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Cardiorespiratory fitness, cardiovascular workload and disease among cleaners

Submission date
12/12/2011

Recruitment status
No longer recruiting

Registration date
14/02/2012

Overall study status
Completed

Last Edited
23/01/2019

Condition category
Circulatory System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Contrary to high occupational physical activity (physical activity at work), leisure time physical activity and exercise are well known to prevent cardiovascular disease and enhance cardiorespiratory fitness. The reasons for such differences are not well known. Cleaners represent a group with high occupational physical activity and a high risk of cardiovascular disease.
The aims of the study is to find out whether the participation in an exercise at work in order to improve cardiorespiratory fitness can reduce the risk factors for cardiovascular disease or affect the cardiovascular workload among cleaners. The aim is also to assess whether such an exercise can be successfully implemented at cleaning companies, with high participation throughout one year.

Who can participate?
Cleaners of either gender aged 18 65 years old will be invited to participate through their company. Participants that are pregnant or suffering from cardiovascular diseases, other serious or chronic illness, severe trauma or frequent migraine will not be able to participate. Participants who are allergic to band aids will be excluded from daily measurements.

What does the study involve?
The participants will be randomly allocated to either exercise or lectures for the whole period of the study. Participation involve three health checks and daily measurements. Health checks include measurement of height, weight, fat percent, blood pressure, cardiorespiratory fitness and a blood sample. Daily measurements include four 24-hour measurements of heart rate and physical activity, and one 24-hour measurement of blood pressure.

What are the possible benefits and risks of participating?
Participants will gain extra knowledge regarding their own health through either the exercise or the lectures. There are no known risks when criteria for participation are followed.

Where is the study run from?
The study is managed from the National Research Centre for the Working Environment in Denmark, Copenhagen.

When is the study starting and how long is it expected to run for?
The project started in August 2011 and is anticipated to end in August 2014. The participating companies will be involved in the study for the duration of approximately 14 months.

Who is funding the study?
The Danish Working Environment Research Fund and University of Copenhagen (Denmark).

Who is the main contact?
Mette Korshøj Larsen

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Cardiorespiratory fitness, cardiovascular workload and disease among cleaners: a cluster randomised worksite intervention

Study objectives
Baseline measurements
1. Cleaners with high cardiorespiratory fitness have lower cardiovascular workload (% of heart rate reserve) than cleaners with low cardiorespiratory fitness
2. Occupational physical demands (i.e. cardiovascular workload and upper body work) are positively related to diurnal ambulatory blood pressure

The four months intervention with aerobic exercise will:
1. Increase cardiorespiratory fitness
2. Decrease diurnal ambulatory blood pressure
3. Improve self-rated work productivity
4. Reduce rate of perceived exertion (RPE) during work
5. Improve metabolic cardiovascular risk factors
6. Reduce the need for recovery

A one year aerobic exercise intervention will:
1. Sustain cardiorespiratory fitness from measurements after 4 months
2. Successfully result in high long-term participation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committees on Biomedical Research Ethics of the Capital Region of Denmark, 10 November 2011 ref: H-2-2011-116

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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 patient information sheet

Health condition(s) or problem(s) studied
Aerobic exercise for prevention of cardiovascular disease among cleaners.

Interventions
Participants will be randomised in clusters to receive one of the following interventions for one year. The clusters will relate to their work team where possible or groups where participants report to the same manager or work in close proximity.

Worksite aerobic exercise:
Supervised intervention at the worksite with aerobic exercise of 60 minutes duration parted in 2-3 weekly sessions are offered during the first four months of intervention. The amount of supervision is reduced during the last six months of the intervention, in which the participants are encouraged to continue with the exercise themselves.

The aerobic exercise will be aimed to be performed at an intensity of > 60% of maximal oxygen consumption. The types of aerobic exercise are tailored to the specific worksite through a modified intervention mapping approach, including organisation, leaders and employees.

Reference group:
Receives 5 lectures concerning healthy living during the one year intervention period; none of the lectures will address physical activity.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cardiorespiratory fitness will be measured before the randomisation at baseline, after the 4 months intervention and after the 1 year intervention

Secondary outcome measures
1. Diurnal heart rate
2. Diurnal ambulatory blood pressure
3. Self-rated work productivity
4. RPE during work
5. Intensity and number of regions with self-rated musculoskeletal pain
6. High Sensitivity C-reactive protein (hsCRP)
7. High density lipoprotein (HDL)
9. Self-rated need for recovery
10. Participation in intervention

Measured before the randomisation at baseline, after 4 months intervention and after 1 year intervention

Overall study start date
01/08/2011

Completion date
01/08/2014

Eligibility

Key inclusion criteria
Companies:
1. Cleaning companies (> 50 employees)
2. Implementation of project activities during working hours

Participants:
1. Working > 20 hours/week
2. Age 18 65 years old
3. Signed informed consent

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120 participants

Key exclusion criteria
Exclusion from physical tests:
1. Cardiac insufficiency
2. Acute myocardial infarction or acute coronary syndrome within the last few years
3. Hypertension (> 160/> 100 mmHg)
4. Serious or chronic illness
5. Severe trauma
6. Frequent migraine
7. Pregnancy
8. Fever

Exclusion from diurnal measurements:
1. Allergic to band aid
2. Pregnancy
3. Fever

Date of first enrolment
01/08/2011

Date of final enrolment
01/08/2014

Locations

Countries of recruitment
Denmark

Study participating centre
Lersø Parkallé 105
Copenhagen
Denmark
2100

Sponsor information

Organisation
Danish Working Environment Research Fund (Denmark)

Sponsor details
Landskronagade 33
Copenhagen
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Sponsor type
Government

Website
http://www.arbejdstilsynet.dk

ROR
https://ror.org/05fm0gf36

Funder(s)

Funder type
Government

Funder Name
Danish Working Environment Research Fund (Denmark)

Funder Name
University of Copenhagen (Denmark)

Alternative Name(s)
university_of_copenhagen, Københavns Universitet - University of Copenhagen, University of Copenhagen (UCPH), Copenhagen University, Københavns Universitet – Københavns Universitet, University of Copenhagen (KU), Denmark, Københavns Universitet – University of Copenaghen (UCPH), koebenhavns_uni, Københavns Uni, University of Copenhagen, KU, UCPH

Funding Body Type
Government organisation

Funding Body Subtype

Universities (academic only)

Location
Denmark

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/08/2012		Yes	No
Other publications	of whether an aerobic exercise worksite intervention changes the level of inflammation biomarkers among cleaners.	01/02/2016	23/01/2019	Yes	No
Results article	results	01/03/2015	23/01/2019	Yes	No
Results article	results of an aerobic exercise intervention targeting cardiovascular health, evaluated for its long term side effects on musculoskeletal pain.	01/12/2018	23/01/2019	Yes	No
Results article	results of does aerobic exercise increase 24-Hour ambulatory blood pressure among workers with high occupational physical activity?	01/04/2017	23/01/2019	Yes	No
Results article	results of effects of 12 months aerobic exercise intervention on work ability, need for recovery, productivity and rating of exertion among cleaners.	01/02/2018	23/01/2019	Yes	No
Results article	results of is aerobic workload positively related to ambulatory blood pressure?	01/01/2016	23/01/2019	Yes	No
Results article	results of long term effects on risk factors for cardiovascular disease after 12-Months of aerobic exercise intervention.	11/08/2016	23/01/2019	Yes	No
Results article	results of the effect of an aerobic exercise intervention on cardiac autonomic regulation.	01/02/2017	23/01/2019	Yes	No