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Smart technologies proof of concept programme

Submission date 01/08/2023	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 02/08/2023	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 05/09/2023	**Condition category** Other	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
Recognising quickly if a person's health is deteriorating gives doctors and other healthcare professionals a chance to intervene early and stop problems from getting worse. That can make treatment more effective and means patients can recover better. Often it even avoids admissions or urgent visits to hospital. This study is testing if we can find out really early when someone is becoming ill and may need medical help. It is testing if taking regular health measurements can give us this information.

Who can participate?
People aged over 18 years and living in the Lincolnshire area who have two or more long-term health problems. They might be living in a care home or they might be living in their own homes.

What does the study involve?
Regular health measurements will be taken using new medical technologies that are installed on a smartphone, tablet or smart wristband. They are very simple to use and can read vital signs such as blood pressure, heart rhythm and oxygen saturation by using the camera on a smartphone or tablet. The wristband can be worn constantly like a normal wristwatch and records sleep patterns. This means they are far less intrusive than the traditional medical devices used to take these readings and you don't need to go to a doctor's surgery or hospital to have them taken.
In addition to the data collected directly, the researchers also plan to collect health, social care and environmental data from the area participants live in, such as weather and air quality. This is so that they can produce a very detailed report on all the things that affect people's health and wellbeing.
Once they have measurements from a large number of people, scientists will use artificial intelligence to see if they can use the information to spot when treatment from a doctor would have been beneficial. They will use all the information to write reports on how the NHS can improve patient care by using these types of technologies and Smart Devices.

What are the possible benefits and risks of participating?
As the researchers will only analyse all the information once the study is completed, participants will not benefit from taking part in this study. Nevertheless, it is hoped that people in the future

with similar health problems will receive better treatment earlier, helping them live longer happier lives. There were no significant risks identified other than the time it would take people to participate in this study.

Where is the study run from?
Lincolnshire Integrated Care Board (UK)

When is the study starting and how long is it expected to run for?
June 2019 to March 2023

Who is funding the study?
NHS England (UK)

Who is the main contact?
Jimmy Pryke-Walker, j.pryke-walker@nhs.net

Study website
http://nhsts.org

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
286225

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 286225, CPMS 47024

Study information

Scientific Title
Smart technologies proof of concept programme: South Lincolnshire / Lincolnshire Integrated Care Board

Study objectives
If information about patient behaviour, conditions and events captured from wearables, monitors and other smart technologies, can predict illness and demand for services, then providing these technologies to patients will enable providers to pre-empt illness and redirect demand, or design new services

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/12/2020, West Midlands - Solihull Research Ethics Committee (2 Redman Place, London, E20 1JQ, United Kingdom; +44 (0)207 104 8345; southbirmingham.rec@hra.nhs.uk), ref: 286225

Study design
Distributed observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Care home, Home, Internet/virtual, Medical and other records

Study type(s)
Diagnostic, Prevention, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Adults with two or more long-term conditions

Interventions
This was an observational study.

Participants were provided with a smartphone pre-loaded with apps, a wearable device and an email address to receive questionnaires.

Participants regularly recorded their health measurements at home using the devices/apps provided.

Most participants wore a wristband that collected data on sleep and activity.
Participants received an electronic questionnaire every week and answered questions relating to their health and well-being.

All medical devices were safe, fit for purpose, easy to use and the wearable was designed to be comfortable to wear with specific options for those with very slim or swollen wrists.

The apps and wearables were approved for use in the PoC by the Health Research Authority and the local Research Ethics Committee.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lifelight, Fibricheck, Activinsights, Thermometer, HowRYou / HowRWe

Primary outcome measure
1. Apps based on photoplethysmography (PPG) were used daily (five times) a week to provide indicative estimates of:
1.1. Blood pressure (mmHg)
1.2. Pulse rate (beats per minute)
1.3. Respiration rate (respirations per minute)
1.4. Heart rhythm
1.5. Sinus rhythm
1.6. Atrial Fibrillation
1.7. Extrasystoles

1.8. Bradycardia
1.9. Increased heart rate variability (HRV)
1.10. Tachycardia
1.11. Pulse rate
1.12. Respiratory rate
1.13. Diastolic blood pressure (Dia BP)
1.14. Systolic blood pressure (Sys BP)
2. Sleep, exercise and activity measured using a wearable device worn on average for 1 to 3 months continuously including:
2.1. Acceleration
2.2. Physical Activity intensity
2.3. Sedentary vs movement activity
2.4. Posture changes
2.5. Sleep/wake time
2.6. Sleep event characterisation
3. Temperature in degrees Celsius measured daily using a thermometer

Secondary outcome measures

Person-related experience measures (PREMS) were measured by weekly electronic surveys:
1. Quality of life:
1.1. Health status (howRu) – pain, distress, disability, dependence
1.2. Personal wellbeing (PWS) – satisfaction, worthwhile, happy, anxious
1.3. Person-specific outcome (PSO) – issue #1, issue #2
1.4. Sleep – sleep time, wake time, wake refreshed, sleep well
1.5. Fatigue – energy, tiring fast, concentration, stamina
2. Individual care:
2.1. Health confidence (HCS) – knowledge, self-management, get help, share decisions
2.2. Patient experience (howRwe) – kind, talk to me, prompt, organised
2.3. Service integration – communication, awareness, repetition, teamwork
2.4. Self-care – diet, exercise, weight, medication
2.5. Shared decisions – benefits, downside, choices, involvement
2.6. Behaviour change – capability, opportunity, motivation, automatic
2.7. Adherence – remember, take if bad, take if good, treatment satisfaction
2.8. Acceptance of loss – know capability, recognition, change activity, move on
2.9. Privacy – data are secure, data are shared, can check data, privacy satisfaction
2.10. Product confidence – use often, confident user, positives, negatives
2.11. User satisfaction (UX) – helps me, easy to use, support available, product satisfaction
2.12. Training – reaction, learning, behaviour, results
3. Community:
3.1. Social determinants (SDoH) – education, self-esteem, environment, poverty
3.2. Social contact – companionship, can confide, people to help, join in
3.3. Loneliness – no friends, isolated, alone, lonely
3.4. Neighbour relationships – know neighbours, trust, share information, help each other
3.5. Personal safety – safe at home, respected at home, safe out, respected out

Overall study start date

21/06/2019

Completion date

01/03/2023

Eligibility

Key inclusion criteria
1. Individuals over the age of 18 years
2. Have two or more long-term conditions AND/OR
3. Have a medium to high frailty score AND/OR
4. Are suffering from unsteadiness or falls AND/OR
5. Those who are found to have paroxysmal and/or asymptomatic atrial fibrillation (AF), hypertension or heart failure
6. Live in their own homes or in residential care homes or in nursing care homes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
The research team aimed to recruit up to 500 participants to take part in the study

Total final enrolment
443

Key exclusion criteria
1. Children
2. Individuals for whom consent cannot be obtained (i.e. individuals with severe mental impairments or learning difficulties)
3. Patients on palliative care
4. Individuals lacking mental health capacity or whose mental health conditions might be influenced by participating in the study
5. Individuals whose mental capacity deteriorates during the study period will be removed from the study

Date of first enrolment
01/04/2022

Date of final enrolment
13/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Lincolnshire Integrated Care Board
Bridge House
The Point
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Sponsor information

Organisation
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Sponsor type
Government

Website
https://lincolnshire.icb.nhs.uk/

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Publication and dissemination plan
The study results have been presented in full to NHS Lincolnshire Integrated Care Board representatives. A workshop has been organized in October 2023 to enable detailed questions to be asked and answered. A presentation of the results will be made to NHS England in Autumn 2023. Participants will receive a letter of thanks in August 2023. A copy of the summary final report can be obtained on request from Tony Bowden, Chief Executive Officer, Helicon Health. Email: tonybowden@heliconhealth.co.uk.

Intention to publish date
13/01/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed are not expected to be made available due to information governance regulations.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 2		02/08/2023	No	No