STUDY PROTOCOL

TITLE

Improving communication and patient safety in multimorbidity: Feasibility study

SHORT TITLE

Improving communication and patient safety

REFERENCE NUMBERS

Protocol version number and date
v1.2 09/12/2020

IRAS project ID
264183

Funder reference
PB-PG-0816-20035
DRF-2017-10-038

This protocol has regard for the HRA guidance and order of content.

TABLE OF CONTENTS

KEY STUDY CONTACTS

Chief Investigator

Peter Bower
Professor of Health Services Research
The University of Manchester
5th Floor, Williamson Building
Oxford Road, Manchester, M13 9PL
Telephone: 0161 275 7638
Email: peter.bower@manchester.ac.uk

Co-Investigators

Rebecca Goulding
Research Associate and NIHR Doctoral Research Fellow
Centre for Primary Care and Health Services Research, The University of Manchester, Manchester, UK

Dr Sarah Peters
Senior Lecturer in Psychology
Centre for Health Psychology, The University of Manchester, Manchester, UK

Dr Thomas Blakeman
Clinical Senior Lecturer in Primary Care
Centre for Primary Care and Health Services Research, The University of Manchester, Manchester, UK

Prof Harm van Marwijk
Professor in General Practice
Brighton and Sussex Medical School, University of Brighton, Brighton, UK

Collaborators

Mr Mark Hann
Research Fellow
Centre for Primary Care and Health Services Research, The University of Manchester, Manchester, UK

Sponsor

Lynne Macrae
The University of Manchester
Faculty Research Practice Governance Coordinator
Faculty of Biology, Medicine and Health
5.012 Carys Bannister Building
University of Manchester
M13 9PL
FBMHethics@manchester.ac.uk
0161 275 5436

FUNDER

Rebecca Goulding is funded by a National Institute for Health Research (NIHR) Doctoral Research Fellowship. The project is co-funded by the NIHR Research for Patient Benefit programme.

This protocol describes independent research funded by the NIHR. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

STUDY SUMMARY

Title	Improving communication and patient safety in multimobidity: Feasibility study
Short title	Improving communication and patient safety
Study design	Mixed methods will be used to investigate the feasibility of delivering an intervention, developed during earlier stages of this project, in four general practices. Quantitative data will be collected alongside and through the main study, and qualitative data will be collected during a process evaluation.
Study participants	Participants will be recruited from participating general practices and will be a) older people with multimorbidity (patients), and b) clinical and administrative staff with direct patient contact (staff).
Sample size	In total, 48 patients and 32 staff will take part in the feasibility study. A sub sample of 16 patients and 8 staff will take part in the process evaluation.
Follow up duration	Four to eight weeks after the intervention is delivered.
Study period	The work described here is expected to take 12 months. 1/11/2020 to 31/10/2021.
Aims	We aim to determine whether it is possible to deliver a patient safety intervention in routine general practice, to improve communication for older people with multimorbidity.
Patient and public involvement	Patients, carers and other stakeholders have been involved in the design and development of the project and the intervention. Patients, carers and other stakeholders will continue to be involved throughout, for example, in the management of the research, analysis of results, and dissemination of findings.
Key words	Older people, multimorbidity, primary care, healthcare communication, behaviour change

PLAIN LANGUAGE SUMMARY

Although care in the NHS is generally very good, problems do occur, such as missed diagnoses or medication errors. In these situations, patients sometimes suffer harm.

Trying to avoid harm from healthcare is called 'patient safety'.

People who have multimorbidity (two or more long-term conditions) often receive more healthcare than others. Thus, they may be more likely to experience risks to their patient safety.

Older people (aged 65+) are more likely to have multimorbidity, and be more vulnerable to harm. We have researched how risks to patient safety arise for older people with multimorbidity. Risks arise for a range of reasons, including poor communication.

We shared our findings with a group of carers and older people with multimorbidity. They considered good communication to be the most important issue for patient safety.

Good communication can be difficult for older people with multimorbidity, especially those who

- Have many, complicated health problems.
- Have mental health as well as physical health problems.
- Are prescribed multiple, regular medicines.
- Find it difficult to manage their treatments or day-to-day activities.
- Need help from different staff in different parts of the NHS.

Evidence suggests it is possible to empower patients to communicate better with healthcare staff.

Working closely with patients, we have designed materials to support them when talking to healthcare staff. We have ensured the materials are easy to use and meet patients' needs.

We are now doing a feasibility study see if we can recruit people to a study to assess these materials and if people find these materials useful and acceptable. We hope to then do a larger study to test whether our new materials empower patients, improve communication and reduce risks to patient safety.

STUDY PROTOCOL

1. Title

Improving communication and patient safety in multimorbidity: Feasibility study

2. Background

More people are living with two or more long-term conditions (multimorbidity) (1). Having more conditions often leads to more contacts with healthcare services. However, people with multimorbidity experience difficulties accessing and interacting with a range of healthcare staff from potentially fragmented services (2). These patients may be prescribed multiple, potentially interacting, medications; receive conflicting advice; feel burdened by treatments; and have needs that are not being addressed (3,4). As such, older people with multimorbidity are likely to be more at risk of 'patient safety incidents'. Patient safety is defined as the "avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of healthcare" (5). Safety encompasses a range of objective to subjective issues, from the wrong medication to a lack of trust in a provider. Patient safety research has focused on hospitals but there is growing interest in safety in primary care. A recent review found patient safety incidents occur in around 3% of primary care consultations. Issues relating to prescribing and diagnosis, which rely heavily on communication, were identified as being the most likely to result in avoidable harm (6). A recent review of qualitative studies of patient safety in primary care showed safety could be promoted or threatened through the actions of patients as well as staff (7). There is significant interest in the role of patients in improving patient safety. A recent summary of safety research suggested 'the role of the patient in promoting their own safety is possibly the biggest and yet least understood spatial domain for safety' (8).

Through an ethnographic study in primary care, we explored threats to patient safety for older people with multimorbidity and opportunities for improvement (9). Our initial findings showed a range of 'precursors to safety failures' that are frequently not addressed by patients or staff, irrespective of their specific health problems or the reason for contact with healthcare services (10). At times, this was due to both parties assuming the other would speak up if they had concerns so important communication did not occur.

Communication breakdowns can leave a lasting impression if these are not addressed, and threaten patients' personal identity and psycho-social safety (11,12). Patients may avoid contact with staff where they have experienced previous difficulties, a finding reflected in our ethnographic study (10). We found patients 'put off' making appointments with staff who commented on their mobility difficulties but did not offer help, or those who made referrals despite patients' preferences for alternatives.

Street et al. (2005) believed the communication behaviour of staff would strongly influence that of patients (13). They explored why some patients were more likely to express their opinions and concerns and ask questions. In contrast to their hypothesis, they discovered these behaviours were predominately patient-initiated. Thus, interventions to help patients communicate more effectively could reduce communication problems and potentially improve patient safety. To-date, communication-based interventions for patients have focused on increasing the number of questions they ask during consultations and many of these have been successful (14,15).

Despite these positive findings, relatively few studies have sought to improve older peoples' communication. A systematic review found only three relevant studies (16). One intervention successfully trained patients to provide and check information, as well as ask questions (17). Another study, designed to empower patients and increase their participation, found trained patients were more satisfied with their interactions. The review noted the potential for study bias due to quality issues, but concluded their positive effects should not be ignored (16). However, there remains a lack of high-quality research concerning interventions to enhance older peoples' communication, and no such intervention has been developed from a strong theoretical and evidence-base, or for people with multimorbidity who could benefit most.

We have attempted to address this gap by drawing on relevant theories, and carrying out primary research to identify how we can support older people with multimorbidity to communicate more effectively. We have developed a simple, acceptable and useable behaviour change intervention; and now want to see if it is feasible to deliver this in primary care and evaluate its effects. Such an intervention has the potential to improve communication, empower patients, increase satisfaction with care, and improve patient safety.

3. Aims

We aim 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.

4. Study design

This feasibility study is a single arm study. Thus, there will be no control group. This is in line with current guidance (www.rds-sw.nihr.ac.uk/dloads/RfPB_Feasibility_Trials_Guidance.pdf).

At the beginning of the study, we will ask patient participants to complete a number of self-report questionnaires which ask about their background, health, experience of healthcare and patient safety.

Patient participants will then receive the intervention materials and, where needed, some support from the research team in how to use them.

At follow-up, we will ask patient participants to complete the self-report questionnaires on their experience of healthcare and patient safety for a second time, as well as an additional questionnaire asking about their use of and views on the intervention materials. We will also ask staff to complete questionnaires.

Some of the study participants (both patients and staff) will also be invited to take part in a process evaluation, where we will collect qualitative data through brief semi-structured interviews.

5. Study setting

We will recruit four General Practices in England. General practices will be invited to take part based on capacity and number of eligible patient participants. This will be determined, in part, through liaison with local NIHR CRNs.

6. Sample and recruitment

A research information sheet for practices (RISP) will be sent to and distributed through Clinical Commissioning Groups (CCGs), Local Medical Committees (LMCs), research and other local networks and direct mailings to general practices. The RISP provides details of the study and highlights the ways in which a practice could be involved. All practices will be asked to help us recruit patient participants. Optionally, practices will also allow us to a) distribute questionnaires to clinical and administrative staff with direct patient contact and invite some of these staff members to an interview, and/or b) provide guidance on how they can support their patients with the intervention.

Patient participants will be recruited through a number of means. Practices will be able to choose from the following options: display an advert in the waiting room, speak to patients about the study and/or send out letters of invitation to the study.

Practices will be asked to identify between 30 and 45 older people with multimorbidity, on one or two occasions, focussing on those who have an appointment within two-eight weeks. Practice staff (including CRN nurses) will contact these potential patient participants by phone or letter, and send them a participant information sheet. Posters and leaflets will also be made available to participating sites so interested and eligible patients can enquire about the study themselves. One reminder letter will be sent or follow-up telephone call made, where practices are happy to do this.

All recruitment materials will include information on how interested patients and staff can contact the research team for more information. Potential participants will be sent a copy of the participant information sheet and invited to discuss the study with a member of the research team (either in-person, over the phone or via video-call), to check their eligibility and give them the opportunity to ask questions about the study. In instances where a person expresses an interest and would be eligible but we have already recruited the desired number of people, we will inform them that we are currently at capacity but will let them know if things change.

Potential participants will contact the study team after receiving an invitation letter or after seeing a study poster. Potential participants will be screened for eligibility. Those who are eligible to participate and confirm their interest in the study will be invited to discuss the study in more detail with a member of the research team, at a time and location convenient for them. This conversation could take place over the phone, in-person or via video-call. Meetings that take place in-person could be at participants' own homes, within the primary care setting, on University of Manchester premises, or in the community. During these conversations, the researcher will talk through the participant information sheet and seek informed consent. The potential participant will be asked to initial and sign a consent form, or provide verbal consent. Verbal consent would involve the researcher reading out the consent form and the potential participant responding. Where participants choose to give verbal consent, for example, over the phone, this will be audio-recorded in an encrypted Dictaphone.

In total, 48 older people with multimorbidity will be recruited. There will be no control group in this feasibility study. Thus, the sample size is based on the findings of a recent simulated study, which recommended a minimum of 35 participants per group (18).

Based on a conservative estimate of 25% uptake, it is anticipated that 200 patients will need to be invited to participate by practices.

General practices will be asked if they are happy for their staff to be invited to participate in the study. Participating general practices who agree to this will be asked to distribute the study documents to all their clinical and administrative staff with direct patient contact. Staff members can then contact the research team to discuss the study. We anticipate recruiting approximately 32 members of staff, including GPs, practice nurses, practice managers, and receptionists.

As part of the feasibility study, a sub-sample of participants (both patients and staff) will be invited to participate in the process evaluation. Participants will be sampled to represent the range of practices. Patient participants will be stratified according to self-reported use of the intervention, and staff particpants by profession. We hope to recruit 16 patients and 8 staff members for this stage of the study.

6.1 Inclusion criteria

Patients:

- Aged 65 and over, and
- Have two or more long-term conditions (multimorbidity), specifically, at least two physical long-term conditions or a physical and mental health condition.

Primary care staff:

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

All:

- Have capacity to provide informed consent.
- Be able to read and write in English.

6.2 Exclusion criteria

The following exclusion criteria also apply to patients:

- Live in a care home or rely on a carer to manage their health.
- Have severe mental health problems, or significant cognitive impairment.

6.3 Sample size

We aim to recruit 48 patient participants (of which 16 will also take part in the process evaluation) and up to 32 staff participants (of which 8 will also take part in the process evaluation).

6.4 Participants who withdraw consent or lose capacity to consent

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. However, it will not be possible to remove data from the project once it has been anonymised and forms part of

the data set. This will happen one month after participantse have completed the second set of questionnaires and one week after the interview.

The research team will not be assessing or monitoring capacity. GP's will initially assess capacity of patients before including them in the practice mail out.

7. The intervention

The intervention has been described, according to the Template for Intervention Description and Replication (TIDieR) checklist in Table 1 (19). The materials are still in development and a version of the patient booklet, as an example, will be submiited with the study application.

Table 1: Description of the intervention as per the TIDieR (Template for Intervention Description and Replication) checklist for a protocol

Item number	Item
	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, four to eight 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.

8. Data collection and analysis

8.1 Study assessments

Data will be collected via questionnaires and interviews. The questionnaires will take between 30 and 60 minutes to complete. Interviews for the process evaluation will last up to 60 minutes.

For patient participants, baseline assessments may take place immediately after informed consent has been given, or on another occasion depending on the preferences of the participants. Patient particpants will be asked to complete a demographics and other relevant background information form as well as the following measures:

- Empowerment Scale (ES) (20)
- Consultation and Relational Empathy (CARE) measure (21)
- Multimorbidity Treatment Burden Questionnaire (TBQ) (22)
- Primary Care Patient Measure of Safety (PC PMOS) (23)

Four to eight weeks after the baseline assessment, patient participants will be asked to complete the same set of measures and a structured pro forma to provide information on their interaction with, use of, and views about the intervention, for example, whether they would recommend the materials to others.

At the end of the intervention period at a practice, staff participants will be asked to complete a demographics and other relevant background information form, and a structured pro forma with questions on their experience of and views on the delivery, usability and acceptability of the intervention.

8.2 Process evaluation

Brief semi-structured interviews will be conducted with a sub-sample of 16 patients and 8 staff, approximately two weeks after the end of the study period.

All participants in this aspect of the study will be asked about their experiences of recruitment and data collection, and for their thoughts on the intervention.

8.3 Data analysis

Feasibility study
We will not formally test the effects of the intervention and a conventional power calculation is not appropriate (www.rds-sw.nihr.ac.uk/dloads/RfPB_Feasibility_Trials_Guidance.pdf). Instead, collected data will be used to determine if it is feasible to evaluate the effectiveness of the intervention in a trial. It will be deemed feasible if it is possible to recruit at least 40 patient participants, and 80% complete follow-up.

We are also looking for use and acceptability of the intervention equivalent to that shown in similar studies. For example, the percentage of patients recommending the intervention to others.

Process evaluation
All interviews will be transcribed and analysed thematically, using principles of constant comparison to identify issues around the acceptability, usefulness and value of the intervention, and feasibility of a definitive trial.

9. Data Monitoring and Quality Assurance

The study will be subject to the audit and monitoring regime of the University of Manchester.

10. Ethical considerations

The main ethical considerations relate to research burden; data protection and confidentiality, including arrangements for the transfer and storage of data; risk of potential harm, from the intervention materials; and researcher safety.

Before the start of the study, a favourable opinion will be sought and obtained from an NHS Research Ethics Committee.

10.1 Research burden

The processes to be followed in this study have been designed in an effort to minimise possible burdens for practices and potential participants.

Potential participants will not be asked to complete any questionnaire measures to assess their eligibility to participate but rather answer a few brief questions over the phone. Potential participants will be given time to read and consider the participant information sheet and ask questions before informed consent is sought. No formal procedure will be employed by the

researchers to assess potential participants' capacity to provide informed consent but the researchers have experience working with vulnerable populations, including older people with long-term conditions.

Meetings and interviews will be arranged at a time and place convenient for the participants. We will offer the option of participation by phone and video-call. The range of information to be collected through the demographics and other relevant background information form has been carefully considered and kept to a minimum.

Primary care practices will be reimbursed for staff participants' time. Per person rates will vary in line with the average per hour cost for each profession (as calculated by and agreed with the local NIHR CRN). Patient participants will also be offered payment for their time, and all reasonable expenses will be covered for practices and all participants.

10.2 Data protection and confidentiality

Only the researchers who are actively involved in recruiting participants and collecting data will routinely have access to potential participant and participant contact details. Contact details will be stored in password protected files in a folder on server at the University of Manchester that is only accessible by members of the research team. Contact details of potential participants will be deleted when they are no longer needed, that is, at close of recruitment for each practice. As per our lone working policy, the address and name of the person or site being visited will be left with another person during recruitment and research visits, and destroyed on the researchers' safe return. Consent forms and background information forms completed by participants will be returned to and stored on University of Manchester premises as soon as practical.

Interviews and, where applicable, verbal consent will be audio-recorded on an encrypted digital device that requires a PIN to unlock. Recordings will be removed from this device as soon as they have been transferred to a secure server at the University of Manchester. Paper documents will be kept in a locked storage unit, within a locked office, only accessible by members of the research team. The interview recording and audio-recorded verbal and written consent will be retained for 5 years after the last publication of the study or for 10 years, whichever is the greater. Research data will be stored in a separate location to consent forms. A participant reference code will be created to ensure different types of research data, that is completed background information forms, interview transcripts and researchers' notes can be linked together for each participant. The pseudoymisation key will be held in a password protected file on the secure server at the University of Manchester.

Interview recordings will be sent away for professional transcription by a University of Manchester approved service. Recordings and transcripts will be transferred to the service through a secure online portal, which requires a log-in to access. Once received, transcripts will be anonymised, by removing the names of people and places. Although anonymised, only members of the research team will be able to access complete transcripts. Where patient and public involvement members of the research team are provided with copies for analysis, they will be asked to delete digital copies and return paper copies for shredding. Transcripts will be stored on secure University server.

Direct written quotations from respondents may be used in publications and handouts but all such quotes will be brief and completely anonymised.

If at any point during a telephone or video-call, the line between the researcher and participant becomes disconnected, the researcher will attempt to reconnect with the participant. Where this is not possible the researcher will attempt to contact the participant via another means (for example, email) to offer further contact.

If at any point during the interview studies, a researcher becomes aware of a serious risk to the safety of a participant, or someone connected to them, it will be reported to the relevant authority. Where the risk is health-related, the researcher will initially discuss this with a clinical member of the team (Dr Thomas Blakeman and Prof Harm van Marwijk are both practicing GPs), and they will be asked to decide on the best course of action. We will inform all potential participants of the circumstances that would lead to us breaking confidentiality, and participants will be required to state they understand this as part of the informed consent process.

All researchers will comply with Good Clinical Practice guidelines, The University of Manchester Research Data Management Policy, the Data Protection Act 2018 and subsequent legislation. Study data and material may be looked at by individuals from the University of Manchester or from regulatory authorities for monitoring and auditing purposes.

10.3 Risk of potential harm

The intervention materials have been designed to empower patients to improve communication and reduce risks to patient safety. However, there are potential risks. For example, raising awareness of risks to patient safety could make patients more fearful of healthcare, and encouraging patients to raise concerns could lead them to become more demanding. These risks have been considered in partnership with patients and staff throughout the design process, and steps have been taken to mitigate them. For example, the materials focus on the positive health consequences of good communication as opposed to the negative health consequences of poor communication, and the materials provide instructions on how to raise concerns without demanding alongside encouragement to raise concerns.

10.4 Researcher safety

The risks to researchers are primarily associated with lone-working including risks to personal safety whilst traveling and during recruitment and research visits. A risk assessment has been completed and the risks are considered to be low and adequately controlled. Researchers have attended lone worker training and will follow recommended guidelines, including not entering an environment perceived to be risky and having a pre-planned exit strategy. Researchers will travel during daylight hours and via planned routes where possible, being aware of surroundings and associated risks. Researchers will also follow a lone working policy that includes informing others of travel plans, and a procedure for others to follow if the researcher does not confirm safe arrival or return.

11. Statement of Indemnity

The University has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-

negligent harm to research subjects occasioned in circumstances that are under the control of the University.

12. Peer review

An advisor from the NIHR Research Design Service North West reviewed the research plan for the wider project. Their comments and feedback were taken on board. The selection and interview panels for the NIHR Doctoral Research Fellowship and NIHR Research for Patient Benefit schemes reviewed the revised plan and approved the project for funding. Further modifications were made to the research plan as a result of feedback from these bodies.

13. Stakeholder involvement

The Multimorbidity Research Advisory Group (MRAG) is a patient and public involvement group. Its members have multimorbidity and/or care for people who do. The MRAG were involved in the design and development of this study, and the wider project.

The intervention materials being used in this study were designed in collaboration with patients (older people with multimorbidity), carers, staff working in general practices (people in clinical and administrative roles who have direct patient contact) and other experts (including experts in communication, patient safety and behaviour change).

Patients, carers and other stakeholders will continue to be involved throughout the project. Our project advisory group includes four older people with multimorbidity and/or carers of older people with multimorbidity. These individuals will contribute to study design and management, data analysis, reporting and dissemination.

14. Potential outcomes and dissemination plan

Information on our research and patient and public involvement activities will be provided though a number of formats to reach a range of audiences. We plan to engage with and disseminate findings to academics, healthcare staff and service managers, participants and involvement members, and potential users of the intervention throughout the project.

The study is also for educational purposes, and when completed will form part of the PhD thesis for Ms Rebecca Goulding (student), who is supervised by Prof Peter Bower.

We will make use of and build on the networks and structures of the NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre (Greater Manchester PSTRC) and:

☐ Publish manuscripts in influential, open-access, peer-reviewed journals.

☐ Present at academic and health-focused conferences.

☐ Send copies of publications and plain-English summaries to study participants, involvement members, and stakeholders (where we have their consent to do so).

☐ Provide information through social media, including the Greater Manchester PSTRC eNewsletter (https://tinyurl.com/kgspouw), blog (https://gmpstrc.wordpress.com/), and YouTube channel (https://tinyurl.com/kyyx5aa).

REFERENCES

1. Department of Health. Long Term Conditions Compendium of Information: Third Edition. Department of Health; 2012. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/216528/dh_134486.pdf

2. Goodwin N, Dixon A, Poole T, Raleigh V. Improving the quality of care in general practice: report of an independent inquiry commissioned by the King's Fund. London: King's Fund; 2011. Available from: https://www.kingsfund.org.uk/publications/improving-quality-care-general-practice

3. Hobbs FR, Baker M, Davies DSC. Morbidity matters: challenges for research. Br J Gen Pract. 2015;65(633):e215–6.

4. Tinetti ME, Bogardus Jr. ST, Agostini JV. Potential pitfalls of disease-specific guidelines for patients with multiple conditions. N Engl J Med. 2004;351(27):2870–4.

5. Vincent C. Patient Safety. 2nd Edition. Oxford: Wiley Blackwell; 2010. Available from: http://file.zums.ac.ir/ebook/011-Patient%20Safety-Charles%20Vincent-1405192216-BMJ%20Books-2010-432-$71.pdf

6. Panesar SS, deSilva D, Carson-Stevens A, Cresswell KM, Salvilla SA, Slight SP, et al. How safe is primary care? A systematic review. BMJ Qual Saf. 2016;25(7):544–53.

7. Daker-White G, Hays R, McSharry J, Giles S, Cheraghi-Sohi S, Rhodes P, et al. Blame the patient,blame the doctor or blame the system? A meta-synthesis of qualitative studies of patient safety in primary care. PloS One. 2015;10(8):e0128329.

8. Lamont T, Waring J. Safety lessons: shifting paradigms and new directions for patient safety research. J Health Serv Res Policy. 2015;20(1 suppl):1–8.

9. Daker-White G, Hays R, Esmail A, Minor B, Barlow W, Brown B, et al. MAXimising Involvement in MUltiMorbidity (MAXIMUM) in primary care: protocol for an observation and interview study of patients, GPs and other care providers to identify ways of reducing patient safety failures. BMJ Open. 2014;4(8):e005493.

10. Hays R, Daker-White G, Esmail A, Barlow W, Minor B, Brown B, et al. Threats to patient safety in primary care reported by older people with multimorbidity: baseline findings from a longitudinal qualitative study and implications for intervention. BMC Health Serv Res. 2017;17:754. DOI:10.1186/s12913-017-2727-9

11. Rhodes P, McDonald R, Campbell S, Daker-White G, Sanders C. Sensemaking and the co-production of safety: a qualitative study of primary medical care patients. Sociol Health Illn. 2016;38(2):270–85.

12. Coyle J. Exploring the meaning of 'dissatisfaction' with health care: the importance of 'personal identity threat'. Sociol Health Illn. 1999;21(1):95–123.

13. Street Jr RL, Gordon HS, Ward MM, Krupat E, Kravitz RL. Patient participation in medical consultations: why some patients are more involved than others. Med Care. 2005;43(10):960–9.

14. Kinnersley P, Edwards A, Hood K, Ryan R, Prout H, Cadbury N, et al. Interventions before consultations to help patients address their information needs by encouraging question asking: systematic review. BMJ. 2008;337:a485.

15. Trevena LJ, Barratt A, Butow P, Caldwell P. A systematic review on communicating with patients about evidence. J Eval Clin Pract. 2006;12(1):13–23.

16. Wetzels R, Harmsen M, Van Weel C, Grol R, Wensing M. Interventions for improving older patients' involvement in primary care episodes. Cochrane Database of Systematic Reviews; 2007. Available from: http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004273.pub2/abstract

17. Cegala DJ, Post DM, McClure L. The effects of patient communication skills training on the discourse of older patients during a primary care interview. J Am Geriatr Soc. 2001;49(11):1505–11.

18. Teare MD, Dimairo M, Shephard N, Hayman A, Whitehead A, Walters SJ. Sample size requirements to estimate key design parameters from external pilot randomised controlled trials: a simulation study. Trials. 2014;15:264.

19. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014 Mar 7;348. Available from: https://www.bmj.com/content/348/bmj.g1687

20. Small N, Bower P, Chew-Graham CA, Whalley D, Protheroe J. Patient empowerment in long-term conditions: development and preliminary testing of a new measure. BMC Health Serv Res. 2013;13:263.

21. Mercer SW, Maxwell M, Heaney D, Watt GC. The consultation and relational empathy (CARE) measure: development and preliminary validation and reliability of an empathy-based consultation process measure. Fam Pract. 2004 Dec 1;21(6):699–705.

22. Duncan P, Murphy M, Man M-S, Chaplin K, Gaunt D, Salisbury C. Development and validation of the Multimorbidity Treatment Burden Questionnaire (MTBQ). BMJ Open. 2018 Apr 1;8(4):e019413.

23. Hernan AL, Giles SJ, O'Hara JK, Fuller J, Johnson JK, Dunbar JA. Developing a primary care patient measure of safety (PC PMOS): a modified Delphi process and face validity testing. BMJ Qual Saf. 2016 Apr 1;25(4):273–80