Study Title: Service demand prediction based on information from connected devices - ADDENDUM

Internal Reference Number / Short title: Service demand prediction based on information from connected devices

Ethics Ref: TBC

IRAS Project ID: 276149

Date and Version No: 22/10/2020 V2.3

Chief Investigator:	Dr Thomas Hughes
Investigators:	Dr Thomas Hughes (L2S2), Dr Philip Gaffney (L2S2), Jane Aldridge (L2S2)
Sponsor:	NHS West Essex Clinical Commissioning Group Building 4, Spencer Close St Margaret's Hospital The Plain Epping CM16 6TN
Research Team:	L2S2 Ltd 2a Oakington Business Park Dry Drayton Road Cambridge CB24 3DQ
Chief Investigator Signature:	Dr Thomas Hughes [signed electronically in IRAS form]

Statistician Signature: Not interventional – Not applicable

Declaration of Conflicts of Interest: None

Confidentiality Statement

This document contains confidential information that must not be disclosed to anyone other than the Sponsor, the Research Team, Health Research Authority, host organisation, and members of the Research Ethics Committee, unless authorised to do so.

Patients at Home

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1. KEY CONTACTS

Chief Investigator	Dr Thomas Hughes, Medical Director, L2S2 Ltd 01223 234550, Tom.Hughes@l2s2.com
Sponsor	NHS West Essex Clinical Commissioning Group Peter Wightman, Director of Primary Care, West Essex Clinical Commissioning Group
Funder(s)	NHS England, via NHS West Essex Clinical Commissioning Group (Contracting Authority)
Research Team	L2S2 Ltd 2a Oakington Business Park Dry Drayton Road Cambridge CB24 3DQ philip.gaffney@l2s2.com
Statistician	Dr Thomas Hughes, Medical Director, L2S2 Ltd 01223 234550, Tom.Hughes@l2s2.com
Committees	West Essex Proof of Concept Project Board

2. LAY SUMMARY

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.

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. This hypothesis will be tested in a PoC trial.

3. SYNOPSIS

Study title	Service demand prediction based on information from connected devices		
Internal ref. no. / short title	Service demand prediction based on information from connected devices		
Study registration	IRAS Project ID 276149 17-11-2019		
Sponsor	NHS West Essex Clinical Commissioning Group, Building 4, Spencer Close, St Margaret's Hospital, The Plain, Epping, CM16 6TN.		
Funder	NHS England, Charter House, Parkway, Welwyn Garden City, AL8 6JL.		
Study Design	Clinical investigation or other study of a medical device		
Study Participants	Patients older than 65 years AND more than 2 comorbid conditions AND / OR more than one requirements for unscheduled urgent care in previous year AND / OR medium or high frailty score		
Sample Size	Phase 1: 100; Phase 2: 500		
Planned Study Period	Maximum project study period: 11 months Maximum patient participation period 24 weeks		
Planned Recruitment period	Phase 1: April/May 2020 Phase 2: July/August 2020		
	Objectives	Outcome Measures	Timepoint(s)
Primary	To test the hypothesis: 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.	Phase 1: 100 patients: Optimised models generate dynamic personalised monitoring plan for each participant. Phase 2: 500 patients: Model linking health outcomes to NHS activity will be developed and tested. Confidence of correlations between measured data and observed data from actual unscheduled care data during study period.	January 2021 April 2021

Secondary	Dropout Percentage: Number of readings taken by patients compared to their agreed plan.	Two percentages. Participants who can / want to receive automated compliance reminders. Participants who cannot / don't want to receive automated compliance reminders.	April 2021
	Correlation between adherence to agreed plan and the participant's frailty score.	Correlation	April 2021
	Number of visits required for each complication group by number of comorbid conditions to achieve best value	Table / charts / recommendations with confidence levels	April 2021
	Correlation of each type of device with each complication group as a predictor of exacerbation (i.e. determine which device(s) are most useful).	Table of devices / correlations / confidence levels.	April 2021
	Identify support functions that best enable patients in this category to effectively self-monitor using technology.	Table of support functions vs effectiveness of data collection / data quality	April 2021
	Identify how participants feel about being involved in the trial and obtain feedback on different aspects. Identify whether they perceive any aspects of the trial procedures could have positive or negative effects for them such as decreased anxiety about health, behavioural changes to healthier lifestyle.	Identify any other benefits / disbenefits to patients of remote monitoring and support services	April 2021
	Report any other anecdotal observations		April 20201
Intervention(s)	There are no clinical interventions in this study.		

Comparator	Comparison data will be obtained from GP surgeries participating in the study.

4. ABBREVIATIONS

CI	Chief Investigator
CRF	Case Report Form
CTRG	Clinical Trials & Research Governance, University of Oxford
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
NHS	National Health Service
RES	Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
SOP	Standard Operating Procedure

5. BACKGROUND AND RATIONALE

The original study protocol was split into two phases, a first phase in care homes and a second phase in patients' own homes as well as in care homes. Ethics committee permission has been granted for phase 1 in care homes with permission for phase 2 in patients' own homes deferred until results from phase 1 are available.

However, the global COVID pandemic delayed the start of phase 1 and made it significantly more difficult to obtain cooperation from care homes on this proof of concept trial. Moreover, the original protocol for both Phases made provision for health care assistants visiting participants in care homes if care home staff were unable to undertake the job of taking measurements from them, and such contact with vulnerable people was considered unacceptable in the light of the COVID-19 pandemic.

In this document, we adapt the trial protocol for the HRA approved Phase 1 to minimise person to person contact with participants. We also adapt the protocol for Phase 1 to allow participation by people in their own homes as well as in care home settings.

Instead of all Phase 1 trial participants being care home residents as originally planned, due to COVID-related problems with recruiting care homes as collaborators, we expect that the majority (and possibly all) of the participants will be individuals living in their own homes. Participants will each receive a set of

equipment and will self-monitor. They will not receive visits from carers but will be intensively supported in their use of the IT and monitoring equipment by health research assistants via phone and video calls.

A new outcome of this project will be to evidence an innovative method of remote monitoring of patients that does not require in person assistance but that is adapted for the needs of a trial cohort in which many participants may be relatively uncomfortable with technology. These modifications have the agreement of West Essex CCG and support from GPs.

If this method of monitoring proves successful it will provide a real opportunity for service transformation. It will enable patients, many of whom will be vulnerable, to be kept safe through monitoring and regular assessments. It will avoid unnecessary harm of possible COVID exposure from traditional regular face to face consultations. In particular, enlisting specialist staff to support patients in their use of IT will minimise the burden of support on qualified healthcare staff who will be free to provide skilled care to their patients. It may also significantly increase the efficiency and effectiveness of clinical staff.

The main change to the phase 1 study proposed here concerns the additional focus on elderly people living independently in their own homes, rather than just in care homes. The participant inclusion criteria will otherwise remain the same as already agreed by the HRA for phase 1 of this study. (To reach a statistically significant number of data points, whilst keeping cost and duration down, the study will target high risk patients who either have a history of repeat hospitalisations or have complex co-morbidities which result in frequent GP consultations and A&E visits.)

These participants will be recruited through collaboration with the Stansted Surgery. Dr Angus Henderson, a partner at the surgery, also works in the West Essex CCG medical directorate and is the Clinical Sponsor of this Proof of Concept Trial. Dr Henderson will be the key point of contact with the Stansted surgery.

The relationship with the Stansted Surgery is considered to be particularly beneficial during the global pandemic. Moreover, it will enable the study protocol to be tested and any learning from this process will be used to improve the protocol for Phase 2 of this Trial before it is submitted to the REC for approval.

L2S2 (the company responsible for conducting this proof of concept trial) has implemented many changes in its technology and workflow to make it possible for participants to use the equipment independently without face to face contact from Health Research Assistants as envisaged in the original protocol, to which this document is an addendum. These changes derive partly from learning acquired through operating remote monitoring applications in secondary care settings for more than a year.

As originally planned, we will still attempt to obtain support from care homes and recruit as many care home residents as possible to be trial participants. Participating care home residents will be recruited through their care homes and will be monitored using equipment operated by their care home staff as described in the original protocol to which this document is an addendum. As in private homes, there will be no direct face to face contact with L2S2 healthcare research assistants. These L2S2 representatives will provide remote IT support to internal care home staff. This will allow the research team to study the differences between those provided with in person support in care homes and those participating in their own homes with remote support.

The following highlighted paragraphs are reproduced verbatim from the protocol already accepted by the Ethics Committee.

This study focuses on the elderly for hypothesis testing. Our population is aging rapidly, driving changes in health and care needs in society. Between 2006 and 2016, the number of people over 65 years rose by 21% (1.7 million), with the 85's rising by more than 31% in England [1]. These demographic changes have been seen to have a significant impact on primary care - between 2011 and 2014, the number of annual GP appointments per person grew by 15.4%, mostly driven by growth among people over 65 years (growth among people under 65% was only 4% and population growth was 2%) [1]. Delays in accessing primary care have serious consequences for time-sensitive conditions such as ambulatory care sensitive conditions (ACSCs). Delayed interventions may result in avoidable ambulance and emergency department use, necessitate more intensive therapy and hospitalisation, or lead to increased morbidity or mortality. Hospital admissions for elderly with ACSCs have risen rapidly over the last decade and are currently estimated to account for 20-30% of hospitalisations [2,3]. Those suffering from multiple chronic conditions are most vulnerable [4-6]. Hospital admissions can be particularly disruptive to the elderly, exposing them to hospital acquired infections, functional decline and increasing dependency. With patients over 65 years accounting for 80% of the emergency admissions who stay for more than 2 weeks, these risks are very severe [7,8].

Studies have previously demonstrated the ability of telemedicine to decrease use of emergency departments and hospitalisations among vulnerable populations such as children and the elderly [9-12]. However, existing tools and guidelines were developed for the identification and management of individual health issues, verticalising problems. Yet, a complex patient suffers from multi-morbidity and polypharmacy. Consequently, they are often treated via a conglomeration of juxtaposed guidelines, taking more than 10 drugs a day with no certainty of efficacy [13]. Hence, the current disease-focused approach has been repeatedly subjected to scrutiny, calling instead for a patient-centred approach focused on personalised appropriateness and adherence [13,14]. The impact of a high-intensity telemonitoring model for holistic geriatric health (identification of acute disease & chronic exacerbations) implemented in senior communities has been documented by Shah et al [15,16]. Building upon this preliminary evidence, the study will conduct a structured evaluation of the ability of a holistic data collection process in the community to enable early detection of unplanned health needs in complex patients such as the elderly. Moreover, as evident from data submitted by the Authority, in West Essex, people over 65 constitute the majority of patients with complex healthcare needs and lead to the majority of expenditure on hospital admissions (Figure 2).

5.1 Population to be Studied

Patients older than 65 years AND more than 2 comorbid conditions AND/OR more than two requirements for unscheduled urgent care in previous year AND/OR medium or high frailty score. The study participants will live in the South Uttlesford area of East Anglia, in the north of the West Essex CCG territory unless we are unable to recruit sufficient patients, in which case the study area may be extended.

6. Method

a) Selection of participants

The study will use patient data held in records by the Stansted surgery to identify potential participants. Initially, a script will be run on the practice EMIS Electronic Health Record system to identify candidates using the inclusion and exclusion criteria. This script will be supplied by L2S2 to minimise the workload on the surgery.

The output will be ranked using use of urgent care services in the previous twelve months and number of comorbidities as the criteria. Recruitment will be aimed in the first instance at the individuals who have needed most urgent care and who have the largest number of comorbidities. This list will remain internal to the GP practices and will be reviewed by the GPs prior to participants being contacted. It will not be shared with L2S2 or with the CCG.

If it proves possible to recruit care home residents, candidate selection will be undertaken as described in the protocol approved by the HRA to which this document is an addendum.

A total of 100 participants (initial phase 1 target) will be enrolled who meet the study inclusion criteria.

b) Consenting process

The GP surgery staff will send the Information Pack comprising Invitation Letter, Consent Form, Patient Information Leaflet and a prepaid return envelope to potential participants identified as above and process the returned forms.

The research team has the agreed support of the North Thames Clinical Research Network, whose staff will support the consenting process. Participants will be advised in the information leaflet that they can call the CRN to provide consent over the telephone if they wish to. This will also provide them with the opportunity to ask further questions. Alternatively, the participant has the option to complete and return the consent form provided in their information pack, if they are satisfied they understand the study and are happy to take part without speaking to the CRN first.

CRN staff will be provided with a secure electronic version of the Consent Form to complete with the participant that guides the consent process and enables them to confirm that each stage of the consenting process has been performed. This form will be hosted on L2S2's NHS approved servers and the completed form will be stored in the trial record. Paper consent forms will also be securely stored by L2S2 until three months after the end of the study when they will be securely destroyed, the destruction being recorded. A copy of the completed form will be sent to participants when devices are posted to them.

On receipt of consent from the participant's personal data required for study purposes from the records of consented patients will be requested by L2S2 from the GP surgery. An EMIS script will be provided by L2S2 to run on the GP record system to extract these data. The use of this script will minimise the workload on the surgery.

This script will prepare an extract of the participants' data and this will be securely transferred via HSCN to L2S2. This will require minimal work on the part of the surgery. These data will include Name, Address, Telephone number, Email address, NHS number, Health conditions, Drugs, Record of last 12 months' clinical activity. These data will be used for the following purposes:

1) To uniquely identify the patient (Name, Address, NHS number)
2) To communicate with the patient via email, telephone and physical mail (Name, Address, Email address, Telephone number)
3) To send devices to the patient (Name, Address)
4) To inform the selection of monitoring devices (Health conditions, Record of last 12 months' clinical activity)
5) To provide contextual information for the analysis of remote monitoring data. (Health conditions, Record of last 12 months' activity)

In confirmation, there will be no transfer of participant data until consent has been received.

L2S2 will take over from the CRN staff at this point.

Electronic copies of the paper consent forms will be securely archived in the trial record following secure destruction of the paper versions three months after the end of the study. This is in line with the procedure to be followed for the electronic-only versions.

c) Choice of devices for each patient and support

Those participating in the study from their own homes will do so autonomously using the internet-enabled smartphone, the L2S2 Reassure application loaded onto the smartphone, and a set of devices appropriate to their co-morbidities.

Care home residents participating in the study will be assessed by care home staff using a set of devices, smartphone and Reassure application.

In order to minimise the effort required by the participants and to maximise likely compliance, participants will only be asked for measurements that generate vital signs data pertinent to their individual medical conditions. This will be guided by the initial rules set out in this protocol and by review of received data from each participant by L2S2's senior emergency care consultant (Dr Thomas Hughes OBE).

A member of the L2S2 trained and governance approved IT Health Research Assistants will be assigned to each participant and participating care home and, as far as possible, only this person will interact with these participants. This person will be responsible for liaising with each participant to make sure each stage of the protocol is carried out correctly and for building rapport with participants to make them feel more comfortable whist taking part.

d) Provisioning participants in their own homes with remote monitoring equipment

A package comprising a pre-configured dedicated smart phone with appropriate medical monitoring devices will be issued to each participant following consent. The equipment will be supplied with laminated guides, one for each device, bound into a booklet, that show the participant using simple diagrams with large text how to use each device.

The monitoring equipment package will be delivered to the participant's home by a courier who will follow COVID safe practices.

e) Technical support provided to participants

It has been acknowledged that the target cohort for this study is one that in general has lower familiarity and comfort in using technology than the population average. Therefore, special attention has been paid to developing protocols for assisting participants. In particular, L2S2 will utilise a team of Health Research Assistants who will not have any healthcare or healthcare-related role, but whose sole purpose will be to provide technical support and assistance to train participants in use of the technology and then support them throughout the trial.

The reason for using Health Research Assistants who are solely responsible for helping participants to use the equipment is that if it proves successful, then this trial will have evidenced an important move forward in the use of remote monitoring in this cohort. It has often been reported that it is difficult to implement remote monitoring, and clinical staff do not have the time to undertake the type of intensive support envisaged here; they should be free to provide care. Yet there is a clear need from the reports in the literature to be addressed.

All support provided by Health Research Assistance will be done so remotely by telephone or video conference.

f) Training participants in use of the equipment

The participant's allocated Health Research Assistant will contact the participant using the participant's own telephone as soon as the package is delivered.

Once identity has been confirmed, the first step will be to confirm that the Health Research Assistant is talking to the participant. Following this the Health Research Assistant will guide the participant through unpacking the monitoring devices.

The Health Research Assistants will ask the participant to turn on the supplied smart phone. As soon as the smart phone is turned on, secure video communication with the health research assistants will also be available at a single click to the participant. If it proves necessary, this will be used to show the participant what to do and to assist with instructions. If the 3G/4G data enabled smart phone cannot connect to the mobile network, short pre-installed video clips will be available to assist the commissioning process.

The next step is for the Health Research Assistants to give the participant a four digit PIN code to enter into their smart phone. This is part of a digital key pre-installed uniquely into each device prior to shipment to the patient. The participant's PIN will only work on their issued device and will ensure that the participant's privacy will be maintained. A simple number pad is provided with brightly coloured large numbers to make it easy for participants with poor eyesight. (See Appendix)

Once the participant has entered the Reassure app, they will be taught how to use their equipment. The Health Research Assistants will go through a training protocol that is supported by the information booklet supplied and support videos in the app as well as audio prompts on each screen.

These audio and video prompts are designed to remind participants how to use each device should they forget and a 'Request Help' feature will route a secure request for help to the participant's Health Research Assistant who will call the participant back.

g) Ongoing support throughout the trial

The Health Research Assistants will call the participants each week to ascertain if there are any problems and resolve them. The health research assistants will attempt to build up a rapport with the participants

and will also check how each one is feeling and whether there have been any health incidents in the previous week. A key aim will be to identify any stress in the use of the equipment, to ascertain the cause and resolve the issues that are causing the stress.

The Health Research Assistants will also call participants who fail to take measurements and will attempt to resolve any problems.

All calls to participants will be recorded.

In the event that there is a problem with a smart phone, or one needs to be replaced, a secure mechanism has been built into the Reassure application to enable the new device to use the same PIN and present an exact copy of the device being replaced, with all existing data being preserved.

Similarly, if there is a problem with a device, then the device will be swapped.

h) Participant's right to leave the trial

At any time, the participant can inform L2S2 either in discussion with the Health Research Assistant or via the messaging function in the app that they wish to leave the trial. If they do so, the Health Research Assistant will contact them to request that they allow L2S2 to keep their data in anonymised format.

i) Collection of measurement data

Measurement data will be sent to the Reassure servers automatically if the participant's Reassure smart phone is able to communicate via 3G/4G (estimated to be about 80% of participants – accurate numbers will be reported in the study report).

When connectivity is not available the smart phone will work normally and collect measurement data. The participant's Health Research Assistant will arrange for the smart phone to be swapped by courier at approximately four week intervals (COVID safe), so that research data can be received. The new smart phone will be pre-configured to be identical to the original phone and work with the same PIN code.

j) Learning from participants

Anecdotal information about use of the equipment, problems and other feedback will be collected routinely from participants through discussion with the health research assistants. This will also inform the design of a questionnaire that all participants will be asked to complete on leaving the trial. It is hoped that this learning will prove useful to help the design of future protocols for the use of self-monitoring in this cohort.

k) Analysis of data

Machine learning and statistical analysis will be used to determine the validity of using home collected and care home collected data from smart medical devices to predict future likelihood of requirements for unscheduled urgent care.

l) Monitoring of participants in care homes

The protocols developed for participants in care homes that have already been approved by the HRA will be used and so are not described here.

7. Risks (additional or different to those listed in the approved care home protocol)

L2S2 perform risk analyses to ISO 14971 as part of the company ISO 13485 Quality Management System (QMS).

L2S2 uses the following risk severity levels and risk matrix.

Severity Levels - Medical	
Term	Description
Catastrophic	Results in death
Critical	Results in permanent impairment to Life-threatening injury
Serious	Results in injury or impairment requiring medical intervention
Minor	Results in injury or impairment not requiring medical intervention
Negligible	Inconvenience or temporary discomfort

		Severity Levels				
		Negligible	Minor	Serious	Critical	Catastrophic
Probability Levels	Frequent	R2	R2	R3	R3	R3
	Probable	R2	R2	R2	R2	R3
	Occasional	R2	R2	R2	R2	R3
	Remote	R1	R1	R2	R2	R3
	Improbable	R1	R1	R2	R2	R3

R1 is acceptable risk, R2 is reasonable risk, R3 is unacceptable risk.

Risks for this project are listed below:

001 **Risk:** Participant finds the technology too difficult or becomes confused

Hazard: For some people the technology though simple will be too difficult to use

Hazardous Situation: The participant becomes anxious or stressed. This may happen at any time during the study.

Harm: Taking part in the study may turn out to be too difficult for some participants

Probability: Occasional

Severity: Serious

Risk Assessment: Reasonable

Mitigation: The assigned health research assistants will speak with the participant at least once per week, and more frequently when they join the study, to provide assistance and assess whether the participant is finding the study taxing. The Reassure app will provide information on the frequency

of use of the devices and failure to take readings will trigger a follow up call. If the participant remains anxious after a support call a review will be triggered to consider suggesting that the participant is taken out of the study.

Residual Risk: Acceptable

002 **Risk:** Contact Dermatitis

Hazard: Patient's skin reacts with surfaces of any of the medical devices

Hazardous Situation: Allergic or rash reaction happens after wearing / touching the devices

Harm: Discomfort, rash or swelling requiring intervention

Probability: Remote

Severity: Minor

Risk Assessment: Acceptable

Mitigation: Patients will be asked if they have a history of adverse effects from any contact materials as part of the study inclusion criteria and throughout the study. The participant's Health Research Assistant will check each time they communicate with the participant that no new rashes or soreness has developed through the use of any device, and to minimise any effects, the particular device will be withdrawn from the patient if any adverse effects are detected.

Residual Risk: Acceptable

003 **Risk:** COVID Contamination

Hazard: COVID infection is transferred between the participant and any study people or equipment

Hazardous Situation: COVID is potentially deadly and highly contagious. Physical contact between the participant and the courier or surface contamination of any physical devices may occur

Harm: Transfer of pathogen

Likelihood: Improbable

Severity: Critical

Risk Assessment: Reasonable

Mitigations: The activities that could result in transfer of pathogens are as follows:

1) **Packaging of the device kit**
   The kit will be assembled and configured in a room used only for this purpose. Safe handling procedures (gloves, face mask and visor, hydrogen peroxide cleaning etc.) will be used. All devices except the smart phone which is easily cleansed will be packed at least 72 hours before shipment. The devices will be sealed in plastic bags and shipped in an overall box container.

2) **Transfer of the device kit to the participant by the courier**
   The courier will deliver the sealed box to the patient following social distancing rules.
3) **Exchange of smart phone if connectivity is not available in the participant's home**
   The kit supplied to the patient will contain sealable, pre-labelled plastic biohazard bags and a pre-labelled sealable cardboard box into which the sealed plastic bag containing the item for return is placed. The L2S2 Health Research Assistant will liaise with the participant to ensure the exchange is carried out at a time and date convenient to the participant. The returned package will be stored unopened at L2S2 for 72 hours before being opened in a room used only for this purpose. The devices will be cleansed before data is extracted.
4) **Replacement of any medical devices required due to damage / failure etc. during the study**
   The L2S2 Health Research Assistant will liaise with the patient to ensure the exchange is carried out efficiently, following the same procedures as in 3 above.
5) **Final collection of devices and reprocessing**
   The devices will be returned in sealed bags in a pre-labelled cardboard box. The collection of devices will be organised by the L2S2 health research assistant. Devices will be held in quarantine for at least 72 hours before the cleaning and repatriation process is undertaken.

Residual Risk: Acceptable

004. **Risk:** During a call between a participant and a Health Research Assistant (HRA), the HRA, becomes aware of a potential serious patient health issue that may require urgent medical attention that the participant and their family / carers are not aware of.

Note. No harm will result directly from participation in the trial

Hazard: In the absence of action by the HRA, the participant and / or their family / carers may be unaware of the health issue or its seriousness and fail to request medical assistance.

Hazardous situation: The trial participant could suffer deterioration or complications from a health issue.

Harm: Whilst a health issue could result in deterioration or complications for the participant, any deterioration or complications would not have been caused by participation in the trial. **Thus no harm will result directly from participation in the trial.**

Probability: Occasional

Severity: Serious

Risk Assessment: Reasonable

Mitigations:

1) If the HRA is aware of a potential serious health issue, they will contact an appropriate healthcare provider, e.g. GP / 111 / 999.
2) Full notes will be made in the trial record of the circumstances and action taken.

Residual Risk: Acceptable

005 **Risk:** During the trial, the participant mentions a concern they have regarding their health to the HRA instead of to their GP.

Hazard: Instead of reporting the concern to the GP, the participant reports it to the HRA.

Hazardous situation: The trial participant could suffer deterioration or complications from a health issue that the GP is unaware of.

Harm: The participant suffers deterioration or complications that would have been avoided had they contacted their healthcare provider.

Probability: Occasional

Severity: Serious

Risk Assessment: Reasonable

Mitigations:

1) If the HRA is made aware of a potential serious health issue, they will advise the participant to contact an appropriate healthcare provider e.g. GP / 111 / 999. If they are not confident that the patient will be able to do this, they will do so themselves
2) Full notes will be made in the trial record of the circumstances and action taken.

Residual risk: Acceptable.

8. Conditions Determined at Initial Triage and Discussion with GP if Applicable

For **Phase 1**, in care homes, all devices will be used to take measurements from all participants. Devices will be issued to care home staffs who will use them to ensure correct use and valid data. Participants in their own homes will be allocated devices as follows:

Heart failure
Heart rate, BP, spO2, CO2 (using N-Tidal device if CE approved in time)

COPD / Asthma
Peak flow, spO2, respiration rate, thermometer, CO2 (using N-Tidal device if CE approved in time)

Frailty / Falls / possible Syncope
Heart rate, ECG, BP, spO2, CO2 (using N-Tidal device if CE approved in time)

High frailty bedbound
Heart rate, spO2, thermometer, respiration rate, CO2 (using N-Tidal device if CE approved in time), BP

Blood disorders / immune suppression / post chemotherapy
Temperature, spO2, respiration rate, CO2 (using N-Tidal device if CE approved in time)

Diabetes
Blood sugar, temperature

Renal failure / Liver failure

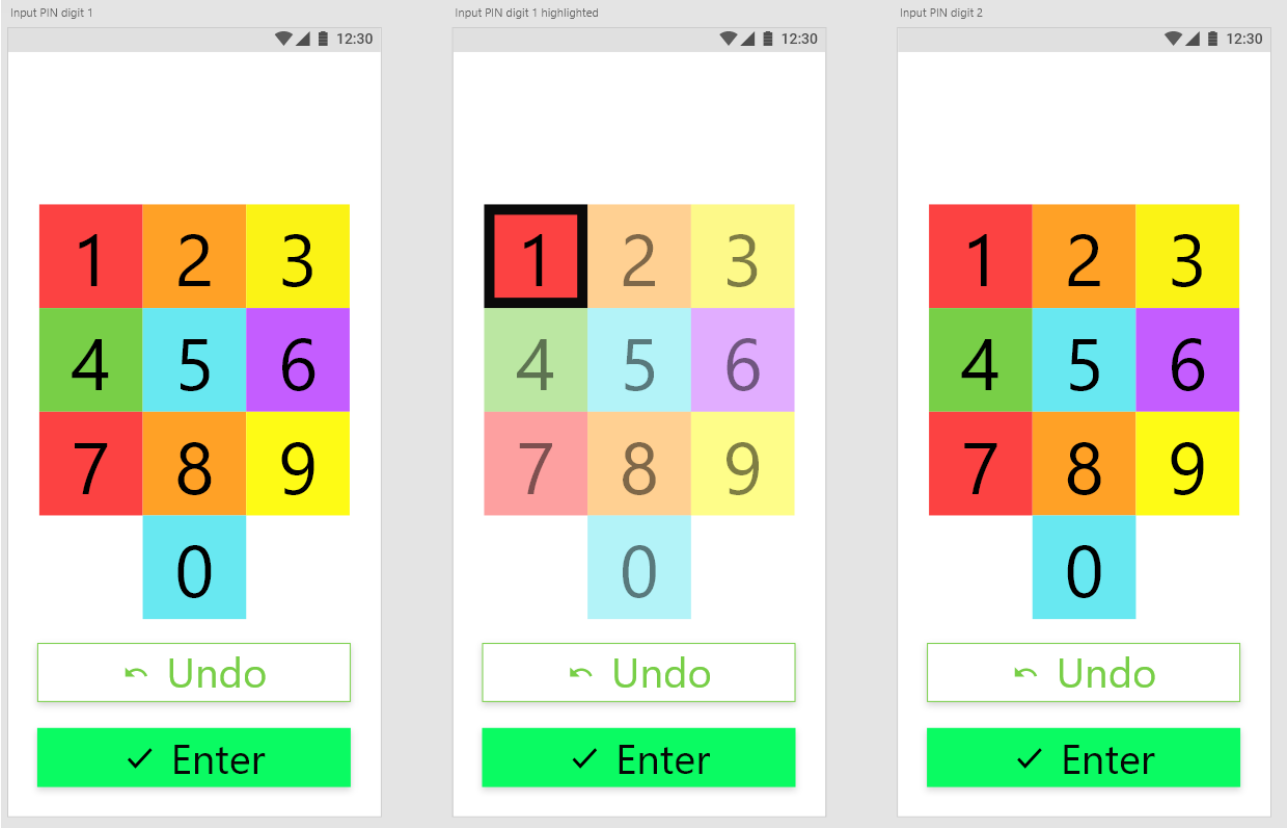
Blood pressure, temperature, blood sugar

This protocol addendum includes all additions and amendments to the research protocol already submitted and agreed.

Appendix – PIN number entry

It is important that when participants use the app on the supplied mobile device that they are positively identified.

Given the cohort, it was decided that the native number entry functions on Apple and Android phones could potentially prove too complicated. For this reason, the following screen layouts have been designed. The user will enter their PIN number using the keypad which will appear as shown on the phone screen.



The large buttons will help people with poor eyesight and / or dexterity to enter their PIN code.