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Measuring stress among intensive care unit healthcare workers

Submission date
16/08/2022

Recruitment status
No longer recruiting

Registration date
28/09/2022

Overall study status
Completed

Last Edited
07/09/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Challenging situations in the intensive care units (ICU) due to a high number of medical complications and/or deaths alongside prolonged working hours can lead to excessive stress among healthcare workers in these units. This can easily lead to burnout of the ICU healthcare worker. Current research shows that a large proportion of ICU workers are affected by stress and burnout across the globe. However, almost all of these studies are based on some form of survey questionnaires. There is no study to date to our knowledge attempting to physically measure stress and its effects on the body of ICU healthcare workers. The aim of this study is to investigate the use of various markers related to external (or physical) load, internal (or physiological) load, and sleep in measuring stress among healthcare staff working in the ICU.

Who can participate?
NHS health care staff (doctors or nursing colleagues) working in the paediatric ICU for at least 2 months

What does the study involve?
The study involves monitoring physiological variables using wearable, lightweight, waterproof devices for a continuous period of 7 days with participants performing a cluster of ICU shift work in between this time period. Devices include a sleep recording wristwatch and an ECG (electrocardiogram: measuring electrical signals of the heart) recorder applied to the participant's chest wall. Data about their physical activity, heart rate changes, and sleep will be recorded for a continuous period of 7 days. The recording period will involve 2-3 day or night shifts working in the ICU. The participants will also be asked to complete a sleep diary daily and an online anonymised questionnaire about the ease of use of the devices at work and home environment. No follow-up of the participants is required.

What are the possible benefits and risks of participating?
Taking part in this study will not benefit the participant directly. The information collected will show whether the proposed markers for measuring stress and its effect on healthcare workers are good enough to be used for this purpose in an even bigger study. If proven successful, these

markers may be used routinely in the future to monitor stress and study the effects of interventions to reduce stress levels on an individual basis. The researchers do not expect any significant risks to the participants as a result of taking part in this study.

Where is the study run from?
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2021 to December 2024

Who is funding the study?
Paediatric Critical Care Society (UK)

Who is the main contact?
Dr Rohit Saxena, Rohit.saxena@gosh.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Rohit Saxena

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309034

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
21HL18, IRAS 309034, CPMS 53690

Study information

Scientific Title
Quantitative assessment of stress among intensive care unit workforce - a proof of concept study

Acronym
MESSI

Study objectives
Proposed metrics related to external (physical) load, internal (physiological) load and sleep are useful in quantifying stress among healthcare staff working in the intensive care setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not required as the study is on NHS staff.

Study design
Prospective non-randomized cohort proof of concept two-centre study

Primary study design
Observational

Secondary study design
Cohort study

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
Stress among healthcare workers in intensive care unit

Interventions
The study involves monitoring physiological variables (physical activity, heart rate variation and sleep parameters) using wearable, lightweight, waterproof devices for a continuous period of 7 days with participants performing a cluster of ICU shift work in between this time period. Devices include a sleep recording wristwatch and an ECG (electrocardiogram: measuring electrical signals of the heart) recorder applied to the participant's chest wall. Data about their physical activity, heart rate changes, and sleep will be recorded for a continuous period of 7 days. The recording period will involve 2-3 day or night shifts working in the ICU. The participants will also be asked to complete a sleep diary daily and an online anonymised questionnaire about

the ease of use of the devices at work and home environment. No follow-up of the participants is required.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
MotionWatch 8, Actiheart5

Primary outcome measure
Measured continuously over a period of 7 days using MotionWatch 8 and Actiheart5 devices:
1. Heart rate variability
2. Sleep parameters: sleep latency, sleep duration, sleep efficiency and wakefulness after sleep onset

These outcome measures will be monitored for a total of 7 days (at home and work environment) with participants performing a cluster of ICU shift work in between this time period.

Secondary outcome measures
Ease of use of the monitors measured using an anonymised online questionnaire at the end of the measurement period of 7 days

Overall study start date
01/02/2021

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. Informed consent to participate
2. Medical or nursing NHS healthcare staff working in the ICU for at least 2 months

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Known to have significant arrhythmia or on antiarrhythmic medications
2. Active pharmacological or psychological therapy for stress

Date of first enrolment
09/01/2023

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children
Great Ormond Street
London
United Kingdom
WC1N 3JH

Study participating centre
St Mary's Children Hospital
Praed Street
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
Great Ormond Street
London
England
United Kingdom

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research.governance@gosh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Other

Funder Name
Paediatric Critical Care Society, UK

Results and Publications

Publication and dissemination plan
Planned publication in a subject relevant peer reviewed journal

Intention to publish date
31/03/2025

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