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Holly Health: Personalised, scalable health coaching intervention for patients living with hypertension, anxiety and/or depression

Submission date
06/12/2023

Recruitment status
No longer recruiting

Registration date
06/12/2023

Overall study status
Completed

Last Edited
03/12/2024

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Hypertension (high blood pressure) affects over 19 million of UK adults and is a major risk factor for cardiovascular disease). The good news is that it can be prevented (and better managed) through behaviours including changes to nutrition and exercise, as well as stress reduction and mood management. In addition, hypertension often occurs with mental health challenges (around 30% of people with hypertension also meet the diagnosis threshold for depression /anxiety), making health self-management even more challenging. However, in the current care pathway, there is a lack of support available for physical and mental health simultaneously. Investigating the feasibility and acceptability of providing an evidence-based, fully digital health coaching service for people with hypertension and depression/anxiety in a primary care setting is the first step towards designing a bigger clinical trial to assess its clinical effectiveness. Providing cost-effective personalised behaviour change support to people with hypertension and mental health challenges at a national level can result in better health outcomes through increased self-management abilities and a reduction of associated NHS costs.
The aim of this study is to use those insights to understand how feasible and acceptable it is to offer the Holly Health service as extra support to self-manage high blood pressure and mental health challenges, and to improve the Holly Health service as a whole.

Who can participate?
People who are 40-65 years old who have high blood pressure and depression or anxiety, and who would like to get digital health coaching support.

What does the study involve?
The first step of this study will involve having an optional chat with one of the members of the research team to go through any questions participants may have. After obtaining informed consent to be a part of this study, there will be four main assessment points:
1. Initial assessment: Participants will be invited to the 49 Marine Avenue GP surgery to go through a couple of questionnaires about their mood, and general information about themselves. A research nurse will also measure their blood pressure and waist circumference. After this initial session, participants allocated to the intervention condition will get free access

to the Holly Health app for 12 months. When they first access the app, participants will go through a series of questions about their current lifestyle and about their health (this will take 5-10 minutes) called a behavioural health check. Based on their answers, the Holly Health app will suggest a couple of different small actions you can take to start improving their physical and mental wellbeing, and participants will receive ongoing coaching and support from the Holly Bird (Holly Health's digital health coach).
2. After 8 weeks participants will be invited to answer these same questions with the Holly Bird to assess for any changes.
3. When participants have been using the app for 12 weeks, the researchers will invite them to a second visit with the research nurse to go through the same questionnaires and measurements and to do a quick interview about their experience using the Holly Health app.
4. After 6 months from when they first signed up for the service, participants will receive the behavioural health check questions again and they will be invited to take their own blood pressure reading and record it in the Holly Health app (if participants don't have a blood pressure monitor, the researchers can provide them with one).

What are the benefits of the study?
As part of this study, participants will have access to an evidence-based digital service (the Holly Health app) designed to help them improve their physical and mental wellbeing. Results from this study will inform how we can better adapt the recommendations, the content, and the accessibility of the service to better serve people with physical and mental health conditions such as high blood pressure and depression/anxiety.

What are the risks of participation?
There may be some slight discomfort associated with completing questionnaires evaluating your health and emotions, although all the questions we ask are very widely used and usually do not cause distress. If the researchers identify that participants may require professional support outside of this study for a physical or mental health condition, they will signpost them to the relevant sources where they can seek out support.

Where is the study run from?
The study will take place mainly online (while participants use the Holly Health app in their own time), and there will be two in-person sessions at 49 Marine Avenue GP surgery to go through a few questionnaires and to take their blood pressure reading.

When is the study starting and how long is it expected to run for?
July 2023 to December 2024

Who is funding the study?
Innovate UK

Who is the main contact?
Dr Daniela Mercado Beivide, daniela@hollyhealth.io

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Ms Liliana Chow

Contact details
12-18 Hoxton Street
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
333701

ClinicalTrials.gov number
Nill known

Secondary identifying numbers
IRAS 333701

Study information

Scientific Title
Holly Health: A feasibility randomised controlled trial of a personalised, scalable health coaching intervention for patients living with hypertension, anxiety and/or depression

Study objectives
Providing a digital self-management tool (i.e., Holly Health) to patients with hypertension and mild to moderate depression/anxiety will be feasible and acceptable.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/02/2024, East of Scotland Research Ethics Service (EoSRES) (Tayside Medical Science Centre, George Pirie Way, Ninewells Hospital, Dundee, DD1 9SY, United Kingdom; +44 1382 383878; tay.eosres@nhs.scot), ref: 24/ES/0012

Study design
Single-centre feasibility randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Other

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
Condition management for patients with hypertension and mild to moderate anxiety/depression

Interventions
Eligible primary care patients will be randomised to receive access to a digital health coaching service (Holly Health) as a self-management tool or to a waiting list control. Allocation to treatment will be by minimisation to control for gender. After onboarding, participants in the intervention group are expected to engage with the service 3-4 times/week for 6 months. Outcome measures and qualitative feedback will be assessed throughout.

Intervention Type
Behavioural

Primary outcome measure
Feasibility and acceptability of providing a digital health coach service to primary care patients living with hypertension and depression/anxiety by assessing recruitment, engagement, retention rates and qualitative feedback at 12 weeks and 6 months after initial signup.

Secondary outcome measures
1. Health behaviours measured using a bespoke questionnaire at baseline vs 8 weeks and 6 months post-signup
2. Personal wellbeing measured by ONS-4 at baseline vs 8 weeks and 6 months post-signup
3. Blood pressure readings at baseline vs 12 weeks and 6 months post-signup

Overall study start date
03/07/2023

Completion date
02/12/2024

Eligibility

Key inclusion criteria
1. Male or female participants
2. 40-65 years old
3. Hypertension diagnosis
4. Mild to moderate symptoms of depression and/or anxiety
5. Fluent in English
6. Have a smartphone or tablet with internet access
7. Informed consent (written and witnessed)

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Having a current other major psychiatric disorder (e.g., major depression, major suicidality, substance dependence, psychosis) needing treatment in its own right
2. Having recently started psychotropic medication or increased the dose (i.e. within the previous 2 weeks)
3. Taking medication for weight loss
4. Visual impairments that cannot be corrected with contact lenses or glasses

Date of first enrolment
22/04/2024

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Northumbria Primary Care
Contact
49 Marine Avenue Surgery
Whitley Bay
Tyne and Wear
United Kingdom
NE26 1NA

Sponsor information

Organisation
Holly Health

Sponsor details
12-18 Hoxton Street
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Sponsor type
Industry

Website
https://hollyhealth.io/

Funder(s)

Funder type
Government

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
02/12/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Daniela Mercado Beivide (daniela@hollyhealth.io).

All trial data will be stored in line with the General Data Protection Regulation (GDPR). All participants will be allocated a numeric code, which will be used to identify their data. The master list of names which corresponds to each participant's numeric identification code will be stored electronically and will be password protected. Only key researchers will have access to participants information.

Confidentiality and anonymity of all personal data will be retained throughout the entire study. Data will be stored in electronic files and all electronic files will be password-protected. Identifying information will be removed from the data, stored separately and replaced with a numeric identification code.

Anonymised study results will be shared and discussed with the research team of the company Holly Health prior to publication. Data sharing (meta-data) with other external researchers (e.g. for further analyses) after data collection and publication will be considered only if requested personally to the CI. All shared data will be anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		02/12/2024	03/12/2024	No	No