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Participatory digital interventions for front-line staff during the coronavirus (COVID-19) pandemic

Submission date
21/12/2020

Recruitment status
No longer recruiting

Registration date
11/01/2021

Overall study status
Completed

Last Edited
20/01/2022

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Frontline staff are at risk of poor mental health during pandemics. Ths study aims to use a digital platform to facilitate NHS Highland staffs' psychological self-care strategies and monitor their mood and anxiety in a way that gives them feedback and provides a method of evaluating the intervention.

Who can participate?
NHS Highland staff

What does the study involve?
Participants will be randomly allocated to either receive access to additional support or to no additional support. The study will use participatory methods that enable participants to develop personalised mental health strategies via a digital platform. These strategies are rooted in evidence-based positive psychology principles (such as mindfulness-based interventions) and will be used with the aim of treating both psychological distress and enhance resilience during the COVID-19 pandemic. Ongoing feedback and interactive messaging will promote self-awareness and prompt participants to utilise their strategies optimally.

What are the possible benefits and risks of participating?
Participants who are randomly allocated to receive the intervention will have extra mental health support during the pandemic.

There may be some level of emotional upset relating to the issues discussed, but no other risks are anticipated.

Where is the study run from?
The University of the Highlands and Islands (UK)

When is the study starting and how long will it run for?
From June 2020 to October 2020

Who is funding the study?
The Chief Scientist Office (CSO) of the Scottish Government (UK)

Who is the main contact?
Dr Hannes de Kock
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
284547

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 284547, v5 04/06/2020

Study information

Scientific Title
Using participatory digital platforms to enhance resilience and mental health of Scottish frontline health and care staff during COVID-19

Study objectives
1. To investigate whether digital psychological interventions have a positive influence on NHS Highland frontline staff psychological well-being and resilience during the COVID-19 pandemic.
2. To investigate whether digital psychological interventions have a mitigating influence on NHS Highland frontline staff levels of depression and anxiety during the COVID-19 pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/06/2020, South West - Frenchay REC (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8028; frenchay.rec@hra.nhs.uk), ref: 20/SW/0098

Study design
A single centre randomized controlled trial with a cross sectional survey

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental wellbeing of NHS staff during the COVID-19 pandemic

Interventions
The three arms of the pilot RCT were made up of the intervention (The NHS Highland Staff Wellbeing Project), treatment as usual app (MPS), and a control condition (wait list). The NHS Highland Staff Wellbeing Project is a digital platform providing personalised mental health strategies, monitoring of anxiety and mood, and feedback and interactive messaging to support NHS staff in maintaining or improving their mental health during the COVID-19 pandemic. The roll-out of the intervention to the waitlist control group will take place after the RCT. Recruited participants were randomly assigned (1:1:1) to one of the three conditions prior to the RCT.

From the literature, PPI feedback, and the funding call to provide rapid research into COVID-19, the research team decided to restrict the intervention (and all other conditions) to 4 weeks. The first two weeks of the intervention focused on building resilience and the character strength of gratitude, whilst the last two weeks focused on dealing successfully with low mood and anxiety. The treatment as usual intervention was a generic NHS trusted app designed to support psychological well-being and decrease depression and anxiety.

All participants were contacted via email and text in preparation of the RCT starting on 7 September. Participants allocated to different conditions will receive different messages via email and text. The treatment as usual and intervention ntervention groups' emails (from UHI) and texts (automated) were designed to appear very similar (as to blind these participants from knowing which app they will be receiving). The control group received an email (from UHI) & text message (from MPS) stating that they are on the waiting list and that they will receive the app after the RCT.

All participants will complete a series of questionnaires using OnlineSurveys.ac.uk at the start, middle and end of the study.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 10/11/2021:
1. Psychological changes:
1.1. Anxiety symptoms and depressive symptoms measured using the Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder Assessment (GAD-7) at baseline, 2, and 4 weeks
1.2. Psychological well-being measured using the Edinburgh Well-being Scale (WEWBS) at baseline, 2, and 4 weeks

Previous primary outcome measure:
1. Psychological changes:
1.1. Anxiety symptoms and depressive symptoms measured using the Patient Health Questionnaire (PHQ-9) and Generalised Anxiety Disorder Assessment (GAD-7) at baseline, 2, and 4 weeks
1.2. Psychological well-being and mental toughness measured using the Edinburgh Well-being Scale (WEWBS) and Mental Toughness Index (MTI) at baseline, 2, and 4 weeks

Key secondary outcome(s))
Current secondary outcome measures as of 10/11/2021:
1. State of participants' mental toughness measured using the Mental Toughness Index (MTI) at baseline, 2, and 4 weeks
2. State of participants' mental health measured using the and Gratitude Questionnaire (GQ-6) survey at baseline, 2, and 4 weeks

Previous secondary outcome measures:
1. State of participants' mental health measured using the and Gratitude Questionnaire (GQ-6) survey at baseline, 2, and 4 weeks

Completion date
14/10/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Front line health care staff employed by NHS Highland
3. Capacity to give consent

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
180

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/06/2020

Date of final enrolment
14/09/2020

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Highland
Assynt House
Beechwood Park
Old Perth Road
Inverness
United Kingdom
IV2 3BW

Sponsor information

Organisation
NHS Highland

ROR
https://ror.org/010ypq317

Organisation

University of the Highlands and Islands

ROR
https://ror.org/02s08xt61

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office, Scottish Government Health and Social Care Directorate

Alternative Name(s)
Chief Scientist Office, Scottish Government Health Directorate CSO, Chief Scientist Office, Scottish Government Health Directorates, Chief Scientist Office of the Scottish Government Health Directorates, Scottish Government Health and Social Care Directorate of the Chief Scientist Office, Scottish Government Health Directorate Chief Scientist Office, The Chief Scientist Office, CSO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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 (https://myuhi.sharepoint.com/sites/eo-crhwb/Psychological_Resilience/SRUC%20Shared%20Documents/SitePages/Home.aspx). The data is stored securely in the university's SharePoint site. Only anonymised data will be shared with statisticians. Only the research team will have access to raw data and the data will be kept only for the duration of the data analyses.

IPD sharing plan summary
Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/01/2022	20/01/2022	Yes	No

HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		03/10/2021	10/11/2021	No	No