FULL/LONG TITLE OF THE STUDY

Scaling up Remote-by-Default Models of Care to Help Reduce the Spread of COVID-19

SHORT STUDY TITLE / ACRONYM

Remote by Default Primary Care

PROTOCOL VERSION NUMBER AND DATE

Version 8 22.03.21

IRAS Number:	283196
Ethics Ref:	20/EM/0128
FUNDER:	Economic and Social Research Council
Chief Investigator	Professor Trish Greenhalgh, Nuffield Department of Primary Care Health Sciences, University of Oxford
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Sponsor	University of Oxford

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and

transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature: 

Date: ..22.../..03..../.2021.....

.....

Name: (please print): TRISH GREENHALGH

The chief investigator and all co-investigators declare no conflicts of interest.

CONTENTS

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ABBREVIATIONS

CA	Conversation Analysis
CCG	Clinical Commissioning Group
CTRG	Clinical Trials and Research Governance

CP	Community Pharmacist
ED	Emergency Department
EHC	Emergency Hormonal Contraception
GDPR	General Data Protection Regulation
GP	General Practitioner
HRA	Health Research Authority
IRAS	Integrated Research Application System
NHS	National Health Service
NHSE	National Health Service England
PMG	Project Management Group
PPI	Patient and Public Involvement
REC	Research Ethics Committee
SSG	Study Steering Group
WP	Work Package

STUDY SUMMARY

Study Title	**Scaling up Remote-by-Default Models of Care to Help Reduce the Spread of COVID-19**
Short title	Remote by Default Primary Care
Study Design	Qualitative and Quantitative (mixed method)
Study Participants	Clinical and non-clinical NHS primary care health care staff establishing hot hub and related remote-by-default services during the COVID-19 pandemic and COVID-19 suspected patients/their carers who experience primary care services during the pandemic.
Planned Size of Sample	Qualitative interviews (~60 clinical and non-clinical NHS health care and -40 patients) Focus groups (4 x 15 people) and patient interviews (approx. 20) on experiences of accessing GPs remotely about 'long' Covid Online surveys of professionals and of patients ~ 400 respondents and follow up interviews with approximately 40 staff Video and audio recording of up to 20 remote consultations between clinicians and patients. Qualitative interviews ~ 75 pharmacy staff from ~4 community pharmacies in England consisting community pharmacy/ NHS health care and 25 of their patients)
Planned Study Period	2 years
Aim	1) To conduct a rapid evaluation that generates an up-to-date overview of existing and emerging video consulting services in

	health care from clinicians and non-clinicians (e.g. service managers) with first-hand experience of setting up, running and/or working in video consultation services in primary and secondary care across the UK. 2) To delineate what patients consider models of good practice for GPs managing 'long Covid' symptoms in a remote-by-default context 3) Through in-depth longitudinal case studies, to support and inform the rapid implementation, spread and scale-up of remote-by-default service models in primary care. 4) Through detailed cross-sectional case studies, to support primary care clinicians in assessing symptoms remotely during the COVID-19 pandemic and in future. 5) Describe the models of general remote pharmacist consultation practice, to support and inform the rapid implementation, spread and scale-up of remote consultations in community pharmacy
Research Question	What is the new and emerging organisational, regional and national level context for video consulting in the COVID-19 pandemic? How can general practice best support and manage 'long Covid' in a remote-by-default context? How can action research, informed by complexity principles, support the rapid implementation, spread and scale-up of remote-by-default models of primary care in the Covid-19 crisis? How do health care professionals assess symptoms associated with COVID-19 by phone/video? How should community pharmacist remote consultations best be set up?

PROTOCOL CONTRIBUTORS

Catherine Pope, Alex Rushforth, Rebecca Boden, Trish Greenhalgh, Richard Byng, Sara Shaw, Chrysanthi Papoutsi, Joseph Wherton, Lucas Seuren, Mona Koshkouei.

STUDY PROTOCOL

Scaling up Remote-by-Default Models of Care to Help Reduce the Spread of COVID: Rapid Evaluation of Primary Care 'Hot Hubs' and Longitudinal Follow-Up Action Research

1. BACKGROUND

COVID AND A RAPIDLY CHANGING NHS

With a view to containing novel coronavirus (COVID-19), healthcare organisations in the UK (and beyond) are rapidly introducing new service models which avoid direct clinician-patient contact. This shift from in-person to remote consulting is the **fastest and most extensive scale-up of a radical service innovation** since the NHS was established in 1948. The change is **logistical and cultural** as well as technical. Clinicians are faced with a **triple challenge**: a new **disease** (uncertain, serious and highly contagious) and a new **way of interacting** with patients (e.g. individual or group video consultations) and major changes to **team interactions, workflows and clinical pathways**. These are challenging times.

For the first time since the NHS began, it is impossible now to walk into a GP surgery and book an appointment. People must enter their symptoms online (or, if they are not digitally connected, by phone), and are then channelled through what is known as **'total triage'** to either self-care, call-back (phone or video) from a clinician, or a face-to-face appointment in a 'hot hub' (most usually, to assess if their COVID is bad enough to need hospital admission).(NHS England, 2020. Accessed 31.3.20 at https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/remote-total-triage-model-in-general-practice-27-march-2020.pdf). Alternatively, they can telephone NHS111, from which they could be referred for a GP call-back or sent direct to a hot hub. This complex arrangement, which was **mandated by a recent national directive** (NHS England, 2020. Accessed 31.3.20 at https://www.england.nhs.uk/coronavirus/primary-care/.) and is being variably interpreted in different localities, is likely to continue in some form for at least the next two years. This is not the case for community pharmacy. Patients are able to access pharmacy services to obtain their routinely prescribed medicines in addition to other common services such as: asking advice on side effects, minor ailments, smoking cessation and emergency hormonal contraception (EHC) as over the counter (OTC) treatment following a consultation with a pharmacist. With social distancing measures in place, reports of shortage of PPE in community pharmacies and debate on what is effective level of PPE during pharmacist consultations, and importance in containing the spread of the outbreak it is imperative that an alternative way of working is explored to allow continued accessibility for patients whilst protecting the public and professionals from the risk of infection.

The hot hub model, supported with various forms of remote support including 'virtual hot hub' video monitoring of patients, is revealing tensions between the **technological infrastructure** of the NHS (especially interoperability between GP, out-of-hours and emergency 'add-on' electronic record systems), the **professional networks** through which responsibility for care is shared and distributed, and the **material infrastructure** of buildings, supply chains and so on. Infection control regulations, for example, list various standards for contagion hubs, including the quality of personal protective equipment (PPE) and the levels of ventilation needed to clear airborne viruses (partly for this reason, some 'hot hubs' are actually draughty tents erected in car parks). Logistical solutions (e.g. unmanned specimen dropboxes) have emerged to ensure that no two people meet in person unless unavoidable. There is a shortage of PPE in some hot hubs.

Another aspect of the remote-by-default model is remote management of long-term conditions (LTCs). Many tried and tested technologies exist for this. 'Florence' (www.getflorence.co.uk), for example, is a chatbot text messaging service that prompts patients via their mobile phones (usually daily) to monitor their LTC (e.g. high blood pressure, diabetes, depression). A service evaluation in Scotland showed improvements in self-monitoring, patient satisfaction, access, service usage and disease control

(Alexander 2019) though research studies gave a mixed picture.(Kinnafick et al., 2016, Cottrell et al., 2015a, Cottrell et al., 2015b, Unal et al., 2018) First-generation technologies like Florence are now seen as old-fashioned (they run on simple text messaging rather than smartphone apps; they don't give patient an overview of their results; and they are not interoperable with electronic records). One development during the COVID crisis is the emergence of numerous next-generation technologies offering all the above features, but most developers are hazy about how their product will interface with NHS electronic records and new, virtual care pathways.

At the same time as hot hubs and virtual consultations, through necessity primary care sites are also for the first time having to adopt new care in the community services (for Covid-suspected patients staying at home) linking to other organisations such as pharmacies, secondary and palliative care and local volunteer groups. In short, remote-by-default is a paradigm case of a **disruptive innovation**. It is complex, uncertain, challenging and risky. Furthermore, it is abruptly **redefining what it means to be a patient, a doctor/nurse, a healthcare assistant and so on, and what it is to provide excellent healthcare**.

A later development in the Covid emergency has been the emergence of *post-acute Covid-19* defined as extending beyond three weeks from the onset of first symptoms and *chronic covid-19* defined as extending beyond 12 weeks (together these are heron referred to as '**long Covid'**). Since many people were not tested, and false negative tests are common, Greenhalgh et al have suggested that a positive test for covid-19 is not a prerequisite for diagnosis (Greenhalgh et al., 2020). This has however, brought new challenges to the remote-by-default care model that has emerged to deal with the crisis and whether it can effectively manage patients presenting with longer-term symptoms.

We'd like to apply our expertise to the new challenges thrown up by the pandemic – specifically the question of **how to achieve rapid spread and scale up of video consulting, and – longer term - new remote-by-default models** in primary care. To do so, our study will consist of three components:

a) A rapid evaluation phase that maps different types of video consulting activities, delivering rapid learning and feedback to sites and policymakers about what works well and what does not.
b) A cross-sectional study of primary care sites across England, conducting micro-analysis of remote service models, delivering rapid feedback on how remote assessment works and can be improved.
c) Longitudinal comparative case studies of primary care sites across England and Scotland, generating rich in-depth narratives of scale-up of remote-by-default models in primary care and the impacts on staff and patients.
d) A rapid evaluation phase to describe the models of general remote pharmacist consultation practice; to examine whether the capacity they offer matches demand for appointments; to explore the factors which determine their quality and safety (for staff and patients).
e)

The sheer urgency of generating rapid learning and feedback on novel and potentially risky hot hubs, and the impending need for wider lessons about rapid scale-up of remote services as primary care approaches the 'new normal', justifies our three-pronged approach.

2. RESEARCH QUESTIONS/AIMS

Questions:

How can action research, informed by complexity principles, support the rapid implementation, spread and scale-up of hot hubs and related remote-by-default activities in the COVID-19 crisis?

How do primary care clinicians assess symptoms associated with COVID-19 by phone/video?

How have patients experienced GP services with respect to 'long Covid' symptoms and what are potential models of good practice in a remote-by-default context?

How should community pharmacist remote consultations best be set up?

How can action research, informed by complexity principles, support the rapid implementation, spread and scale-up of remote consultation models of community pharmacists in primary care in the Covid-19 crisis?

AIMS:

1) Through a rapid evaluation, to generate an up-to-date overview of existing and emerging video consulting services in health care across the UK.
2) Through in-depth longitudinal case studies, to support and inform the rapid implementation, spread and scale-up of remote-by-default service models in primary care.
3) Through detailed cross-sectional case studies, to support primary care clinicians in assessing symptoms remotely during the COVID-19 pandemic and in future.

Objectives

In the context of COVID-19:

1. To map existing and emerging video consulting services in UK health care. To share widely and quickly lessons on video consulting activities and to alert people to what doesn't work.
2. In a sample of longitudinal case studies, surface and explore the technical, human/relational, material, organisational, ethical and regulatory challenges of shifting from a face-to-face to a remote-by-default service model for general practice and other community-based services.
3. Generate insights on how digital innovation can both support, and be supported by, a rapidly changing NHS infrastructure.
4. Using participatory and co-design principles, support cross-sector deliberation and targeted action, thereby addressing priority infrastructural challenges.
5. To find out how clinicians are currently assessing symptoms associated with COVID-19 (e.g. breathlessness) when using video/phone consultation and to understand subjective sense-making, words and terms used and responses to assessment questions.
6. To identify the needs for the type of services and equipment required to carry out remote consultations from community pharmacy.
7. To identify the varieties of remote consultations models emerging in community pharmacy practice.
8. To share widely and quickly, lessons on pharmacist remote consultation models that work and to alert professionals as to what doesn't work.

3. STUDY DESIGN / METHODS

Multi-site case, mixed method study with action research. We will use a combination of methods in a pragmatic, reflexive and theory-informed way to generate data, synthesise and share it with participating teams, and inform both team- and wider system learning.

In late March a non-scientific, straw-poll survey to gather information about primary care hot hubs was conducted by the study chief investigator, TG, through Twitter, attracting over 300 responses from GPs in 24 hours. **For the rapid evaluation and feedback stage**, we will produce a new online survey, using hypothesis-driven questions to generate an updated and theory-driven overview of video consulting activities. We will seek to enrol clinicians and non-clinicians (e.g. service managers and stakeolders) with first-hand experience of setting up, running and/or working in video consultation services in primary and secondary care across the UK., via Twitter and professional networks. Those that complete the survey will be given the option of leaving their emails to be contacted for a follow-up interview. We will use qualitative methods to conduct follow-up interviews with approximately 40 survey respondents (up to 10 in each of the devolved nations), ensuring a diversity of sites, clinical settings, video consultation services and platforms. Participants can signal via verbal consent forms whether they are willing to reconnect for a second interview 8-12 weeks later to capture and reflect on changes over time.

In early April a number of pharmacists, pharmacy professional bodies and digital companies offering video consultation platforms were contacted for a non-scientific, information gathering exercise to identify a need for alternative ways of working in community pharmacy during the pandemic and possible digital platforms available for immediate use or rapid development for this purpose. We will seek to enrol Pharmacists with first-hand experience of establishing and/or using remote consultation technology, via Twitter and professional networks. Those that complete the survey will be given the option of leaving their emails to be contacted for a follow-up interview.

For longitudinal part of this study, our over-arching ‘case’ is the UK National Health Service. Within that case, we will study five primary care sites (three in England, one in Wales, one in Scotland), representing maximum diversity in how the remote-by-default model is understood and implemented on the ground. Our cases will be technology-agnostic in that we will study the technologies that are being contemplated and used by locality-based teams, rather than setting out to ‘test’ particular technologies. Given current circumstances, remote interviews and remote ethnographic observation accompanied by analysis of documents (e.g. pathways, emails, websites) will be our primary methods. We will use these approaches in a pragmatic, reflexive and theory-informed way to generate data, synthesise and share it with participating teams, and inform both team- and wider system learning.

We will identify cases via our professional networks and via the online survey, ‘snowballing’ from our initial contacts to others in their organisations. We aim to interview staff from a range of roles, including: senior clinical leaders; front line 'Covid/suspected Covid clinicians'; clinicians seeing non-Covid patients and back office and support staff (some of these will be providing support in reception or technical support). We will ask open-ended questions about the emergence of new work routines, patient flows and pathways, assessment methods, patient-clinician interactions and aspects of NHS infrastructure that support or inhibit their work. We estimate that we will conduct approximately 60 interviews with NHS staff by phone/using online video (e.g. MS Teams, Skype), or near verbatim notes will be made contemporaneously.

Alongside staff interviews, we will remotely interview approximately 20 patients/their carers who have recently crossed paths with primary care remote-by-default services during the crisis (e.g. hot hubs, individual and group video consultations, remote monitoring, care in the community), asking open ended questions to understand subjective sense-making and mapping their pathways. Volunteer patients will be sought via advertising on social media. Further to this, we will conduct and video record (via Zoom or MS Teams) 4 virtual focus groups, two with approximately 15 patients,, and another two with approximately 15 clinicians with confirmed or suspected diagnosis of 'long Covid' about encounters with primary care and related services regarding access and quality of care. For those unable or uncomfortable with participating in a focus group, we will offer the option of one-to-one interviews instead (approximately 20 patients and 20 clinicians). Data sources will include ethnographic fieldnotes (~100h per case) of local practice team meetings, training sessions and stakeholder engagement meetings, providing naturalistic insight into acceptability of digital technology among professionals and stakeholders. Participants are likely to include members of a typical GP practice team, clinical, administrative, and external stakeholders (e.g. vendors, related clinical services, external trainers).

In the pharmacy element of the project, we will ask frontline teams (e.g. pharmacists and pharmacy technician and dispensers) to recruit and issue a survey via an online link to approximately 25 patients/their carers from each pharmacy research site who have recently crossed paths with pharmacist remote consultation services during the crisis (e.g. individual (EHC consultations) video consultations, group video consultations (e.g. smoking cessation support groups), remote monitoring/medication reviews, support of other professional services e.g. care/advice to care homes), asking open ended questions to understand subjective sense-making and mapping their pathways.

All staff and patient participants will be given the option via the consent form of indicating whether they are willing to be contacted for a second interview, with details laid out in the participant information leaflet. This will help us to track fast evolving changes longitudinally. Audio/video recorded interviews will be transcribed and de-identified. All data collection will be undertaken by experienced qualitative researchers.

In the context of group video consultations, we will recruit patients who have taken part in virtual group clinics to provide feedback through an online survey. The survey link will be shared with patients by their clinicians at the end of the virtual consultation. We expect to collect 300 responses which will feed into iterative adaptations of remote-by-default models of care. Patients who complete the survey will be given the option of leaving their contact details for follow-up research.

We will work with primary care clinicians to record video consultations and telephone consultations for **detailed conversation analysis**. For video consultations, we will use videoconferencing systems in place and approved for use in the respondent's NHS practice setting. For telephone consultations, clinicians will use established telephone services. We will then conduct conversation analysis of the video- and audio-recorded consultations to investigate how clinicians assess symptoms associated with COVID-19 in practice and how patients make sense of the procedure. Recordings will be transcribed by using specialised transcription systems to capture both the spoken and non-verbal communication. Through repeated viewing and tagging of the data we will identify the communication strategies used to assess the symptoms – focusing on questions and assessment tools/scores they use and how they use them. We will then investigate how these different strategies affect the responses by patients – whether they can follow the instructions or experience problems describing symptoms, and if so, what types of

problems and how those are subsequently managed. Participants -both clinicians and patients -will have the option to remain identifiable or be de-identified using established techniques that allow replay of sound and obscured 'greyscale' images that show outlines/blurred head and shoulders, and backgrounds (this allows analysis of gestures and movement but does not reveal identity). All identifying information will removed from the audio streams with specialised software (Adobe Premiere Pro).

Data Analysis

Interview, observational, focus group and document data analysis will be informed by established qualitative approaches for thematic analysis (moving from coding through thematic analyses to build causal explanations). Software such as Atlas.ti or NVivo may be used for data archiving and management.

Video and audio recordings of consultations will be analysed using conversation analysis, a data-driven methodology that uses recordings of naturally occurring interaction to (inductively and incrementally) conduct detailed micro-analytic studies of the verbal and non-verbal communication strategies used in conversation. Specialised software such as Transana (see figure 1) will be used for data transcription, tagging, and management.

Quantitative data will be aggregated and analysed using basic statistical methods.

Analysis will be undertaken by a core analytical team and will include PPI members. The project steering group will provide virtual comments on the themes emerging from the data and to consider the veracity and credibility of interpretations.

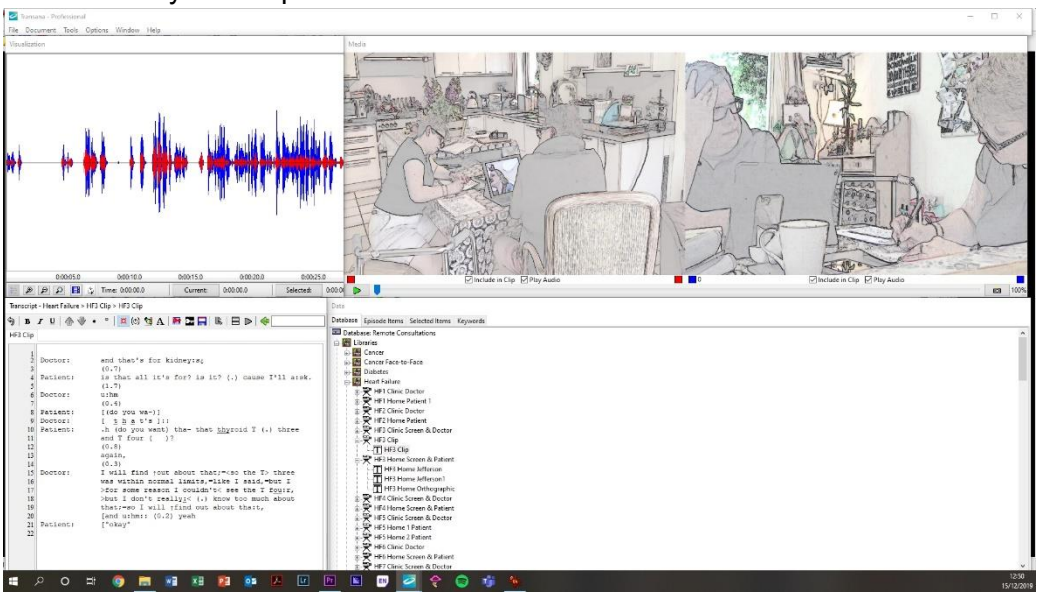

Figure 1 Transana workspace with anonymised recording of video consultation

4. STUDY SETTING

The video consulting survey will be shared with NHS organisations across the United Kingdom. The pharmacy survey will be shared with pharmacists across the United Kingdom.

For the case studies, four primary care sites will be approached (three from England, one from Wales and one from Scotland), in addition to four community pharmacy sites in England. Our intention is to build a collection of sites that represent maximum diversity in how the remote-by-default model is understood and implemented on the ground, as well as trying to capture differences in geographical setting, jurisdiction, and demography.

The patient online survey will be provided to the participating pharmacy sites for recruitment.

5. SAMPLE AND RECRUITMENT

Inclusion criteria for interviews

Willing and able to give informed consent for participation

Aged 18 years or above

Staff involved in delivering remote-by-default services in the frontline or 'back offices'

Patients/carers who have crossed paths with primary care services during the Covid pandemic.

Pharmacy case studies:

Staff involved in delivering remote pharmacist consultation services in the frontline or 'back offices'

Patients/carers who have crossed paths with community pharmacy primary care services during the COVID-19 pandemic.

Inclusion criteria for video and telephone consultations

Patients who have remote primary care consultation regarding symptoms associated with COVID-19 and their clinicians (based in Oxford/Thames Valley) who have agreed to participate in the study

Inclusion criteria for focus groups

Patients that have experienced self-reported 'long Covid' symptoms (for patient only focus groups)

Clinicians that have experienced self-reported 'long Covid' symptoms (for clinician only focus groups)

Exclusion criteria

Patients or clinicians who are too ill to be interviewed

Sampling technique:

In the evaluation phase we will use convenience sampling to conduct an online survey of NHS staff professionals video consulting services. For the community pharmacist remote consultations the evaluation phase will use convenience sampling to conduct an online survey of community pharmacy primary care professionals setting up and running pharmacist remote consultations.

For the second phase, we will use theoretical sampling to select four primary care sites (three in England, one in Wales and one in Scotland), and four community pharmacy sites, that represent maximum diversity in how the remote-by-default model is understood and implemented on the ground, as well as trying to capture differences in geographical setting, jurisdiction, and demography.

Researchers will interview pharmacy participants at each of the pharmacy sites by telephone or video. The mode of interview will be chosen by the participant as so what is most convenient to them. There will be two interviews each of 60 minutes maximum. Where researchers are to directly observe a remote consultation with a patient/carer, verbal consent will be obtained by the pharmacist conducting the consultation from the patient/carer for the researcher to be present as an observer within the consultation. The length of the consultation will be determined by the needs of the patient/carer and the pharmacist conducting the consultation.

Recruitment: The online survey will be advertised via Twitter and professional networks, where they can follow a link onto the online survey tool and, if they wish, leave details to be contacted about an interview.

For interviews and focus groups, we will advertise across Twitter and our professional networks. Participants will be invited to contact a member of the research team with their email or phone number, with a University researcher getting in touch. For virtual ethnographic observation of meetings in the case studies, the research team will request access through the chair of the meeting, who will be asked to share with attendees our participant information sheet and a short description about the study and why we want to attend and raise our request as an agenda item at their next meeting.

For the video and telephone consultation recordings, clinicians will be invited to participate by a member of the research team (by email, phone or social media direct message) to clinicians in existing professional networks including CRN and PCN. Clinicians will select patients who make an appointment for COVID-19 related symptoms.

Consent: Interview and focus group participants will receive a participant information leaflet by email prior to the interview or focus group and will be asked by a University researcher to provide oral consent at the start of the interview or focus group. In the case of a participant being deaf or hard of hearing an interpreter will be used. In the case of a participant having low literacy levels, ‘easy read’ versions of documents will be provided. The Researcher will record the consent on a “record of verbal consent form”. A copy of the form will be forwarded to the participant by post or email at the completion of the interview or focus group.

Participants will have opportunities to ask questions during the interview or focus group and afterwards via email or phone to the researcher.

For ethnographic observation of meetings in our case study sites, the chair will consult with attendees (see 'Recruitment' above). Researchers will not be present at the time the item is discussed. The group will use its own procedures to decide whether to accept the request or not. If the group decides that they are happy for us to observe, we will attend the subsequent meeting of the group as observers and take handwritten field notes without tape recording. The agreement of the group to participate in the study will be recorded in the minutes. A copy of the minutes will be retained by the research team at the University of Oxford.

Between 5-6 clinicians will record consultations involving symptoms associated with COVID-19 using videoconferencing systems in place and approved for use in their NHS practice setting or telephone, having consented to do this when invited to participate by a member of the research team. In the pharmacy element of the study, 8 -12 clinicians (pharmacists) will record the remote consultations with patients with any condition using videoconferencing systems in place and approved by their organisation, having consented to do this when invited to participate by a member of the research team. We will invite clinicians to participate in the study by recording one or more video consultations. If they are open to the idea, we will provide them with the Participant Information Sheet. We will contact them seven days later by phone/videoconferencing to secure consent verbally. Researchers will provide them with a copy (password-protected via email).

At the start of the consultation, the clinician will record the patient's consent for the consultation to be recorded. If the patient consents, the clinician will initiate the recording. If the patient does not consent, no recording will be made.

At the end of the consultation, the clinician will inform the patient briefly about the study, and that we want to include the video-recording or audio-recording of the consultation in the study. If this is not acceptable to the patient, the recording will be deleted.

If the patient is open to this idea, the clinician will provide the patient with a link to a website containing the Participant Information Sheet, and ask whether they are happy to be approached by a researcher. If so, they will obtain permission to provide researchers with the patient's contact information.

A researcher will then contact the patient by phone/videoconferencing and explain the study in more detail. If they agree to participate, the researcher will go through the verbal consent form with them, and provide them with a copy (password protected via email).

Video- and audio-recording consultations places a burden on the participants in terms of the access given to the videographer. However, in a previous study of a similar nature, (REC ref: 13/EM/0370), we found that participants were happy to volunteer to be recorded and have raw data be used for analysis.

Withdrawal of participants

Participants may withdraw from the study at any point but data obtained up until the point of the withdrawal will be retained for analysis.

Definition of End of Study

The end of the study is the point at which all study data has been collected by the University researcher.

6. DATA MANAGEMENT

No patient records will be collected for this study. Video and audio recordings with identifying information will be de-identified if participants do not consent to the identifying information being used. Digital data (e.g. interview, focus group and video consultation audio/video recordings) will be transferred to password protected storage on University computers / servers as soon as possible and de-identified.

7. ETHICAL AND REGULATORY CONSIDERATIONS

This is a low risk study involving NHS staff and patients. It is possible that the staff might disclose evidence of poor practice (either theirs or colleague/institutions) during interview. Should we suspect or detect poor practices we will immediately discuss this within our core team (which includes practising clinicians) and if necessary communicate straight away with the relevant regulatory authority. For patient interviews and focus groups researchers will take care to establish fitness to take part, and recommend the patient call 999 if they significantly deteriorate during the interview. There are no direct benefits to participants but knowledge gathered will inform policy and practice dealing with Covid-19 pathways in primary care.

Assessment and management of risk

The research team include clinical and non-clinical researchers. The investigation will be conducted remotely, so researchers will not come into physical contact with participants who have or may have an infection, so there is no risk of disease transmission. Researchers will comply with research best practice and local policies regarding safeguarding. Non-clinical researchers will seek advice from local clinicians/managers as appropriate should issues arise. Clinically trained researchers will follow regulatory /governance policies pertaining to their professional status/ registration.

Research Ethics Committee (REC) and other Regulatory review & reports

Following Sponsor approval, the protocol, informed consent form, participant information and other relevant documents e.g. advertisements will be submitted to an appropriate Research Ethics Committee (REC), HRA, and host institution(s) for written approval.

The Investigator will agree substantial amendments with the Study Steering Group. They will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

All correspondence with the REC will be retained. The Principal Investigator will oversee the submission of reports as required and notify the REC of the end of the study. If the study is ended prematurely, the Principal Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Principal Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Data protection and patient confidentiality

All investigators, research staff, and steering group members will comply with the requirements of the Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2016/679 with regards to the collection, storage, processing and disclosure of data including any personal information. The Principal Investigator (Greenhalgh) is the data custodian. University of Oxford is the data controller.

At the end of the study data (including consent forms) will be stored for 10 years in accordance with University of Oxford policy and then destroyed. After the 10 year retention all research data (including consent forms) will be securely destroyed using the appropriate procedure advised at that time by the University of Oxford research data team. Any personal identifiers relating to individual participants will be held for less than six months after the end of this 24 month study.

Indemnity

Insurance and indemnity arrangements lie with the sponsor (University of Oxford). The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

Access to the final study dataset

Greenhalgh, Rosen, Rushforth, Byng, Shaw, Pope, Papoutsi, Wherton, Seuren, Wieringa, Finlay, Hughes, Husain, Koshkouei, Leone, Ladds, and Rybczynska-Bunt will have access to the full dataset. De-identified data will be shared with additional investigators who join the team. Use of de-identified data for research or teaching will only be undertaken with the consent of the participants. Direct access will be granted to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki.

Contractual arrangements

None.

8. DISSEMINATION POLICY

Final report synthesising the findings which will also be presented via academic peer-reviewed publications (including rapid publications in BJGP or BMJ if possible) and appropriate conferences and meetings, regular lay summaries to participating practices and relevant national groups such as RCGPs.

Outputs

a) Targeted Dissemination - Feedback meetings with health professionals and stakeholders; Public and patient facing feedback; Website and social media.
b) Final Report and papers: open access where funding and journal allows, and prepublication copies will be available from the study team and in University repositories.
c) Archive of de-identified data for further research/teaching

Archiving

Where possible and subject to relevant consents qualitative data will be de-identified, archived and made available for reuse/secondary analyses. Ownership of IP generated by employees of the

University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the study, conforming to contractual arrangements specified by the Funder.

9. REFERENCES

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10. Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	2	13.05.20	Lucas Seuren Alex Rushforth	Protocol Sections: 1: Added one research objective (now (b)) 2: Added one research question (3), one aim (3), and one objective (6) 3: Added description of workpackage1: how we will record video consultation, procedure for making the recordings, securing consent, where appropriate de-identify the recordings, and conduct the conversation analysis of the recordings. 5: Added inclusion criteria, recruitment method and consent procedure for recordings of video consultations

				6: Added sentence how we will manage identifying information from video-recordings of video consultations 7: Added output that we archive data for further research/teaching (video-recordings of video consultations)
2	3.0	13.08.20	Alex Rushforth	Protocol sections: Study Summary: modified one aim of the study, one research question, one sample size. Section 2: Aims – question 1 changed; Objectives – 1 and 2 changed Section 3: Study design/method description changed in second paragraph Section 5: Sampling technique – 1st paragraph changed; Recruitment – 1st paragraph changed
3	4.0	17.08.20	Alex Rushforth	Protocol sections: Study Summary: Added to planned sample size, aims, and research question. Section 1: Added to background on long Covid Section 2: Added research question. Section 3: Added focus groups and interviews to study design and data analysis description. Section 5: Added focus group information to inclusion and exclusion criteria, consent procedure, and recruitment details. Section 6: Added focus group information to data management description Section 7: Added focus group information to ethical and regulatory considerations. Section 9: Added long Covid reference
4	5.0	08.09.20	Mona Koshkouei Alex Rushforth	1- Study summary section. Planned sample sizes for the pharmacist/pharmacy recruitment updated to 75 clinicians and 5 patient/carers.

				2- Section 1: background. Pharmacy objective added as point d). 3- Section 3: study design/methods and section4: study settings. Pharmacy sections integrated into full text of body and individual paragraphs removed. 4- Patient consent process added for pharmacy recruitment for videoconferencing and recording. Protocol updated throughout to reflect pharmacist inclusion in the term 'clinician'. List of investigators updated throughout protocol to include new recruits into research study team.
5	6.0	08.10.20	Alex Rushforth, Sarah Rybcynska-Bunt	Changes to protocol in: Section 3 – Added description of ethnographic observation to the subsections on design, methods and data analysis. Section 5 - Added description of ethnographic observation to the subsections on recruitment and consent.
6	7.0	01.03.21	Lucas Seuren, Alex Rushforth	Protocol updated throughout to reflect inclusion of audio-recordings of telephone consultations, in addition to video-recordings of video consultations.
7	8	22.03.21	Stuart Faulkner, Alex Rushforth	Protocol updated throughout to reflect revised or additional consent and PIL documentation to account for interviews of deaf or hard of hearing participants who may need a translator, and those who may be low literacy.

List details of all protocol amendments here whenever a new version of the protocol is produced.
Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.