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

Submission date
24/10/2019

Recruitment status
No longer recruiting

Registration date
29/10/2019

Overall study status
Completed

Last Edited
13/09/2022

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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's 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 ½ portion for vegetables and fruits, ¼ portion for whole and intact grains, and ¼ 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number

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

Study type(s)
Other

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 is 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 ½ portion for vegetables and fruits, ¼ portion for whole and intact grains, and ¼ portion for protein

Intervention Type
Behavioural

Primary outcome(s)
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

Key secondary outcome(s))
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

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/m²
3. Has low physical activity level measured by global physical activity questionnaire

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. BMI at and over 39.9kg/m² or below 23kg/m²
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
Malaysia
59100

Sponsor information

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

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

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?
Protocol file			13/09/2022	No	No