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Evaluation of the effectiveness of a multi-component intervention at the workplace for the prevention and management of musculoskeletal pain in nursing staff: design of a study where hospital units are randomly selected to receive the intervention or usual care of occupational health. The INTEVAL_Spain project.

Submission date
25/05/2018

Recruitment status
No longer recruiting

Registration date
13/07/2018

Overall study status
Completed

Last Edited
06/08/2024

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
Musculoskeletal pain (MSP) is the most common work-related health problem in Europe and Spain; in order to reduce sickness absence this is one of the greatest health challenges. Previous interventions have been developed to improve the return-to-work of employees with MSP, but combined approaches and exhaustive evaluation are required. The objective of INTEVAL_Spain project is to evaluate the effectiveness of a multi-component intervention at the workplace to prevent and manage MSP in workers.

Who can participate?
Adult nursing staff who work in the study units

What does the study involve?
Hospital units are randomly allocated to one of two arms. Those in the first arm receive an intervention for 1 year, which is made up of three components:
a) Identifying and improving the working conditions associated with the onset of MSP
b) Diagnosis, management and support for workers with MSP
c) Regular activities associated with health benefits

Those in the control group only receive usual care.
Participants take a series of questionnaires before the intervention, and at 6 and 12 months.

What are the possible benefits and risks of participating?
There are no direct benefits or risks for those taking part in the study.
Where is the study run from?
1. Parc de Salut Mar (Spain)
2. Corporació Santaria Parc Tauli (Spain)

When is the study starting and how long is it expected to run for?
November 2015 to June 2019

Who is funding the study?
Carlos III Health Institute (Instituto de Salud Carlos II) (Spain)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
FIS FEDER/ PI14/01959

Study information

Scientific Title
Evaluation of the effectiveness of a multi-component intervention at the workplace for the prevention and management of musculoskeletal pain in nursing staff: design of a cluster-randomized controlled trial. The INTEVAL_Spain project.

Acronym
INTEVAL_Spain

Study objectives
An innovative multicomponent intervention at the workplace that combines primary, secondary and tertiary prevention, and health promotion, will have a positive impact on musculoskeletal health in healthcare workers by reducing the frequency and duration of MSP and will be cost-effective for the company/hospital. Considering the prevalence of MSP in workers as a representative indicator of the impact on health, we estimate that this multicomponent intervention will reduce this outcome by 25%.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Clinical Research Ethical Committee of the Parc de Salut Mar (CEIC-Parc de Salut Mar), 14/07 /2014, ref: 2014/5714/1

Study design
Two-armed cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Work related-musculoskeletal pain and sickness absence

Interventions
The study is designed as a two-armed cluster randomized controlled trial, with a late intervention control group where clusters are independent hospital units, and participants are the nursing staff- workers exposed to musculoskeletal risks. This study is a randomized trial, in which the employees are randomized after signing informed consent together with formal information about the study. A total of eight clusters have been selected for the randomization. The condition of being included in the intervention or the control group cannot be blinded. All clusters are Hospital Units where nurses and aids are at risk of high physical demands due to the characteristics of the patients cared for in them (dependents and semi-collaborative patients). All data collected from both groups (intervention and control groups) is anonymized before the analyses. An independent researcher assigns the clusters to the intervention or to the control group by a simple randomization stratified by center, obtaining 4 clusters in each group.

The intervention is based on the available scientific evidence and consists of three components that encompass the three levels of prevention and health promotion:
a) participatory ergonomics, to identify and improve the working conditions associated with the onset of MSP in workers
b) case management, including early diagnosis and personalized management of workers with disabling MSP (secondary prevention) and the adaptation and facilitation of return to work after a sickness absence episode and/or workers' maintenance in their jobs (tertiary prevention)
c) health promotion, through activities scheduled during the second and third quarter until the end of the intervention, associated with evidence based health benefits (physical exercise, stress management, healthy eating and education on health beliefs).
The intervention group also receive care as usual, and the control group will receive only usual care of occupational health.

The intervention lasts one year, and data are collected at baseline, 6 and 12 months follow-up.

Intervention Type
Mixed

Primary outcome measure
1. Musculoskeletal self-perceived pain data are collected using the Spanish version of the Nordic Questionnaire, at baseline, 6 months and 12 months follow-up.
2. Sickness absence data are collected from one year before the intervention was implemented until the end of the intervention, and number of episodes and their duration is analyzed.

Secondary outcome measures
1. Work functioning is measured by the Work Role Functioning Questionnaire-Spanish Version at baseline, 6 and 12 months follow up.
2. Quality of life is measured by the European Questionnaire 5 Dimensions 3 Levels (EQ-5D-3L) at baseline, 6 and 12 months follow up.
3. Preventive culture is measured by the Institute for Work & Health Organizational Performance Metric (IWH-OPM), at baseline, 6 and 12 months follow up.

Overall study start date
01/11/2015

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. Nursing staff (nurses and aides) including employees in sickness absence who work in the study units/clusters
2. Voluntarily willing to participate in the study

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
From the sample calculations, 8 clusters of 20 to 60 participants each have agreed to participate.

Total final enrolment
473

Key exclusion criteria
1. Temporary staff who work at the study units only infrequently and/or for short periods
2. Employees on leave, except on sickness absence, during most of the study period

Date of first enrolment
01/05/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
Spain

Study participating centre
Parc de Salut Mar
Barcelona
Spain
08003

Study participating centre
Corporació Santaria Parc Taulí
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Sponsor information

Organisation
FUNDACIÓ IMIM

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Sponsor type
Research organisation

ROR
https://ror.org/042nkmz09

Funder(s)

Funder type
Government

Funder Name
Instituto de Salud Carlos III

Alternative Name(s)
SaludISCIII, InstitutodeSaludCarlosIII, Instituto de Salud Carlos III | Madrid, Spain, Carlos III Institute of Health, Institute of Health Carlos III, Carlos III Health Institute, ISCIII

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Funder Name
Prevent Foundation - Barcelona (Spain)

Results and Publications

Publication and dissemination plan
Planned publications in a high-impact peer reviewed journal during the period comprised from 01 /09/2018 to 01/03/2019.

Intention to publish date
01/03/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available. The study participants signed a form to give their informed consent to participate in the study. The objectives and scope of the study were specified in the form, informing that all the personal data as well as the information provided at all times would be anonymous and would only be used in the INTEVAL study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/03/2019	23/11/2020	Yes	No
Results article		18/11/2019	19/07/2021	Yes	No
Other publications	Process evaluation	06/10/2021	23/08/2023	Yes	No
Other publications	Cost effectiveness	05/08/2024	06/08/2024	Yes	No