Research Protocol

Full title

Inter-shift need for recovery of Emergency Medicine Advanced Clinical Practitioners in the United Kingdom: a cross-sectional study.

Short title

The Advanced Clinical Practitioner Inter-shift Need for Recovery (ACP I-NFR) study

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Sponsor: Not applicable

Version: 3.0

Updated: 07/07/20

IRAS Number: N/A

Sponsor Number: N/A

Twitter: @ACP_INFRstudy

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

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Inter-shift need for recovery of Emergency Medicine Advanced Clinical Practitioners in the United Kingdom: a cross-sectional study

1. Introduction

1.1 Background

In the United Kingdom (UK), providing effective and safe emergency care has become increasingly difficult as patient demand increases and resources become more constrained (Royal College of Emergency Medicine (RCEM) 2018).

Advanced Clinical Practitioners (ACPs) have been employed in UK Emergency Medicine (EM) since 2006 as part of a blended workforce solution to the problems of increasing demand, inadequate medical staffing provision and as a way of keeping senior and experienced staff clinically focussed. ACPs are typically from a nursing or paramedicine background and have gained considerable clinical experience prior to starting the ACP role (Crouch & Brown 2018).

Emergency Departments (ED) provide emergency care to patients 24 hours a day for the entirety of the year. This regularly requires ACPs and other staff to work long and unsociable shifts for consecutive periods, which can result in fatigue.

It is recognised that fatigue in healthcare has multiple negative effects including a reduced productivity and an increased risk of human error (Dawson et al 2012). It may also impact safety, effectiveness and experience of care (Olds & Clarke 2010).

A validated scale has been developed in the Netherlands to assess how work demands affect intershift recovery. This “need for recovery” (NFR) score consists of an 11 item questionnaire with each question requiring a “yes or no” answer. The questionnaire can be completed

within a few minutes and results are summated to provide an NFR score of 0-100, with 100 representing the highest need for recovery and 0 representing the lowest need.

The NFR score has been validated in two large cross-sectional (over 80,000 participants) studies where mean values for the Dutch population have been generated and good levels of reliability have been observed (Cronbach α=0.82) (Jansen et al 2002, Van Veldhoven & Broersen 2003).

Additional smaller studies have demonstrated the NFR scores for a range of healthcare and non-healthcare related occupations (table 1) (Kompier 1988, Bridger et al 2010, Morguchi et al 2013, Sluiter et al 2003, Sluiter 1999).

Table 1: NFR score—International Comparisons by Occupation and compared to 'whole population' average of Dutch Validation Study (Jansen et al 2002).

Occupation	Bus drivers	Merchant Sailors	Nurses	**Whole Population**	Nurses	Paramedics	Miners
Country	NL	UK	BR	**NL**	NL	NL	IL
n	920	332	128	**12038**	922	53	80
NFRS	**27.2**	**36.4**	**36.4**	**38**	**39.4**	**43.6**	**55.2**

BR=Brazil; IL=Israel; NL=Netherlands; UK=United Kingdom; NFRS=Need for Recovery Scale

A large professional survey of UK Emergency Medicine (EM) medical staff NFR has recently been undertaken by the RCEM Trainee-led Emergency Research Network (TERN) who have kindly shared their study protocol. It is hoped that the TERN and the ACP-INFR study will provide insight into both the results and validity of the NFR score in a UK-based clinician groups.

This work builds upon previous work by investigating NFR with previously validated burnout inventories.

1.2 Feasibility

A local feasibility study was conducted in October 2019 (appendix 1). 91% of the local EM ACPs responded, providing an excellent response rate and indicating enthusiasm for the study. The overall NFR score within the local ACP group was 65, which is considerably higher than the previous international professions for comparison (appendix 1).

1.3 Rationale for current study

Fatigue and burnout represent a risk to both patients and healthcare professionals (Hooper & Reimels 2009, Al-Abdallah & Malak 2019). Comparison is needed between EM ACPs and other workers previously studied to identify the baseline NFR score and to identify factors which may mitigate risk of burnout.

1.4 Research question

There is a 2-part research question:

- What is the baseline NFR score for EM ACPs in the UK and which factors influence NFR?
- Can the NFR score predict risk of burnout in clinicians?

1.5 Patient and public involvement

The James Lind Alliance Priority Setting Partnership determined the wellbeing of staff as a top ten priority after extensive consultation with patients, carers and the public (Smith et al 2017). This demonstrates that the wellbeing of staff is a key priority and measures to reduce fatigue would be well received.

2. Study aims

- Conduct a national survey of EM ACPs to ascertain the baseline NFR score

- Identify whether any associations or differences between baseline NFR score exist with regard to reported selected variables (demographic, occupational and personal wellbeing, rota or organisational characteristics).

- Determine whether there is a reliable statistical association between the NFR score and the Copenhagen Burnout Inventory (CBI).

3. Study design

An electronic cross-sectional study using the NFR score.

3.1 Methodology

The methodology has been designed using the Checklist for Reporting Results of Internet E-surveys (CHERRIES).

A 56-item cross sectional survey has been developed for online data collection (appendix 2). This will seek to gather information on consent (1 item), demographic characteristics (8 items), NFR questionnaire (11 items), person characteristics (4 items), occupational characteristics (6 items) and wellbeing characteristics (7 items)

The second part of the survey (after the NFR score) will ask the 19 questions included in the Copenhagen Burnout Inventory (Kristensen et al 2005).

This professional survey should take no longer than 10-15 minutes and each study participant will be informed of this at the start. Questions will use binominal scales and multiple options.

3.2 Survey testing

The investigation team have previously conducted this survey in a single UK ED, as discussed in the background section (appendix 1). This initial work has been used to refine this protocol.

The questions were reviewed by an ED consultant, ACP consultant and lead emergency nurse practitioner.

3.3 Study outcome measures

i) **Primary outcome**

Baseline NFR score amongst UK EM ACPs

ii) **Secondary outcomes**

Determine any associations between NFR score and selected demographic, occupational and personal wellbeing, rota or organisational characteristics and geographical region variables. Determine if any statistical associations can be found between NFR score and CBI result.

4. Participant entry

EM ACPs will be invited to participate if they are currently working within the UK at the time of the survey.

4.1 Recruitment

Participation in the study is voluntary and consent will be given at the point of accessing the survey. UK sites which are known to utilise ED ACPs will be contacted to identify local "site leads" (who will be responsible for the local recruitment into the study). In advance of data collection, the site leads will provide details on their local service (including the number of ACP, so that an accurate response rate can be calculated).

4.2 Informed consent

Consent will be explicit prior to the completion of the survey. A participant information sheet will be provided at the start of the survey and they will be required to confirm that they have read and understand the information prior to commencing.

4.3 Inclusion criteria

Trainee and qualified ACPs working in UK EM (inclusive of all professional backgrounds, level of experience and practice).

4.4 Exclusion criteria

ACPs whose current main place of employment is outside of the ED or the UK.

4.5 Withdrawal

Participants can exit the survey online if they no longer wish to take part, however it will be clear in the introductory statement that questions already completed will be collected and data reviewed.

4.6 Administration

The survey will be administered via the online platform “Google Docs”. Individual pages will be produced for each hospital site so that response rates can be monitored and feedback to the site leads.

5. Adverse events

This is a low risk cross-sectional survey and there are no anticipated adverse events. The NFR questions used in the survey have been well validated in large populations. It is possible that questions relating to personal health and wellbeing and occupational burnout may trigger emotive responses in participants. If the study causes distress participants will be encouraged to discuss with site leads who will direct participants towards local resources to obtain support. National advice numbers and websites will also be provided.

6. Assessment and follow up

The anonymised results of the study will be widely disseminated in multiple formats including national and regional conferences, posters, podcast and a peer-reviewed journal article.

7. Statistics and data analysis

Statistical support will be sought in advance to inform the survey design and the selection of scales. Data analysis will be conducted by the research team with the support of a biostatistician.

Descriptive statistics will be analysed using Microsoft Excel. Further analysis will use IBM SPSS. The data will be ranked to identify to identify the positive and negative outliers.

7.1 Description of statistical methods

The overall baseline NFR score will be determined and will then be associated with the demographic, occupational and wellbeing characteristics using Kendall's tau-b, Jonckheere-Terpstra test and the Kruskal-Wallis test. In a similar manner, the Jonckheere-Terpstra test and Kendall's tau-b will be used to identify any correlation between NFR and CBI (and quantify that association).

7.2 The number of participants

The survey will be open for a period of one calendar month (anticipated September 2020). The number of participants will not be limited. Hospital "site leads" will be identified through professional network groups, social media publicity and targeted contact. They will be asked to voluntarily be asked to co-ordinate the data collection at their site and will be asked to provide accurate information regarding the number of ACPs working in the ED. This figure will be used to determine the overall response rate (aiming to be in excess of 80%).

7.3 Criteria for termination of the trial

The termination of the trial will be reached when the online survey has been open for one calendar month.

7.4 Procedure for accounting for missing, unused and spurious data

The online survey will require an answer to be recorded for all questions prior to submission of the form, therefore all submitted data will be complete.

7.5 Procedures for reporting any deviation(s) from the original statistical plan

Any requirement to deviate from the original statistical plan will be discussed with the research team and appropriately documented with full explanation and reasoning.

7.6 Inclusion analysis

All eligible participants submitting completed surveys will be included in the analysis.

8. Archiving

Anonymous data will be stored for 10 years and then destroyed.

9. Ethical and regulatory compliance

9.1 Ethics and HRA approval

This work will represent a professional survey and is therefore exempt from formal ethical approval. The work has been discussed with the local research and development team in advance of data collection to ensure no other ethical concerns were raised. A HRA assessment was completed and is shown in appendix 3.

9.2 Confidentiality

To comply with the Data Protection legislation all data must be collected and used fairly, stored safely and not disclosed to any unauthorised person (Pope & Mays, 2006, Green & Thorogood, 2018).

The Chief Investigator will preserve the confidentiality of participants taking part in the study and ensure the EU General Data Protection Regulation (GDPR) in conjunction with the UK Data Protection Act 2018, which sets out the statutory requirements for the processing of personal data is adhered to.

All investigators will comply with regards to the collection, storage, processing and disclosure of personal information in accordance with current regulations.

No personally identifiable information will be collected. Survey information will be stored on the secure electronic database used for data collection. There will be no paper copies. When data is exported from the electronic database it will be anonymised. If data is required to be transferred or sent this will be done using encrypted digital files or storage media. Only the CI, co-investigators and persons conducting the study will have access to information. The Sponsor will have access to the data on request.

9.3 Sponsor

Sponsor support is not required owing to the nature of the survey.

9.4 Funding

This study has received no external funding.

10. Study management

The day-to-day management of the study will be co-ordinated by the research team. The group will meet monthly either face to face or via teleconference.

11. Dissemination

On completion of the study the data will be analysed, tabulated and a final study report will be produced. No participants or specific departments will be identified in any report, presentation or publication. Regional variation will only be commented on if individual ED's cannot be identified from the presented data.

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Appendix 1 – Local feasibility study

Building healthier lives

NHS
University Hospitals Birmingham
NHS Foundation Trust

Fatigue in Emergency Medicine Advanced Clinical Practitioners: Examination of intershift recovery

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Jo Watts, ACP EM, UHB (HGS)

Background

In the United Kingdom (UK), providing effective and safe emergency care has become increasingly difficult as patient demand increases and resources become more constrained (Royal College of Emergency Medicine (RCEM) 2018).

Advanced Clinical Practitioners (ACPs) have been employed in UK Emergency Medicine (EM) since 2006 as part of a blended workforce solution to the problems of increasing demand, inadequate medical staffing provision and as a way of keeping senior and experienced staff clinically focussed. ACPs are typically from a nursing or Allied Health Professional (AHP) background and have gained considerable clinical experience prior to starting the ACP role.

Emergency Departments (ED) provide emergency care to patients 24 hours a day for the entirety of the year. This regularly requires ACPs and other staff to work long and unsociable shifts for consecutive periods, which can result in fatigue.

While numerous objective measures of fatigue exist, indirect measurement of fatigue using the Need For Recovery (NFR) score is an attractive alternative as it is relatively quick to perform and has previously been validated in large populations including healthcare workers (Jansen et al 2002, Van Veldhoven & Broersen 2003).

The NFR score consists of 11 questions and was originally developed in the Netherlands (NL) to assess how work demands affect intershift recovery. It has been suggested that the NFR between shifts is an early feature of (or potentially a discrete precursor to) occupational burnout.

This work sought to determine the baseline NFR score for a group of EM ACPs and to pilot the score for a larger national study.

Methodology

All local EM ACPs were invited to participate in an online anonymous survey which was open to responses for 7 days. The ACPs worked between two hospital sites, seeing the full spectrum of patient acuity and are deployed to different clinical areas at the discretion of the EM consultant on duty for that shift.

The primary outcome was the baseline NFR score. Secondary outcomes included self-assessment of current burnout and the perceived risk of future occupational burnout.

The survey consisted of the 11 questions of the NFR score which were then used to generate an overall percentage (0-100%, with 100% indicating the highest levels of fatigue). Participants were additionally asked to record current and perceived risk of occupational burnout by recording "yes", "no", or "prefer not to say"

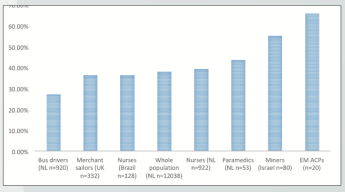
The results were compiled and analysed on Microsoft Excel.

Results

A total of 20 ACPs completed the survey, reflecting a response rate of 91% of the local team. This consisted of 15 trained and 5 trainee ACPs. The overall NFR score was 65.91%. This was only slightly different between qualified (65.45%) and trainee (67.27%) respondents.

One respondent (5%) indicated they felt they were currently suffering with occupational burnout with another two preferring not to say (10%). 35% (n=7) indicated they felt they were at high risk of future burnout at the time of the study. In this group, the NFR score was 77.92% compared to 58.56% in those who didn't feel they were at risk (n=11).

Table 1 – International comparison of EM ACP NFR score with other professions (additional data from Jansen et al 2002).



Discussion

It is recognised that fatigue in healthcare has multiple negative effects including reduced productivity and an increased risk of human error (Rosenberg 2014). It may also impact safety, effectiveness and experience of care (Rosenberg 2014). The NFR score has the potential to identify fatigue and act as an early indicator of occupational burnout. Burnout is characterised as a syndrome which may include symptoms such as a loss of job satisfaction, depersonalisation, emotional exhaustion and also been linked to worse health outcomes for sufferers (e.g. depression and suicide) (Arora et al 2013).

This is the first examination of the NFR in EM ACPs. It has demonstrated a substantially higher NFR in this group than in any of the other previously published studies (table 1). Although not powered to detect significant differences, there is also an increased NFR in those respondents who self-report a high risk of future burnout (77.92% vs 58.56%).

These findings should be used to inform a national baseline EM ACP NFR study, with a focus on identification of factors which are amenable to change and may reduce fatigue.

Conclusion

In this study, the NFR score of EM ACPs is higher than any other professional group previously included in the published literature.

Given the links between fatigue and occupational burnout, strategies to reduce the NFR (and therefore intershift recovery) should be examined further so that effective solutions can be identified and implemented proactively.

A national examination of the baseline NFR amongst EM ACPs is planned and will be informed by this work.

References

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Appendix 2 – Questionnaire

1. General Demographic Characteristics:

- Age
- Gender
- Professional background (Nurse/ paramedic/ physio)
- Years since professional qualification
- Contracted hours per week
- Agenda For Change banding
- Current role (trainee/ trained ACP)
- Years qualified (for trained ACPs)
- Are you currently registered with RCEM as a trainee ACP/ ACP?

2. Need for Recovery score questions (yes/no answers):

1. I find it difficult to relax at the end of the working day?
2. By the end of the working day I feel really worn-out?
3. Because of my job, at the end of the working day I feel rather exhausted?
4. After my breaks, I feel fresh to continue my work?
5. Generally speaking, I only start to feel relaxed on my second non-working day off?
6. I find it difficult to concentrate in my free time after work?
7. I find it hard to show interest in other people when I have just come home from work?
8. In general, it takes me over an hour to feel fully recuperated after work?
9. When I get home, I need to be left in peace for a while?
10. Often, after a day's work I feel so tired that I cannot get involved in other activities?
11. A feeling of tiredness prevents me from doing my work as well as I normally would during the last part of the working day?

3. Copenhagen Burnout Inventory questions (5 possible responses weighted at 100/75/50/25/0%):

Personal burnout

1. How often do you feel tired?
2. How often are you physically exhausted?
3. How often are you emotionally exhausted?
4. How often do you think "I can't take it anymore"?
5. How often do you feel worn out?
6. How often do you feel weak and susceptible to illness?

Work-related burnout

7. Do you feel worn out at the end of the day?
8. Are you exhausted in the morning at the thought of another day at work?
9. Do you feel that every working hour is tiring for you?
10. Do you have enough energy for friends and family during leisure time? (inverse scoring)
11. Is your work emotionally exhausting?
12. Does your work frustrate you?
13. Do you feel burnt out because of your work?

Patient related burnout

14. Do you find it hard to work with patients?
15. Does it drain your energy to work with patients?
16. Do you find it frustrating to work with patients?
17. Do you feel that you give more than you get back when you see patients?
18. Are you tired of working with patients?
19. Do you sometimes wonder how long you will be able to continue to work with patients?

Additional variable to be collected:

4. Person characteristics:

- Do you have caring responsibilities outside work?
- Number of dependents (under 18 years old)
- How long does it take you to travel to work? (length of commute)
- Do you find it easy to park before shifts?

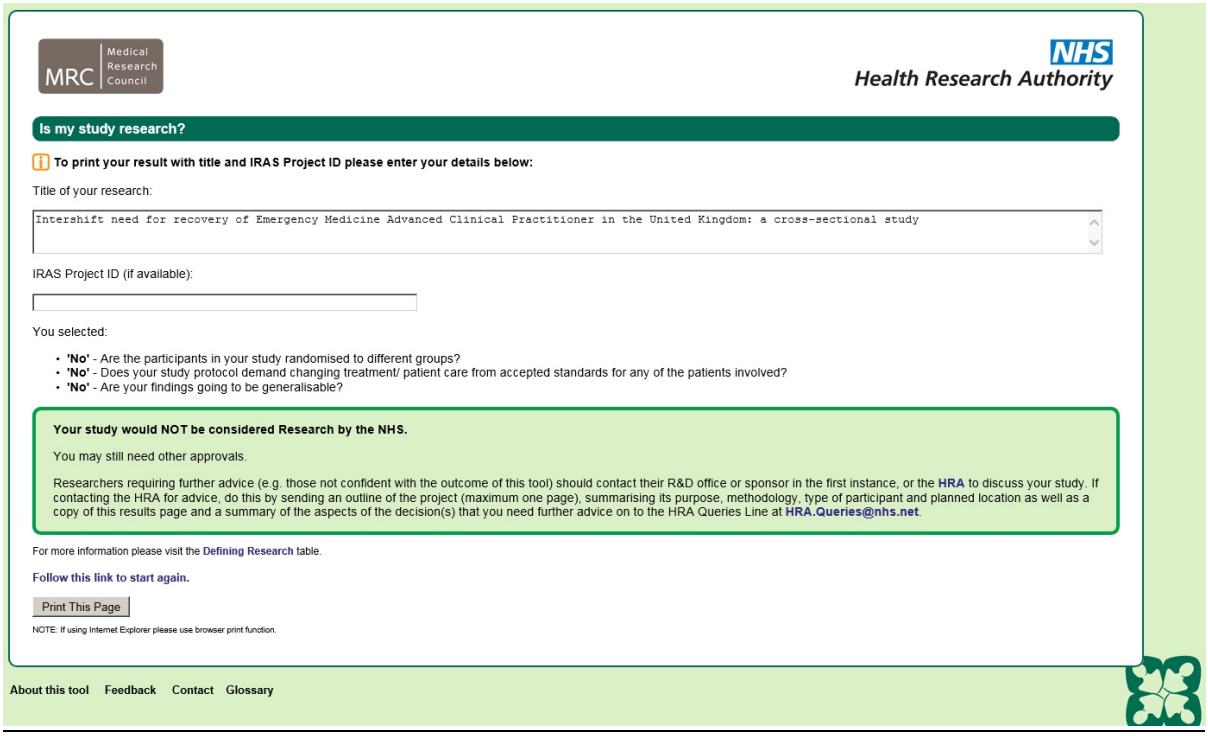
5. Occupational characteristics:

- What is your average clinical shift duration?
- How many nights do you work per month?
- Are you currently studying for an academic qualification?
- What is your clinical/non-clinical split?
- Do you have a designated lead ACP in your department?
- How many staff do you have direct managerial responsibility for?

6. Wellbeing characteristics

- Do you always finish your shift on time?
- Do you always get your breaks?
- Are breaks taken in a designated area?
- Do you have adequate access to senior clinical support when required?
- How often do you feel overwhelmed at work?
- Do you feel at risk of burnout in the future?
- Do you feel you are currently suffering with burnout?

Appendix 3 – Health Research Authority assessment (27/01/2020)



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Is my study research?

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Title of your research:

Intershift need for recovery of Emergency Medicine Advanced Clinical Practitioner in the United Kingdom: a cross-sectional study

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the **HRA** to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at **HRA.Queries@nhs.net**.

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