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Recruitment for exercise or physical activity interventions: A protocol for systematic review

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Recruitment for exercise or physical activity interventions: A protocol for systematic review

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ABSTRACT

Introduction

Recruiting participants into research trials is essential for the advancement of scientific knowledge that depends on clinical research studies. For the field of exercise and physical activity, there is an added difficulty in recruiting participants because participants must be willing to participate in an intervention that requires a significant commitment of both time and physical effort. Therefore, we have planned a series of systematic and quantitative reviews to analyze how methodological factors, intervention characteristics, and participant demographics impact recruitment rates in specific populations. This information will help researchers improve the design and recruitment approach in future studies.

Methods and analysis

A series of systematic and quantitative reviews will be performed on studies that implement physical activity interventions and present data on participant recruitment. A standardized approach will be used to identify studies through a review of titles, abstracts, and reference lists. The process for each eligible study is to determine their eligibility, extract data from eligible studies, and rate each eligible study's methodological quality. Exploratory multivariate regression models will be used to determine the effects of methodological factors, intervention characteristics, and participant demographics on the recruitment variables of interest.

Ethics and dissemination

Because all of the data utilized in this systematic and quantitative review has been published, this review does not require ethical approval. The results of this review will be disseminated through peer-reviewed publication as well as through conference presentations.

Prospero registration number

CRD42017057284

Keywords

Exercise, Physical Activity, Participant Recruitment, Quantitative Review

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This systematic review protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines.
- The results of these reviews aim to provide an empirical analysis of how methodological, intervention, and demographic variables impact participant recruitment variables.
- By gathering objective data pertaining to methodological, intervention, and demographic variables, researchers can make evidence-based decisions when planning and designing future studies, which could serve to optimize the results that are garnered from these studies.
- We will comprehensively search the Pubmed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases to find all relevant studies pertaining to participant recruitment and exercise.
- A limitation is that many relevant exercise studies may not have produced a publication focusing on recruitment or included recruitment variables as a primary or secondary outcome, which would have rendered those studies ineligible.

INTRODUCTION

In research studies, physical activity and exercise interventions have generally been found to be efficacious in a variety of populations. The efficacy of these interventions is noted in improved mortality rates[1], cardiovascular health[2-4], cancer risks[5], sleep quality[6], and quality of life[7]. Just as important, the benefits of these interventions also span a broad range of conditions, diseases, and demographics including older adults[8], patients with breast cancer[9], Parkinson's Disease[10], smokers[11], osteroarthritis[12-14], and diabetes[15 16] amongst others. As such, encouraging participation in exercise and physical therapy intervention studies can have tremendous benefits for the participant as well as other individuals who could be positively impacted by the results of those studies.

A lack of research participants or the inability to recruit them effectively can lead to failed clinical trials[17 18]. Only approximately half of studies reach their a priori recruitment goal[19], and the same proportion of multicenter studies encounter problems in recruiting enough participants[20].

Recruitment has the potential to impact research studies in a positive or negative manner. In terms of positive effects, the recruited sample will be more representative of the target population[21], and having a sufficient sample size becomes an ethical issue when researchers begin to decipher the significance of the analysis results[22]. The underlying goal is that the results of a properly recruited study will be more generalizable because of the recruited sample and thus further scientific knowledge. In terms of negative effects, poor recruiting can have benefits extending far beyond lower generalizability. Previous research has indicated that poor recruitment increases the length of the study due to accommodating longer recruitment periods[17 18] and greater financial costs to complete the study[19]. Recruitment also has the potential to negatively impact the overall study budget, and many pharmaceutical studies are forced to close their studies prematurely primarily due to financial costs[23].

Traditionally, pilot and feasibility studies have been carried out to demonstrate that a study is possible[24]. These studies often examine whether the research design, intervention, and even recruitment methods are reasonable to complete[24]. These studies also require a financial budget, although they often require less time, money, and resources[25]. While these resources are generally less than what would be spent on a full-scale study, pilot and feasibility studies do require financial and human resources that could be more effectively focused on other aspects of study development if participant recruitment were optimized through the use of strategies supported by empirical evidence.

Other reviews have examined recruitment[26-32], but no other reviews have quantitatively examined recruitment in exercise-related studies specifically. This gap in the literature impedes the ability of researchers to maximize the benefits of research studies by preventing researchers from designing studies that could optimize participant recruitment.

This systematic review protocol will use the existing literature to empirically demonstrate the impact of research methodology and participant characteristics on recruitment variables in exercise-related studies for specific populations. This manuscript describes our planned approach to analyze the quantitative effects of various methodological designs, intervention factors, and participant characteristics, and their impact on participant recruitment. These results will ideally be used in designing and constructing future studies by allowing researchers to accurately construct research study budgets and timelines as well as to optimize participant recruitment.

Review question

Do methodological factors (e.g., assignment method, independent and dependent variables), intervention characteristics (e.g., length of the study, treatment setting), participant characteristics (e.g., age, gender, race, ethnicity), and author/study characteristics (e.g., year of publication, author's primary discipline) affect participant recruitment in human exercise studies?

METHODS AND ANALYSIS

This systematic review protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines[33] (Figure 1). This review protocol has been registered with the International Prospective Register of Systematics Reviews (PROSPERO) under the registration number CRD42017057284, and the protocol will be updated with amendments as needed.

Eligibility criteria

Our systematic review will focus on clinical research studies that have recruited participants into exercise or physical activity interventions. The selected studies will include randomized trials (e.g., randomized clinical trials, cluster randomized trials) as well as non-randomized studies (e.g., quasi-random assignment studies, matched studies, non-matched studies, single group studies, pilot studies). Cross sectional studies will be excluded, however, because they do not implement a physical activity intervention. Review articles (e.g., literature reviews, systematic reviews, meta-analyses) will be excluded, but they will be used to identify additional eligible articles.

The abstracts of studies identified through the search strategy and through reference harvesting will be screened according to six eligibility criteria by any of the four review authors. These criteria are:

1. Is the study written in English?
2. Is the study including humans as the research subjects?
3. Is the study recruiting adults? Adult is defined as the mean sample age greater than or equal to 18 years of age.
4. Does the study abstract explicitly address recruitment? This is defined to mean that the study is focusing primarily on recruitment (e.g., the written purpose of the manuscript is to evaluate recruitment) or the study is presenting recruitment outcomes as one of the primary outcomes (e.g., articles listing recruitment variables as outcome variables to be analyzed, articles presenting descriptive statistics on the number of participants contacted or screened).
5. Does the study appear to implement an exercise-related intervention? This is defined to mean any study requiring the participant to engage in some sort of physical activity intervention (e.g., walking, riding a bicycle, resistance training).
6. Is the study peer reviewed?

If the reviewing author is unsure of how to classify any of these six criteria, the reviewer will mark the criterion as uncertain. The group of authors will collectively review any criterion that were marked as uncertain to determine its eligibility.

Data sources and search strategy

We plan on searching the Pubmed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) databases for all existing articles as of February 10, 2017 to identify eligible studies. We will utilize the following search string "exercise AND recruitment NOT 'musc* recruit*'" to identify potentially eligible studies. Furthermore, we will attempt to locate more eligible studies by reviewing

the reference lists of all of the eligible studies and all relevant review articles (i.e., review articles pertaining to recruitment and exercise in human adult research studies). No other restrictions (e.g., time, language) will be applied during the database searches.

Data management

The results from the database searches will be uploaded into EndNote citation manager software, which will allow for systematic storage of the search results as well as the ability to remove duplicate articles. The review team will consist of six review authors, and each eligible abstract will be reviewed by one of the review authors according to the inclusion criteria listed previously. The reviewing author will determine whether the abstract appears to be eligible. If the reviewing author is uncertain of how to classify the abstract, he or she will indicate the uncertainty and another reviewer will review that article. The second reviewer's decision will determine the abstract's eligibility.

Data extraction

After all abstracts have been screened and potentially eligible studies have been identified, the review authors will extract data from eligible articles in two rounds, and each round will be performed by a different reviewing author. The following data will be extracted from the studies:

1. Recruitment variables
    a. Number of patients/participants contacted
    b. Length of time spent recruiting
    c. Number of participants enrolled
    d. Number of people recruiting
    e. Background of recruiters
    f. Amount of training for recruiters
    g. Hours per week (total) spent recruiting
    h. Method of recruiting (e.g., flyers, clinic visits, public advertisements)
    i. Money spent on recruiting
2. Methodological quality variables
3. Intervention variables
4. Participant demographics
5. Descriptive characteristics of study and authors

For missing data pertaining to the main recruitment variables, reviewing authors will use a pre-constructed template for any necessary author queries. Review authors will only attempt to contact the author of the publication to gather the missing recruitment information during the first round of data extraction. This will serve to limit unnecessary contacts to authors. Information resulting from author queries will be made available to the reviewing author during the second round of data extraction so that the agreement between reviewers does not suffer as a result of one reviewer having access to more information than the second reviewer. In the event that the author of a publication does not respond to the author query, the requested information will be treated as missing data. For studies where some of the recruitment variables have extracted data and some are missing variables, these studies will still be included in the final analyses. If all of the recruitment variables for a study are categorized as missing data, that study will be deemed ineligible and subsequently excluded from the analyses since failing to have any data pertaining to recruitment does not meet the inclusion criterion for "addressing recruitment."

Upon completion of the second round of data extraction, the two review authors will compare the data that they extracted. This comparison will improve the accuracy of the extracted data as well as allowing for the calculation of a kappa statistic[34] to indicate the general agreement between the review authors. In the event that the two review authors cannot agree on how to rate an aspect of the data, a third review author will be utilized to settle the disagreement.

Outcomes

These systematic reviews will focus on four aspects of recruitment as the primary outcomes. First, we will examine the efficiency rate of recruitment (i.e, the number of participants recruited into the study divided by the number of participants contacted). Second, the rate that the participants were recruited into the study (i.e., the number of participants recruited into the study divided by the number of months taken to recruit them). Third, the monetary cost of recruiting participants (i.e., the total cost of recruiting divided by the number of recruited participants). Fourth, the percentage of enrolled participants who withdrew from the study.

Assessing methodological quality

As a part of the data extraction process, sufficient information for rating each study's quality using the McMaster Critical Review Form - Quantitative Studies criteria[35 36] will be recorded. This will provide information about the quality of the studies being included in our systematic review. The McMaster criteria include detailing the study's purpose, reviewing appropriate background literature, describing the study design, describing the sample, justifying the sample size, presenting reliability statistics for the outcome measures, presenting validity statistics for the outcome measures, describing the intervention, reporting the statistical significance of the results, judging the appropriateness of the analysis methods, avoiding contamination, avoiding co-intervention, reporting the clinical importance, reporting the number of dropouts, and judging the appropriateness of the conclusions given the study's methods and results[35 36]. Each reviewer will indicate dichotomously whether the authors provide information for each criterion. The overall McMaster criteria scores will be graded according to classifications used in previous research[37], and these grades will serve to demonstrate the overall quality of the studies. Additionally, the two reviewing authors will rate the Level of Evidence using the GRADE criteria[38] for each study. As with the data extraction process, any disagreements between the two authors will be discussed, and a third reviewing author may be utilized to resolve any outstanding disagreements.

Data analysis

A series of exploratory multivariate regression models will be used to determine the effects of methodological factors, intervention characteristics, and participant demographics on the recruitment variables of interest. Per Osborne and Waters' 2002 recommendations[39], preliminary analyses will first be conducted to ensure that the robust and non-robust assumptions of multivariate regression have not been violated. These multivariate regression analyses will provide additional information pertaining to how well the independent variables (IV) predict the dependent variables (DV), and the analyses will also demonstrate the relative importance of each individual IV in relation to the other IVs in terms of predicting the DVs (i.e., recruitment variables). Finally, a series of multivariate regressions will allow for moderators and mediators to be added to the model in an attempt to improve overall model fit and predictive validity, which can serve to further improve recruitment.

Subgroup analyses

Provided that we have enough studies to provide information related to variables of interest, we hope to conduct subgroup analyses on logistical factors (e.g., discipline of the lead author, where the study took place), participant demographic factors (e.g., age, gender, race), types of intervention (e.g., aerobic

interventions, strength training interventions), and specific research designs (e.g., randomized control trials, matched research designs). These subgroup analyses will be identical to the primary analyses. Our aim is to identify functional differences within specific participant populations in addition to identifying any differential functioning of methodological factors within certain interventions and research designs.

DISCUSSION

We believe that our systematic reviews will address a gap in the literature by addressing how various factors (e.g., methodological, intervention, participant) impact overall recruitment rates. By empirically demonstrating the effects of these factors, future researchers may be able to recruit participants into their research studies more efficiently and quickly, to budget for recruitment costs more accurately, and to allocate resources for staffing needs more appropriately. Furthermore, resources that are traditionally spent on pilot and feasibility studies[24 25] to examine recruitment can now be spent on other aspects of the intervention and project. This protocol will guide these reviews in a standardized and systematic way. In sum, producing an empirical analysis of recruitment rates has the potential for a significant impact. Since future scientific discoveries in human research are dependent on participation from research participants, information that facilitates that participation can serve to improve future research studies and better the field of exercise research.

LIMITATIONS

Because of the requirement that eligible articles must directly focus on recruitment or clearly elucidate recruitment as one of the outcomes, the included articles may reflect a selection bias that is weighted more heavily towards feasibility and pilot studies. By selecting more pilot and feasibility studies, it is possible that the observed recruitment rates were negatively impacted by the smaller budgets typically associated with these smaller feasibility projects[25]. Additionally, it is possible that relevant studies may have been omitted by not including gray matter publications as well as publications that are in the process of being prepared and/or published at this point in time. Finally, as a third limitation, many relevant exercise studies may not have produced a publication focusing on recruitment or included recruitment variables as a primary or secondary outcome, which would have rendered those studies ineligible.

ETHICS AND DISSEMINATION

Ethical approval is not required for this systematic and quantitative review because all of the data included in the review has been published and is publically available. The purpose of this review is to disseminate the results so that other researchers can improve recruitment for their studies. A manuscript will be submitted to a peer-reviewed journal to present the results of this review, and the results of the review will also be presented at a national conference.

REVIEW STATUS

This is an ongoing review. The first manuscripts are estimated to be completed by March 2018.

AUTHORS' CONTRIBUTIONS

Each author contributed to conceptualizing this project, creating the search strategy, refining the inclusion and exclusion criteria, and producing this manuscript. JCH, AMA, SA, and MMA were involved in the data collection and extraction. All authors provided approval for the final version of this manuscript.

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CONFLICT OF INTEREST

No authors have a conflict of interest.

REFERENCES

1. U.S. Department of Health and Human Services. Physical activity and health: A report of the surgeon general. GA: U.S.: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.
2. Allen J. Coronary risk factor modification in women after coronary artery bypass surgery. *Nursing research* 1996;45(5):260-65.
3. Eckel RH, Jakicic JM, Ard JD, et al. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology* 2014;63(25B):2960-84.
4. Blair SN. Physical activity, fitness and coronary heart disease. Physical activity, fitness and health: International proceedings and consensus statement. Champaign, IL: Human Kinetics 1994:579-90.
5. Magnusson C, Baron J, Persson I, et al. Body size in different periods of life and breast cancer risk in post menopausal women. *International Journal of Cancer* 1998;76(1):29-34.
6. Mendelson M, Borowik A, Michallet A-S, et al. Sleep quality, sleep duration, and physical activity in obese adolescents: Effects of exercise training. *Pediatric Obesity* 2016;11(1):26-32.
7. Blanchard CM, Stein KD, Baker F, et al. Association between current lifestyle behaviors and health-related quality of life in breast, colorectal, and prostate cancer survivors. *Psycholgy & Health* 2004;19(1):1-13.
8. Buman MP, Hekler EB, Haskell WL, et al. Objective light-intensity physical activity associations with rated health in older adults. . *American journal of epidemiology* 2010;172(10):1155-65.
9. McNeely ML, Campbell KL, Rowe BH, et al. Effects of exercise on breast cancer patients and survivors: A systematic review and meta-analysis. *Canadian Medical Association Journal* 2006;175(1):34-41.
10. Goodwin VA, Richards SH, Henley W, et al. An exercise intervention to prevent falls in people with Parkinson's disease: a pragmatic randomised controlled trial. *J Neurol Neurosurg Psychiatry* 2011;82(11):1232-8. doi: 10.1136/jnnp-2011-300919 [published Online First: 2011/08/23]
11. Byberg L, Melhus H, Gedeborg R, et al. Total mortality after changes in leisure time physical activity in 50 year old men: 35 year follow-up of population based cohort. *Bmj* 2009;338
12. Van Baar ME, Dekker J, Oostendorp R, et al. The effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: A randomized clinical trial. *The Journal of Rheumatology* 1998;25
13. Cheung C, Wyman JF, Resnick B, et al. Yoga for managing knee osteoarthritis in older women: a pilot randomized controlled trial. *BMC Complement Altern Med* 2014;14:160. doi: 10.1186/1472-6882-14-160 [published Online First: 2014/06/03]
14. Farr JN, Going SB, McKnight PE, et al. Progressive resistance training improves overall physical activity levels in patients with early osteoarthritis of the knee: a randomized controlled trial. *Physical Therapy* 2010;90(3):356-66. doi: 10.2522/ptj.20090041

15. Adler AI, Stratton IM, Neil HAW, et al. Association of systolic blood pressure with macrovascular and microvascular comoplications of type 2 diabetes (UKPDS 36): Prospective observational study. *Bmj* 2000;321(7258):412-19.
16. Van Dijk JW, Venema M, van Mechelen W, et al. Effect of moderate-intensity exercise versus activities of daily living on 24-hour blood glucose homeostasis in male patients with type 2 diabetes. *Diabetes care* 2013;36(11):3448-53.
17. Damen L, van Agt F, de Boo T, et al. Terminating clinical trials without sufficient subjects. *Journal of medical ethics* 2012
18. Wertheimer A. Non-completion and informed consent. *Journal of medical ethics* 2014;40(2)
19. Sully BG, Julious SA, Nicholl J. A reinvestigation of recuitment to randomised controlled multicenter trials: A review of trials funded by two UK funding agencies. *Trials* 2013;14(1)
20. Puffer S, Torgerson DJ. Recruitment difficulties in randomised controlled trials. Controlled Clinical Trials. New York, NY: Elsevier Science Inc. 2003:214S-15S.
21. Patel MX, Doku V, Tennakoon L. Challenges in recruitment of research participants. *Advances in Psychiatric Treatment* 2003;9(3):229-38.
22. Altman DG. Statistics and ethics in medical research: III How large a sample?. *British Medical Journal* 1980;281(6251)
23. Aung T, Haynes R, Barton J, et al. Cost-effective recruitment methods for a large randomised trial in people with diabetes: A study of cardiovascular events in diabetes (ASCEND). *Trials* 2016;17(1)
24. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *Journal of psychiatric research* 2011;45(5):626-29.
25. National Institute of Mental Health. Pilot intervention and services research grants (R34). 2012. http://grants.nih.gov/grants/guide/pa-files/PAR-09-173.html.
26. Toerien M, Brookes ST, Metcalfe C, et al. A review of reporting of participant recruitment and rentention in RCTs in six major journals. *Trials* 2009;10(52) doi: 10.1186/1745-6215-10-52
27. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: A review of randomised controlled trials. *BMC Medical Research Methodology* 2006;6(34) doi: 10.1186/1472-228-6-34
28. Treweek S, Lockhart P, PItkethly M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open* 2013;3(e002360) doi: 10.1136/bmjopen-2012-002360
29. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7(9) doi: 10.1186/1745-6215-7-9
30. Caldwell PHY, Hamilton S, Tan A, et al. Strategies for increasing recruitment to randomised controlled trials: Systematic review. *PLoS Med* 2010;7(11) doi: 10.1371/journal.pmed.1000368
31. Townsley CA, Selby R, Siu LL. Systematic review of barriers to the recruitment of older patients with cancer onto clinical trials. *Journal of Clinical Oncology* 2005;23(13):3112-24.
32. Ford JG, Howerton MW, Lai GY, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer* 2008;112(2):228-42.
33. Moher D, Shamseer L, Clark M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic reviews* 2015;4(1)
34. Sim J, Wright CC. The kappa statistic in reliability studies: Use, interpretation, and sample size requirements. *Physical therapy* 2005;85(3):257-68.
35. Law M, Stewart D, Pollock N, et al. Critical review form-quantitative studies. http://www.unisa.edu.au/Global/Health/Sansom/Documents/iCAHE/CATs/McMasters_Quantitative%20review.pdf.

36. Law M, Stewart D, Pollock N, et al. Guidelines for critical review form-quantitative studies. 1998. http://srs-mcmaster.ca/wp-content/uploads/2015/04/Guidelines-for-Critical-Review-Form-Quantiative-Studies-English.pdf. .
37. Daly AE, Bialocerkowski AE. Does evidence support physiotherapy management of adult Complex Regional Pain Syndrome Type One? A systematic review. *European Journal of Pain* 2009;13(4):339-53.
38. Guyatt GH, Oxman AD, Shunemann HJ, et al. GRADE guidelines: A new series of articles in the Journal of Clinical Epidemiology. *Journal of clinical epidemiology* 2011;64(4):380-82.
39. Osborne JW, Waters E. Four assumptions of multiple regression that researchers should always test. 2002

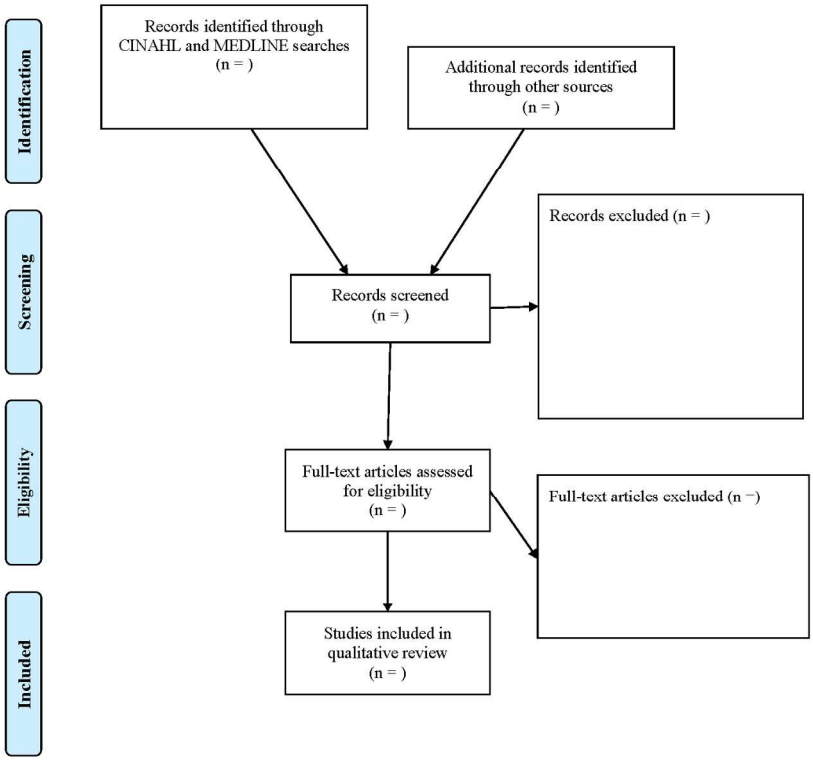

Figure 1

215x279mm (200 x 200 DPI)

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	7
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	4
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	8
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	3, 4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	4, 5
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	4

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	5, 6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	5, 6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	5
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5, 6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	6, 7
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	6, 7
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	6, 7
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	6, 7
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	6

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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ABSTRACT

Introduction

Recruiting participants into research trials is essential for the advancement of scientific knowledge that depends on clinical research studies. For the field of exercise and physical activity, there is an added difficulty in recruiting participants because participants must be willing to participate in an intervention that requires a significant commitment of both time and physical effort. Therefore, we have planned a systematic review to analyze how methodological factors, intervention characteristics, and participant demographics impact recruitment rates in specific populations. This information will help researchers improve the design and recruitment approach in future studies.

Methods and analysis

A mixed methods systematic review will be performed on studies that implement physical activity interventions and present data on participant recruitment. We plan on searching the Pubmed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Online Resource for Recruitment research in Clinical triAls (ORRCA) databases for potentially eligible articles from database inception through February 10, 2017. A standardized approach will be used to identify studies through a review of titles, abstracts, and reference lists. The process for each eligible study is to determine their eligibility, extract data from eligible studies, and rate each eligible study's methodological quality. Exploratory multivariate regression models will be used to determine the effects of methodological factors, intervention characteristics, and participant demographics on the recruitment variables of interest.

Ethics and dissemination

Because all of the data utilized in this systematic review has been published, this review does not require ethical approval. The results of this review will be disseminated through peer-reviewed publication as well as through conference presentations.

Prospero registration number

CRD42017057284

Keywords

Exercise, Physical Activity, Participant Recruitment, Quantitative Review

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This systematic review protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines.
- We will comprehensively search the Pubmed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Online Resource for Recruitment research in Clinical triAls (ORRCA) databases to find all relevant studies pertaining to participant recruitment and exercise.
- This systematic review will use the Cochrane Collaboration assessment tool to assess for risk of bias.
- Some relevant exercise studies may not have produced a publication focusing on recruitment or included recruitment variables as a primary or secondary outcome, potentially limiting the number of eligible studies.

INTRODUCTION

In research studies, physical activity and exercise interventions have generally been found to be efficacious in a variety of populations. The efficacy of these interventions is noted in improved mortality rates[1], cardiovascular health[2-4], cancer risks[5], sleep quality[6], and quality of life[7]. Just as important, the benefits of these interventions also span a broad range of conditions, diseases, and demographics including older adults[8], individuals with breast cancer[9], Parkinson's Disease[10], smokers[11], osteroarthritis[12-14], and diabetes[15 16] amongst others. As such, encouraging participation in exercise and physical activity intervention studies can have tremendous benefits for the participant as well as other individuals who could be positively impacted by the results of those studies.

A lack of, or inability to effectively recruit, research participants can lead to failed clinical trials[17 18]. Only approximately half of studies reach their a priori recruitment goal[19], and the same proportion of multicenter studies encounter problems in recruiting enough participants[20].

Recruitment has the potential to impact research studies in a positive or negative manner. In terms of positive effects, an appropriately recruited sample will be more representative of the target population[21]. Furthermore, having a sufficient sample size becomes an ethical issue when researchers begin to decipher the significance of the analysis results[22]. The underlying goal is that the results of a properly recruited study will be more generalizable because of the recruited sample and thus further scientific knowledge. However, inefficient recruiting can have negative impacts extending far beyond lower generalizability. Previous research has indicated that inefficient recruitment increases the length of the study due to the need for longer recruitment periods[17 18] and increases the financial resources required to complete the study[19]. Indeed, pharmaceutical studies are often forced to close prematurely primarily due to financial costs[23]. Further, inefficient recruitment could delay the availability of new and effective treatments.

Traditionally, pilot and feasibility studies are carried out to demonstrate that a study is possible[24]. These studies often examine whether the research design, intervention, and even recruitment methods are reasonable to complete[24]. These studies also require a financial budget, although they often require less time, money, and resources[25]. While these resources are generally less than what would be spent on a full-scale study, pilot and feasibility studies do require financial and human resources that could be more effectively focused on other aspects of study development if participant recruitment were optimized through the use of strategies supported by empirical evidence.

Although other reviews have examined participant recruitment[26-32], we are not aware of any reviews that have used a mixed methods approach to examine recruitment in exercise-related studies. Because no research has performed a mixed methods examination of exercise-related studies' recruitment, researchers are unable to use an evidence-based approach to identify and maximize recruitment strategies that may be of particular benefit.

This mixed methods systematic review protocol will use the existing literature to empirically examine the impact of research methodology and participant characteristics on recruitment variables in exercise-related studies for specific populations. This manuscript describes our planned approach to analyze the quantitative effects of various methodological designs, intervention factors, and participant characteristics, and their impact on participant recruitment. These results will ideally be used to facilitate the design and construction of future studies that optimize participant recruitment and allow researchers to more accurately construct research study budgets and timelines.

Review question

Do methodological factors (e.g., assignment method, independent and dependent variables), intervention characteristics (e.g., length of the study, treatment setting), participant characteristics (e.g., age, gender, race, ethnicity), and author/study characteristics (e.g., year of publication, author's primary discipline) affect participant recruitment in human exercise studies?

METHODS AND ANALYSIS

This mixed methods systematic review protocol follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocol (PRISMA-P) guidelines (Figure 1)[33 34]. This review protocol has been registered with the International Prospective Register of Systematics Reviews (PROSPERO) under the registration number CRD42017057284, and the protocol will be updated with amendments as needed.

Eligibility criteria

Our mixed methods systematic review will focus on clinical research studies that have recruited participants into exercise or physical activity interventions. The selected studies will include randomized trials (e.g., randomized clinical trials, cluster randomized trials) as well as non-randomized studies (e.g., quasi-random assignment studies, matched studies, non-matched studies, single group studies, pilot studies). Cross sectional studies will be excluded, however, due to their lack of a physical activity intervention. Review articles (e.g., literature reviews, systematic reviews, meta-analyses) will be excluded, but they will be used to identify additional eligible articles.

The abstracts of studies identified through the search strategy and through reference harvesting will be screened according to six eligibility criteria by any of the four review authors. These criteria are:

1. Is the study written in English?
2. Is the study using humans as the research subjects?
3. Is the study recruiting adults? Adult is defined as the mean sample age greater than or equal to 18 years of age.
4. Is the study abstract explicitly addressing recruitment? This is defined to mean that the study is focusing primarily on recruitment (e.g., the written purpose of the manuscript is to evaluate recruitment) or the study is presenting recruitment outcomes as one of the primary outcomes (e.g., articles listing recruitment variables as outcome variables to be analyzed, articles presenting descriptive statistics on the number of participants contacted or screened).
5. Is the study implementing an exercise-related intervention? This is defined to mean any study requiring the participant to engage in some sort of physical activity intervention (e.g., walking, riding a bicycle, resistance training).
6. Is the study peer reviewed?

If the reviewing author is unsure of how to classify any of these six criteria, the reviewer will mark the criterion as uncertain. The group of authors will collectively review any criterion that were marked as uncertain to determine its eligibility.

Data sources and search strategy

We plan on searching the Pubmed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Online Resource for Recruitment research in Clinical triAls (ORRCA) databases for all existing articles from inception through February 10, 2017 to identify eligible studies. The database searches will be completed by one review author (JCH). Database searches will be restricted to English studies because

of limited financial resources necessary for translating studies. Search strategies were formed according to the Cochrane handbook guidelines[35]. The Pubmed search strategy is presented in Table 1, and the full search strategy is presented in a supplemental file. In addition to the database searches, we will attempt to locate additional eligible studies by reviewing the reference lists of all of the eligible studies and all relevant review articles (i.e., review articles pertaining to recruitment and exercise in human adult research studies).

Table 1: Search strategy used in Pubmed – (inception to 2017)

Search date: February 10, 2017

Number	Search items
1	exercise.Mesh
2	exercise.All
3	1 or 2
4	recruitment
5	3 and 4
6	"musc$ recruit$"
7	5 not 6

'$' indicates truncation

Data management

The results from the database searches will be uploaded into EndNote citation manager software, which will allow for systematic storage of the search results as well as the ability to remove duplicate articles. In order to ensure a consistent eligibility screening process, all four reviewing authors (JCH, AMA, SA, and MMA) will screen 100 randomly selected articles. Each reviewing author will mark each article as either eligible, ineligible, or unclear. We will discuss any discrepancies in eligibility decisions in this random set of 100 articles until there is complete agreement between the reviewing authors. After agreeing on the initial 100 articles, the four reviewing authors will review the remainder of the identified articles. The reviewing author will determine whether the abstract appears to be eligible. If the reviewing author is uncertain of how to classify the abstract, he or she will indicate the uncertainty and the reviewers will collectively review that article and determine the article's eligibility.

Data extraction

After all abstracts have been screened and potentially eligible studies have been identified, two review authors will independently extract data from eligible articles. The following data will be extracted from the studies:

1. Recruitment variables
    a. Number of patients/participants contacted
    b. Length of time spent recruiting
    c. Number of participants enrolled
    d. Number of people recruiting
    e. Background of recruiters
    f. Amount of training for recruiters
    g. Hours per week (total) spent recruiting
    h. Method of recruiting (e.g., flyers, clinic visits, public advertisements)
    i. Money spent on recruiting

2. Methodological quality variables
3. Intervention variables
4. Participant demographics
5. Descriptive characteristics of study and authors

For missing data pertaining to the main recruitment variables, reviewing authors will use a pre-constructed template for any necessary author queries. Review authors will only attempt to contact the author of the publication to gather the missing recruitment information during the first round of data extraction. This will serve to limit unnecessary contacts to authors. Information resulting from author queries will be made available to the reviewing author during the second round of data extraction so that the agreement between reviewers does not suffer as a result of one reviewer having access to more information than the second reviewer. In the event that the author of a publication does not respond to the author query, the requested information will be treated as missing data. For studies where some of the recruitment variables have missing data, these studies will still be included in the final analyses. If all of the recruitment variables for a study are categorized as missing data, that study will be deemed ineligible and subsequently excluded from the analyses since failing to have any data pertaining to recruitment does not meet the inclusion criterion for "addressing recruitment."

When both of the independent reviewing authors have completed the data extraction, those two reviewing authors will compare the data that they extracted. If the two reviewing authors have discrepancies in the data that they extracted, they will discuss any discrepancies in the extracted data in an attempt to agree on how to appropriately classify the extracted data. In the event that the two review authors cannot agree on how to rate an aspect of the data, a third review author will be utilized to settle the disagreement.

Outcomes

These systematic reviews will focus on four aspects of recruitment as the primary outcomes. First, we will examine the efficiency rate of recruitment (i.e., the number of participants recruited into the study divided by the number of participants contacted). Second, the rate that the participants were recruited into the study (i.e., the number of participants recruited into the study divided by the number of months taken to recruit them). Third, the monetary cost of recruiting participants (i.e., the total cost of recruiting divided by the number of recruited participants). Fourth, the percentage of enrolled participants who withdrew from the study.

Assessing methodological quality

Included articles will be independently reviewed by two reviewing authors using the Cochrane Collaboration assessment tool to assess risk of bias, which reviews selection bias, performance and detection bias, attrition bias, reporting bias, and other sources of bias[36]. The risk of bias will be rated using three categories: High risk, Low risk, and Unclear risk. As with the data extraction process, any disagreements between the two authors will be discussed, and a third reviewing author will be utilized to resolve any outstanding disagreements. Because this systematic review is focusing on how studies' methodological characteristics affect recruitment, the Cochrane Collaboration assessment tool for risk of bias[36] will provide insight into the extent to which risk of bias is present in the included studies, which will provide helpful contextual details when discussing the results of the analyses.

Data analysis

A series of exploratory multivariate regression models will be used to determine the effects of methodological factors, intervention characteristics, and participant demographics on the recruitment

variables of interest. Per Osborne and Waters' 2002 recommendations[37], preliminary analyses will first be conducted to ensure that the robust and non-robust assumptions of multivariate regression have not been violated. These multivariate regression analyses will provide additional information pertaining to how well the independent variables (IV) predict the dependent variables (DV), and the analyses will also demonstrate the relative importance of each individual IV in relation to the other IVs in terms of predicting the DVs (i.e., recruitment variables). Finally, a series of multivariate regressions will allow for moderators and mediators to be added to the model in an attempt to improve overall model fit and predictive validity, which can serve to further improve recruitment.

Subgroup analyses

Provided that we have enough studies to provide information related to variables of interest, we hope to conduct subgroup analyses on logistical factors (e.g., discipline of the lead author, where the study took place), participant demographic factors (e.g., age, gender, race), types of intervention (e.g., aerobic interventions, strength training interventions), and specific research designs (e.g., randomized control trials, matched research designs). These subgroup analyses will be identical to the primary analyses. Our aim is to identify functional differences within specific participant populations in addition to identifying any differential functioning of methodological factors within certain interventions and research designs.

DISCUSSION

We believe that our systematic reviews will address a gap in the literature by addressing how various factors (e.g., methodological, intervention, participant) impact overall recruitment rates. By empirically demonstrating the effects of these factors, future researchers may be able to recruit participants into their research studies more efficiently and quickly, to budget for recruitment costs more accurately, and to allocate resources for staffing needs more appropriately. Furthermore, resources that are traditionally spent on pilot and feasibility studies[24,25] to examine recruitment can now be spent on other aspects of the intervention and project. This protocol will guide these reviews in a standardized and systematic way. In sum, producing an empirical analysis of recruitment rates has the potential for a significant impact. Since future scientific discoveries in human research are dependent on participation from research participants, information that facilitates that participation can serve to improve future research studies and better the field of exercise research.

LIMITATIONS

Because of the requirement that eligible articles must directly focus on recruitment or clearly elucidate recruitment as one of the outcomes, the included articles may reflect a selection bias that is weighted more heavily towards feasibility and pilot studies. By selecting more pilot and feasibility studies, it is possible that the observed recruitment rates were negatively impacted by the smaller budgets typically associated with these smaller feasibility projects[25]. Additionally, it is possible that relevant studies may have been omitted by not including gray matter publications as well as publications that are in the process of being prepared and/or published at this point in time. Finally, as a third limitation, many relevant exercise studies may not have produced a publication focusing on recruitment or included recruitment variables as a primary or secondary outcome, which would have rendered those studies ineligible.

ETHICS AND DISSEMINATION

Ethical approval is not required for this systematic review because all of the data included in the review has been published and is publically available. The purpose of this review is to disseminate the results so that other researchers can improve recruitment for their studies. A manuscript will be submitted to a

peer-reviewed journal to present the results of this review, and the results of the review will also be presented at a national conference.

REVIEW STATUS

This is an ongoing review. The first manuscripts are estimated to be completed by March 2018.

AUTHORS' CONTRIBUTIONS

Each author (JCH, AMA, SA, MMA, JR, and PMK) contributed to conceptualizing this project, creating the search strategy, refining the inclusion and exclusion criteria, and producing this manuscript. JCH, AMA, SA, and MMA will be involved in the data collection and extraction, the risk of bias assessment, and data analyses. JR and PMK provided oversight to the project. All authors (JCH, AMA, SA, MMA, JR, and PMK) provided approval for the final version of this manuscript.

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CONFLICT OF INTEREST

No authors have a conflict of interest.

REFERENCES

1. U.S. Department of Health and Human Services. Physical activity and health: A report of the surgeon general. GA: U.S.: Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, 1996.
2. Allen J. Coronary risk factor modification in women after coronary artery bypass surgery. *Nursing research* 1996;45(5):260-65.
3. Eckel RH, Jakicic JM, Ard JD, et al. 2013 AHA/ACC guideline on lifestyle management to reduce cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *Journal of the American College of Cardiology* 2014;63(25B):2960-84.
4. Blair SN. Physical activity, fitness and coronary heart disease

Physical activity, fitness and health: International proceedings and consensus statement. Champaign, IL: Human Kinetics 1994:579-90.
5. Magnusson C, Baron J, Persson I, et al. Body size in different periods of life and breast cancer risk in post menopausal women. *International Journal of Cancer* 1998;76(1):29-34.
6. Mendelson M, Borowik A, Michallet A-S, et al. Sleep quality, sleep duration, and physical activity in obese adolescents: Effects of exercise training. *Pediatric Obesity* 2016;11(1):26-32.
7. Blanchard CM, Stein KD, Baker F, et al. Association between current lifestyle behaviors and health-related quality of life in breast, colorectal, and prostate cancer survivors. *Psycholgy & Health* 2004;19(1):1-13.
8. Buman MP, Hekler EB, Haskell WL, et al. Objective light-intensity physical activity associations with rated health in older adults. . *American journal of epidemiology* 2010;172(10):1155-65.
9. McNeely ML, Campbell KL, Rowe BH, et al. Effects of exercise on breast cancer patients and survivors: A systematic review and meta-analysis. *Canadian Medical Association Journal* 2006;175(1):34-41.
10. Goodwin VA, Richards SH, Henley W, et al. An exercise intervention to prevent falls in people with Parkinson's disease: a pragmatic randomised controlled trial. *Journal of neurology,*

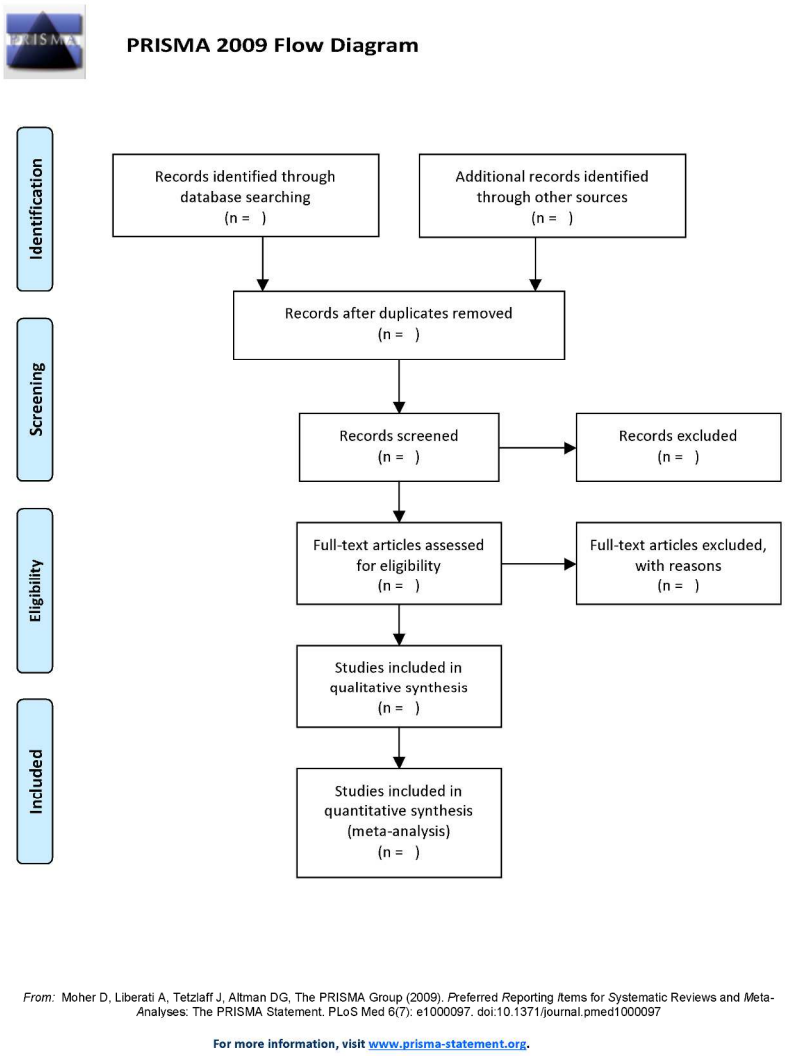
neurosurgery, and psychiatry 2011;82(11):1232-8. doi: 10.1136/jnnp-2011-300919 [published Online First: 2011/08/23]
11. Byberg L, Melhus H, Gedeborg R, et al. Total mortality after changes in leisure time physical activity in 50 year old men: 35 year follow-up of population based cohort. *Bmj* 2009;338
12. Van Baar ME, Dekker J, Oostendorp R, et al. The effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: A randomized clinical trial. *The Journal of Rheumatology* 1998;25
13. Cheung C, Wyman JF, Resnick B, et al. Yoga for managing knee osteoarthritis in older women: a pilot randomized controlled trial. *BMC complementary and alternative medicine* 2014;14:160. doi: 10.1186/1472-6882-14-160 [published Online First: 2014/06/03]
14. Farr JN, Going SB, McKnight PE, et al. Progressive resistance training improves overall physical activity levels in patients with early osteoarthritis of the knee: a randomized controlled trial. *Physical Therapy* 2010;90(3):356-66. doi: 10.2522/ptj.20090041
15. Adler AI, Stratton IM, Neil HAW, et al. Association of systolic blood pressure with macrovascular and microvascular comoplications of type 2 diabetes (UKPDS 36): Prospective observational study. *Bmj* 2000;321(7258):412-19.
16. Van Dijk JW, Venema M, van Mechelen W, et al. Effect of moderate-intensity exercise versus activities of daily living on 24-hour blood glucose homeostasis in male patients with type 2 diabetes. *Diabetes care* 2013;36(11):3448-53.
17. Damen L, van Agt F, de Boo T, et al. Terminating clinical trials without sufficient subjects. *Journal of medical ethics* 2012
18. Wertheimer A. Non-completion and informed consent. *Journal of medical ethics* 2014;40(2)
19. Sully BG, Julious SA, Nicholl J. A reinvestigation of recuitment to randomised controlled multicenter trials: A review of trials funded by two UK funding agencies. *Trials* 2013;14(1)
20. Puffer S, Torgerson DJ. Recruitment difficulties in randomised controlled trials. Controlled Clinical Trials. New York, NY: Elsevier Science Inc. 2003:214S-15S.
21. Patel MX, Doku V, Tennakoon L. Challenges in recruitment of research participants. *Advances in Psychiatric Treatment* 2003;9(3):229-38.
22. Altman DG. Statistics and ethics in medical research: III How large a sample?. *British Medical Journal* 1980;281(6251)
23. Aung T, Haynes R, Barton J, et al. Cost-effective recruitment methods for a large randomised trial in people with diabetes: A study of cardiovascular events in diabetes (ASCEND). *Trials* 2016;17(1)
24. Leon AC, Davis LL, Kraemer HC. The role and interpretation of pilot studies in clinical research. *Journal of psychiatric research* 2011;45(5):626-29.
25. National Institute of Mental Health. Pilot intervention and services research grants (R34). 2012. http://grants.nih.gov/grants/guide/pa-files/PAR-09-173.html.
26. Toerien M, Brookes ST, Metcalfe C, et al. A review of reporting of participant recruitment and rentention in RCTs in six major journals. *Trials* 2009;10(52) doi: 10.1186/1745-6215-10-52
27. Watson JM, Torgerson DJ. Increasing recruitment to randomised trials: A review of randomised controlled trials. *BMC Medical Research Methodology* 2006;6(34) doi: 10.1186/1472-228-6-34
28. Treweek S, Lockhart P, PItkethly M, et al. Methods to improve recruitment to randomised controlled trials: Cochrane systematic review and meta-analysis. *BMJ Open* 2013;3(e002360) doi: 10.1136/bmjopen-2012-002360
29. McDonald AM, Knight RC, Campbell MK, et al. What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. *Trials* 2006;7(9) doi: 10.1186/1745-6215-7-9
30. Caldwell PHY, Hamilton S, Tan A, et al. Strategies for increasing recruitment to randomised controlled trials: Systematic review. *PLoS Med* 2010;7(11) doi: 10.1371/journal.pmed.1000368

31. Townsley CA, Selby R, Siu LL. Systematic review of barriers to the recruitment of older patients with cancer onto clinical trials. *Journal of Clinical Oncology* 2005;23(13):3112-24.
32. Ford JG, Howerton MW, Lai GY, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer* 2008;112(2):228-42.
33. Moher D, Liberati A, Tetzlaff J, et al. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA Statement. *BMJ* 2009;339 doi: 10.1136/bmj.b2535
34. Moher D, Shamseer L, Clark M, et al. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015 statement. *Systematic reviews* 2015;4(1)
35. Higgins JPT, Green S, eds. Cochrane handbook for systematic reviews of interventions version 5.1.0 [updated March 2011]: The Cochrane Collaboration 2011.
36. Higgins JPT, Altman DG, Gotzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomized trials. *BMJ* 2011;343
37. Osborne JW, Waters E. Four assumptions of multiple regression that researchers should always test. 2002

Figure Legends

Figure 1

Flow diagram for study selection based on the PRISMA guidelines



Flow diagram for study selection based on the PRISMA guidelines

215x279mm (300 x 300 DPI)

CINAHL – (inception to 2017)
Search date: February 10, 2017

S1	Exercise
S2	recruitment
S3	S1 and S2
S4	"musc* recruit*"
S5	S3 not S4

'*' indicates truncation

Table 1 Search strategy used in Pubmed – (inception to 2017)
Search date: February 10, 2017

1	exercise.Mesh
2	exercise.All
3	1 or 2
4	recruitment
5	3 and 4
6	"musc$ recruit$"
7	5 not 6

'$' indicates truncation

ORRCA – (inception to 2017)
Search date: February 10, 2017

1	Exercise.ti,ab
2	"Physical activity",ti.ab

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on Page #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	4
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2, 4
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	8
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	4
Support:			
Sources	5a	Indicate sources of financial or other support for the review	8
Sponsor	5b	Provide name for the review funder and/or sponsor	8
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	8
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	4
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	4, 5

Study records:			
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)	4-6
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators	5, 6
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications	5, 6
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale	5, 6
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	6
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised	6, 7
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)	6, 7
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	6, 7
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned	N/A
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	6, 7
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	6

*** It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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