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Working collaboratively with staff to develop initiatives to help mitigate fatigue risks during night shift work

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
28/02/2020

Overall study status
Completed

Last Edited
27/09/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Fatigue affects everyone's performance, with negative impacts on quality of care and patient and staff safety. Other industries have fatigue management cultures to manage night shift sleepiness, in contrast to the NHS where priority is given to getting through the emergency workload, often without breaks.
The researchers aim to co-design a fatigue risk management strategy with nurses, doctors and others in our acute setting that helps whole teams to manage night shift fatigue effectively, and test interventions using wearable technology used to monitor and manage fatigue in other safety-critical settings.

Who can participate?
All midwives, theatre nurses, healthcare assistants, anaesthetists, obstetricians and other staff working on the labour ward over the period of the study and covering the labour ward overnight, including doctors, nurses and midwives who have managerial or educational responsibility for rotas on the labour ward.

What does the study involve?
- Focus groups with a range of staff to gather experiences and ideas for ways to alleviate fatigue. Information about fatigue will be given so there is an educational element.
- Those volunteering to participate in work package 1 will be asked to wear an accelerometer for ~4 weeks, and fill-in a wellbeing questionnaire before and after the period and be interviewed about the experience at the end of WP1.
- Analysis of focus group ideas and other data will be used to plan new interventions for WP2 (e. g. possibly a sleep rota).
- In WP2 we will try out the 'new' interventions and again ask staff to wear an accelerometer for ~4 weeks. And fill-in a before and after wellbeing questionnaire and be interviewed at the end of WP2.
- For both WPs retrospective routine data for the clinical setting (e.g. staff absences, how busy the setting has been etc) will also be analysed.
- A co-development group comprised of a range of staff will meet between each WP to discuss

the findings from each element and discuss and agree interventions and the development of a bigger ‘strategy’ document.
- If necessary we will refine the intervention(s) and repeat the cycle in a 3rd WP

What are the possible benefits and risks of participating?
Some of the participants will be offered the opportunity to wear an activity monitor for a one month period, and to have their personal data sent to them on an app. This could be beneficial for them personally as it may help them understand their own personal activity and sleep patterns.
However there is a risk in that they may discover that they have a problem or sleep disorder,- if this is the case they will be referred in the ordinary way to the sleep physician.
There is the possibility that in discussing fatigue and previous experiences participants may become distressed or feel guilty or worried. The research team are all very experienced health professionals working within their own respective codes of conduct and will be vigilant for any such psychological or emotional distress. If any evidence of such distress is noticed the data collection will be stopped and the participant offered the opportunity to withdraw, if needed they will be referred to staff wellbeing services. If this happens within a focus group much care will be taken to handle the situation in a sensitive manner and not ‘single out’ the participant which may increase the distress.

Where is the study run from?
Freeman Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2019 to August 2020

Who is funding the study?
1. Health Foundation (UK)
2. National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
256060

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 42391, IRAS 256060

Study information

Scientific Title
Effective management of staff fatigue during the night shift

Study objectives
This study aims to identify, develop and implement interventions (for example possibly education and/ or sleep facilities) there is better ‘buy-in’ and a greater chance of the risks caused by fatigue on nightshift being mitigated

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 08/08/2019, NHS HRA (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH; no tel. provided; hra.approval@nhs.net), ref: 19/HRA/3321

Study design
Interventional non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Fatigue in health service staff

Interventions
The study will employ a mixed-methods approach underpinned by the principles of Realistic Evaluation methodology and Normalisation process theory. This methodology will help us identify, describe and understand what works, for whom, and under what circumstances in relation to interventions for fatigue management, and describe and understand issues related to the implementation of fatigue management interventions.

The study design will draw on the principles of action research in that it will be organised in up to three work packages (WPs) or 'cycles' of intervention implementation with reflection and refinement between each cycle. Data collection and analysis will be ongoing throughout. Action research is collaborative and iterative, developing interventions over time. Please note WP 3 is optional depending on if it is felt necessary as it may be that two WPs are sufficient to develop impactful and meaningful interventions and inform a fatigue management strategy.

In addition, although we cannot be sure at this stage what types of intervention (over and above the accelerometer use) may be decided upon by the 'co-design' and 'reflect and refine' groups we envisage they may include interventions such as:
• the provision of a safe quiet rest /sleeping space for staff
• bleep/phone free times for Doctors and Midwives
• visualisations of team break strategy perhaps via a notice board
• self-designed rest rota

The steps and stages of the project in which participants are involved are as follows:
Work package 1:
1. Up to 8 Focus groups (each involving up to 8 people) will be held with volunteers who are

members of the multi-disciplinary theatre and obstetric teams (Midwives, Doctors, Theatre Nurses, Operating Department Practitioners, Healthcare assistants etc). The focus groups will last up to 1.5 hours each. [Thus an individual research participant would be involved in one of these initial focus groups, i.e. 1 @1.5 hours]. These will be audio-recorded and observational notes taken by researchers.
2. Education for all staff groups about the impact of tiredness from night shift work.
3. Completion of the SF 36 Wellbeing questionnaire (~15 minutes)
4. Recruitment of a Co-design and Reflect and refine development group (no fixed number but we envisage around 10-15 people).
5. Up to 20 participants from the multi-disciplinary theatre and obstetric teams will then be recruited to take part in studying the first intervention cycle (these will be some of the same participants involved in the Focus groups)
6. The ~20 participants for WP 1 will complete the SF 36 Wellbeing questionnaire (~15 minutes) and use an accelerometer for ~4 weeks.
7. The ~20 participants for WP 1 will complete the SF 36 Wellbeing questionnaire for the second time post cycle 1 and be interviewed (~1 hour)
8. The Co-design development group will meet to discuss emerging findings and design an intervention(s) for cycle 2 (~1.5 hours). This meeting will be observed and recorded by researchers.

Work package 2:
9. Up to 20 participants from the multi-disciplinary theatre and obstetric teams will then be recruited to take part in the second intervention cycle (these may be some of the same participants involved in the Focus groups, WP 1 and the co-design group –or may be new participants)
10. New participants will complete the SF 36 Wellbeing questionnaire (~15 minutes)
11. All WP 2 participants will use an accelerometer for ~4 weeks and undertake the intervention (s) that have been implemented.
12. All WP 2 participants will complete the SF 36 Wellbeing questionnaire post cycle 2 and be interviewed (~1 hour)
13. The Reflect and refine development group (no fixed number but we envisage around 10-15 people) will meet (~1.5 hours) to discuss emerging findings and decide if WP 3 is necessary. This meeting will be observed and recorded by researchers.

Work package 3 (If deemed necessary)
If WP 3 is deemed necessary the group will reflect on and refine the intervention(s) for WP 3.
14. Up to 20 participants from the multi-disciplinary theatre and obstetric teams will then be recruited to take part in the third intervention cycle (these may be some of the same participants involved in the Focus groups, WPs 1&2 and the co-design and refine groups –or may be new participants)
15. New participants will complete the SF 36 Wellbeing questionnaire (~15 minutes)
16. All WP 3 participants will use an accelerometer for ~4 weeks and undertake the intervention (s) that have been refined and implemented.
17. All WP 3 participants will complete the SF 36 Wellbeing questionnaire post cycle 2 and be interviewed (~1 hour)
18. The Reflection and finalising group (no fixed number but we envisage around 10-15 people- may be same as previous group meetings) will meet (~1.5 hours) to discuss emerging findings and decide final fatigue strategy contents. This meeting will be observed and recorded by researchers.

Intervention Type
Behavioural

Primary outcome measure
Wellbeing will be measured using the SF36 questionnaire before and after FITBIT use

Secondary outcome measures
Fitbits will be worn for up to a month and data from them will be used as an outcome measure of fatigue Individual interviews with participants after they have worn the fit bits will also act as a form of outcome measure

Overall study start date
05/02/2019

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. All midwives, theatre nurses, healthcare assistants, anaesthetists, obstetricians and other staff working on the labour ward over the period of the study and covering the labour ward overnight
2. Doctors, nurses and midwives who have managerial or educational responsibility for rotas on the labour ward

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/2019

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Richardson Rd
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United Kingdom
NE3 3HD
+44 (0)1912825789
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Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
31/08/2021

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

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Funder report results		01/10/2020	27/09/2022	No	No