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Preventive Occupational Health Intervention to promote Quality of life of nursing staff aged 45 years and older

Submission date
19/06/2015

Recruitment status
No longer recruiting

Registration date
08/07/2015

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Shortfalls in nursing numbers already exist throughout most European countries. Demographic changes in the structure of the population have profound consequences for work strain as well as for working conditions in health care. Working conditions have changed within the last years (e.g. increase of people in need for care, number of patients with multimorbidity (suffering from a number of health conditions), time pressure, and documentation obligations) leading to an worsening of work strain and work related stress. Prior research indicates that work ability of nurses decreases with age. Poor workability seems to be closely related to an intention to leave nursing. As a consequence to those changes according to the statistics by the German Federal Statistical Office there will be a real shortage of full time nursing staff within the next 10 years. Aggravating this situation, nursing causes a lot of psychological and physiological stresses. Many studies have shown that levels of psychological distress at work are high in healthcare workers. Health and pension insurance statistics indicate high sick leave rates among nurses due to mental health-related diagnoses. In order to cope with the mentioned problems there is a need to develop prevention programs that address the workforce of nursing staff aged 45 and older to enable them to remain healthy until retirement age. In the last decades the effectiveness of general preventive strategies of dealing with work related stress has been examined in a number of studies. Most of those strategies such as cognitive-behavioral or relaxation techniques focus on individual coping strategies. In addition organizational interventions (programs) focus on the development of the individual´s working environment. Our aim was to develop and to evaluate a complex prevention program that combined key elements of a SOC Training (Selection, Optimization, Compensation) with other components of occupational health interventions, guided by theory and evidence.

Who can participate?
Nurses who are at least 45 years old.

What does the study involve?
A small group treatment (a group consists of approximately 10 employees) is offered to eligible participants. All participants are randomly allocated to either a control (waiting Group) or an

intervention group. The training given to the intervention group includes 7 sessions, 2 hours a week for a period of 7 weeks. After a 6 weeks break there is another Booster-session. The control Group (waiting Group) receives the same treatment after a break of several weeks after the Booster-session of the intervention group. The training contains several components including relaxation techniques, life Review, working with age stereotypes, promotion of nurses' individual strategies to adapt and to cope actively with their working conditions based on the principles of "selection, optimization and compensation (SOC)".

What are the possible benefits and risks of participating?
All participants will be assessed by a professional team at the beginning of the study. Participants of both groups may benefit from the small Group intervention. By taking part in this study there are no risks of physical injury or harm.

Where is the study run from?
University Hospital of Heidelberg, the University of Duesseldorf and the University Hospital Ulm (Germany)

When is the study starting and how long is it expected to run for?
September 2013 to July 2015

Who is funding the study?
Ministry of Research, Science and Arts Baden-Württemberg (Germany)

Who is the main contact?
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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
Healthy Aging at work - Preventive Group Intervention to promote Quality of life of nursing staff aged 45 years and older

Study objectives
The aim of the study is to assess the efficacy of a Group intervention targeting well being and Quality of life in nursing staff aged 45 years and older. The primary hypothesis of the randomized controlled trial (RCT) is that compared to the control Group (waiting Group), the intervention group shows a better outcome regarding well being (WB) and health-related quality of life (HRQOL) at follow-up

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Heidelberg, Glockengießerei 11/1, 24/03/2014, ref: S-663 /2013

Study design
Randomized controlled two-armed multicentre trial in a waiting list control group design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Nursing provides a lot of psychological and physiological stresses that affect well being, health related Quality of life and workability of an aging workforce (nurses aged 45 years and older).

Interventions

A small group treatment (a group consists of approximately 10 employees) is offered to eligible participants. All participants are randomly allocated to either a control (waiting Group) or an intervention group.
1. Intervention group: The training given to the intervention group includes 7 sessions, 2 hours a week for a period of 7 weeks. After a 6 weeks break there is another Booster-session.
2. The control Group (waiting Group): receives the same treatment after a break of several weeks after the Booster-session of the intervention group. The training contains several components including relaxation techniques, life Review, working with age stereotypes, promotion of nurses' individual strategies to adapt and to cope actively with their working conditions based on the principles of "selection, optimization and compensation (SOC)".

Intervention Type
Behavioural

Primary outcome measure
1. Well being, measured by the WHO-5-questionnaire after the Booster session of the intervention
2. Health related Quality of life, measured by the WHO-QOL Bref after the Booster session

Secondary outcome measures
1. Depressive symptom severity measured by the PHQ-9 after the Booster session
2. Generalized anxiety symptom severity measured by the GAD-7 after the Booster session
3. Working conditions measured by the TAA questionnaire after the Booster session
4. Performance of Selection, Optimization, Compensation measured with SOC-questionnaires after the Booster session
5. Perceived emotional and cognitive strain measured by the Irritation scale after the Booster session
6. Workability measured by the WAI-Scale after the Booster session
7. Self efficacy at work measured by the BSW after the Booster session
8. Quality adjusted life year (QALYS) will be calculated to define the cost-effectiveness of the study

Overall study start date
01/09/2013

Completion date
31/07/2015

Eligibility

Key inclusion criteria
1. Nurses who were practicing their job
2. Aged 45 years or older
3. Not part of the management team
4. Knowledge of German
5. Given written approval

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
144

Key exclusion criteria
1. Occupational disability or to work over a longer period
2. Cognitive impairment
3. Serious physical or psychiatric illness.

Date of first enrolment
25/03/2014

Date of final enrolment
10/06/2014

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of Heidelberg
Department of General Internal Medicine and Psychosomatics
Heidelberg
Germany
-

Study participating centre
University of Duesseldorf
Institute for Occupational Medicine and Social Medicine
Duesseldorf
Germany
-

Study participating centre
University Hospital Ulm
Department of Psychosomatic Medicine and Psychotherapy
Ulm
Germany
-

Sponsor information

Organisation
Ministry of Research, Science and Arts Baden-Württemberg

Sponsor details
Königstraße 46
Stuttgart
Germany
70173

Sponsor type
Government

Website
https://mwk.baden-wuerttemberg.de/de/startseite/

ROR
https://ror.org/01hc18p32

Funder(s)

Funder type
Government

Funder Name
Ministry of Research, Science and Arts Baden-Württemberg (Germany)

Results and Publications

Publication and dissemination plan
Development of the Intervention and study protocol are published in the next months (09/2016). Main results (Quality of life) will be published at the end of 2016. Data on health economical efficiency (QALYS) will be published at the beginning of 2017. Secondary outcomes like use of SOC-strategies will be published in 2017.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/01/2018	22/01/2019	Yes	No
Dataset	Data with missing values	19/01/2018	18/08/2023	No	No
Dataset	Data with replaced missing values	19/01/2018	18/08/2023	No	No
Protocol (other)		19/01/2018	18/08/2023	No	No