Study Title: Evaluating video and hybrid group consultations in general practice: mixed-methods, participatory study

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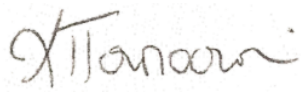
Chief Investigator Signature:	

No conflicts to declare.

TABLE OF CONTENTS

1. KEY CONTACTS

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Committees	Steering committee Chair: Ms Anica Nishio-Alvarez

2. LAY SUMMARY

AIM: To better understand how group consultations for chronic conditions can benefit patients and the health service when delivered on video and/or in-person sessions in general practice.

BACKGROUND: Before the pandemic, group consultations were starting to gain ground in the UK as a new way of delivering clinical care to multiple patients at the same time, with potential benefits resulting from peer support and time efficiencies. When in-person care was restricted due to Covid-19, clinicians started delivering group consultations over video, supported by a training programme commissioned by the government. Despite significant interest, we still know little about how group consultations delivered over video or hybrid models combining video and in-person sessions can be best implemented.

STUDY DESIGN AND METHODS: In 5 GP practices across England, where group consultations are already being delivered, we will evaluate how these new approaches to clinical care are implemented, and how they may support an inclusive service that engages patients with different needs and preferences. The evaluation will include interviews with patients, carers, NHS staff, policy-makers and commissioners, as well as group discussions and observations, including research led by patients themselves. We will also collect numerical data on the number and type of patients attending, whether they are more satisfied or confident with their self-management, or less likely to need to go to hospital. We will explore costs

associated with these new ways of delivering care and will develop comparisons to face-to-face individual appointments. We will also work with 5 practices only delivering one-to-one appointments, to collect numerical data on patient attendance, satisfaction and use of health services. With the involvement of our PPI group, we will bring together our data to develop practical knowledge.

PATIENT AND PUBLIC INVOLVEMENT: Our PPI group have provided input to this protocol and agreed to support the study going forward. The group includes people with a range of conditions, ages, genders and ethnicities.

DISSEMINATION: We will tailor our outputs for different audiences: user-friendly guides for patients/carers, implementation resources for service providers, briefings and presentations for policymakers/commissioners, and peer-reviewed, high-impact journal articles and conference presentations for academics/researchers.

3. SYNOPSIS

Study Title	Evaluating video and hybrid group consultations in general practice: mixed-methods, participatory study
Internal ref. no. / short title	VGC evaluation
Study registration	N/A non-interventional study
Sponsor	University of Oxford, Research Governance Ethics and Assurance, Joint Research Office, Boundary Brook House, Churchill Drive, Headington, OX3 7GB RGEA T: 01865 616480 E: rgea.sponsor@admin.ox.ac.uk
Funder	National Institute for Health Research - Health Services and Delivery Research (HSDR) programme
Study Design	Mixed methods research, including survey questionnaire, co-design workshops and multi-site, participatory process evaluation (qualitative, quantitative and cost-related) in general practice
Study Participants	Patients and carers, NHS clinical and non-clinical staff, national policy-makers and local commissioners
Sample Size	Qualitative research: 64-98 patients and carers in interviews and focus group, 20-30 clinical and non-clinical NHS staff in interviews, 5-10 national decision-makers and 5-7 commissioners, plus ethnographic observation in up to 25 video and hybrid group consultations. Quantitative and health economics research: 50 patients in each of the 10 study sites – 500 patients in total.
Planned Study Period	01 March 2022 – 31 May 2025
Planned Recruitment period	01 March 2022 – 31 May 2025

4. ABBREVIATIONS

CI	Chief Investigator
GCP	Good Clinical Practice
GP	General Practitioner
HE	Health Economic
HRA	Health Research Authority
HRQoL	Health Related Quality of Life
ICF	Informed Consent Form
NASSS	Non-adoption, Abandonment and challenges to Scale-up, Spread and Sustainability
NHS	National Health Service
NIHR	National Institute for Health Research
RES	Research Ethics Service
PI	Principal Investigator
PIL	Participant/ Patient Information Leaflet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RGEA	Research Governance Ethics and Assurance
SOP	Standard Operating Procedure
VHGC	Video and hybrid group consultations

5. BACKGROUND AND RATIONALE

5.1. What is the problem being addressed?

As general practice is assuming a key role in managing the long-term health consequences of the pandemic and the rising wave of delayed care, changes to service delivery and workforce deployment are urgently needed (1-3). This compounds challenges pre-dating the pandemic, such as the increasing prevalence of long-term conditions, unsustainable workloads, workforce retention, and lack of appropriate, proactive service models to better engage vulnerable groups, preventing poor health outcomes and emergency care use (1, 4, 5). Unless new ways of delivering care are established in the near future, chronic disease management is likely to become unaffordable and undeliverable.

Different models of care have been adopted during the pandemic, including telephone-first and remote triage. It is imperative that these continue to provide good value and improve quality, access and organisation of health services. There have been calls for better evaluations, especially on remote consultations, to understand their impact on ‘patient experience, health inequalities and relationship-based care’ (1). There has also been interest in novel approaches, including video group consultations,

where clinical care is provided remotely on video to groups of patients at the same time, rather than on a one-to-one basis (e.g. (6-9)).

Group consultations (in-person) were introduced in the UK before the pandemic (10-13). They were seen as a way to address rising costs and demand pressures, with the potential to improve efficiency and self-care (14). Group consultations have been delivered in a variety of formats to patient groups with specific long-term conditions or shared health concerns (10). They incorporate elements of group education and peer support, and include clinical discussion on individual treatment, self-management and prescribing decisions, all undertaken in a group setting (15).

When in-person care was restricted due to Covid-19, clinicians in the UK started delivering group consultations over video. In a UK-wide survey of NHS staff that our team carried out in August-September 2020, 354/809 (44%) respondents indicated that video group consultations had been set up in their organisation, service or team (16). A small number (4.4%, n=36) already had video group consultations in place prior to the pandemic. These observations suggest substantial and rapid growth of this new service model. However, implementation remains ad hoc (e.g. see 17 for a recent example), without independent evaluation data or capacity for transferable learning. Research is urgently needed to inform how best to deliver remote group-based care, how to embed and sustain this model in different contexts, and how to provide value and minimise risks from delivery at scale.

5.2. Why is this research important?

In the UK there has been a strong policy push to establish 'digital first' primary care including online and video consultations as required by the latest GP contract (4, 18, 19). This drive has been substantially accelerated by the pandemic, with practices adopting triage models to minimize patient contact. In July 2020, the Secretary of State for Health announced the 'remote-by-default' policy would remain even after the pandemic had receded (20). However, more recently GP practices were asked to increase in-person appointments, a move that was met with substantial backlash from GPs (21). It is becoming clear that, in the context of ongoing Covid disruption and efforts at recovery, there is an immediate and substantial need to understand how best to balance remote and in-person care. This includes development of new care models that enable effective management of an unprecedented workload and ongoing provision of high quality care that fulfils Quality and Outcomes Framework (QOF) requirements. All at a time when general practice is at breaking point, with decreasing numbers of GPs and more clinicians considering leaving the NHS (3, 21).

In a parallel response to Covid-19 in early 2020, NHS England and Improvement (NHSE/I) commissioned and supported the delivery of a year-long training programme and the development of a toolkit on video group consultations (Papoutsi led its evaluation), with NHS Wales following suit. Approximately 500 clinical and non-clinical staff completed training in England. Health Education England also developed an e-learning package to support service delivery (https://www.e-lfh.org.uk/programmes/video-group-clinics/). These developments build on previous NHS initiatives on face-to-face group consultations, including the General Practice Forward View which identified group consultations as one of 10 high-impact innovations to help manage capacity in general practice (4).

There is an expressed and urgent need to better understand how and why video group consultations (and combinations with in-person sessions) can support patient care and self-management, save costs or allow more capacity and health gains with the same budget, especially in the context of increasing system pressures. Research on this topic must also address digital inclusion and equity, if these new models of care are to spread and scale up in a sustainable way.

5.3. Review of existing evidence

A recent NIHR HS&DR-funded review identified significant methodological weaknesses in studies on group consultations, including lack of evidence pertaining to ethnic minorities (22). The authors recommended more 'UK-centred evaluations using rigorous research designs and economic models with robust components' (22). There has been little research on *Video or Hybrid Group Consultations (VHGCs), which involve group consultations delivered over video or hybrid models where some sessions are delivered remotely on video and others are delivered in-person* (e.g. initial sessions take place in-person so that patients meet each other and with growing familiarity more remote sessions are added). Questions remain on whether VHGCs delivered at scale increase system efficiency over time or whether they result in increased demand.

Our team carried out a small-scale qualitative evaluation of video group consultations in England during the pandemic (04/2020–06/2021). Groups included patients with asthma, diabetes, COPD, cancer, mild and long Covid, and at-risk groups (e.g. vulnerable families with new babies). Most patients welcomed group support; some were surprised by how much peer input they gained and how their own experiences could help other patients. However, not everyone agreed to participate in video group consultations or was able to access IT equipment. System-level challenges included protecting patient confidentiality online, maintaining professional indemnity cover, and ensuring patient safety. There were operational and cultural challenges, including changes in staff roles and training needs. Some clinicians found increased job satisfaction and saw potential for staff upskilling and leadership development. Overall, the evaluation showed that our understanding of how to balance opportunities and challenges is currently limited. There is still much to examine, especially when looking at feasibility of combining video and in-person group sessions. To our knowledge only two pilot studies have been published on VHGCs, one on video and in-person group consultations for Idiopathic Intracranial Hypertension in a UK clinic (17), and the other on video group consultations for diabetes patients in Guam (23). Both reported VHGCs to be feasible and resulting in improved patient and service outcomes, but their sample sizes were small and the balance between clinical and educational focus was unclear.

Growing evidence on face-to-face group consultations (mainly from the US and Australia) suggests that they have the potential to improve patient health and wellbeing, support workforce retention, and contribute to health service improvement (24). By fundamentally changing the way patients interact with the service, group consultations reduce isolation, and increase vicarious, practical learning and motivation (24). Experimental studies in diabetes show improvements in glycaemic control, problem-solving ability, quality of life, and reduced time commitment for clinicians, compared with one-to-one consultations (25-28). In a randomized trial, a group-based intervention for minority ethnic groups was associated with higher attendance and patient enablement scores (29). In UK general practice, there is some evidence that face-to-face group consultations result in service efficiency and improvement, increasing both patient-

centred care and job satisfaction for staff, although implementation and spread challenges need to be better understood (13, 30).

Our recent NIHR-funded (through previous commissioned call) 3-year evaluation of co-designed group consultations for young adults with diabetes, identified positive patient experiences and better engagement with self-management, although local implementation encountered operational complexities (12, 31). In our systematic review underpinning this evaluation, we developed four overarching principles for better engagement in group consultations: emphasising self-management as practical knowledge; developing a sense of affinity between patients; providing safe, appropriate care for different groups of patients (e.g. young people); and balancing group and individual needs [19]. Two systematic reviews on in-person group consultations are also currently in progress by a research team at Newcastle University (32, 33).

The evidence base on video consultations has also been growing, including 10+ years of research by our teams e.g. on the 'remote-by-default' policy in England, the NHS Near Me service in Scotland (34-41). Learning shows that spread of remote care is characterised by multiple interacting complexities for which there are few standardised solutions. Local teams need to work collaboratively to find workable ways forward through close dialogue and practical problem-solving; co-evolve introduction of technology-supported models with development of team roles and processes; and accommodate competing policy priorities (34, 36, 42, 43).

This research seeks transferable insights into the development of sustainable VHGCs beyond the crisis context. Our focus is on understanding complex, dynamic interdependencies in implementation and scale-up, including potential for improved patient care, staff wellbeing and service improvement. Co-design of VHGCs with service users and staff means outcomes are more likely to meet current and emerging needs (44).

6. OBJECTIVES AND OUTCOME MEASURES

Aim: To generate a strong evidence base for successful co-design and implementation of Video and Hybrid Group Consultations (VHGCs) for chronic conditions in general practice.

Objectives

1. To carry out mixed methods, formative evaluation of VHGC service models and support their implementation by facilitating knowledge sharing across participating GP sites.

2. To perform a summative assessment of feasibility and acceptability, as well as of the potential of VHGCs to improve patient and service outcomes, and contain costs.

3. To assess the feasibility of collecting multimodal data (video, audio and screen capture) from video and hybrid group consultations.

4. To draw transferable learning on the development, implementation and mainstreaming of new, group-based and technology-supported service models.

The project is also looking to map existing provision of VHGC services in the UK and to support practices in co-designing their existing VHGC models, but we are not asking for NHS ethics as these two activities fall under service evaluation/audit.

Research questions

1. What is the feasibility and acceptability of VHGCs to different population groups? What are their (perceived) implications for access, efficiency and safety in general practice?

2. How do patients, carers and NHS staff experience these new models of care, compared to standard one-to-one service provision and face-to-face only group consultations?

3. What are the costs of introducing VHGCs? What is the organisational impact on general practice and other system-level stakeholders?

4. What would be the optimal design of a large-scale evaluation to assess clinical benefits and key outcome/activity parameters?

Objectives	**Outcome Measures**	**Timepoint(s) of evaluation of this outcome measure (if applicable)**
Objective 1 To carry out mixed methods, formative evaluation of VHGC service models and support their implementation by facilitating knowledge sharing across participating GP sites.	Qualitative experiences of staff, patients and national and local policy-makers and commissioners	March 2022 - Nov 2023
Objective 2 To perform a summative assessment of feasibility and acceptability, as well as of the potential of VHGCs to improve patient and service outcomes, and contain costs.	i) Quantitative measures of VHGC delivery and resource use ii) Quantitative measures of patient experience, satisfaction, activation and health-related quality of life iii) Quantitative measures of healthcare utilisation (primary and secondary care)	March 2022 - Nov 2023
Objective 3 To assess the feasibility of collecting multimodal data (video, audio and	Multimodal data on 10-12 video and hybrid group consultations	February 2023- Nov 2024

screen capture) from video and hybrid groups.		
Objective 4 To draw transferable learning on the development, implementation and mainstreaming of new, group-based and technology-supported service models.	Transferable principles on the development, implementation and mainstreaming of new, group-based and technology-supported service models	March 2022 – Nov 2024

7. STUDY DESIGN

Mixed methods, multi-site, participatory process evaluation in general practice in England (10 GP practices in total, 5 case sites where VHGCs are already delivered and 5 control sites that do not deliver VHGCs-see appendix table). The study will build on a scoping survey and co-design workshops with health professionals for which we are not requesting NHS ethics as they fall under the service evaluation/audit category.

A. The **qualitative evaluation** will focus on 5 case sites (where VHGCs are already implemented independently of this project) and will include interviews, focus groups and ethnographic observation to examine the experiences of patients, carers, clinical and non-clinical NHS staff, commissioners and policy-makers (including with patients as co-researchers). We will study how different GP practices make decisions about integrating VHGCs in their processes, how responsibilities are distributed, what is the impact on existing practices, and how clinical care and service provision are affected (e.g. impact on workload). We will explore how best to collect and analyse data about the way patients and clinicians interact and communicate in video and hybrid group consultations, and will develop a detailed understanding of good practice and will also generate transferable VHGC implementation lessons.

B. The **quantitative evaluation** will focus on the following 3 domains: i) measures of VHGC delivery and resource use, ii) measures of patient experience, satisfaction, activation and health-related quality of life, and iii) healthcare utilisation (primary and secondary care).

i. Description of VHGC delivery and resource use

In each of the 5 case sites we will collect descriptive data on the way VHGCs are delivered and the resources needed. This data will include the number and type of VHGC sessions, the number of patients participating in each VHGC and the number of patients invited to take part who choose not to participate (with whom we will follow-up in qualitative interviews to understand why, as described above). We will also collect key data on timing and duration of VHGCs, resources needed (e.g. staff members) to deliver the sessions, and time and resources required to prepare for and follow up from each VHGC.

ii. Impact of VHGCs on patient experience, satisfaction and quality of life

We will use an online and offline survey questionnaire comprising patient experience, satisfaction and health-related quality of life components. The survey will be administered online

(through the Oxford or Exeter JiscMail account), or in paper copies, immediately following VHGC attendance (through a link shared on the same platform, e.g. Microsoft Teams, by text messaging (e.g. accurx) or distributed in paper copies by the research or clinical team), and will examine both patient experiences which relate directly to VHGCs (e.g. satisfaction with care received, inclusion and access implications, quality and safety of care, need for additional follow-up, travel time saved, time off work avoided etc.) as well as to wider experiences of healthcare in the practice (e.g. satisfaction with 1:1 care, perceptions on access, quality and safety).

In addition to the 5 case sites we will recruit a further 5 control practices where VHGCs are not being employed (matched with case study sites on location, setting, size, deprivation, QOF). Patients in control sites will receive a shorter version of the patient questionnaire used in case study sites including only questions relating to wider experiences of healthcare at their practice (Primary Care Outcomes Questionnaire [57]).

Healthcare teams ask patients to complete the Patient Activation Measure (PAM) on patient knowledge, beliefs and confidence in self-management as part of their local service improvement., The research team will access this service improvement data from control and case sites. To examine any differences in PAM scores we will make comparisons between case and control sites, rather than repeated measurements for the same patients over time. This is because some patients will have already been involved in VHGCs before the study starts, and even for new patients the frequency with which they participate in VHGCs over the study period may not be sufficient to record changes in PAM scores.

We will work with practices over a 12 month period to collect data on patients' primary care utilisation including the number, type (staff members involved, e.g. GP, nurse or other healthcare professional, and mode of consultation e.g., face-to-face, telephone, online, eConsult) and duration of appointments. Comparisons will be made between patients at case study and control practices in terms of number and duration of primary care consultations. We will also request data from NHS digital on secondary care usage including outpatient appointments, admitted patient care and Accident and Emergency attendances. Data requested from NHS digital will be the minimum required to identify episodes of care, and for the admitted patient care, data required to link episodes of care into continuous inpatient spells. For admitted patient care we will also seek diagnosis codes associated with episodes of care such that we can identify admissions for ambulatory care sensitive conditions, i.e. those admissions for conditions which may have been avoided with better management in primary care. Consent will be sought from participants for the research team to be given details of their primary care utilisation and secondary care utilisation. Participants may give consent to one, both, or neither of these data sources being shared with the research team.

C. **Health economics**

We will conduct a health economic (HE) evaluation (in the form of model-based cost-effectiveness analysis) to assess the value for money of alternative modes of delivery (i.e. one-to-one, group, in-person, video or hybrid) for GP consultations compared to in-person one-to-one contacts, from the perspective of the NHS and Personal Social Services. The HE analysis will complement (and integrate with) the qualitative and quantitative analyses.

All patients attending VHGCs for the first time (i.e. VHGC-naïve patients) - in two of the GP case sites - will be invited to continue completing a focused online HE survey at the end of each VHGC during a 9-month period. The sites will focus on common long-term conditions that more naturally lend themselves to VHGC, such as menopause or diabetes. Our HE survey will include health-related quality of life items (i.e. EQ-5D-5L or disease-specific variations), patient satisfaction (i.e. SAPS items on time to wait for consultation; manner of doctor or nurse; explanation; treatment or advice; and, overall satisfaction) and a series of questions on patients' demand for GP consultations (number, format and purpose) in-between VHGCs as well as participants' clinical and socio-demographic characteristics.

Conceptualisation and development of the decision model [61] will be guided by the NASSS framework (i.e. clinical condition, technology, value proposition, adopter system, organisation, wider system and temporal change) including their recent adaptation for remote consultations [46]. The process of conceptualising and developing the decision model will involve decomposing and characterising discrete elements of GP models of care. We will describe elements in a format that enables us to estimate their individual contribution to the treatment effect of GP consultations associated with alternative modes of delivery. Our HE modelling approach will make explicit each of the different elements of treatment effect associated with different modes of delivery of GP consultations. The model will be populated using cost, health-related quality of life (HRQoL) and healthcare demand data described below.

Model inputs: a detailed costing analysis of VHGCs will be conducted in two of the five GP case study sites (one in high and one in low deprivation areas). Monthly data on VHGC timings, resources, organisational processes and workload allocation will be collected using instruments described in the quantitative section (e.g. data on clinical and non-clinical time required to organise VHGCs and how this changes over the study period). We will aim to determine whether alternative modes of delivery are likely to result in significant variations in healthcare provision (i.e. are specific modes of delivery of consultations more likely to enable GPs to increase the expected number of patients they are able to reach per day? If so, how many more?). The answer to this will depend on both supply (GP practice) and demand-side (patients) characteristics and preferences.

8. PARTICIPANT IDENTIFICATION

8.1. Study Participants

Study participants will include: i) NHS patients participating in VHGCs, patients who have declined or withdrawn from participation in VHGCs, and patients in control practices which are not delivering VHGCs, and carers, ii) clinical and non-clinical staff in general practice, and iii) local commissioners and national policy-makers.

8.2. Inclusion Criteria

- Participants must be 18 years or older
- Willing and able to give informed consent for participation

- Patient participants will be included if they have been diagnosed with a relevant condition, receiving care from participating services
- Carer participants will be included if they care for someone diagnosed with a relevant condition, receiving care from participating services
- Staff will be included if they are involved in implementing or supporting VHGCs in participating GP practices
- Commissioning and policy stakeholders will be included if they are involved in planning or commissioning remote services including VHGCs, or wider aspects of general practice commissioning relevant to this study.

8.3. Exclusion Criteria

- Inability to read or speak English unless a relevant translator/translated study materials are available.
- Co-morbidity preventing participation (for patient participants).
- No specific exclusions for staff and commissioning/policy participants.

9. PROTOCOL PROCEDURES

9.1. Recruitment

Recruitment of study sites

Our sampling strategy for the 5 case sites aims to achieve maximum variation in characteristics that influence how VHGCs are delivered, such as geographical location, practice size (e.g. number of GPs), patient population (size of patient list, ethnic background, digital literacy/confidence and deprivation) and digital maturity of practices (digital readiness, capability and infrastructure as defined in our previous work [46]). We also aim to include practices where VHGCs are led by different professional groups, such as GPs, nurses or pharmacists. Guided by our methodological approach to theoretical sampling we will seek sufficient representation of these characteristics in our sample to be able to qualitatively analyse and understand their influence on the development, implementation and spread of VHGCs. In addition to the 5 case study practices we will recruit a further 5 control practices for the quantitative arm of the study where VHGCs are not being employed (matched with case study sites on location, setting, size, deprivation, QOF). Recruitment will be supported by the local CRNs and our professional networks.

Recruitment of participants

a) **Patient and carer participants (for qualitative and quantitative arm)**: They will be recruited once at the beginning of the study by local clinicians and researchers as appropriate (i.e., where they are also members of the care team) in the 5 case and 5 control sites. Patient and carer participants will include those who have taken part in VHGCs, those who declined participation or were unable to attend sessions (e.g. due to digital exclusion), and those who have not been offered the option to participate (in control sites). We will use maximum variation sampling to guide recruitment of patients across sociodemographic and ethnic backgrounds, health needs and conditions, and with different levels of self-assessed digital literacy/confidence. Groups with higher general practice

consultation rates will be particularly targeted (asking each practice which groups tend to make most use of services locally), including those with long-term conditions, those with multi-morbidities, and people from deprived communities (45).

b) **NHS staff (for qualitative arm)**: We will recruit NHS staff clinical and non-clinical NHS staff in qualitative interviews (4-6 per practice) including GPs, GP trainees, practice nurses, healthcare assistants, pharmacists, practice managers, administrators, reception, IT staff and secondary care staff as relevant. Staff participants will be recruited by the research team primarily from the 5 control and 5 case sites.

c) **National and local policy-makers and commissioners (for qualitative arm):** We will involve 5-10 key national decision-makers (e.g. NHSE/I, NHSx) and 5-7 local commissioners (mainly from the areas the GP case sites are based) in qualitative interviews. Recruitment will take place through snowball and purposive sampling.

9.2. Screening and Eligibility Assessment

Patient and carer participants (>18 years old) will include those who have taken part in VHGCs, those who declined participation or were unable to attend sessions (e.g. due to digital exclusion), and those who have not been offered the option to participate (in control sites). There will be no exceptions made regarding eligibility, i.e., that each participant must satisfy all the approved inclusion and exclusion criteria of the protocol.

9.3. Informed Consent

We have engaged our PPI group in developing our participant information and consent materials. Participants must provide informed consent either in person or remotely before any study specific activities are undertaken.

Study participants will receive a participant information leaflet (PIL) by email, text message or in person at the GP practice and will be asked by the local clinician or a University researcher to provide consent prior to their participation in the study. The PIL will detail: the exact nature of the study; what it will involve for the participant; the implications and constraints of the protocol; any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care (for patient participants), and with no obligation to give the reason for withdrawal. When consent is taken remotely, the researcher will record the consent on a "record of consent form". A copy of the form will be forwarded securely to the participant by post (marked confidential) or email (marked confidential with document password-protected). The original signed form will be retained at the study site.

The participant will be allowed as much time as wished to consider the information (at least 72 hours), and the opportunity to question the researcher or other independent parties to decide whether they will participate in the study. Participants will have opportunities to ask questions via email or phone to the researcher. The researcher who obtains the consent will be suitably qualified and experienced, and have been authorised to do so by the Chief Investigator.

The participant must provide consent using the latest approved version of the Informed Consent form, whether in person or remotely, before any study specific procedures are performed.

For the health economic survey (Measures of Health Benefits - section 7C and 9.8), the survey will either be administered online (through the Oxford or Exeter JiscMail account), in paper copies, or over the telephone immediately following Video or Hybrid Group Consultation (VHGC) attendance (case site), or face to face attendance (control site) (through a link shared on the same platform, e.g. Microsoft Teams, by text message (e.g. accurx) sent by the GP, or distributed in paper copies by the research or clinical team. The consent form is embedded within the online survey. A link to the PIL will be sent to potential participants along with the link to the survey.

For the online survey a single link will be issued. A consent form will be filled in and submitted online using this link. Once consent is confirmed, the next page, a 'decision page' will then direct patients to the appropriate part of the survey depending on their attendance to VHGC or face to face consultation. Separate paper copies (for case and control sites) of the survey, PIL and ICFs will be available for distribution for paper completion or completion of over the phone.

Where survey administration is performed over the phone, a member of the site clinical team (i.e. GP) or a member of the research team will take verbal consent over the phone, before proceeding with survey administration.

9.4. Randomisation

No randomisation is taking place in this study.

9.5. Blinding and code-breaking

There is no blinding or no code breaking procedure in the study.

9.6. Description of study intervention(s), comparators and study procedures (clinical)

There is no study intervention and/or comparator. The study is examining usual care provided by the case study practices recruited.

9.7. Study procedures

Mixed methods, multi-site process evaluation in 5 case & 5 control sites (GP practices in England).

A. Qualitative evaluation

Patients and carers: We will involve 40-50 patients and carers (~10 per case site) in semi-structured qualitative interviews. We will also involve 24-28 patients and carers who have not already participated in interviews in 4-6 focus groups. We will engage patients and carers who have taken part in VHGCs, as well as those who declined participation or were unable to attend sessions (e.g. due to digital exclusion).

NHS staff: In the 5 case study practices we will involve 20-30 NHS staff clinical and non-clinical NHS staff in qualitative interviews (4-6 per practice) including GPs, GP trainees, practice nurses, healthcare assistants, pharmacists, practice managers, administrators, reception and IT staff. Interviewees may also include secondary care clinicians involved in VHGCs in these practices to understand impact on secondary care use.

National and local policy-makers and commissioners: We will involve 5-10 key national decision-makers (e.g. NHSE/I, NHSx) and 5-7 local commissioners (mainly from the areas the GP case sites are based) in qualitative interviews. Recruitment will take place through snowball and purposive sampling.

Interviews will follow a flexible topic guide, will last 30-45mins, and will take place remotely (on the phone or video) or in-person, at patients' homes, the GP practice or another location of their choice, where feasible depending on pandemic-related restrictions and geographical spread. Focus groups (either online or in-person) will last 60-80 minutes and will be led by an experienced moderator using a topic guide to maintain focus on predetermined questions, while allowing flexibility to explore topics that are important to participants. Interviews and focus groups will be audio-recorded (with consent) and notes will be taken in parallel.

Video and hybrid group consultations: We will carry out ethnographic observation on back-end operational and technical processes required to run VHGCs, to enrol patients in VHGCs and support their participation (at least 2 visits per GP practice over 12 months). The team will observe 25 VHGCs (virtually or in-person) across the 5 GP practices (~5 each), using video/audio recordings and field notes , as we have done in previous NIHR-funded research (31). In some practices where it is feasible to separate the interaction of individual patients within a group consultation (i.e. where individual consultations between a patient and a clinician take place consecutively in a group setting without involvement from other patients) we will be able to pause recording for any patients who do not consent to this. Otherwise we will require consent from all patients before proceeding with recording (either using MS Teams or other secure screen capture tools and/or audio-recording).

To assess the feasibility of collecting multimodal data, in 1-2 selected practices we will use additional means of video recording (with participant consent) up to 10-12 video and hybrid group consultations, following the same procedures as in previous work where we have collected video recordings successfully (e.g. SCiP study ethics reference 21/EM/0082). We will use MS Teams/other screen capture tools as already approved in Protocol v1.2, and following 21/EM/0082, we will also use small digital camcorders positioned unobtrusively (e.g. on a shelf) to capture as much as possible of the individual(s) and their orientation towards the screen (monitor, laptop or computer, mobile phone or tablet) or other patients in the in-person setting, as well as contextual detail in the room. Please see below for more detail on how we expect to operationalise this, based on previous experience:

- Video group consultations: in these consultations everyone is participating remotely so we will capture three video streams at the same time, a) the practice end: what the clinician sees and does in the clinic (or other location, sometimes from home) using a digital camcorder, b) the patient end: we will recruit one patient per session who will allow us to video-record using a digital camcorder from their preferred location (usually their home) and c) the group consultation as recorded using the built-in functionality in MS Teams (typically used to deliver group sessions) or a different screen capture and audio-recording tool.

- Hybrid group consultations: in these consultations some patients participate in-person at the practice while others join remotely on MS Teams, as part of the same session. We will capture these consultations using three video streams: a) the practice end: what the clinician and the patients in the room see and do in the clinic using a digital camcorder, b) the remote patient end: we will recruit one of the patients joining remotely who will allow us to video-record using a digital camcorder from their preferred location (usually their home) and c) the group consultation as recorded using the built-in functionality in MS Teams or a different screen capture and audio-recording tool.

If clinicians use screens additional to the one where the video or hybrid group consultation is projected, we will use commercially available screen capture software to record screen images as a video file. We will use an encrypted USB device to run this software, but where not technically possible to do this, we will capture screens using a digital camera. We will not ask patients to video-record consultations themselves and will not enable them to retain copies of any recordings.

After the consultation, the researchers will confirm that participating patients and NHS staff are still willing for the video material to be used in the research. It will also be made clear to patients that sections of the consultation could also be deleted. For example, if the consultation included a specific topic that the patient would not wish to be included in the recording, they can highlight this and ask it be deleted from the file.

Any documentation, VHGC materials developed by the practice, significant event details or other relevant records (without patient-identifiable details) will be retained for analysis. We will also work with PPI contributors as co-researchers (with appropriate training by our team) to review de-identified/pixelated clips from video or audio recordings and contribute to data analysis. Brief discussions between patients in group consultations will cover what has gone well and what has gone less well during each VHGC (up to 25 in total across each of the 5 case study practices) with the aim to provide feedback to practices and inform the evaluation. Encouraging feedback discussions in the context of ongoing group consultations (rather than as a separate activity organised by researchers) will enable better distribution of power dynamics in a context where patients are already building relationships (this draws on previous unpublished research in face-to-face group consultations).

Analysis will be undertaken by a core analytical team and will include PPI members. We will use theory-informed thematic and abductive analysis, as well as conversation analytic methods. The project steering group will provide comments on the themes emerging from the data and to consider the veracity and credibility of interpretations.

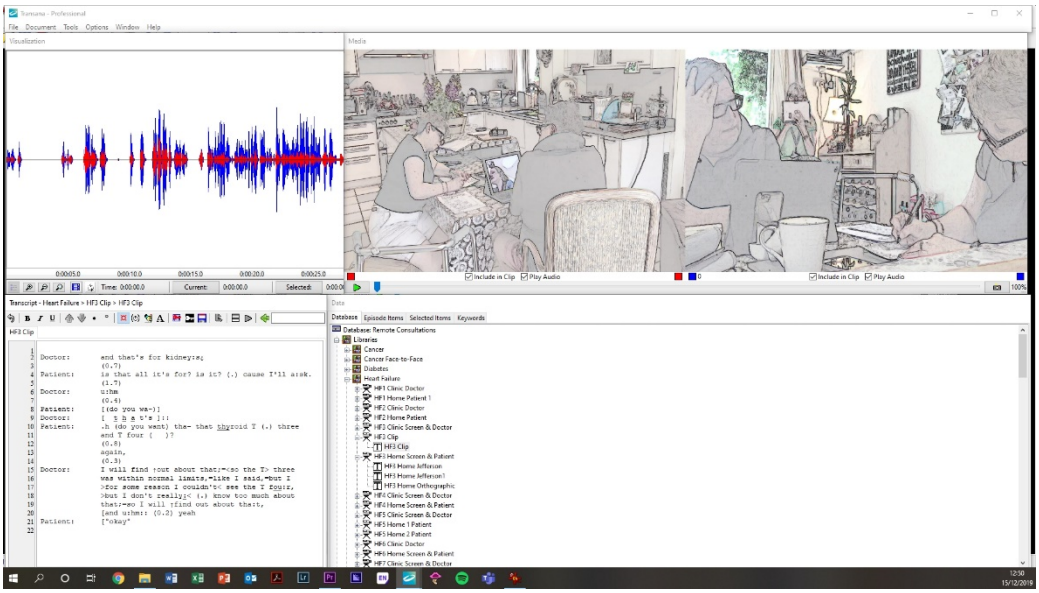

Figure 1 Software workspace showing example of blurred recording of video consultation and relevant transcript (example from previous work)

B. Quantitative evaluation

Patients: 50 patients per practice (case and control sites) will participate in a one-off survey questionnaire comprising quantitative patient experience, satisfaction and health-related quality of life measures (the survey will be administered online and offline, immediately following VHGC attendance). The survey will examine both patient experiences which relate directly to VHGCs (e.g. satisfaction with care received, inclusion and access implications, quality and safety of care, need for additional follow-up, travel time saved, time off work avoided etc.) as well as to wider experiences of healthcare in the practice (e.g. satisfaction with 1:1 care, perceptions on access, quality and safety). The questionnaire will also adopt or adapt items from existing surveys including: the GP Patient Survey; the Primary Care Outcomes Questionnaire (PCOQ) designed to measure a wide range of outcomes in primary care [57]; the Short Assessment Patient Satisfaction (SAPS) questionnaire which is a validated measure of patient satisfaction with GP services in the UK [58]; and the EQ-5D-5L (or disease-specific variations) which is a preference-based generic patient-reported outcome measure using five health-related quality of life domains (self-care, activities of daily living, mobility, pain, anxiety/depression) [59]. Respondents will be provided with an option to share their email address or other contact details so they can be contacted for an interview if they so wish.

Patients in control practices will receive a shorter version of the patient questionnaire (as paper copy or link by email or text message) used in case sites including only questions relating to wider experiences of healthcare at their practice (Primary Care Outcomes Questionnaire (46)).

Patients in control and case study sites will also be asked to complete the Patient Activation Measure (PAM) on patient knowledge, beliefs and confidence in self-management. PAM will be administered by practice staff in the context of local service improvement, with practices co-designing use of PAM into their VHGC models. Our team will provide support and training if needed, and can assist with analysis for service improvement. We will also carry out data analysis for purposes of this project.

We will work with practices to collect data on consenting patients' primary care utilisation including the number, type (staff members involved, e.g. GP, nurse or other healthcare professional, and mode of consultation e.g., face-to-face, telephone, online, eConsult) and duration of appointments. Comparisons will be made between patients at case study and control practices in terms of number and duration of primary care consultations. Data on secondary care utilisation will be requested from NHS digital at a single point in time for all participants, covering a period of up to 12 months following recruitment.

9.8. Subsequent Visits

Qualitative evaluation

Patients and carers: A subset of 5-10 participants (primarily those who continue to engage in video or hybrid group consultations and those who explicitly decide to withdraw from clinical provision) will be invited to one follow-up interview 12 months after their initial involvement in the study to reflect on longitudinal changes.

NHS staff: A subset of 5-10 staff participants will be interviewed twice over 12 months, to be able to follow up on growing familiarity with VHGCs and any longer-term impacts on the service.

Health economics

Patients: In two GP case sites, patients attending VHGCs for the first time at the time of completing the quantitative one-off survey, will be invited to continue completing a focused online HE survey at the end of each VHGC during a 6-month period (this will extend quantitative data collection). The sites will focus on common long-term conditions that more naturally lend themselves to VHGC, such as menopause or diabetes. Our HE survey will include a sub-set of items from the quantitative survey instrument, including on health-related quality of life (i.e. EQ-5D-5L or disease-specific variations), patient satisfaction (i.e. SAPS items on time to wait for consultation; manner of doctor or nurse; explanation; treatment or advice; and, overall satisfaction) and a series of questions on patients' demand for GP consultations (number, format and purpose) in-between VHGCs as well as participants' clinical and socio-demographic characteristics.

9.9. Sample Handling

No samples will be taken.

9.10. Early Discontinuation/Withdrawal of Participants

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during the study
- Inability to comply with study procedures
- Participant decision

Participants may choose to stop their active involvement in the research but choose to remain on passive study follow-up (i.e. those wanting to receive a summary of findings from the study). Participants may also withdraw their consent, meaning that they wish to withdraw from the study completely. Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

Withdrawn participants will be replaced if there is capacity and time left to recruit more participants.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

9.11. Definition of End of Study

The end of study is the point at which all the study data has been entered, queries resolved, analysis has been completed (which in this project will coincide with the end of the funding period in February 2024).

10. SAFETY REPORTING

Safety reporting is not applicable to the study as we are observing how care is delivered already in GP practices rather than introducing a new intervention.

11. STATISTICS AND ANALYSIS

11.1. Statistical Analysis Plan (SAP)

The plan for the statistical analysis of the study are outlined below. There is not a separate SAP document in use for the project.

11.2. Description of the Statistical Methods

The quantitative evaluation will focus on the following 3 domains: i) measures of VHGC delivery and resource use, ii) measures of patient experience, satisfaction, activation and health-related quality of life, and iii) healthcare utilisation (primary care).

i) Measures of VHGC delivery and resource use

This data will include the number and type of VHGC sessions, the number of patients participating in each VHGC and the number of patients invited to take part who choose not to participate. We will also collect key data on timing and duration of VHGCs, resources needed (e.g. staff members) to deliver the sessions, and time and resources required to prepare for and follow up from each VHGC. We will perform descriptive analysis to provide an overview of VHGC in each of the GP case sites.

ii) Measures of patient experience, satisfaction, activation and health-related quality of life

We aim to recruit up to 50 patients per practice (case and control practices) who will consent to participate in survey questionnaires comprising patient experience, satisfaction and health-related quality of life components, and to allow research access to their healthcare utilisation data. The findings will be used in descriptive analyses to provide a quantitative overview of patient experience of VHGCs, comparing between case study and control practices, rather than repeated measurements for the same patients over time.

iii) Healthcare utilisation (primary care)

We will work with practices to collect data on patients' primary care utilisation including the number, type (staff members involved, e.g. GP, nurse or other healthcare professional, and mode of consultation e.g., face-to-face, telephone, online, eConsult) and duration of appointments. Comparisons will be made between patients at case study and control practices. Mixed effects models, with random intercepts for practice, will be used to analyse healthcare utilisation data with the form of the model appropriate to the outcome (i.e. Poisson models for count of appointments/admissions and linear models for consultation durations). Adjustments will be made for patient factors including age, gender, deprivation, ethnicity and comorbidity status. Similar analyses will be applied to secondary care utilisation data considering the number of A&E attendances, outpatient appointments (including numbers or proportion of eligible patients waiting more than six months), hospital admissions, unplanned hospital admissions and hospital admissions for ambulatory care sensitive conditions (conditions for which admissions could, in principle, be avoided by good primary care).

11.3. Sample Size Determination

Given the exploratory nature of this work we have not performed any formal power calculations and will interpret the results accordingly. The sample size has been decided by the ability to study the theoretical and practical aspects of the study design from a feasibility and acceptability perspective.

11.4. Analysis populations

All participants meeting the inclusion criteria.

11.5. Decision points

Not applicable.

11.6. Stopping rules

There are no interventions or safety concerns that would necessitate stopping rules.

11.7. The Level of Statistical Significance

Rather than focus on the presence or absence of statistically significant differences between groups, the analysis will instead examine confidence intervals as a guide to potential differences between the groups, to guide a larger, definitive study.

11.8. Procedure for Accounting for Missing, Unused, and Spurious Data.

We will make significant effort and have resources available to ensure data collection will proceed as planned. Given the exploratory nature of this work, we will describe the feasibility of data collection in detail, but will not use specific procedures for handling missing data.

11.9. Procedures for Reporting any Deviation(s) from the Original Statistical Plan

Any deviation(s) from the original statistical plan will be described and justified in the final report.

11.10. Health Economics Analysis

To assess the value for money of GP models of healthcare provision with and without VHGC we will conduct an early health economic evaluation (HEE) - in the form of a model-based cost-effectiveness analysis. The perspective for the evaluation will be the NHS and Personal Social Services. The cost-effectiveness analysis will complement the qualitative and quantitative analyses conducted in WP1-3. The health economics (HE) team will contribute to the development of quantitative and qualitative data collection tools to be used in WP1-3. Findings from WP1 (scoping survey) and WP2 (co-design) will inform the process of: i) defining the decision problem for the early economic evaluation ii) conceptualising a decision model structure that represents the decision problem; and iii) generating a set of initial model inputs for a preliminary evaluation of the decision model. Furthermore, in preparation for a large definitive trial, the early HEE study will ascertain the feasibility (and best practice for) of collecting data – at GP practice level – on healthcare resource use (e.g. venue, staffing, consultations' duration, set-up time, technology costs) and patient reported outcomes (e.g., health related quality of life, satisfaction) associated with the delivery of VHGCs.

Decision Model: conceptualisation and development of the decision model (47) will be guided by the NASSS domains (i.e. clinical condition, technology, value proposition, adopter system, organisation, wider system and temporal change) (53) including their recent adaptation for remote consultations (48). The process of conceptualising and developing the decision model will involve decomposing and characterising discrete elements of GP models of care. The decision model will enable estimation of the value for money of a GP model of healthcare provision that includes alternative types (i.e. one-to-one, group) and modes (i.e. one-to-one, group, in-person, home, video or hybrid) of GP consultations including VHGC, compared to a GP model of healthcare provision that does not provide VHGC.

Model inputs: the focus of the VHGC (e.g., diabetes annual reviews; peri and post menopause consultations) will be defined in consultation with case and comparison sites in WP3. A micro-costing analysis of VHGCs will be conducted in one of the five case study sites in WP3 GP. Data on consultations (e.g. number and type of VHGCs and non-VHGC consultations taking place) will be collected prospectively. The main source to estimate the unit cost of different types and modes of GP consultations will be Unit Costs of Health and Social Care Manual (https://www.pssru.ac.uk/unitcostsreport/). Over an up to 6-month period, all patients attending a GP consultation (any type and mode, but with the same focus for VHGC) in a case and comparison site will be invited to complete an online Measures of Health Benefit survey. This will include questions on utility-based health-related quality of life (i.e. EQ-5D-5L) (54); patient satisfaction (i.e. SAPS adaptation) ; and, personal details (e.g. age, weight, height).

Initial model inputs will be based on estimates of consultation costs, utility and satisfaction

Given the limited data available to populate our decision model, and the need to make a number of expert-informed structural assumptions, we expect the results and conclusions derived from the HE analysis to be subject to uncertainty. The impact of this on the decision uncertainty to consider VHGC a cost-effective addition to exiting models of GP healthcare provision will be explored using value of information analysis (VOI)(52). This methodology will enable us to identify the model parameters (and structural assumptions) considered to be the key drivers of decision uncertainty. Results from the VOI analysis will be used to inform the design of a future definitive study of a GP model of healthcare provision with VHGCs.

DATA MANAGEMENT

The plan for the data management of the study is outlined below. There is no separate Data Management document in use for the study.

11.11. Source Data

The only data collected from GP records will be on primary care consultations for patients recruited in control and case sites.

11.12. Access to Data

Direct access will be granted to authorised representatives from the Sponsor and host institution for monitoring and/or audit of the study to ensure compliance with regulations.

11.13. Data Recording and Record Keeping

All data from the study (audio and video recordings, transcripts, field notes, survey responses and other quantitative data) will be password-protected and kept on encrypted, non-networked computers at the Universities of Oxford, Exeter and York. In those stored data, participants will be referred to only by a unique study number. We will keep a separate, password-protected record of participants' real names and corresponding pseudonyms (accessed by members of the team only). Any personal identifiers relating to individual participants will be held for less than six months after the end of this 24-month study.

Interviews and focus group recordings will be recorded and transferred onto an encrypted University of Oxford laptop and downloaded straight away into a protected folder on the H: drive (a secure university drive which only approved members of the research team have access to). Interview, focus group or any other recordings will be transcribed by a professional transcriber under a non-disclosure confidentiality agreement and destroyed after the transcripts have been checked for accuracy. Quotes used in publications will not include any identifiable details. Any video clips, stills and associated transcripts from group consultations used in presentations and publications to illustrate findings will be in pseudonymised or in pixelated format (using video editing software such as Adobe Premiere Pro CC, Adobe Inc). We will apply a visual filter (see figure 1) and remove any names and mask voices from the audio track. Research data will be stored for 15 years after the end of data collection.

Any recordings made using Microsoft Teams by clinicians will be transferred to the research team using FILR, a secure cloud-based service with files managed and stored on secure University of Oxford MSDIT Services' fileservers. We will provide clinicians with a secure link where they can upload the recording. The servers are located in the UK and comply with relevant regulations. The use of FILR has been approved by The University of Oxford Information Security. We will also use FILR and encrypted hard drives to share data with any members of the research team or other approved collaborators who will need to work outside the University network.

Data will be stored and managed according to the University of Oxford data management and security policies. All investigators, research staff, and steering group members will comply with the requirements of the Data Protection Act 2018 and UK General Data Protection Regulation (UK GDPR) with regards to the collection, storage, processing and disclosure of data including any personal information. The Principal Investigators are the data custodians. University of Oxford is the data controller.

12. QUALITY ASSURANCE PROCEDURES

The study may be monitored, or audited in accordance with the current approved protocol, GCP, relevant regulations and standard operating procedures. A steering committee will oversee the study.

12.1. Risk assessment

A risk assessment and monitoring plan will be prepared before the study opens and will be reviewed as necessary over the course of the study to reflect significant changes to the protocol or outcomes of monitoring activities.

12.2. Study monitoring

No GCP monitoring will be undertaken for this non-interventional study.

12.3. Study Committees

The study is overseen by a steering committee as appropriate for this type of research and in accordance to the quality assurance procedures outlined above.

13. PROTOCOL DEVIATIONS

A study related deviation is a departure from the ethically approved study protocol or other study document or process (e.g. consent process or administration of study intervention) or from Good Clinical Practice (GCP) or any applicable regulatory requirements. Any deviations from the protocol will be documented in a protocol deviation form and filed in the study master file.

14. SERIOUS BREACHES

A "serious breach" is a breach of the protocol or of the conditions or principles of Good Clinical Practice which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the trial subjects; or

(b) the scientific value of the research.

In the event that a serious breach is suspected the Sponsor must be contacted within 1 working day. In collaboration with the C.I., the serious breach will be reviewed by the Sponsor and, if appropriate, the Sponsor will report it to the approving REC committee and the relevant NHS host organisation within seven calendar days.

15. ETHICAL AND REGULATORY CONSIDERATIONS

15.1. Declaration of Helsinki

The Investigator will ensure that this study is conducted in accordance with the principles of the Declaration of Helsinki. NB. The 2008 Declaration of Helsinki provides detail on what must be included in a protocol: funding, sponsorship, affiliations and potential conflicts of interest, incentives to participate and compensation for harm.

15.2. Guidelines for Good Clinical Practice

The Investigator will ensure that this study is conducted in accordance with relevant regulations and with Good Clinical Practice.

15.3. Approvals

Following Sponsor approval the protocol, informed consent form, participant information sheet and any proposed advertising material will be submitted to an appropriate Research Ethics Committee (REC), and HRA (where required) and host institutions for written approval.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

15.4. Other Ethical Considerations

Depending on the patient population of the GP practices to be recruited we may involve interpreters to support qualitative data collection and translate study materials in languages other than English.

15.5. Reporting

The CI shall submit once a year throughout the study, or on request, an Annual Progress report to the REC Committee, HRA (where required) host organisation, Sponsor and funder (where required). In addition, an End of Study notification and final report will be submitted to the same parties.

15.6. Transparency in Research

Details of the study will be available on HRA Research Summaries https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/ and NIHR database.

15.7. Participant Confidentiality

The study will comply with the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

15.8. Expenses and Benefits

Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate.

GP practices will be offered compensation (£1500 for case study and £500 for control sites, given different data collection burden).

16. FINANCE AND INSURANCE

16.1. Funding

The study is funded by the National Institute for Health Research, Health Services and Delivery Research (HSDR) programme. A small amount of add-on funding has been awarded by the National Institute for Health Research School for Primary Care Research.

16.2. Insurance

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity will apply in respect of the clinical care provided.

16.3. Contractual arrangements

Appropriate contractual arrangements will be put in place with all third parties.

17. PUBLICATION POLICY

The Investigators will be involved in reviewing drafts of the manuscripts, abstracts, press releases and any other publications arising from the study. Authors will acknowledge that the study was funded by the National Institute of Health Research. Authorship will be determined in accordance with the ICMJE guidelines and other contributors will be acknowledged.

19. DEVELOPMENT OF A NEW PRODUCT/ PROCESS OR THE GENERATION OF INTELLECTUAL PROPERTY

Not applicable.

18. ARCHIVING

Research data (without identifiable details) will be stored for at least 3 years after the end of data collection. Consent forms will be kept in secure storage or encrypted drives at the University of Oxford.

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20. APPENDIX A: FLOW CHART

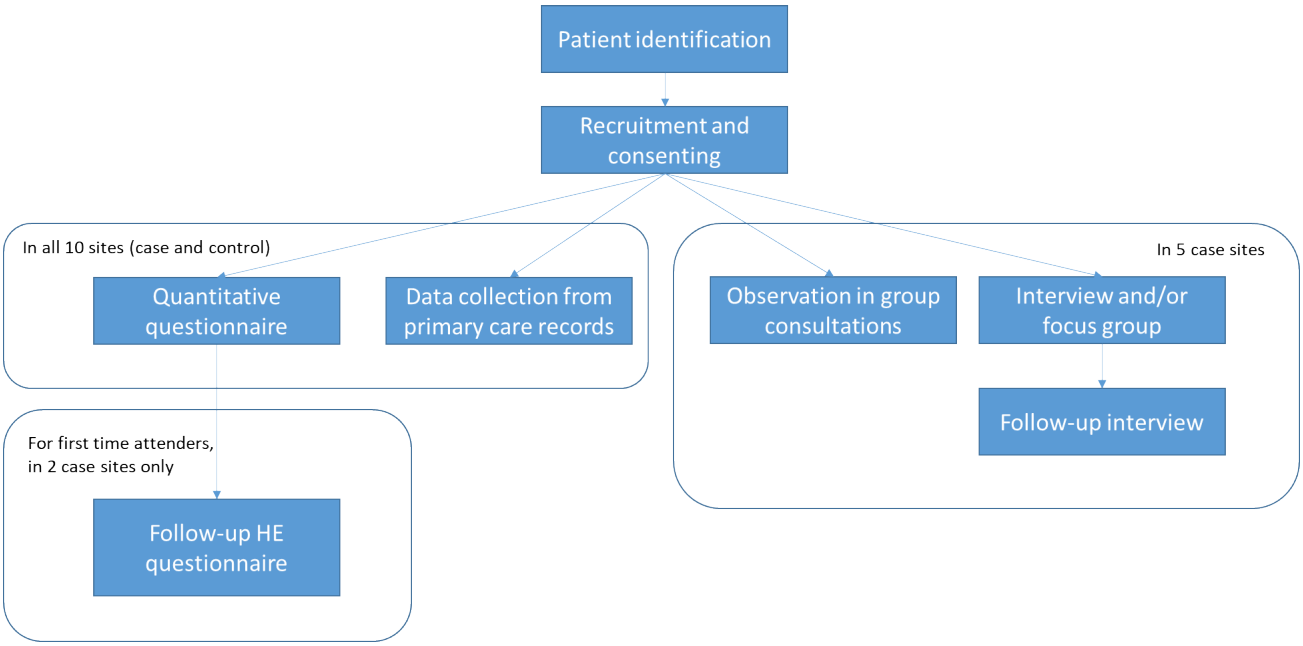

Figure 1: Flow chart illustrating patient participation in the study (patients can participate in one or more of these activities depending on their preferences)

21. APPENDIX B: AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
1	1.2	21/07/2022	Gary Abel, Chrysanthi Papoutsi	Added access to and analysis of secondary care data, inclusion of paper copies as a mode of data collection of patient surveys, and provision for recruitment of participants in the qualitative arm through contact details provided in the quantitative arm.

2	1.3	30/11/2022	Chrysanthi Papoutsi	Added multimodal data collection, option for GP practices to communicate with potential participants by text message,
3	1.4	11/5/2023	Stuart Faulkner	Change of CI, addition of study sites, and changes to study documentation to reflect change of PI
4	1.5	17/7/2023	Stuart Faulkner	9 month no-cost extension to end date, and inclusion of details about a measurement of health benefits survey (case and control sites).
5	1.6	01/04/2024	Stuart faulkner	Change of PI and change in study documentation to reflect this, addition of new study site, modification of protocol to reflect changes in some data collection.

6	1.7	1/10/2024	Chrysanthi Papoutsi	Change in study end date until May 31st 2025