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CONtact TrAcing in Care homes using digital Technology (CONTACT) - A Non-Randomised Feasibility Study

Study Title:	CONtact TrAcing in Care homes using digital Technology (CONTACT) – a non-randomised feasibility study
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1. KEY CONTACTS:

Study enquiries	**Email: contact-trial@leeds.ac.uk**

Chief Investigator:

Professor Carl Thompson	
School of Healthcare, Faculty of Medicine and Health, University of Leeds, Leeds, LS2 9JT	**Email:** C.A.Thompson@leeds.ac.uk **Tel:** 07939254863

Funder:

National Institute for Health Research	
COVID-19: Recovery and Learning cross-programme stream	**Email:** enquiries@nihr.ac.uk

Sponsor:

University of Leeds	
Faculty Research Office Faculty of Medicine and Health Level 9 Worsley Building University of Leeds, LS2 9JT	**Email:** governance-ethics@leeds.ac.uk **Tel:** 0113 343 7587

Lead Methodologist:

Professor Amanda Farrin	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** A.J.Farrin@leeds.ac.uk

Supervising Statistician

Bonnie Cundill	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** B.E.Cundill@leeds.ac.uk

Trial Statistician

Ellen Mason	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** E.Mason1@leeds.ac.uk

CTRU Project Delivery Lead

Suzanne Hartley	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** S.Hartley@leeds.ac.uk

Senior Trial Manager

Amanda Lilley-Kelly	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** A.C.Lilley-Kelly@leeds.ac.uk

Data Manager

Tom Shillito	
Clinical Trials Research Unit (CTRU) University of Leeds, Leeds, LS2 9JT	**Email:** T.D.Shillito@leeds.ac.uk

Health Economics Lead

Professor Chris Bojke	
Academic Unit of Health Economics, Leeds Institute for Health Sciences University of Leeds, Leeds, LS2 9JT	**Email:** C.Bojke@leeds.ac.uk

Senior Research Fellow

Dr Amrit Daffu-O'Reilly	
School of Healthcare, Faculty of Medicine and Health, University of Leeds, Leeds, LS2 9JT	**Email:** A.K.DaffuOReilly@leeds.ac.uk

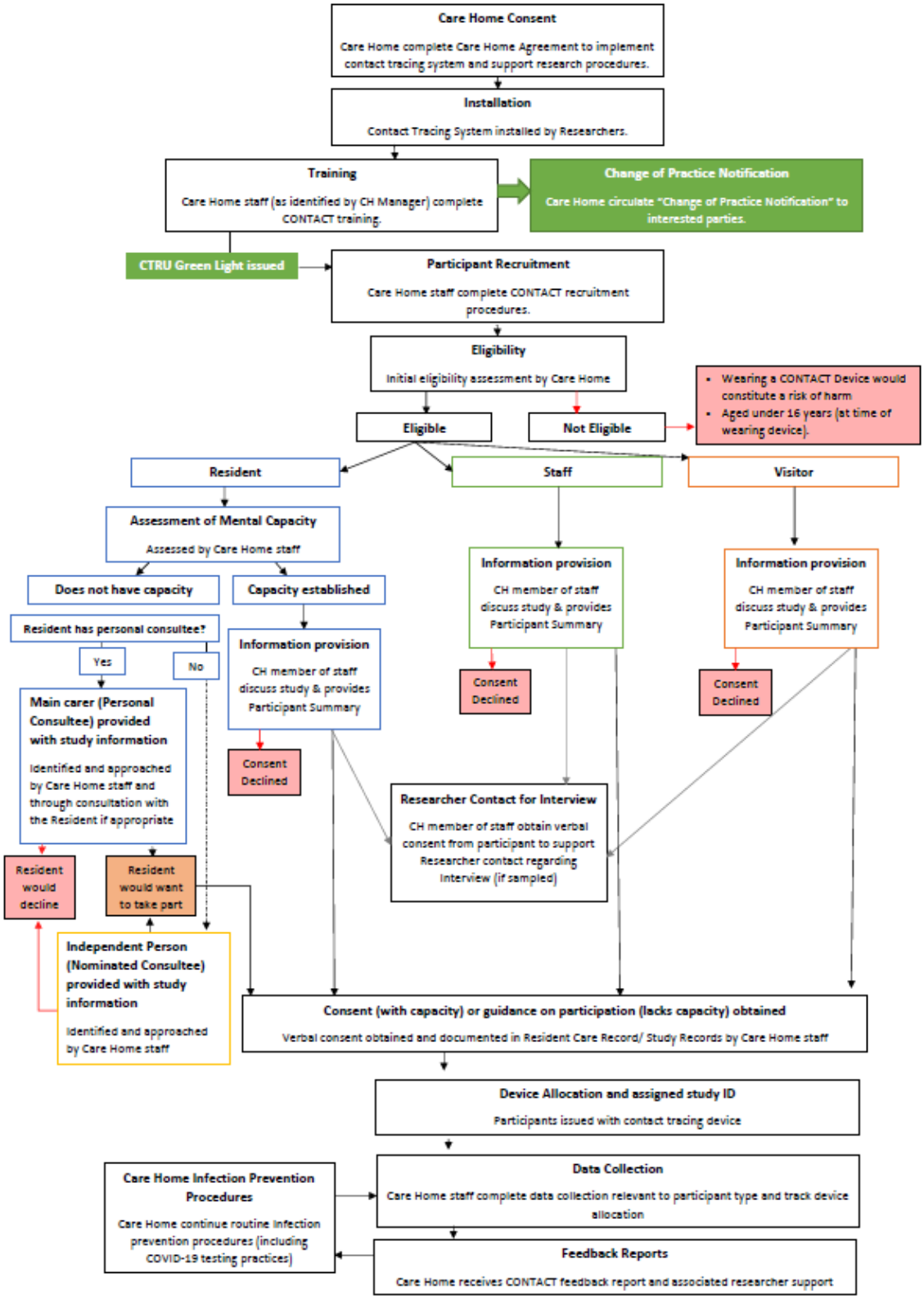
Co-Applicants

Professor Adam Gordon	
Professor in the Care of Older People University of Nottingham	**Email:** Adam.Gordon@nottingham.ac.uk
Dr Tom Hall	
Director of Public Health South Tyneside Council	**Email:** Tom.Hall@southtyneside.gov.uk
Professor Catherine Noakes	
School of Civil Engineering, University of Leeds, Leeds, LS2 9JT	**Email:** C.J.Noakes@leeds.ac.uk
Professor Andrew Kemp	
University of Leeds, Leeds, LS2 9JT	**Email:** A.H.Kemp@leeds.ac.uk
Professor Karen Spilsbury	
School of Healthcare, University of Leeds, Leeds, LS2 9JT	**Email:** k.spilsbury@leeds.ac.uk
Ms Cyd Akrill	
PPI Representative Springfield Healthcare	**Email:** cyd.akrill@springfieldcarevillages.com
Mr Peter Hodkinson	
PPI Representative Westward Care	**Email:** PHodkinson@westwardcare.co.uk

2. CONTENTS

3. STUDY FLOW CHART

3.1. Study Design



3.2. Intervention installation, training and delivery

Development of contact tracing "system plan" tailored to individual care home set-up based on CH floor/site plans.

Installation of LoraWAN network (beacons) and delivery of contact tracing devices – including validation of system to ensure accurate data collection.

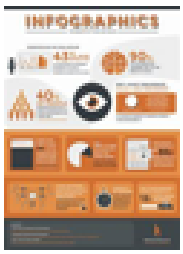
Staff Training (Research Lead/Senior Management Team/Gate keeper) including issuing and monitoring allocation of devices.

Implementation of contact tracing with records of devices allocation (existing/new)

Data collection

(Devices/Care Home Demographics/COVID testing/Safety)

Care Home Feedback

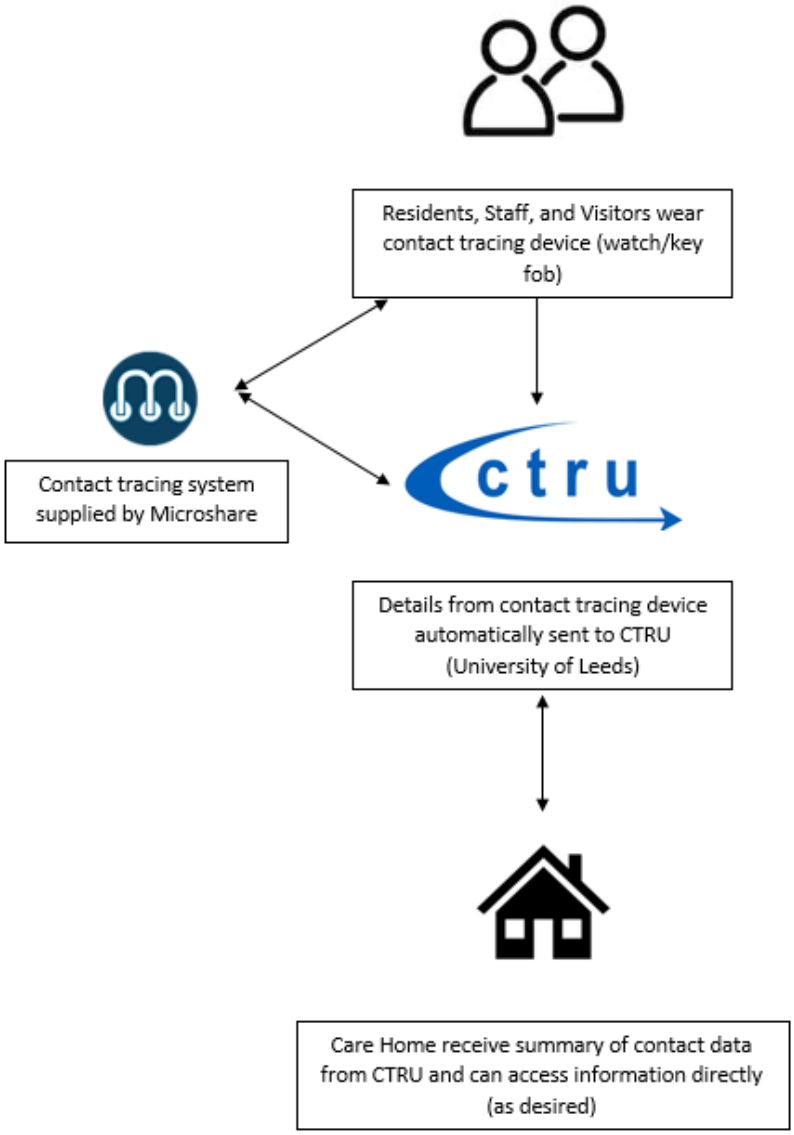


CONTACT summary infographic outlining key messages for infection prevention strategies.

CONTACT researcher discussions to support review of information summarised in infographic.

Care Home access to Microshare dashboard to review additional contact tracing data (as desired).

3.3. Data Flow



The following IT system providers will store and process data for this project:

- Clinical Trials Research Unit (CTRU), University of Leeds
  The CTRU has a current NHS Digital Data Security and Protection Toolkit accreditation
- Microshare
  Microshare hold a current UK Cyber Security Essentials accreditation
- Elsevier Veridata EDC
  Elsevier has a current NHS Digital Data Security and Protection Toolkit accreditation as well as a current ISO27001 accreditation

Each IT system provider will:

- Only collect, store and process the data required to conduct this study
- Restrict access to this data to just members of the study team
- Not pass on any identifiable data to any 3rd party

When data is being transferred between IT systems it will be done using an encrypted https connection using modern encryption ciphers.

3.4. Study Progression

Acceptability and provision of the intervention, as well as acceptability of the CONTACT feedback report and data flows will be assessed at the end of the two months feasibility phase in order to inform progression to the definitive cluster randomised trial.

Criterion	Objective	Green	Amber	Red
Acceptability of the intervention	Proportion of participants wearing the device	71%+	51-70%	<50%
Provision of the intervention	Proportion of active CONTACT devices not recording data for >1 week	20%	21%-30%	>31%
Acceptability of CONTACT feedback report	Demonstrated acceptability of outputs ascertained through Manager interviews.			

4. BACKGROUND

4.1. Nature of the problem

The COVID-19 pandemic has had a tragic impact on the ~411,000 older people that live in 15,517 care homes in England and Wales. There is no vaccine, and even if a vaccine is developed the levels of immunity and optimal immunisation regimen for the very elderly will likely differ from the (younger) general population.[1] With >17,509 deaths (possibly as high as 30,000) since the start of the pandemic, infection rates within homes as high as 80% and mortality rates of 30-50%[2, 3] it is clear that infection control, informed by regular testing for active virus via reverse-transcriptase polymerase chain reaction (rt-PCR) antibody testing and effective management of contacts between staff, residents and visitors in homes (currently weekly for staff and monthly for residents) will be key to managing and containing COVID-19.[2] Cohort studies, simulations and epidemiological studies have found staff are a key source of outbreaks and transmission in homes[2]; in particular, staff entry/re-entry, including community and agency nurses.[4, 5]

4.2. Rationale for the present approach

Testing of staff and residents without contact tracing will not be enough for effective public health interventions and reduced community transmission.[6] Conventional structured interview and documentary contact tracing is likely ineffective in care homes. In the many homes where 70-80% of residents live with dementia and staff have more than 50 contacts per day [26] recalling historic contacts using interviews is unfeasible.

NHS Test and Trace-style contact tracing is labour intensive, inefficient and burdensome for contacts and tracers alike.[6] Smartphone-based solutions to support contact tracing have limited utility even in the general population [27], but have even less in care homes – where few residents use such technology and staff are sometimes discouraged from using them in the workplace.

Wearable digital devices can help overcome the flaws in contact tracing in care homes using human tracers and smartphones. Advances in network technology mean small, discrete, wearables, with battery life of up to a year can capture contacts between individuals and their environments. Key information for contact tracing (when, who, where and how long and frequency of contacts) is easily generated, stored and recalled. Lightweight tags on lanyards, clothing or wristbands, often used already in homes for access control and resembling fitbits™, make real-time and retrospective capture, encryption, storage and recall of contacts realistic.

We are planning to evaluate, through a large scale cluster randomised trial in care homes in Yorkshire and the East Midlands, whether wearable digital contact tracing devices and tailored feedback of results (CONTACT intervention) are a cost-effective means of generating contact data in care homes, improving infection control and COVID-19 resident infection rates and mortality, compared with contact tracing as usual. Although contact tracing devices are widely used in manufacturing and other high risk industries and have been used in academic research contexts [28] they are mostly enacted in

the form of smartphone or other "smart" device apps that make use of Bluetooth and similar facilities. Systematic reviews suggest such approaches are limited by (low or partial) take up and empirical evidence of benefits are scarce. [29] Whilst mooted as an industry "solution" to the problems of care home based contact tracing [30] we are not aware of any rigorously evaluated non smartphone based digital device contact tracing empirical studies. Whilst devices are beginning to be used in small scale industry context, evaluations have been restricted to simulation-based modelling. [31] Therefore, prior to the definitive trial we will assess the acceptability and feasibility of intervention delivery processes, and trial design/implementation, in a single arm feasibility study, in six care homes.

This protocol is for the single arm feasibility study.

5. FEASIBILITY STUDY AIMS AND OBJECTIVES

5.1. Aims

The aim of this feasibility study is to 1) assess acceptability and feasibility of intervention delivery processes; and 2) assess the acceptability and feasibility of study design and implementation process; to inform processes for the subsequent definitive cluster randomised controlled trial of the CONTACT Intervention versus Usual Care (UC).

5.2. Objectives

Objectives of the feasibility study are to assess the:

<u>Acceptability and feasibility of intervention delivery processes</u>

Contact Tracing Devices

- Ease of administering the devices to people living and working in the care home, as well as family caregivers, health care professionals and external visitors to the home
- Feasibility of completing the associated paperwork, including the linkage of devices with individual identities for residents, staff and visitors in the homes
- Acceptability of wearing the devices and reasons for non-wear
- Evaluate loss/breakage/replacement requirements in a one month period

Tailored feedback

- Explore feasibility of proposed methods of CONTACT tracing feedback (format, content, frequency)
- Explore feasibility of linking information with established COVID-19 research database to correlate infection control measures (Vivaldi – DHSC)
- Explore feasibility of developing relevant viewable data in Microshare dashboard platform
- Accessibility and engagement of the homes with the Microshare dashboard
- Establish research team processes and capacity to handle queries or problems from sites in relation to intervention delivery

Site engagement – intervention delivery

- Assess any barriers to being a study champion in the sites
- Attendance and engagement with face-to-face training for the champion and/manager understanding on how to use the CONTACT technology
- Feasibility of conducting engagement phone calls to homes
- Attendance and engagement with engagement webinars for homes

To assess the acceptability and feasibility of study design/implementation processes

Device software

- Evaluate success/failure in data capture, transmission and analysis as well as rates of contacts and contextualized data behind the data driven picture.
- Ensure data transmission software works (transfer-reading of data at trials unit; storage; analysis)
- Investigate non-compliance/site adaptations of technology or study processes.

Site engagement – study delivery

- Evaluate site willingness and capacity for the main trial – are they committed to the study?
- What issues do sites have with managing the study?
- Any issues from study team in delivery in the real world?

Data collection

- Feasibility of gathering data on COVID-19 testing and results to inform proposed primary outcome for the definitive trial
    - Feasibility of gathering data on other infections (Infection data – rates of communicable transmissible diseases relevant to infection prevention management)
-
- Feasibility of collecting demographics at the care home, staff and resident levels
- Feasibility of collecting economic data (i.e. resource use data – hospital episodes) at the resident level

Progression Criteria

At the end of this feasibility study, we aim to have acceptable levels of feasibility and acceptability to proceed to definitive cluster randomised Controlled Trial (cRCT):

a. Acceptability of the intervention - through proportion of participants wearing the device;
b. Provision of the intervention - through the proportion of CONTACT data obtained from those wearing the device;
c. Acceptability of the CONTACT feedback report – demonstrated acceptability of outputs ascertained through manager interviews;
d. Acceptable data flows – demonstrated feasibility of data collection processes through data completion rates

We will also explore feasibility and acceptability in the process evaluation running alongside the main trial and when planning for dissemination and tailoring of messages to encourage adoption (should

results merit this) as part of our Knowledge-to-Action approach designed to optimise the chances of successful spread and adoption within multi-level networks of policy and organisational actors and communities. (see process evaluation section 12)

6. DESIGN

The CONTACT feasibility study is a single arm non-randomised trial, taking place across 6 care homes in North and West Yorkshire, with approximately 1200 frontline staff, residents and visitors. As this is feasibility for a large scale cluster randomised trial permission will be sought from each Care Home manager (or delegate) to participate in the study (delivery of contact tracing system to be implemented as new standard care). Permission will include implementation of the contract tracing intervention for all residents, staff and visitors.

CONTACT is a whole-home intervention – all residents, staff and visitors within the home will be eligible for the intervention except for those residents for whom the wearable device would constitute a risk of harm as assessed by care home manager (or delegate). Those eligible will be invited to wear the CONTACT intervention device for the duration of the study, but this will not be compulsory. Reasons for non-wear will be documented.

Each wearable device has a unique ID. The wearable device scans for other devices nearby and records the other device ID, signal strength (proxy for distance), duration and timestamp. If devices have been in close contact, a "proximity event" will be recorded by the device, and this will be transmitted to Microshare with the device IDs. No personal information is stored on the device.

Data received from Microshare (proximity events/signal strength/battery life/date and time) will be shared with Researchers at the University of Leeds, who will process it to develop tailored feedback reports on contact patterns and trends (for example, decreasing/increasing staff-resident contacts, location of contacts, number of 'close' (current guidance <2M – 15min) contacts, or increasing/decreasing compliance with contact-related infection control) for each home. Researchers will support care homes to understand the reports, and data within the reports, to help inform their infection control measures. We will explore the feasibility of developing and utilising Microshare dashboards, and make available to the care homes to provide real time data on contacts.

Data transmitted to Microshare from devices will be retained on the Microshare network for up to 1 week (7 days) before being deleted. This data will act as a back-up in the event of issues with data download at the University of Leeds, ensuring robust data capture mechanisms.

Homes will maintain details (via a database or paper based system) of device IDs assigned to each resident, staff and visitor. Information on COVID-19 test results, and changes in residents. Including residents leaving and joining the home, and deaths. Care home, resident and staff demographics will be recorded to aid in the interpretation of the findings.

The research team will be responsible for installation, training and ongoing support. Residents, Staff, and visitors will be invited to take part in interviews to explore knowledge and experience with use of

device, feedback and data collection (where appropriate). Data on this will be recorded. Mechanisms to combine information from CONTACT with wider NHS and PHE processes will be explored. The project PI will contact local Directors of Public Health, Health Protection Teams and Test and Trace leads, making them aware of the study and the ability to provide them with detailed within-home contact information on request from them or as a result of a positive test in the home and the desire of external (to the home) test and trace infrastructure for contact information. No identifiable information will be shared with wider NHS or PHE by the research team.

Contact data will be collected over a minimum of two months from installation of the devices, to inform progression to the cluster Randomised Controlled Trial (cRCT). We propose to continue collecting data on acceptability of feedback reports in two homes (initial feasibility) for up to 12 months to allow homes to further make use of the technology to work with the homes as a testbed for working hypotheses developing as a result of the study or from approaches from other COVID-19 research (subject to approval).

7. ELIGIBILITY

7.1. Care Home eligibility

The feasibility study will take place in 6 care homes in North and West Yorkshire.

These care homes will agree to the following:

- Willing to provide a care Home Manager or nominated person to act as *research lead* for the duration of the project.
- Agree to release staff for brief training, intervention implementation and provision of data, and process evaluation activities.
- Agree to support the use of the contact tracing wearable in the care home.

These care homes do not have any of the following:

- Their own contact tracing technology to supplement planned activities by local authorities and / or Public Health England.
- Any role in another study which conflicts with CONTACT or data collection

7.2. Participants (Residents/Staff/Visitors)

All-home eligibility will be assessed by the care home manager (or delegate), with support from the CONTACT research team. The CONTACT study aims to be inclusive of all contacts (Residents/Staff/Visitors) occurring within a care home to maximise success of contract tracing data, therefore limited criteria apply for participation.

7.2.1 Inclusion criteria:

- Resident, Staff member, or visitor at participating care home during active participation.

- Willing to wear contact tracing device during presence in care home.

7.2.2 Exclusion criteria

- Wearing a CONTACT Device would constitute a risk of harm (for example, pica disorders), in the opinion of the care home manager (or other care home staff)
- Aged under 16 years (at time of wearing device).

8. INVOLVEMENT OF CARE HOMES AND PARTICIPANTS

8.1. Care Home

The feasibility study will take place in 6 care homes in Leeds, West Yorkshire.

Care homes have an obligation to implement a system to request and record details of residents, staff and visitors, and to use this information to track and trace people who may have been exposed to COVID-19, and support implementation of effective infection control.

CONTACT provides a potential mechanism for homes to fulfil their obligation to implement track and trace measures, and is of public interest. By agreeing to participate in the CONTACT study, the care home is agreeing to implement a contact tracing system as a new standard of care, with all residents (fulfilling the eligibility criteria), staff and visitors to be asked to wear a device, and for contacts within the care home to be used for the purposes of contract tracing.

8.2. Participant

As part of implementing a new standard of care, care homes will be asked to support residents, staff, and visitors in wearing a contact tracing *device* on either a bracelet or on a key ring that can be affixed to a lanyard or clothing, and use of contact data collected by the *device* to be used as contract-tracing.

CONTACT aims to include everyone present within (or with access to) the care home following contact system installation and activation. Potential participants (Residents/Staff/Visitors) will be assessed for eligibility by trained care home staff, with all those eligible approached regarding participation. Reasons for ineligibility will be documented. Each participant will be allocated a study specific ID, which will be used to identify each individual.

8.2.1 Residents

Once all eligible residents are identified, the care home manager (or delegate) will undertake an assessment of the capacity of each eligible resident to consent to take part in the trial. All residents will be assumed to have capacity to consent unless assessed to lack capacity in accordance with Mental Capacity Act 2005 [90] guidance. The care home manager (or delegate) will then consult with appropriate parties to obtain written consent to participate. The consent process will be undertaken and witnessed by trained members of the care home team and evidenced in the appropriate records

(resident care plan/ study records), including date written consent obtained, by whom, and how (including details of information provision – i.e. email/postal).

To ensure interested parties (i.e. all family members/visiting friends) are aware of changes in care home practice information will be available within the home (PIS/Poster) and directed communications (Change of practice Notification) in accordance with usual practice will be sent to all interested parties (as determined by CH Manager or delegate) not present within the home (i.e. email/newsletter/meetings). This will include details of how more information can be obtained about the study.

*8.2.1.1 Consent for those **with** capacity*

Where a resident is deemed to have capacity to give informed consent, a trained member of staff will discuss the study with the resident and provide them with an Information Sheet. Up to 24 hours later, to allow the resident time to consider the information and discuss taking part with a relative or close friend if they wish, the resident will be given the opportunity to ask any further questions they might have. Written consent to participate in the study will then be sought and evidence will be documented in the residents care plan.

*8.2.1.2 Consent for those **without** capacity*

Where a resident is assessed to lack capacity to give informed consent a 'Personal Consultee' will be appointed who can be consulted about what the Resident's wishes would be if they did have capacity. This will normally be a relative or close friend. Where the Resident has no close family or friend able or willing to act as Personal Consultee, another appropriate independent person, who knows them well but who is not actively involved in any elements of the research process, will be appointed as a 'Nominated Consultee'.

The following process will be followed to appoint a consultee and gain their advice on the resident's wishes.

Following the capacity assessment, the care home manager (or delegate) will identify the Resident's main carer / point of contact. The care home will then send the identified person a Personal Consultee Information Sheet, and the associated Participant Information Sheet via the usual method of contact (for example email/postal).

After 48 hours the care home manager (or delegate) will phone the main carer to discuss the information and determine if they are willing to act as a personal consultee. After undertaking appropriate consultation with the Resident and other relatives/close friends and carers within the home, where appropriate, the consultee will be asked to determine if they feel the resident would like to take part.

If the home are unable to identify a personal consultee, fail to establish contact with identified person, or the identified person is unable to take on the role of a consultee following discussion with the care home team (anticipated 48 hours after information provision); an appropriate independent person within the home will be approached with a Nominated Consultee Information Sheet, and associated Participant Information Sheet to help determine the resident's wishes.
A Personal or Nominated Consultee can indicate at any time if they feel the person they are representing has changed their mind about participating in the study and to withdraw them from

participation. Likewise if the care team feel that during the study, the wishes of a person who lacks capacity may have changed in regard to participating in the trial, they will seek advice from the personal or nominated consultee about the resident's continued inclusion.

8.2.2 Staff

Once all appropriate staff members have been identified, the home manager (or delegate) will discuss the study with all eligible staff members and provide them with an Information Sheet. Up to 24 hours later, the home manager (and witness) will review participation allowing staff members to raise any questions they may have. If appropriate verbal consent to participate in the study will then be sought.

The consent process will be undertaken and witnessed by trained members of the care home team and evidenced in the appropriate records.

8.2.3 Visitors

At the time of visiting the home, following determination of eligibility all visitors will be informed of the study and provided with an Information Sheet. Following review of information, and the opportunity to ask any questions the home manager (or trained delegate) will determine participation and obtain verbal consent to participate. The consent process will be witnessed and appropriately evidenced in the study records.

8.3. Transparency information

As study activity will be undertaken by trained care home staff with remote Researcher support we will have multiple methods of providing information on the purpose and benefits to all people that may access the home to ensure participants are well informed, whilst minimizing workload for the care home. We will use posters and infographics in prominent areas of the home to raise awareness of contact tracing and the study (data collection), with supplementary information (information sheets/pamphlets) tailored to audience (resident/staff) available upon request. These will also aim to provide reassurance to device users that they themselves are not being traced or tracked.

Study materials will be designed to implement a layered-approach to information provision, with an aim to simply portray key study activities proportionate to anticipated risk. All materials will be provided to homes in English. As part of feasibility activity the CONTACT Researchers will explore requirements for translation of materials.

9. INTERVENTION DETAILS

In accordance with a cluster design, care homes will be asked to implement the contact tracing system as a new standard care. Participation (Residents, staff, and relatives) in the study will entail provision of information.

The study intervention will use contact event data, captured by contract tracing technology, to inform tailored feedback to each care home. The feedback, provided periodically, will include contact patterns and trends, which can be used to help homes plan and evaluate their infection control procedures, such

as grouping of residents/staff, environmental zoning and modification, to reduce COVID-19 infection rates.

The contact information (feedback reports) from contact tracing devices is only designed to inform infection prevention in the best interests of the individual and the home when a confirmed COVID+ contact has happened, with care homes making decisions on appropriate course of action dependent on usual care practices. Contact tracing devices do not use GPS and do not "track" participant movements within a home. Devices collect limited information (Device IDs from interactions, signal strength, duration, and battery life) with no personal details linked to devices – only members of the care home and relevant CONTACT team would be able to link people to devices for the purpose of effective infection control. Device data (feedback reports) will not provide details on individual's movements around the home.

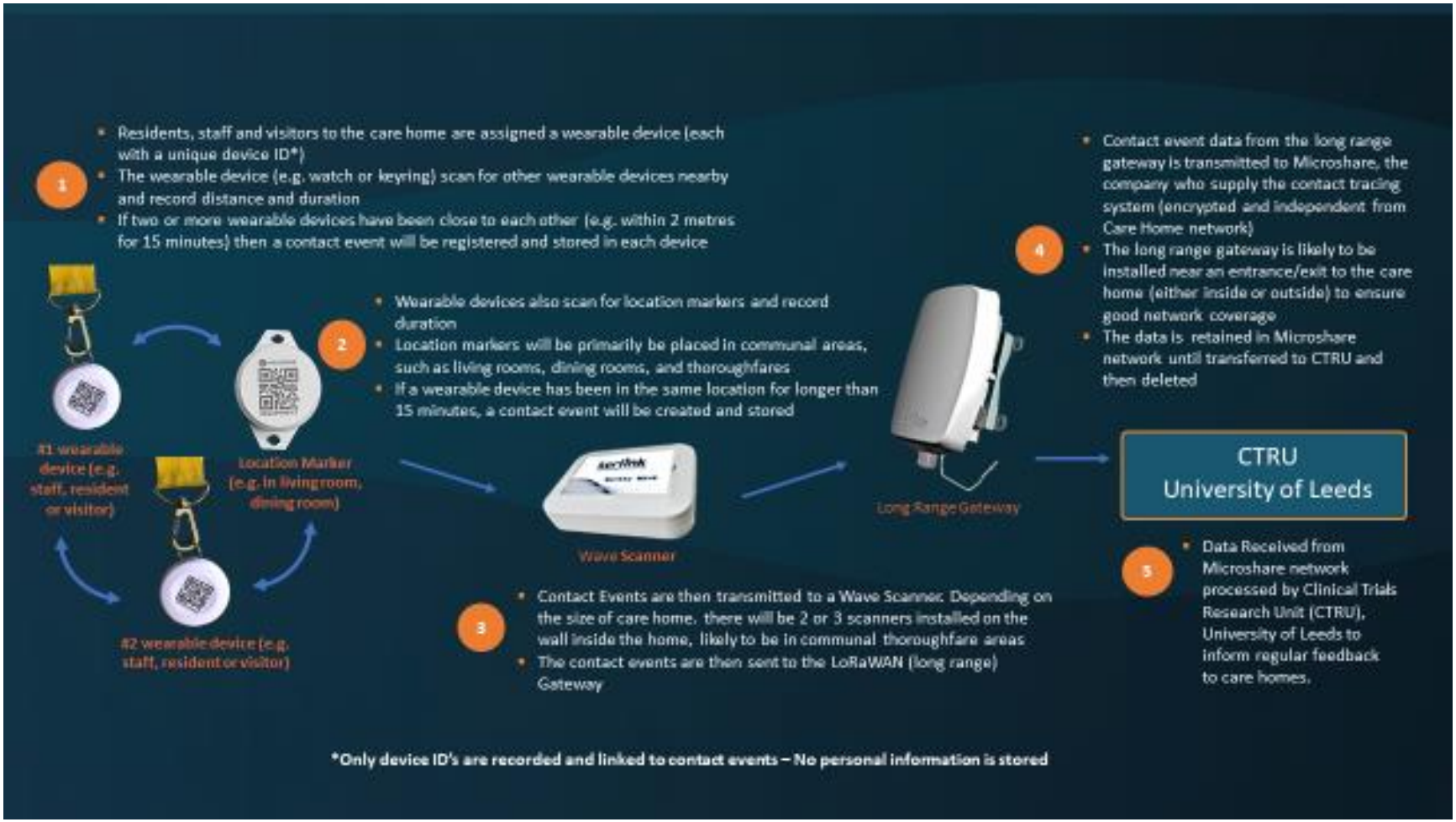
9.1. About the contact tracing system

CONTACT's 'Universal Contact Tracing technology is provided by Microshare® Inc4.

Personal, wearable devices use sensors, scanning continuously to detect and record a contact event while in the proximity of other wearable devices or location markers. Location markers are similar in size to a wearable device but placed in a static location; the location markers also use sensors to detect contact events. A wave scanner then retrieves the contact events from wearable devices and location markers via BLE (Bluetooth Low Energy) transport. Upon successful retrieval of the contact events, the wearable device memory and clock is reset.

The wave scanner acts as a boost to then transmit the contact event data from the wearable devices and location markers to Long Range Wide Area Network (LoRaWAN) gateway (referred to as gateway) via LoRaWAN technology. The gateway is defined as the "middleman" between the Microshare® Network and the wearable device and location markers. Microshare® receives and processes the raw data. The event contact data received by Microshare® includes ID of the wearable device or location marker, contact durations and relative timestamp. Anonymised data will be exported to University of Leeds, Clinical Trials Research Unit secure data infrastructure to inform the care home feedback and analysis.

The CONTACT wearable devices are slim, waterproof, light (~10 grams including battery), have a battery life of ~1 year, and have none of the vulnerabilities of smartphone approaches (disabled data, dead batteries or lack of ownership). The network that the devices use avoids the security problems that are associated with WiFi and mobile data technologies. The wearable devices have no GPS, no cellular connectivity, no camera, audio recording or other monitoring functionality and devices are effective in the care home only. Once issued, the wearable devices require no active attention or input from wearers beyond changing the watch-style battery around once per year and strap/key ring renewal, if required.


1
Residents, staff and visitors to the care home are assigned a wearable device (each with a unique device ID*)
The wearable device (e.g. watch or keyring) scan for other wearable devices nearby and record distance and duration
If two or more wearable devices have been close to each other (e.g. within 2 metres for 15 minutes) then a contact event will be registered and stored in each device
#1 wearable device (e.g. staff, resident or visitor)
#2 wearable device (e.g. staff, resident or visitor)
2
Wearable devices also scan for location markers and record duration
Location markers will be primarily be placed in communal areas, such as living rooms, dining rooms, and thoroughfares
If a wearable device has been in the same location for longer than 15 minutes, a contact event will be created and stored
Location Marker (e.g. in living room, dining room)
3
Contact Events are then transmitted to a Wave Scanner. Depending on the size of care home, there will be 2 or 3 scanners installed on the wall inside the home, likely to be in communal thoroughfare areas
The contact events are then sent to the LoRaWAN (long range) Gateway
Wave Scanner
4
Contact event data from the long range gateway is transmitted to Microshare, the company who supply the contact tracing system (encrypted and independent from Care Home network)
The long range gateway is likely to be installed near an entrance/exit to the care home (either inside or outside) to ensure good network coverage
The data is retained in Microshare network until transferred to CTRU and then deleted
Long Range Gateway
CTRU
University of Leeds
5
Data Received from Microshare network processed by Clinical Trials Research Unit (CTRU), University of Leeds to inform regular feedback to care homes.
*Only device ID's are recorded and linked to contact events – No personal information is stored

9.2. Intervention set-up

To initiate set-up of contact tracing systems, physical details on each care home, including floor and site plans, entrances, exits, and types of room, will be used to determine the most appropriate location(s) of the gateways, waves and location marker (static devices that relay contact event data). Based on this information a system plan will be made for each care home.

Once appropriate, and in accordance with care home requirements at the time (adhering to social distancing, Personal Protective Equipment (PPE), and staff tested prior to entry) CONTACT Researchers will commence installation of gateways, wave scanners and location markers. These static devices are required to link wearable devices to the Microshare network (for transferring contact event data from personal devices) and do not require any special arrangements except a power socket.

Location markers will be positioned strategically within the home to maximise predicted proximity to wearable devices i.e. the locations will primarily be in communal areas, such as living rooms, dining rooms, kitchens, thoroughfares and staff rooms. Each location marker can be assigned a tag (or ID), agreed with the CONTACT research team, to enable identification of the event contact data to its physical location.

Each personal badge (or wearable device) has a unique device ID number and a QR code (label on the device). In addition, tags can be added to help with tracking and identification of event contact data and this will be agreed with the CONTACT research team. For example, the care home ID may be included in the tag. Tags can be amended as required.

Wearable devices will be available in two options; embedded in a watch strap or attached to a key ring which can be added to a lanyard, for example. Wearable devices (in particular those allocated for visitor use) will be stored in protected packaging between each use to block or minimise event contact data transmission when not in use.

All hardware for the contact tracing system will be shipped to care homes once appropriate (relevant permissions in place). For efficient installation there is an associated application (for use on smart device) to input the device ID or use the devices QR code (so the device ID does not need to be typed in) to register the device and complete installation. As part of this process care homes will need to enter their unique care home ID as one of the tags.

Training will be provided to relevant care home staff members identified by the care home manager ahead of device use, with additional informational videos to support installation.

9.3. Assignment and use of CONTACT devices

Following consent appropriately evidenced, each staff member, resident and visiting relative(s) and health and social care professionals (e.g. GPs, nurses, social workers) will be assigned an antivirally cleaned device (bracelet or key ring in line with their preferences). Administration of the CONTACT devices will be undertaken by Care Home staff, with support from CONTACT Researcher(s) as desired. Devices will be linked to individuals using a tracking system maintained at the care home with linked-anonymised (participant data) transferred outside of the care home (where practicable). Annonymised data will also be collected on those who opt-out of wearing a CONTACT device, with a reason why (if given).

Devices will be linked-anonymised to a participant's study ID to support correlation of positive COVID-19 results to associated contacts and necessary infection prevention strategies.

This data, and knowledge created from environmental analysis, will inform modifications to environments to minimise contacts but maintain caring functions and efficient delivery of work – and thus encourage adoption and sustainability. It will also allow monitoring of compliance with infection control protocols. This real-world data will also be used in control laboratory conditions to validate aspects such as signal strength and reliability of "contact definitions" and the effects of directionality (for example, people facing away from each other) on contact data.

Appropriate tracking and storage (using lined, signal blocking, "Faraday" bags) of unallocated/redundant devices will be maintained to avoid erroneous data.

9.4. Device data

<u>Daily operational flow of data</u>

1) Data from devices automatically sent to Microshare.
2) CTRU pulls data from Microshare to CTRU infrastructure.
3) The location Meta Data (location marker ID) data is pushed from CTRU into Veridata EDC to enable the Researcher/home to specify the physical location of the device (which is meaningful to the care home and used in feedback).
4) CTRU staff enter information about care home into Veridata EDC.
5) Researcher/Home add the following information dependent on device type:
    - Participant type (Staff (including their role)/ Resident/ Visitor)
    - Device ID issued
    - Device type issued
6) Regular checks will be performed to identify contact tracing data from devices that are not linked to a participant or erroneous device IDs.
7) The care home with support from the Researcher provide ongoing monitoring to check and report any changes to the device status, for example, lost or broken.

9.5. Feedback from CONTACT devices

Data from the CONTACT devices will be analysed, summarized and contextualised by the research team to provide a formal, structured and tailored PDF (emailed and printed/posted) for each Care Home, on a regular basis. Data may include trends in contact numbers/volume, changing nature of contacts staff-resident, staff-staff, inflow and outflow from homes; infection control process measures (breaches of zones; visitors in communal areas; or inflow-outflow of controlled areas in a home – such as kitchens); infection rates by residents and staff. Content will be agreed with Care Home and public health experts, and care home staff.

A member of the research team will contact the care home after approximately 3 days after sending feedback, to clarify any uncertainties, and answer any questions. Care home staff will also be able to contact the research team at any time. Researcher contact and queries (including frequency, method of contact, type of query) with care homes will be documented, to inform processes for the main trial, and allow for refinement of the feedback, and associated process.

In the event of a positive COVID-19 test care homes will be advised to contact the research team to obtain real-time analysis of associated contacts. The primary aim of this is to explore ability to provide tailored feedback to the care home associated with the positive case, which should enable implementation of timely infection control. The study ID will be used to produce reports with no personal identifiers referenced outside of the home.

The CONTACT team will work with Microshare to explore the feasibility of using their platform and making it accessible for care homes to allow them to see their own data via a web accessible password protected dashboard. This may include information including quantity of contacts in a selected area of the home, inflow-outflow of the home, and checks on devices being operational. Care homes will also be able to download data for their own perusal.

9.6. Care home training and engagement

Implementing CONTACT does not need specialist input, extensive training or detailed technical support. It comprises:

i) gatekeeper virtual consultations with each home nominating a staff member to be a study "champion"/main point of contact between home and study team;
ii) One hour initial face-to-face training for the champion (adhering to social distancing, PPE, and research staff tested prior to entry) in how to use CONTACT technology (affix tags and placement) and answer questions;
iii) Laminated printed instructions FAQs, and contact details for the research team in A4 and A1 poster sizes in each home, including emphasis on NIHR and NHS-supported study to encourage visiting professional compliance;
iv) Regular phone calls to the study champion or manager to address ongoing issues, complaints etc; and a dedicated phone number and email for help, assistance with urgent queries.

9.7. Risk management and safeguarding

Care home risk assessments / local infection control protocols will be updated to document processes for handling CONTACT devices.

CONTACT Researchers may have to perform visits to the care home during the study. These will only be performed if permitted by the care home, and will follow measures required by the care home for Personal Protective Equipment (PPE) at the time of the visit. Remote forms of contact (telephone/online conferencing) will be used as a default to ensure timely support and minimise infection risk.

Researchers may observe poor or potentially abusive practice while visiting the care homes, or in discussion with care homes. Local Authority and care organisation will have safeguarding adult's policy and process which outlines the reporting process and investigation procedures for any case of suspected abuse. Should any cases of suspected abuse be observed during research site visits the appropriate local reporting process will be consulted and implemented by the Researcher in consultation with the Chief Investigator.

10. WITHDRAWAL OF USE OF CONTACT DEVICE

All residents, staff or visitors will have the right to stop wearing the CONTACT intervention device(s) and to withdraw or be withdrawn at any time for any reason without prejudice, and with no obligation to give a reason. Device data collected to the point of withdrawal will be used in the analysis, and any relevant feedback to care homes.

COVID-19 test results will continue to be collected and reported, and used in the analysis and any relevant feedback to care homes.

11. ASSESSMENTS/DATA COLLECTION

Study Objective	Data collection method/outcomes
Contact Tracing Devices	
Ease of administering the devices to people living and working in the care home, as well as family caregivers, health care professionals and external visitors to the home	Collected via a CRF consisting of a likert scale question(s) for ease of use/administration of devices across participants.
Feasibility of completing the associated paperwork, including the linkage of devices with individual identities for residents, staff and visitors	Completion levels of resident, staff and visitor wear logs detailing device ID
Acceptability of wearing the devices and reasons for non-wear	Completion of resident, staff and visitor logs and opt-out logs at registration and throughout

	if participants no longer wish to wear the device at a later date. Outcome – percentage of participants wearing the device (for the duration of the study) and reasons for non-wear
Evaluate loss/breakage/replacement requirements in a one month period	Completion of number (percentage) of active devices lost/broken/replaced reported in device wear log
Tailored feedback	
Explore feasibility of proposed methods of CONTACT tracing feedback (format, content, frequency)	Interviews to gain feedback on the understanding and usability of the feedback, alongside preferences for content, frequency and format of the feedback.
Explore feasibility of developing relevant viewable data in Microshare dashboard platform.	Interviews to gain feedback on acceptability of information provision.
Accessibility and engagement of the home with the Microshare dashboard	Summary statistics from Microshare (e.g. number of times accessed over the course of the study)
Establish research team processes and capacity to handle queries or problems from sites in relation to intervention delivery	Logs detailing the number and nature of queries from each site and the time taken to resolve queries.
Site engagement – intervention delivery	
Assess any barriers to being a study champion in the sites	Interviews to gain feedback on study procedures and any potential barriers to engagement.
Attendance and engagement with face-to-face training for the champion and understanding on how to use the CONTACT technology	Training CRFs will be completed by the training provider. These will record the number of attendees of those expected, a checklist for the delivery of each element of training, details of any changes to training and reasons why, and understanding of key learning objectives.
Feasibility of conducting phone calls to intervention homes	Call logs completed by the Researcher will record the frequency and number (percentage) of successful phone calls completed for each site, how long each call takes and reasons for calls not taking place.
Attendance and engagement with regular webinars for intervention homes	Webinar logs completed by the training provider will collect the number of attendees at each webinar and knowledge based test upon completion as required.
Device software	
Evaluate success/failure in data capture, transmission and analysis as well as rates of	Completion of resident, staff and visitors logs cross-checked with flagged data from a random sample (resident/staff) of contact tracing reports

contacts and reasons behind the data driven picture.	to ensure appropriate data capture with documented reason for missing data (i.e. resident bed-bound/staff leave)
Ensure data transmission software works (transfer-reading of data at trials unit; storage; analysis)	Verification of data retrieved from Microshare against list of devices known to be sent to home.
Investigate non-compliance/site adaptations of technology or study processes	Reports generated to identify devices that appear inactive which can be used as an indicator of staff non-compliance at site.
Site engagement – study delivery	
Evaluate site willingness and capacity for the main trial – are they committed to the study?	Interviews to gain feedback on participation and any potential barriers.
What issues do sites have with managing the study?	Logs detailing the nature of queries will be recorded. Additional Feedback from interviews with manager/gatekeeper.
Any issues from study team in delivery in the real world?	Interviews with key staff on study procedures.
COVID-19 testing uptake and results	
Feasibility of collecting the primary outcome data for the definitive study	Ease of extracting data from care home records; overall number and percentage of residents we know had a COVID-19 test (minimum monthly). The number of positive COVID-19 tests out of those that had a test.

Care home characteristics will be collected at baseline and include details such as; Resident, staff and visitor demographics (age, sex, ethnicity and initials – resident only) and previous history of a COVID-19 infection will be obtained via CRF prior to registration.

Care Homes, with the support of CONTACT Researchers will be expected to maintain accurate records, with the majority of data to be completed on electronic records, with any paper materials to be returned to CTRU for storing centrally. The following information outlines the types of data anticipated during feasibility testing in advance of main trial.

Care Home level data:

- Demographics – including number of staff, residents, proportion of local authority funding, number of visitors, access to PPE, access to oxygen and fluidsFloor map

Resident data (Linked to Study ID):

- Demographics – initials, age, gender, ethnicity, previous COVID diagnosis, dementia status
- Resource Use – primary and secondary healthcare provider use
- Resident log - For those eligible to wear a CONTACT device, data will be collected on whether they accepted to wear the CONTACT device (and if not, reason for decline, if given), the

Device ID, type of Device, date of joining and/or leaving the care home, changes to whether or not they agree to wear the device

- For those who are ineligible, data will be collected on age, sex, ethnicity and reason for ineligibility.
- Latest COVID-19 result – collected on a regular basis via secure database (current recommendation – monthly)
- Other infections – details on other infections (communicable transmissible disease) relevant to infection prevention management (i.e. influenza / gastroenteritis)

Staff data (Linked to study ID):

- Demographics – including role, whether they work in another care home,
- Staff logs - including CONTACT Device ID, age, initials, gender.
- Staff opt-out log - including age, gender, reason for decline (if given)
- Staff questionnaires – administering devices, completing logs, training,
- Uptake of testing and latest COVID-19 result – collected on a regular basis via secure database (current recommendation – weekly)

Visitor data (Linked to study ID):

- Visitor log – including CONTACT Device, age, initials, gender, date of visit,
- Visitor opt-out log - including age, gender, reason for visit, reason for decline (if given)
- COVID-19 result – collected ad hoc upon notification of positive via secure database.

Care Homes will be expected to maintain a file of essential study documentation (Investigator Site File) which will be provided by CTRU, and to keep copies of paper-based study documentation (i.e. Device allocation log), except any questionnaires which will be sent to CTRU and stored centrally.

11.1. Data processing and linkage

Data management activities will be undertaken by CTRU to support production of data summaries for care homes (regular feedback reports/Microshare dashboard). Data from contact tracing may be linked by homes to individuals (i.e. COVID-19 positive test) as required to support infection prevention procedures.

11.2. Development of Feedback

As part of feasibility testing we will implement a feedback strategy – based on established best practice in feedback studies in a healthcare context [32] - to underpin development of CONTACT information provision (reports/dashboard) to ensure information is relevant and tailored to audiences to maximise impact on infection prevention procedures.

12. PROCESS EVALUATION

A range of methods will be used to explore intervention implementation within the two care homes. Methods will be based on Normalisation Process Theory (NPT) and its approach to explaining and predicting the embedding of CONTACT technology in work "as done" (rather than imagined), and will explore:

- Implementation: the structures, resources and processes by which delivery of CONTACT is achieved, and the quantity and quality of what is delivered;
- Mechanisms of impact: how CONTACT intervention activities, and participants' interactions with them, trigger change;
- Context: how external factors influence the delivery and functioning of CONTACT wearables, feedback and information use.

Operationally, this is likely to include:

- CONTACT Researchers and Chief Investigator building a relationship with a study champion in each care home to:
    - Formally using an interview schedule adapted from NPT's NOMAD questions and four key constructs;
    - Informally, via regular support calls to each care home, including after receipt of their tailored analysis.
- Statistical descriptive exploration and analysis of changing patterns, trends and differences based on the contact data and engagement with dashboards, phone helplines.
- Process data such as time taken to complete questionnaires and other measures and data on non-completion, for example.
- Measuring costs incurred by and at various points in the care system (owners, managers, training and implementation) will also entail description of process variables and factors such as time.
- Measures such as non-compliance, refusal to wear devices, deliberate damage to equipment and feedback from residents, staff and visitors will allow exploration of some dimensions of acceptability (of the technology). However, we will use an adapted (for the care home context) a version of the 23 item NOMAD questionnaire with managers and staff.
- Mediating variables such as average staffing ratios and turnover that may impact on implementation will be captured via the care home context questionnaire to be designed for the study and available on paper or electronically and via the study Researchers having access to staffing records, rosters and care home managers.
- Safety and unintended consequences/adverse events to be recorded and explored either during regular support phone call from team to each home or via self-declaration from homes to team at the point of CQC notification (or if a non-notifiable event via phone or email).

12.1. Sample identification:

A purposive sample of staff, residents, and visitors will be used and will be targeted to ensure maximum variation to support further intervention optimisation – within the resource constraints of a feasibility study.

12.2. Recruitment and consent:

To identify participants (staff, residents, and visitors) willing to undertake a brief telephone interview we will ask participants to indicate their willingness to be approached by one of the research team at device allocation.

If sampled for participation in interviews the care home manager (or delegate) will be asked to issue an information sheet (Participant Summary_Interviews) to potential participants and confirm continued acceptability of Researcher contact. If agreeable, the care Home manager (or delegate) will support arrangements for Researcher contact to discuss participation and support the process for obtaining written informed consent to interviews.

We will seek written informed consent from all participants sampled to undertake interviews.

12.3. Data collection and storage:

Observational/ interview and self-completion questionnaires will be analysed and stored at the School of Healthcare, University of Leeds.

Audio files will be uploaded to a secure platform. Data will be stored on secure servers at the University of Leeds and removed from the recording device.

Alpha-numeric files, e.g. monitoring data or transcripts, will be stored in password protected Word/Excel files on password protected encrypted laptops until such time as they can be uploaded to a secure server at University of Leeds. They will then be removed from the portable device.

Paper records will be stored in a locked cabinet at the University of Leeds, accessible only by authorised members of the study team. Both electronic and paper data will be stored for a period of 5 years, before proceeding to authorised destruction.

12.4. Analysis:

Qualitative data will be analysed abductively guided by NPT core concepts (coherence, cognitive participation, collective action and reflexive monitoring) [33,34,35] by the research team (senior research fellow, research assistant and selected co-applicants). For each element of the process evaluation transcripts and/or observational field notes will be organised initially into themes [36] using matrices with rows constituting the data source and columns the core NPT constructs.

For quantitative data (including time), the team will collate, clean and describe summary measures of central tendency, variability, missing values and bias.

The aim of both sets of analyses is to assess the feasibility of collecting fit-for-purpose data that leads to viable information for understanding the adoption, implementation and adaptation of the technology and feedback. The research team will examine the analyses and data and reach a collective judgement of the quality and quantity of findings, given the aims of the process evaluation.

13. DEFINITION OF END OF TRIAL

The end of the study is defined as the date of last care home observation or interview.

14. SAFETY

14.1. Definitions

Term	Definition
Adverse Event (AE)	An adverse event is; • any unintentional, unfavourable clinical sign or symptom • any new illness or disease or the deterioration of existing disease or illness
Serious Adverse Event (SAE)	A serious adverse event is any untoward medical occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other 'important medical events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences. NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Related Unexpected Serious Adverse Event (RUSAE)	The National Research Ethics Service (NRES) defines related and unexpected SAEs as follows: • 'Related' – that is, it resulted from administration of any research procedures; and • 'Unexpected' – that is, the type of event is not listed in the protocol as an expected occurrence.

14.2. Adverse event reporting and harms

Safety and unintended consequences/adverse events routinely provided to commissioners/CQC by homes as part of their registration to operate, will be recorded.

Managers will be encouraged to report any adverse events relevant to the study at regular follow up call from the research team or via the dedicated contact mechanism between the home and the research team at any time. Processes will be optimized for the main trial.

14.3. Deaths

All deaths occurring from the date of device deployment, up to the last data collection visit should be notified to the study Researcher by the care home (within a week of becoming aware). This will include date, and cause of death if known at time.

Death reports will be reviewed by the Chief Investigator on a regular basis, and the Trial Steering Committee (TSC) and Sponsor will be informed of deaths where the Chief Investigator highlights concerns regarding the overall number of deaths.

15. STATISTICAL CONSIDERATIONS

15.1. Sample size:

Formal sample size and power calculations are not required for trials designed to determine the feasibility of a definitive trial. We anticipate that 2 care homes will provide sufficient data to refine and assess the feasibility of the intervention implementation and delivery.

15.2. General Considerations

Statistical analysis is the responsibility of the CTRU Trial Statistician under the supervision of the Supervising Statistician.

The analysis plan outlined in this section will be reviewed and a detailed, final statistical analysis plan will be written before any analysis is undertaken. The analysis plan will be written in accordance with current CTRU standard operating procedures (SOPs) and guidelines and will be finalised and agreed by the following people: the Trial Statistician, the Supervising Statistician, the Chief Investigator, the CTRU Principal Investigator and the Senior Trial Manager. Any changes to the finalised analysis plan and reasons for change will be documented.

15.3. Analysis Populations

15.3.1 Frequency of Analyses

No formal interim analyses are planned. A single final analysis is planned at the end of the formal feasibility period (two months after device registration) and when the database has been cleaned and locked.

15.3.2 Outcome Analysis

The analysis will focus on descriptive statistics rather than formal hypothesis testing to determine progression to main trial.

Baseline characteristics of the care home and participants will be summarised. Number (percentage) will be presented for binary and categorical outcome measures as detailed in section 11, while mean (variance) will be summarised for any continuous outcomes.

16. TRIAL MONITORING

A Monitoring Plan will be developed and agreed by the Trial Management Group (TMG) and TSC based on the trial risk assessment; this may include on site monitoring.

16.1. Trial Steering Committee (TSC)

The TSC will provide overall supervision of the study - in particular, study progress, adherence to protocol, participant safety, and consideration of new information. The committee will meet once during the set-up period and at least annually thereafter for the duration of the study. A subcommittee of the PSC will be convened where necessary to monitor safety data.

16.2. Data Monitoring

Data received from the care home will be monitored for quality and completeness by the CTRU, using established verification, validation and checking processes. Missing data will be chased until it is received, confirmed as not available or the study is at analysis. Discrepant data will be queried.

Data received from Microshare (i.e. contact event data from the CONTACT devices) will be monitored to identify any device IDs that are found to have a significant gap in their reporting of contact events. In collaboration with the CONTACT Researcher and care home, CTRU will seek information to establish the device status (e.g. battery died, device broken/damaged, misplaced, spare).

The CTRU/Sponsor will reserve the right to intermittently conduct source data verification exercises on a sample of sample of residents, staff and care homes, which will be carried out by staff from the CTRU/Sponsor. Source data verification will involve direct access to participant notes at the participating care homes and other relevant investigation reports.

16.3. Clinical Governance Issues

To ensure responsibility and accountability for the overall quality of care received by participants during the study period, clinical governance issues pertaining to all aspects of routine management will be brought to the attention of the TSC and, where applicable, to individual Care Homes.

17. QUALITY ASSURANCE AND ETHICAL CONSIDERATIONS

17.1. Quality assurance

The study will be conducted in accordance with current MRC Good Clinical Practice (GCP) guidelines, UK Policy Framework for Health and Social Care Research 2017 and complies with the Mental Capacity Act (2005), through adherence to CTRU standard operating procedures (SOPs) and relevant study-specific SOPs.

17.2. Serious Breaches

Care Home staff and Researchers are required to promptly notify the CTRU of a serious breach (as defined in the latest version of the National Research Ethics Service (NRES) SOP). A 'serious breach' is defined as a breach of the protocol or of the conditions or principles of GCP (or equivalent standards for conduct of non-CTIMPs) which is likely to affect to a significant degree the safety or physical or mental integrity of the study subjects, or the scientific value of the research.

In the event of doubt or for further information, the Investigator should contact the Trial Manager at the CTRU.

17.3. Ethical considerations

The study will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, amended at the 52nd World Medical Association General Assembly, Edinburgh, Scotland, and October 2000. The right of the patient to refuse wearing a contact tracing device without giving reasons must be respected. The patient must remain free to stop wearing the device and related contact data collection at any time without giving reasons and without prejudicing their care or treatment. The study documentation will be submitted by CTRU to the identified Research Ethics Committee (REC). The study must be approved by that REC and receive Management approval from each participating Care home prior to any research activity taking place.

Care home residents that lack mental capacity will be included following a best interest's assessment as outlined in the Mental Capacity Act. Residents that decline to participate, will not be obliged to do so in keeping with Good Clinical Practice.

No identifiable information regarding the residents will leave the direct care team. Researchers will access linked anonymized data only. We have taken steps to ensure we collect the minimum amount of data necessary.

17.4. Submission of Study Data

Case Report Forms (CRFs)
Data will be recorded by Researchers / care home staff on study-specific electronic CRFs (eCRFs) and submitted electronically to the CTRU at the University of Leeds. Where necessary, paper CRFs will be supplied to facilitate tracking and data capture for submission electronically.

For residents, only the study number and initials will be used to minimise identifiable data that leaves the care home. A copy of the Resident consent form will be sent to CTRU – all consent forms will be sent separately to participant data. For staff, only the study number plus initials will be used as an identifier. Following receipt, the CTRU will contact the Researcher / care home staff to resolve any missing or discrepant data queries.

The CTRU will seek to adopt all reasonable measures to record data in accordance with the protocol. Under practical working conditions some minor variations may occur due to circumstances beyond the control the CTRU. All such deviations will be documented on the study records, together with the reason for their occurrence; where appropriate, deviations will be detailed in the published report.

Device data
Anonymous contact event data from CONTACT devices is automatically sent to Microshare. CTRU then pulls data from Microshare to CTRU data infrastructure which is then stored on a secure Veridata EDC database. The contact event data collected will be deleted from Microshare infrastructure and retained at CTRU.

Observation and Interview data
Data collected through observations (field notes and observational records, audio recorded interviews, summaries of documentary analysis), and reflective reports will be anonymised and stored within School of Healthcare, University of Leeds.

18. CONFIDENTIALITY

All information collected during the course of the study will be kept strictly confidential. Information will be held secure electronically (paper back-up) at the Clinical Trial Research Unit (CTRU) or the Leeds School of Healthcare. The CTRU and Health Care will comply with all aspects of the 2018 Data Protection Act and operationally this will include

- minimised personal details, including initials, age, gender, ethnicity, COVID test results, and date of death and cause of death (suspected to be related to COVID.
- appropriate storage, restricted access and disposal arrangements for participant personal and clinical details. Consent forms (with full names) will be stored separately to all other study records. Interview transcripts and field notes will not be linked to other study data.
- organisational approval for access care home records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to study participation.

- data collected for the study to be used to evaluate safety and develop new research in accordance with general notice.
- all data collected are transferred coded with a study number.
- where central monitoring of source documents by CTRU / Healthcare (or copies of source documents) is required, the participant's name must be obliterated before sending.
- where anonymisation of documentation is required, sites are responsible for ensuring only the instructed identifiers are present before sending to CTRU/Healthcare.

If a participant objects to further collection of data during the course of data collection, their data collected up to that point will remain on file and will be included in the final study analysis.

19. ARCHIVING

At the end of the study, data will be securely archived at the CTRU/Healthcare for a minimum of 5 years. Data held will be archived in the Leeds Sponsor archive facility and including pertinent care home data and documents. Following authorisation from the Sponsor, arrangements for confidential destruction will then be made.

20. STATEMENT OF INDEMNITY

The proposed study is sponsored by the University of Leeds as the employer of the Chief Investigator.

Any care home (a non-NHS organisation) involved as a case site (all from the one care organisation) would need to have public liability indemnity in place to indemnify the conduct of the research at their sites.

21. STUDY ORGANISATIONAL STRUCTURE

21.1. Responsibilities

21.1.1 Chief Investigator

As defined by the UK Policy Framework for Health and Social Care Research 2017, the Chief Investigator is responsible for the design, management and reporting of the study.

21.1.2 Operational structure

The **Trial Steering Committee (TSC)** – The TSC, with an independent Chair, will provide overall supervision of the trial, in particular progress, adherence to protocols, safety and consideration of new information.

The **Trial Management Group** (TMG) comprises of the Chief Investigator, Co-Applicants, research fellows and CTRU staff. The TMG will meet at key points during the study to oversee the study including the set-up, on-going management, promotion of the study and the results.

It is anticipated that the Chief Investigator, the research fellows and CTRU staff will regularly meet to discuss the study. They will be responsible for the set-up of the study, including gaining ethical and R&D approval, appointment of additional Researchers if required, management and overall supervision of the study team, collection and analysis of data, and drafting/finalizing publications. The Chief Investigator will be responsible for the day-to-day running of study.
The CTRU will be responsible for: registration, database development and provision, CRF design, data management and quantitative analysis.

22. PUBLICATION POLICY

The study will be registered with an authorised registry, according to the International Committee of Medical Journal Editors (ICMJE) Guidelines. The success of the study depends upon the collaboration of all participants. For this reason, credit for the main results will be given to all those who have collaborated, through authorship and contributorship. Uniform requirements for authorship for manuscripts submitted to medical journals will guide authorship decisions. These state that authorship credit should be based only on substantial contribution to:

- conception and design, or acquisition of data, or analysis and interpretation of data,
- drafting the article or revising it critically for important intellectual content, and final approval of the version to be published,
- and that all these conditions must be met (www.icmje.org).

In light of this, the Chief Investigator and relevant members of the TMG staff will be named as authors in any publication, and an appropriate first author agreed through discussion amongst the TMG members.

The timing of any publication from the programme and this study will ensure scientific integrity is maintained. Individual collaborators must not publish data concerning their participants which is directly relevant to the questions posed in the study until the first publication of the analysis is reported. The publication policy for this study will follow the publication policy agreed by the TSC.

23. REFERENCES

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