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Preventing stress-related ill health among new registered nurses

Submission date
26/01/2017

Recruitment status
No longer recruiting

Registration date
31/01/2017

Overall study status
Completed

Last Edited
19/07/2018

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
In a nationally representative sample in Sweden, one in five new nurses had experienced high levels of stress-related ill health at some point during the first three years in the profession. There is evidence to suggest that this may be because many engage in behaviours that only deal with short-term stress rather than lowering overall stress levels, which would reduce stress in the long-run. Evidence of the effects of treatments for stress-related ill health is limited. Yet, analyses of stress-management programs have shown that person-directed programs that are developed based on the principles of cognitive behavior therapy (a type of talking therapy that helps people to change the way they think and behave) are effective for reducing stress-related ill health among experienced nurses. These programs typically support the development of behaviors that help people to better manage stressful situations and thereby reduce the experience of stress over time. This study aims to investigate the effect of a behavior change program which has been developed to prevent stress-related ill health among new registered nurses.

Who can participate?
Newly graduated nurses working within their first months of the professional career, and participating in a transition-to-practice program for new registered nurses.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group take part in the behaviour change program. This consists of three sessions, each lasting for three hours, in groups of 10-15 participants. The sessions are given every other week and are lead by a psychologist. The work in the program is based on a set of behavior change techniques that are used to prevent stress-related ill health among new registered nurses. The sessions include education, group discussions, individual exercises, and homework exercises. Those in the second group participate in activities of the transition-to-practice program as they had originally planned to do. This involves simulator skills training, lectures on specific subjects such as pain and how to manage the patient records. At the start of the study and then one and seven weeks after the programs have ended, participants in both groups complete a range of questionnaires to assess their stress and general wellbeing levels.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction of stress-related ill health. There are no notable risks associated with participating in this study.

Where is the study run from?
Akademiska sjukhuset (Sweden)

When is study starting and how long is it expected to run for?
February 2016 to August 2017

Who is funding the study?
AFA Insurance (Sweden)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A behavior change intervention for preventing stress-related ill health among new registered nurses: a randomized controlled trial

Study objectives
Participants in the intervention will report lower levels of stress at post-intervention as compared to controls.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala Etikprövningsnämnden Stockholm (Regional Ethical Review Board, Stockholm), 09/10/2014, ref: 2014/1531-31/5

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Stress-related ill health

Interventions

Participants are randomly assigned to one of the two conditions using simple randomization. In cases where there are more than one nurse from the same clinical ward participating in the study adjustments will be made so that the nurses will be evenly allocated to both the experimental and the control arm to ensure that the ward is not left short of staff on the days of the intervention.

Experimental arm: Participants take part in a group behaviour change intervention of 3x3hours lead by a licensed psychologist. The primary behaviour change techniques included in the intervention are systematic exposure, action planning, and reinforcing approach behaviour, with the aim of increasing engagement in proactive behaviours. All sessions include didactics, group discussions, individual assignments, and homework assignments. The total time of 9 hours for the intervention is implemented during a period of 4 weeks (session 1 – session 2 two weeks later – session 3 two more weeks later).

Control arm: While the experimental group participates in the sessions of the intervention at trial, the control group participates in activities as part of a transition-to-practice program for new registered nurses. The exact content of these activities will vary for different participants depending on the schedule of the transition-to-practice program, but the active time will be the same as for the experimental group. Examples of the control activities are simulator skills training, lectures on specific subjects such as pain and how to manage the patient records.

Participants in both groups are followed up 1 and 7 weeks post-intervention. However, between-groups comparisons will only be made at 1 week post-intervention as the subjects randomized to the control group will participate in the intervention starting two weeks following the last session of the subject randomized to the experimental group.

Intervention Type
Behavioural

Primary outcome measure
Stress and energy is measured using a self-report measurement with 12 items responded to on a 6 point Likert scale at baseline, 1 and 7 weeks post-intervention.

Secondary outcome measures
1. Role clarity is measured using a self-report measurement with three items responded to on a 5 point Likert scale at baseline, 1 and 7 weeks post-intervention
2. Task mastery is measured using a self-report measurement with two items responded to on a 5 point Likert scale at baseline, 1 and 7 weeks post-intervention
3. Social acceptance is measured using a self-report measurement with two items responded to on a 5 point Likert scale at baseline, 1 and 7 weeks post-intervention
4. Proactivity is measured using a self-report measurement with six items responded to on a 5 point Likert scale at baseline, 1 and 7 weeks post-intervention

Overall study start date
01/11/2013

Completion date
01/08/2017

Eligibility

Key inclusion criteria
1. Aged 18 years and over
2. Licensed nurse
3. Participant in transition-to-practice program for newly licenced nurses

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
Not newly registered nurse participating in the transition-to-practice program

Date of first enrolment
29/02/2016

Date of final enrolment
22/02/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Akademiska sjukhuset
Sjukhusvägen 10
Uppsala
Sweden
751 85

Sponsor information

Organisation
Karolinska Institutet

Sponsor details
Solnavägen 1
Solna
Sweden
17177

Sponsor type
University/education

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Industry

Funder Name
AFA Försäkring

Alternative Name(s)
AFA Insurance

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Sweden

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date