A randomised controlled trial complemented with biosignal diary data to evaluate a newly developed system for work-related stress management and prevention for older adults (mHealthINX)

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51412

Source
ToetsingOnline

Brief title
mHealthINX

Condition

- Other condition

Synonym
stress, wellbeing

Health condition

the research does not aim at a particular mental health disorder. We aim to study healthy individuals with varying degrees of work-related stress and then see if that stress has been

reduced through the intervention.

Research involving
Human

Sponsors and support

Primary sponsor: Stichting tanteLouise
Source(s) of monetary or material Support: EU - AAL Programme

Intervention

Keyword: aging workforce, Innovation, Stress reduction, Well-being

Outcome measures

Primary outcome

The primary outcome is self-reported stress, including cognitive, somatic and general stress. We will use items from the Copenhagen Psychosocial Questionnaire6 (COPSOQIII). For the assessment of pre-post interventions stress we will use the SmartPWA to measure pulse waves and electrocardiogram.

Secondary outcome

In addition, several secondary outcomes will be assessed, also derived from the COPSOQIII:

- Self-rated health

- Burnout symptoms

- Depressive symptoms

- Sleep quality

Because occupational well-being is contingent to psychosocial factors at work, we will also assess job demands and resources as well as work-person interface parameters. These assessments will help the system to improve the suggestions for interventions. Within the trial, this data could also unearth potential

mediating effects of these variables between the experimental group (control vs. intervention group) and the aforementioned health-related outcomes. For the assessment of job demands and resources and work-person interface we have used items from COPSOQIII and the Work Design Questionnaire7 (WDQ). Assessed variables are:

Job demands: Quantitative demands, emotional demands, physical demands, work pace, job insecurity, cognitive demands

Job resources: role clarity, support from supervisor, support from colleagues, sense of community at work, meaning of work, autonomy, task variety, possibilities for development, feedback from others.

Work-person interface: Work engagement, job satisfaction, work-life conflict, self-efficacy.

Finally, participants in the intervention group will fill out the System Usability Scale (SUS)8 and additional questions about technology acceptance, usability and user-experience regarding the mHealthINX system in order to receive additional information and feedback from their perspective.

Communication and user involvement will be assessed based on the log files of the mHealthINX system.

Study description

Background summary

There is an EU subsidy program within the framework of the AAL, whereby innovations in (elderly) care are stimulated. It concerns a collaboration between 9 parties in 3 different countries and runs from March 2020 to February 2023. TanteLouise is a partner in this project and is involved as an end user

with knowledge of the elderly, elderly care and the employees who work in it. Within the project, a prevention program is being developed for employees with the aim of better managing their (work) stress. This involves measuring, assessing and understanding one's own stress level. During the study, participants can use the interventions that are offered via a smartphone and VR glasses.
The project has completed a development phase; experiences have been gathered from end users in, among other things, surveys and workshops. This feedback has been processed into a final prototype, which is used in the study.

Study objective

We hypothesise that mHealthINX will help lower stress in 50+ workers, as assessed both through pulse wave analysis & electrocardiogram analysis (i.e. biosignals captured through the hand-held SmartPWA3 developed by AIT) and self-reported measures (i.e. questionnaires of somatic, cognitive and general stress).

Study design

In the period January to November 2022, research will be conducted among 128 participants, spread over the Netherlands and Switzerland. Research partners in the project are Medical University of Vienna (MUW) and Zurich University of Applied Sciences (ZHAW).
In the Netherlands, 64 participants are recruited from the population of employees of 50 years and older, who work for tanteLouise. Participants are asked to participate in the study for 12 weeks. As described in the study protocol, this group is divided into intervention and control groups by means of randomisation.
The participants in the intervention group are asked to use the 3 components of mHealthINX for 12 weeks:
- PWA (pulse wave analysis) > non-intrusive measure of heart rate variability
- App on smartphone > Developed within the project
- VR glasses > Software developed within the project
The stress level can be measured by using the PWA device, but also by answering questions in the app on the smartphone and filling the logbook function in the app.
The app then gives advice based on these results; for example, the advice to do a mindfulness exercise, play a relaxing game or view an image in the VR environment.
By using the system at various times during the week during the test period, the participant gets to know his/her own stress factors and moments, and at the same time the participant learns which interventions are effective for him/her.
Both the intervention group and the control group are asked to complete an online questionnaire 3 times, namely in weeks 0, 6 and 12. The questionnaires are described in detail in the study protocol and have been added as an

appendix.

Intervention

The participants in the intervention group are asked to use the 3 components of mHealthINX for 12 weeks:
- PWA (pulse wave analysis) > Measure heart rate and heart rate
- App on smartphone provided by the project > Developed within the project
- VR glasses > Software developed within the project
The stress level can be measured by using the PWA device, but also by answering questions in the app on the smartphone and filling the logbook function in the app.
The app then gives advice based on these results; for example, the advice to do a mindfulness exercise, play a relaxing game or view an image in the VR environment.

Study burden and risks

VR headsets can sometimes lead to headache or dizziness. Participants are debriefed of this potential risk in the informed consent and prompted to stop using the headset if headaches persist.
In addition, participants can become more aware of their own stress level (more/ less and whether or not related to work) than before participating in the study. There is a support system (manager, HR advisor and social advisor) available for employees if they need it.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

To be included in the study, participants need to i) be 50 years of age or older ii) currently holding a paid work for at least 24 hours per week (iii) have no record of repeated seizures or loss of balance, (iv) have enough language skills in German or Dutch to participate, v) give written and oral informed consent.

Exclusion criteria

Participants that i)are younger than 50 years ii) work less than 24 hours a week iii) have a record of repeated seizures or loss of balance iv) do not have enough language skills in German or Dutch to participate v) do not give written and oral consent

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2022
Enrollment:	64
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-04-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL79919.028.21