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Testing the mHealth app SyD to improve the physical and mental wellbeing of UK healthcare workers

Submission date
14/03/2023

Recruitment status
No longer recruiting

Registration date
12/04/2023

Overall study status
Completed

Last Edited
13/06/2023

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Preventable diseases like heart disease, diabetes, and joint problems can make people sick and reduce their quality of life. Mental health problems like stress, anxiety, and depression affect a lot of people too. The COVID-19 pandemic has made things worse. People may have trouble following lifestyle changes to improve their health, but things like self-monitoring and goal-setting can help. Using mobile health (mHealth) interventions, like an app called SYD, can personalize recommendations to help people make these changes. We want to see if using SYD can improve people's quality of life and mental health.

Who can participate?
Active NHS staff with an NHS email address, aged at least 18 years, own a smartphone, Hospital Anxiety and Depression Scale (HADS) test score between 8 and 14 inclusive, indicating mild to moderate anxiety or depressive symptoms

What does the study involve?
As part of the study you will be asked to:
1. Engage with the SYD application on your smartphone
2. Complete study assessments involving questions regarding your quality of life and wellbeing using a study website

What are the possible benefits and risks of participating?
Potential participants who score between 8-14 inclusive will be eligible, as these scores indicate individuals most likely to benefit from interventions of wellbeing like SYD and to be considered safe as higher scores may indicate depression/anxiety levels needing formal psychological evaluation.
We do not anticipate there being any risk associated with participating in this study. All information provided on the SYD app is intended for general information and educational purposes only, not as medical advice or a substitute for medical advice provided by a doctor or other qualified health practitioner.

Where is the study run from?
Southern Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
December 2020 to March 2022

Who is funding the study?
iamYiam (UK)

Who is the main contact?
Prof Shanaya Rathod, shanayarathod@nhs.net
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294071

Protocol serial number
IRAS 294071, CPMS 48382

Study information

Scientific Title
Randomised controlled trial of the mHealth app SyD to improve the physical and mental wellbeing of UK healthcare workers

Study objectives
To quantify the change in Quality of Life (QOL) following an intervention with SYD, a personalised preventive mHealth partner. Measures of mental health (stress, anxiety and depression) will also be tracked as a way to assess the wellbeing potential of this non-clinical intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/02/2021, HRA and Health Care Research Wales (Health and Care Research Wales Support and Delivery Centre, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 2920 230457; healthandcareresearch@wales.nhs.uk), ref: 21/HRA/0308

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Mental health (anxiety, depression, stress), quality of life

Interventions
The trial is designed carefully and deliberately to fully and prospectively elucidate all elements of comparison of the impact of SYD.

Participants would be randomly assigned to one of the two trials cohorts (PHE, 2020).

For cohort one, the study allows data collection as part of a 'Before and After Study', with SYD as the intervention provided to participants, to engage with, for 3 months as a minimum. Additionally, by having a further cohort (cohort two) without SYD being engaged for the first 3 months, the study allows 'Case Controlled' cross comparisons between the two cohorts. Additionally, by collecting data on the first cohort further to 6 months, we can review persistence of effects from 3 to 6 months of SYD and whether participants voluntarily continue using SYD or not beyond the primary endpoint.

Bringing on board the second cohort to have SYD switched on after 3 months, allows a comparison within this cohort 'Before and After' at a different time-point to the switch on for cohort one. This allows for any effects of SYD to be evaluated as COVID-19 levels themselves change over time.

Meanwhile comparing the two cohorts after the second cohort is exposed to SYD will allow comparisons of an early (in second cohort) versus a more experienced group (first cohort) using SYD contemporaneously.

Intervention Group: Participants in the Intervention Group will be asked to complete baseline assessments (Month 0) and download / interact with the SYD app (Months 0-3). Participants will

complete monthly assessments for a period of 3 months (Months 1-3) to analyse the primary endpoint. A final assessment will be performed at Month 6, to monitor longer term effects of the intervention.

Control Group: Participants in the Control Group will be asked to complete baseline assessments (Month 0) and monthly assessments (Months 1-3) to provide control data in a comparable population

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SyD app

Primary outcome(s)
1. WHO Quality of Life-BREF (WHOQOL-BREF) survey assessed global quality of life in the Control and Intervention group at Baseline, Month 1, 2, 3 & 6
2. EuroQoL EQ-5D-5L assessed Health-related quality of life in the Control and Intervention group at Baseline, Month 1, 2, 3 & 6

Key secondary outcome(s))
1. Perceived Stress Scale (PSS-4) was used for the Control and Intervention group at Baseline, Month 1, 2, 3 & 6
2. Hospital Anxiety and Depression Scale (HADS) was used for the Control and Intervention group at Baseline, Month 1, 2, 3 & 6

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. NHS staff with an NHS email address which can be used for this study
2. Age ≥ 18 years
3. Own a personal smartphone device (iOS or Android-based) which can be used for this study
4. Sufficient English language ability to familiarise themselves with and engage with SYD and study assessments
5. Hospital Anxiety and Depression Scale (HADS) test score between 8 and 14 inclusive, indicating mild to moderate anxiety or depressive symptoms
6. Provision of informed consent

Participant type(s)
Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
595

Key exclusion criteria
1. Unwilling or unable to participate
2. Any other concurrent psychological interventions
3. Concurrent participation in an interventional clinical trial
4. People considered clinically extremely vulnerable from COVID-19: https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19)

Date of first enrolment
01/06/2021

Date of final enrolment
15/04/2022

Locations

Countries of recruitment
United Kingdom

England

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Moorgreen Hospital
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Sponsor information

Organisation

Southern Health NHS Foundation Trust

ROR
https://ror.org/03qesm017

Funder(s)

Funder type
Industry

Funder Name
iamYiam

Results and Publications

Individual participant data (IPD) sharing plan
Data will not be shared with anyone outside of the Sponsor and iamYiam research project teams, unless needed to independently verify results at the request of regulators.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		13/06/2023	13/06/2023	No	No
Participant information sheet	version 1.8	26/10/2021	29/03/2023	No	Yes
Protocol file	version 2.0	13/04/2022	29/03/2023	No	No