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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
19/06/2015		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/07/2015	Completed	[X] Results		
Last Edited 18/08/2023	Condition category Mental and Behavioural Disorders	[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

Contact name

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Additional identifiers

Protocol serial number 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

Study type(s)

Quality of life

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(s)

- 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

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

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

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Study participating centre University of Duesseldorf

Institute for Occupational Medicine and Social Medicine Duesseldorf Germany

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Study participating centre University Hospital Ulm

Department of Psychosomatic Medicine and Psychotherapy Ulm

Germany

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Sponsor information

Organisation

Ministry of Research, Science and Arts Baden-Württemberg

ROR

https://ror.org/01hc18p32

Funder(s)

Funder type

Government

Funder Name

Results and Publications

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
<u>Dataset</u>	Data with replaced missing values	19/01/2018	18/08 /2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes
Protocol (other)		19/01/2018	18/08 /2023	No	No