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Investigation of wellbeing interventions in NHS staff

Submission date
13/02/2017

Recruitment status
No longer recruiting

Registration date
17/02/2017

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Stress, anxiety and depression are significant causes of sickness absence among NHS employees, and contribute to the NHS having higher rates of sickness absence than any other public sector organisation in the UK. The effects of mental distress not only impacts healthcare workers as individuals, but can also have negative consequences for their patients via a compromised quality of care. Mindfulness is a technique which involves a specific way of paying attention, non-judgmentally, to the present moment. The development of mindfulness skills can lead to a number of therapeutic benefits including increased compassion for oneself and others, and reductions in negative emotional states. Recent studies have shown that traditionally delivered, face-to-face mindfulness-based treatments among NHS employees, and mindfulness-based self-help (MBSH) treatments among medical students can be effective. Given shortages of trained therapists and the 24/7 nature of NHS working hours, MBSH may offer particular potential among NHS employees in terms of flexibility, accessibility and cost-effectiveness. The primary aim of this study is to investigate the effectiveness of a smartphone-delivered MBSH program called 'Headspace' in reducing stress among NHS staff.

Who can participate?
Adults who are currently employed by an NHS trust in Kent, Surrey or Sussex who meet the inclusion criteria.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group one are given access to Headspace which is a website and smartphone application (app) that primarily provides users with mindfulness meditation practices. Those in group two are told to use Moodzone which is a NHS website that has advice and ideas on how to deal with stress from work. Participants in both groups are asked to use the treatments every day for one month for at least ten minutes per day. They are encouraged to continue to use the websites for a further three months. Participants are followed up at the end of the study to measure their levels of stress.

What are the possible benefits and risks of participating?
Participants may benefit from learning a variety of techniques on how to reduce stress, anxiety and depression as well as a year's free subscription to the Headspace mobile application and

website, while Moodzone is free to use. There are no direct risks of participating however participants may find it difficult to reflect on their thoughts, feelings and experiences and may feel distress.

Where is the study run from?
This study is run from the University of Sussex and takes place in NHS trusts in Kent, Surrey and Sussex.

When is the study starting and how long is it expected to run for?
October 2015 to March 2019

Who is funding the study?
1. Economic and Social Research Council (UK)
2. Headspace Meditation Limited (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
210175

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 32617, IRAS 210175

Study information

Scientific Title
A definitive randomised controlled trial investigating two online wellbeing interventions to reduce NHS staff stress

Acronym
MindSHINE 3

Study objectives
The primary aim of this study is to investigate the effectiveness of smartphone-delivered mindfulness-based self-help (MBSH) intervention 'Headspace' in reducing stress among NHS staff.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of Sussex, Sciences & Technology C-REC, 15/10/2016, ref: ER/HT207/8
2. Health Research Authority (HRA), 23/01/ 2017, ref: 16/HRA/ 5525

Study design
Randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Anxiety - stress; UKCRC code/ Disease: Mental Health/ Neurotic, stress-related and somatoform disorders

Interventions
Participants are allocated to one of two unguided online wellbeing interventions, using block randomisation within the survey platform, Qualtrics.

Participants in the experimental arm are given access to Headspace which is a mindfulness app and website. Headspace can be viewed via either smartphone app (Apple or Android) or website and offers participants psychoeducation and guided mindfulness meditation practices.

Participants in the active-control arm are directed to Moodzone which is a NHS website for helping people to deal with work-related stress. Moodzone is delivered via a NHS webpage and offers advice and exercises designed to help manage work-related stress.

Participants in both arms are asked to engage with the exercises suggested within their given intervention for a minimum of ten minutes per day for the initial 30-days of the study, and are encouraged to continue to engage with their given intervention for a follow-up period of 120-days. Objective and subjective measures of engagement are measured at follow up. Also, meditation and moderation analysis conducted in order to establish the processes and factors influencing mindfulness-based self-help (MBSH) engagement and outcomes.

Intervention Type
Other

Primary outcome measure
Stress is measured using the Depression, Anxiety and Stress Scale (DASS – 21; Lovibond & Lovinbond, 1995) at baseline and 125 days.

Secondary outcome measures
1. Depression is measured using the DASS-21 at baseline, day 35 and 125
2. Anxiety is measured using the DASS-21 at baseline, day 35 and 125
3. Mindfulness is measured using the Five-Facet Mindfulness Questionnaire – Fifteen Items (FFMQ-15; Baer et al., 2008; Gu et al., 2016) at baseline, day 35 and 125
4. Self-compassion is measured using the Self-Compassion Scale – Short Form (SCS-SF; Raes, Pommier, Neff, & Gucht, 2011) at baseline, day 35 and 125
5. Well-being is measured using the Short Warwick-Edinburgh Mental Well-being Scale (SWEMWS; NHS Health Scotland, University of Warwick & University of Edinburgh, 2007) at baseline, day 35 and 125
6. Burn-out is measured using the Maslach Burnout Inventory (MBI; Maslach & Jackson, 1986) at baseline, day 35 and 125
7. Compassion-for-others is measured using the Compassionate Love For Humanity Scale (CLS; Sprecher, & Fehr, 2005) at baseline, day 35 and 125
8. Rumination is measured using the Ruminative Response Scale (RRS; Nolen-Hoeksema & Morro, 1991; Treynor, Gonzalez, & Nolen-Hoeksema, 2003) at baseline, day 35 and 125
9. Worry is measured using the Penn State Worry Questionarre (PSWQ; Mayer, Miller, Metzger, & Borkovek, 1990) at baseline, day 35 and 125
10. Sickness absence concerning the 3 months prior to the intervention, and the 3 months following the initial 30-day intervention period is measured using a non-validated questionnaire at baseline and 125-days, and where consent has been obtained, via objective sickness absence data provided by NHS Human Resources departments, after trial completion.
11. Adherence to and engagement with both interventions is measured using non-validated questionnaires and objective usage data provided by Headspace for participants assigned to the Headspace condition, at day 35 and 125
12. Beliefs about engaging with Headspace is measured using a non-validated questionnaire at baseline and 35 days
13. Expectations of Headspace and Moodzone is measured using non-validated questionnaires at baseline

14. A control variable of prior mindfulness experience is measured using a non-validated questionnaire at 125-days
15. Stress (as a secondary outcome when measured at these timepoints) is measured using the DASS-21 at baseline and day 35

Overall study start date
01/10/2015

Completion date
01/04/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or older
2. Currently employed by an NHS trust in Kent, Surrey or Sussex
3. Work in a role that involves direct contact with patients for at least one day per week .
4. Currently in work (i.e. are not on long term sickness absence)
5. Not currently undertaking and/ or are willing to refrain from engaging in any other psychological intervention during the 125-day course of the study
6. Self-reported sufficient English language ability to read and listen to the MBSH intervention materials
7. Regular personal access to an Apple or Android smartphone/ tablet or to a computer with internet access

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2108; UK Sample Size: 2108

Key exclusion criteria
Not meeting inclusion criteria.

Date of first enrolment
20/02/2017

Date of final enrolment
01/10/2018

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Sussex (Lead centre)
University of Sussex
Falmer
Brighton
United Kingdom
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Study participating centre
NHS Trusts in Kent, Surrey and Sussex
-
United Kingdom
-

Sponsor information

Organisation
University of Sussex

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Sponsor type
University/education

ROR
https://ror.org/00ayhx656

Funder(s)

Funder type
Research council

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
Headspace Meditation Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high impact journal

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan
The current 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/08/2022	26/08/2022	Yes	No
Participant information sheet	version 8.0	03/05/2018	04/06/2024	No	Yes