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Contact tracing in care homes using digital technology for improving infection control including COVID-19

Submission date
29/01/2021

Recruitment status
No longer recruiting

Registration date
17/02/2021

Overall study status
Completed

Last Edited
07/10/2024

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
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. Even with a vaccine the levels of immunity and optimal immunisation regimen for the very elderly will likely differ from the (younger) general population. Pandemic infection rates within homes have been as high as 80%, and mortality rates as high as 30-50% - infection control and effective management of contacts between staff, residents and visitors in homes will be key to managing and containing COVID-19.
Conventional interviews and documentary-based contact tracing are likely ineffective in care homes. Many homes have 70-80% of residents with memory and cognitive limitations and staff often have more than 50 contacts per day. Recalling historic contacts using interviews is unfeasible.
Wearable digital devices may help improve contact tracing in care homes. Advances in network technology mean small, discrete, wearables, with long battery lives can easily capture, store and recall the information required for contact tracing: when, who, where, how long and frequency of contacts.
Researchers are undertaking a large-scale cluster randomised trial in care homes in Yorkshire and the East Midlands to test 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. They are not aware of any rigorously evaluated non-smartphone-based digital device contact tracing empirical studies. Before the definitive trial, the researchers will assess the acceptability and feasibility of intervention delivery processes and trial design/implementation in a single-arm feasibility study in two care homes.

Who can participate?
Six care homes in West Yorkshire have been selected to take part in “extended feasibility” work. All residents, staff, and visitors within these homes will be able to take part if eligible, and willing to do so.

What does the study involve?
The study involves all consenting participants (residents, staff, and visitors) wearing a small button-type device on a key fob or watch strap that will record contacts (person-to-person or person-to-location), and additional data collection (collected from Care Home CONTACT Lead) to support the study evaluation.

What are the possible benefits and risks of participating?
It is hoped that this study will provide information on how small, wearable devices can be used by care homes to reduce the risks of COVID-19 infection transmission. The researchers do not expect there will be any direct risks or disadvantages to taking part.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2020 to May 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Carl Thompson
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Study website
https://ctru.leeds.ac.uk/contact

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
292204

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47853, IRAS 292204

Study information

Scientific Title
CONtact TrAcing in Care homes using digital Technology (CONTACT) – a non-randomized feasibility study

Acronym
CONTACT feasibility study

Study objectives
Testing of staff and residents without contact tracing will not be enough for effective public health interventions and reduced community transmission. 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 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. Smartphone-based solutions to support contact tracing have limited utility even in the general population, 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 a 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.

The researchers are planning to evaluate, through a large scale cluster randomised trial in care homes in West 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 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. Whilst mooted as an industry “solution” to the problems of care home-based contact tracing the researchers 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. Therefore, prior to the

definitive trial the researchers will assess the acceptability and feasibility of intervention delivery processes, and trial design/implementation, in a single-arm feasibility study, in two care homes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2020, Yorkshire and Humber – Bradford Leeds SCREC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048083; bradfordleeds.rec@hra.nhs.uk), REC ref: 20/YH/0326

Study design
Both; Design type: Prevention, Process of Care, Device, Complex Intervention, Management of Care, Active Monitoring, Qualitative

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
The CONTACT feasibility study (in preparation for large cluster randomised control trial) is a single-arm non-randomized trial, taking place across two care homes in West Yorkshire, with approximately 400 frontline staff, residents and visitors. In accordance with the intended cluster design for the main trial, permission will be sought from each Care Home manager (or delegate) to participate in the study and implement the contact tracing system as a new standard of care within the home.

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 scan 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 stored on 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 <2 m – 15 min) 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. The researchers will explore the feasibility of developing and utilising Microshare dashboards, and make available to the care homes to provide real-time data on contacts.

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. Staff will be invited to take part in interviews to explore knowledge and experience with the use of device, feedback and data collection. 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.

Contact data will be collected over a minimum of 2 months from installation of the devices, to inform progression to the cluster Randomised Controlled Trial (cRCT). The researchers propose to continue collecting data on the acceptability of feedback reports in these two homes 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).

The researchers will also use a range of methods 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:
1. Implementation: the structures, resources and processes by which delivery of CONTACT is achieved, and the quantity and quality of what is delivered
2. Mechanisms of impact: how CONTACT intervention activities, and participants' interactions with them, trigger change
3. 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:
1. Formally using an interview schedule adapted from NPT's NOMAD questions and four key constructs
2. Informally, via regular support calls to each care home, including after receipt of their tailored analysis

To identify participants (staff, residents, and visitors) willing to undertake a brief telephone interview the researchers 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.

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

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
CONTACT

Primary outcome measure
Proof of feasibility for the main trial:
1. Ease of administering the devices to people living and working in the care home, as well as family caregivers, healthcare professionals and external visitors to the home, assessed using Likert scale on ease of use across participants at 2 months following contact tracing system activation
2. The feasibility of completing the associated paperwork, including the linkage of devices with individual identities for residents, staff and visitors, assessed using CRF compliance at 2 months following system activation
3. The acceptability of wearing the devices and reasons for non-wear, assessed by completion of CRFs linked to device allocation and percentage of active devices at 2 months following system activation
4. Loss/breakage/replacement requirements in a 1-month period assessed by completion of CRFs linked to device allocation at 2 months following system activation
5. The feasibility of proposed methods of CONTACT tracing feedback assessed by qualitative feedback/interview at 2 months following system activation
6. Barriers to being a study champion in the sites assessed using qualitative interviews at 2 months following system activation
7. The feasibility of conducting phone calls to intervention homes assessed using contact history and determination of success at 2 months following system activation
8. Data transmission software (transfer-reading of data at trials unit; storage; analysis) assessed using manual verification with device allocation CRFs during the active study period
9. The feasibility of collecting the primary outcome data for the definitive study assessed using compliance reporting of data capture methods at 2 months following system activation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date

01/10/2020

Completion date
31/05/2022

Eligibility

Key inclusion criteria
1. Resident, staff member or visitor at participating care home
2. Willing to take part, and wear contact tracing device during presence in care home

Participant type(s)
Healthy volunteer, Health professional, Resident

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 400

Total final enrolment
783

Key exclusion criteria
1. Wearing a contact device would constitute a risk of harm
2. Aged under 16 years

Date of first enrolment
05/01/2021

Date of final enrolment
09/03/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Westward Care Ltd
Pennington Court
27 Hunslet Hall
Leeds

United Kingdom
LS11 6TT

Study participating centre
Springfield Healthcare
Seacroft Green
The Green
Seacroft
Leeds
United Kingdom
LS14 6PA

Study participating centre
Manor House Residential Home
Hall Lane
Leeds
United Kingdom
LS12 5HA

Study participating centre
The Old Chapel Care Home
Haigh Lane
Haigh
Barnsley
United Kingdom
S75 4DB

Study participating centre
Chocolate Works Care Village
The Chocolate Works
Bishopthorpe Road
York
United Kingdom
YO23 1DE

Study participating centre
Fulford Nursing Home
43 Heslington Lane
Fulford

York
United Kingdom
YO10 4HN

Sponsor information

Organisation
University of Leeds

Sponsor details
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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR132197

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Protocol to be available on the study website: https://ctru.leeds.ac.uk/contact
2. As this is feasibility work the researchers have yet to determine if protocol and SAP papers will be published – main trial documents will be published
3. Planned publication in a high-impact peer-reviewed journal by January 2024

Intention to publish date
01/01/2024

Individual participant data (IPD) sharing plan
Data supporting this work are available on reasonable request. All requests will be reviewed by relevant stakeholders, based on the principles of a controlled access approach. Requests to access data should be made to CTRU-DataAccess@leeds.ac.uk in the first instance.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2.0	12/11/2020	17/02/2021	No	Yes
Participant information sheet	version V3.1	23/11/2020	17/02/2021	No	Yes
Protocol file	version V3.1	23/11/2020	17/02/2021	No	No
Plain English results		14/06/2023	16/06/2023	No	Yes
HRA research summary			28/06/2023	No	No
Other publications	Process evaluation	04/12/2023	05/12/2023	Yes	No
Other publications	Performance of the wearable devices in care home environments	08/09/2023	25/06/2024	Yes	No
Other publications	Quality in care home; the value of wearable-enabled devices for quality improvement in care homes	15/05/2024	25/06/2024	Yes	No
Preprint results		12/10/2023	25/06/2024	No	No
Results article	Feasibility and acceptability	02/10/2024	07/10/2024	Yes	No