Umeh, SN1; Ibeneme, SC2; Ekechukwu, EN3; Irem, F4.

Review question / Objective: What are the effects of physical exercises on sex hormones, bone health and functional performance (gait speed, fall index and hand-grip strength) in postmenopausal women compared to usual care, other interventions that do not include exercises?

Condition being studied: Postmenopausal health challenges/ ageing.

Information sources: Searches will be performed for Randomized Controlled Trials (RTCs) using electronic databases; MEDLINE, COCHRANE, CINAHL, PUB MED, PEDRO and others for published studies.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 February 2021 and was last updated on 15 February 2021 (registration number INPLASY202120045).

# **INPLASY** PROTOCOL

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**Review Stage at time of this** submission: Preliminary searches.

**Conflicts of interest:** None declared.

# INTRODUCTION

**Review question / Objective: What are the** effects of physical exercises on sex hormones, bone health and functional performance (gait speed, fall index and hand-grip strength) in postmenopausal women compared to usual care, other interventions that do not include exercises?

Rationale: Postmenopausal women all over the world face diverse health challenges which are more prevalent with ageing such as osteoporosis, cardiovascular diseases &cancer. These challenges are worsened with ageing, which is associated with a decline in metabolic processes, diminished antioxidant level and compromised immune system. The sequalae, amplified by

physical inactivity entail an increase in the activity of free oxygen radicals which induces cell injury, with subsequent methylation of the DNA triggering genetic mutation/cancer. Postmenopausal women experience decline in the level of sex hormones which are involved in bone metabolism, resulting to an increase in bone demineralization, fracture and limited functional performance which may aggravate/reinforce the bidirectional relationship between physical inactivity and consequential adverse metabolic processes that underlie postmenopausal changes. These changes should be amenable to physical exercises which reduce inflammation, free oxygen radicals, while promoting the antioxidant activity, sex hormone, bone health, functional performance and general wellbeing of postmenopausal women. The effects of estrogen withdrawal and the importance of physical activity at all stages of life for optimal bone health are well documented. Several observational studies have found an inverse association between physical activity and circulating estrogen levels while some studies reported no association. In contrast, Pia K Verkasalo, et al reported estradiol decrease with increasing physical activity in postmenopausal women. Thus, regular physical exercise is generally recommended for primary/secondary prevention of health-related problems and as alternative therapy to hormone replacement therapy in postmenopausal women. However, a lack of scientific consensus on the true effect of exercise in postmenopausal women is obvious and warrants a synthesis of evidence from the literature. The question then arises: What are the effects of physical exercises on sex hormones, bone health and functional performance (gait speed, fall index and hand-grip strength) in postmenopausal women compared to other interventions that do not include.

**Condition being studied:** Postmenopausal health challenges/ageing.

Search strategy: The search strategy will be of the Patient-Intervention-Comparison-Outcome (PICO) format for studies on postmenopausal women with intervention as physical activity/ exercise and outcome measures included any or a combination of these variables; sex hormones, bone turnover, bone mineral density, fall index, hand-grip strength and physical performance. Search strategy will involve several combinations of search terms from Pub Med, Medical subject headings (MeSH terms) and keywords in the Titles, abstracts and text in (PICO) format utilizing Boolean logic and lots of truncaters. Searches will be performed for Randomized Controlled Trials (RTCs) using electronic databases; MEDLINE, COCHRANE, CINAHL and others for published studies from January 1980-August 2020.

Participant or population: postmenopausal women who had physical exercise as intervention.

Intervention: Physical exercises.

**Comparator:** Usual care/ no physical exercises.

Study designs to be included: Randomized Controlled Trials (RTCs).

Eligibility criteria: Only randomized controlled trial studies that evaluated the effects of physical exercises on postmenopausal women on all or any of the outcome variables published in English language will be included.

Information sources: Searches will be performed for Randomized Controlled Trials (RTCs) using electronic databases; MEDLINE, COCHRANE, CINAHL, PUB MED, PEDRO and others for published studies.

Main outcome(s): Sex hormones (Estrogen and progesterone).

Additional outcome(s): Bone health, physical performance.

## **METHODS**

Data management: The search results will be checked for duplication using reference manager- Ref works. In like manner, bibliographic records will be exported from ref works to Microsoft Excel (Microsoft 2010) to facilitate seamless article inclusion and exclusion. Adequate data management care will be taken at this stage in relation to eligibility, inclusion and exclusion criteria.

### Quality assessment / Risk of bias analysis:

The quality of the study will be assessed using the Cochrane Collaboration's Tool for assessing risk of bias. We will assess the quality of study based on the six major elements of an inferential study which includes; randomization, allocation, concealment, assessor blinding, incomplete outcome reporting and selective outcome reporting as these elements have a high potency of introducing either selection, performance, detection, attrition, reporting bias and other bias respectively. For each bias domain, a judgment of "low risk", "high risk" or "unclear risk" of bias is assigned depending on its level of potency in introducing bias to the study (Higgins et al., 2011). Data extraction will comply with PRISMA guidelines and reason/s for exclusion will be clearly stated.

Strategy of data synthesis: This review is to identify and evaluate existing studies on the effects of physical exercises on sex hormones, bone health and physical performance in postmenopausal women, therefore standardized statistical methods of data synthesis such as descriptive or interpretive approach will be utilized. Summarizing all literature of the included studies and grading the level of evidence attributed to the findings by the study type. Depending on the heterogeneity/ homogenous nature of reported outcomes, other forms of appropriate data synthesis will be applied. Investigation and presentation of outcomes will be made by using the main outcome variables. Appropriate statistical techniques will be used for each type of outcome result presentation. Interpretation of heterogeneous results will be done by narrative approach following the guideline

of Centre for Reviews and Dissemination (Akers et al., 2009).

Subgroup analysis: No subgroup analysis is intended in the first instance except if it becomes imperative.

Sensitivity analysis: This will be dependent on heterogeneity/ homogeneity of available data.

Language: English.

Country(ies) involved: Nigeria (Africa).

Keywords: physical exercises; sex hormones; bone health; physical performance; postmenopausal women.

**Dissemination plans:** Dissemination is planned to be through publication in periodicals, peer review journals and conference presentations.

#### **Contributions of each author:**

Author 1 - Sunday N. Umeh conceived and conceptualized the study and will actively participate in the study design, literature review/search, quality and risk of bias assessment as well as manuscript drafting. Email: umehsn@yahoo.com

Author 2 - Sam Chidi Ibeneme assisted in the conceptualization and will provide final opinion as a reviewer in case of divergent opinions. Will also provide statistical expertise among other contributions. Email: sam.ibeneme@unn.edu.ng

Author 3 - Echezona Nelson Ekechukwu will participate in data extraction and analysis and quality appraisal.

Email: nelson.ekechukwu@unn.edu.ng Author 4 - Franklin Irem will actively be part of database search, data extraction and review as well as manuscript drafting. Email: franklin.irem.183015@unn.edu.ng