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Can biometric data collected from people self-measuring at home be used to predict urgent care?

Submission date
07/02/2022

Recruitment status
No longer recruiting

Registration date
09/02/2022

Overall study status
Completed

Last Edited
02/05/2025

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The NHS faces an unprecedented demand for services. Contributing to this increasing demand is a population who are living longer but not necessarily in good health. There is a rise in patients with long-term conditions requiring regular care from the NHS. As part of the response to this problem, this research is aimed at investigating possibilities for system-wide transformation. The research will focus on testing the theory that information about patient behaviour, conditions, and events can be gleaned from wearables, monitors, and other smart technologies. This information could enable a better understanding of drivers or triggers for the demand of services and therefore inform strategic health commissioning.
Studies have previously demonstrated the ability of telemedicine (the practice of medicine using technology to deliver care at a distance) to decrease the use of emergency departments and hospitalisations among vulnerable populations such as children and the elderly.
This study aims to find out whether information about patient behaviour, conditions, and events, captured from wearables, monitors and other smart technologies, can predict demand for services, and whether providing these technologies to patients and using the data generated will enable providers to pre-empt and redirect demand or design new services.

Who can participate?
Patients older than 65 years living in their own homes or in care homes who have more than two comorbid conditions AND/OR more than two requirements for unscheduled urgent care in the previous year AND/OR medium or high frailty score. Comorbid conditions include heart failure, COPD/asthma, frailty/falls/possible syncope, high frailty bedbound, blood disorders/immune suppression/post-chemotherapy, diabetes, kidney/liver failure.

What does the study involve?
Daily data are collected from patients who self monitor using certified medical devices and captured using the Reassure app. Data on exacerbations are collected subsequently from the patient's record. The data are analysed to identify whether deterioration leading to exacerbation could have been identified from the patient's data in time to enable preventative treatment and avoid unscheduled emergency care.

What are the possible benefits and risks of participating?
There is no payment of any kind for participation in this study. It is probable that participants will not directly benefit from taking part in this study, other than any enjoyment in participation or improvements in the self-awareness of a participant's own health. The research team hopes that people in the future with similar health problems will receive better treatment earlier, helping them live longer, happier lives. Participants will have helped to make this happen through participation in this study. With regards to the risks of participation, the research team have set up this study very carefully. The risks of harm to a participant are the same as or less than the risk for them of using any normal sort of electronic equipment at home. Certified medical devices are provided to participants for use that have been carefully tested, minimising the risk of harm. Risk assessments have been carried out to ensure that risks of participation are mitigated.

Where is the study run from?
Participants for Phase I of this study have been recruited from the Stansted GP Practice (UK). The research team are based in the offices of L2S2 Ltd. Participants will be recording measurements from their own homes for the duration of the study, with no face-to-face contact with the research team.

When is the study starting and how long is it expected to run for?
October 2019 to February 2024

Who is funding the study?
NHS England (UK)

Who is the main contact?
Jane Aldridge, jane.aldridge@l2s2.com

Contact information

Type(s)
Principal investigator

Contact name
Ms Jane Aldridge

Contact details
L2S2 Ltd, 2a / 2b Oakington Business Park
Cambridge
United Kingdom
CB24 3DQ
+44 (0)7748 708558
Tom.Hughes@l2s2.com

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)

276149

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 276149

Study information

Scientific Title
Service demand prediction based on information from connected devices

Acronym
SerPICoD

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/06/2020, East of England - Essex Research Ethics Committee, (The Old Chapel, Royal Standard Place, Nottingham NG1 6FS, UK; +44 2071048227; essex.rec@hra.nhs.uk), REC ref: 20/EE/0029

Study design
Observational case-control study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Participants aged >65 years with multiple co-morbidities, and/or frailty and/or recent episodes of unscheduled acute care

Interventions
Daily biometric data are collected from patients who self monitor using certified medical devices and then capture the data using the Reassure app. Data on exacerbations are collected subsequently from the patient record. The data are analysed using data science techniques to identify whether deterioration leading to exacerbation could have been identified from the biometric data in time to enable preventative treatment and avoid unscheduled emergency care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
Primary outcome measures are collected once daily for 12 weeks (unless otherwise stated) by participants self-measuring using devices selected for them by a qualified doctor using professional judgment following review of the participant's primary care record. Participants are asked to self-monitor daily but adherence to the requested frequency of measurements will vary between participants. These primary measures are:
1. Blood pressure – reported as systolic pressure in mmHg, diastolic pressure in mmHg, pulse in beats per minute, and measured using a CE-certified commercially available blood pressure monitor, data transcribed into the Reassure app running on iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database.
2. Temperature – reported as degrees Centigrade and measured using a CE-certified commercially available forehead thermometer, data transcribed into the Reassure app running on iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database.
3. Blood oxygen saturation – reported as a percentage of the maximum concentration of oxygen in blood and pulse in beats per minute and measured using a CE-certified commercially available pulse oximeter, data transcribed into the Reassure app running on iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database.
4. Respiration rate – reported as breaths per minute and measured using the Reassure app (CE-certified medical device) and transferred via the internet to the L2S2 database
5. Urine protein – measured using Siemens Uristix, reported as negative, trace, 0.3, 1, 3, or ≥20 g of protein/litre urine. Reported by participant by assessing colour change visually and entering result into the Reassure app running on iOS or Android smartphone or tablet. The result is transferred via the internet to the L2S2 database
6. Urine ketones - measured using Siemens Ketostix, reported as negative, trace, 0.05, 0.15, 0.4, 0.8, or 1.6 g ketone/litre urine. Reported by the participant by assessing colour change visually and entering result into the Reassure app running on an iOS or Android smartphone or tablet. The result is transferred via the internet to the L2S2 database
7. Weight – measured in kg using participant’s own scales, entered by the participant into the Reassure app running on an iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database. Only those participants who already self-monitor for weight under the instruction of their GP will be asked to report this parameter. Measurement frequency will be that requested by the GP (generally several times per week) and data will be collected for 12 weeks.
8. ECG - measured using CE-certified commercially available electrocardiogram, reported as normal or arrhythmia, data transcribed into the Reassure app running on an iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database.
9. Peak flow – reported as litres per minute breathed out and measured using a CE-certified commercially available peak flow meter, data transcribed into the Reassure app running on an iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database.
10. Participant self-assessment of state – reported through answering the question, “How are you feeling today” and assessed by the participant selecting one of five faces showing very sad /miserable, unhappy, neither happy nor sad, fairly happy, very happy in the Reassure app running

on an iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database
11. Blood glucose – reported as mmol/l and measured using a CE-certified commercially available glucometer, data transcribed into the Reassure App running on an iOS or Android smartphone or tablet and transferred via the internet to the L2S2 database. Only those participants who already self-monitor for blood glucose under the instruction of their GP will be asked to report this parameter. Measurement frequency will be that requested by the GP (generally several times per week) and data will be collected for 12 weeks.
12. Participant complication group – participants are categorised by primary and any secondary complication group they fall into. The complication groups are:
12.1. Circulation/blood
12.2. Respiratory
12.3. Gastrointestinal
12.4. Endocrine / Rheumatology
12.5. Renal/urology
12.6. Neurology
12.7. Psychiatry/psychology
12.8. Developmental
12.9. Sensory/age-related
12.10. Social/drug/ alcohol
This outcome measure is researched by inspection of the participant primary care record. This record is obtained with participant consent from their General Practice. This outcome measure is ascertained once before self-monitoring commences. If a participant falls into multiple Complication Groups then they will be categorized by the Complication Group into which their most serious condition falls.

Key secondary outcome(s))

1. Dropout percentage defined as the ratio of the number of days on which readings were taken by participants divided by the number of days the person participates in the study (84 being 12 weeks). This measure is determined after 12 weeks of self-measurement by the participant.
2. Frailty score is as extracted from the participant's medical record as the NHS electronic Frailty Index. The NHS Frailty Index is a risk stratification tool and frailty is confirmed using a validated tool such as the Gait Speed Test, PRISMA-7 or Timed Up and Go test. This measure is determined after 12 weeks of self-measurement by the participant.
3. Technical support calls, reported as the number of technical support calls made by trained Research Assistants to participants categorised by primary Complication Group. Technical support calls will be logged as they are made in the Reassure participant management system. Technical support calls will be categorised as:
3.1. Training the participant in the use of devices
3.2. Provision of additional training in the use of devices
3.3. Troubleshooting issues in the use of devices
This measure is determined after 12 weeks of self-measurement by the participant.
4. Identification of participants feelings about being involved in the trial, including feedback on different aspects of the study. Aspects will include:
4.1. Participant Information Leaflet
4.2. Recruitment procedure
4.3. Equipment set up procedure
4.4. Use of devices
4.5. Provision of technical support by Research Assistant
Feedback will be obtained by interviewing participants using qualitative and categorical questions to ascertain and categorise their feedback on the above aspects. This measure is determined after 12 weeks of self-measurement by the participant.

5. Identification of participants' perception of positive or negative effects resulting from participation in the study. Participants will be asked to provide feedback through structured interviews on their perception of the positive and negative effects of participation. This will be determined twice, once at around week 8 and once after 12 weeks of self-measurement. Categorical feedback will be requested to assess whether participants perceive benefit or disbenefit in the following attributes:
5.1. Anxiety about health
5.2. Behavioural changes to healthiness of lifestyle
Categories will be:
5.3. Large benefit
5.4. Small benefit
5.5. No change
5.6. Small disbenefit
5.7. Large disbenefit
Qualitative questioning will also be used to collect data on other attributes where participants perceive either benefit or disbenefit. These will be reported as a list and the number of times each one is reported. Qualitative questioning will also be used to collect other anecdotal observations from participants. These will be reported as a list and the number of times each one is reported.

Completion date
29/02/2024

Eligibility

Key inclusion criteria
1. Age >65 years
2. More than two comorbidities AND/OR
3. Medium or high frailty score AND/OR
4. More than one unscheduled urgent care attendances in the previous year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Children
2. Individuals for whom consent cannot be obtained (i.e. individuals with mental impairments)
3. Individuals who have rare chronic conditions which cannot be monitored with the devices used in the study (e.g. complex musculoskeletal conditions like ankylosing spondylitis, liver failure patients)
4. Patients on palliative care
5. Individuals whose wellbeing might be compromised through the measurements, such as an

individual with bullous skin disease or osteogenesis, imperfect with a blood pressure cuff
6. Individuals with mental health conditions whose wellbeing and care could be compromised by the introduction of measurements
7. Individuals living in locations significantly far away geographically from other prospective participants (e.g. in locations where domiciliary carers might not be able to cost-effectively reach to collect measurements)
8. Individuals who lose mental capacity during the study period will be removed from the study

Date of first enrolment
18/10/2021

Date of final enrolment
22/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Stansted Surgery
1st Floor Castle Maltings
Lower Street
Stansted
United Kingdom
CM24 8XG

Sponsor information

Organisation
NHS West Essex Clinical Commissioning Group

Funder(s)

Funder type
Government

Funder Name
NHS England

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the work being commissioned by the NHS and having commercial sensitivity.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version 0.02	21/10/2020	08/02/2022	No	Yes
Protocol file	version 2.2	12/06/2020	08/02/2022	No	No
Protocol file	Addendum version 2.3	22/10/2020	08/02/2022	No	No