Research Study Protocol: Using health information systems to address patients concerns in general practice: the COAC Intervention development and feasibility study

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Abstract

Background

Problems are missed in up to 50% of primary care consultations. This is costly for the NHS, both in terms of reconsultation rates and in missed opportunities to increase patient empowerment. Research suggests that interventions at each end of the consultation can help to address patient concerns. At consultation initiation, sharing the results from electronic patient-reported outcome measures (ePROMs) with clinicians can help to elicit concerns. At consultation closure, providing the patient with written information to supplement spoken can improve recall and adherence.

Aims and Objectives

Aim: To develop and test a complex intervention designed to more comprehensively address patients' concerns in general practice, thereby reducing re-consultation rates, improving patients' well-being and health knowledge, reducing health concerns and increasing patients' confidence in their health provision and health plan. The aims will be achieved through two studies. Firstly a complex intervention will be designed, which uses an ePROM at consultation opening and a report printed or texted at consultation closure. Secondly, this intervention will be tested to establish the feasibility both of the intervention and of a randomised control trial (RCT) of the intervention.

Methods

1. Intervention Design Study: This will involve:

1. Design of an online questionnaire system using practice SMS/email systems and online survey software to allow patient self-completion of a pre-consultation questionnaire and a report showing low-scoring questionnaire items, which is shared with GPs or nurses.
2. Testing the pre-consultation system with 45 patients in 3 rounds, using a person-based approach, with iterative adjustments made based on patient, administrator, receptionist, nurse and GP feedback after each round.
3. Design of an electronic template, integrated with the patient record, to provide a printable consultation-closure report to patients on issues raised in the consultation, advice given, treatment, follow-up and safety-netting.
4. Testing the consultation-closure report iteratively with 45 patients in 3 rounds, using a person-based approach, with iterative adjustments made based on patient and GP/nurse feedback after each round.

2. Feasibility Study: The intervention will be tested in a cluster-randomised framework as follows:

1. Refinement of the intervention and update to programme theory.

2. Randomisation of six practices: four randomised to intervention, and two to control.
3. Recruitment of 30 patients per practice: 120 intervention and 60 control.
4. Data Collection of quantitative data via GP/nurse-report, patient-report and health records. Interview of GPs, nurses, practice manager, administrators and receptionists and up to 30 patients.
5. Realist evaluation of the data to identify and understand the mechanisms by which outcomes have occurred within the programme theory.
6. Data analysis of recruitment rates, follow-up rates, data completeness, re-consultation rates within one/three months and other outcomes measures to assess feasibility of a future RCT.
7. Evaluation of pre-agreed success criteria to decide whether to continue to RCT, stop, or modify the intervention.

Timelines for delivery

Study 1 will be completed from October 2019 – March 2021 and study 2 from April 2021 – April 2022.

Anticipated impact and dissemination

Results will be disseminated through targeted communications in social media, the University of Bristol website, policy briefings, academic papers, patient participation groups, community associations and seminars and conferences. The study output resources will be made available for immediate use. If progression criteria are met, we will aim to complete a randomised control trial within five years.

1 Introduction

1.1 Summaries

1.1.1 Plain English Summary

Problems are missed in 50% of primary care consultations. This might be because of insufficient time for patients to discuss all their problems, or they could be interrupted by the GP when they start to explain. Sometimes, patients are unclear after the consultation about advice given.

In this study we will develop and test the Consultation Open and Close (COAC) intervention, aimed at improving clinician/patient communication. The intervention involves: 1) a pre-consultation questionnaire which patients complete on smartphone/computer before their consultation and is shared with GPs or nurses; and 2) a printed report given to patients at the end of their consultation or sent via text message. The pre-consultation questionnaire will identify the patient's reasons for consulting and other health issues, and may include problems troubling the patient that would otherwise not have been raised. The

consultation-closure report will provide an agreed understanding between the patient and GP or nurse and help the patient remember advice given.

To do this, we will carry out two studies: one to develop the intervention and one to test it. In study 1 (Intervention Development Study), both the pre-consultation questionnaire and consultation-closure report will be developed in rounds, by starting with a prototype and piloting it in three health centres sequentially, with 15 patients each. Data gathered through interview/questionnaire from patients/GPs/nurses/administrators will be used to improve the questionnaire and report, and the improved versions will be tried in the next health centre. Study 1 will result in a final intervention ready to test.

In study 2 (Feasibility Study), we will test this intervention in four health centres and collect information about how this worked for 120 patients. We will collect the same data from 2 health centres (60 patients) running standard consultations. Through Study 2, we will find out if it is feasible to run a larger study to compare the two groups.

1.1.2 Scientific Summary

Background

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1.2 Rationale for Study

1.2.1 What is the problem being addressed?

Patients often leave GP consultations with unaddressed concerns.[1] [2] This can lead to high rates of re-consultation and increased morbidity in the population. Previous research shows that approximately 27% of patients consulting in primary care have seen a doctor or nurse for the same problem in the last four weeks[3], and more recently published research that up to 50% of consultations in primary care are followed by another consultation within two weeks.[4] Although there are no estimates of re-consultation for unaddressed concerns in primary care, we know that problems are missed in up to 50% of primary care consultations,[2] and that reducing consultation rates by just 1% in 2016 could have saved the NHS over £100 million.[5] Primary care patients often present with multiple problems, many of which are unrelated to physical symptoms, and include informational needs on symptom-management or self-care, emotional problems, health concerns or social problems.[6] In the context of multiple presenting problems, GPs tend to focus on physical symptoms.[7] While this prioritisation is entirely appropriate to ensure correct diagnosis and patient safety, any missed opportunities to improve patient understanding and ability to self-care is also costly: a study in 2015 found that increasing patient engagement in their own health could save the NHS £2 billion by 2020.[8] Small changes to improve the ability of GPs to address patients' presenting problems, concerns and questions could therefore have considerable impact on the overall NHS budget.

The Calgary-Cambridge guide, which is used as a basis for training medical students and doctors, identifies six steps to conducting a GP consultation: initiating, information gathering, providing structure, relationship building, explanation/planning and closing.[2] Opportunities to address patients problems are commonly missed at consultation initiation (when the GP should elicit the patients reason for attendance).[2] Problems can remain unaddressed at consultation closure, if advice given is unclear, particularly with regards "safety-netting": i.e. advising patients what to do if the problem does not resolve, or gets worse.[9] Research suggests that interventions at each end of the consultation can help to address patient concerns. At consultation initiation, sharing the results from patient-reported outcome measures (PROMs) with clinicians can help to elicit concerns.[10] At consultation closure, providing the patient with written information as well as spoken can improve recall and adherence.[11]

This project proposes the development and testing of an intervention, incorporating use of an individual-level PROM at consultation opening and written information at consultation closure. The primary aim is to develop and test the feasibility of a complex intervention designed to more comprehensively address patients' concerns in general practice, thereby reducing re-consultation rates, improving patients' well-being and health knowledge, reducing health concerns and increasing patients' confidence in their health provision and health plan.

1.2.2 Why is this research important in terms of improving the health and/or wellbeing of the public and/or to patients

and health and care services?

The study is important to patients because it is designed to more comprehensively address patients' concerns in general practice, thereby improving patients' health and engagement in their health. NHS GP consultations are currently among the shortest in Europe.[12] Within this context, there are substantial numbers of patients who are a) not having their primary concerns addressed during the consultation and b) receiving advice they do not agree with, understand or remember. In the context of increasing use of smartphones, mobile health apps and widespread use of text reminders from practices to patients, there is an opportunity to use technology to allow patients to share their concerns more efficiently, and for GPs to feedback advice to patients in a more structured way. The intervention is expected to help patients reflect on their concerns before attending a GP or nurse, enhance clinician-patient communication, increase patient's health knowledge and ability to self-care, increase patients' confidence in and adherence to their health plan, reduce patient concerns and increase their confidence in their health providers.

The study is important to health services because reduction of re-consultation rates, even by a small amount, could ultimately save the NHS considerable sums of money. This is particularly important currently, because patients are increasingly accessing their GP patient record online. GPs have expressed concerns that unlimited access to the patient record may lead to misinterpretation and compromise patient safety.[13] The templates designed in this study will allow GPs or nurses to provide access to consultation contents in a structured way, which patients can understand.

If the intervention is feasible, we will apply for funding for an RCT to evaluate its impact. The results could have wide-reaching impacts on primary care patients and cost savings to the NHS.

1.3 Review of Existing Evidence

1.3.1 Consultation initiation: Eliciting all concerns

Active listening was described by Carl Rogers as absorbing everything a person says without "subtracting" or "amending".[14] Many patients regard the ability to listen as the single most important characteristic of a good doctor.[15] The importance of active listening has long been recognised and incorporated into undergraduate medical curriculae.[16]

Despite this, studies have shown that GPs often interrupt patients, particularly during the patient's opening statement (or patient monologue).[2] Although GPs may perceive that the patient monologue is wasting time, in fact, it take only 30 seconds on average.[17] One study showed that doctors wait 23 seconds on average before interrupting the patient's opening statement[1] when less than ten seconds more would usually allow the patient to finish. When GPs interrupt, they are nearly always doing with their patients interests in mind: recognising the importance of listening, but having limited time to gather

essential information from patients before moving onto diagnosis and advice.[18] In many cases, GPs interrupt because a patient is providing medical history which the clinician already knows. One approach to dealing with this problem is “physician goes first”: whereby the doctor starts the consultation with a very short synopsis of what he/she knows about the patient’s recent medical history, before asking the patient about their goals for consulting and allowing them to speak uninterrupted.[19]

This approach can be facilitated by a review of the patient’s medical record before the start of the consultation, and also by patient completion of a PROM, which is shared with the GP or nurse before the consultation. This can save valuable consultation time, by giving the GP or nurse an immediate oversight of the patient’s current state of health and immediate presenting problems.[20]

1.3.2 Consultation closure: Provision of written information

The closing steps of a consultation are when clinicians summarise, make a plan with the patient, safety-net and check the patient’s understanding.[21] Patients often raise last-minute concerns at this point, particularly if all concerns have not been elicited early on.[22] Patients’ memory for advice on treatment and follow-up after the consultation tends to be worse with older people; if the information given contradicts existing beliefs; or if potentially life-altering diagnostic information is given.[11]

Written advice can be provided at any point in the consultation, but is most often provided at consultation closure. This may be general information on a specific condition, healthy lifestyle advice or safety-netting advice. Provision of written information can improve patient understanding, memory of the consultation and subsequent adherence.[11] [23] Patients remember specific advice which is individually tailored to them more easily than generic advice provided in patient information leaflets.[11] Where patients are routinely provided with information on their medication and consultation, through direct patient record access, this has improved patient safety and adherence.[13]

1.3.3 Use of electronic PROMs at an individual level primary care

Patient-reported outcome measures (PROMs) were originally designed for use at aggregate level, to compare the scores of groups of patients receiving different care.[10] However, PROMs are increasingly being used at an individual-level to inform a consultation, set priorities or aid diagnosis.[10] Feedback of individual-level PROMs information to clinicians has been used most widely in cancer; it has an effect on patient care and the patient experience but there is less evidence for an impact on outcomes.[24] Trials of PROMs feedback to clinicians which *have* shown effects on patient outcome tend to use randomisation at the physician or practice level, rather than the patient-level.[25] PROMs feedback to clinicians can improve patient care through promoting patient self-reflection thereby helping patients remember their main concerns,[26] by improving patient-clinician communication[27] and by making it easier for patients to share information which they find it difficult to share verbally.[28]

In the USA, the COOP-Charts have been used in some practices as a patient-clinician feedback tool for over 25 years.[29] More recently the use of depression screening questionnaires were incentivised under

the Quality and Outcomes Framework (QOF). Many GPs found these impersonal and intrusive to the consultation, and preferred patients to complete them outside the consultation.[30]

A realist review of feedback of individual-level PROMs to clinicians found that one mechanism by which individual-level PROMs can work is by raising clinicians' awareness of patient concerns.[10] In the context of increasing GP workload, it is important that these PROMs capture relevant information, delivered succinctly. Benefits of electronic PROMs (ePROMs) include; remote completion, instant transfer, and filtering and summarising of data so clinicians see only the most important information. They also solve problems with questionnaire completion in waiting rooms; most primary care patients book an appointment only one or two days in advance so recruiting patients before a primary care consultation normally requires waiting room recruitment.[31] This limits the time for questionnaire completion, and some patients will be called to their consultation before completing the questionnaire.[32] The current widespread digitisation in general practice[33] offers a timely opportunity to integrate an ePROM into clinical practice for use at an individual-level to help identify patient concerns.

1.3.4 Feasibility studies of RCTs for PROMs feedback

The NIHR draws a distinction between a "pilot" study (a full trial in miniature, including assessment of outcomes) and a "feasibility" study (research designed to investigate whether a trial will be feasible, which does not include assessment of the primary outcomes).[34] Some feasibility studies test feasibility of the intervention only; for example, the recent eRAPID feasibility study found that using PROMs to monitor adverse events after cancer surgery was reassuring to patients and valuable to clinicians without increasing their workload. The study did not include a control arm.[35] In contrast, the DIAT feasibility study of PROMs feedback to clinicians in diabetes included a control arm and showed that, despite the intervention being acceptable, it was not feasible to run an RCT, because the burden of the study on patients and clinicians meant that not enough patients were recruited, and too many were lost to follow-up.[36] In such feasibility studies the complexity of the intervention and of randomisation, the burden of questionnaires on patients and the ease of obtaining outcome measure data from the clinical record needs to be carefully assessed during study design.

1.4 Study Aim and Objectives:

Study Aim

To develop and test a complex intervention designed to more comprehensively address patients' concerns in general practice, thereby reducing re-consultation rates, improving patients' well-being and health knowledge, reducing health concerns and increasing patients' confidence in their health provision and health plan.

The aim will be achieved by two objectives.

Objective 1

To design a complex intervention (The Consultation Open and Close Intervention) to improve the ability of GPs or nurses to address patients' concerns, incorporating the use of an ePROM at consultation opening and a report at consultation closure, which is either printed, texted to the patient or accessible from the patient record.

Objective 2

To test the Consultation Open and Close intervention in a cluster-randomised framework to establish the feasibility both of the intervention and of a randomised-control trial of the intervention.

These objectives will be achieved through two corresponding studies, which are described separately in this protocol, as the Intervention Development study (Study 1) and the Feasibility Study (Study 2)

2 Administrative Information

2.1 Study Applicants

This study is hosted by Bristol, North Somerset and South Gloucestershire CCG (BNSSG CCG), and undertaken by the University of Bristol (UoB). The University of Bristol is the research sponsor. The study applicants are named below.

Chief Investigator	Mairead Murphy	University of Bristol
Co-Investigator	Chris Salisbury	University of Bristol
Co-Investigator	Tom Palmer	University of Bristol
Co-Investigator	Geoff Wong	University of Oxford
Co-Investigator	Jude Hancock	BNSSC CCG
Host organisation manager	Paul Roy	BNSSC CCG

2.2 Feasibility Study Registration

The study will be registered firstly on the Central Portfolio Management System (CPMS) and secondly on the ISRCTN database.

The application for CPMS Registration will be made to the NIHR Clinical Research Network (CRN) in March/April 2019. This will be done through the Integrated Research Application System, which allows concurrent application for ethical approval and CRN support.

All studies eligible for Clinical Research Network support which have a study identifier are able to register for an ISRCTN using the CPMS and we will register this study on ISRCTN following CRN approval.

As the study is non-CTIMP research, these registrations represent good practice, as opposed to a legal requirement.

3 Study Design

3.1 Study Setting

This study is based in primary care involving general practices serving different patient populations in Bristol, North Somerset and South Gloucestershire. Practices will be selected from areas within a range of socioeconomic deprivation levels as well as urban, suburban and rural areas.

3.2 Study design

Study 1 (Intervention Development Study)

A complex intervention was designed to improve the ability of GPs and nurses to address patients' concerns. Developing the intervention was done in two steps. In the first step, we developed an online 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 were be designed to provide patients with information on consultation closure, either printed, texted or emailed to the patient.

Study 2 (Feasibility Study)

The complex intervention designed in study 1 was tested for feasibility in a cluster-randomised framework with a targeted 120 patients in four practices receiving the intervention and a targeted 60 patients in 2 practices as a control, with a view to improving the ability of GPs and nurses to address patient concerns.

3.3 Eligibility Criteria

Practices were recruited with the following characteristics

- A minimum of three GP partners
- Minimum list size 5000
- Use the patient records system EMIS
- Use MJOG SMS alerts to patients (or a similar patient alerts system)

For the intervention development study (3 practices) we purposely selected one practice in the top deprivation quartile, one at the median, and one at the bottom quartile.

For the feasibility study (6 practice), we selected 3 practices in the top two deprivation quartiles and three practices in the bottom two. Practices were then randomised such that there were

Patients in both studies were included who were:

- Aged 17 or over (on date of SMS invitation to participate)
- Had an upcoming appointment with a recruiting GP within the next week

Patients were excluded if they were:

- Housebound
- Had not given permission to receive SMS messages from the practice
- Had a recent diagnosis of life-limiting or life-threatening illness,
- Were deemed by the GP to be at serious suicidal risk,
- Were unable to complete questionnaires in English even with the help of carers.

3.4 COVID-19 pandemic related protocol updates

The risk of face-to-face contact during the COVID-19 pandemic, which occurred six months into this study, required that research study protocols were adjusted to remove face-to-face contact between researchers and participants. Even prior to the COVID-19 pandemic this protocol allowed for the entire intervention to take place remotely, as the pre-consultation report is sent electronically to GPs and the consultation-closure report can be either printed and given to the patient or sent via SMS/email. However, the previous protocol made reference to 1) face-to-face on-site training of GPs and administrators 2) the possibility of researcher presence on site to observe consultations and assist with technical problems 3) Patient and GP interviews taking place face-to-face. Under an NIHR directive, the study was paused in March 2020 and restarted in September 2020. The protocol was updated before the study restarted in September

4 Research Steps

4.1 Overall design

4.1.1 Two study design

The study will incorporate two studies: an Intervention Development Study (Study 1) and a Feasibility Study (Study 2). The Intervention Development Study will itself be carried out in two distinct parts, one for development of the online pre-consultation questionnaire and one for development of the closure report. These will be designed and evaluated separately, in accordance with MRC guidance for design of complex interventions.[37] The two technologies will be tested with actual patients using a person-based approach, which involves using mixed-methods research to systematically investigate the needs, attitudes and situation of the people who will be using the intervention.[38] Through the person-based approach, each step of the intervention is tested in rounds and adjusted after each round according to the feedback given from patients and clinicians. This protocol was updated after completion of the Intervention Development Study. As agreed with the REC, the protocol has been left in the same format as

before, so it refers to the Intervention Development study as being in the future even though the study has already been completed as of 1st March 2021 (date of this protocol). An update on the progress made in the Intervention Development Study is provided in Sect. 4.3.2.

4.1.2 Questionnaire as intervention

This study uses an electronic questionnaire sent to the patient before the consultation which is shared with the GP or nurse before the consultation. Because questionnaires in research studies are normally used to collect data for research purposes, as opposed to being part of an intervention, this is a potentially confusing aspect of this study, and it is thus explicitly clarified here. In the Intervention Development study (study 1), the questionnaire is used to share information between the patient and clinician and is referred to as “the pre-consultation questionnaire”. In the Feasibility Study (study 2), there is a baseline and follow-up questionnaire. The baseline questionnaire encompasses the pre-consultation questionnaire and the EQ-5D, and is used both to share information between the patient and clinician AND to collect data for research purposes. The follow-up questionnaire is used for research purposes only.

To avoid confusion, this application uses the word “pre-consultation questionnaire” to refer to the questionnaire used in study 1 (the Intervention Development study) and “baseline” and “follow-up” questionnaires to refer to the questionnaires used in study 2 (the Feasibility Study).

4.2 Study 1: Complex Intervention Development

4.2.1 Objective

To design a complex intervention (The Consultation Open and Close Intervention) to improve the ability of GPs and nurses to address patients’ concerns, incorporating the use of an ePROM at consultation opening and a report at consultation closure, which is either printed, texted to the patient, or accessible from the patient record.

4.2.2 Starting position: pre-consultation questionnaire

A standard questionnaire and report have already been developed, based on the Primary Care Outcomes Questionnaire (PCOQ) and these will be used as the starting point for person-based development and testing. The PCOQ is a validated generic questionnaire which was developed to capture the main outcomes which can be influenced by primary care. It has 24 items which include physical and emotional symptoms and function, self-care, health behaviour, adherence, and a sense of support.[32, 39]

Pre-consultation questionnaire

The pilot work with PPI/GPA groups suggested that the pre-consultation questionnaire should include both individualised information (a list generated by the patient, of their reasons for attending, and the key issues they would like to discuss) and standardised information (a short list of questions on common symptoms and problems, with tick-box answers). The pre-consultation questionnaire has been put into an

online survey using the University of Bristol database system REDCap: a low-cost, secure, web-based electronic data capture system for clinical research.[40] Only 18 of the 24 PCOQ items have been included, as six items refer to the patient's confidence in seeking healthcare, and are not suitable for sharing patient concerns with a clinician. Versions have been developed for smartphone and computer. A screenshot of one of the phone-version questions is shown below. The full questionnaire is shown in Appendix A.

Pre-consultation clinician report

The information from the pre-consultation questionnaire will be downloaded from REDCAP and attached to EMIS in a pdf report format for the GP or nurse to review before the consultation. Rather than simply attaching the full questionnaire, this will be formatted so that it is short and easy for clinicians to digest. It will contain two sections: an individualised section with the patients' reasons for attending, and a standardised section, which will be a colour-coded list of responses to standard questions. The individualised section will help set the consultation agenda, and identify the ostensible reason for the encounter.[41] The standardised section will act as what Carter/Greenhalgh refer to as a "tin-opener": i.e. rather than giving answers, it will open up potential problems which may have gone unrecognised, and it requires the clinicians probing and examination to further investigate these.[10] The format of the report is essential in making sure that it can be quickly and easily reviewed by clinicians. In common with other current studies we plan to use a report based on a fixed list of domains, with colour-coding reflecting the severity. This means that after becoming used to the report, clinicians will obtain information on the patient's problems from the colour pattern; for example, if the second line is red, this always means the patient has indicated severe emotional problems (depression or anxiety). The 18 PCOQ items will be grouped into eight report rows.

4.2.3 Starting position: consultation closure report

Based on initial PPI/GPA consultations the report is likely to have four sub-headings as follows:

1. Issues raised in the consultation today
2. Advice given
3. Treatment,
4. Follow-up and safety netting

Unlike the pre-consultation questionnaire and report, there has not yet been any electronic configuration, testing or validation of this report (as of start of study in October 2019. See 4.3.2 for an update on this.

4.2.4 Study 1 activity plan

This study will be completed in the first year of the project, from October 2020 – October 2021. From the starting points described above, the following activities will be carried out.

- 1. Pre-consultation report PPI and GPA consultation:** We will consult with the PPI and GPA groups on the initial pre-consultation Questionnaire and feedback report. 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. Pre-consultation report: practice recruitment, training and testing :** Three practices will be recruited. Administrative staff will be trained to send scheduled texts to patients by SMS with information on the study an individualised link to the pre-consultation questionnaire, and to upload the summary report from REDCAP to the EMIS patient record system.
- 3. Pre-consultation report: patient recruitment:** Administrative staff will recruit patients via text over a period of two weeks.
- 4. Pre-consultation report: Intervention testing:** Three GPs or nurses, at least one in each recruited practice, will test the system with 15 patients each. A researcher will observe the consultation if the patient provided consent for this in the pre-consultation questionnaire. The exception to this is for recruitment taking place during the COVID-19 pandemic. During this period, there will be no consultation observation.
- 5. Pre-consultation report: Interviews, Iterative Evaluation and Refining:** The GPs, nurses, reception staff, administrative staff and up to twenty patients will be interviewed in two or three rounds. 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.
- 6. Specification and development of closure report:** An EMIS template will be developed for the consultation closure report. The GP advisory (GPA) and PPI groups will be consulted on the report content, in a series of 4 meetings: two GPA meetings and two PPI meetings.
- 7. Person-based testing of closure report: Recruitment, training and testing:** Three GPs and/or nurses (at least one per practice) will be trained in completion of this consultation-closure report template and will test the report with 15 patients each.
- 8. Iterative Evaluation and Refining:** As with the pre-consultation questionnaire testing, all clinicians and up to twenty patients will be interviewed in two or three rounds. Topic guides will include questions about the technical feasibility and usefulness of the report; suitability of the eligibility criteria, time taken and whether clinicians 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.

If practices agree, a researcher will be present in the practices during the six recruitment days for the pre-consultation report development to observe the administrative process, observe some consultations (with prior patient consent) and offer technical assistance to the administrator who will need to send out daily texts, using practice SMS software, to a patient list and upload the individual patient reports from the University of Bristol system REDCAP to EMIS. As of March 2020 to the date of this protocol, the

agreement with the practices is that there will be no researcher presence on site, so such assistance will instead be provided remotely until the situation changes.

4.3 Study 2: Complex Intervention Feasibility Study

4.3.1 Objective

To test the Consultation Open and Close intervention in a cluster-randomised framework to establish the feasibility both of the intervention and of a randomised-control trial of the intervention.

4.3.2 Starting position

The electronic tools were updated and developed during study 1, following the process described under 4.2. The tools now consist of the following:

Pre-Consultation questionnaire

The pre-consultation questionnaire was shortened from 24 to 14 questions. The report provided to GPs now has ten colour-coded rows. The first block of 5 rows are about the patient's health and well-being (pain, physical and mental symptoms, effect on normal activities and health concerns). The second block or 5 rows is about patient's wider support needs (health knowledge, support needed, adherence, health lifestyle and confidence in health plan).

1 Dizziness	consulted about 3-4 times
2 Insomnia	new problem

The list below highlights some other problems your patient might have. Green indicates no problems. Light green indicates slight problems. Amber is moderate and red is severe.				
1 Pain	(1)	1		None
2 Other Physical Symptoms	(1)	4		Quite a bit
3 Effect on normal activities	(1)	4		Quite a bit
4 Low mood / Anxiety	(2)	3		Moderate
5 Concerns about serious illness	(1)	1		None
6 Health Knowledge	(2)	3		Somewhat lacking
7 Support	(2)	3		Somewhat lacking
8 Adherence to treatment	(1)	1		All advice
9 Healthy lifestyle	(1)	3		Some of the time
10 Confidence in health plan	(1)	3		Moderately confident

REMEMBER TO TELL THE PATIENT THAT YOU HAVE READ THIS REPORT
Blue signifies free-text written by the patient. Black text is based on patient's selected responses.

See the Annex for the up-to-date questions and the file: COAC Pre-consultation GP training pack v1 March 2020 for GP training on the pre-consultation report.

Consultation-closure report

The co-investigators have engaged with One Care, the GP Federation for Bristol, North Somerset and South Gloucestershire to develop an EMIS protocol, clinical template and document template which the clinician launches towards the end of the consultation. This has four sections:

1. Advice given in the consultation today
2. Tests ordered
3. Safety-netting,
4. Next steps

After the GP completes the clinical template, the protocol launches a document to be provided to the patient. This document has two sections, plans and advice and next steps. The GP has the option to a)

print the report and hand to the patient (for face-to-face consultations only) b) send via email c) send via SMS message using accuRX, a desktop-based SMS system that is integrated with the patient record.

An example patient consultation-closure report is shown below. Full details of the template and process can be found in the file Closure Report Instructionsv1.6.

We are working with the University of Bristol to try out this form. If you are willing to discuss how clear you found the form with a researcher, please email bris-coac-study@bristol.ac.uk or phone/text 07841 434 525. You will receive a £20 voucher for your time.

Plans and advice from One Care Practice 1 today (22-Feb-2021)

- There could be a number of reasons for your symptoms.
- The following tests are required:
 1. urine test
 2. stool test
 3. blood test
- You should bring in a sample for the urine and stool test.
- You should contact your GP surgery reception to book an appointment for the blood test.

What happens next

- The surgery will contact you with your test results.
- You can also review your results in the NHSApp. If you don't have this already you can download from this link: <https://www.nhs.uk/apps-library/nhs-app/>
- The test results will be ready after 5 days for the blood and urine tests and 8 days for the stool test.
- If your test results show anything unusual we will discuss this with you when we contact you.
- If your test results are normal, but you are still experiencing symptoms, please book another appointment to discuss the next steps.
- Contact the surgery if your symptoms get worse, you feel unwell, or you develop any other symptoms of concern as we discussed. When we are closed you can call 111 to speak to an Out of Hours GP.

Intervention

The intervention is likely to comprise the following:

1. Patients with an upcoming GP or nurse appointment are sent a text with the baseline and are invited to complete this before the consultation.

2. PREPARATION STEP: The pre-consultation questionnaire report (see Fig. 2) is delivered to GPs/nurses before the consultation (manually uploaded to EMIS from REDCap by practice administrative staff) and clinicians take about 20–30 seconds to review this information as well as patient history.

3. INITIATION: At the start of the consultation, the GP/nurse greets the patient with a brief verbal synopsis of the patients recent medical history/ PROM report, then invites the patient to speak without interrupting for up to 45 seconds. Following this, if the patient is still talking about the first presenting problem, the

clinician may interrupt to refer to a second problem, if raised, or to ask, “is there some other problem or concern you want to discuss today?” The idea of the clinician beginning like this (which we called “physician goes first”) is for the clinician to reassure the patient that they have seen the information, and prevent the patient from giving a long introduction which the GP or nurse is already aware of. However, research shows that patients like to be offered a general enquiry near the beginning of the consultation (e.g., What can I do for you today?) versus closed-down via a request for confirmation (e.g., Sore throat, huh?) (Heritage and Robinson 2006). Therefore, after the brief synopsis, the GP/nurse will then offer a general enquiry (e.g. “are those the main things you want to discuss?” or “is there something else you want to discuss today”) and will give the patient a reasonable length of time to respond before interrupting, redirecting or closing down. So in the example shown in Fig. 2, the GP/nurse might say: “I see from the information you provided that you are here about your heartburn, a cough and the sore foot. I can see the pain and discomfort from the cough and the foot are affecting you, and I can also see you are really worried about the cough. Is there something else you want to discuss today before we go through those things now?”

4. CONSULTATION: Clinician carries out the consultation according to his or her normal practice.

5. CLOSURE: Clinician provides eligible patients with a written print-out (given on paper for face-to-face patients, or sent by SMS for telephone patients) of what was agreed in the consultation, including specific safety-netting advice. This will only be provided to patients who have either had tests ordered, safety netting advice given a referral made or other specific follow-up.

A workflow for this intervention is shown in Fig. 3, and a proposed initial programme theory for how this intervention is intended to work is shown Fig. 4.

4.3.3 Study 2 activity plan

1. Refining and agreeing the intervention: The project steering group will sign-off the intervention and the proposed progression criteria for determining whether funding should be sought for an RCT following completion of the feasibility study. See Fig. 6 for the initial proposed criteria.

2. Ethics and revised protocol: The necessary ethic amendments and protocol updates will be made. A substantial amendment will be submitted to the research ethics committee that approved this study. The amendment will provide context of what has already happened, including the details of REC/HRA approval for the Intervention Development Study, a summary of the results of the intervention development study, and a summary of the changes resulting from this. Practices will only be recruited once this amendment has been approved.

3. 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 practices will be randomised one to control and two to intervention and similarly with the three least deprived practices.

4. Training: One GP and or nurse per treatment practice will be trained in the intervention. Control practice GPs/nurses will receive a shorter training. Administrators, practice managers and receptionists in both treatment and control practices will receive the same training, as the process will be similar. (see Fig. 3)

5. Patient recruitment and intervention: Each of the practices will recruit 30 patients, resulting in 120 in the intervention and 60 in the control. This will give a sample size of 180 overall, 120 of which receive the intervention. (see Table 1 below).

Table 1 Patient recruitment target in control and intervention practices			
	Intervention	Control	Total
Practices	4	2	6
Patients	120	60	180

An estimated 1,200 texts will need to be sent to recruit 180 patients. Figure 5 shows this in an anticipated CONSORT flowchart of recruitment. Clinicians in the intervention arm will carry out the consultation based on the intervention with the starting point described in 4.3.2.

6. Data Collection: Qualitative and quantitative data will be collected.

- a. A list of quantitative data is shown in Table 3, Sect. 6.1.
Qualitative data on fidelity, acceptability, feasibility, perceived benefit and other possible mechanisms will be captured via clinician questionnaires, interview of staff in each practice (GPs, nurses, practice managers, administrators and receptionists) and up to thirty purposively-sampled patients.
- b. A list of quantitative data is shown in Table 3, Sect. 6.1.

7. 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. See Data Analysis Sect. 6.2.2 for more details.

8. Process Evaluation. As well as informing feasibility, the data collected will inform the process evaluation. 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 shown in Fig. 4 will be refined based on a realist analysis of these data. (See data analysis Sect. 6.2.2 for more information).

9. 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.

5 Participants And Recruitment

5.1 Sampling Methodology

As this is a feasibility study, the sample size should be sufficient to measure feasibility parameters such as the recruitment rate, the retention rate and data completeness with adequate precision. It is estimated that at least 115 patients (64%) will provide follow-up data. A sample size of **180** would mean that a two-sided 95% confidence interval for a 64% follow-up rate, will have a width of $\pm 14\%$. An improved follow-up rate would generate a narrower confidence interval. A sample size of 180 will also allow a sufficient pool of participants for interview, presuming 20% will consent to this. (see data analysis).

5.2 Recruitment Procedures

5.2.1 Recruitment of General Practices

Practices will be approached by the NIHR Clinical Research Network for the West of England (hereafter referred to as the CRN) with the information on the study. Practices will be recruited to the two phases separately; with practices who participate in the Intervention Development study actively encouraged to continue their participation in the Feasibility study.

For each study, the CRN will share the Research Information Sheet for Practices (RISP) which has been developed for the study (see Appendix) with a range of practices meeting the inclusion criteria. Interested practices will then agree to be contacted by the CI, who will arrange a meeting(s) with the practice manager, GP partners and practice nurse(s).

Practice representatives will be asked to sign a practice agreement consenting to the practice taking part in the study. Practices will be approached for study 1 in November 2019 (three practices are required for study 1); and for Study 2 in April/May 2021 (six practices are required for study 2). Practices who were involved in Study 1 will be invited to continue onto Study 2.

All selected practices will already use SMS software (MJOG or accuRx) and the patient records system EMIS. Administrators are expected to be familiar with the process of sending batch texts using practices SMS software (e.g. MJOG) and in uploading reports to and setting alerts in EMIS.

5.2.2 Identification, recruitment and consent of patients

Feasibility Study:

General practices agreeing to participate will be asked to search their practice database using an electronic search strategy which identifies patients with upcoming appointments, and excludes patients based on pre-defined READ codes. A GP will then screen the list for the exclusion criteria. This will be done on a daily basis for fifteen days. Administrative staff will send scheduled texts to patients by SMS with an individualised link to the baseline questionnaire hosted on REDCap, and will download the summary report from REDCap to pdf and attach to the EMIS patient record system once the questionnaire is completed. The fifteen-day recruitment period has been planned based on the total patients who need to be texted to recruit target numbers. With four practices, reaching 800 patients involves contacting approximately 13–14 patients per day for ten days, which should be feasible based on GP/nurse lists (see Fig. 5). However, if this period needs to be extended, the cost will not be material (see risk log). As the intervention represents a low-risk change to practice, with randomisation happening at a health centre level, not an individual level, patients will not need to be informed about randomisation.[42] The baseline questionnaire will include a covering letter explaining the purpose of the study and how the data will be used. Return of the questionnaire will indicate consent. Patients will also be asked to consent to their contact phone number being shared with the University of Bristol for the purposes of sending a follow-up questionnaire. Consent for use of that phone number to contact the patient for interview and for access to the patients record for demographics and reconsultation rates will be requested in the follow-up questionnaire.[42] A similar approach has been taken for a number of other cluster trials.[43] [44] The researcher will then take full informed consent from patients who agree to be interviewed prior to their interview. This consent will be written for face-to-face interviews and audio-recorded consent for telephone interviews. For the audio-recorded consent, the researcher will first ask the interviewee to confirm their name and then read out each of the points in the consent form and ask the patient to confirm whether they verbally agree. If the patient does not wish to complete the consent process, the recorder will be stopped and the recording deleted.

Intervention development study:

Recruitment for development and person-based testing of the pre-consultation questionnaire will happen in the same way as study 2, except that patients will not be asked for consent to access their record (as this is not required from the intervention development study).

Recruitment for person-based development and testing of the consultation closure report will be done by GPs and nurses at the end of the consultation, followed by a follow-up text. As provision of this report represents a low-risk change to practice, without randomisation, GPs/nurses will not need to formally

consent patients to receive the report. Clinicians will simply tell patients that they are trying out providing a written report of the consultation and ask the patient if they would like to receive this report. Along with the written report, the clinician will provide the patient with an information leaflet on this part of the study, with the researcher contact details. Patients who are willing to be interviewed will contact the researcher. In case patients do not contact the researcher, a follow-up text will be sent to all participating patients who received the patient information leaflet reminding patients of the request to interview and asking them to respond “OK” if they are happy for their contact details to be shared with the researcher. The researcher will then take full informed consent from patients who agree to be interviewed prior to their interview.

A summary of the information leaflets and consent forms received in each of the studies is shown below. The Intervention Development Study has been split into Study 1a (development of the pre-consultation questionnaire) and Study 1b (development of the consultation-closure report). Study 2 is the Feasibility Study.

Table 2
Provision of information and consent in each sub study

#	Type of patient information or consent	Study 1a	Study 1b	Study 2
1	Initial Patient information leaflet	Received via texted questionnaire link from practice (see Appendix A File 4, Study1a-pre-consultationv1.4.docx)	Received from clinician at consultation end [or via SMS for telephone consultations] (see Appendix A, file 10 PatientInfo-InterviewStudy1b.doc)	Received via texted questionnaire link from practice (see Appendix A File 18, Study2-Baselinev1.5.docx)
2	Patient information leaflet for potential interviewees	Received from clinician at consultation end (see Appendix A, file 5 PatientInfo-InterviewStudy1av1.4.doc)		Received from clinician at consultation end (see Appendix A, file 16 PatientInfo-InterviewStudy2v.14.doc)
3	Consent for patient-reported data shared with researcher	Received via same texted questionnaire link from practice as #1. (File 4)		Received via same texted questionnaire link from practice as #1. (File 18)
4	Consent for interview	At start of interview (see Appendix A File 24, PatientConsent-Interviewsv1.3.docx)		
5	Consent for data sharing from medical record			Received via follow-up questionnaire texted from University of Bristol (see Appendix A File 19, Study2-FollowUpv1.4.docx)

5.2.3 Randomisation

The intervention development study does not involve randomisation.

For the feasibility study, randomisation will be done at the practice level. Cluster trials are most appropriate for interventions using PROMs feedback to clinicians, because contamination at the level of clinician or practice is a common problem with such RCTs; clinicians who are trained to make use of certain techniques at consultation opening and closure do not readily “forget” this training for control arm patients in an individually randomised trial.[25] Trials of PROMs feedback to clinicians which have shown effects on patient outcome tend to use randomisation at the level of physicians or practices, rather than individual patients.[25] Randomisation at the clinician or practice level also offers the potential for minimising the potential confusion that individual-level randomisation could cause for patients. In low-

risk contexts, a cluster design in which physicians or practices are randomly assigned to prescribe an alternative treatment can be implemented without obtaining individual patient consent for randomisation. [42] In the case of this feasibility study, this will mean that although patients in the treatment and control arms will receive similar questionnaires, treatment arm patients will be informed that the questionnaire will be used by the clinician in the consultation, and control arms will be informed that it is for research purposes only; patients will not need to be informed about randomisation.

5.2.3.1 Control Group

Feasibility study practices allocated to the control arm will continue care as usual. This will mean that clinicians carry out the consultation according to usual practice. The pre-consultation report will not be uploaded to EMIS, nor will a consultation-closure report be provided to patients. Control patients will still be prompted to complete a baseline questionnaire, via a text in advance of their appointment, to gather the baseline data, and consent for access to the patients record for demographics and reconsultation rates will be requested in the follow-up questionnaire.

Information workflow and procedures for the control group is shown in Fig. 3.

5.2.3.2 Blinding

It is not possible to mask participants or health care professionals to the group allocation of their practice. It is also not feasible to blind all members of the study team actively involved in the execution of the study. However, as far as possible, data analysis will be performed blind.

5.3 Withdrawal

5.3.1 Practice Withdrawal

A practice can decline to take part at any time during the initiation and set-up phase of practice

recruitment. Practices which participate in study 1 will be encouraged to continue to study 2. If they do not wish to continue, a new practice will be recruited. Non-continuation will not be considered as withdrawal. When practices agree to participate in either of the studies, they will be asked to sign an agreement confirming that they are committed to continue until the end of recruitment and will only withdraw in extreme and unexpected circumstances. If a practice wishes to withdraw, the situation should be discussed with the local team, steering group members and CI. All avenues should be explored to try to resolve the problems and concerns of the practice. If a practice must be withdrawn, then, time permitting, an additional site will be recruited, and allocated to the same randomisation group (if withdrawn in study 2). Data which has already been gathered from practices who withdraw will still be included in the analysis.

5.3.2 Patient Withdrawal

The intervention is designed to occur within a single consultation, therefore the only point at which patients could withdraw is from the follow-up data collection (i.e. completing questionnaires and/or allowing researchers to access their medical records). As this is a feasibility study, not a full trial, a key part of the analysis will be the follow-up data collection rates. Any data collected from the patient prior to withdrawal will therefore still be included in the final analysis of the data. Withdrawal from the study will not affect the patients' treatment or access to NHS services.

5.4 Safety

5.4.1 Researcher Safety

The Chief Investigator and the research associate will interview patients for both studies on a one-to-one basis in a location convenient to them. While social distancing is in place in the UK, this will be by telephone or video link. If face to face interviews are allowable these will normally be in the health centre, or the University of Bristol. Patients may wish to meet at their home. To protect the researcher in cases like this Bristol University have implemented a fieldworker safety policy, which will be followed throughout. This involves agreeing a safety protocol between the researchers, in this case between the CI and the research associate. A copy of this protocol has been attached in the Appendix.

5.4.2 Patient Safety

As this is a non-clinical feasibility study, adverse reactions to drugs or other interventions are not applicable. Participants and GP practice staff will be asked to notify either their practice or the chief investigator of anything they believe has affected their safety as a result of participating in the study. Any such notifications will be logged and discussed within two weeks of notification in a joint meeting with the practice research lead, the CI, Dr. Geoff Wong (GP co-applicant) and Professor Chris Salisbury (co-applicant and steering group member), who will agree the required action to be taken.

If a potential instance of clinical malpractice is either raised by a patient in interview or observed by the researcher in a consultation (Intervention Development Study only, as observation has been removed for the Feasibility Study), the following process will be followed:

1. The researcher will inform the CI of the observed incident or reported incident within 24 hours and, if reported during a patient interview, provide the audio-recording.
2. The CI will document the incident and inform the two GP co-applicants Dr. Geoff Wong and Professor Chris Salisbury within a further 24 hours.
3. The CI and at least one of the GP co-applicants will meet within one week to make a judgement on whether the incident constitutes reportable clinical malpractice - i.e. whether the clinician has behaved in a way may have breached their professional codes of practice as set out by the General Medical Council.

4. If the GP co-applicants confirm that the incident reported was one of potential malpractice, the CI will inform the local Principal Investigator, via secure email and requesting acknowledgement, copying the two GP co-applicants. If the local Principal Investigator is implicated in the potential incident of malpractice, the CI will instead email the Practice Manager to establish what the practice's processes are for taking forward such matters.

5. If no acknowledgement is received from the email within two days, one of the GP co-applicants will contact the local Principal Investigator/Practice Manager by telephone.

If the CI believes that a patient is in immediate danger, then he/she will bypass the above process and inform the local Principal Investigator/Practice Manager of the reported/observed incident directly, via secure email copying the two GP co-applicants, followed by a phone call.

6 Data Collection, Analysis Plan And Data Management

6.1 Data Collection

Intervention development study

Data collected in the intervention development study includes clinician questionnaire data and qualitative interviews from the person-based testing of the intervention elements and was described in Sect. 4.2.4. The interviews in study 1 (up to 40 patients and 12 practice staff) will be conducted by the CI (Mairead Murphy) and the project research associate. The interviews will be conducted face-to-face in the patients' own homes, health centre or other location of their choice, or by telephone, with consent taken immediately prior to the interview. For the period of the COVID-19 pandemic, we will only conduct interviews by telephone. The purpose of these interviews is to inform development of the intervention through a person-based approach (which takes place in rounds, with the intervention changed at the end of each round). Topic guides will focus on the feasibility and perceived usefulness of each of the two technologies, and on the proposed design of the intervention surrounding the technologies (see Appendix).

Feasibility study

Feasibility study data will include interview data clinician questionnaire data, patient reported data and information queried from the patient record.

Interviews in this study (up to 30 patients and 24 practice staff) will be conducted by the CI and the project research associate. These interviews will inform the realist/process evaluations and will be longer and analysed in more detail than study 1 interviews. We expect a sample of 54, but in practice patients and practitioners will be interviewed to the point of theoretical sufficiency, i.e. when the data analysis has yielded one or more coherent theories which are clearly grounded in the data.

The patient-reported data collected in the feasibility study is a combination of pre-consultation form data (included as part of the intervention to inform the consultation) and data collected for research purposes. There is overlap between these since some of the PCOQ questionnaire items are used both for the intervention and as a research outcome measure. At the start of the intervention development study the pre-consultation form had 18 questions based on 3 domains of the PCOQ. Through the intervention development process, 5 questions were dropped and the two “support” questions reworded to better identify potential social prescribing needs. As a result, 11 of the 13 questions from the pre-consultation form overlap with the PCOQ, but there is a need to ask seven more questions from the PCOQ for research purposes. The forms therefore contain:

Baseline: 26 questions

- 14 for the intervention (to be shared with the GP): 1 on the main problem, 11 directly from the PCOQ and 2 derived from the PCOQ but re-worded.
- An additional 12 for research purposes, 5 from EQ5D and 7 to complete the PCOQ.

Follow up: 37 questions

- 4 single-item questions on patient satisfaction,
- 18 PCOQ questions (to be measured against baseline)
- 5 EQ5D questions (to be measured against baseline)
- 10 Consultation and relational empathy tool questions. (We may remove or reduce the length of this questionnaire depending on feedback from practices – see Table 3 below).

The quantitative/questionnaire data which will be collected in the feasibility study is listed in the table below. All of the proposed outcomes are provisional and will be refined in the light of the intervention development phase and the qualitative research.

Table 3
List of quantitative and questionnaire data collected in the feasibility study

Measure	Tool used
Proportion of patients with at least one follow-up appointment with 1) one month 2) three months	Reconsultation with GP or practice nurse. A&E or a walk-in centre collected from EMIS.
Extent to which consultation uncovers problems, identified by the number of times each of the following was coded in the consultation: 1. Consultation about pain 2. Consultation about mental health problems 3. Consultation involved multiple diagnoses 4. Referral made to social prescriber or other allied health professional 5. Consultation involved health education or promotion 6. Two or more preventative/routine tasks carried out	Code lists linked to the patient record.
Perceived clinician empathy and doctor-patient communication	The consultation and relational empathy tool (10 items – follow-up only). This is a valuable outcome measure but relatively long. We may therefore remove or reduce it in length after consultation with practices. If we remove it, the item “Patient overall satisfaction with the consultation” (see below) will be used as a proxy for this.
Health and well-being	Three domains from the primary Care Outcomes Questionnaire (18 items – baseline and follow-up). The fourth domain – Confidence in Health Plan, will not be collected.
Health Knowledge and Self-care	
Confidence in Health Plan	
Patient satisfaction	Patient overall satisfaction with the consultation (single item – follow-up only)
Index value of health-related quality of life for economic evaluation purposes	EQ-5D (5 items – baseline and follow-up)

Measure	Tool used
Extent to which the patient's main problem was resolved	Single item adapted from other studies in primary care (follow-up only)
Extent to which consultation addresses patients' priorities	Single item adapted from LTC6 (follow-up only)
Extent to which consultation provided patients with information to manage their health	Single item adapted from LTC6 (follow-up only)
Length of consultation	EMIS
Fidelity to the intervention	GP/nurse questionnaire and interview
Administrator time taken on SMS recruitment and uploading reports	Administrator questionnaire

All information from patient-report will be collected on REDCap and will only be linked to the patient record after consent is received. Administrator and clinician questionnaires will be paper-based. Double data-entry will be carried out to check the accuracy of the data entered.

6.2 Analysis Plan

6.2.1 Study 1: Intervention Development Study

Interviews will be transcribed and analysed using a structured framework. Each researcher will analyse the interviews which they conducted plus a sample of five to six of interviews conducted by the other researcher to check for consistency of coding. Suggested changes to the technology or intervention arising from the data analysis will be agreed with the co-applicants at the end of each round.

6.2.2 Study 2: Feasibility Study

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[45] 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. Characteristics of patients in control and

intervention arms will be compared to see if there is any systematic difference in recruitment and follow-up rates.

Realist Process Evaluation

The process evaluation will be carried out using MRC guidance on process evaluation of complex interventions and based within a realist evaluation framework. Realist evaluation is a theory-driven approach which aims to identify core theories about how a programme is supposed to work and test them out to see if they are plausible, practical and valid. Realist evaluation seeks to explain the complex relationship between context, mechanisms and outcome. The explanatory proposition of realist evaluation is that interventions work (i.e. have successful outcomes) only in so far as the individuals involved take up ideas and opportunities (mechanisms) within the social and practical conditions they are operating in (contexts). (Pawson and Tilley, 1997).

In line with MRC guidance, the process evaluation questions will include:

1. Implementation factors (recruitment and response of practice teams, recruitment and drop-out of patients, fidelity to the intervention, adaptations, reach, time-taken, acceptability).
2. Contextual factors (practice resources, systems and structures),
3. Mechanisms of action (how participants responded to the intervention, how it achieved the outcome, unintended consequences).
4. Outcomes (what was achieved through the intervention, intended and unintended consequences as perceived by patients and clinicians)

Findings will be expressed as context-mechanism-outcome-configurations which explain what worked (and did not work), for whom, how, why and in what circumstances during the process of implementing the intervention in practice. Through this we will identify theories and counter-theories of how the intervention works. The hypothesised programme theory shown in Fig. 4 will be refined based on this realist analysis. Analysis of the data at control practices will include whether practices will participate even where there is no intervention and whether there are any unforeseen difficulties of implementing control arms.

To achieve this, the data will be analysed as follows:

Interview analysis

The CI will read and re-read the initial interview transcripts from both patients and practitioners, in order to gain an overall view of the accounts given, to identify patterns in the data, develop an initial coding frame and initial programme theories about the intervention. This coding frame will be discussed and agreed with the project research associate and the two GP co-applicants (Geoff Wong and Chris Salisbury). The remainder of the interviews will then be coded by the CI and the project research associate using the qualitative data analysis package NVivo10™. The researchers will each code a set of interviews, meeting regularly to discuss any new patterns in the data, theory confirmation or counter theories.

Questionnaires

Self-report questionnaires will be triangulated with the interview analysis to draw conclusions.

Based on the evaluation, the pre-agreed success criteria (see Fig. 6) will be evaluated, to decide whether to continue (i.e. apply for funding for an RCT), stop (do not progress to RCT), or modify the intervention.

6.3 Data Management

6.3.1 Confidentiality

Confidentiality of data will be safeguarded following the GDPR guidance issued for researchers by the NHS Health Research Authority (HRA) as follows:

1. **Consent:** All participants will be clearly informed verbally and in writing about the use of their information before consenting to their information being shared with the researcher or to the researcher access of their medical record. Patients can complete the pre-consultation questionnaire to be used by their GP or nurse without necessarily giving consent for their contact details to be shared with the researcher and can give consent to this without necessarily giving permission for access to their medical record.
2. **Data controllers and personal data:** Patients will be recruited to the study through their healthcare provider who will text them. Patients will be invited to give consent for their contact details to be provided to the researcher so that she can contact them for interview and with a follow-up questionnaire. Contact details will be held in a separate location from any other personal information and destroyed at the end of the study. All information will be held in accordance with the general data protection ruling on UoB secure servers. The UoB researcher will not have direct access to the patient medical record at any point. If patients consent to information from their medical record to be shared with the researcher, this will be provided to the researcher by the practice. Anonymisation of EMIS number will be done when the data is downloaded from REDCap onto the University of Bristol computers for analysis. At this point, EMIS number will be removed from the data, and participants will be given a unique identifier. The mapping from EMIS number to this identifier will be stored in a separate spreadsheet in a different folder which is only accessible by the CI. This mapping will be destroyed along with personally identifiable information within 3 months of project end.
3. **Transparency:** Patient information leaflets will be clear about exactly what information the patients are consenting to be shared with researchers.
4. **Data subject rights:** Participants will have the choice to opt out if they do not wish their anonymised data to be directly quoted, or if they wish to withdraw from the study at any point.

6.3.2 Data Transfer and Access

No-one outside the research team named in this application will have access to personal data during the study. After the study, with participants consent, anonymised study data will be made available to bona

fide researchers on request. These will only be made available to other researchers who have a valid reason for wanting to use the information, have a protocol detailing how the data will be used and have ethical approval for their research. All requests for sharing will be assessed by a data access committee to check they are authentic research requests.

Patient reported data and data from the patient medical record will be stored directly onto the UoB secure network and will not be transferred outside the UoB without prior consent. Interview data will be recorded onto encrypted digital recorders and will be transferred onto the UoB server as soon as possible.

6.3.3 Data Protection

All collection, storage, processing and disclosure of personal information will be performed in compliance with the GDPR. All investigators and study staff will uphold the Act's core principles, including storing contact information separately from patient-reported outcome data, and destroying contact information after the patient interviews have been completed. The University of Bristol have a data protection policy (see Appendix), which the chief investigator and UoB co-applicants have been briefed in according to the University of Bristol compulsory online training in *GDPR: Data Protection Essentials*

Any communications, reports or published results will not contain any personal data that could allow identification of individual participants. All computers used to collate data will have limited access measures via user names and passwords. Electronic mobile devices used to collect data will be encrypted. Databases and servers are stored in right-restricted areas with limited access. All data will be stored in locked facilities within secure offices.

6.3.4 Records Retention

The non-identifiable data arising from this study will be held for up to 5 years in accordance with UoB data retention policy. Patient contact details will be deleted after the interviews. All data will be anonymised.

7 Patient And Public Involvement

This study involves PPI throughout and therefore needs an effective PPI group. Comprised mostly of people with PPI experience, the current group would benefit from expanded membership, including people with a fresh perspective.

In summer 2019 we plan to recruit new members using values-based selection criteria, including interest in the topic, reasons for involvement and commitment for the study duration. We will revise the role description and working agreement with PPI contributors, who will receive expenses and reimbursement in line with INVOLVE guidance.[46]

The PPI group will be involved in intervention design, evaluation and dissemination as follows:

Intervention design

Study 1 involves design, development and testing of both the pre-consultation questionnaire and the consultation closure report. The PPI group will advise on the design of both of these, to ensure an optimal starting-point for person-centred testing. In discussion groups, members will firstly review and comment on the usability of the smartphone/computer REDCap versions of the initial pre-consultation questionnaires and report; and secondly on the usability and clarity of the draft consultation closure report. In Study 2 (the feasibility study), the group will review and comment on the intervention, the recruitment process, and the clarity of the patient recruitment email/text.

Evaluation

The PPI group will comment on the realist process evaluation, whether the programme theory is meaningful and on the proposed outcome measures found within the programme theory.

Dissemination

The PPI group will help to disseminate the intervention by co-presentation at relevant conferences, community groups and seminars; and co-writing the PPI involvement paper. They will also identify and post on relevant dissemination outlets, for example blogspots, Twitter, organisational Facebook pages. Funding will be sought separately for PPI to run six months beyond project end.

8 Dissemination, Outputs And Anticipated Impact

Dissemination strategy

This research will generate both new knowledge and new resources, which we will disseminate to practitioners, patients and academics. In the Centre for Academic Primary Care (CAPC) Bristol we have a dedicated communication manager who will help to ensure that both the knowledge and the resources reach those can use them, including through social media, the CAPC website, targeted emails, policy briefings, academic papers, seminars and conferences. We also have a close working relationship with the Senior Research Commercialisation Manager in University of Bristol who provides us with advice on Intellectual Property (IP). We will formulate an engagement plan at the end of year 1, and update at the end of year 2 to include dissemination of findings. We expect the following outputs:

Outputs: Resources

1. The EMIS template for the consultation closure report and training guide will be made available to GPs and nurses.
2. The pre-consultation questionnaire and report will be added to the REDCap public library after finalisation, and thereby made available to anyone using the REDCap system.
3. A report on the patient recruitment and follow-up system, and how this can be implemented using REDCap, EMIS and MJOG will be made available on the University of Bristol CAPC website.
4. We will produce a 'lessons learned' toolkit for use by commissioners, service providers and patient partners preparing to undertake similar research.

We anticipate four peer-reviewed publications as follows:

1. Designing the consultation open and close intervention through the person-based approach.
2. Insights from Patient and Public Involvement in designing a complex intervention in primary care.
3. A realist programme theory for the consultation open and close intervention.
4. The consultation open and close intervention: feasibility study of an RCT.

The fourth paper will be the key paper of the research, and we aim to publish this in a top international journal. We also anticipate eight presentations within six months of study completion, to include four conference presentations and four seminar presentations and will hold a stakeholder event, facilitated by the CCG, to which we will invite GPs, nurses, commissioners and PPG representatives. We will work with stakeholders during the feasibility study and in any subsequent RCT to develop a sustainable impact generation plan; this may ultimately include working with EMIS or a similar organisation to sustain the intervention beyond the research. We also plan to make as many of the outputs as possible freely available to non-commercial users under Creative Commons style licence.

9 Reporting

9.1 Progress reporting

A six-monthly progress report on study recruitment, retention, changes to protocol, issues or complaints will be reported and discussed with the study co-applicants. This report will be shared annually with the study steering group.

9.2 Budget

The summary project budget is shown in Table 4 below. Regular budget reports will be shared between the CI and the host organisation (BNSSG CCG). The host organisation will transfer all project funds to the University of Bristol on a quarterly basis, apart from those directly incurred by the BNSSCG and University of Oxford co-applicants, and the University of Bristol will be responsible for disbursements.

The left-hand section of the table shows the original project budget for funding the study up to October 2021. There was a 5.5-month delay to the study during the start of the COVID-10 pandemic. We have applied to the NIHR for an extension to 31st March 2022. This will increase the study costs by £66,307, as shown in the last two columns of Table 4 below.

Table 4
Project budget

Cost category	Year 1	Year 2	Total costs	% reim-bursed	Total budget	Additional applied for	Revised budget
NHS staff costs	2,747	2,747	5,494	100%	5,494	1,249	6,743
HEI staff costs	66,429	68,489	129,424	80%	103,539	28,564	132,103
NHS non-staff costs	12,033	9,423	21,456	100%	21,456	1,970	23,426
HEI non-staff costs	11,697	13,308	25,005	80%	20,004		20,004
Indirect costs	62,793	62,678	125,470	80%	100,376	34,525	134,901
Total			306,849		250,870	66,307	317,177

9.3 Gantt Chart

Study 1 will be completed in from October 2019 – March 2021 and study 2 from April 2021 – March 2022. These dates differ from the pre-COVID version of this protocol which planned for Study 1 to be completed from October 2019 – October 2020 and Study 2 from October 2020 to October 2021. The new dates include a delay resulting from the pause in patient-facing research during the first wave of the COVID-19 pandemic. We have submitted an application for funding for the extension to March 2022. The pre-consultation questionnaire and closure report will be developed in the first six months and tested in the second six months. In year 2, the first six months will focus on training, recruitment and intervention; and the second six months on the realist evaluation, preparing publications and finalising the protocol for the substantive trial. Ethical approval will be done in advance. A Gantt chart is shown in Fig. 7. Diamonds represent project milestones.

9.4 Audit Plan

All aspects of the study will undergo regular internal monitoring by the co-applicants, and annual external monitoring from the steering group. It may also be open to audit and monitoring from local NHS R&Ds.

9.5 Risk Log

In agreement with the sponsor, the host organisation and all co-applicants, this study has been deemed to post a low risk to participants: i.e. no higher than the risk of standard medical care.

The potential risks to patients are mostly around ensuring the confidentiality of their information. These are covered in Q A22 of the ethics application, which will need to be approved by the ethics committee assigned to this project before the research can commence.

The risks to delivery of the project will be monitored through a risk log (Table 5) which will form part of the project protocol and will, along with an issues log, be updatable by any team member, and form part of the six-monthly reporting.

Table 5
Project risk log

Risk	Mitigation
Failure to recruit staff	Staff for three of the five roles (GP trainer, REDCap consultation, PPI coordinator already identified). Advisory and steering group roles already filled.
Practices reluctant to participate	Seek study adoption by PCRN. Early approach of practices prior to project commencement.
GP/nurse resistance to implementing intervention	Use of person-centred approach in study 1 to refine the intervention so it is acceptable to clinicians.
Failure to recruit patients	Use of person-centred approach to develop system to maximise chance of recruitment. Minimisation of baseline questionnaires. Cluster-randomisation design to minimise information patients need to process (patients do not need to be told about practice randomisation).
Delay in recruitment of patients	The ten-day recruitment period was planned based on the numbers needed to text. With four practices, reaching 890 patients involves contacting approximately 22 patients per day for two weeks, which should be feasible based on GP and nurse lists. However, if this period needs to be extended, the cost will not be material.
Possible problems with the technical infrastructure required to deliver the PROMs feedback to GPs and nurses	Use of well-established system (REDCap) rather than purchase of a new app. Inclusion of REDCap technical support resource in the plan. Low-edge manual technology solution for attachment of report to EMIS.
Possible problems with the technical infrastructure required to deliver feedback to patients	Use of mainstream primary care technology (EMIS template). Inclusion of EMIS training for MM in the plan. Advice on hand from CS.
Pause of the study during the COVID-19 pandemic	Stay engaged with practices throughout pause. Apply for a costed extension as soon as the NIHR allow (Note – this application has now been submitted).
Difficulty restarting after patient-facing research commences again.	Update the protocol to ensure that the intervention can be delivered remotely. Engage with practices to ensure the intervention is as simple as possible and does not take up unreasonable amounts of time.

10 Study Conduct And End Of Study Responsibilities

10.1 Protocol Amendment

Any changes in research activity procedures, except those necessary to remove an apparent, immediate hazard to the participant, will be reviewed by all co-applicants and approved by the Chief Investigator. Amendments to the protocol will be submitted to the REC for approval. The sponsor will also be notified at this point.

Protocol amendments may be substantial (requiring full review and favourable ethical opinion from the REC) or minor (not requiring review). Only once the amendment has been approved by REC and trust R&Ds (or acknowledged in the case of a minor amendment) can the amended protocol be implemented.

10.2 Protocol Violations and Deviations

Researchers or investigators should not implement any deviation from the protocol without agreement from the Chief Investigator and with REC and R&D approval, except where necessary to eliminate an immediate hazard to trial participants.

In the event that a researcher inadvertently or needs to deviate from the protocol, the nature and reasons for the deviation will be recorded in a file note to be kept in the study site file and a copy sent to the CI for the Study Master File. If this necessitates a subsequent protocol amendment, this will be submitted to the REC and trust R&Ds for review and approval if appropriate.

10.3 End of study Archiving

All study documentation will be kept for a minimum of 5 years after the end of the final analysis of the study. All paper records will be stored in secure university storage facilities. Personal identifiable paper records (hard copy consent forms) will be kept separate from anonymised paper records (questionnaires) and will be stored in locked filing cabinets in locked offices. All electronic records will be stored on password protected servers on secure computer networks in the UoB.

10.4 End of Study

The REC which gave a favourable opinion of the research will be notified of its conclusion, in writing, using the appropriate form, which will be emailed to the REC within 90 days of the end of the study.

A draft final report and a final summary report will be delivered to the NIHR RfPB as per the requirements of the contract.

10.5 Future Funding and work required

If progression criteria are met, we aim to complete an RCT within five years of project end. This is expected to be a pragmatic trial with an economic evaluation. The trial will use a parallel cluster design, with practices randomly assigned to intervention or control. Outcomes will be analysed at the individual level allowing for clustering on the GP practice level on an intention-to-treat basis. We recognise that feasibility studies are by nature relatively high risk, because the end result may confirm that the main study/full trial is not feasible or funding for the full trial may ultimately not be obtained.[47] We will seek to mitigate these risks by:

1. Applying for Research Capability Funding (RCF) within the last six months of the study to develop the proposal for the full study. CAPC Bristol team have a successful record of obtaining RCF for this purpose. We will use the RCF period to apply to NIHR HTA & EME. Other funders will also be considered.
2. Provided the approach is deemed acceptable and valuable by patients and clinicians, ensuring the new methods and templates are disseminated so that the feasibility study is of value within itself, even before the full trial is carried out. (see Dissemination above)

11 Governance

11.1 Sponsorship and Ethical Arrangements

This study will be sponsored by the University of Bristol. Ethics approval will be sought from the National Research Ethics Service (NRES) for ethical review, and from BNSSG CCG Research and Evidence Team for research and development approval. The researchers will obtain a 3-year research passport and letters of access to carry out research in health centres within BNSSCG. The CI will have an honorary contract with BNSSCG for the duration of the study. The study is NIHR funded and is eligible for support from the NIHR Clinical Research Network which will liaise with centres, where appropriate, on the researcher's behalf.

This study involves NHS patients and will thus require NHS ethical approval. Study 2 requires access to the patient record, and will therefore require ethical reviews from the full panel (not proportionate review). REC, R&D and HRA approvals will all be obtained in advance, and are expected to be in place by July 2019. The University of Bristol Research and Enterprise Development (RED) will act as research sponsor. The key ethical issue is ensuring patients fully understand the intervention and are properly consented to data-sharing. This will be tested and refined in year 1 with the PPI group and through qualitative research using the person-centred approach. An ethics amendment will be submitted before commencing the feasibility study.

The study sponsor and funders will not have any role in study design; data collection, management, analysis, and interpretation of data; writing of the report; or the decision to submit the report for publication.

The feasibility study will be registered in the ISCTRN registry and on the CRN portfolio.

11.2 Insurance

Insurance will be provided by University of Bristol as project sponsor.

11.3 Study Personnel

The study will be managed on a day-to-day basis by the chief investigator (MM) who will also carry out much of the intervention development and data analysis. She will manage the outputs of five staff: a research associate, who will assist with the data collection and analysis; a REDCap technician who will assist with operationalising the pre-consultation report; A GP trainer who will co-deliver training in the intervention and assist with EMIS report configuration and a PPI co-ordinator who will manage the PPI and a project administrator.

11.4 Study management group

The study management group will meet quarterly to ensure that the project is meeting study targets and adhering to protocol. The group will consist of the CI and the co-applicants. Regular reports for study recruitment, retention, issues, risks of complaints will be reported and discussed.

11.5 Study Steering Group

A study steering group will be establishing consisting of six independent members and two of the co-applicants. The independent members will be Prof Pete Bower from Manchester (expert in PROMs development and complex interventions), Dr Jo Protheroe from Keele (GP and expert in individual-level feedback of PROMs to clinicians), Dr Julia Frost from Exeter (co-lead of a recent feasibility study on individual-level PROMs feedback to clinicians), an independent statistician, a member of the public and a non-academic GP. The PI will have responsibility for IP identification and will work closely with Andrew Wilson, Senior Research Commercialisation Manager at University of Bristol on issues relating to protection, licensing and impact realisation. The steering group will meet annually. (see Gantt chart for sign off responsibilities)

Declarations

Conflicts of Interest

The co-applicants have no conflicts of interest to declare.

Abbreviations

BNSSG CCG	Bristol North Somerset and South Gloucestershire Clinical Commissioning Group
CAPC	Centre for Academic Primary Care (University of Bristol)
COAC Intervention	Consultation Open and Close Intervention
CONSORT	Consolidated Standards of Reporting Trials
CPMS	Central Portfolio Management System
CPMS	Clinical Portfolio Management System
CRN	Clinical Research Network
CTIMP	Clinical Trial of and Investigational Medicinal Product
GDPR	General Data Protection Regulation
HRA	Health Research Authority
IRAS	Integrated Research Application System
ISRCTN	International Standard Registered Clinical/social sTudy Number
NIHR	National Institute for Health Research
PCOQ	Primary Care Outcomes Questionnaire
PPI	Patient and public involvement
PROM	Patient reported outcome measure
RCT	Randomised Control Trial
RfPB	Research for patient Benefit
SPIRIT checklist	Recommended items to address in a clinical trial protocol
TIDieR	Template for intervention description and replication
UoB	University of Bristol

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Figures

Messages 4G 14:24 31%

University of Bristol

At the moment:
How worried or concerned are you
About your current state of health

😊 Not at all

😊 Slightly

😐 Moderately

😞 Quite a bit

😞 Extremely

reset

question number 7 of 24

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Figure 1

pre-consultation questionnaire screenshot

Pre-consultation Report for Sarah McAllister

Your patient gave the following reasons for attending:

- 1 Indigestion and heartburn
- 2 Night cough
- 3 Really sore left foot when walking

The list below highlights some other problems your patient might have.

Green indicates no problems. Red is severe and amber is moderate

1 Pain and other symptoms	3		In moderate pain. Moderate physical symptoms : described as 'cough, heartburn and sore foot'
2 Daily Life	2		Symptoms slightly affect daily life: More info given 'can't sleep at night because of the cough, can't walk with the foot'
3 Emotions	1		NOT Anxious or stressed
4 Health Concerns	4		Is very worried about health. More info given: 'worried about this cough'
5 Health Knowledge	3		Feels lacking in knowledge about health. More info given: 'Want to know what is causing this cough, also can I keep using the previous medication for the heartburn'
6 Support in life	1		Has enough support to manage in life or deal with anxiety
7 Confidence in health plan	1		Has confidence that they are dealing with the cause of their health problems
8 Adherence	1		Has no problems adhering to their medication

Figure 2

Clinician pre-consultation report example

Figure 3

Workflow. 2. During recruitment SMS messages will be sent twice daily, to patients with bookings that day or the next day 4. Reports will be attached to EMIS twice daily, and an EMIS flag set for records with attached report. 7. A follow-up text will be sent from REDCap to patients in both arms 9. Only patients with EMIS access will access the report online. Other patients will receive a printed or texted copy.

Figure 4

Proposed initial programme theory of COAC.

Figure 5

Feasibility study: recruitment process and targets

		Apply for RCT funding	Modify Intervention	Stop
1	Perceived benefit / acceptability of the intervention	Majority of clinicians and patients find the intervention feasible, acceptable and potentially useful.	Interviews suggest intervention would be feasible and potentially useful with modifications	Intervention unfeasible / unacceptable in any form
2	Recruitments rates	At least 15% of eligible patients who receive the recruitment text respond to the invitation to complete the pre-consultation questionnaire. ¹	Interview data suggest modification could increase rates to the desired percentage	No suggestion from interviews that rates could be increased.
4	Completion rates of baseline patient data	Above 80% of patients who respond to the invitation provide a complete set of baseline data.	As above	As above
5	Completion rates of clinician questionnaire	At least 80% of clinicians return the questionnaires	As above	As above
6	Follow-up rates	At least 80% of patients who consented to receive a follow-up questionnaire complete the questionnaire.	As above	As above

Figure 6

Progression criteria for feasibility study. 1. This was previously 9% based on 30% identifying with the intervention as useful and 30% of those responding ($0.3 \times 0.3 = 0.09$). At that point we had anticipated patients would find the form useful if they had more than one problem. Through the Intervention Development Study we found more patients that this find the form useful; 15% responded in the first two practices, but nearly 50% in the last practice when the intervention had been improved.

The yellow area of the chart shows the extension which will be required to complete the study due to the delay from April – August 2020.

Figure 7

Project Gantt Chart (revised for COVID-19 related delay)

Figure 8

Project governance

Supplementary Files

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