

Diet, exercise and emotional health in workers of the SEAT car factory

Submission date 07/11/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/10/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/10/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Health lifestyle habits are important for keeping in good health, improving quality of life and preventing illnesses. Following a healthy diet during youth and the middle stages of life is key to reducing the probability of suffering diseases in the later stages of life. This study aims to look at the healthy lifestyle habits of SEAT workers and to look at the effect of health promotion activities on these workers and their families.

Who can participate?

Adults working at SEAT in Barcelona

What does the study involve?

Participants will be randomly allocated to either the intervention group or the control group. The intervention group will receive the Multifactorial Healthy Lifestyle intervention, which involves promotion of a Mediterranean diet, discounts in vegetable stores, changes in snacks in vending machines for healthier ones, and promotion of physical activity, along with sessions to improve emotional health. Participants in the control group will receive treatment as usual.

What are the possible benefits and risks of participating?

The possible benefit of participating in this study is that participants may improve their cardiovascular health, levels of physical activity and emotional health. There are no known risks to participants.

Where is the study run from?

Two SEAT factories in Barcelona (Spain)

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

March 2018 to January 2019

Who is funding the study?

SEAT SA (Spain)

Who is the main contact?

Dr. Ramon Estruch
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Contact information

Type(s)

Scientific

Contact name

Dr Ramon Estruch

Contact details

Hospital Clinic,
Villarroel 170
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Spain
08036

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2018/01

Study information

Scientific Title

MEDCARS: MEDiterranean lifestyle habits in the workers of the CARS factory SEAT

Acronym

MEDCARS

Study objectives

A multifactorial lifestyle interventions including promotion of Mediterranean Diet (DMed), increase in physical activity and behavioral support for improvement emotional health, will lead to a significant improvement in the health status compared with usual care of SEAT workers.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board of the Hospital Clinic of Barcelona, 24/04/2018, HCB/2018/0227

Study design

Interventional cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Other

Study type(s)

Quality of life

Participant information sheet

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

Health condition(s) or problem(s) studied

Cardiovascular risk factors

Interventions

Centers are cluster randomised using a computer-generated random number sequence to either the intervention or the control group.

The intervention group will receive the Multifactorial Healthy Lifestyle intervention, which includes promotion of a Mediterranean diet with supplemental extra virgin olive oil and nuts, discounts in vegetable stores, changes in snacks in vending machines for healthier ones, and promotion of physical activity. Participants in this group are also invited to several sessions for the improvement of emotional health for at least 6 months.

Participants in the control group will receive care as usual.

There will be a 6 month follow-up period.

Intervention Type

Mixed

Primary outcome measure

The following are assessed at the baseline and at the end of the study:

1. Changes in cardiovascular risk measured according to the following risk factors:

1.1. Blood pressure, assessed using a validated semiautomatic oscillometer

1.2. Plasma fasting glucose, assessed using a fasted blood test

1.3. HbA1c, assessed using a fasted blood test

1.4. Total cholesterol, assessed using a fasted blood test

1.5. LDL cholesterol, assessed using a fasted blood test

1.6. HDL cholesterol, assessed using a fasted blood test

1.7. Triglycerides, assessed using a fasted blood test

1.8. Smoking status, assessed by self-report (classified as "current", "former" or "non-smoking")

1.9. Alcohol consumption, assessed by self-report as total grams of ethanol per day

2. Changes in:

2.1. Body weight, measured using a calibrated balance beam scale

2.2. Height, measured using a wall-mounted stadiometer

- 2.3. Waist circumference, measured using an anthropometric tape
- 3. Changes in the intestinal microbiome, assessed using microbiota analysis of stool samples

Secondary outcome measures

The following are assessed at the baseline and at the end of the study:

- 1. Changes in silent target organ damage:
 - 1.1. Microalbuminuria, assessed by analysing the albumin/creatinine ratio from spot morning urine samples
 - 1.2. Ventricular hypertrophy, assessed using an electrocardiogram
- 2. Changes in quality of life, assessed using:
 - 2.1. Goldberg Depression Test (Spanish version)
 - 2.2. Wagnild and Young's resilience scale (Spanish version)
- 3. Changes in Mediterranean Diet adherence, assessed using the PREDIMED score
- 4. Changes in physical activity and sedentarism, assessed using the International Physical Activity Questionnaire (IPAQ) (Spanish version)
- 5. Changes in emotional health, assessed using the 25-item item Resilience Scale of Wagnild and Young
- 6. Association between Mediterranean diet adherence (assessed as per secondary outcome measure 3) and inflammatory biomarkers. Inflammatory biomarkers, including C-reactive protein (CRP), interleukin-6 (IL-6), ICAM and VCAM will be assessed using:
 - 6.1. Enhanced immunoturbidimetry
 - 6.2. ELISA
- 7. Association between inflammatory biomarkers (assessed as per secondary outcome measure 3) and changes in intestinal microbiome (assessed as per primary outcome measure 3)

Overall study start date

08/03/2018

Completion date

31/01/2019

Eligibility

Key inclusion criteria

- 1. Subjects ≥ 18 years
- 2. Active workers of SEAT company with a theoretical working life ≥ 12 months
- 3. Willingness to follow the multifactorial interventions (diet, physical exercise and emotional health) proposed in the study
- 4. Written informed consent

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600

Key exclusion criteria

1. Documented psychiatric disorders (schizophrenia, bipolar disorder, and/or major depression)
2. Allergies or intolerances to the principal components of the Mediterranean diet such as nuts or olive oil
3. Workers who in the opinion of the researcher, consider that they will not follow the recommendations of the study
4. Affected by any of the following circumstances:
 - 4.1. Confirmed gastrointestinal pathology, such as a history of inflammatory bowel disease, malabsorption, or previous bowel surgery (with the exception of appendicitis)
 - 4.2. Confirmed autoimmune pathology
 - 4.3. Strict vegan diet or other types of diets that may difficult the following of the traditional Mediterranean diet
 - 4.4. Previous treatments with antibiotics the month prior to their inclusion in the study
 - 4.5. Liver cirrhosis or confirmed chronic liver disease.

Date of first enrolment

15/03/2018

Date of final enrolment

15/06/2018

Locations

Countries of recruitment

Spain

Study participating centre

SEAT, SA

Autovía A-2, Km.585

08760 Martorell (Barcelona)

Barcelona

Spain

08760

Sponsor information

Organisation

SEAT SA

Sponsor details

Autovía A-2, Km. 585.
Apdo. de Correos 91
08760 Martorell
Barcelona
Spain
08760

Sponsor type

Industry

ROR

<https://ror.org/024kx0v68>

Funder(s)

Funder type

Not defined

Funder Name

SEAT SA

Results and Publications

Publication and dissemination plan

We expect preliminary publication around April-May 2019.

Intention to publish date

01/05/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository

IPD sharing plan summary

Stored in repository