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# Chatbot use and mental wellbeing of health workers

**Submission date**
27/04/2022

**Recruitment status**
No longer recruiting

**Registration date**
12/05/2022

**Overall study status**
Completed

**Last Edited**
29/05/2024

**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
The HRH2030 program and the University of Malawi will study the effect of using a mental health chatbot named 'Vitalk' on the mental wellbeing of health workers. The aim of this study is to test whether the use of Vitalk over a period of eight weeks leads to better mental health outcomes. To achieve the this aim we will compare changes in mental wellbeing in a group that uses Vitalk with the changes in another group that has access to websites about mental health. We will measure mental wellbeing asking study participants to complete commonly used test for depression, anxiety, resilience, burnout, and loneliness. In addition, we are interested in measuring how active study participants are in building their resilience in coping with daily challenges in their work and personal life, which includes activities for managing stress, raising self-awareness, performing self-care, finding purpose, and connecting with others.

Who can participate?
Health workers in Malawi.

What does the study involve?
Participants will be asked to take the mental health tests three times throughout the study period. Participants using Vitalk interact daily with the mobile phone app, which guides health workers through exercises that can increase self-awareness and provides them with self-help and coping tips. Participants that have access to websites about mental wellbeing but not to Vitalk can use these on their initiative; this group is self-directed and does not have an interactive element.

What are the possible benefits and risks of participating?
The expected benefit of the study is a greater attention to work-related stress that healthcare providers face especially during the COVID-19 pandemic of 2020/21, which overwhelmed countries' health systems and increased care-related pressure in the effort of ensuring patient care and staff safety.

Where is the study run from?
University of Malawi

When is the study starting and how long is it expected to run for?
July 2021 to February 2022

Who is funding the study?
United States Agency for International Development (USA)

Who is the main contact?
Ekhard Kleinau, ekleinau@urc-chs.com
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# Contact information

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## Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
Nil known

## Study information

### Scientific Title
Effectiveness of a chatbot in improving the mental wellbeing of health workers in Malawi during the COVID-19 pandemic: A randomized, controlled trial

### Acronym
HRH2030-Vitalk

### Study objectives
The use of a chatbot such as Vitalk over a period of eight weeks results in different mental health outcomes in a treatment and control group of health workers in Malawi.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 08/10/2021, University Research Co., LLC IRB (5404 Wisconsin Ave., Ste 800 Chevy Chase, MD 20815-3594, USA; +1 301-654-8338; bturesson@URC-CHS.COM)

### Study design
Interventional randomized controlled trial

### Primary study design
Interventional

### Secondary study design

Randomised controlled trial

## Study setting(s)
Internet/virtual

## Study type(s)
Quality of life

## Participant information sheet

## Health condition(s) or problem(s) studied
Mental health outcomes (including depression, anxiety, burnout, loneliness, and resilience) among health workers in Malawi

## Interventions
The study is a two-arm, parallel randomized controlled trial with a pre-treatment assessment, 8-week intervention period and mid-study assessments at 4-5 weeks and an end-of-study assessment at 9 weeks. Interested study participants will be randomly assigned to either the treatment or control group at the time of registration. Vitalk, the developer of the app, will create a study web portal where study participants register, give their consent, are assigned to one of the study arms, are given a unique study identification number, and enter their demographic information. Depending on the random assignment, participants will be taken to either the treatment app, Vitalk, or the website for the control group. This is a single-blinded design because only the research team will be blinded to the study arm assignments; all participants in both study arms will be told they are participating in 'an online self-help for mental wellbeing'.
Originating from Brazil, Vitalk is an automated chatbot delivering mental health content to its users using a conversational format, with the aim of improving well-being by reducing stress, anxiety and depression using a preventative approach to mental health (Daley, Hungerbuehler et al., 2020). The Vitalk app uses psychoeducation, cognitive restructuring, behavioral activation, gratitude, and practical exercises (such as breathing, relaxation and meditation) to bring about improvements in users' mental health (ibid). These techniques and strategies are rooted in CBT and Positive Psychology, two commonly used psychotherapy methodologies that have been used widely in various settings and have registered high effectiveness among patients presenting with various psychological challenges (Beck, 2011; Seligman, 1998; Wills, 2009). Only the treatment arm of the study will have access to Vitalk. The control arm of the study will have access to a website with links to mental health resources from WHO and other self-help providers as well as contact information for psychologists and mental health counselors in Malawi. This website consists of a few pages with basic mental health and coping information, links to mental wellbeing resources, mood meter and standardized mental health tests. Its content is static without user interaction beyond clicks to access web-based mental health resources. Whether or not these resources are used depends entirely on the initiative of control group participants.

## Intervention Type
Behavioural

## Primary outcome measure
Measurements at baseline, 4-5 weeks, and 9 weeks:
1. Anxiety symptoms are measured using the Generalized Anxiety Disorder (GAD-7) scale.
2. Depression symptoms are measured using the Patient Health Questionnaire (PHQ-9).

3. Burnout is measured using the Oldenburg Burnout Inventory (OLBI).
4. Loneliness is measured using the UCLA Short Loneliness Scale.
5. Resilience is measured using the 14-item Resilience Scale (RS-14).

### Secondary outcome measures
1. Resilience building behaviors measured through questionnaires in Vitalk at baseline, 4-5 weeks, and 9 weeks
2. Frequency and use of treatment app and control website, measured throughout the trial through app and website usage data
3. Qualitative patient experiences measured using an anonymous online survey at 9 weeks

### Overall study start date
01/07/2021

### Completion date
08/02/2022

## Eligibility

### Key inclusion criteria
1. Currently employed as one of the types of service providers (cadres) listed: doctors, nurses, medical assistants, clinical officers, laboratory technicians, physiotherapy technicians, pharmacists, physiotherapists
2. Employed in public or private primary, secondary, or tertiary care facility in Blantyre and Lilongwe districts of Malawi
3. Possess some degree of English language proficiency
4. Own a smartphone with an Android operating system
5. No history – past or current – of counseling or therapy for severe mental health disorders
6. Not have self-reported suicidal ideation
7. Score below “very high risk” levels on the initial assessments for anxiety and depression
8. Diploma in their respective fields of specialization, in adherence to the Ministry of Health employment criteria for the respective cadres of health workers (Medical Assistants who completed 2 years of college will be allowed to participate even though their qualification is a certificate)
9. Adults (18 years or older)

### Participant type(s)
Health professional

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
1280

### Total final enrolment
1584

### Key exclusion criteria
1. All other hospital- or health-related personnel, such as health surveillance assistants, hospital assistants or laboratory assistants, due to their lower educational qualification requirement for employment.
2. Health workers with a history – past or current – of counseling or therapy for a severe mental disorder
3. All study applicants at “very high risk” of depression and anxiety according to their initial scores from standard mental health tests
4. Participants who check suicidal ideation in question nine of the PHQ-9

### Date of first enrolment
18/10/2021

### Date of final enrolment
19/11/2021

## Locations

### Countries of recruitment
Malawi

### Study participating centre
**Malawi University of Business and Applied Sciences**
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Blantyre
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N/A

### Study participating centre
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### Sponsor type
Other

### Website
https://www.chemonics.com/

## Funder(s)

### Funder type
Government

### Funder Name
United States Agency for International Development

### Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United States of America

## Results and Publications

### Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

### Intention to publish date
30/09/2023

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the study will be made available to the public through the USAID Development Data Library database (DDL, https://data.usaid.gov/). Data will be anonymized and made available to the public following the data privacy measures established in the protocol and communicated to participants in the informed consent process. The data will be submitted to the database following publication and will be publicly available upon review and acceptance by the USAID DDL. The dataset will include anonymized data on responses to mental wellbeing questions, data on app or website usage, and limited personal data (e.g. health worker cadre).

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 09/05/2022 | No | Yes |
| Protocol file | | | 09/05/2022 | No | No |
| Other files | | | 02/02/2023 | No | No |
| Results article | | 28/05/2024 | 29/05/2024 | Yes | No |