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Motion sensors in a health promotion programme for healthcare workers doing shift work

Submission date	Recruitment status	[ ] Prospectively registered
22/08/2018	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/07/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/07/2019	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Past clinical experiences and medical research have shown that health promotion programmes usually fail to last for a long period, or do not demonstrate promising effects. This can be particularly a problem in healthcare professionals, especially those who have to work on shifts. This study aims to look at if using body motion sensors in a health promotion programme will help attendees (healthcare professionals) to do more for their health.

Who can participate?
Adult healthcare professionals in the Tsaotun Psychiatric Centre in Taiwan, who do shift work

What does the study involve?
The participants will be randomly assigned to two groups - the intervention and control groups. The intervention group will receive an active motion sensor, whereas the control group will receive a disabled sensor. Both groups will be asked to wear the motion sensor for most of the day during the period of the study. All participants will be encouraged to attend to the 24-week health promotion programme.

What are the possible benefits and risks of participating?
We expect that all the participants in the study will benefit from attending to the health promotion programme. However, the benefit may be larger for the people in the intervention group, as they will have access to their exercise information. There are no known risks to participants taking part in this study.

Where is the study run from?
Tsaotun Psychiatric Centre (Taiwan)
All the activities in the health promotion programme will be held in a government-run mental hospital in central Taiwan and will take place at the time after regular work. All the study, including the body motion sensors will be funded by the research grant offered by the hospital, and there will be no additional cost for the participants.

When is the study starting and how long is it expected to run for?
October 2017 to March 2019

Who is funding the study?
Tsaotun Psychiatric Centre (Taiwan)

Who is the main contact?
Ms. Wang (Ya-Hui Wang)
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Contact information

Type(s)
Scientific

Contact name
Dr Yung-Jen Yang

Contact details
No 161, Yu-Ping Road, Tsao-Tun Township
Nan-Tou County
Taiwan
54249

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
107013

Study information

Scientific Title
The effectiveness of motion sensors in a health promotion programme for healthcare staff on shift work: a randomised controlled trial

Study objectives
Motion senors may improve the effectiveness of an existent health promotion programme.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Tsaotun Psychiatric Center, 02/04/2018, IRB number: 106055

Study design
Interventional single-centre assessor-blinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Community

Study type(s)
Treatment

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
Health behaviours of healthcare staff on shift work

Interventions
An independent research agent will use computer statistical software to generate random sequence numbers for allocating participants into the intervention and control groups. The generated number for each participant will be sealed in an opaque envelope and then delivered to the research team members for recruitment. Each participate will receive their number and motion sensor in the envelope. The motion sensors will be pre-set according to the group they belong to - for the intervention group, they will be active; for the control group, they will be disabled. Participants in both groups will be asked to wear the motion sensor for most of each day of the study period. Participants in both groups are asked to attend to a 24-week health programme, in which a weekly aerobic physical exercise training course will be instructed and assigned. In the programme, participants in both groups will be asked to record their daily health-related profiles in a health log. The research team will also provide health promotion information, including the ways to control body weight, healthy diets, tips for health behaviours.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
1. Attendance rate to the health promotion programme, assessed by tracking how many times participants attend the programme over the course of the 24 week programme
2. Completeness of daily personal health behaviour log, assessed using the total number of completed logs at the end of the 24 week programme

Secondary outcome measures

All secondary outcome measures will be assessed by 2 members of the research group who are blind to the assigned group of the participants and will be assessed at the baseline, after 12 weeks and after 24 weeks (end of the intervention):
1. Objective measurements including changes in the following:
1.1. Physical efficiency index (PEI), assessed by measuring heart rate after exercise according to the Harvard Step Test
1.2. Body mass index (BMI), assessed using personal bodymetrics (weight in kg divided by height in m, squared (kg/m^2))
1.3. Body fat, assessed using skinfold calipers at the biceps, triceps, subscapular and suprailiac areas
2. Subjective measurements, including the following:
2.1. Self-developed questionnaires measuring health behaviours
2.2. EuroQol-5D (EQ-5D)
2.3. General Self-Efficacy Scale (GSES)

Overall study start date
02/10/2017

Completion date
31/03/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Health care professionals
3. Shift work
4. Working in a mental hospital (Tsaotun Psychiatric Centre)

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Unable to participate in the health promotion programmes for any reason
2. Unable to wear motion sensors for most of a single day during the period of study

Date of first enrolment
01/09/2018

Date of final enrolment
14/09/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Tsaotun Psychiatric Centre
No 161, Yu-Ping Road, Tsao-Tun Township
Nan-Tou County
Taiwan
54249

Sponsor information

Organisation
Tsao-Tun Psychiatric Center, Ministry of Health and Welfare, Executive Yuan

Sponsor details
No. 161
Yu-Ping Road
Tsao-Tun Township
Nan-Tou County
Taiwan
54249

Sponsor type
Hospital/treatment centre

Website
http://www.ttpc.mohw.gov.tw

ROR
https://ror.org/024w0ge69

Funder(s)

Funder type
Government

Funder Name
Tsao-Tun Psychiatric Center, Ministry of Health and Welfare, Executive Yuan

Results and Publications

Publication and dissemination plan
We plan to present our results at an international health-related scientific conference. We also plan to publish our results in a high-impact peer-reviewed journal in 2020.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The 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