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Prevention of low back pain and its consequences among elderly care workers

Submission date
24/01/2013

Recruitment status
No longer recruiting

Registration date
21/02/2013

Overall study status
Completed

Last Edited
22/04/2015

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A high prevalence of work-related musculoskeletal disorders among elderly care workers has persisted over the years despite extensive efforts in primary prevention in Denmark. Thus, effective and feasible interventions for preventing low back pain (LBP) and reducing consequences of LBP remain to be found. Many single interventions have been carried out at workplaces to prevent and reduce LBP, but with a low success rate. This may be due to single interventions only addressing one aspect of the multi-factorial origin of LBP. Therefore, the main aim of this study is to examine whether a multifaceted worksite intervention among elderly care workers consisting of participatory ergonomics (applied science of equipment design, as for the workplace, intended to maximize productivity by reducing operator fatigue and discomfort.), physical exercise and cognitive behavioural training combined will prevent LBP and consequences of LBP such as pain-related influence on work and leisure activities and other long-term consequences of LBP (e.g. sickness absence and work ability).

Who can participate?
Both male and female elderly care workers will be invited to participate in the study if they are 18-65 years old. They may participate if they are currently working more than 20 hours a week. Elderly care workers with pain and elderly care workers without pain may participate.

What does the study involve?
The participants will be asked to answer questionnaires about work and health related factors as well as leisure time activities, perform a short health check, and participate in initiatives at their workplace consisting of participatory ergonomics, physical exercise and cognitive behavioural training. The participatory ergonomics will be carried out in small working groups in two workshops led by an ergonomist where they will discuss ergonomic problems and solutions. The working teams will participate in physical exercise one hour per week led by an instructor. The workers will also participate in two workshops consisting of cognitive behavioural training, where the main aim is to give tools to better cope with and to prevent pain. The participants will be divided into groups based on their working teams. Then they will be randomly assigned to one of four starting points 3 months apart, where they will begin the initiatives. Until they begin the initiatives, they will be considered a control group in order to better evaluate the results of the study. All participants will receive the same intervention initiatives.

What are the possible benefits and risks of participating?
The participants will gain knowledge about their own health and how to reduce the risk for LBP, prevent LBP and cope with LBP. Participation in the study involves no known risks.

Where is the study run from?
The study takes place in a municipality in Denmark, which is divided into nine geographical areas. In this study four of those areas will be participating. Each geographical area has between 1-5 nursing centers, giving a total of 13 participating centers. The nursing centers consist of approximately 53 working teams in total. The study is managed from The National Research Centre for the Working Environment in Copenhagen, Denmark.

When is the study starting and how long is it expected to run for?
The baseline testing began in November 2012 followed by a 3-month burn-in period. The intervention will begin in February 2013 and is anticipated to end in the spring of 2014. Recruiting of participants ended in November 2012. The participants will be involved in the initiatives at the worksite for the duration of approximately 18 months beginning in November 2012.

Who is funding the study?
The Danish Working Environment Research Fund.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
A multifaceted intervention to prevent low back pain and its consequences among elderly care workers: A stepped-wedge cluster randomized controlled trial

Study objectives

1. A 3-month multifaceted intervention among elderly care workers will reduce low back pain compared to a control group with no intervention.
2. A 3-month multifaceted intervention among elderly care workers pain-free at baseline will prevent low back pain compared to a control group with no intervention.
3. A 3-month multifaceted intervention among elderly care workers with pain at baseline will reduce consequences of low back pain compared to a control group with no intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committees on Biomedical Research Ethics of the Capital Region of Denmark, 10/10/2012, ref: H-4-2012-115

Primary study design
Interventional

Study design
Stepped-wedge cluster randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Elderly care workers with and without low back pain

Interventions
Baseline testing will begin 01/11-2012, Intervention will begin 18/02/2013

The multifaceted intervention will consist of:
1. Participatory ergonomics
2. Physical exercise
3. Cognitive behavioural training
The intervention is an integrated intervention targeting pain and is tailored to the specific worksite through a modified intervention mapping approach, with participation from the organisation, leaders and employees.

The intervention consists of group activities with one hour of physical training per week, 2 workshops of participatory ergonomics and 2 workshops of cognitive behavioural training. The intervention lasts three months. Local instructors will conduct the intervention after training from researchers in the intervention activities and will follow a written manual. The intervention is followed by a sustainability phase where the activities are reduced to a maintenance level and without project funded instruction.

Control group/period:
While a group is in a control arm no other intervention is received.

Intervention Type
Other

Phase

Not Applicable

Primary outcome(s)
1. LBP is measured by days with and intensity of pain each month throughout the data collection period.
2. Consequences of pain among elderly care workers with pain at baseline measured by days with bothersomeness due to LBP each month throughout the data collection period. Because LBP is a fluctuating condition, monthly monitoring will be conducted by using mobile phone text messages. In addition to the frequent measuring of LBP, bothersomeness due to LBP will also be measured monthly by text messages.

Key secondary outcome(s)
1. Sickness absence due to LBP measured each month (Self-reported)
2. Work ability measured each 3 months
3. Occupational lifting and carrying measured each 3 months
4. Self-rated physical exertion measured each 3 months
5. Support from management measured each 3 months

Completion date
15/06/2015

Eligibility

Key inclusion criteria
1. Male and female elderly care workers working more than 20 hours a week
2. Age 18 - 65 years old
3. Signed informed consent
4. Do not fulfill the exclusion criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unwilling to participate in the multifaceted intervention
2. Sick-listed (long-term)

Date of first enrolment
18/02/2013

Date of final enrolment
15/06/2015

Locations

Countries of recruitment
Denmark

Study participating centre
Lersø Parkalle 105
Copenhagen
Denmark
2100

Sponsor information

Organisation
Danish Working Environment Research Fund (Denmark)

ROR
https://ror.org/05fm0gf36

Funder(s)

Funder type
Research organisation

Funder Name
The Danish Working Environment Research Fund (Denmark)

Funder Name
The Prevention Fund (Denmark)

Results and Publications

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?
Results article	results	01/05/2014		Yes	No
Protocol article	protocol	21/11/2013		Yes	No