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Physical activity to prevent deterioration in cleaners

Submission date	Recruitment status	[_] Prospectively registered
04/04/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/02/2013	Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TKIF2006-018

Study information

Scientific Title
Preventing deterioration among cleaners

Acronym
FINALE 4

Study objectives
1. Physical coordination training reduces shoulder and neck pain in cleaners
2. Physical coordination training is more effective than cognitive behavioural training in reducing pain in the short term (months)
3. Cognitive behavioural training is more effective than physical coordination training in increasing physical activity in the long term (years)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Committees on Biomedical Research Ethics of the Capital Region of Denmark on the 13th May 2008 (ref: H-C-2007-0033).

Study design
Cluster randomised controlled intervention trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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
Shoulder and neck pain

Interventions
Participants are randomised in clusters related to their team at the workplace to receive one of the following for one year:

1. Physical coordination training:
Three weekly training sessions at the work place of 20 minutes duration is offered to the participants during the first three months of intervention. The training persists of physically hard exercises that demands high activation of stabilising muscles around the trunk and shoulder girdle. The amount of training sessions is slowly reduced during the subsequent three months

and during the last six months, there will only be one meeting every month, where the participants are introduced to new interesting types of physical activity.

2. Cognitive behavioural training:
Two monthly training sessions at the work place of two hours duration is offered to the participants during the first three months of intervention. The training persists of information and cognitive exercises regarding biological causes of pain, differentiation between pain and injury, and strategies for relaxation. The amount of training sessions is reduced to one every month during three months and then the duration of the sessions is reduced to one hour per session during the last six months. Here the participants' success with training cognitively and behaviourally is evaluated and the participants receive help to proceed.

3. Health check (control):
The reference group receives one health check during the whole one year intervention period of one-hour duration. The health check is given in order to give the participants a feeling of output for their participation in the tests and questionnaires. The health check includes pulmonary-function test and fitness test. The results are given to the participants but no instruction is given regarding treatment, unless it is ethically irresponsible.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Sick leave, obtained through participating companies annual registrations
2. Work ability, measured using the Work Ability Index Questionnaire (developed by the Finnish Institute of Occupational Health)

Both primary and secondary outcomes will be measured before the intervention (timepoint 1 [Oct/Nov 2008]), after the first intensive intervention period (timepoint 2 [Jan/Feb 2009]) and after the one-year intervention (timepoint 3 [Oct/Nov 2009]).

Secondary outcome measures
1. Musculoskeletal pain, measured using the Nordic Council of Ministers quiestionnaire on musculoskeletal complaints
2. Physical capacity (strength, coordination), measured as isometric maximal voluntary contraction in four exercises:
2.1. Trunk flexion
2.2. Trunk extension
2.3. Shoulder lift
2.4. Shoulder abduction
As a measure of postural sway on a force platform and as a measure of stability in a force steadiness exercise for the shoulder muscles
3. Kinesiophobia

Both primary and secondary outcomes will be measured before the intervention (timepoint 1 [Oct/Nov 2008]), after the first intensive intervention period (timepoint 2 [Jan/Feb 2009]) and after the one-year intervention (timepoint 3 [Oct/Nov 2009]).

Overall study start date
01/08/2007

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Cleaners at larger cleaning departments
2. Aged 18 - 65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Angina pectoris
2. Pregnancy
3. Life-threatening diseases

Date of first enrolment
01/08/2007

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Denmark

Study participating centre

Lersø Parkallé 105
Copenhagen Ø
Denmark
2100

Sponsor information

Organisation
The Ministry of Culture Committee on Sports Research (Denmark)

Sponsor details
H.C. Andersens Boulevard 2
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Sponsor type
Government

Website
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ROR
https://ror.org/04qdzjg14

Funder(s)

Funder type
Government

Funder Name
The Ministry of Culture Committee on Sports Research (Denmark) (ref: TKIF2006-018)

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	09/03/2010		Yes	No
Results article	results	14/06/2010		Yes	No
Results article	results	10/10/2011		Yes	No
Results article	results	22/02/2012		Yes	No