

# Effect of an incremental workplace exercise program on women's fitness

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<b>Registration date</b> 29/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/09/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Women are more inactive when compared to men and this is a concern as physical inactivity puts women at risk of adverse health effects. Women tend to drift into a less active lifestyle starting in their 20s, during their transition from school to the workplace. Due to the unique and varied challenges faced by working women, places of employment is an ideal avenue to implement programs to increase physical activity. The aim of this study is to evaluate the effectiveness of incremental workplace exercise intervention designed to increase fitness level among women with low physical activity

### Who can participate?

Women employee of University Malaya Medical Center who has low physical activity level, between the age of 25 and 49, and who have no limitation to exercise

### What does the study involve?

Seventy women will be randomly assigned to either an intervention group (exercise) or a control group (pedometer). In the intervention group, participants will aim to meet the 150 minutes of moderate-intensity exercise a week. Participants will have two familiarization sessions to exercise in the first week. In the next eight-weeks of the active phase, participants will perform two supervised exercise video sessions weekly. Additional moderate-intensity exercise sessions are encouraged at participants' own time. In the following eight-weeks maintenance phase, participants will continue to meet and maintain the exercise goal on their own.

In the control group, participants will aim to reach 10,000 steps/day. Each participant will receive a pedometer which will have to be worn for the whole of the waking time during the study period (16 weeks). In the first eight weeks of the active phase, participants will be guided to build on their total steps a day to reach the 10,000 steps/day goal. In the following eight weeks of the maintenance phase, participants will continue to maintain and reach their goal on their own. Participants will need to log in their daily steps on an online website.

For both groups, participants required to adhere to the healthy eating plate guide to eating choices with  $\frac{1}{2}$  portion for vegetables and fruits,  $\frac{1}{4}$  portion for whole and intact grains, and  $\frac{1}{4}$  portion for protein.

Participants will go through several fitness assessments and answering several exercise-related behaviour questionnaires at baseline, week-nine and week-17, post commencement of the study

What are the possible benefits and risks of participating?

Possible benefits include improvement of physical fitness and several aspects related to behavioural changes related exercise (see primary and secondary outcomes and hypotheses). Potential risks are those intrinsically associated with exercise, such as potential injuries. However, this is unlikely to occur as all sessions will be closely supervised by qualified professionals

Where is the study run from?

University of Malaya Medical Center, Malaysia

When is the study starting and how long is it expected to run for?

February 2019 until July 2021 (updated 24/02/2020, previously: February 2020)

Who is funding the study?

The Academy of Family Physicians Malaysia (AFPM) and Malaysian Primary Care Research Group

Who is the main contact?

Dr Khasnur Abd Malek

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## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Khasnur Abd Malek

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

600-IRMI (5/1/6)

## **Study information**

**Scientific Title**

Effects of a 16-week incremental workplace exercise program on fitness level among female workforce with low physical activity

**Study objectives**

Intervention group will see a bigger improvement gains in fitness level as compared to control group

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 0201/2019, Research Ethics Committee of the Universiti Teknologi MARA (UiTM) (Aras 3, Bangunan Wawasan, 40450 Shah Alam, Selangor, Malaysia; +603 5544 2094; irmiuitm@salam.edu.my), ref: 600-IRMI (5/1/6)

**Study design**

Single centre quasi-experimental randomized controlled study

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

Other

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**Health condition(s) or problem(s) studied**

Prevention of chronic disease with exercise

**Interventions**

Intervention group consists of incremental exercise and control group consists of incremental steps/day. The total study period for this study is 16 weeks, including eight-week active phase and eight-week maintenance phase. Consented participants will be randomly assigned to either

the intervention group or control group, using a systematic allocation method. This allocation will take into account perceived commitment, and working schedule. A single-blinded method will be used where outcome assessors and statistics analyzer will be blinded.

**Intervention group:** Participants in this group will be instructed to gradually achieve and maintain 150 minutes of moderate-intensity physical activity (PA) per week. Participants will go through two sessions of exercise familiarization in week one. In the following eight-weeks of the active phase, participants are required to attend two observed exercise sessions and will be encouraged to increase their moderate-intensity exercise sessions to 150-minute a week. In the following eight-weeks maintenance phase, participants will be encouraged to continue their PA without push encouragement. For the study duration, participants will self-report their additional exercise sessions to the researchers.

**Control group:** This is an active control group. Participants will wear a pedometer daily during their waking time for a total of 16 weeks. In the first eight-weeks of active phase, participants will receive guidance to increase their daily steps by 10% with the aim to reach 10,000 steps/day. In the following eight-weeks maintenance phase, participants will continue to reach and maintain their 10,000 steps a day without guidance. Participants are required to log their daily steps into an online system.

For both intervention and control groups, participants are required to adhere to the healthy eating plate guide to eating choices with  $\frac{1}{2}$  portion for vegetables and fruits,  $\frac{1}{4}$  portion for whole and intact grains, and  $\frac{1}{4}$  portion for protein

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Cardiorespiratory fitness assessed using an estimated maximal oxygen uptake using the Åstrand-Rhyming cycle ergometer test at baseline, week-9 and week-17 post commencement of the study

## **Secondary outcome measures**

Fitness assessment:

1. Muscle strength fitness is assessed using three repetition maximum (3RM) test for chest and leg press at baseline, week-9 and week-17 post commencement of the study
3. Muscle endurance fitness is assessed using prone plank technique at baseline, week-9 and week-17 post commencement of the study.
4. Flexibility fitness is assessed using sit-and-reach test at baseline, week-9 and week-17 post commencement of the study
5. Body composition analysis will be measured using bioelectrical impedance analysis instrument at baseline, week-9 and week-17 post commencement of the study

Behavioural changes:

1. Perceived readiness to changes physical activity level is assessed using Exercise Stages of Change Questionnaire at baseline, week-9 and week-17 post commencement of the study
2. Perceived exercise-related efficacy is assessed using Bandura's Self-Efficacy to Exercise questionnaire at baseline, week-9 and week-17 post commencement of the study
3. Perceived readiness to changes physical activity level is assessed using Exercise Stages of Change Questionnaire at baseline, week-9 and week-17 post commencement of the study
4. Perceived barriers and benefit to exercise is assessed using Exercise Benefits/Barriers Scale at

baseline, week-9 and week-17 post commencement of the study

5. Perceived barriers to being active are assessed using Barrier to Being Active Questionnaire at baseline, week-9 and week-17 post commencement of the study

6. Subjective response to exercise stimuli within the intervention group is assessed using the Subjective Exercise Experience scale at the end of an exercise session at week-1, week-9 and week-17 post commencement of the study

**Overall study start date**

01/01/2018

**Completion date**

30/07/2021

## **Eligibility**

**Key inclusion criteria**

1. Healthy working women with no limitation or restriction to exercise
2. BMI between 23 to 29.9kg/m<sup>2</sup>
3. Has low physical activity level measured by global physical activity questionnaire

**Participant type(s)**

Healthy volunteer

**Age group**

Adult

**Sex**

Female

**Target number of participants**

72

**Key exclusion criteria**

1. BMI at and over 39.9kg/m<sup>2</sup> or below 23kg/m<sup>2</sup>
2. Physical disability to exercise
3. Not able to commit to the study schedule
4. Enrolled in a structured exercise programme over the past 6 months
5. Has moderate or vigorous physical activity level as measured by Global Physical Activity Questionnaire (GPAQ)
6. Currently pregnant
7. Meet the 'high risk' for American College of Sports Medicine (ACSM) risk stratification

**Date of first enrolment**

01/02/2019

**Date of final enrolment**

30/07/2021

## **Locations**

**Countries of recruitment**

Malaysia

**Study participating centre**

**University of Malaya Medical Centre**

Lembah Pantai

Kuala Lumpur

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## **Sponsor information**

**Organisation**

The Academy of Family Physicians Malaysia (AFPM) and Malaysian Primary Care Research Group (MPCRG)

**Sponsor details**

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**Sponsor type**

University/education

**Website**

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## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

The Academy of Family Physicians Malaysia (AFPM) and Malaysian Primary Care Research Group (MPCRG)

# Results and Publications

## Publication and dissemination plan

The results will be presented at national and international conferences and will be published in peer reviewed international journals.

## Intention to publish date

31/12/2022

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon reasonable request from Dr Khasnur Abd Malek (drkhasnurabdmalek@gail.com). To gain access, data requestors will likely need to sign a data access agreement. The data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. The personal information obtained from the participants would be kept confidential. The data will be available from 9 months to 36 months following article publication.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>			13/09/2022	No	No