Author's response to reviews

Title: Cost-effectiveness of an exercise intervention program in perimenopausal women. The Fitness League Against MENopause COst (FLAMENCO) randomized controlled trial.

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Author's response to reviews: see over
Dear editors,

We are submitting you an original methodological article entitled “Cost-effectiveness of an exercise intervention program in perimenopausal women. The Fitness League Against MENopause COst (FLAMENCO) randomized controlled trial.” The manuscript is based on original and unpublished research. The study is not currently being considered by any other journal. All authors have seen and approved the contents of the submitted manuscript, and we have assurance from all those acknowledged.

**Why do we think our manuscript is appropriate for BMC Public Health?**

The primary aim of the FLAMENCO project is to assess the cost-effectiveness of a primary care-based exercise intervention program (16 weeks) in perimenopausal women. In addition, we will address the following specific objectives: i) to determine the associations between physical activity, sedentary behaviour and physical fitness with CVD biomarkers, body composition, dietary patterns, glycaemic and lipid profile sleep quality, quality of life, mental health, positive health and menopause symptoms; and ii) to study the associations between the above mentioned variables with pharmacological and health service costs.

A total of 150 eligible women will be recruited and randomly assigned to either a 16 weeks exercise intervention (3 sessions/week), or to usual care (control) group. The primary outcome measure is the incremental cost-effectiveness ratio. The secondary outcome measures are: i) socio-demographic and clinical information; ii) body composition; iii) dietary patterns; iv) glycaemic and lipid profile; v) physical fitness; vi) physical activity and sedentary behaviour; vii) sleep quality; viii) mental health, quality of life and positive health; ix) menopause symptoms. All outcomes will be assessed at baseline and post intervention. The data will be analysed on an intention-to-treat basis and per protocol. In addition, we will conduct a cost-effectiveness
analysis from a health system perspective. The intervention designed is feasible and if it proves to be clinically and cost effective, it can be easily transferred to other similar contexts. Consequently, the findings of this project might help the Health Systems to identify strategies for primary prevention and health promotion as well as to reduce health care requirements and costs.

We hope that you find this work of interest.

**Ethics and funding approval:** The study was approved by the Ethics committee for human subjects’ experimentation from the University of Granada (Spain). The funding source was not commercial and the project had undergone peer review process. We have sent the ethics and funding approval to BMCSeriesEditorial@biomedcentral.com

**Study Status:** This is an ongoing study, in which we are undertaking the interventions and we are still to have final evaluations and data analysis within the next 3-4 months.

**Related articles:** No publications containing the results of this study have already been published or submitted to any journal.

**ClinicalTrials.gov Identifier:** NCT02358109; https://clinicaltrials.gov/ct2/show/NCT02358109?term=flamenco&rank=1

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Yours sincerely,

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