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Working with patients, carers and healthcare professionals to develop and test a guide for patients and carers in primary care

Submission date
21/10/2019

Recruitment status
No longer recruiting

Registration date
10/02/2020

Overall study status
Completed

Last Edited
22/01/2021

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The study will pilot the use of a patient safety guide for patients and carers to examine the acceptability of the guide. The Guide has been co-developed with patients, carers and healthcare professionals to provide patients and carers with information that they can use to make their contacts with general practice and primary care safer.

Who can participate?
Patients consulting with any healthcare professionals at a participating general practice at least four times in the previous year (or carer or a patient consulting)

What does the study involve?
The first round of this study will be to co-develop the Guide App for patients and carers. It will be developed for Apple (IOS) and Android devices for patients and carers alongside developing a support toolkit for healthcare professionals to support the use of the Guide in primary care. The support toolkit will include written and online support materials. Two workshops will be held with patients, carers and health professionals to work together to (1) develop the App to explore content, how it will work and what it is meant to achieve, and (2) develop the support toolkit for healthcare professionals to support the use of the guide.
In the second round of the study, the acceptability of the Guide package for patients and carers (including the paper version of the guide, web-based platform and apps) will be explored with patients, carers and health care professionals (including GPs, nurses and pharmacists based within the practice) and general practice staff (including practice managers and receptionists) by piloting the Guide with two general practices. An introductory workshop will include healthcare professionals and general practice staff and will explore opportunities and problem-solving (e.g. logistical challenges) that may be identified to support the rollout of the Guide within the practice. Introductory workshops will be co-facilitated with members of the patient and public involvement (PPI) group.
The third round of the study will be to test the Guide and support toolkit in a larger scale pilot of the Guide and support toolkit with six general practices. There will be a continuous cycle of evaluation during the project to ensure that the lessons learned from the range of stakeholders

will guide future rollout at other sites. The evaluation will include interviewing patients, practice staff and other key stakeholders (e.g. pharmacists), to understand if and how the Guide was used, which formats of the Guide were used, feedback and improvements for the Guide and facilitators and barriers to using it. The experiences of patients, carers and healthcare professionals will examine how people have been involved in their care and safety through communication support. Throughout the study, this approach will build on the existing PPI and wider stakeholder involvement (with GPs, pharmacists and carers) in the development of the Guide by continuing to involve PPI contributors and health care professionals in co-designing the intervention, working together to plan and manage the study, co-delivering the support toolkit to the practices, and in sharing the results of the study to different audiences. Wider stakeholder involvement will be ongoing with decision-makers and commissioners and providers of healthcare to maximise improvements in patient safety.

What are the possible benefits and risks of participating?
The researchers do not expect there to be any potential adverse effects for patients or health professionals from participating in this pilot study. Patients and/or carers will be asked to complete two questionnaire packs which take around 30 minutes to complete in total and these will be done 6 months apart. At the end of the study a sample of patients, carers and also health professionals will be asked about their experience of using the guide which will last about 40-60 minutes. The researcher conducting the interviews will be sensitive to the participants' needs and the interview can be stopped if they become upset but the researchers do not expect this to be the case.

Where is the study run from?
NIHR Greater Manchester Patient Safety Translational Research Centre (UK)

When is the study starting and how long is it expected to run for?
October 2019 to March 2022 (updated 23/11/2020, previously: March 2021)

Who is funding the study?
NIHR Greater Manchester Patient Safety Translational Research Centre (UK)

Who is the main contact?
Dr Rebecca Morris
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Study website
www.patientsafety.manchester.ac.uk/

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261685

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44476, IRAS 261685

Study information

Scientific Title
Developing and testing a co-designed patient safety guide: pilot study

Study objectives
Is the primary care patient safety guide for patients and carers acceptable for patients and carers in routine practice?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/09/2019, NHS London-West London & GTAC Research ethics committee (Boardroom, Commonwealth Building, Hammersmith Hospital, London, W12 0NN, UK; Tel: +44 (0)207 104 8007; Email: NRESCommittee.London-WestLondon@nhs.net), ref: 19/LO/1289

Study design
Non-randomised feasibility study (single-arm) study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)

GP practice

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Patients and carers in routine practice

Interventions
The study will pilot the use of a patient safety guide for patients and carers which has been co-developed with patients, carers and healthcare professionals to examine the acceptability of the guide. The Guide has been developed to provide patients and carers with information that they can use to make their contacts with general practice and primary care safer.

The first round of this study will be to co-develop the Guide App for patients and carers. It will be developed for Apple (IOS) and Android devices for patients and carers alongside developing a support toolkit for healthcare professionals to support the use of the Guide in primary care. The support toolkit will include written and online support materials. Two workshops will be held with patients, carers and health professionals to work together to (1) develop the App to explore content, how it will work and what it is meant to achieve, and (2) develop the support toolkit for healthcare professionals to support the use of the guide.

In the second round of the study, the acceptability of the Guide package for patients and carers (including the paper version of the guide, web-based platform and apps) will be explored with patients, carers and health care professionals (including GPs, nurses and pharmacists based within the practice) and general practice staff (including practice managers and receptionists) by piloting the Guide with two general practices. An introductory workshop will include healthcare professionals and general practice staff and will explore opportunities and problem solving (e.g. logistical challenges) that may be identified to support the rollout of the Guide within the practice. Introductory workshops will be co-facilitated with members of the patient and public involvement (PPI) group.

The third round of the study will be to test the Guide and support toolkit in a larger scale pilot of the Guide and support toolkit with six general practices. There will be a continuous cycle of evaluation informed by Normalisation Process Theory that will be undertaken during the project to ensure that the lessons learned from the range of stakeholders will guide future rollout at other sites. The evaluation will include interviewing patients, practice staff and other key stakeholders (e.g. pharmacists), to understand if and how the Guide was used, which formats of the Guide were used, feedback and improvements for the Guide and facilitators and barriers to using it. The experiences of patients, carers and healthcare professionals will examine how people have been involved in their care and safety through communication support. Throughout the study, this approach will build on the existing PPI and wider stakeholder involvement (with GPs, pharmacists and carers) in the development of the Guide by continuing to involve PPI contributors and health care professionals in co-designing the intervention, working together to plan and manage the study, co-delivering the support toolkit to the practices, and in sharing the

results of the study to different audiences. Wider stakeholder involvement will be ongoing with decision-makers and commissioners and providers of healthcare to maximise improvements in patient safety.

Intervention Type
Behavioural

Primary outcome measure
Recruitment rate recorded as the number of eligible participants who consent to participate in the study by 12 months

Secondary outcome measures
1. Patients' perceptions of patient safety measured using PC-PMOS at baseline and 6 months
2. Health service utilisation measured using the Client Service Receipt Inventory (CSRI) at baseline and 6 months
3. Patients' health status measured using the 5-level EQ-5D (EQ-5D-5L) at baseline and 6 months
4. Patient empowerment measured using the Empowerment Scale at baseline and 6 months
5. The acceptability of the Patient Safety Guide measured using free text evaluation questions in the 6-month follow-up questionnaire, and semi-structured interviews with patients, carers and healthcare professionals at 6 months

Overall study start date
01/10/2019

Completion date
01/03/2022

Eligibility

Key inclusion criteria
Patient consulting with any healthcare professionals at the practice at least 4 times in the previous year (or carer or a patient consulting)

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Under the age of 18
2. Has not consulted 4 times or more within the last 12 months

Date of first enrolment

01/11/2019

Date of final enrolment
03/10/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NIHR Greater Manchester Patient Safety Translational Research Centre
University of Manchester
6th Floor Williamson Building
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Sponsor information

Organisation
University of Manchester

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Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
NIHR Greater Manchester Patient Safety Translational Research Centre

Alternative Name(s)
Greater Manchester PSTRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be published. The results of the study will be published in open-access journals as well as in plain English formats through the researchers' website and presented at national and international conferences as well as stakeholder events. As this feasibility study which is not powered for a statistical test, only descriptive statistics will be reported at the final publication.

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan
The data will not be made available as it may contain sensitive information. It will be held by the research team at the University of Manchester.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/01/2021	22/01/2021	Yes	No
HRA research summary			28/06/2023	No	No