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Mindfulness and response in NHS staff engagers

Submission date	**Recruitment status**	[X] Prospectively registered
17/08/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/09/2023	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Stress in healthcare is at record levels as employees struggle with burnout and poor mental health and well-being. Healthcare staff were already one of the most stressed workforces in the UK. Then the COVID-19 pandemic happened. According to recent polls, at least a quarter of staff are considering leaving their jobs. For those who remain, compassion fatigue may be a growing problem. Thus, there is an urgent need to support healthcare staff with stress and related issues:
1. To protect and retain our most important healthcare assets
2. To avoid a significant toll on patients

Mindfulness could offer one vital means of support. Mindfulness refers to the awareness that comes from paying attention on purpose to thoughts and feelings in the present moment, without judgement. The benefits of mindfulness are well established and include improvements in stress, mental health, wellbeing, and compassion. Training is available in a variety of formats, such as groups, books, and apps. Furthermore, national policies advocate its use and development to improve well-being in the workplace.

This study aims to clarify several areas of uncertainty in the greater mindfulness literature that should help to optimise mindfulness in healthcare:
1. To determine how much healthcare staff with some prior engagement with mindfulness currently engage with mindful practices, formally and informally, and whether the dose is predictive of outcomes at baseline and over time
2. To test factors of engagement, including facilitators and barriers, thought to be important for practice/ implementation
3. To better understand staff attitudes to groups and the role of social identification with mindfulness in relation to psychological engagement and outcomes
4. To empirically validate a new measure of work-related burnout in healthcare staff

Who can participate?
Healthcare staff who are currently practising or have previously practised mindfulness at any level of experience

What does the study involve?
This study will test relationships between practice dose and outcomes, and potential influencing factors, over time. 2000 healthcare staff with mindfulness experience will complete three online

questionnaires at three-month internals for six months. A new measurement tool for workplace burnout will be included, to aid future research. Additionally, 12-20 participants will be invited to remote interviews on the unexplored topic of social identification with mindfulness in healthcare. Research in these areas is crucial:
1. To better understand staff engagement with mindfulness
2. So employers may successfully enact policy recommendations nationwide

What are the possible benefits and risks of taking part?
Participants will be contributing to active research in an understudied area, thus helping to answer many important unanswered questions. This could lead to future recommendations that influence policy and further help to support NHS colleagues. It is anticipated that some participants will feel positive about this contribution. In addition, participants will have the opportunity to be entered into a prize draw where completion of all three questionnaires can win a £50 Amazon gift voucher.
The risk of adverse events in this study is very low. Healthcare staff who meet inclusion criteria will either already be practising or have stopped practising mindfulness of their own choice. Nonetheless, mindfulness isn't easy and can lead to frustration or boredom. There are also some potential risks associated with mindfulness. For example, it is feasible that centring attention on painful experiences could be distressing or emotionally taxing.

Where is the study run from?
The University of Sussex is sponsoring this study (United Kingdom)
The host Trust is Sussex Partnership NHS Foundation Trust (United Kingdom)
The study is projected to include numerous other NHS care providers across England (United Kingdom)

When is the study starting and how long is it expected to run?
November 2021 to September 2023

Who is funding this study?
Doctoral research award, awarded jointly by
1. Economic and Social Research Council (ESRC) (United Kingdom)
2. South-East Network for Social Sciences (SeNSS) (United Kingdom)
3. Sussex Partnership NHS Foundation Trust (SPFT) (United Kingdom)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
313225

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

IRAS 313225, CPMS 53303

Study information

Scientific Title
A longitudinal mixed-methods study of MINDfulness And Response In Staff Engagers (NHS)

Acronym
MIndArise

Study objectives
This study aims to clarify several areas of uncertainty in the greater mindfulness literature that should help to optimise mindfulness in healthcare:
1. To determine how much healthcare staff with some prior engagement with mindfulness currently engage with mindful practices, formally and informally, and whether dose is predictive of outcomes at baseline and over time
2. To test factors of engagement, including facilitators and barriers, thought to be important for practice/ implementation
3. To better understand staff attitudes to groups and the role of social identification with mindfulness in relation to psychological engagement and outcomes
4. To empirically validate a new measure of work-related burnout in healthcare staff

Objective 1:
To test for a dose-response between self-reported formal and informal mindfulness practice and primary and secondary outcomes.
H1a: Higher self-reported formal practice and informal practice will be associated with lower stress (primary outcome) at baseline and greater improvements in stress over time. Improvements will also be seen in secondary outcomes (burnout, mental health [anxiety & depression], well-being, and compassion for self and others).
H1b: Higher self-reported formal practice and informal practice will be associated with higher mindfulness (primary mechanism), which will mediate the relationship between engagement and improvements in primary and secondary outcomes.
E1a (Exploratory analysis of potential influence of healthcare role; no hypothesis)
E1b (Exploratory analysis of potential influence of demographic factors; no hypothesis)

Objective 2:
To test factors of engagement thought to be important for engagement with, and implementation of, mindfulness in relation to outcomes.
H2a: The relationship between current mindfulness practice (formal and informal) and stress will be moderated by internal facilitators (readiness for change and motivation for mindfulness).
H2b: The relationship between current mindfulness practice (formal and informal) and stress will be moderated by internal barriers (stigma in mental health and burnout).
E2 (Exploratory analysis of additional facilitators and barriers using categorical variables from bespoke mindfulness questions; no hypothesis)

Objective 3:
To qualitatively explore social identification with mindfulness and psychological engagement, in healthcare staff in different roles and at different levels of seniority; and to test whether social identification explains variance in stress and other outcomes over and above that of mindfulness.
H3: Social identification with mindfulness will explain some of the variation in stress and secondary outcomes over and above mindfulness and will mediate the relationship between

practice dose and outcomes.
E3 (Exploratory thematic analysis of social identification with mindfulness; no hypothesis)

Objective 4:
To test the psychometric properties of the Sussex Burnout Scale, including factorial validity, concurrent validity, predictive validity, test-retest reliability, and internal consistency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is an observational study of healthcare professionals, which does not require ethical approval under the United Kingdom's law. The study was submitted to the Health Research Authority for the NHS governance review assessment portion of HRA Approval.

Study design
Multi-centre prospective longitudinal observational mixed-methods study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Internet/virtual

Study type(s)
Treatment

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 in healthcare staff

Interventions
This study is observational in nature and therefore does not include an intervention. However, the focus will be on the mindfulness practice of healthcare staff.

There is an urgent need to support healthcare staff with their stress, burnout, mental health (anxiety & depression) and wellbeing. While mindfulness is widely recommended as part of the solution, researchers and employers are in the precarious position of not knowing what exactly to recommend to potential practitioners. It is unclear how much healthcare staff with experience in mindfulness currently practice, whether more practice is actually better, what might help or hinder practice, or whether there is a role for social identification with mindfulness regarding engagement and outcomes; social identification, according to Tajfel's Social Identity Theory, is "the positive emotional valuation of the relationship between self and in-group".

To test the questions raised, 2000 healthcare staff will be recruited from a range of healthcare providers to engage in three questionnaires hosted on the online platform, Qualtrics (at baseline, 3 months, 6 months). Optional online interviews will also be conducted via Zoom for 12-20 consenting participants. The study will be advertised through a variety of means including email distribution lists, posters/leaflets, local intranet and social media. Quantitative data will be analysed using a range of statistical techniques will be used including multiple regression, multilevel modelling, structural equation modelling, hierarchical linear regression and mediation analysis (to be presented in subsequent papers). These analyses will help to test for significant effects and correlations among the variables and to see how much of the variation each variable accounts for. Further tests will be conducted on the validity and reliability of a new measure of burnout, i.e. the SBS, to find out if this new measure works as well as other measures with healthcare staff. Qualitative data will also be investigated using thematic analysis.

Intervention Type
Other

Primary outcome measure
Stress in healthcare staff measured using the Perceived Stress Scale at baseline, 3 months and 6 months

Secondary outcome measures
The following secondary outcome measures will be measured at baseline, 3 months and 6 months:
1. Mindfulness measured using the Five-Facet Mindfulness Questionnaire (FFMQ-15)
2. Burnout measured using the Copenhagen Burnout Inventory (CBI [work burnout subscale])
3. Mental health measured using the Patient health questionnaire for depression and anxiety (PHQ-4)
4. Wellbeing measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWS)
5. Compassion for self and others measured using the Brief Sussex-Oxford Compassion Scales (for self [Brief SOCS-S] & others [Brief SOCS-O])

The following will also be measured for validation purposes at baseline:
6. Burnout measured using the Maslach Burnout Inventory (MBI) * First 100 participants to complete psychometric validation of the Sussex Burnout Scale only

7. The object for validation: Sussex Burnout Scale (SBS; Strauss & Cavanagh, n.d.) will be measured at all time-points

Overall study start date
12/11/2021

Completion date
28/09/2023

Eligibility

Key inclusion criteria
1. Currently practising or previously practised mindfulness, either formally or informally, at any level of experience
2. Aged 18 years old and over

3. Healthcare staff, e.g., nurse, nursing assistant, doctor, pharmacist, manager, social worker, psychologist, occupational therapist, porter, administrator, medical/nursing students, or non-patient-facing role. (These are just examples. We accept all healthcare roles, including people working in a voluntary capacity)
4. Currently employed by an NHS Trust or Primary Care Service in England (full-time, part-time or voluntary)
5. Not currently on long-term sickness absence (i.e., 4+ weeks of sickness)
6. Sufficiently able to read and understand questions written in English to be able to answer these questions
7. Have access to email and a computer or suitable electronic device (this includes personal devices/computers). Alternatively, will be willing to request paper copies of documentation by phone.

Participant type(s)
Health professional

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Total final enrolment
2210

Key exclusion criteria
1. Never practised mindfulness
2. Ages 17 years old and under
3. Not a member of healthcare staff
4. Currently not employed at one of the participating NHS workplaces
5. Currently off work with sickness absence (i.e., 4+ weeks of sickness)
6. Unable to read and understand questions written in English to be able to answer these questions
7. Either no access to a computer or suitable electronic device (this includes personal devices /computers) or unwilling to request paper copies of documentation by phone

Date of first enrolment
01/09/2022

Date of final enrolment
28/02/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Sussex Partnership NHS Foundation Trust
Trust Hq
Swandean
Arundel Road
Worthing
United Kingdom
BN13 3EP

Study participating centre
50+ sites across England (individual sites to be determined)
United Kingdom
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Sponsor information

Organisation
University of Sussex

Sponsor details
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Sponsor type
University/education

Website
https://www.sussex.ac.uk/

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Government

Funder Name
Economic and Social Research Council

Alternative Name(s)
ESRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
South East Network for Social Sciences

Funder Name
Sussex Partnership NHS Foundation Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan

1. Planned publication in a high-impact peer-reviewed publication
2. PhD thesis
3. Conference presentations
Intellectual property rights will be held by the University of Sussex

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. Specifically, de-identified data from this study will be retained for 10 years on password-protected cloud-based servers, for access by the current research team or other research teams in the future. These data will also be retained in a repository at the University of Sussex. Raw data will be available by request, conditional on participant consent. A one-year embargo will also apply from the study end date, during which time researchers will need to submit a proposal to use the anonymised data.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	V1.5 is the version that predates the study, with the old sample size of 1500 version 1.5	27/07/2022	13/06/2023	No	No
Protocol file	V2.0 is the updated version with the amended sample size of 2000 version 2.0	30/11/2022	13/06/2023	No	No