ISRCTN18283628 https://doi.org/10.1186/ISRCTN18283628

A study to assess workers' knowledge of the Mediterranean diet and physical activity and how this results in weight change in workers

Submission date
12/04/2025

Recruitment status
No longer recruiting

Registration date
17/04/2025

Overall study status
Completed

Last Edited
17/04/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The workplace has a high potential for health promotion in terms of healthy eating and physical activity. In fact, proper nutrition and an active lifestyle reduce the risk of disease and improve mood, performance, and productivity, creating a better working atmosphere and greater satisfaction with activities. The primary aim of this study is to determine the effectiveness of the health promotion intervention in terms of improving knowledge, attitudes, and behaviors (KAB) in both nutrition (Mediterranean diet) and physical activity. The secondary aim is to assess variation in body mass index (BMI) in the experimental groups.

Who can participate?
Policlinico Umberto I health care workers and Sapienza University of Rome employees aged over 18 years found to be overweight or obese (BMI ≥25.00 kg/m2) will be recruited during the occupational medicine visit held at their respective centers of reference.

What does the study involve?
Participants will be randomly divided into three intervention groups and a control group. Specifically:
1. The control group will be prescribed only the diet
2. The second group, in addition to the diet, will be prescribed the viewing of short educational videos related to the Mediterranean diet
3. The third group, in addition to the diet, will be prescribed the viewing of short videos in which notions of physical activity will be imparted and exercises suggested to be performed independently
4. The fourth group, in addition to the diet, will be prescribed the viewing of both types of videos
All participants will make an initial visit with the dietitian (T0) during which questionnaires assessing knowledge, attitudes, and behaviors related to the Mediterranean diet and physical activity will be administered; in addition, an appropriate diet will be prescribed.
All participants will make a second visit 1 month after the first visit (T1), during which anthropometric data will be measured and any diet changes evaluated. Two months after the second visit (T2), participants will make a final visit with the dietitian during which

anthropometric data will be collected and the same questionnaires submitted at T0 will be administered.

What are the possible benefits and risks of participating?
The researchers are not able to guarantee that participating in this study will bring direct benefits to employees, but the eventual demonstration of improved employee knowledge, attitudes, and behaviors will incentivize the introduction of workplace health promotion programs for all employees and allow for increased employee health, with the aim of reducing medical and public service errors and to raise the performance standards of companies.

Where is the study run from?
Sapienza University of Rome (Italy)

When is the study starting and how long is it expected to run for?
January 2025 to May 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof. Giuseppe LaTorre, giuseppe.latorre@uniroma1.it

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Workplace health promotion: a randomized clinical trial to assess knowledge, attitudes and behaviors on Mediterranean diet and physical activity

Study objectives
Increased knowledge of the Mediterranean diet and physical activity combined with diet prescription results in greater weight reduction than Mediterranean diet prescription alone

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 20/01/2025, Lazio Area 1 Territorial Ethics Committee (Viale del Policlinico, 155, Rome, 00161, Italy; +39 (0)649979822; comitatoetico.lazioarea1@policlinicoumberto1.it), ref: Rif. 7798, Prot. 0043/2025

Study design
Multicenter four-arm randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention, Quality of life

Health condition(s) or problem(s) studied
Knowledge improvement and weight reduction

Interventions
This study will be a multicenter four-arm randomized controlled trial conducted among overweight and obese employees of Policlinico Umberto I and Sapienza University of Rome. Workers will be recruited at the occupational medicine visit held at their respective centers. Patients found to be overweight or obese (BMI ≥25.00 kg/m2) once anthropometric parameters are collected will be offered enrollment in the study. Participants will be randomly divided into three intervention groups and a control group. To avoid imbalance among intervention groups, stratified randomization will be carried out according to gender and place of work. All participants during the first visit with the dietitian (T0) will be prescribed an appropriate diet and issued a vademecum explaining the main dietary guidelines. Specifically:
1. The control group will be prescribed only the diet
2. The second group, in addition to the diet, will be prescribed the viewing of short educational videos related to the Mediterranean diet
3. The third group, in addition to the diet, will be prescribed the viewing of short videos in which notions of physical activity will be imparted and exercises suggested to be performed independently
4. The fourth group, in addition to the diet, will be prescribed the viewing of both types of videos

All participants will make a second visit 1 month after the first visit (T1), during which anthropometric data will be measured and any diet changes evaluated. Two months after the

second visit (T2), participants will make a final visit with the dietitian during which anthropometric data will be collected and the same questionnaires submitted at T0 will be administered.

Intervention Type
Behavioural

Primary outcome(s)
Knowledge of nutrition (Mediterranean diet) and physical activity measured using:
1. Questionnaire on adherence to the Mediterranean diet: this assesses the frequency of consumption of the various food groups (cereals, fruits, vegetables, meats, etc), time spent preparing and eating meals
2. Questionnaire on knowledge of the principles of the Mediterranean diet: consists of 15 closed questions with four answers of which only one was correct, structured by the experimenters related to the contents of 12 videos sent to participants on a weekly basis
3. IPAQ-SF (International Physical Activity Questionnaire - Short Form validated in Italian) with seven questions + three questions formulated by the researchers: the short version of the questionnaire in Italian is a translation of the English version of the IPAQ-SF. It includes seven items to assess the level of physical activity based on time (given in days and minutes per day) spent on vigorous and moderate intensity activities, time spent walking and sitting. The duration of the different activities is multiplied by the respective metabolic rates, expressed as MET (metabolic equivalent of activity) in order to obtain the energy expenditure at work and during leisure time; the final score allows the identification of three distinct categories: subject "inactive," "sufficiently active," and "active or very active." Three questions formulated by the researchers assessing the type of physical activity performed and frequency, attitude to physical activity and the impact that, according to the participant, it has on various health conditions (diabetes, cancer, etc) were added to the questionnaire
4. Questionnaire on knowledge in the field of physical activity: a questionnaire of 15 closed questions with four answers of which only one was structured by the experimenters, related to the contents of eight information documents sent to participants biweekly
Measured at T0, T1 and T2 as defined in the Interventions field

Key secondary outcome(s))
Body mass index (BMI) obtained from the ratio of body weight (kg) to height expressed in meters squared (kg weight/height in m2) measured at T0, T1 and T2 as defined in the Interventions field

Completion date
15/05/2025

Eligibility

Key inclusion criteria
1. Employee or equivalent staff of the Policlinico Umberto I or Sapienza University of Rome who undergoes the occupational medicine visit
2. Over 18 years old
3. Overweight or obese (BMI ≥25.00 kg/m2)

Participant type(s)
Health professional, Employee

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
71 years

Sex
All

Total final enrolment
87

Key exclusion criteria
1. Staff with nephrological pathologies under treatment
2. Staff who have undergone abdominal surgery in the last month
3. Staff with psychiatric pathologies under treatment
4. Staff with grade III obesity (BMI ≥40.00 kg/m2)
5. Staff who cannot follow a specific diet due to pathologies or problems expressed to the doctor during the occupational medicine visit

Date of first enrolment
21/01/2025

Date of final enrolment
31/01/2025

Locations

Countries of recruitment
Italy

Study participating centre
Azienda Ospedaliero - Universitaria Policlinico Umberto I
Viale del Policlinico, 155
Roma
Italy
00161

Study participating centre
Sapienza Università di Roma
Piazzale Aldo Moro, 5

Roma
Italy
00185

Sponsor information

Organisation
Sapienza University of Rome

ROR
https://ror.org/02be6w209

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof. Giuseppe La Torre (giuseppe.latorre@uniroma1.it).
Dates of availability: 01/09/2025
All information related to participation in the study will be treated strictly confidentially in accordance with the rules for the protection of persons and other subjects with regard to the processing of personal data (pursuant to Articles 13 and 14 of EU Regulation No. 679/2016 of 27.04.2016 “General Data Protection Regulation” and Legislative Decree No. 196/2003 “Code on the Protection of Personal Data,” as amended by Legislative Decree No. 101 of 10.08.2018, laying down provisions for the adaptation of the national system to the European Regulation). All results obtained are to be considered strictly confidential and subject to professional secrecy and the relevant legislation in force. Personal data collected anonymously (biographical information, and other “sensitive” data) will be recorded, processed, managed and stored in computer form for the exclusive purposes related to the performance of this study.

IPD sharing plan summary
Available on request