**Research Information Sheet for Practices (RISP)**

**The Consultation Open and Close (COAC) study (Phase 1):**

**Development and testing of two technologies to help share information between patients and GPs in general practice**

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| **R&D assurances** | Bristol, North Somerset and South Gloucestershire |
| **CPMS ID** | 42005 |
| **IRAS ID** | 259186 |
| **Type of study** | Intervention development study |
| **Study design and background** | There is great pressure on GPs to effectively manage within the 10-minute consultation time, and this sometimes leads to patient problems being missed, especially when a patient wants to discuss multiple problems. Patients might also be reluctant to share “softer” concerns, such as how worried they are about their health, whether they are low in mood or finding it difficult to adhere to their medication or other health advice. Research has shown that sharing the results from electronic patient-reported outcome measures (ePROMs) with clinicians at the start of a consultation can help to elicit these problems that might otherwise have been missed. At consultation closure, providing the patient with written as well as spoken information can improve recall and adherence.  In this study, we aim to develop and test two tools to help share information between GPs and patients consulting with multiple problems. Firstly, an online form and a process for sharing this with clinicians at an individual patient-level before the consultation will be designed. Secondly, a process and template will be designed to provide patients with a printed summary report of the consultation on consultation closure.  We will use these tools in a feasibility study, due to start in 2020. We will provide training in their use but will also be seeking your views on how the tools should be used to inform the consultation and will adjust the tools and the training before the feasibility study based on your feedback. If you participate in the current study, you will also be invited to the feasibility study. However, this will form part of a separate RISP; participating in this study does not commit you to the feasibility study. |
| **Study aim and objectives** | **Aim:** To design a complex intervention (The Consultation Open and Close Intervention) to improve the ability of GPs to address patients’ concerns, incorporating the use of an ePROM at consultation opening and a report at consultation closure, which is either printed or accessible from the patient record.  **Objectives**   * To test an online questionnaire system which will allow patient self-completion of a pre-consultation questionnaire and a report showing low-scoring questionnaire items, to be shared with GPs with 45 patients in three practices sequentially, using a person-based approach, with iterative adjustments made based on patient, administrator, receptionist and GP feedback in each practice * To test a consultation-closure report with 45 patients in three practices sequentially, using a person-based approach, with iterative adjustments made based on patient and GP feedback in each practice. |
| **Primary care organisation target** | 15 patients per practice for each of the tools, 30 patients in total. |
| **Duration of study recruitment** | Recruitment of 15 pre-consultation questionnaire study participants will be done during a two-week period in December 2019/January 2020. A researcher will be present in the practices during the six recruitment days in this period to 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. Qualitative patient, clinician and administrator interviews will run from December 2019 – March/April 2020  Recruitment of the 15 consultation-closure report participants will be done during a two-week period in April 2020 or May 2020. Qualitative patient and clinician interviews will run from April 2019 – June/July 2020 |
| **Service Support Costs (SSCs)** | SSCs: £168 per practice (pre-consultation questionnaire only) |
| **Research Costs (RC)** | Pre-consultation questionnaire design and testing: £415 per practice  Consultation closure report design and testing: £477 per practice |
| **ETCs** | There are no excess treatment costs (ETCs). |
| **Eligibility criteria** | **Pre-consultation questionnaire inclusion criteria:**   * Aged 18 or over (on date of SMS invitation to participate) * Have an appointment with their GP within the next two days   **Consultation-closure report inclusion criteria:**   * Aged 18 or over (on date of SMS invitation to participate) * Discussed more than one problem   Inclusion criteria will be revised during the study, as we assess report usefulness for different patients.  **Exclusion criteria**   * patients with a recent diagnosis of life-limiting or life-threatening illness, * patients with a life expectancy of less than 12 months, * patients deemed by the GP to be at serious suicidal risk, * patients unable to complete questionnaires even with the help of carers. |
| **Study activities** | |
| **Primary care organisation activities** | **Pre-consultation questionnaire activities:**  **Set-up:** A practice manager will meet the chief investigator, agree the researcher conduct on site.  **Training - administration**: An administrator and practice manager will be asked to attend a 1 ½ hour training session in how to send individualised links to patients and how to upload report from REDCAP to EMIS and set a pop-up alert for GPs.  **Training - GP**: A GP will be asked to attend a 1 ½ hour training on how to access the report, and how to interpret and use the report in the consultation.  **Recruitment:** An administrator will carry out a daily process of sending out the SMS alerts (30 minutes per day) and uploading reports to EMIS (30 minutes per day).  **Intervention**: The GP will access the reports during the consultation. If patients have consented, a researcher may observe the consultation.  **Interviews**: GPs and receptionists will be interviewed about the process for up to 1 hour.  **Consultation closure report activities**  **Initiation:** A practice manager will attend an initiation meeting for 1 hour.  **EMIS report configuration:** A GP and administrator will support local configuration for up to one hour.  **Training:** The GP will attend a 2-hour training/ Q&A session about the template.  **Recruitment/Intervention**: GPs will provide patients with the report and a Patient Information Leaflet (PIL).  **Interviews**: GPs and receptionists will be interviewed about the process for up to 1 hour. |
| **Patient involvement** | **Pre-consultation questionnaire**   * Patients will receive a text message on their phone up to 2 days before their appointment, with a link to a questionnaire. This will invite them to complete the questionnaire and advise them that this information will be shared with the GP. * If the patient wishes to complete the questionnaire they will click on the link. Completion of the questionnaire should take approximately 5 minutes of the patient’s time. Patients will also be asked to optionally give consent to their consultation being observed, and to share a phone number with the researcher to arrange an interview. * Patients will be given a PIL at the end of their consultation which contains details of the interview and data storage. * Patients willing to discuss the process with a researcher will receive a phone call after two days to arrange a telephone or a face-to-face interview. * Patients will be interviewed at a location convenient to them, or by telephone.   **Consultation-closure report**   * Patients seeing the relevant GP will be given a PIL on the study as they arrive for their appointment, which contains a tear-off form with contact details of the researcher. * Eligible patients will receive a consultation-closure report from their GP. * Patients willing to discuss the process with a researcher will hand the tear-off form to the receptionist. * Patients willing to discuss the process with a researcher will receive a phone call after two days to arrange a telephone or a face-to-face interview.   Patients will be interviewed at a location convenient to them, or by telephone. |
| **What are the likely benefits to the patient/primary care organisation?** | We want to ascertain the acceptability and usefulness of the pre-consultation form and report and the consultation-closure report for a future feasibility study to evaluate the use of these tools in an intervention. Participating practices will be instrumental in the design of these tools, how they should be used by GPs and eligibility criteria for patients.  Patients participating in this study may benefit, in that the tools are designed to promote communication with the GP; the NHS has paid for and approved this study because they believe it is a viable means of using technology to help uncover patient concerns. |
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| **Additional information** | |
| **LCRN contact** | CRN West of England  Email: primarycare.westengland@nihr.ac.uk |
| **RSI Contract** | |  | | --- | | This is a recruiting study | |
| **Recruitment upload route** | EDGE |