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# Improving communication and patient safety in primary care for people aged 65+ with multiple long-term conditions

**Submission date**
21/01/2021

**Recruitment status**
No longer recruiting

**Registration date**
04/02/2021

**Overall study status**
Completed

**Last Edited**
08/01/2024

**Condition category**
Other

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

## Plain English summary of protocol

Background and study aims
Good communication between patients and healthcare staff is essential for patient safety as communication can impact all aspects of healthcare, including diagnosis and treatment. People who have two or more long-term conditions (multimorbidity) often receive more healthcare than others. They can also have complex and unmet needs. This can make communication more difficult. People aged 65+ are more likely to have multimorbidity, and may be more vulnerable to harm arising from communication problems. Patients can be empowered to improve communication with healthcare staff. Working with patients, researchers have designed materials to help people with multimorbidity talk to and be heard by healthcare staff. They have ensured these materials are relevant and easy to understand.
They now want to do a feasibility study and process evaluation to see if they can recruit people to a study to assess these materials, and if people find these materials useful and acceptable.

Who can participate?
Patients aged 65 and over with two or more long-term conditions and clinical and administrative members of staff with direct patient contact at four participating general practices in England

What does the study involve?
Participating patients will be given a copy of the materials and asked to use them in any contacts they have with their general practice for 4 to 8 weeks. Participating patients and staff will be asked to complete questionnaires. Some will also be invited to take part in an interview about their experience (the process evaluation).
What the researchers learn from this study will help them to decide if and how they can do a larger study to test whether the materials empower patients, improve communication and reduce risks to patient safety.

What are the possible benefits and risks of participating?
The researchers do not expect participants to benefit from completing questionnaires or taking part in an interview. However, many people find such experiences positive. Patient participants may find the materials useful when communicating with staff from their general practice, and

practice staff may find the materials help improve their patients' communication with them. The study will take participants away from their normal responsibilities for a time. However, the researchers have and will make every effort to ensure this time is minimal. The research will be carried out remotely, if needed, to reduce risks related to COVID-19. Physical distancing and all other restrictions will be followed in line with national and university guidance. It is possible that patient participants may become distressed when reflecting on their experiences of healthcare and their use of the materials. The researchers have a lot of experience discussing issues relating to health and healthcare, including issues around communication and patient safety. If at any point a participant becomes distressed, the research will be paused or stopped and the researcher and stay with the participant for as long as necessary.

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

When is the study starting and how long is it expected to run for?
August 2015 to October 2021

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

Who is the main contact?
Rebecca Goulding
rebecca.goulding@manchester.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Ms Rebecca Goulding

### ORCID ID
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Integrated Research Application System (IRAS)
264183

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
CPMS 47670, IRAS 264183

# Study information

### Scientific Title
Improving communication and patient safety in multimorbidity: a feasibility study

### Study objectives
The aim is to conduct a feasibility study (including a process evaluation) to determine whether it is possible to deliver a patient safety intervention in routine general practice to improve communication for older people with multimorbidity.

The study will test the following:

Recruitment:
1. Can the researchers recruit general practices to identify patients for the study and how long does this process take?
2. Can the researchers recruit enough patients, and what proportion of those able to take part are willing to do so?

Delivery and data collection:
3. Is it practical to deliver the intervention to patients in general practice?
4. Do patients and staff find the intervention useable and acceptable, and to what extent do they engage with it?
5. Will patients and staff complete questionnaires before and after the intervention? If so, how many and how much of the questionnaires?

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 21/12/2020, London Bridge Research Ethics Committee (Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)207 104 8019, +44 (0)207 104 8124; londonbridge.rec@hra.nhs.uk), REC ref: 20/LO/1284

### Study design
Non-randomized; Both; Design type: Process of Care, Education or Self-Management, Psychological & Behavioural, Complex Intervention, Qualitative

### Primary study design
Interventional

### Study type(s)

Other

## Health condition(s) or problem(s) studied
Multimorbidity

## Interventions
Description of the intervention as per the TIDieR (Template for Intervention Description and Replication) checklist for a protocol:

Brief name:
1. SPEECH (Safer Patients Empowered to Engage and Communicate about Health)

Why:
2. The Behaviour Change Wheel was used to a) explore barriers to and enablers of communication, and b) design a patient-focused intervention to address and support prioritised barriers and enablers. The intervention functions of education, persuasion, training, environmental restructuring, modelling and enablement are used.

What:
3. Materials: Booklets and linked videos. The patient booklet and linked video are the intervention materials. This booklet has three main sections: 1) Information about staff and services, 2) Skills to prepare and explain, and 3) Confidence to speak up and ask. The practice booklet and linked video are the implementation materials. This booklet explains the purpose of the intervention and how practices and their staff can support the intervention.

4. Procedures: Participating patients will be given a copy of the patient booklet and linked video. They will be asked to read the booklet and watch the video, and try to make use of the suggestions and guidance within. If patient-participants have any questions or queries about the materials or how to use them they will be able to contact the research team for support. The research team will also contact participating patients on one occasion after they have received the materials to ask if they need support. Participating practices will be given the practice booklet and linked video. They will be asked to read the booklet and watch the video, and try to make use of the suggestions and guidance within.

Who provided:
5. The research team will provide the intervention and implementation materials, and provide support as needed.

How:
6. The booklets and linked videos will be distributed in-person, by post and/or via email according to the participants' preferences. Support will be provided by telephone, video-call or email according to the participants' preferences.

Where:
7. NHS General Practices in England.

When and how much:
8. Patients will be given copies of the intervention materials at the start of their participation in the study. Participating patients will be able to contact the research team throughout the study. The research team will also contact participating patients two-four weeks after they have received the materials to ask if they need support. Practices will be given copies of the implementation materials at the start of the study period.

Tailoring:
9. N/A

How well:
11. Planned: At follow-up, 4 to 8 weeks after receiving the intervention materials, participating patients will be asked to complete a structured pro forma to provide information on their interaction with the patient booklet and linked video, and whether or not they tried to make use of the suggestions and guidance within. At the end of the intervention period at a practice, staff will be asked to complete a structured pro forma to provide information on their interaction with the practice booklet and linked video, and whether or not their practice tried to make use of the suggestions and guidance within.

### Intervention Type
Behavioural

### Primary outcome(s)
Recruitment assessed using:
1. Number of general practices recruited and time taken to recruit, measured at baseline
2. Number of patients recruited and the number of expressions of interest as a proportion of the number of eligible patients invited to participate, measured at baseline

### Key secondary outcome(s))
Delivery and data collection:
1. Feasibility of delivery assessed through in-depth interviews at 2 weeks after follow-up for patients and 2 weeks after the end of the study period for staff
2. Usability and acceptability of and engagement with the intervention measured using the patient and staff proformas (4- and 5-point Likert scales and free-text box) at 4-8-week follow-up for patients and at the end of the study period for staff, and through in-depth interviews at 2 weeks after follow-up for patients and 2 weeks after the end of the study period for staff
3. Number of questionnaires returned and the number of items completed per returned questionnaire, measured at baseline and 4-8-week follow-up for patients and at the end of the study period for staff

### Completion date
31/10/2021

## Eligibility

### Key inclusion criteria
Patients aged 65+ with at least two long-term conditions

Primary care staff:
1. Have direct contact with patients, that is, face-to-face and/or via telephone or the internet, and
2. Work in a clinical or administrative role. Clinical roles include GPs, practice nurses and practice pharmacists. Administrative roles include practice managers, and receptionists.

All participants must have the capacity to provide informed consent, and be able to read and write in English to engage with study materials. This study does not have the scope to translate materials.

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Mixed

### Sex
All

### Key exclusion criteria
Patients:
1. Live in a care home or rely on a carer to manage their health
2. Have severe mental health problems, or significant cognitive impairment

### Date of first enrolment
31/12/2020

### Date of final enrolment
31/08/2021

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**NIHR CRN: Greater Manchester**
2nd Floor
Citylabs
Nelson Street
Manchester
United Kingdom
M13 9NQ

### Study participating centre
**NIHR CRN: North West Coast**
iC1 Liverpool Science Park
131 Mount Pleasant
Liverpool
United Kingdom
L3 5TF

# Sponsor information

**Organisation**
University of Manchester

**ROR**
https://ror.org/027m9bs27

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0816-20035

# Results and Publications

**Individual participant data (IPD) sharing plan**
The quantitative datasets generated and analysed during the current study will be available to researchers running other research studies at the University of Manchester. The other research studies will need to be of a similar nature to the current study and concern health and social care research. The datasets will be available after the findings of the current study have been published. They will not include information that identifies the participants. Participants will be asked to agree to this as part of the informed consent process. In the first instance, requests for access to the data should be sent to Rebecca Goulding (rebecca.goulding@manchester.ac.uk).

**IPD sharing plan summary**
Available on request

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 05/01/2024 | 08/01/2024 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Participant information sheet | Participant information sheet version V1.2 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 09/12/2020 | 04/02/2021 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |