

Measuring stress among intensive care unit healthcare workers

Submission date 16/08/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/09/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/09/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

309034

Protocol serial number

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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

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

ROR
<https://ror.org/03zydm450>

Funder(s)

Funder type
Other

Funder Name
Paediatric Critical Care Society, UK

Results and Publications

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

