Physical Activity Initiated by Employer and its health effects: an eight-week follow-up study

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/07/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
21/08/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
05/09/2023	Circulatory System			

Plain English summary of protocol

Background and study aims

In this project we will study whether physical activity motivated at the workplace among road workers and their managers, all with predominantly sedentary work, can have a positive influence on their heart health. Road workers are exposed to diesel exhaust and road dust, which can possibly negatively affect their heart health. Roadworkers spend much of the workday sitting in big machines. Senior and middle managers work long hours, which can also lead to negative consequences for their health. The results will also be of interest to working life in general and for the general population.

Who can participate? Healthy volunteers aged over 18.

What does the study involve?

You will undergo two or three health surveys. The health survey will be conducted in your local workplace and last about 45 minutes. The examination will consist of an interview/questionnaire regarding work history, history of heart disease or other serious illness, and use of drugs and tobacco. Your height, blood pressure and weight will be measured and we will take blood samples to find out whether you have substances in your blood that may be signs of inflammation. Your aerobic fitness will be determined using a graded test on a cycle ergometer. You will then participate in a physical activity program. Your steps will be measured by a wristband pedometer. Both team and individual performance will be monitored and the best performance will be rewarded at the end of the study. After eight weeks you will undergo the tests from the start of the study again.

What are the possible benefits and risks of participating?

The advantage of the project is that it will give us new knowledge about potential health effects of increasing physical activity. This could provide an opportunity to prevent health problems and eventual illness and may affect the assessment of potential occupational diseases, and may also contribute to general public health. Some may find the blood sampling unpleasant. Blood sampling is usually a procedure that does not involve any risks, but injuries (bruising under the

skin) may occur. To reduce risk, only trained personnel will take the blood samples. Certain blood tests used in the project may detect disease that was unknown to you before, in which case you will be notified and referred for further investigation.

Where is the study run from?

The study is carried out by the National Institute of Occupational Health (STAMI) in collaboration with Mesta company.

When is the study starting and how long is it expected to run for? From August 2014 to October 2015.

Who is funding the study? Statoil's Fund for Research in Occupational Medicine (Norway).

Who is the main contact? Dr Marit Skogstad

Contact information

Type(s)

Scientific

Contact name

Dr Marit Skogstad

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Physiological effects of employers motivated physical activity

Acronym

PAIE

Study objectives

In this project we will study whether physical activity motivated at the workplace, increased physical activity among road workers and their leaders, all with predominantly sedentary work, can have a positive influence on their cardiovascular status. Road workers are exposed to diesel exhaust and road dust, which can possibly affect their cardiovascular status negatively. Roadbuilders spends much of the workday sitting in big machines. Senior and middle managers in the construction industry are exposed to high work and long working hours, which can also lead to negative consequences for their health. The results will also be of interest to working life in general and for the general population .

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethics Committee in Oslo (2014/1521), 04/12/2014, ref: 2014/1521/REK sør-øst B

Study design

Single-center observational prospective study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

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

Health condition(s) or problem(s) studied

Cardiovascular status

Interventions

All subjects participating in the physical activity program got organized in teams and competed against each other in a virtual internet mountain track. Steps measured by a wrist-band pedometer were recorded on the personally designated profile on the competition website. Both team and individual performances could be continuously monitored and the best performance was rewarded at the end of the program.

Maximal oxygen uptake, blood pressure, resting heart rate (RHR) and blood samples (glycosylated hemoglobin, lipids and C-reactive protein) were obtained at baseline and after eight weeks.

Intervention Type

Behavioural

Primary outcome measure

Aerobic fitness was tested using a graded test on a cycle ergometer (Monark 874 E, Monark Exercise AB, Vansbro, Sweden). The starting load was 70 W with a cadence of 70 revolutions per minute (RPM). Every minute the resistance was increased by 35 W until the subject was exhausted (cadence <65 RPM). Oxygen uptake was measured continuously with a Cosmed K4b2 breath by a breath metabolism analyser (Cosmed Srl, Rome, Italy) and was calculated from the highest 30 s averaging interval at the conclusion of the test.

Secondary outcome measures

- 1. Blood pressure and resting heart rate (RHR) were measured on the left arm after five minutes of rest. The measurements were taken three times in intervals of one minute. The average of the last two measurements of both the systolic (sBP) and the diastolic pressure (dBP) was used in the statistical analysis. Blood pressure and RHR was measured with BpTRU® (Bp TRU medical devices, Coquitlam, Canada) on both occasions. All tests were performed using the same device and by the same researchers at the same time of the day both at baseline registration and at follow-up.
- 2. Glycosylated hemoglobin (HbA1c) was collected in EDTA blood. Serum for investigation of lipids (cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL) and C-reactive protein (CRP) was collected on gel tubes and then centrifuged 35 x 1000 rpm for 15 minutes within 60 minutes after the blood had been drawn from a vein. The tubes were sent by mail to the Department of Medical Biochemistry Oslo University Hospital and analyzed within 24 hours. HbA1c EDTA blood was analyzed with a Tosoh G7 HPLC analyser (Tosoh Bioscience, Inc., San Francisco, CA, USA) which uses "high performance liquid chromatography" as the separation principle. The analytical variation is 1.7 %.
- 3. Cholesterol, LDL and HDL in serum were analyzed by the enzymatic colorimetric method in the Cobas 8000. Analytical variation coefficients are respectively 3.0, 4.0 and 3.5 %.
- 4. CRP in serum was quantified by the particle enhanced immunoturbidimetric method on Cobas 8000 (Cobas 8000 Modular Analyzer Roche Diagnostics, www.roche.com). Analytical variation is 8.0 %.

Blood was collected at the same time of the day on both occasions.

Overall study start date

01/08/2014

Completion date

31/10/2015

Eligibility

Key inclusion criteria

Healthy volunteers aged over 18

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

More than 100

Key exclusion criteria

Some disorders will disqualify for participation in the study, such as serious heart disease and cancer

Date of first enrolment

01/08/2014

Date of final enrolment

01/09/2014

Locations

Countries of recruitment

Norway

Study participating centre National Institute of Occupational Health

Gydas v 8, Pb 8149 Dep Oslo Norway N-0033

Sponsor information

Organisation

National Institute of Occupational Health (Norway)

Sponsor details

Box 8149 Dep Oslo Norway N-0033

Sponsor type

Government

Website

www.stami.no

ROR

https://ror.org/04g3t6s80

Funder(s)

Funder type

Charity

Funder Name

Statoil's Fund for Research in Occupational Medicine

Results and Publications

Publication and dissemination plan

- 1. Oral feedback will be given to the participants in the study
- 2. The results are presented on the Intranet in the company
- 3. The results will be presented in national and international scientific meetings
- 4. Publication in national journals and international peer-reviewed journals in 2015

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/05/2016		Yes	No
Results article		09/02/2017	05/09/2023	Yes	No