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

Submission date	Recruitment status	[ ] Prospectively registered
07/11/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/10/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/10/2019	Circulatory System	[ ] 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

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Hospital Clinic,
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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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(s)
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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
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08760

Sponsor information

Organisation
SEAT SA

ROR
https://ror.org/024kx0v68

Funder(s)

Funder type
Not defined

Funder Name
SEAT SA

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository

IPD sharing plan summary

Stored in repository