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The effectiveness of SLIM SHAPE 2.0 interventions in improving the health, wellness, and work productivity among working adults with overweight and obesity

Submission date
03/08/2023

Recruitment status
No longer recruiting

Registration date
09/08/2023

Overall study status
Completed

Last Edited
08/08/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] 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
Approximately half of Malaysian employees are overweight and obese. It imposes a financial burden for employees and employers as it increases absenteeism and healthcare cost; decreases productivity and quality of life. Many weight reduction programs are effective but not sustainable. Thus, this study aims to determine the effectiveness and sustainability of a multicomponent weight loss program among employees with overweight and obesity in the workplace. In addition, factors influencing weight lost maintenance will be determined.

Who can participate?
Permanent staff of Universiti Kebangsaan Malaysia (Bangi campus) aged 20-59 years old

What does the study involve?
Participants are allocated into either the SLIMSHAPE 2.0 or control group based on their office zone. Participants in the SLIMSHAPE 2.0 group will receive multicomponent interventions that include dietary management, physical activity and exercise training, and aspect of mindfulness. These interventions will be delivered through lectures, interactive activities, and group exercise training provided by dietitians and sports physiologists. On the other hand, the control group will receive conventional dietary and health counseling at UKM Health Centre delivered by a dietitian and Medical Officer. They will also be given hand-outs on weight management and healthy lifestyle.

What are the possible benefits and risks of participating?
Participants will be able to learn about their health status through body composition measurements, blood tests, dietary intake, and physical activity status which will be explained in the first week of intervention.
No risks.

Where is the study run from?
Universiti Kebangsaan Malaysia

When is the study starting and how long is it expected to run for?
January 2019 to March 2021

Who is funding the study?
Universiti Kebangsaan Malaysia

Who is the main contact?
Associate Professor Dr Zahara Abdul Manaf, zaharamanaf@ukm.edu.my

Contact information

Type(s)
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Additional identifiers

Protocol serial number
UKM FPR.4/244/DCP-2018-005/1

Study information

Scientific Title
The effectiveness of SLIM SHAPE 2.0 interventions in improving the health, wellness, and work productivity among the staff of Universiti Kebangsaan Malaysia

Study objectives
The SLIMSHAPE 2.0 interventions is more effective in reducing cardiovascular disease risks, maintaining ideal body weight, and improving quality of life and work productivity of the staff of Universiti Kebangsaaan Malaysia (Bangi) as compared to the control group

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/07/2019, Secretariat of Medical Research and Innovation (Faculty of Medicine, Universiti Kebangsaan Malaysia, Level 6, Preclinical Building, Jalan Yaacob Latif, Bandar Tun Razak, Cheras, Kuala Lumpur, 56000, Malaysia; +603-91455003; nasirshafiee@ukm.edu.my), ref: UKM FPR.4/244/DCP-2018-005/1

Primary study design
Interventional

Study design
Single-center interventional non-randomized trial

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Reduction in cardiovascular risks and body weight, and improvement of work productivity and quality of life in employees with overweight and obesity

Interventions
Employees with overweight and obesity will be assigned to either the SLIMSHAPE 2.0 or control group based on their office zone in order to avoid selection bias. Those from Zone 1 will be assigned to the SLIMSHAPE 2.0 group, whereas employees from Zone 3 will be assigned to the control group.

Participants in the SLIMSHAPE 2.0 group will receive interventions that include dietary management, physical activity and exercise training, and aspects of mindfulness, flow, and spirituality. The SLIMSHAPE 2.0 Intervention Program will be conducted weekly in a 3-hour

session for 12 weeks. Lectures related to dietary management and four interactive and hands-on activities related to healthy eating such as calorie counting for food and drinks, healthy cooking demonstrations, a visit to the supermarket, and understanding food labels will all be delivered by a dietitian. Aspects related to physical activity will be delivered through lectures, demonstrations, and group exercise training. These activities will be carried out by sports physiologists and physiotherapists. In addition to these, participants will also receive mindfulness, flow, and spiritual interventions through Apps called MyMind throughout the intervention program.

Participants in the control group will receive one face-to-face consultation about diet, physical activity, and behavior modification for weight loss from the Dietitian and Medical Officers at the Universiti Kebangsaan Malaysia Health Centre. Participants will also be given pamphlets on proper diet, exercise, and maintaining a healthy lifestyle.

Intervention Type
Behavioural

Primary outcome(s)
Body weight change calculated as the difference (in kilograms) between measured weight at baseline and approximately 12 weeks after the intervention

Key secondary outcome(s)
1. Body weight change calculated as the difference (in kilograms) between measured weight at baseline and approximately 9 months after enrollment
2. Body composition (body fat, fat-free mass, muscle mass) measured using a bioelectrical impedance analyzer (TANITA DC-360) at baseline, 3 months, and 9 months
3. Waist circumference measured using a non-extensible measuring tape at baseline, 3 months, and 9 months
4. Blood pressure measured using an automated sphygmomanometer at baseline, 3 months, and 9 months
5. Blood glucose, lipid and uric acid measured through a blood sample after an overnight fast as baseline, 3 months, and 9 months
6. Dietary intake assessed retrospectively using a validated Diet History Questionnaire (DHQ) at baseline, 3 months, and 9 months
7. Physical activity assessed using Malay-translated Global Physical Activity Questionnaire (GPAQ) at baseline, 3 months, and 9 months
8. Mindful eating behavior assessed using Malay-translated Mindful Eating Questionnaire (MEQ-M) at baseline, 3 months and 9 months

Completion date
29/03/2021

Eligibility

Key inclusion criteria
1.Permanent staff of Universiti Kebangsaan Malaysia (Bangi)
2. Age between 20-59 years old
3. Non-shift worker
4. No chronic diseases such as cancer and renal failure
5. In either contemplation, preparation, action, or maintenance stage of change

Participant type(s)
Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
20 Years

Upper age limit
59 Years

Sex
All

Total final enrolment
152

Key exclusion criteria
1. Temporary staff of Universiti Kebangsaan Malaysia (Bangi)
2. Pregnant staff
3. Blood pressure >=160/100 or <90/60mmHg
4. Uncontrolled blood glucose (HbA1c >=9.0%)
5. History of weight loss participation in the last 3 months prior to study
6. History of bariatric surgery
7. Prolonged sick leave (more than a month)
8. Chronic joint pain

Date of first enrolment
01/10/2019

Date of final enrolment
31/01/2020

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Kebangsaan Malaysia
Bangi
Malaysia
43600

Sponsor information

Organisation
Universiti Kebangsaan Malaysia

Funder(s)

Funder type
University/education

Funder Name
Universiti Kebangsaan Malaysia

Alternative Name(s)
Universiti Kebangsaan Malaysia (UKM), Universiti Kebangsaan Malaysia (UKM), Malaysia, ukminsta, Universiti Kebangsaan Malaysia - UKM, Universiti Kebangsaan Malaysia (Malaysia), University Kebangsaan (Malaysia), UKM

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during'/ the current study are not expected to be made available as data sharing has not been included as part of agreement in participant's consent form.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in English		08/08/2023	No	Yes
Participant information sheet	in Malay		08/08/2023	No	Yes
Protocol file	in English		08/08/2023	No	No

Protocol file	in Malay	08/08/2023	No	No