Development of methods to identify digitally excluded older people, and tailoring of interventions to meet their digital needs

Submission date	Recruitment status	[X] Prospectively registered
21/11/2023	Recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/11/2023	Ongoing	Results
Last Edited	Condition category	Individual participant data
05/12/2023	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

Older people are more likely to be 'digitally excluded'. This refers to them not using the internet, so missing out on things that could be helpful to their well-being and health (e.g. making appointments, banking, connecting with family). Support and training is available to increase digital inclusion but there is no process in place to identify everyone needing help. Support tends to be offered when people come into contact with health, social care or community services, rather than through actively identifying people who are digitally excluded. This means that some older people who might benefit from support are not offered it, and we don't know what support is best for them.

This study aims to:

- Develop an inclusive way of identifying older people who are digitally excluded
- Explore older people's views of the internet and what might help them get online
- Adapt available digital support so it addresses a wide range of needs
- Test this new approach with a group of older people

Who can participate?

Everyone aged 65+ years on 2-3 GP registers

What does the study involve?

We will send a survey to ask about their internet use. Using their responses we will develop a model that predicts who is more likely to not use the internet.

We will talk to older people about their internet use (interviews). We will also talk to voluntary and community organisations that currently provide digital help and support to find out what they do. In workshops with older people and service providers (in a process called co-production) we will explore the needs of those who don't use the internet. We will review and adapt existing digital support services to make them more accessible to and appropriate for people who are digitally excluded. We will test the adapted service with a group of older people to find out whether it is acceptable.

What are the possible benefits and risks of participating?

There are no direct benefits from taking part in the research. However, we hope participants enjoy taking part and value contributing to providing better services for older people in the future. Researchers will aim to sign-post people to appropriate services or information should problems be identified during researcher conversations. This sign-posting may support participants to access services or information that supports some aspect of their daily living. We will be asking participants to take part in an interview or a workshop with a researcher. Whilst we do not foresee any risks to this - we will be talking about digital engagement rather than any particularly sensitive topics - people may become anxious or tired during the interview, or discussions may be upsetting if people have experienced frustrations due to difficulties with the internet. Researchers will be vigilant for distress or fatigue, and will offer to stop the interview / discussion where this is the case. We will at all times be respectful of and sensitive to people's needs.

Where is the study run from?
Bradford Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for? November 2023 to August 2026

Who is funding the study? The Dunhill Medical Trust (UK)

Who is the main contact?
Dr Liz Graham, liz.graham@bthft.nhs.uk

Study website

https://ageingstrokeresearch.org/research-projects/include/

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

332940

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 58769, SDAF2302\15, IRAS 332940

Study information

Scientific Title

INCLUDE Study - Digital exclusion amongst older people

Acronym

INCLUDE

Study objectives

This study aims to:

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- 2. Explore older people's views of the internet and what might help them get online
- 3. Adapt available digital support so it addresses a wide range of needs
- 4. Test this new approach with a group of older people

Ethics approval required

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Ethics approval(s)

Approved 24/10/2023, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, United Kingdom; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 23/YH/0234

Study design

Interventional non-randomized feasibility study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Home, Telephone

Study type(s)

Other

Participant information sheet

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

Health condition(s) or problem(s) studied

Digital use in older people

Interventions

Workstream 1 - Survey (Months 1-6)

A survey will be sent by participating GP practices (using text message and DocMail) to all those on their registers aged 65+ who are eligible to receive the survey. Recipients of the survey will be asked to complete it and send it back (in a pre-paid envelope) to the research team. It will take about 10-15 minutes of their time, and this is the only task we will ask them to do. There will be an opt-out period, after which time, a researcher based at the GP practice will telephone them to see if they would be willing to complete the survey over the phone.

We will also explore other ways to administer the survey to maximise engagement - for example, researchers attending GP practices for drop-in sessions, researchers visiting community or faith groups.

Surveys will be anonymous, but participants will have the option to provide their contact details if they would like to be entered into a prize draw (a thank you for taking part), hear about the study findings, or be contacted about future parts of this research project.

Workstream 2 - Interviews (Months 5-11)

Approximately 20 participants who agreed to further contact when they returned their workstream 1 surveys will be invited to take part in interviews. We will sample participants based on characteristics that have been identified in the literature as influencing digital exclusion e.g. age, gender, living status, deprivation, ethnicity; as well as a range of digital use. A researcher will telephone people to invite them to participate. Where the telephone conversation identifies concerns with capacity, the researcher will, sensitively, ask to speak to someone else who might support the person's involvement, if available, and if feasible. Where a Consultee can be identified, they will be invited to provide agreement to the person's

participation, as well as potentially support the person during the interview. Consent or agreement will be obtained before interviews take place. Interviews are expected to last for around 1 hour, and will happen on one occasion. They will be audio recorded with the participants' permission. Participants will be given the choice of location for the interview - they will probably be at their home, but alternative community venues will be identified if preferable.

Workstream 3 - service mapping (Months 5-10)

A literature review will identify existing evidence for digital support services for older people. Researchers will work with collaborating community partners (Age UK Leeds, Carers' Resource) and others who provide digital inclusion services to identify components of existing service provision. Each service will articulate the target population, format, content and purpose of their current offer. This information will be recorded and mapped by the research team, and cross checked with the providers to ensure accuracy and understanding. (TO NOTE: We have produced a short information sheet for service providers to explain what we would like them to do, but we do not consider them research participants as they are staff whose involvement is limited to them providing information about their professional activities. We will not be asking them for any personal information.)

Workstream 4 - Workshops (Months 10-21)

Approximately 6 older people (who have agreed to further contact after completing their survey) and 4 service providers will be invited to take part in workshops to identify key components of an intervention (or interventions) that would address digital exclusion. As for workstream 2, we will not exclude people lacking capacity if they have an appropriate consultee who can provide agreement and support for their participation. The exact location for workshops will be

decided upon once participants have been recruited; taking into account their accessibility needs, travel distance and transport requirements. It is possible that meeting room facilities in the Bradford Institute for Health Research (Bradford Royal Infirmary site), or Age-UK Leeds offices might be used for workshops; but there may be other locations (e.g. community group spaces) that would be more convenient. Each workshop will last for around 2 hours, and participants will be asked to attend 4-5 such workshops - alternate months for around 7-8 months involvement in total. Workshops will be audio recorded and notes taken. We will use pictorial representations of concepts and media clips to illustrate points for discussion. Other approaches to maximise workshop inclusion and engagement will be agreed in consultation with our PPIE group and wider PPI engagement. We will ask for and act on participants' feedback between workshops to ensure the presentation style and content are tailored to their needs and preferences; and they are able to actively contribute to the process.

At the end of workstream 4 an intervention will have been developed (months 17-21) that can be tested in workstream 5B.

Workstream 5A - Testing the identification model (Months 22-27)

Methods described for Workstream 1 will be used to distribute the survey from 1-2 GP practices. We require a minimum sample of 100 responses from those who are digitally excluded, so expect to need to distribute at least 2,500 surveys. The survey will be adapted to include factors identified as predictors for digital exclusion. Again, responses will be anonymous, and the survey should only take 10-15 minutes of people's time. Responses received will be used to test the validity of the model - whether it accurately predicts who is digitally excluded.

Workstream 5B - Feasibility testing the new intervention (Months 22-32)

We will undertake a mixed-methods single-arm feasibility study. A non-randomised design with quantitative and qualitative outcomes is appropriate during the early stages of intervention development, where key questions regarding intervention acceptability and feasibility need to

be explored. We will invite 30 older people to take part, contacting those who indicated when they returned the survey that they were willing to be contacted about later stages of the research. It is not yet possible to specify the time commitment or location of the intervention as it has not yet been developed; however, we expect that it will be delivered in a suitable community location (for example, Age-UK premises) but with the option for it to also be delivered remotely (perhaps over the telephone). Similarly, we will be able to collect data from participants in-person (in their home or a community location to suit them) or over the telephone. We expect follow-up (from joining to completing the study) to be around 4 months in duration. A sub-set of people will be invited to an interview to elicit their views on the intervention. All participants will be asked to provide baseline and follow-up measures (e.g. level of internet use).

Intervention Type

Behavioural

Primary outcome measure

- 1. The interviews in workstream 2 will explore:
- 1.1. extent of digital use (e.g. internet and device use);
- 1.2. what internet/devices are used for (e.g. finances, socialising);
- 1.3. whether technology helps or hinders management of health and social aspects of life;
- 1.4. extent to which they feel included/excluded and the associated impacts;
- 1.5. financial concerns;
- 1.6. privacy and security concerns;
- 1.7. digital needs;
- 1.8. how interventions can better address their needs and skills;
- 1.9. factors that influence digital behaviours (framed around the COM-B model) Thematic analysis will be used.
- 2. In Workstream 5, feasibility testing the invervention, baseline and follow-up measures regarding their internet use and a measure of their satisfaction with the intervention will be used. But until we have completed workstream 4, we are not able to define the intervention, and therefore are not able to specify in detail what data will be collected to describe it, and which measures will be most appropriate to monitor its acceptability and feasibility.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/11/2023

Completion date

31/08/2026

Eligibility

Key inclusion criteria

1. For the survey work (workstreams 1 and 5A), we will include all older people registered at participating GP practices who are aged 65 years and over. For all later workstreams we will also include those aged 65 years and over.

Additional inclusion criteria for workstreams 2 (interviews) and 4 (workshops) are:

2. Consented to further researcher contact upon completion of the workstream 1 survey.

Additional inclusion criteria for workstream 5B (feasibility study) are:

- 3. Have never used the internet, or not used it within the last 3 months; and
- 4. Consented to further researcher contact upon completion of either the workstream 1 or workstream 5A surveys.

Participant type(s)

Patient

Age group

Adult

Lower age limit

65 Years

Sex

Both

Target number of participants

Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria

For the survey work (workstream 1 and 5A), we will exclude:

- 1. Those who have opted out of data sharing for research purposes, and
- 2. Those receiving palliative / end of life care

For the interviews (workstream 2) and workshops (workstream 4), we will exclude:

- 3. Those who lack capacity to contribute to the interviews, even with the help of a supporter
- 4. Those with no consultee available or willing to support involvement where a potential participant lacks capacity to consent.
- 5. For workstream 4 (workshops) we will also exclude those who took part in workstream 2 interviews.

For workstream 5B (feasibility study) we will exclude those who:

- 6. Lack capacity to engage with the intervention or provide data; or
- 7. Took part in earlier workstreams.

Date of first enrolment

01/01/2024

Date of final enrolment

31/03/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Bradford Royal Infirmary

Duckworth Lane Bradford United Kingdom BD9 6RJ

Sponsor information

Organisation

Bradford Teaching Hospitals NHS Foundation Trust

Sponsor details

Bradford Royal Infirmary, Duckworth Lane Bradford United Kingdom BD9 6RJ +44 1274382575 jane.dennison@bthft.nhs.uk

Sponsor type

Hospital/treatment centre

Website

https://www.bradfordhospitals.nhs.uk/

ROR

https://ror.org/05gekvn04

Funder(s)

Funder type

Charity

Funder Name

Dunhill Medical Trust

Alternative Name(s)

The Dunhill Medical Trust, DMT

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

Publication and dissemination plan

On completion of the study, a final study report will be submitted to the funding body (Dunhill Medical Trust), and primary findings will be written up for publication in an appropriate academic journal (to be made available via appropriate open access publishing sites within six months of publication). A lay summary of project findings will be produced for dissemination to participants who took part in workstreams 2, 4 and 5B; and a summary of findings will be sent to participating GP practices for onward dissemination to their patients via posters or newsletters. Commissioners, policymakers, voluntary sector organisations, practitioners and older people themselves are the target audiences for our outputs, which will be developed alongside academic outputs (papers, presentations). Dissemination activities will include articles, blogs, infographics and presentations.

Intention to publish date

31/08/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr Liz Graham (Chief Investigator) liz.graham@bthft.nhs.uk Data arising from the study is owned by the Sponsor organisation - Bradford Teaching Hospitals NHS Foundation Trust. Following publication and dissemination of findings, reasonable requests from external researchers for the anonymised dataset would be considered and agreed by the Project Management Group.

IPD sharing plan summary

Available on request