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Using health information systems to address patients concerns in general practice

Submission date
27/01/2020

Recruitment status
No longer recruiting

Registration date
05/02/2020

Overall study status
Completed

Last Edited
06/03/2024

Condition category
Other

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

Plain English summary of protocol

Background and study aims
When patients visit their doctor, problems are missed 50% of the time. This might be because appointments are too short, or because doctors don't let patients explain their problems fully. Sometimes, patients are confused by the doctor's advice but don't have time to get it clarified. To improve this situation this study will develop and test the Consultation Open and Close (COAC) intervention. Patients will be asked to fill in an online form before they see the doctor, which will be shared with the doctor. Afterwards patients will get a printed report. The online form will say why they have come and give details of their health problems. This means the patient can tell the doctor everything they are concerned about. The printed report the patient gets at the end will show what the doctor and patient agreed. Having the doctor's advice in writing should make it easier to remember.

Who can participate?
Patients aged 18 or over who have an appointment with their GP within the next two days

What does the study involve?
The researchers will do two studies: one to develop the intervention and one to test it. In study 1 the online form and printed report will be tried out in 3 health centres one after the other (15 patients from each). The researchers will talk to patients, doctors and practice staff and use their feedback to improve the form and report. Each improved version will be tried in the next health centre. Study 1 will result in a final version intervention ready to test. In study 2 the researchers will try the intervention in 4 health centres with 72 patients and also collect information about how well the consultations worked. They will collect the same information from 2 health centres (36 patients) that aren't using the new online form and final report. Study 2 will let them work out if it is practical to do a larger study to compare the two groups.

What are the possible benefits and risks of participating?
The researchers are doing this study to see if the form improves communication between patients and their doctor or nurse, so one possible benefit is improved communication. Patients who take part will be helping to improve patient care which could eventually benefit all NHS

patients. There are also no direct disadvantages, apart from giving up time. Patients who participate in the interview will get any travel costs paid back, plus a £20 shopping voucher as a thank you for their help.

Where is the study run from?
1. NIHR CRN: West of England (UK)
2. Courtside Surgery (UK)
3. Nightingale Valley Practice (UK)

When is the study starting and how long is it expected to run for?
October 2019 to March 2022

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

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 42005

Study information

Scientific Title
The Consultation Open and Close study on using health information systems to address patients concerns in general practice: an intervention development and feasibility study

Acronym
COAC

Study objectives
When patients visit their doctor, problems are missed 50% of the time. This might be because appointments are too short, or because doctors don't let patients explain their problems fully. Sometimes, patients are confused by the doctor's advice but don't have time to get it clarified.

To improve this situation this study will develop and test the Consultation Open and Close (COAC) intervention. Patients will be asked to fill in an online form before they see the doctor, which will be shared with the doctor. Afterwards patients will get a printed report. The online form will say why they have come and give details of their health problems. This means the patient can tell the doctor everything they are concerned about. The printed report the patient gets at the end will show what the doctor and patient agreed. Having the doctor's advice in writing should make it easier to remember.

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In study 2 the researchers will try the intervention in 4 health centres with 72 patients and also collect information about how well the consultations worked. They will collect the same information from 2 health centres (36 patients) that aren't using the new online form and final report. Study 2 will let them work out if it is practical to do a larger study to compare the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2019, South West – Frenchay Research Ethics Committee (Health Research Authority, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; Tel: +44 (0)207 104 8360, +44 (0)207 104 8041; Email: nrescommittee.southwest-frenchay@nhs.net), ref: 19/SW /0096

Study design
Randomised; Both; Design type: Process of Care, Complex Intervention, Qualitative

Primary study design
Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied
General practice

Interventions
This research comprises two studies, as follows:

Study 1 (Intervention Development Study): A complex intervention will be designed to improve the ability of GPs to address patients' concerns. This will involve two steps. In the first step, the research team will develop an online pre-consultation questionnaire and a process for feeding this back to clinicians at an individual patient-level before the consultation to help identify patient concerns. In the second stage, a process and template will be designed to provide patients with printed advice on consultation closure.

Study 2 (Feasibility Study): The complex intervention designed in study 1 will be tested for feasibility in a cluster-randomised framework with 72 patients in four practices receiving the intervention and 36 patients in 2 practices as a control. The purpose of this study is to assess if it is feasible to run a future randomised control trial of the intervention, and analysis will include reporting of data that will be used for planning and assessing the feasibility of the full trial, and a realist process evaluation with an embedded programme theory. As this is a feasibility study, not a trial, the analysis does not include comparison of the outcomes between intervention and control arms. The purpose of the control arm is simply to establish whether it is feasible to collect data from this arm, or whether there are any unforeseen difficulties with this which would make a clinical trial unfeasible.

The activity plan for each study is described below.

Study 1 activity plan
This study will be completed in the first year of the project, from September 2019 – August 2020. The following activities will be carried out.

Part a: Pre-consultation questionnaire element of the Intervention Development Study

1. Patient public involvement (PPI) and GP advisory (GPA) consultation (2 months): The research team will consult with the PPI and GPA groups on a prototype pre-consultation questionnaire. There will be two PPI meetings and 2 GPA meetings. The groups will comment on the process, eligibility criteria, questionnaire and report format and content. The PPI group will also advise on the recruitment process and patient information materials.

2. Practice recruitment: Three practices will be recruited. The Intervention Development study uses an iterative approach, whereby the questionnaire and accompanying process will be tested sequentially in these three practices, and adjusted, before testing in the next practice. The following steps will therefore take place in each practice in turn, rather than simultaneously.

3. Practice training and testing: Administrative staff and GPs will be trained as follows:
A) Administrative staff will be trained to carry out two activities on a daily basis over six days. Firstly they will be trained to run a daily query on the patient records system to identify eligible patients with upcoming appointments, and send batch texts to these patients with an individualised link to the pre-consultation questionnaire for patients to click on and complete. Secondly, from day 2 of the study (once the first patients have completed the pre-consultation questionnaires), administrators will download the questionnaires from REDCAP onto individual

pdf files; and attach these one-by-one to the patient record so that they are available for GPs to view before the consultation.
B) GPs will be trained in the initial programme theory for the intervention (see protocol) and on how to use the reports in the context of this theory; including how to access the pre-consultation questionnaire reports at the start of the consultation, verbally summarise the information for patients to show they have seen it and ask the patient if there is anything else they wish to discuss, with a view to better eliciting patients' concerns.

4. Patient recruitment: Following the training of GPs and administrators, patients will be recruited during a six-day period in each practice. One GP in each of the three recruited practices will test the system with 15 patients each. This will involve each eligible patient receiving a text from the practice in advance of their consultation, and completing a questionnaire which the practice administrator will save to pdf and attach to the patient record. When completing the questionnaire, patients will provide consent to the information being shared with a researcher and will optionally be invited to provide contact details, consent to their consultation being observed by a researcher, and consent to be contacted by a researcher with a view to being interviewed.

5. GP Consultation: Patients will attend their consultation and GPs will use the pre-consultation report to inform the consultation. If the patient provided consent for this, a researcher may observe this consultation. At the end of the consultation the GP will provide an information leaflet on the interview element of this study.

6. Interviews, Iterative Evaluation and Refining: The GPs, reception staff, administrative staff and up to twenty patients will be interviewed in three rounds (one round per practice). Informed consent will be taken at the start of the interview. Interviews will focus on feasibility and perceived usefulness. The process, eligibility criteria, questionnaire and report format and content will be adjusted after each round, in accordance with the iterative nature of the person-based approach, before the process begins again in the next practice.

Part b: Consultation-closure report element of the Intervention Development Study

The development of the consultation-closure report will take place in the same three practices, after development of the pre-consultation questionnaire. Again, this will be done sequentially in the three practices rather than simultaneously.

7. Specification and development of closure report: An EMIS template will be developed for the consultation-closure report. The GPA and PPI groups will be consulted on the prototype report content in a series of 4 meetings: two GPA meetings and two PPI meetings.

8. Person-based testing of closure report: Recruitment, training and testing: Three GPs (one per practice) will be trained in completion of this consultation-closure report template and will test the report with 15 patients each. From the patient perspective, this will mean receiving the report, with an information leaflet, and a tear-off slip to provide contact details so that they can be interviewed about their experience.

9. Iterative Evaluation and Refining: As with the pre-consultation questionnaire testing, both GPs and up to twenty patients will be interviewed in two or three rounds. Informed consent will be taken at the start of the interview. Topic guides will include questions about the technical feasibility and usefulness of the report; suitability of the eligibility criteria, time taken and whether GPs and patients saw the benefits as a worthwhile trade-off for this time. The report, the process and the eligibility criteria will be adjusted after each round.

Study 2 activity plan:
1. Randomisation and recruitment of practices: Six practices will be recruited. Three of these will already have been recruited in the previous phase (provided they agree to continue with this phase of the study). Two will be randomised to control, and four to intervention. To achieve a balance on deprivation, the three most deprived practises will be randomised one to control and two to intervention and similarly with the three least deprived practices. The unbalanced allocation of practices to intervention and control is because we want the test the intervention in as many patients and different practices as possible in order to test its feasibility and acceptability in different contexts. The only purpose of the control arm is to assess possible recruitment rates from the questionnaire within a randomised design.

2. Training: One GP per treatment practice will be trained in the intervention, which will incorporate use of the pre-consultation questionnaire and the consultation-closure report in a single consultation. Administrators, practice managers and receptionists in both treatment and control practices will receive the same training, as the process will be similar.

3. Patient recruitment: Each of the practices will recruit 18 patients, resulting in 72 in the intervention and 36 in the control. Patients will be recruited via a text sent from the practice, which will invite them to complete a baseline questionnaire before their consultation and provide a phone number and online consent to receive a follow-up questionnaire and/or interview from a researcher. This will give a sample size of 108 overall, 72 of which receive the intervention.

4. Intervention: The intervention will take place during a single consultation. GPs in the intervention arm will be asked to read the questionnaire information before the consultation, and use it in their consultation initiation conversation, and provide the printed consultation-closure report at the end of the consultation. If the patient provided consent for this, a researcher may observe this consultation. At the end of the consultation the GP will provide an information leaflet on the interview element of this study.

5. Patient Follow-up questionnaires: Patients in both arms who gave consent to receive a follow-up questionnaire will receive this follow-up questionnaire. This will also request consent for their practice to share data on their age, ethnicity, gender, number of long-term conditions and number of reconsultations both in total and for the same problem within one and three months.

6. Patient interviews: Patients who consented to be contacted for interview will be contacted by a researcher and interviewed in a location of their choice. Informed consent for the interview will be taken at the start of the interview.

7. Practice staff questionnaires: A GP, practice manager, receptionist and administrator in each practice will complete a brief questionnaire.

8. Practice staff interviews: A GP, practice manager, receptionist and administrator in each practice will be interviewed.

9. Quantitative Data analysis: As this is a feasibility study, outcomes in the intervention and control groups will not be compared through formal statistical testing. Instead the analysis will focus on reporting data that will be used for planning and for assessing the feasibility of the full trial. A CONSORT flow diagram will be produced. Proportions with 95% confidence intervals calculated using the Exact Binomial Method will be produced for the number of patients recruited, retained and completing outcome data. Baseline characteristics will be tabulated both

overall and by treatment group (defined by intention to treat) to assess whether patients recruited to the control and intervention arms differ. Means and SDs (or medians and IQRs) will be reported for continuous measures and proportions for binary measures. Differences in follow up rates between the treatment and control groups will be estimated.

10. Realist Process Evaluation. As well as informing feasibility, the data collected will inform the process evaluation. The purpose of the process evaluation is to establish how well the intervention worked in practice, what the difficulties were and what could be improved. This will include a realist logic to identify and understand the mechanisms by which outcome patterns found in have occurred within the programme theory. The hypothesised causal model will be refined based on a realist analysis of these data.

11. Future trial protocol development: A summary statement of the future trial will be developed by project end with the full protocol completed within six months. The summary statement will include a revised description of the intervention, the primary and secondary outcome measures and procedures for recruitment and data collection. The feasibility study will be used to select outcomes for the main trial; the decision on primary outcome will be based on the importance of outcomes to patients and clinicians, fit with the programme theory, variability and amount of missing data, and the requirement to power a future trial.

Intervention Type
Behavioural

Primary outcome(s)
Proportion of patients with at least one follow-up appointment for the same problem with 1 month and 3 months measured through the patient record at 1- and 3-month follow-up

Key secondary outcome(s))
1. Index value of health-related quality of life for economic evaluation purposes measured though the EQ-5D at baseline and 2-week follow-up
2. Profile of health and well-being, health knowledge and self-care and confidence in health plan measured though the Primary Care Outcomes questionnaire at baseline and 2-week follow-up
3. Perceived clinician empathy and doctor-patient communication measured through the consultation and relational empathy tool at 2-week follow-up
4. Patient satisfaction measured through a single item on patient overall satisfaction with the consultation at 2-week follow-up
5. The extent to which the patient's main problem was resolved measured through a single item adapted from other studies in primary care at 2-week follow-up
6. The extent to which consultation addresses patients' priorities measured through a single item adapted from the LTC6 at 2-week follow-up
7. The extent to which consultation provided patients with information to manage their health measured through a single item adapted from the LTC6 at 2-week follow-up

Completion date
31/03/2022

Eligibility

Key inclusion criteria
1. Aged 18 or over (on date of SMS invitation to participate)
2. Have an appointment with their GP within the next two days

The inclusion criteria will be revised during the studies, as the researchers assess which patients the intervention is most useful for.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients with a recent diagnosis of life-limiting or life-threatening illness
2. Patients with a life expectancy of less than 12 months
3. Patients deemed by the GP to be at serious suicidal risk
4. Patients unable to complete questionnaires even with the help of carers

Date of first enrolment
09/12/2019

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR CRN: West of England
United Kingdom
BS1 2NT

Study participating centre
Courtside Surgery
Kennedy Way
Yate

Bristol
United Kingdom
BS37 4DQ

Study participating centre
Nightingale Valley Practice
Brooklea Health Centre
Wick Road
Brislington
Bristol
United Kingdom
BS4 4HU

Study participating centre
Pioneer Medical Group
Ardenton Walk
Brentry
Bristol
United Kingdom
BS10 6SP

Sponsor information

Organisation
University of Bristol

ROR
https://ror.org/0524sp257

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-1217-20012

Funder Name

National Institute for Health Research (NIHR) (UK)

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

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. Although the repository is publicly available (visible and indexed via search engines) the data itself has controlled access.
Repository: https://data.bris.ac.uk/
Type of data that will be shared: Interview transcripts and questionnaire data (where consent has been given) in .csv and .doc format
When the data will become available: January 2022
For how long: 20 years
By what access criteria the data will be shared including with whom: Data will only be made available to bonafide researchers, subject to verification by the University of Bristol Research Data Service, and released under a legally binding data access agreement.
For what types of analyses: This was not specified in the consent form, and will depend on the study in question. The Research Data Service will make the decision on whether it is appropriate to share based on the information given in the application and supporting documents from the researcher applying to access the data.
By what mechanism: By secure file transfer
Whether consent from participants was obtained: Yes. Consent is optional. Only patients who have consented to data sharing will have their data uploaded to the website.
Comments on data anonymisation: Data will be anonymised. The Research Data Service will establish the level of anonymisation and including disclosure risk before uploading the data.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		21/02/2022	06/03/2024	Yes	No
Results article	Revised version	29/07/2022	06/03/2024	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes

Protocol (preprint)	Study website	03/09/2021	20/09/2021	No	No
Study website		11/11/2025	11/11/2025	No	Yes