Study Title: Exploring the wellbeing of doctors: Surveys and individual interviews.

Exploring Wellbeing

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Amendment:

Investigators:	**Centre for Workforce Wellbeing**
Sponsor:	**University of Southampton**
Funder:	**External restricted funding from Health Education England**
Chief Investigators:	Dr Gemma Simons
Investigators:	Prof. David S Baldwin (Supervisor), Mrs Aimee O'Neill, Prof. Julia MA Sinclair (Supervisor).

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Contents

1. Amendment History

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
	0.1	23/05/2019		
	0.2	11/06/2019		Formatting AO/GS Input into design AO
	0.3	13/06/2019		Consideration of other recruitment sites
	0.4	26/06/2019		Response to first peer review comments. Research questions, hypotheses, objectives and endpoints numbered. More detail added tp Data collection in Section 6. More detail in Section 7.
	0.5	02/07/2019		Response to second peer review comments. UK specified in the background

2. Synopsis

Study Title	Exploring the wellbeing of doctors: surveys and individual interviews.
Study Design	Surveys and Individual Interviews
Study Participants	Foundation, core, speciality trainee doctors, speciality and associate specialists, consultants
Planned Sample Size	250
Planned Study Period	30 minute surveys face to face or online from the end of July to October 2019, 30 minute individual interviews September to November 2019.
Recruiting Centres	University Hospital Southampton Foundation Trust, and other local trusts Centre for Workforce Wellbeing, University of Southampton
Chief Investigator	Prof. David S Baldwin
Investigators	Dr Gemma Simons, Mrs Aimee O'Neill, Prof. Julia MA Sinclair
Primary Objectives	To define what format is acceptable for the measurement of wellbeing of doctors in the National Health Service. To understand break-taking behaviours of doctors in the National Health Service.
Secondary Objectives	To define how the wellbeing of doctors in the National Health Service should be measured. To define what measures of wellbeing in doctors in the National Health Service should be used for. To explore barriers to engaging in wellbeing measurement. To explore break behaviours. To explore barriers and incentives to doctors taking their breaks.
Primary Endpoints	A definition of what acceptable formats for measurement of wellbeing of doctors in the National Health Service are. An understanding of the improvements or interventions that might improve break behaviours.
Secondary Endpoints	A consensus on what measures should be used to for the wellbeing of doctors in the National Health Service. A consensus on what measures of the wellbeing of doctors in the National Health Service should be used for. Identification of themes of barriers to engagement in wellbeing measurement. Identification of themes of break behaviours. Identification of barriers and incentives to doctors taking their breaks.

3. Abbreviations

C4WW	**Centre for Workforce Wellbeing**
CRF	**Case Report Form**
NHS	**National Health Service**
PIS	**Participant Information Sheet**
UHSFT	**University Hospital Southampton Foundation Trust**
UOS	**University of Southampton**

4. Background and Rationale

Study overview

The importance of doctors' wellbeing is evidenced by 80% of doctors in the UK being at high risk of burnout [1] and a current 11,576 UK doctor vacancies [2]. Policy documents such as the Health Education England Mental Wellbeing Review [3] recommend intervention at a system, group and individual level across all grades of doctor to try and improve recruitment, retention and timely retirement. Many Trusts are keen to "do something", to improve on the 6% that said their Trust takes positive action on health and wellbeing, in the 2018 NHS Staff survey [4], and are spending money on interventions. Many are implementing group interventions, which are poorly evidenced and evaluated, and no widespread consensus has been achieved on which outcome measures should be utilised.

A survey conducted for the Health Education England Mental Wellbeing Review[3] suggested 60% of clinical staff had not taken a lunch break at least weekly in the past 6 weeks. Nationally, all Trusts have signed up to the BMA 2018 Fatigue and Facilities Charter (a good practice guide to improving facilities and rest opportunities), and further lobbying from the BMA secured an investment of £10 million from the Department of Health and Social Care to improve rest facilities across Trusts[5]. These investments show a clear need for research on doctors' break-taking behaviours, including the barriers preventing and incentives to encourage break-taking during shifts so that doctors are able to provide the high standards of care expected by patients.

Research questions

Wellbeing Measures

1. What can measures of wellbeing in doctors in the NHS be used for?

2. What measures of wellbeing in doctors should be used?

This questions encompasses the following components:

Who should do the measuring?

Objective measures: made by an independent, impartial third party, could be verified by another independent, impartial third party because they can be standardised.

Subjective measures: made by the individual themselves, unique to that individual and cannot be verified, or standardised, the answers can be ranked with numbers (strongly agree, agree etc, to make ordinal data).

How should they measure?

Qualitative measures: exploratory and descriptive, cannot be quantified, but can be categorised.

Quantitative measures: conclusive, numerical, and can therefore be counted. This can include yes no answers (nominal data), where "Yes" can be assigned 1 and "No" 2, and a frequency counted.

When should they measure?

Evaluative measures: ask a person what they thinks about their life in general, over an undefined time period

Experienced measures: ask a person how they feel now, they often specify a short time period of less than 2 weeks

3. What formats of measurement of wellbeing are acceptable to doctors?

4. What are the barriers to engagement with wellbeing measurement?

Breaks

5. What are break behaviours?

6. What are the barriers preventing and incentives encouraging break taking?

Study hypotheses

Wellbeing measures

1. Measures of wellbeing in doctors can be used for governance nationally and locally, research, for personal growth, and workforce planning.

2. A toolkit of wellbeing measures would be appropriate to measure wellbeing in doctors including evaluative, experienced, objective, subjective quantitative and qualitative measures. The same measures should be used across these domains.

3. Measures of wellbeing that are quick, easy to complete, available in multiple formats and acted on will be utilised more.

4. Barriers to engaging with wellbeing measurement will include time pressure, workload pressure, the perceived utility, the workplace culture, the location of the measurement and cost.

Breaks

5. Breaks will not be routinely taken by doctors due to workload pressures, the expectations of others, and will be interrupted by bleeps.

6. Breaks would be taken more with senior encouragement, good facilities, distractor activities and a lack of bleeps.

5. Objectives and Endpoints

Primary Objectives:

To define what format is acceptable for the measurement of wellbeing of doctors in the National Health Service.

To understand break-taking behaviours of doctors in the National Health Service.

Secondary Objectives:

To define how the wellbeing of doctors in the National Health Service should be used.

To define what measures of wellbeing in doctors in the National Health Service should be used for.

To explore barriers to engaging in wellbeing measurement.

To explore break behaviours.

To explore barriers and incentives to doctors taking their breaks.

Primary Endpoints:

A definition of what acceptable formats for measurement of wellbeing of doctors in the National Health Service are.

An understanding of the improvements or interventions that might improve break behaviours.

Secondary Endpoints:

A consensus on what measures should be used to measure the wellbeing of doctors in the National Health Service.

A consensus on what measures of the wellbeing of doctors in the National Health Service should be used for.

Identification of themes of barriers to engagement in wellbeing measurement.

Identification of themes in break behaviours.

Identification of barriers and incentives to doctors taking their breaks.

6. Study Design

Summary of Study Design

This study utilises the philosophy of 'constructivist epistemology'. Constructivism is a philosophy based on the concept that our knowledge is built from our experiences and social interactions. It differs from empiricism in that it does not assume that our knowledge gained from our experiences is generalisable and considers that our knowledge may not necessarily reflect the external reality. This philosophy does not require external reality to follow a rational structure that can be deduced by intuition and argument, as in rationalism. This is a pragmatic philosophy therefore in that it only agrees that something is "true" as long as it works in predicting the external reality. This philosophy allows for more than observable, empirical, measurable evidence as required in Positivism, to represent external reality. This study, therefore, aims to measure the wellbeing of doctors using an outcome measure construct, including both quantitative and qualitative methods, to explore the experience of doctors.

Questions for the survey and individual interview will be piloted with approximately 5 doctors to further refine the questions for clarity and content.

<u>Survey questions to add to the results of a Delphi Study</u>

To explore the views of all doctors on the above questions, this study will recruit doctors at all levels of training: Foundation, Core and Speciality Trainees, Speciality doctors and Associate specialists and Consultants attending induction at University Hospital Southampton Foundation Trust. Doctors will also be recruited at generic teaching events at other local trusts. This will ensure that doctors from all specialities and across all demographics will be included.

Doctors will be identified through their attendance at the University Hospital Southampton Foundation Trust induction, or at teaching at other local trusts, where they will be invited to take part in the survey and provided with a participant information sheet and consent form. If the number of doctors consenting to take part from induction and at other local trust teaching events is low, participants will be recruited through posters.

Only those who have given informed consent will be invited to complete the Case Report form, and the survey. The total time required for the survey is 30 minutes. If time is available in the induction this will be undertaken face to face using an app on their smartphone, a provided tablet, or paper, if not participants will be emailed a link to complete an online survey in their own time. For those participants who are recruited via posters and cannot therefore be given paper Participant Information Sheets and consent forms, the Participant Information Sheet will preface a consent tick box on the online survey for these participants.

Open questions will be asked initially in the survey to prevent any bias from the researchers impacting the output of the group. Participants will then be asked to use their smart

phones, if face to face, to access an online poll. Tablets will be provided to those who cannot use their mobile phone. In the event of electrical or technical failure paper forms will be given out. If participants complete the survey in their own time, a link will be emailed to them to an online survey.

Participants will be told not to speak to each other, or share their answers until they have answered each question. This will prevent the views of more dominant, prominent, or eminent, participants biasing the group.

Answers to the questions will be shown to the group in real-time, if the survey is completed face to face using an app, as frequencies and percentages. If the survey is completed in their own time, or in the event of electrical or technical failure, the answers to the questions will be summarised and emailed to those participants at a later time. Their responses will be confidential, but not anonymous if they want to verbalise a free text response face to face.

Participants who take part in the survey will be asked if they consent to being contacted to take part in subsequent rounds of the survey, or other surveys, or in individual interviews.

A Delphi study will have been undertaken before this survey to obtain a consensus opinion among experts on:

a) What measures of the wellbeing of doctors in the National Health Service should be used for.
b) What measures should be used to measure the wellbeing of doctors in the National Health Service.

The results of the questions in this study that repeat those in the expert Delphi Survey will be summarised and anonymised and utilitsed as part of the Delphi study, to inform subsequent rounds of the Delphi Study.

Individual Interviews

Doctors will be invited at the induction and teaching groups to provide their contact details to arrange an individual interview.

The interviews will be conducted at the Southampton General Hospital, University Hospital Southampton Foundation Trust.

Participants will be offered food or a £10 voucher.

The interviews will be conducted in a room in which only the participant and interviewer is present and the interview will be audio recorded, for later transcription.

The semi-structured questions that will be asked will follow the Interviewer Script.

Data Collection

The data collection will be the overall responsibility of the Chief Investigators at the Centre for Workforce Wellbeing (Professor Baldwin). Data collection may be delegated to investigators who have been appropriately trained. If live electronic surveys or paper surveys are utilised the collected data is automatically anonymised, as only participant identification numbers are captured. If electronic surveys are completed in the delegates own time IP addresses will be captured by the software, but will be removed from all study files by the researchers. Only participant numbers will be used on audio recordings of individual interviews and on transcripts. Any personal identifiers, such as participant names, the names of associates, or participants', or associates', roles/teams will be removed from transcripts.

7. Selection of participants

The population to be studied comprises of all grades of doctors, in all specialities and across all demographics. Doctors of all levels of training: Foundation, Core and Speciality Trainees, Speciality, Associate Specialists and Consultants will be invited to participate. Doctors will be invited to participate at the University Hospital Southampton Foundation Trust induction. Induction sessions will be run for all levels of training, which are mandatory and will therefore capture all grades of doctor. To capture doctors already working at the Trust, invitations to take part in the study will be given out at Trust teaching and through posters. The same will occur at other local trusts. To ensure that doctors across all demographics are represented in this study, special category data will be requested.

Doctors will be identified through their attendance at the University Hospital Southampton Foundation Trust mandatory inductions and teaching, at other local trust teaching, or through responses to posters.

Withdrawal of participants

Participants will be withdrawn from the study if:

- Consent is withdrawn. Participants may withdraw at any time for any reason.

However, data that has already been anonymised cannot be withdrawn from the study.

8. Selection of centre

The University Hospital Southampton Foundation Trust has been chosen for the mixture of specialities and demographics available at each Foundation, Core, Speciality and Consultant Induction, as well as the large number of doctors present. Other trusts in Southampton have smaller numbers of doctors available at their inductions and therefore invitations will be made at general teaching events there. The appropriate research infrastructure is present in the Centre for Workforce Wellbeing, University of Southampton.

9. Statistics and Data Analysis

Sample Size

The primary questions to address are: a) What format measurement of wellbeing should take to be acceptable to doctors in the National Health Service? And b) What are the barriers and incentives to doctors taking their breaks? The size of the group of doctors approached to answer these questions, will be displayed, as will the number who consented to take part in the survey and the number who answered each question. The size of the sample is not considered important in Delphi methodology[6, 7], or for individual interviews. A pragmatic approach has to be taken in considering the fact that not everyone invited will take part. Problems with recruitment will be minimised by inviting participants face to face, at a mandatory induction.

Analysis of Endpoints

For the four closed questions exploring wellbeing Delphi methodology will be utilised. A consensus will be considered established when 75% of participants vote for an option. This is based on the use of this percentage as an acceptable cut off, or higher than an acceptable cut off by a number of published studies looking to reach a consensus on outcome measurement for obesity [8], appendicitis in children [9], primary care [10] and multiple myeloma [11].

This study involves descriptive rather than inferential statistical analysis so sufficient statistics expertise is available within the research team, with the option of further statistical support being available within the department, or wider university, if necessary.

Quantitative data analysis plan

Survey

The number of participants invited to the survey and individual interviews and the number who completed them will be displayed.

The number that answered each question will be displayed as well as what percentage this was of those invited, or who consented.

Bar graphs demonstrating the answer options, such as the 9 point Likert scale on the horizontal axis and the percentage of participants that chose that score on the vertical axis will be displayed.

Where a 9 point Likert scale is used and 75% of participants have scored an outcome 1-3, this outcome will be considered of limited importance. Where an outcome is score 4-6 by 75% of participants, an outcome will be considered important, but not critical. When an outcome is scored 7-9 by 75% of participants it will be considered critical. This is in line with the statistical methodology of Delphi studies used to choose outcome measures [12-14].

Individual Interviews

Again the number invited to take part in individual interviews will be displayed, the number who consented and the number who answered each interview question will be displayed.

The frequency, fraction and percentage of doctors whose dialogue falls into themes identified by thematic analysis will be presented.

Qualitative data analysis plan

Answers to open questions to be summarised and presented.

Rationales for outlier scores will be summarised and presented.

Criteria for acceptable formats of wellbeing measures for doctors in the National Health Service will be listed.

Individual Interviews

Thematic and discourse analysis will allow answers to open questions to be summarised and presented.

10. Ethics

Quality control and assurance
The study will be conducted in accordance with the current revision of the Declaration of Helsinki. It will be carried out in accordance with Good Clinical Practice (GCP) as set down in ICH E6. Only the approved protocol and its amendments will be used.

Consent
All participants are expected to have the capacity to provide consent. All participants will be given a Participant Information Sheet.

Risks: There are no anticipated risks associated with the answering the survey questions.

The individual interviews may uncover health concerns, emotions, or work related issues that the individual may require further support for. The interviewers will be trained to sign post individuals to:

Their GP, for health concerns

The BMA peer support service for emotional, financial, contractual concerns

Their Trusts Welfare Officer for bullying and harassment.

Benefits: Food and drink will be offered or a £10 voucher. The study aims to improve understanding of measurement of doctors' wellbeing and their break behaviours in the National Health Service, in the hope that interventions can be adequately designed, analysed and evaluated and money only spent on those that seem likely to be effective and feasible in practice.

Participant Confidentiality
Surveys: The participants will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic files or publications. All question responses will be anonymized to maintain participant confidentiality.

Interviews: The face-to-face interviews will be audio recorded. Audio recordings will be labelled with a participant number and will be given to a typist who will type out what was said to produce a transcript. The typist will have signed an agreement to keep everything said in the interview strictly confidential. Any personal identifiers, such as participant names, the names of associates, or participants' roles/teams will be removed from transcripts. The transcript will only be identified through the participant number. The recordings will be password protected, and only accessible by the research team and transcriber. All consent forms, audio recordings and the decryption file will be stored securely in a locked filing cabinet, only accessible by the study investigators, in a limited access room in the restricted access Academic Centre. The investigators involved with this study will not disclose, or use for any purpose other than performance of the study, any

confidential information disclosed to them for the purpose of the study. Consent forms and decryption files will only be available to the Investigators.

Study Governance
As part of the University of Southampton Ethics and Research Governance process. Peer review by 2 external researchers is required and has been obtained.

Steering Committee:
The research activity of the Centre for Workforce Wellbeing is overseen by its Steering Committee, which meets every 6 months. The members of the committee are listed below:

- Prof. Jane Ball (Professorial Research Fellow Nursing Workforce, University of Southampton)
- Dr Nick Broughton (Chief Executive, Southern Health NHS Foundation Trust)
- Prof John Clark (Dean and Director of Education & Quality, HEE South)
- Dame Denise Coia (Chair of Healthcare Improvement Scotland)
- Prof. Clare Gerada (Medical Director Practitioner Health Programme)
- Prof. Peter Hockey (Professor of Clinical Education and Director of Western Sydney LHD Education Network, University of Sydney)
- Prof. Jill Maben (Professor in Nursing and Sociology Research, University of Surrey)
- Dr Ira Madan (Reader in Occupational Health, King's College London)
- Prof. Karen Morrison (Associate Dean for Education & Student Experience, and Director of Education, Faculty of Medicine, University of Southampton)
- Dr Paul Sadler (Postgraduate Dean, HEE Wessex)
- Prof. Rhema Vaithianathan (Professor of Economics and Co-Director of the Centre for Social Data Analytics, Auckland University of Technology)
- Prof. Karen Walker-Bone (Director of Arthritis Research UK/MRC Centre for Musculoskeletal Health, University of Southampton)

Inspection of Records - Investigators and institutions involved in the study will permit study related monitoring and audit on behalf of the sponsor, Ethics Committee review, and regulatory inspection(s). In the event of an audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

Investigator Responsibilities - The Chief Investigator will be responsible for the overall conduct of the study and compliance with the protocol and any protocol amendments, in accordance with the principles of ICH GCP. Responsibilities may be delegated to an appropriate member of investigator team. The Chief Investigator will be responsible for ensuring that the approved consent procedures are followed before any protocol specific procedures are carried out, and for ensuring that all delegated investigators are familiar

with the protocol, the study requirements, and their study related duties, as well the quality of the

data. Prior to beginning the study, each Investigator will be asked to provide the following: Curriculum vitae (CV) signed and dated by the Investigator indicating that it is accurate and current, and evidence of current GCP training.

11. Governance, data handling and record keeping

This is an investigator initiated and led study.

It is sponsored by the University of Southampton.

The Centre for Workforce Wellbeing Steering Committee will provide oversight to the research activities of investigators. Amendments to the protocol will be submitted to ERGO, the University of Southampton ethics and research governance online system prior to participants being enrolled into an amended protocol.

The participants will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic file. The decryption key files and audio recordings will be kept separately in a locked filing cabinet, in a security accessed room, in the security accessed Academic Centre.

All anonymised electronic data will be stored on the secure University of Southampton network and require password input for access. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so.

Confidentiality*:*
All question responses and reports will be identified in a manner designed to maintain participant confidentiality. All consent forms and the decryption file will be stored securely in a locked filing cabinet, in a limited access room in the limited access Academic Centre. The Investigators involved with this study will not disclose, or use for any purpose other than performance of the study, any confidential information disclosed to those individuals for the purpose of the study. To ensure that doctors across all demographics are represented in this study, special category data will be requested. Consent forms and decryption files will only be available to the Investigators.

Data Protection
All electronic data will be stored on the secure University of Southampton network and require password input for access. The study will comply with the Data Protection Act, which requires data to be anonymised as soon as it is practical to do so. The participants' survey answers and transcripts will be identified by a study specific participant number. Their name and any other identifying detail will NOT be included in any study data electronic file and audio recording files will be password protected. A validated data entry system will be utilised in this study and has a standard operating procedure. The database will have an audit trail.

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have

agreed to take part in research. This means that when a participant agrees to take part in a research study, we will use information about them in the ways needed, and for the

purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses personal data when a person takes part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which a participant can be identified directly, it will not be disclosed to anyone else without their consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that they are responsible for looking after participant information and using it properly. The University of Southampton will keep identifiable information for 15 years after the study has finished after which time any link between the person and their information will be removed.

To safeguard participant rights, we will use the minimum personal data necessary to achieve our research study objectives. Participant data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with personal data that would not be reasonably expected.

Study Record Retention

All study documentation will be kept for a minimum of 15 years.

12. Financing and Insurance

Restricted grant award from Health Education England.

University of Southampton is the sponsor for the study.

13. Publication Policy

A report containing the results of this study will be written, presented at scientific meetings and possibly published in a scientific journal. The Standards for Reporting Qualitative Research (SRQR) [15] will be used.

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