome measure(s) (select all that apply)

	Select outcomes	Describe
Behavior (e.g. physical activity, dietary behaviors)	☐	
Physical health (e.g., fitness)	☐	
Mental health (e.g., depression, stress, anxiety)	☐	
Psychosocial (e.g., coping, social support)	☐	
Anthropometric (e.g., body weight, fat, weight circum.)	☐	
Non-fatal health effect	☐	
Other intermediate or mediating outcome	☐	

Part 2. Descriptive Information

What is the purpose of the intervention?
Describe the level or scale of focus (individual, family, group, community, general public). Describe the services, materials, or other information that were delivered, or the policy or law that was enacted (including information about enactment, implementation, and enforcement).

How is the intervention being delivered?
Describe who delivered the intervention (health professional, volunteer, peer) how they were trained, and how they were assigned. Describe the time period, frequency, and duration of the intervention. Describe the scope of the intervention (how many members of the target group(s) were reached by the intervention)

Who is being targeted?
This may be broader than the population that was studied in the evaluation; briefly describe the characteristics of the target population.

Where is the intervention being delivered?
The intervention might be delivered in a particular type of setting or community-wide. This parameter should be described for the intervention as it is implemented, which might be in a setting broader than that which was studied in the evaluation.

Did authors describe the theoretical basis or constructs upon which the intervention was developed?

- ○ _____ Yes
- ○ No

Language of the published study

- ○ English
- ○ Spanish
- ○ _____ Other

What type of organization implemented the intervention (i.e., directly interacted with population under study, not organization that might have provided scientific or financial support)? (check all that apply)

	Select all that apply	Select all that apply				Provide detail
	Organization	Public health agency	Federal	State	Local	Describe
Managed care organization	☐	☐	☐	☐	☐	
Other clinical organization	☐	☐	☐	☐	☐	
Academic organization	☐	☐	☐	☐	☐	
Community-based organization	☐	☐	☐	☐	☐	
Other	☐	☐	☐	☐	☐	
Unknown	☐	☐	☐	☐	☐	
Does not apply	☐	☐	☐	☐	☐	

Describe any interventions deliberately or inadvertently applied to the comparison or control group(s):

	Group type	Provide detail
	Select all	Describe
No comparison group	○	
No intervention for comparison group (purposefully or inadvertently)	○	
Intervention applied to comparison group	○	

Part 2. Descriptive Information -- B. Evaluation Study Characteristics

Place/Time

	Location Select all	Details Provide details
United States	☐	
Latin America or the Caribbean	☐	
Other	☐	

Population density (check all that apply)

- ☐ Urban
- ☐ Suburban
- ☐ Rural
- ☐ Mixed
- ☐ Not reported

Setting (check all that apply)

- ☐ Park
- ☐ Clinic or health-care provider office
- ☐ Hospital
- ☐ Child day care center
- ☐ Drug treatment facility
- ☐ Mental health setting
- ☐ Community-based organization
- ☐ School
- ☐ Workplace
- ☐ Religious institution
- ☐ Nursing Home
- ☐ Home
- ☐ Prison
- ☐ Shelter
- ☐ Street
- ☐ Community wide
- ☐ Other

Neighborhood SES, select all that apply and briefly describe

- ☐ _____ Low-income
- ☐ _____ Middle-income
- ☐ _____ High-income
- ☐ Not specified

How were outcomes and other independent (or predictor) variables measured? (check all that apply). Provide information on observer or interviewer training and masking, as well as inter-observer agreement as appropriate.

	Outcome Select all	Describe Provide details
Resource utilization	☐	
Observation	☐	
Interview	☐	
Self-administered questionnaire	☐	
Laboratory test	☐	
Record review	☐	
Other	☐	
Not reported/did not assess	☐	

Where were outcomes measured?

	Outcome(s) Answer 1	Describe Answer 1
Same as intervention setting	○	
Different from intervention setting. If yes, describe.	○	

Time period and intervals outcome(s) measured?

Part 2. Descriptive Information -- Study Population

For studies in which the investigator allocated subjects to intervention/comparison groups, describe the groups or individuals who were allocated and the total number eligible for inclusion in the study (N=sampling frame). Of those eligible, provide the numbers of groups/or individuals who were allocated. Also provide descriptions of the groups or individuals who were observed and included in analyses and provide the numbers of groups or individuals who were observed and included in analyses. For observational studies in which the investigators did not allocate intervention and control conditions, describe the groups or individuals who were observed and included in the analysis; enter NA in the allocation columns for these studies. Many study designs have samples selected or make measurements at multiple points in time; include this information if it is provided.

Eligibility criteria (describe):

Levels of allocation and analysis: description and numbers of groups and individuals and methods of sampling.

	Description of groups or individuals N= sampling frame	Allocation: Intervention (n)	Allocation: Intervention (sample)	Allocation: Comparison (n)	Allocation: Comparison (sample)	Number analyzed
Group 1						
Group 2						
Group 3						
Group 4						
Individuals						

If the study is an observational study, please describe the groups or individuals who were observed and included in the analysis.

For designs using follow-up of the study population, calculate the completion rate(s) for the study population.

Number analyzed/Number allocated X 100

Assessment of exposure to the intervention. Provider the definition of each exposure variable and the level of exposure in the space provided for each.

	Select all	Describe
Resources utilization		
Observation		
Interview		
Self-administered questionnaire		
Laboratory test		
Record review		
Other		
Not reported/did not assess		

Study population demographics - Age

	Group 1	Group 2	Group 3	Group 4
Mean				
Range				
Not reported				

Sex

	Group 1	Group 2	Group 3	Group 4
% Male				
% Female				
% Unknown				
Not reported				

Race (%)

	Group 1	Group 2	Group 3	Group 4
American Indian or Alaska Native				
Asian				
Black or African American				
Native Hawaiian or Other Pacific Islander				
White				
Other/unknown				
Not reported				

Ethnicity (%)

	Group 1	Group 2	Group 3	Group 4
Hispanic/Latino				
Not Hispanic/Latino				
Other/Unknown				
Not reported				

Socioeconomic status, if described in the study

	Group 1	Group 2	Group 3	Group 4
Low	☐	☐	☐	☐
Middle	☐	☐	☐	☐
Upper	☐	☐	☐	☐
Not reported	☐	☐	☐	☐

Other population and demographic risk factor chacteristics

	Specify
Group 1	
Group 2	
Group 3	
Group 4	

Some interventions are directed at a specific study population, but ultimately affect health or other related outcomes (e.g., behaviors) that are measured in a different population. For example, a provider education intervention is directed at health care providers (the "study population"), but the health outcome occurs in their patients (the "ultimately affected" population). Another example is when an educational intervention directed at parents (the "study population") ultimately affects their children (the "ultimately affected" population). Does this study report demographic information for or measure an outcome in a population in a population of persons who were ultimately affected by the intervention applied to the study population?

"Ultimately affected" population described or outcomes reported?

- ○ Yes (go to next question)
- ○ No (skip to results section)

Number of groups in "ultimately affected" population?

Number and description of members in each group:

"Ultimately affected" population demographics

	Group 1	Group 2	Group 3	Group 4
Age (mean)				
Age (range)				
Not reported				

Ultimately affected populations - Sex

	Group 1	Group 2	Group 3	Group 4
Male				
Female				
Unknown				
Not reported				

Ultimately affected populations - Ethnicity (%)

	Group 1	Group 2	Group 3	Group 4
Hispanic/Latino %				
Not Hispanic/Latino %				
Other/Unknown %				
Not reported				

Ultimately affected populations - Socioeconomic status, if described in the study

	Group 1	Group 2	Group 3	Group 4
Low	☐	☐	☐	☐
Middle	☐	☐	☐	☐
Upper	☐	☐	☐	☐
Not reported	☐	☐	☐	☐

Other population demographic and risk factor characteristics

	Specify
Group 1	
Group 2	
Group 3	
Group 4	

Part 2. Descriptive Information - Results

Primary study results: Describe each of the primary outcome measures used in this study and the effect measure as reported by the author. Indicate the table number (in the paper) form which the data are taken, if applicable. For each outcome measure report eh results for each arm of the intervention group (as applicable) and for each of the comparison groups (as applicable); report the results for each time period measured as applicable to the study design (i.e., before and after the intervention, only after the intervention, for each time period in a time series design). Fill in the time periods as shown).

Primary outcome #1

	Effect size E.S.	Confidence Interval or p-value (level of significance) Significance	Outcome; Details from article about E.S. testing and interpretation Details	Specify table/page found in the article Specify
Intervention Arm 1				
Intervention Arm 2				
Intervention Arm 3				
Comparison Group 1				
Comparison Group 2				
Comparison Group 3				

Primary outcome #2

	Effect size: for studies with pre-post measurements		Effect size: for studies with multiple measurements over time				Software used, hypothesis test p values, CI, etc.	Describe outcome and table/page found in the article
	Pre	Post	Time 1	Time 2	Time 3	Time 4	Specify	Specify
Intervention Arm 1								
Intervention Arm 2								
Intervention Arm 3								
Comparison Group 1								
Comparison Group 2								
Comparison Group 3								

Primary outcome #3

	Effect size: for studies with pre-post measurements		Effect size: for studies with multiple measurements over time				Software used, hypothesis test p values, CI, etc.	Describe outcome and table/page found in the article
	Pre	Post	Time 1	Time 2	Time 3	Time 4	Specify	Specify
Intervention Arm 1								
Intervention Arm 2								
Intervention Arm 3								
Comparison Group 1								
Comparison Group 2								
Comparison Group 3								

Primary outcome #4

	Effect size: for studies with pre-post measurements		Effect size: for studies with multiple measurements over time				Software used, hypothesis test p values, CI, etc.	Describe outcome and table/page found in the article
	Pre	Post	Time 1	Time 2	Time 3	Time 4	Specify	Specify
Intervention Arm 1								
Intervention Arm 2								
Intervention Arm 3								
Comparison Group 1								
Comparison Group 2								
Comparison Group 3								

Power calculation, other statistical analysis, or citation?

- ○ Yes
- ○ No; was sample size sufficient? Justify

Were secondary results of interest reported (including subpopulation differences, dose-response relationships, or others)? If yes, describe those results (include page and table number).

- ○ Yes; if yes, specify
- ○ Not reported

Feasibility and other key issues addressed in the paper

- [ ] Costs
- [ ] Potential harms
- [ ] Other benefits
- [ ] Implementation
- [ ] Barriers to implementation
- [ ] Community acceptance or involvement
- [ ] Formation or use of existing coalitions to develop, implement, or evaluate interventions
- [ ] Ethical constraints
- [ ] Other
- [ ] Not discussed

Other important information:

Relevant references:

Part 3. Study Quality Instructions

Study quality is evaluated using six categories of common problems (descriptions, sampling, measurement, analysis, interpretation of results, and other). Study validity poses a complex problem when evaluating the quality of studies. It is possible that elements of each of the six categories contribute to problems with study validity. Therefore, we have tried to elicit information in each category that may contribute to poor study validity which potentially limit our ability to interpret the results of the study.

Was the study population (i.e., the intervention and comparison population) well described? The study population should be described by time (e.g., when the study population received the intervention), place, and person. Information about "person" should include at least age (for all studies) and should include other relevant characteristics of participants that are key to a particular study (e.g., SES, gender, other). Important potential confounding factors should also be described.

- ○ Yes
- ○ No

Was the intervention well described (what, how, who, where)?

- ○ Yes
- ○ No

Did the authors specify the sampling frame or universe of selection for the study population?

- ○ Yes
- ○ No
- ○ N/A

Did the authors specify the screening criteria for study eligibility?

- ○ Yes
- ○ No
- ○ N/A

Was the population that served as a unit of analysis the entire eligible population or a probability sample at the point of observation?

- ○ Yes
- ○ No
- ○ N/A

Are there other selection bias issues not otherwise addressed? Describe.

- ○ Yes
- ○ No
- ○ N/A

Part 3. Study Quality - Measurement & Data Analysis

Did the authors attempt to measure exposure to the intervention?

- ○ Yes
- ○ No
- ○ N/A

Were the exposure variables valid measures of the intervention under study?
Authors should have reported one or more of the following:
1. Clear definition of the exposure variable.
2. Measurement of exposure in different ways.
3. Citation or discussion as to why the use of these measures is valid.

- ○ Yes
- ○ No
- ○ N/A

Were the exposure variables reliable (consistent and reproducible) measures of the intervention under study?
The authors should have reported one or more of the following:
1. Measures of internal consistency (e.g., Cronbach's alpha; confirmatory factor analysis)
2. Measurement of exposure in different ways
3. Inter-rater reliability checks (if exposure was determined by an observer) (e.g., percent agreement, Kappa)
4. Citations or discussion as to why the use of these measures is reliable.
5. Other

- ○ Yes
- ○ No
- ○ N/A

Were the outcome and other independent (or predictor) variables valid measures of the outcome of interest?
The authors should have reported one or more of the following:
1. Clear definition of the outcome variable.
2. Measurement of the outcome in different ways (e.g., correlation analysis, discriminant validity).
3. Citations or discussion as to why the use of these measures is valid.
4. Other (e.g., authors fail to mask observers to treatment vs. comparison).

- ○ Yes
- ○ No
- ○ N/A

Were the outcome and other independent (or predictor) variables reliable (consistent and reproducible) measures of the outcome of interest?
The authors should have reported one or more of the following:
1. Measures of internal consistency
2. Measurement of the outcome in different ways
3. Considered consistency of coding, scoring or categorization between observers (inter-rater reliability checks) or between different outcome measures (percent agreement, Kappa)
4. Considered how setting or sampling of the study population might affect reliability
5. Citations or discussion as to why the use of these measures is reliable
6. Other

- ○ Yes
- ○ No
- ○ N/A

Did the authors conduct appropriate statistical testing by:

	Select one		
	Yes	No	N/A
Conducting statistical testing (when appropriate)?	○	○	○
Reporting which statistical tests were used?	○	○	○
Controlling for design effects in the statistical model?	○	○	○
Controlling for repeated measures in populations that were followed over time?	○	○	○
Controlling for differential exposure to the intervention?	○	○	○
Using a model designed to handle multi-level data when they included group-level and individual covariates in the model?	○	○	○

Are they other problems with the data analysis? Describe.

Did at least 80% of enrolled participants (i.e., intervention AND comparison groups) complete the study? If the authors did not report >=80% follow-up but conducted an alternative analysis that concluded that the high attrition did not influence the results of the study, check "yes."

- ○ Yes
- ○ No
- ○ N/A

Did the authors assess:

	Select one		
	Yes	No	N/A
Whether the units of analysis were comparable prior to exposure to the intervention?	○	○	○
Correct for controllable variables or institute study procedures to limit bias appropriately (e.g., randomization, restriction, matching, stratification, or statistical adjustment)?	○	○	○

Check "yes" and describe all potential biases or unmeasured/contextual confounders described by the authors. You may also check "no" and describe other potential biases or unmeasured/contextual confounders NOT identified by the authors. For all responses indicated the likely direction of effect on the results, if possible.

- ○ Yes
- ○ No

Other important limitations of the study not identified elsewhere (specify):