

# BMJ Open

BMJ Open is committed to open peer review. As part of this commitment we make the peer review history of every article we publish publicly available.

When an article is published we post the peer reviewers' comments and the authors' responses online. We also post the versions of the paper that were used during peer review. These are the versions that the peer review comments apply to.

The versions of the paper that follow are the versions that were submitted during the peer review process. They are not the versions of record or the final published versions. They should not be cited or distributed as the published version of this manuscript.

BMJ Open is an open access journal and the full, final, typeset and author-corrected version of record of the manuscript is available on our site with no access controls, subscription charges or pay-per-view fees (<http://bmjopen.bmj.com>).

If you have any questions on BMJ Open's open peer review process please email [info.bmjopen@bmj.com](mailto:info.bmjopen@bmj.com)

# BMJ Open

**Protocol for a qualitative study to explore acceptability, barriers, and facilitators of the implementation of new teleophthalmology technologies between community optometry practices and hospital eye services**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-060810
Article Type:	Protocol
Date Submitted by the Author:	05-Jan-2022
Complete List of Authors:	Blandford, Ann; University College London, UCL Interaction Centre Abdi, Sarah; University College London, UCL Interaction Centre Aristidou, Angela; University College London, School of Management Carmichael, Josie; University College London, UCL Interaction Centre; Moorfields Eye Hospital NHS Foundation Trust Cappellaro, Giulia; University College London, School of Management; Bocconi University, Department of Social and Political Sciences Hussain, Rima; Moorfields Eye Hospital NHS Foundation Trust, NIHR Biomedical Research Centre; UCL, Institute of Ophthalmology Balaskas, Konstantinos; Moorfields Eye Hospital NHS Foundation Trust
Keywords:	OPHTHALMOLOGY, Medical retina < OPHTHALMOLOGY, PRIMARY CARE

SCHOLARONE™  
Manuscripts

# HCI study protocol manuscript

## TITLE

**Protocol for a qualitative study to explore acceptability, barriers and facilitators of the implementation of new teleophthalmology technologies between community optometry practices and hospital eye services**

## Authors

**Ann Blandford<sup>1</sup>, Sarah Abdi<sup>1</sup>, Angela Aristidou<sup>2</sup>, Josie Carmichael<sup>1,3</sup>, Giulia Cappellaro<sup>2,4</sup>, Rima Hussain<sup>3</sup> and Konstantinos Balaskas<sup>1,3</sup>**

## Affiliations

<sup>1</sup>UCL Interaction Centre (UCLIC), University College London (UCL), WC1E 6EA, London, United Kingdom

<sup>2</sup>School of Management, University College London (UCL), E14 5AA, London, United Kingdom

<sup>3</sup>Moorfields Eye Hospital, City Road, EC1V 2PD, London, United Kingdom

<sup>4</sup>Bocconi University, Department of Social and Political Sciences, Milan, Italy

## Corresponding author

Ann Blandford, [a.blandford@ucl.ac.uk](mailto:a.blandford@ucl.ac.uk)

**Word count (excluding title page, abstract and references): 4730**

## ABSTRACT

**Introduction** Novel teleophthalmology technologies have the potential to reduce unnecessary and inaccurate referrals between community optometry practices and hospital eye services and as a result improve patients' access to appropriate and timely eye care. However, little is known on the acceptability and facilitators and barriers of the implementations of these technologies in real-life.

**Methods and analysis** A theoretically informed, qualitative study will explore patients' and healthcare professionals' perspectives on teleophthalmology and Artificial Intelligence Decision Support System (AI DSS) models of care. A combination of situated observations in community optometry practices and hospital eye services, semi-structured qualitative interviews with patients and healthcare professionals and self-audio recordings of healthcare professionals will be conducted. Participants will be purposively selected from 4-5 hospital eye services and 6-8 affiliated community optometry practices. The aim will be to recruit 30-36 patients and 30 healthcare professionals from hospital eye services and community

1  
2  
3 optometry practices. All interviews will be audio-recorded, with participants' permission, and  
4 transcribed verbatim. Data from interviews, observations and self-audio recordings will be  
5 analysed thematically and will be informed by Normalisation Process Theory (NPT) and an  
6 inductive approach.  
7  
8  
9

10 **Ethics and dissemination** Ethical approval has been received from London-Bromley  
11 research ethics committee. Findings will be reported through academic journals and  
12 conferences in ophthalmology, health services research, management studies and human-  
13 computer interaction (HCI).  
14  
15  
16

### 17 18 19 **Key words**

20 Teleophthalmology, Artificial Intelligence, primary eye care, optometrists, ophthalmologists,  
21 retinal disease, human-computer interaction, Normalization Process Theory (NPT), clinical  
22 referral.  
23  
24  
25  
26

### 27 28 **STRENGTH AND LIMITATIONS OF THIS STUDY**

- 29 • This study forms part of a large multi-center study (The HERMES study) that will  
30 collectively provide real-world evidence on the implementation of novel  
31 teleophthalmology technologies.  
32
- 33 • A key strength of this study is analysing the facilitators and barriers of the  
34 implementation of novel teleophthalmology technologies from the perspectives of  
35 multiple stakeholders including patients and primary and secondary eye care  
36 professionals.  
37
- 38 • Another strength of this study is using multiple methods (observations, interviews,  
39 self-audio recording) to collect data from multiple hospital eye services and affiliated  
40 community optometry practices in England.  
41
- 42 • One limitation of this study is that most interviews will be conducted via video  
43 conferencing or telephone, limiting the researcher's ability to build rapport with the  
44 interviewees.  
45  
46  
47  
48  
49  
50  
51  
52

### 53 54 **INTRODUCTION**

55 Ophthalmology is one of the busiest outpatient clinics in England, accounting for 8% of all  
56 hospital outpatients' attendances [1]. Most hospital eye services (HES) referrals originate  
57 from community optometrists (CO) in high street optician practices, who are the main  
58  
59  
60

1  
2  
3 providers of primary eye care in the UK [2]. Retinal disorders (e.g., macular pathologies,  
4 retinal vascular pathologies and suspect retinal tears/detachments) are the most referred  
5 conditions [3]. The growing use of optical coherence tomography technology (OCT) in  
6 community optometry practices is believed to have contributed to the increase in retinal  
7 referrals to hospitals [4,5]. OCT is a non-invasive scanning technology that generates high-  
8 resolution, three-dimensional images of the retina [6]. OCT has transformed ophthalmology  
9 practice in the last decade, leading to better detection and understanding of common retinal  
10 conditions such as age-related macular degeneration (AMD) [6]. However, the success of this  
11 technology in improving retinal care for patients may have been limited by the referral  
12 process between CO and HES. Unnecessary and inaccurate referrals, re-referrals from CO,  
13 and deficits in replies from HES are common issues in the referral process, increasing the  
14 burden on secondary care and, consequently, delaying access to timely eye care for patients  
15 who need it [2,3]. Therefore, there is an urgent need to explore potential solutions to improve  
16 the referral process and manage patient flow between CO and HES.

17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
Teleophthalmology has emerged as a viable alternative to delivering eye care that may  
improve patients' access to timely and appropriate care [7-9]. Teleophthalmology is a means  
to provide ophthalmic care at a distance using information and communication technology [8,  
10]. A variety of eye care delivery models have been reported to benefit from  
teleophthalmology. For example, Caffrey et al. [8] identified 62 discrete models of care that  
can be improved by teleophthalmology, including eye screening, patients' consultations,  
emergency services, supervision of procedures, staff training, and remote supervision. In the  
referral process, teleophthalmology services typically involve primary healthcare  
professionals (e.g., community-based optometrist) obtaining images (e.g., OCT, slit-lamp, or  
retinal imaging) and transmitting them via an electronic system to secondary care [8]. A  
secondary care ophthalmologist then reviews these images and decides on the management of  
the case, which might involve meeting the patient, remotely monitoring them, or continuing  
their management in primary care [8, 11]. Teleophthalmology can have several benefits in the  
context of triage. For example, in one scoping review, teleophthalmology was found to  
contribute to reducing face-to-face appointments with ophthalmologists by 16-48% through  
reducing inappropriate and unnecessary referrals [7]. Similarly, implementing remote retinal  
imaging-based referrals reduced the waiting time for patients to see an ophthalmologist from  
14 weeks to four weeks [7]. Teleophthalmology has been found to improve elderly patients'  
access to specialist eye care and reduce workload on specialist centres and unnecessary visits  
[10]. Patients also reported high levels of satisfaction with teleophthalmology services due to

1  
2  
3 reduced cost and time of travel, as well as increased accessibility to services [11].  
4  
5 Additionally, in recent years, advances in Artificial Intelligence (AI), particularly in deep  
6  
7 learning, hold great promise for expanding the use of teleophthalmology [12-15]. Deep  
8  
9 learning can improve referrals by identifying patients who are more likely to develop a  
10  
11 specific condition and require urgent care or frequent follow-ups, increasing patients' access  
12  
13 to appropriate eye care [12,14]. Several recent studies have demonstrated comparable  
14  
15 performances of deep learning algorithms to experts in diagnosing different eye conditions  
16  
17 [13, 16, 17]. For instance, in one study, a deep learning algorithm reached or exceeded  
18  
19 experts' performance in assessing urgent referrals from two independent sets of OCT scans  
20  
21 (n=997, n=116) for a range of retinal conditions [16]. Similarly, the accuracy of a deep  
22  
23 learning algorithm to assess AMD from fundus images has been found to range between  
24  
25 88.4% and 91.6% compared to human experts [17].

26  
27 However, despite these promising findings, triaging referrals via teleophthalmology has  
28  
29 been limited in practice. For example, during the COVID-19 pandemic, a period associated  
30  
31 with increased adoption of telehealth applications [18], primary care optometrists were less  
32  
33 willing to adopt teleophthalmology in the context of referrals [19]. Although the study did not  
34  
35 explore in depth reasons for this limited adoption, this finding is not surprising. Generally,  
36  
37 implementing digital health interventions in practice is acknowledged to be complex due to  
38  
39 the multiple components that should be considered during implementation [20-23]. These  
40  
41 include professionals' and patients' acceptance of the technology, staff training and  
42  
43 education, changes in staff roles and practices, the organisation culture, capacity and  
44  
45 readiness to accept innovations, and the wider context (e.g., policy and regulations) [21, 23].  
46  
47 The application of deep learning algorithms in ophthalmology referrals also brings with it a  
48  
49 new set of challenges. Deep learning algorithms are characterised by a lack of transparency  
50  
51 or explainability, sometimes referred to as the 'black box' phenomenon, which makes it  
52  
53 difficult for healthcare professionals and patients to understand how they reached their output  
54  
55 [13, 14, 16]. This raises the question of whether health professionals and patients would trust  
56  
57 the use of a 'black box' for referrals [16]. There are also risks related to data security and  
58  
59 privacy, as well as potential harm from false negative diagnosis that may impact the  
60  
61 implementation and acceptance of deep learning algorithms for clinical images classification  
62  
63 [13-15].

64  
65 Overall, recent evidence suggests that teleophthalmology and AI decision support tools  
66  
67 have the potential to improve the referral process between CO and HES. However, to

1  
2  
3 improve the uptake of these technologies in practice, it is important to identify the factors that  
4 facilitate or hinder their implementation.  
5  
6

## 7 **AIMS AND OBJECTIVES**

9 Previous research on facilitators and barriers of teleophthalmology implementation has  
10 mainly focused on diabetic retinopathy screening [24-26], with limited research focusing on  
11 facilitators and barriers in the referral process between CO and HES on other retinal  
12 conditions. Therefore, this study aims to assess patients' and healthcare professionals'  
13 acceptance of, and barriers and enablers for, the adoption of two innovative digital  
14 technologies supporting referral pathways between CO and HES. These are a  
15 teleophthalmology platform and the Moorfields-DeepMind Artificial Intelligence Decision  
16 Support System (DSS). A human-computer interaction (HCI) approach will be used in this  
17 study, to understand professionals' and patients' interactions with the proposed technological  
18 solutions as well as the contexts in which these technologies will be implemented. Five  
19 research objectives address the overall aim of this study:  
20  
21  
22  
23  
24  
25  
26  
27

- 28 1. To understand current workflows and practices of staff and patients in community  
29 optometry and HES so as to identify key user requirements for tele-ophthalmology  
30 tools from the perspectives of both groups.  
31  
32
- 33 2. To understand workflows and practices of staff and patients in community optometry  
34 practices and HES with already established tele-ophthalmology pathways to identify  
35 technical, logistical and human factors affecting implementation of tele-  
36 ophthalmology in practice.  
37  
38
- 39 3. To identify factors that shape professionals' and patients' attitudes to, and trust in, the  
40 Moorfields-DeepMind AI, and how to present information in ways that instil  
41 appropriate confidence.  
42  
43
- 44 4. To understand whether and how work practices are likely to change following the  
45 adoption of Moorfields-DeepMind AI.  
46  
47
- 48 5. To identify factors that ease the deployment of a digital referral platform to ensure  
49 acceptability and acceptance by all user groups, and to understand the adoption  
50 process.  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## METHODS AND ANALYSIS

### The HERMES study

The current protocol focuses on the detailed design of the qualitative element of the HERMES study. HERMES is an interventional superiority cluster randomised trial that aims to compare standard practice for referral of suspected retinal diseases with a teleophthalmology digital link between CO and HES. A prospective observational sub-study will also be conducted as part of HERMES that integrates the data of the trial to assess the diagnostic (referral) accuracy of an advanced AI DSS (the Moorfields-DeepMind algorithm) for the automated referral recommendation for retinal disease. Detailed methods of the HERMES study are described elsewhere [27]. The qualitative research element presented in this paper will run across both studies to provide evidence on implementation.

### Study design and setting

A theoretically informed, qualitative study will be performed to explore patients' and healthcare professionals' perspectives on teleophthalmology models of care and AI Decision Support System (AI DSS). A combination of situated observations in clinical settings, semi-structured qualitative interviews with patients and healthcare professionals and self-audio recording of healthcare professionals will be conducted. This approach will enable us to understand the contexts in which the two new technologies will be implemented, focusing on understanding workflows, practices, and user requirements, as well as identifying potential barriers and facilitators to implementation. It will also enable us to gain an in-depth understanding of staff and patients' expectations and experiences with the implementation of the new technologies. The study will be conducted at 4-5 hospital eye services and 6-8 affiliated optometry community practices. Data collection is planned to start in November 2021 and end in May 2022.

### Participant selection

#### Sampling

Purposive sampling will be applied to recruit participants who are representative of relevant patient and professional groups. This type of sampling is used to select participants who are most likely to produce valuable data [28]. Patient participants will be selected if they meet the following criteria:

- Able to communicate in English, understand the study, and give informed consent.



- Adults ( $\geq 18$  years) attending the involved community optometry practices who underwent an OCT scan.
- Individuals who in the opinion of the community optometrist have any suspicion of a retinal condition (including dry AMD, wet AMD, diabetic retinopathy, macular oedema, macular holes, epiretinal membranes, central serous chorio-retinopathy, genetic eye disease).

Patients with known retinal co-morbidities in either eye triggering the referral or those with conditions that prevent acquisition of good quality OCT scan will be excluded.

Professional participants will include community optometrists and clinicians (medics or specialist optometrists) with a minimum of two years' experience of independent practice in retinal clinics in hospital eye services. Some of the participants' characteristics (e.g., their level of experience) will be monitored during recruitment to ensure that diverse views are included in the sample.

Participants will be recruited from three settings: 1) community optometry clinics in the control arm (pre-transitioning to teleophthalmology); 2) community optometry clinics in the intervention arm (post-transitioning to teleophthalmology); and 3) hospital eye services. These settings will help us understand and compare experiences and work practices before and after implementing the new teleophthalmology technologies, as well as identifying barriers and facilitators during their implementation. A total of 4-5 hospital eye services and 6-8 community optometry practices (3-4 practices from the control arm and 3-4 practices from the intervention arm) will be included in the study.

For the observations, it is expected that valuable insight will be obtained from observing a total of 10-15 clinician-patient consultations (3-5 consultations in each setting).

For the interviews, the aim is to interview a total of 30-36 patients from 6-8 CO practices (5-6 patients from each participating CO) and up to 30 healthcare professionals (up to 10 in each setting, noting that many of the participating CO practices employ fewer than 5 optometrists). Data saturation, that is, no new information emerges from the sampled units, will also guide sample size [29, 30].

For the self-audio recording, the aim is to collect self-audio recordings of referral decisions of participating healthcare professionals in CO and HES.

## Methods of approach

### *Observations*

The observations will focus on understanding general clinical practices and work routines. Thus, the observations might involve patients, but not specifically those with suspected retinal diseases. Managers of community optometry practices and secondary eye clinics will be approached to gain permission to conduct observations in their practices.

### *Interviews*

Two sets of interviews will be conducted.

A first set of interviews will focus on individuals with suspected retinal disease. Only patients who undergo an OCT and, in the opinion of the community optometrist, have any suspicion of a retinal condition will be invited to participate in an interview. Potential patient participants will be invited to participate following their consultation at a participating CO practice. The optometrist will explain the study to potential participants, highlighting its purpose, possible advantages and disadvantages, and what it entails. Potential participants will be given sufficient time to think about their participation and ask questions about the study. The researcher will call potential participants to obtain their decision to participate and book a provisional interview date for those who agree to participate. Interviews will be conducted at the optometry practice where the participant was recruited, or via telephone or video conferencing.

A second set of interviews will focus on professional participants at the hospital eye service and the community optometry practices, who will be invited to participate in interviews by the researcher. Interviews with professional participants will be conducted via video conferencing, or at the hospital or practice.

### *Self-audio recording*

During the initial interview with healthcare professionals at the community optometry practices and the HES, participants will be invited to participate in the self-audio recording data collection exercise described below.

## **Data collection and analysis**

### Theoretical approach

Most digital health interventions can be viewed as complex interventions as they include multiple components that interact at both individual and organisational levels [20, 22, 31].

1  
2  
3 The explicit use of a theoretical lens when evaluating the implementation of these  
4 interventions can enhance our understanding of factors that may influence their success or  
5 failure [32, 33]. In this study, Normalisation Process Theory (NPT) will be used as a  
6 theoretical lens in gathering and analysing the data. NPT is concerned with understanding  
7 and explaining factors that may facilitate or inhibit the incorporation of complex  
8 interventions into routine practice [34, 35]. NPT focuses on understanding the work that  
9 individuals and groups need to do for a complex intervention to become 'normalised' and  
10 embedded in practice, particularly in a healthcare context [35-38]. Thus, a starting point of  
11 this theory is understanding current practices, i.e., how people work and what they actually  
12 do [36]. NPT comprises four components that determine the normalisation of a complex  
13 intervention in practice [35, 36]. These are: 1) coherence, which refers to participants'  
14 understanding of new technology and practices associated with it; 2) cognitive participation,  
15 which refers to the preparedness of participants to engage and use the technology; 3)  
16 collective action, which refers to the work that participants do to use the technology; and 4)  
17 reflective monitoring, which refers to participants' appraisal of the new technology [22, 35,  
18 38]. There is evidence for the stability and consistency of NPT constructs across various  
19 contexts, advocating their use to assess, describe or improve the implementation potential of  
20 complex interventions [35, 37, 39]. NPT has also been used to explore users', including  
21 patients and healthcare professionals, expectations of digital health interventions as well as  
22 barriers and facilitators of engaging with these interventions [33, 38, 40, 41], although limited  
23 evidence is available on teleophthalmology and AI DSS. In this study, it is envisaged that the  
24 use of NPT will help better understand the implementation process of these two technologies  
25 in routine practice and identify factors that may contribute to a successful implementation.  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44

## 45 Design of observations, interviews and self-audio recordings

### 46 *Observations*

47  
48 The aim of the observations is to gain a familiarity with the contexts in which the two  
49 innovative technologies will be implemented, and to establish an understanding of current  
50 practices and work routines. This is an important step given that understanding what people  
51 do and how they work in real life is a core focus for NPT. Observations will be conducted in  
52 all settings (optometry practices and hospital eye services), focusing on clinician-patient  
53 interactions around the diagnostic and referral process. Specifically, the researcher will take  
54 field notes on the workflow, how referral decisions are made and communicated to patient,  
55  
56  
57  
58  
59  
60

1  
2  
3 the clinician interaction with the new teleophthalmology platform, and any facilitators or  
4 barriers experienced during the interaction. To facilitate capturing this data, the flow and  
5 sequence work models from Contextual Design will be used [42]. The flow model describes  
6 communication and coordination patterns that are important to accomplish the work, while  
7 the sequence model represents the detailed steps that people do to accomplish the tasks and  
8 the problems that they may encounter whilst doing them [42]. Detailed work model diagrams  
9 will be kept of all observations conducted in CO and HES.  
10  
11  
12  
13  
14  
15  
16

### 17 *Interviews*

18 The aim of the interviews is to gain an in-depth understanding of the expectations,  
19 perceptions, and experiences of patients and health professionals with the new technologies.  
20 All interviews will be semi-structured, allowing us to address the study aim, informed by  
21 NPT, while also following up on new insights as they emerge [43]. All professional  
22 participants will be interviewed once, with the option of participating in two further short  
23 interviews. The purpose of these additional interviews is to gain professionals' reflections on  
24 their propensity to adopt AI tools and to change their work practices following AI adoption.  
25 Two approaches will be used to conduct the semi-structured interviews with healthcare  
26 professionals: contextual inquiry interviews and critical incident technique.  
27  
28  
29  
30  
31  
32  
33  
34  
35

36 Contextual inquiry is a method commonly used in the HCI field to gain a deep understanding  
37 of users' work practices [42, 44]. It is based on the premise that users are tacitly aware of  
38 their own work practices as they are immersed in their everyday activities [42]. To  
39 understand their actions and reveal their motivations, intents, and strategies, it is important to  
40 observe and speak to them in the context in which they perform their day-to-day activities  
41 [42]. In other words, contextual inquiry involves conducting observations and following them  
42 up with questions to understand the work at hand [43]. In this study, contextual inquiry with  
43 healthcare professionals will complement the observations made in hospital eye services and  
44 optometry practices.  
45  
46  
47  
48  
49  
50  
51  
52

53 Critical decision method (CDM), originated from the critical incident technique, is a  
54 cognitive task analysis approach used to elicit expert knowledge [45]. The CDM focuses on a  
55 retrospective analysis of critical incidents experienced by the interviewees [46]. In the  
56 context of HCI studies, critical incidents can include events when the technology failed or the  
57 system experienced particular demands [43]. The CDM uses a set of techniques to minimise  
58  
59  
60

1  
2  
3 recall biases and aid the interviewees to recall critical decisions as accurately as possible [46].  
4 For example, the technique involves probing the interviewee to identify and describe a  
5 specific critical incident or incidents from beginning to end [45]. The researcher then  
6 composes a decision timeline and employs probe questions which allow the interviewee to  
7 provide corrections or more details [45]. The interviewee is also asked “what-if?” questions  
8 to understand what might have happened differently. In this study, critical incident interviews  
9 will be conducted with healthcare professional participants in the intervention arm, to gain a  
10 deep understanding of their perceptions and experiences with the teleophthalmology platform  
11 as well as explore barriers to its implementation in practice (e.g., when the platform failed  
12 and reasons for that).  
13  
14  
15  
16  
17  
18  
19  
20  
21

22 A semi-structured topic guide will be used in all interviews and will include questions related  
23 to the research topic and NPT. The topic guide will be tailored to each group (patients and  
24 healthcare professionals in the intervention and control arms) as well as to suit the approach  
25 employed (contextual inquiry and CDM). The interview procedure will follow the 5 steps to  
26 conduct HCI semi-structured interviews [43]. Step 1 (opening the conversation) aims to put  
27 participants at ease and assure them they have the desired knowledge and expertise. Step 2  
28 (introducing the research) aims to introduce the topic and ensure that participants are aware  
29 of the purpose, reaffirming their confidentiality and right to withdrawal, and requesting  
30 permission to record the interview. Step 3 (beginning the interview) aims to gain contextual  
31 information about the participant, such as their role, technology use and prior experience,  
32 which may help formulate the subsequent questions. Step 4 (during the interview) aims to  
33 gain in-depth information about the topic under investigation. NPT components (coherence,  
34 cognitive participation, collective action and reflective monitoring) will inform the questions  
35 in this step. Questions about coherence will focus on participants’ expectations from a digital  
36 referral system, as well as its perceived benefits and barriers. Questions based on cognitive  
37 participation will explore participants’ engagement with the new technologies and the issues  
38 they may face when using the technologies. Questions about collective action will focus on  
39 participants’ views on the impact of the new technologies on eye care and practice, as well as  
40 the changes that may be required to integrate these technologies in routine practices.  
41 Questions based on reflective monitoring will explore participants’ perspectives on how these  
42 technologies should be implemented in the future. For the AI DSS, issues around the ‘black  
43 box’ phenomenon, as well as the optimal place in the care pathway, confidence and trust will  
44 be investigated. Probes such as anonymised screenshots from the digital referral platform and  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 illustrative prototypes from the DeepMind algorithm will be used to support the exploration  
4 of the themes. Step 5 (closing the interview) will include ending the interview, providing the  
5 participant with an opportunity to express more thoughts, and thanking them for their  
6 contribution to the study and the design of the technology. All interviews will be audio-  
7 recorded, with participants' permission, and transcribed verbatim.  
8  
9  
10  
11  
12

### 13 *Self-audio recording*

14  
15 Self-audio recording is a method with demonstrated scientific value for examining the  
16 decision processes of professionals [47]. The aim of the self-audio recordings is to study  
17 whether and how exposure to the Moorfields-DeepMind AI referral decision changes the  
18 work practices of professionals in community optometry and HES.  
19  
20  
21

22 Participants will be invited to record themselves (self-audio record) talking out loud about  
23 referral decisions. Self-audio recordings will take place when healthcare professionals are  
24 alone (i.e. after the patient has exited the room and without a researcher in the room).  
25  
26

27 Following their self-recording, some healthcare professionals will be informed of the referral  
28 decision that the Moorfields-DeepMind AI Decision Support System (DSS) would make for  
29 the same patient, while others will not have this information. Participants will not be aware of  
30 which group they belong to when they first sign up for the study. Those healthcare  
31 professionals informed of the AI DSS referral decision will be further invited to record  
32 themselves talking out loud about the AI DSS referral decision and how it relates to the  
33 original human referral decision. The self-audio recordings are not used to make an  
34 assessment of the referral but to understand how professionals make decisions as an expert.  
35  
36  
37  
38  
39  
40  
41  
42

### 43 *Data analysis*

44  
45 Data gathering and analysis will be interleaved so that later data gathering is informed by  
46 findings from earlier analysis. A combination of inductive and deductive thematic analysis  
47 will be used to analyse data from the interviews, observations and self-audio recordings,  
48 following Braun's and Clarke's guidance on conducting a thematic analysis [48]. The  
49 analysis will start with familiarising oneself with the data early on by listening to audiotapes,  
50 reading transcripts and field notes. An open approach will be followed at the start of the  
51 coding, where data from the first few transcripts and field notes will be open-coded line-by-  
52 line, enabling interesting codes and insights to emerge from the data. Analysis will then be  
53 done deductively where codes will be informed by the research questions. In one analytical  
54  
55  
56  
57  
58  
59  
60

1  
2  
3 direction, codes will be informed by the NPT constructs (coherence, cognitive participation,  
4 collective action, and reflective monitoring). In this direction, coding of the transcripts will  
5 be conducted independently by two researchers (SA & JC) with different backgrounds  
6 (ophthalmology, and digital health). SA & JC will meet regularly to discuss the codes and  
7 will resolve any disagreement by discussion. In a related analytical direction, coding will be  
8 conducted in a 'semi-grounded theory' way [49], whereby the researchers adopt established  
9 professional learning and development constructs in the coding process while still allowing  
10 for a change in the direction of enquiry during the analysis of the data. In this analytical  
11 direction, coding of transcripts will be conducted by two researchers (GC and AA) who will  
12 regularly discuss emerging insights with the broader research team. The coding scheme from  
13 interviews will inform the coding of self-recordings, for which we identify emerging themes  
14 and their evolution over time (per individual participant and per theme). Across both  
15 analytical directions, codes will be reviewed for similarities, differences and relationships and  
16 will be categorised into preliminary themes. These themes will be reviewed against the codes  
17 and coded text and will be organised into final themes. The wider research team will meet  
18 regularly to discuss the analysis, the preliminary and final themes. NVivo 20 software will be  
19 used to manage data analysis.  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33

### 34 **Patient and public involvement**

35  
36 Eighteen patients were consulted during the preparation phase of the HERMES study. The  
37 consultation focused on patients' general perceptions of teleophthalmology, trust in  
38 technology and potential concerns about impersonal care or reduced opportunities to interact  
39 with healthcare professionals. Patients' perceptions of the central concept of the project was  
40 positive and patients recognised the potential benefits of teleophthalmology such as reducing  
41 waiting times and unnecessary visits to hospital. Several patients also emphasized the  
42 importance of providing information during attendance at community optometry practices  
43 around the pathways, the experience to be expected during their visit and timescale for  
44 obtaining feedback. Generally, patients' inputs reinforced the importance of introducing a  
45 comprehensive qualitative element to the study to capture patients' perceptions around digital  
46 models of eye care.  
47  
48  
49  
50  
51  
52  
53

54  
55 Additionally, the study is overseen by a steering committee including representatives of  
56 patients group. The steering committee will meet at least once a year with provision for  
57 additional meetings when input is required for potential protocol amendments or issues  
58  
59  
60

1  
2  
3 arising during the study. An end of study debrief is planned with all PPI contributors which  
4 will include discussions on the prioritization and dissemination of study results to both the  
5 public and relevant healthcare professionals.  
6  
7

## 8 9 **Ethics and dissemination**

10  
11 Health Research Authority (HRA) and Health and Care Research Wales (HCRW) ethical  
12 approvals have been obtained from London-Bromley Research Ethics Committee (Rec ref  
13 number: 20/LO/1299). Participant information sheets will be provided to all potential  
14 participants. Written or audio/video recorded informed consent will be obtained from all  
15 participants before they participate in the study. All interviews will be conducted at a time  
16 and place convenient to participants. Participants will be reminded of their rights to  
17 withdrawal from the study without there being negative consequences on their work or the  
18 care they receive.  
19

20  
21 All data will be handled following the General Data Protection Regulations (GDPR), UK  
22 data protection act 2018 and the Research Governance Framework for Health and Social  
23 Care. Participants' anonymity and confidentiality will be maintained during the study.  
24  
25 Written informed consent forms will be stored in a locked cabinet in the principal  
26 researcher's office. Interviews will be conducted using encrypted audio recorders and  
27 recordings will be removed from the portable device permanently as soon as they are  
28 transferred to an access-restricted folder on the University home drive. People transcribing  
29 the interviews will be subject to a nondisclosure agreement. Field notes and interview  
30 transcripts will be pseudonymised, which means that any personal information will be  
31 removed from the data before the analysis, and participants will only be identifiable using a  
32 study identification number. Pseudonymised data and the study identification log will be  
33 stored in two separate access-restricted folders on the University's home drive. Access to  
34 data will be restricted to the research team only.  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47

48 Findings will be reported through academic journals and conferences in ophthalmology, health  
49 services research, management studies and human-computer interaction (HCI).  
50  
51

## 52 53 **CONTRIBUTORS**

54 AB and SA designed the study protocol. AA and KB contributed to the study design. SA  
55 prepared the first draft of the manuscript. AB, AA, JC, GC, RH and KB reviewed and  
56 contributed to subsequent drafts. All authors reviewed and approved the final draft of the  
57 manuscript.  
58  
59  
60



## FUNDING STATEMENT

This work is supported by NIHR Health Technology Assessment grant number 18/182. AA is funded through the UKRI Future Leaders Fellowship research grant MR/S033009/1.

## COMPETING INTERESTS

The authors declare no conflict of interest.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study will be available from the corresponding author [AB], upon reasonable request.

## REFERENCES

1. The Royal College of Ophthalmologists. Ophthalmic Services Guidance Primary Eye Care, Community Ophthalmology and General Ophthalmology. *The Royal College of Ophthalmologists* 2019 <https://www.college-optometrists.org/uploads/assets/370d9ca9-6c9a-4518-a6bc1903556642c4/Ophthalmic-Services-Guidance-Primary-Eye-Care-Community-Ophthalmology-and-General-Ophthalmology.pdf> (accessed 7<sup>th</sup> September 2021)
2. Evans BJ, Edgar DF, Jessa Z, et al. Referrals from community optometrists to the hospital eye service in England. *Ophthalmic Physiol Opt* 2021;41(2):365-77
3. Konstantakopoulou E, Harper RA, Edgar DF, et al. Clinical safety of a minor eye conditions scheme in England delivered by community optometrists. *BMJ Open Ophthalmol* 2018;3(1):e000125.
4. Lee JX, Manjunath V, Talks SJ. Expanding the role of medical retina virtual clinics using multimodal ultra-widefield and optical coherence tomography imaging. *Clinical Ophthalmology* 2018;12:2337.
5. Kern C, Fu DJ, Kortuem K, et al. Implementation of a cloud-based referral platform in ophthalmology: making telemedicine services a reality in eye care. *Br J Ophthalmol* 2020;104(3):312-7.
6. Adhi M, Duker JS. Optical coherence tomography—current and future applications. *Curr Opin Ophthalmol* 2013;24(3):213.
7. Caffery LJ, Farjian M, Smith AC. Telehealth interventions for reducing waiting lists and waiting times for specialist outpatient services: A scoping review. *J Telemed Telecare* 2016;22(8):504-12.
8. Caffery LJ, Taylor M, Gole G, et al. Models of care in tele-ophthalmology: a scoping review. *J Telemed Telecare* 2019;25(2):106-22.
9. Sommer AC, Blumenthal EZ. Telemedicine in ophthalmology in view of the emerging COVID-19 outbreak. *Graefe's Archive for Clinical and Experimental Ophthalmology* 2020;1-2.
10. Fatehi F, Jahedi F, Tay-Kearney ML, et al. Teleophthalmology for the elderly population: A review of the literature. *Int J Med Inform* 2020;136:104089.
11. Sreelatha OK, Ramesh SV. Teleophthalmology: improving patient outcomes?. *Clinical Ophthalmology* 2016;10:285.
12. Wong TY, Bressler NM. Artificial intelligence with deep learning technology looks into diabetic retinopathy screening. *Jama* 2016;316(22):2366-7

- 1  
2  
3  
4 13. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. *Nature*  
5 *medicine* 2019;25(1):44-56.  
6  
7 14. Gunasekeran DV, Wong TY. Artificial Intelligence in Ophthalmology in 2020: A Technology on the Cusp  
8 for Translation and Implementation. *Asia Pac J Ophthalmol* 2020;9(2):61–6.  
9  
10 15. Korot E, Wood E, Weiner A, et al. A renaissance of teleophthalmology through artificial intelligence. *Eye*  
11 2019;33, 861–863 (2019)  
12  
13 16. De Fauw J, Ledsam JR, Romera-Paredes B, et al. Clinically applicable deep learning for diagnosis and  
14 referral in retinal disease. *Nature medicine* 2018;24(9), pp.1342-1350.  
15  
16 17. Burlina PM, Joshi N, Pekala M, et al. Automated grading of age-related macular degeneration from color  
17 fundus images using deep convolutional neural networks. *JAMA Ophthalmol* 2017;135(11):1170-6.  
18  
19 18. Blandford A, Wesson J, Amalberti R, et al. Opportunities and challenges for telehealth within, and beyond, a  
20 pandemic. *Lancet Glob Health* 2020;8(11):e1364-5..  
21  
22 19. Nagra M, Allen PM, Norgett Y, et al. The effect of the COVID-19 pandemic on working practices of UK  
23 primary care optometrists. *Ophthalmic Physiol Opt* 2021;41(2):378-92  
24  
25 20. Murray E, Hekler EB, Andersson G, et al. Evaluating digital health interventions: key questions and  
26 approaches. *Am J Prev Med* 2016;51(5):843-851.  
27  
28 21. Greenhalgh T, Wherton J, Papoutsi C, et al. Beyond adoption: a new framework for theorizing and  
29 evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and  
30 care technologies. *JMIR* 2017;19(11):e367.  
31  
32 22. Ong BN, Hodgson D, Small N, et al. Implementing a digital patient feedback system: an analysis using  
33 normalisation process theory. *BMC Health Serv Res* 2020 Dec;20(1):1-6.  
34  
35 23. Chambers D, Cantrell A, Booth A. Rapid evidence review: challenges to implementing digital and data-  
36 driven technologies in health and social care. *The University of Sheffield* 2021  
37 <https://eprints.whiterose.ac.uk/175758/1/Digital%20challenges%20final%20report-for%20repository.pdf>  
(accessed 7<sup>th</sup> September 2021)  
38  
39 24. Liu Y, Zupan NJ, Swearingen R, et al. Identification of barriers, facilitators and system-based  
40 implementation strategies to increase teleophthalmology use for diabetic eye screening in a rural US primary  
41 care clinic: a qualitative study. *BMJ open* 2019;9(2):e022594.  
42  
43 25. Piyasena MM, Murthy GV, Yip JL, et al. Systematic review on barriers and enablers for access to diabetic  
44 retinopathy screening services in different income settings. *PloS one* 2019;14(4):e0198979.  
45  
46 26. De Carvalho AB, Ware SL, Belcher T, et al. Evaluation of multi-level barriers and facilitators in a large  
47 diabetic retinopathy screening program in federally qualified health centers: a qualitative study. *Implement Sci*  
48 *Commun* 2021;2(1):1-3.  
49  
50 27. Han JED, Liu X, Bunce C, et al. Teleophthalmology enabled and Artificial Intelligence ready referral  
51 pathway for community optometry referrals of retinal disease (HERMES): A cluster randomised superiority trial  
52 with a linked observational diagnostic accuracy study protocol. *BMJ Open* (forthcoming)  
53  
54 28. Denscombe M. *The Good Research Guide: For Small-Scale Social Research Projects*. Third edition.  
55 Maidenhead: McGraw-Hill Education 2007  
56  
57 29. Patton, MQ. *Qualitative evaluation and research methods*. Third edition. London: Sage 2002  
58  
59 30. Hennink MM, Kaiser BN, Marconi VC. Code saturation versus meaning saturation: how many interviews  
60 are enough?. *Qual Health Res* 2017;27(4):591-608.

- 1  
2  
3 31. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical  
4 Research Council guidance. *Bmj* 2008;337.  
5  
6 32. Grol RP, Bosch MC, Hulscher ME, et al. Planning and studying improvement in patient care: the use of  
7 theoretical perspectives. *The Milbank Quarterly* 2007;85(1):93-138.  
8  
9 33. de Wet C, Bowie P, O'Donnell CA. Facilitators and barriers to safer care in Scottish general practice: a  
10 qualitative study of the implementation of the trigger review method using normalisation process theory. *BMJ*  
11 *open* 2019;9(9):e02991  
12  
13 34. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process  
14 theory. *Sociology* 2009;43(3):535-54.  
15  
16 35. Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating  
17 and implementing complex interventions. *BMC Med* 2010;8(1):1-1  
18  
19 36. May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: Normalization  
20 Process Theory. *Implement Sci* 2009 Dec;4(1):1-9.  
21  
22 37. May CR, Cummings A, Girling M, et al. Using normalization process theory in feasibility studies and  
23 process evaluations of complex healthcare interventions: a systematic review. *Implement Sci* 2018;13(1):1-27.  
24  
25 38. McCrorie C, Benn J, Johnson OA, et al. Staff expectations for the implementation of an electronic health  
26 record system: a qualitative study using normalisation process theory. *BMC Med Inform Decis Mak*  
27 2019;19(1):1-4.  
28  
29 39. McEvoy R, Ballini L, Maltoni S, et al. A qualitative systematic review of studies using the normalization  
30 process theory to research implementation processes. *Implement Sci* 2014;9(1):1-3.  
31  
32 40. Bouamrane MM, Mair FS. A study of general practitioners' perspectives on electronic medical records  
33 systems in NHS Scotland. *BMC Med Inform Decis Mak* 2013;13(1):1-2.  
34  
35 41. O'connor S, Hanlon P, O'donnell CA, et al. Understanding factors affecting patient and public engagement  
36 and recruitment to digital health interventions: a systematic review of qualitative studies. *BMC Med Inform*  
37 *Decis Mak* 2016;16(1):1-5.  
38  
39 42. Holtzblatt, K, Beyer H. Contextual Design. In: Soegaard, Mads and Dam, Rikke Friis (eds.). The  
40 Encyclopedia of Human-Computer Interaction. *The Interaction Design Foundation* 2013  
41 [http://www.interaction-design.org/encyclopedia/contextual\\_design.html](http://www.interaction-design.org/encyclopedia/contextual_design.html) (accessed 16th of December 2021)  
42  
43 43. Blandford A, Furniss D, Makri S. Qualitative HCI research: Going behind the scenes. *Synthesis lectures on*  
44 *human-centered informatics* 2016 Apr 7;9(1):1-15.  
45  
46 44. Blandford A. Semi-structured qualitative studies. *Interaction Design Foundation* 2013  
47 [https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-](https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/semi-structured-qualitative-studies)  
48 [ed/semi-structured-qualitative-studies](https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/semi-structured-qualitative-studies) (accessed 16th of December 2021)  
49  
50 45. Hoffman RR, Crandall B, Shadbolt N. Use of the critical decision method to elicit expert knowledge: A case  
51 study in the methodology of cognitive task analysis. *Human factors* 1998 Jun;40(2):254-76.  
52  
53 46. Blandford A, Wong BW. Situation awareness in emergency medical dispatch. *Int J Hum Comput Stud*  
54 2004;61(4):421-52.  
55  
56 47. Ericsson KA. Protocol analysis and expert thought: Concurrent verbalizations of thinking during experts'  
57 performance on representative tasks. *The Cambridge handbook of expertise and expert performance* 2006;223-  
58 241  
59  
60 48. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3(2):77-101.

1  
2  
3 49. Orlikowski WJ. Knowing in practice: Enacting a collective capability in distributed organizing.  
4 *Organization science* 2002;13(3):249-73.  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

For peer review only

SRQR guidelines\*—recommended items to be included in reports of qualitative studies

	<b>Item No.</b>	<b>Recommendation</b>	<b>Page No.</b>
<b>Title and abstract</b>			
Title	S1	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	The type of the study is included in the title (see the title on page 1)
Abstract	S2	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Key elements of the abstract as recommended by BMJ open is included in the abstract (see page 1-2)
<b>Introduction</b>			
Problem formulation	S3	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	See page 2-5
Objectives	S4	Purpose or research question	See page 5
<b>Methods</b>			
Qualitative approach and research paradigm	S5	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended	See page 6 on details of the design of the qualitative study. See page 8-9 on the theory informing the data collection and analysis
Researcher characteristics and reflexivity	S6	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	This item will be included in future research articles that report results/findings and the potential influence of the researchers' characteristics on data collection and interpretation of the findings.

			A reflective diary will be maintained during the research to aid with this.
Context	S7	Setting/site and salient contextual factors	See page 6
Sampling strategy	S8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation)	Details on the participants' selection criteria and how they will be selected can be found in Participant Selection section (see page 6-8)
Ethical issues pertaining to human subjects	S9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Details on ethical approvals and other ethical considerations can be found in Ethics and Dissemination section (see page 13-14)
Data collection methods	S10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings	Details on methods of data collection can be found in Data Collection and Methods section (see page 9-12)
Data collection instruments and technologies	S11	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Details on the topic guides that will be used can be found on page 11-12
Units of study	S12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Details on the proposed sample can be found in the Sampling subsection on page 7
Data processing	S13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Details on data management can be viewed in the Ethics and Dissemination section (see page 13-14)

1				
2				
3	Data analysis	S14	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach	Details on data analysis can be found in the Data Analysis subsection (see page 12-13)
4				
5				
6				
7	Techniques to enhance trustworthiness	S15	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation)	Data analysis will be conducted by multiple coders/researchers to increase the credibility of the data analysis. Researchers will meet regularly to discuss the coding strategy, analysis and preliminary findings, see the Data Analysis section on 12-13 for more details
8				
9				
10				
11				
12				
13				
14				
15				
16				
17	<b>Results/findings</b>			
18	Synthesis and interpretation	S16	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	N/A
19				
20				
21	Links to empirical data	S17	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	N/A
22				
23				
24				
25	<b>Discussion</b>			
26	Integration with prior work, implications, transferability, and contribution(s) to the field	S18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	N/A
27				
28				
29				
30				
31				
32				
33				
34				
35	Limitations	S19	Trustworthiness and limitations of findings	N/A
36				
37				
38	<b>Other</b>			
39				
40				
41				
42				
43				
44				
45				
46				

Conflicts of interest	S20	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	A conflict-of-interest statement is included on page 15
Funding	S21	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	A funding statement is included on page 15

\*Recommended by the EQUATOR NETWORK <https://www.equator-network.org/reporting-guidelines/srq/>

For peer review only



# BMJ Open

**Protocol for a qualitative study to explore acceptability, barriers, and facilitators of the implementation of new teleophthalmology technologies between community optometry practices and hospital eye services**

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2022-060810.R1
Article Type:	Protocol
Date Submitted by the Author:	17-Mar-2022
Complete List of Authors:	Blandford, Ann; University College London, UCL Interaction Centre Abdi, Sarah; University College London, UCL Interaction Centre Aristidou, Angela; University College London, School of Management Carmichael, Josie; University College London, UCL Interaction Centre; Moorfields Eye Hospital NHS Foundation Trust Cappellaro, Giulia; University College London, School of Management; Bocconi University, Department of Social and Political Sciences Hussain, Rima; Moorfields Eye Hospital NHS Foundation Trust; UCL, Institute of Ophthalmology Balaskas, Konstantinos; Moorfields Eye Hospital NHS Foundation Trust
<b>Primary Subject Heading</b>:	Ophthalmology
Secondary Subject Heading:	Ophthalmology, Qualitative research
Keywords:	OPHTHALMOLOGY, Medical retina < OPHTHALMOLOGY, PRIMARY CARE

SCHOLARONE™  
Manuscripts

# HCI study protocol manuscript

## TITLE

**Protocol for a qualitative study to explore acceptability, barriers and facilitators of the implementation of new teleophthalmology technologies between community optometry practices and hospital eye services**

## Authors

**Ann Blandford<sup>1</sup>, Sarah Abdi<sup>1</sup>, Angela Aristidou<sup>2</sup>, Josie Carmichael<sup>1,3</sup>, Giulia Cappellaro<sup>2,4</sup>, Rima Hussain<sup>3</sup> and Konstantinos Balaskas<sup>1,3</sup>**

## Affiliations

<sup>1</sup>UCL Interaction Centre (UCLIC), University College London (UCL), WC1E 6EA, London, United Kingdom

<sup>2</sup>School of Management, University College London (UCL), E14 5AA, London, United Kingdom

<sup>3</sup>Moorfields Eye Hospital, City Road, EC1V 2PD, London, United Kingdom

<sup>4</sup>Bocconi University, Department of Social and Political Sciences, Milan, Italy

## Corresponding author

Ann Blandford, [a.blandford@ucl.ac.uk](mailto:a.blandford@ucl.ac.uk)

**Word count (excluding title page, abstract and references): 5097**

## ABSTRACT

**Introduction** Novel teleophthalmology technologies have the potential to reduce unnecessary and inaccurate referrals between community optometry practices and hospital eye services and as a result improve patients' access to appropriate and timely eye care.

However, little is known on the acceptability and facilitators and barriers of the implementations of these technologies in real-life.

**Methods and analysis** A theoretically informed, qualitative study will explore patients' and healthcare professionals' perspectives on teleophthalmology and Artificial Intelligence Decision Support System (AI DSS) models of care. A combination of situated observations in community optometry practices and hospital eye services, semi-structured qualitative interviews with patients and healthcare professionals and self-audio recordings of healthcare professionals will be conducted. Participants will be purposively selected from 4-5 hospital eye services and 6-8 affiliated community optometry practices. The aim will be to recruit 30-36 patients and 30 healthcare professionals from hospital eye services and community

1  
2  
3 38 optometry practices. All interviews will be audio-recorded, with participants' permission, and  
4  
5 39 transcribed verbatim. Data from interviews, observations and self-audio recordings will be  
6  
7 40 analysed thematically and will be informed by Normalisation Process Theory (NPT) and an  
8  
9 41 inductive approach.

10 42 **Ethics and dissemination** Ethical approval has been received from London-Bromley  
11  
12 43 research ethics committee. Findings will be reported through academic journals and  
13  
14 44 conferences in ophthalmology, health services research, management studies and human-  
15  
16 45 computer interaction (HCI).

## 17 46

### 18 47 **Key words**

19  
20  
21 48 Teleophthalmology, Artificial Intelligence, primary eye care, optometrists, ophthalmologists,  
22  
23 49 retinal disease, human-computer interaction, Normalization Process Theory (NPT), clinical  
24  
25 50 referral.

## 26 51

## 27 52 **STRENGTH AND LIMITATIONS OF THIS STUDY**

- 28  
29 53 • This study forms part of a large multi-center study (The HERMES study) that will  
30  
31 54 collectively provide real-world evidence on the implementation of novel  
32  
33 55 teleophthalmology technologies.
- 34  
35 56 • A key strength of this study is analysing the facilitators and barriers of the  
36  
37 57 implementation of novel teleophthalmology technologies from the perspectives of  
38  
39 58 multiple stakeholders including patients and primary and secondary eye care  
40  
41 59 professionals.
- 42  
43 60 • Another strength of this study is using multiple methods (observations, interviews,  
44  
45 61 self-audio recording) to collect data from multiple hospital eye services and affiliated  
46  
47 62 community optometry practices in England.
- 48  
49 63 • One limitation of this study is that most interviews will be conducted via video  
50  
51 64 conferencing or telephone, limiting the researcher's ability to build rapport with the  
52  
53 65 interviewees.

## 54 66

## 55 67 **INTRODUCTION**

56  
57 68 Ophthalmology is one of the busiest outpatient clinics in England, accounting for 8% of all  
58  
59 69 hospital outpatients' attendances [1]. Most hospital eye services (HES) referrals originate  
60  
70 70 from community optometrists (CO) in high street optician practices, who are the main

1  
2  
3 71 providers of primary eye care in the UK [2]. Retinal disorders (e.g., macular pathologies,  
4 72 retinal vascular pathologies and suspected retinal tears/detachments) are the most referred  
5 73 conditions [3]. The growing use of optical coherence tomography technology (OCT) in  
6 74 community optometry practices is believed to have contributed to the increase in retinal  
7 75 referrals to hospitals [4,5]. OCT is a non-invasive scanning technology that generates high-  
8 76 resolution, three-dimensional images of the retina [6]. OCT has transformed ophthalmology  
9 77 practice in the last decade, leading to better detection and understanding of common retinal  
10 78 conditions such as age-related macular degeneration (AMD) [6]. However, the success of this  
11 79 technology in improving retinal care for patients may have been limited by the referral  
12 80 process between CO and HES. Unnecessary and inaccurate referrals, re-referrals from CO,  
13 81 and deficits in replies from HES are common issues in the referral process, increasing the  
14 82 burden on secondary care and, consequently, delaying access to timely eye care for patients  
15 83 who need it [2,3]. Therefore, there is an urgent need to explore potential solutions to improve  
16 84 the referral process and manage patient flow between CO and HES.

17 85 Teleophthalmology has emerged as a viable alternative to delivering eye care that may  
18 86 improve patients' access to timely and appropriate care [7-9]. Teleophthalmology is a means  
19 87 to provide ophthalmic care at a distance using information and communication technology [8,  
20 88 10]. A variety of eye care delivery models have been reported to benefit from  
21 89 teleophthalmology. For example, Caffrey et al. [8] identified 62 discrete models of care that  
22 90 can be improved by teleophthalmology, including eye screening, patients' consultations,  
23 91 emergency services, supervision of procedures, staff training, and remote supervision. In the  
24 92 referral process, teleophthalmology services typically involve primary healthcare  
25 93 professionals (e.g., community-based optometrist) obtaining images (e.g., OCT, slit-lamp, or  
26 94 retinal imaging) and transmitting them via an electronic system to secondary care [8]. A  
27 95 secondary care ophthalmologist then reviews these images and decides on the management of  
28 96 the case, which might involve meeting the patient, remotely monitoring them, or continuing  
29 97 their management in primary care [8, 11]. Teleophthalmology can have several benefits in the  
30 98 context of triage. For example, in one scoping review, teleophthalmology was found to  
31 99 contribute to reducing face-to-face appointments with ophthalmologists by 16-48% through  
32 100 reducing inappropriate and unnecessary referrals [7]. Similarly, implementing remote retinal  
33 101 imaging-based referrals reduced the waiting time for patients to see an ophthalmologist from  
34 102 14 weeks to four weeks [7]. Teleophthalmology has been found to improve elderly patients'  
35 103 access to specialist eye care and reduce workload on specialist centres and unnecessary visits  
36 104 [10]. Patients also reported high levels of satisfaction with teleophthalmology services due to

1  
2  
3 105 reduced cost and time of travel, as well as increased accessibility to services [11]. A recent  
4  
5 106 systematic review has also emphasised the potential of teleophthalmology to serve as an  
6  
7 107 alternative eye care delivery model by demonstrating its feasibility and cost-effectiveness for  
8  
9 108 the management of various eye conditions in several countries including the UK [12].  
10  
11 109 Additionally, in recent years, advances in Artificial Intelligence (AI), particularly in deep  
12  
13 110 learning, hold great promise for expanding the use of teleophthalmology [13-16]. Deep  
14  
15 111 learning can improve referrals by identifying patients who are more likely to develop a  
16  
17 112 specific condition and require urgent care or frequent follow-ups, increasing patients' access  
18  
19 113 to appropriate eye care [13,15]. Several recent studies have demonstrated comparable  
20  
21 114 performances of deep learning algorithms to experts in diagnosing different eye conditions  
22  
23 115 [14, 17, 18]. For instance, in one study, a deep learning algorithm reached or exceeded  
24  
25 116 experts' performance in assessing urgent referrals from two independent sets of OCT scans  
26  
27 117 (n=997, n=116) for a range of retinal conditions [17]. Similarly, the accuracy of a deep  
28  
29 118 learning algorithm to assess AMD from fundus images has been found to range between  
30  
31 119 88.4% and 91.6% compared to human experts [18].

32  
33 120 However, despite these promising findings, triaging referrals via teleophthalmology has  
34  
35 121 been limited in practice. For example, during the COVID-19 pandemic, a period associated  
36  
37 122 with increased adoption of telehealth applications [19], primary care optometrists were less  
38  
39 123 willing to adopt teleophthalmology in the context of referrals [20]. Although the study did not  
40  
41 124 explore in depth reasons for this limited adoption, this finding is not surprising. Generally,  
42  
43 125 implementing digital health interventions in practice is acknowledged to be complex due to  
44  
45 126 the multiple components that should be considered during implementation [21-24]. These  
46  
47 127 include professionals' and patients' acceptance of the technology, staff training and  
48  
49 128 education, changes in staff roles and practices, the organisation culture, capacity and  
50  
51 129 readiness to accept innovations, and the wider context (e.g., policy and regulations) [22, 24].  
52  
53 130 The application of deep learning algorithms in ophthalmology referrals also brings with it a  
54  
55 131 new set of challenges. For example, there are risks related to data security and privacy, as  
56  
57 132 well as potential harm from false negative diagnosis that may impact the implementation and  
58  
59 133 acceptance of deep learning algorithms for clinical image classification [14-16].  
60  
61 134 Deep learning algorithms are also characterised by a lack of transparency or explainability,  
62  
63 135 sometimes referred to as the 'black box' phenomenon, which makes it difficult for healthcare  
64  
65 136 professionals and patients to understand how they reached their output [14, 15, 17]. This  
66  
67 137 raises the question of whether health professionals and patients would trust the use of a 'black  
68  
69 138 box' for referrals [17]. Most work to increase the explainability of AI models has focussed

1  
2  
3 139 on the development of post-hoc explanations of outputs, using methods such as saliency  
4  
5 140 maps. However, these explanations are based on limited access to the 'inner workings' of  
6  
7 141 models and have been criticized for a lack of stability, as well as for failing tests of utility and  
8  
9 142 robustness [25]. To address post-hoc short-comings, self-explaining AI, whereby complex  
10  
11 143 interpretable models are built bottom up, have been proposed and developed. These produce  
12  
13 144 explanations that are intrinsic to the model whilst still maintaining a high performance [26,  
14  
15 145 27]. Overall, recent evidence suggests that teleophthalmology and AI decision support tools  
16  
17 146 have the potential to improve the referral process between CO and HES. However, to  
18  
19 147 improve the uptake of these technologies in practice, it is important to identify the factors that  
20  
21 148 facilitate or hinder their implementation.  
22

149

## 150 AIMS AND OBJECTIVES

151 Previous research on facilitators and barriers of teleophthalmology implementation has  
152 mainly focused on diabetic retinopathy screening [28-30], with limited research focusing on  
153 facilitators and barriers in the referral process between CO and HES on other retinal  
154 conditions. Therefore, this study aims to assess patients' and healthcare professionals'  
155 acceptance of, and barriers and enablers for, the adoption of two innovative digital  
156 technologies supporting referral pathways between CO and HES. These are a  
157 teleophthalmology platform and the Moorfields-DeepMind Artificial Intelligence Decision  
158 Support System (DSS). A human-computer interaction (HCI) approach will be used in this  
159 study, to understand professionals' and patients' interactions with the proposed technological  
160 solutions as well as the contexts in which these technologies will be implemented. Five  
161 research objectives address the overall aim of this study:

- 162 1. To understand current workflows and practices of staff and patients in community  
163 optometry and HES so as to identify key user requirements for tele-ophthalmology  
164 tools from the perspectives of both groups.
- 165 2. To understand workflows and practices of staff and patients in community optometry  
166 practices and HES with already established tele-ophthalmology pathways to identify  
167 technical, logistical and human factors affecting implementation of tele-  
168 ophthalmology in practice.
- 169 3. To identify factors that shape professionals' and patients' attitudes to, and trust in, the  
170 Moorfields-DeepMind AI, and how to present information in ways that instil  
171 appropriate confidence.

- 1  
2  
3 172 4. To understand whether and how work practices are likely to change following the  
4 adoption of Moorfields-DeepMind AI.  
5 173  
6 174 5. To identify factors that ease the deployment of a digital referral platform to ensure  
7 acceptability and acceptance by all user groups, and to understand the adoption  
8 175  
9 process.  
10 176  
11  
12 177  
13

## 14 178 **METHODS AND ANALYSIS**

### 15 179 **The HERMES study**

16  
17  
18 180 The current protocol focuses on the detailed design of the qualitative element of the “Tele-  
19 ophthalmology-enabled and artificial intelligence-ready referral pathway for community  
20 181 optometry referrals of retinal disease trial” (the HERMES study). HERMES is an  
21 182 interventional superiority cluster randomised trial that aims to compare standard practice for  
22 183 referral of suspected retinal diseases with a teleophthalmology digital link between CO and  
23 184 HES. A sub-study will also be conducted as part of the trial that integrates the trial data to  
24 185 assess the diagnostic accuracy of an AI DSS (the Moorfields-DeepMind algorithm) for the  
25 186 automated referral recommendation for retinal disease. Detailed methods of the HERMES  
26 187 study are described elsewhere [31]. The qualitative research element presented in this paper  
27 188 will run across both studies to provide evidence on implementation.  
28  
29  
30  
31  
32  
33  
34  
35

### 36 190 **Study design and setting**

37  
38 191 A theoretically informed, qualitative study will be performed to explore patients’ and  
39 192 healthcare professionals’ perspectives on teleophthalmology models of care and AI Decision  
40 193 Support System (AI DSS). A combination of situated observations with semi-structured  
41 194 interviews with healthcare professionals, semi-structured interviews with patients, and self-  
42 195 audio recording of healthcare professionals will be conducted. This approach will enable us  
43 196 to understand the contexts in which the two new technologies will be implemented, focusing  
44 197 on understanding workflows, practices, and user requirements, as well as identifying  
45 198 potential barriers and facilitators to implementation. It will also enable us to gain an in-depth  
46 199 understanding of staff and patients’ expectations and experiences with the implementation of  
47 200 the new technologies. The study will be conducted at 4-5 hospital eye services and 6-8  
48 201 affiliated optometry community practices. Data collection is planned to start in November  
49 202 2021 and end in May 2022.  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

## 203 **Participant selection**

### 204 **Sampling**

205 Purposive sampling will be applied to recruit participants who are representative of relevant  
206 patient and professional groups. This type of sampling is used to select participants who are  
207 most likely to produce valuable data [32]. Patient participants will be selected if they meet  
208 the following criteria:

- 209 - Able to communicate in English, understand the study, and give informed consent.
- 210 - Adults ( $\geq 18$  years) attending the involved community optometry practices who underwent  
211 an OCT scan.
- 212 - Individuals who in the opinion of the community optometrist have any suspicion of a retinal  
213 condition (including dry AMD, wet AMD, diabetic retinopathy, macular oedema, macular  
214 holes, epiretinal membranes, central serous chorio-retinopathy, genetic eye disease).

215 Patients with retinal conditions that are not routinely visualised or diagnosed using an OCT  
216 scan or those with conditions that prevent acquisition of good quality OCT will be excluded.  
217 This includes peripheral retinal comorbidities such as peripheral retinal degeneration, retinal  
218 tear, retinal detachment, peripheral retino-choroidal tumours, Coat's disease, Retinopathy of  
219 Prematurity, Familial Exudative Vitreoretinopathy, Sickle-cell retinopathy.

220 Professional participants will include community optometrists and clinicians (medics or  
221 specialist optometrists) with a minimum of two years' experience of independent practice in  
222 retinal clinics in hospital eye services. Some of the participants' characteristics (e.g., their level  
223 of experience) will be monitored during recruitment to ensure that diverse views are included  
224 in the sample.

225 Participants will be recruited from three settings: 1) community optometry clinics in the control  
226 arm (pre-transitioning to teleophthalmology); 2) community optometry clinics in the  
227 intervention arm (post-transitioning to teleophthalmology); and 3) hospital eye services. These  
228 settings will help us understand and compare experiences and work practices before and after  
229 implementing the new teleophthalmology technologies, as well as identifying barriers and  
230 facilitators during their implementation. A total of 4-5 hospital eye services and 6-8 community  
231 optometry practices (3-4 practices from the control arm and 3-4 practices from the intervention  
232 arm) will be included in the study.

233 For the observations, it is expected that valuable insight will be obtained from observing a  
234 total of 10-15 clinician-patient consultations (3-5 consultations in each setting). These



1  
2  
3 235 numbers were estimated based on the research team's previous knowledge and experience on  
4  
5 236 conducting observations in healthcare settings. However, insight from the first few  
6  
7 237 observations will further inform the number of consultations required to achieve sufficient  
8  
9 238 input from the observations.

10  
11 239 For the interviews, the aim is to interview a total of 30-36 patients from 6-8 CO practices (5-  
12  
13 240 6 patients from each participating CO) and up to 30 healthcare professionals (up to 10 in each  
14  
15 241 setting, noting that many of the participating CO practices employ fewer than 5 optometrists).  
16  
17 242 Data saturation, that is, no new information emerges from the sampled units, will also guide  
18  
19 243 sample size [33, 34]. Healthcare professionals in the intervention arm or post-transitioning to  
20  
21 244 teleophthalmology should have sufficient experience with the teleophthalmology platform  
22  
23 245 before participating in the interview. However, we don't have a specific period of exposure to  
24  
25 246 the platform as the aim is to gain diverse views from practices at different stages of  
26  
27 247 implementation.

28  
29 248 For the self-audio recording, the aim is to collect self-audio recordings of referral decisions of  
30  
31 249 participating healthcare professionals in CO and HES.

32 250

## 33 251 Methods of approach

### 34 252 *Observations*

35  
36 253 The observations will focus on understanding general clinical practices and work routines.  
37  
38 254 Thus, the observations might involve patients, but not specifically those with suspected  
39  
40 255 retinal diseases. Managers of community optometry practices and secondary eye clinics will  
41  
42 256 be approached to gain permission to conduct observations in their practices.

43 257

### 44 258 *Interviews*

45  
46 259 Two sets of interviews will be conducted.

47  
48 260 A first set of interviews will focus on individuals with suspected retinal disease. Only patients  
49  
50 261 who undergo an OCT and, in the opinion of the community optometrist, have any suspicion  
51  
52 262 of a retinal condition will be invited to participate in an interview. Potential patient  
53  
54 263 participants will be invited to participate following their consultation at a participating CO  
55  
56 264 practice. The optometrist will explain the study to potential participants, highlighting its  
57  
58 265 purpose, possible advantages and disadvantages, and what it entails. Potential participants  
59  
60 266 will be given sufficient time to think about their participation and ask questions about the

1  
2  
3 267 study. The researcher will call potential participants to obtain their decision to participate and  
4  
5 268 book a provisional interview date for those who agree to participate. Interviews will be  
6  
7 269 conducted at the optometry practice where the participant was recruited, or via telephone or  
8  
9 270 video conferencing.

10 271 A second set of interviews will focus on professional participants at the hospital eye service  
11  
12 272 and the community optometry practices, who will be invited to participate in interviews by  
13  
14 273 the researcher. Interviews with professional participants will be conducted via video  
15  
16 274 conferencing, or at the hospital or practice.

17 275

### 18 276 *Self-audio recording*

19 277 During the initial interview with healthcare professionals at the community optometry  
20  
21 278 practices and the HES, participants will be invited to participate in the self-audio recording  
22  
23 279 data collection exercise described below.

## 26 280 **Data collection and analysis**

### 28 281 Theoretical approach

29  
30 282 Most digital health interventions can be viewed as complex interventions as they include  
31  
32 283 multiple components that interact at both individual and organisational levels [21, 23, 35].

33 284 The explicit use of a theoretical lens when evaluating the implementation of these  
34  
35 285 interventions can enhance our understanding of factors that may influence their success or  
36  
37 286 failure [36, 37]. In this study, Normalisation Process Theory (NPT) will be used as a

38 287 theoretical lens in gathering and analysing the data. NPT is concerned with understanding  
39  
40 288 and explaining factors that may facilitate or inhibit the incorporation of complex

41  
42 289 interventions into routine practice [38, 39]. NPT focuses on understanding the work that

43  
44 290 individuals and groups need to do for a complex intervention to become 'normalised' and  
45  
46 291 embedded in practice, particularly in a healthcare context [39-42]. Thus, a starting point of

47 292 this theory is understanding current practices, i.e., how people work and what they actually  
48  
49 293 do [40]. NPT comprises four components that determine the normalisation of a complex

50  
51 294 intervention in practice [39, 40]. These are: 1) coherence, which refers to participants'

52 295 understanding of new technology and practices associated with it; 2) cognitive participation,

53  
54 296 which refers to the preparedness of participants to engage and use the technology; 3)

55  
56 297 collective action, which refers to the work that participants do to use the technology; and 4)

57 298 reflective monitoring, which refers to participants' appraisal of the new technology [23, 39,

58  
59 299 42]. There is evidence for the stability and consistency of NPT constructs across various  
60

1  
2  
3 300 contexts, advocating their use to assess, describe or improve the implementation potential of  
4  
5 301 complex interventions [39, 41, 43]. NPT has also been used to explore users', including  
6  
7 302 patients' and healthcare professionals', expectations of digital health interventions as well as  
8  
9 303 barriers and facilitators to engaging with these interventions [37, 42, 44, 45], although limited  
10  
11 304 evidence is available on teleophthalmology and AI DSS. In this study, it is envisaged that the  
12  
13 305 use of NPT will help better understand the implementation process of these two technologies  
14  
15 306 in routine practice and identify factors that may contribute to a successful implementation.  
16

307

## 308 Design of observations, interviews and self-audio recordings

### 309 *Observations*

20  
21 310 The aim of the observations is to gain a familiarity with the contexts in which the two  
22  
23 311 innovative technologies will be implemented. In particular, it will aim to establish an  
24  
25 312 understanding of current practices and work routines, and identify any differences in the  
26  
27 313 workflows between practices. This is an important step given that understanding what people  
28  
29 314 do and how they work in real life is a core focus for NPT. Additionally, findings from the  
30  
31 315 observations will help set the context for the semi-structured interviews with healthcare  
32  
33 316 professionals. The latter will then be used to have a more in-depth discussion with healthcare  
34  
35 317 professionals regarding what would and wouldn't work in practice which will help to identify  
36  
37 318 the user requirements for the teleophthalmology platform.

38 319 Observations will be conducted in all settings (optometry practices and hospital eye services),  
39  
40 320 focusing on clinician-patient interactions around the diagnostic and referral process.

41 321 Specifically, the researcher will take field notes on the workflow, how referral decisions are  
42  
43 322 made and communicated to patient, the clinician interaction with the new teleophthalmology  
44  
45 323 platform, and any facilitators or barriers experienced during the interaction. To facilitate  
46  
47 324 capturing this data, the flow and sequence work models from Contextual Design will be used  
48  
49 325 [46]. The flow model describes communication and coordination patterns that are important  
50  
51 326 to accomplish the work, while the sequence model represents the detailed steps that people do  
52  
53 327 to accomplish the tasks and the problems that they may encounter whilst doing them [46].

54 328 Detailed work model diagrams will be kept of all observations conducted in CO and HES.

329

330

331

332

### 333 *Interviews*

334 The aim of the interviews is to gain an in-depth understanding of the expectations,  
335 perceptions, and experiences of patients and health professionals with the teleophthalmology  
336 platform. All interviews will be semi-structured, allowing us to address the study aim,  
337 informed by NPT, while also following up on new insights as they emerge [47]. All  
338 professional participants will be interviewed once, with the option of participating in two  
339 further short interviews. The purpose of these additional interviews is to gain professionals'  
340 reflections on their propensity to adopt AI tools and to change their work practices following  
341 AI adoption. Two approaches will be used to conduct the semi-structured interviews with  
342 healthcare professionals: contextual inquiry interviews and critical incident technique.

343  
344 Contextual inquiry is a method commonly used in the HCI field to gain a deep understanding  
345 of users' work practices [46, 48]. It is based on the premise that users are tacitly aware of  
346 their own work practices as they are immersed in their everyday activities [46]. To  
347 understand their actions and reveal their motivations, intents, and strategies, it is important to  
348 observe and speak to them in the context in which they perform their day-to-day activities  
349 [46]. In other words, contextual inquiry involves conducting observations and following them  
350 up with questions to understand the work at hand [47]. In this study, contextual inquiry with  
351 healthcare professionals will complement the observations made in hospital eye services and  
352 optometry practices.

353  
354 Critical decision method (CDM), originated from the critical incident technique, is a  
355 cognitive task analysis approach used to elicit expert knowledge [49]. The CDM focuses on a  
356 retrospective analysis of critical incidents experienced by the interviewees [50]. In the  
357 context of HCI studies, critical incidents can include events when the technology failed or the  
358 system experienced particular demands [47]. The CDM uses a set of techniques to minimise  
359 recall biases and aid the interviewees to recall critical decisions as accurately as possible [50].  
360 For example, the technique involves probing the interviewee to identify and describe a  
361 specific critical incident or incidents from beginning to end [49]. The researcher then  
362 composes a decision timeline and employs probe questions which allow the interviewee to  
363 provide corrections or more details [49]. The interviewee is also asked "what-if?" questions  
364 to understand what might have happened differently. In this study, critical incident interviews  
365 will be conducted with healthcare professional participants in the intervention arm, to gain a  
366 deep understanding of their perceptions and experiences with the teleophthalmology platform

1  
2  
3 367 as well as explore barriers to its implementation in practice (e.g., when the platform failed  
4  
5 368 and reasons for that).  
6  
7 369

8 370 A semi-structured topic guide will be used in all interviews and will include questions related  
9  
10 371 to the research topic and NPT. The topic guide will be tailored to each group (patients and  
11  
12 372 healthcare professionals in the intervention and control arms) as well as to suit the approach  
13  
14 373 employed (contextual inquiry and CDM). The interview procedure will follow the 5 steps to  
15  
16 374 conduct HCI semi-structured interviews [47]. Step 1 (opening the conversation) aims to put  
17  
18 375 participants at ease and assure them they have the desired knowledge and expertise. Step 2  
19  
20 376 (introducing the research) aims to introduce the topic and ensure that participants are aware  
21  
22 377 of the purpose, reaffirming their confidentiality and right to withdrawal, and requesting  
23  
24 378 permission to record the interview. Step 3 (beginning the interview) aims to gain contextual  
25  
26 379 information about the participant, such as their role, technology use and prior experience,  
27  
28 380 which may help formulate the subsequent questions. Step 4 (during the interview) aims to  
29  
30 381 gain in-depth information about the topic under investigation. NPT components (coherence,  
31  
32 382 cognitive participation, collective action and reflective monitoring) will inform the questions  
33  
34 383 in this step. Questions about coherence will focus on participants' expectations from the  
35  
36 384 teleophthalmology platform, as well as its perceived benefits and barriers. Questions based  
37  
38 385 on cognitive participation will explore participants' engagement with the teleophthalmology  
39  
40 386 platform and the issues they may face when using this new technology. Questions about  
41  
42 387 collective action will focus on participants' views on the impact of the teleophthalmology  
43  
44 388 platform on eye care and practice, as well as the changes that may be required to integrate  
45  
46 389 this new technology in routine practices. Questions based on reflective monitoring will  
47  
48 390 explore participants' perspectives on how the teleophthalmology platform should be  
49  
50 391 implemented in the future. For the AI DSS, issues around the 'black box' phenomenon, as  
51  
52 392 well as the optimal place in the care pathway, confidence and trust will be investigated.  
53  
54 393 Probes such as anonymised screenshots from the digital referral platform and illustrative  
55  
56 394 prototypes from the DeepMind algorithm will be used to support the exploration of the  
57  
58 395 themes. Step 5 (closing the interview) will include ending the interview, providing the  
59  
60 396 participant with an opportunity to express more thoughts, and thanking them for their  
397 contribution to the study and the design of the technology. All interviews will be audio-  
398 recorded, with participants' permission, and transcribed verbatim.  
399  
400

### 401 *Self-audio recording*

402 Self-audio recording is a method with demonstrated scientific value for examining the  
403 decision processes of professionals [51]. The aim of the self-audio recordings is to study  
404 whether and how exposure to the Moorfields-DeepMind AI referral decision changes the  
405 work practices of professionals in community optometry and HES.  
406 Both community optometry and HES participants will be invited to record themselves (self-  
407 audio record) talking out loud about referral decisions. Self-audio recordings will take place  
408 when healthcare professionals are alone (i.e., after the patient has exited the room and  
409 without a researcher in the room). Following their self-recording, some healthcare  
410 professionals will be informed of the referral decision that the Moorfields-DeepMind AI  
411 Decision Support System (DSS) would make for the same patient, while others will not have  
412 this information. The allocation of participants in the groups will follow the allocation of the  
413 broader HERMES study. Participants will not be aware of which group they belong to when  
414 they first sign up for the study. Those healthcare professionals informed of the AI DSS  
415 referral decision will be further invited to record themselves talking out loud about the AI  
416 DSS referral decision and how it relates to the original human referral decision. The self-  
417 audio recordings are not used to make an assessment of the referral but to understand how  
418 professionals make decisions as an expert.

419

### 420 Data analysis

421 Data gathering and analysis will be interleaved so that later data gathering is informed by  
422 findings from earlier analysis. A combination of inductive and deductive thematic analysis  
423 will be used to analyse data from the interviews, observations and self-audio recordings,  
424 following Braun and Clarke's guidance on conducting a thematic analysis [52]. The analysis  
425 will start with familiarising oneself with the data early on by listening to audiotapes, reading  
426 transcripts and field notes. An open approach will be followed at the start of the coding,  
427 where data from the first few transcripts and field notes will be open-coded line-by-line,  
428 enabling interesting codes and insights to emerge from the data. Analysis will then be done  
429 deductively where codes will be informed by the research questions. In one analytical  
430 direction, codes will be informed by the NPT constructs (coherence, cognitive participation,  
431 collective action, and reflective monitoring). In this direction, coding of the transcripts will  
432 be conducted independently by two researchers (SA & JC) with different backgrounds  
433 (ophthalmology, and digital health). SA & JC will meet fortnightly to discuss the codes and

1  
2  
3 434 will resolve any disagreement by discussion. In a related analytical direction, coding will be  
4  
5 435 conducted in a ‘semi-grounded theory’ way [53], whereby the researchers adopt established  
6  
7 436 professional learning and development constructs in the coding process while still allowing  
8  
9 437 for a change in the direction of enquiry during the analysis of the data. In this analytical  
10  
11 438 direction, coding of transcripts will be conducted by two researchers (GC and AA) who will  
12  
13 439 discuss fortnightly emerging insights with the broader research team. The coding scheme  
14  
15 440 from interviews will inform the coding of self-recordings, for which we identify emerging  
16  
17 441 themes and their evolution over time (per individual participant and per theme). Across both  
18  
19 442 analytical directions, codes will be reviewed for similarities, differences and relationships and  
20  
21 443 will be categorised into preliminary themes. These themes will be reviewed against the codes  
22  
23 444 and coded text and will be organised into final themes. The wider research team will meet  
24  
25 445 monthly to discuss the analysis, and the preliminary and final themes. NVivo 20 software  
26  
27 446 will be used to manage data analysis.

447

## 448 **Patient and public involvement**

449 Eighteen patients were consulted during the preparation phase of the HERMES study. The  
450  
451 consultation focused on patients’ general perceptions of teleophthalmology, trust in  
452  
453 technology and potential concerns about impersonal care or reduced opportunities to interact  
454  
455 with healthcare professionals. Patients’ perceptions of the central concept of the project was  
456  
457 positive and patients recognised the potential benefits of teleophthalmology such as reducing  
458  
459 waiting times and unnecessary visits to hospital. Several patients also emphasized the  
460  
461 importance of providing information during attendance at community optometry practices  
462  
463 around the pathways, the experience to be expected during their visit and timescale for  
464  
465 obtaining feedback. Generally, patients’ inputs reinforced the importance of introducing a  
466  
467 comprehensive qualitative element to the study to capture patients’ perceptions around digital  
468  
469 models of eye care.

470  
471 Additionally, the study is overseen by a steering committee including representatives of  
472  
473 patients group. The steering committee will meet at least once a year with provision for  
474  
475 additional meetings when input is required for potential protocol amendments or issues  
476  
477 arising during the study. An end of study debrief is planned with all PPI contributors which  
478  
479 will include discussions on the prioritization and dissemination of study results to both the  
480  
481 public and relevant healthcare professionals.

## 466 **Ethics and dissemination**

467 Health Research Authority (HRA) and Health and Care Research Wales (HCRW) ethical  
468 approvals have been obtained from London-Bromley Research Ethics Committee (Rec ref  
469 number: 20/LO/1299). Participant information sheets will be provided to all potential  
470 participants. Written or audio/video recorded informed consent will be obtained from all  
471 participants before they participate in the study. All interviews will be conducted at a time  
472 and place convenient to participants. Participants will be reminded of their rights to  
473 withdrawal from the study without there being negative consequences on their work or the  
474 care they receive.

475 All data will be handled following the General Data Protection Regulations (GDPR), UK  
476 data protection act 2018 and the Research Governance Framework for Health and Social  
477 Care. Participants' anonymity and confidentiality will be maintained during the study.  
478 Written informed consent forms will be stored in a locked cabinet in the principal  
479 researcher's office. Interviews will be conducted using encrypted audio recorders and  
480 recordings will be removed from the portable device permanently as soon as they are  
481 transferred to an access-restricted folder on the University home drive. People transcribing  
482 the interviews will be subject to a nondisclosure agreement. Field notes and interview  
483 transcripts will be pseudonymised, which means that any personal information will be  
484 removed from the data before the analysis, and participants will only be identifiable using a  
485 study identification number. Pseudonymised data and the study identification log will be  
486 stored in two separate access-restricted folders on the University's home drive. Access to  
487 data will be restricted to the research team only.

488  
489 Findings will be reported through academic journals and conferences in ophthalmology, health  
490 services research, management studies and human-computer interaction (HCI).

## 491 **CONTRIBUTORS**

492 AB and SA designed the study protocol. AA and KB contributed to the study design. SA  
493 prepared the first draft of the manuscript. AB, AA, JC, GC, RH and KB reviewed and  
494 contributed to subsequent drafts. All authors reviewed and approved the final draft of the  
495 manuscript.  
496

## 497 **FUNDING STATEMENT**

498 This work is supported by NIHR Health Technology Assessment grant number 18/182. AA is  
499 funded through the UKRI Future Leaders Fellowship research grant MR/S033009/1.  
500



501  
502 **COMPETING INTERESTS**  
503 The authors declare no conflict of interest.

504  
505 **DATA AVAILABILITY STATEMENT**

506 Data sharing not applicable as no datasets generated and/or analysed for this study

## 507 REFERENCES

- 508  
509 1. The Royal College of Ophthalmologists. Ophthalmic Services Guidance Primary Eye Care, Community  
510 Ophthalmology and General Ophthalmology. *The Royal College of Ophthalmologists* 2019  
511 [https://www.college-optometrists.org/uploads/assets/370d9ca9-6c9a-4518-a6bc1903556642c4/Ophthalmic-](https://www.college-optometrists.org/uploads/assets/370d9ca9-6c9a-4518-a6bc1903556642c4/Ophthalmic-Services-Guidance-Primary-Eye-Care-Community-Ophthalmology-and-General-Ophthalmology.pdf)  
512 [Services-Guidance-Primary-Eye-Care-Community-Ophthalmology-and-General-Ophthalmology.pdf](https://www.college-optometrists.org/uploads/assets/370d9ca9-6c9a-4518-a6bc1903556642c4/Ophthalmic-Services-Guidance-Primary-Eye-Care-Community-Ophthalmology-and-General-Ophthalmology.pdf) (accessed  
513 7<sup>th</sup> September 2021)  
514  
515 2. Evans BJ, Edgar DF, Jessa Z, et al. Referrals from community optometrists to the hospital eye service in  
516 England. *Ophthalmic Physiol Opt* 2021;41(2):365-77  
517  
518 3. Konstantakopoulou E, Harper RA, Edgar DF, et al. Clinical safety of a minor eye conditions scheme in  
519 England delivered by community optometrists. *BMJ Open Ophthalmol* 2018;3(1):e000125.  
520  
521 4. Lee JX, Manjunath V, Talks SJ. Expanding the role of medical retina virtual clinics using multimodal ultra-  
522 widefield and optical coherence tomography imaging. *Clinical Ophthalmology* 2018;12:2337.  
523  
524 5. Kern C, Fu DJ, Kortuem K, et al. Implementation of a cloud-based referral platform in ophthalmology:  
525 making telemedicine services a reality in eye care. *Br J Ophthalmol* 2020;104(3):312-7.  
526  
527 6. Adhi M, Duker JS. Optical coherence tomography—current and future applications. *Curr Opin Ophthalmol*  
528 2013;24(3):213.  
529  
530 7. Caffery LJ, Farjian M, Smith AC. Telehealth interventions for reducing waiting lists and waiting times for  
531 specialist outpatient services: A scoping review. *J Telemed Telecare* 2016;22(8):504-12.  
532  
533 8. Caffery LJ, Taylor M, Gole G, et al. Models of care in tele-ophthalmology: a scoping review. *J*  
534 *Telemed Telecare* 2019;25(2):106-22.  
535  
536 9. Sommer AC, Blumenthal EZ. Telemedicine in ophthalmology in view of the emerging COVID-19 outbreak.  
537 *Graefes Archive for Clinical and Experimental Ophthalmology* 2020;1-2.  
538  
539 10. Fatehi F, Jahedi F, Tay-Kearney ML, et al. Teleophthalmology for the elderly population: A review of the  
540 literature. *Int J Med Inform* 2020;136:104089.  
541  
542 11. Sreelatha OK, Ramesh SV. Teleophthalmology: improving patient outcomes?. *Clinical Ophthalmology*  
543 2016;10:285.  
544  
545 12. Walsh L, Hong SC, Chalakkal RJ, and Ogbuehi KC. A systematic review of current teleophthalmology  
546 services in New Zealand compared to the four comparable countries of the United Kingdom, Australia, United  
547 States of America (USA) and Canada. *Clinical Ophthalmology*, 2021;15, p.4015.  
548  
549 13. Wong TY, Bressler NM. Artificial intelligence with deep learning technology looks into diabetic retinopathy  
550 screening. *Jama* 2016;316(22):2366-7  
551  
552  
553 14. Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. *Nature*  
554 *medicine* 2019;25(1):44-56.  
555

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

15. Gunasekeran DV, Wong TY. Artificial Intelligence in Ophthalmology in 2020: A Technology on the Cusp for Translation and Implementation. *Asia Pac J Ophthalmol* 2020;9(2):61–6.
16. Korot E, Wood E, Weiner A, et al. A renaissance of teleophthalmology through artificial intelligence. *Eye* 2019;33, 861–863 (2019)
17. De Fauw J, Ledsam JR, Romera-Paredes B, et al. Clinically applicable deep learning for diagnosis and referral in retinal disease. *Nature medicine* 2018;24(9), pp.1342-1350.
18. Burlina PM, Joshi N, Pekala M, et al. Automated grading of age-related macular degeneration from color fundus images using deep convolutional neural networks. *JAMA Ophthalmol* 2017;135(11):1170-6.
19. Blandford A, Wesson J, Amalberti R, et al. Opportunities and challenges for telehealth within, and beyond, a pandemic. *Lancet Glob Health* 2020;8(11):e1364-5..
20. Nagra M, Allen PM, Norgett Y, et al. The effect of the COVID-19 pandemic on working practices of UK primary care optometrists. *Ophthalmic Physiol Opt* 2021;41(2):378-92
21. Murray E, Hekler EB, Andersson G, et al. Evaluating digital health interventions: key questions and approaches. *Am J Prev Med* 2016;51(5):843-851.
22. Greenhalgh T, Wherton J, Papoutsi C, et al. Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *JMIR* 2017;19(11):e367.
23. Ong BN, Hodgson D, Small N, et al. Implementing a digital patient feedback system: an analysis using normalisation process theory. *BMC Health Serv Res* 2020 Dec;20(1):1-6.
24. Chambers D, Cantrell A, Booth A. Rapid evidence review: challenges to implementing digital and data-driven technologies in health and social care. *The University of Sheffield* 2021 <https://eprints.whiterose.ac.uk/175758/1/Digital%20challenges%20final%20report-for%20repository.pdf> (accessed 7<sup>th</sup> September 2021)
25. Alvarez Melis D, Jaakkola T. Towards robust interpretability with self-explaining neural networks. *Advances in neural information processing systems*. 2018;31.
26. Arun N, Gaw N, Singh P, Chang K, Aggarwal M, Chen B, Hoebel K, Gupta S, Patel J, Gidwani M, Adebayo J. Assessing the trustworthiness of saliency maps for localizing abnormalities in medical imaging. *Radiology: Artificial Intelligence*. 2021;3(6):e200267.
27. Elton DC. Self-explaining AI as an alternative to interpretable AI. *In International conference on artificial general intelligence*. 2020;pp. 95-106.
28. Liu Y, Zupan NJ, Swearingen R, et al. Identification of barriers, facilitators and system-based implementation strategies to increase teleophthalmology use for diabetic eye screening in a rural US primary care clinic: a qualitative study. *BMJ open* 2019;9(2):e022594.
29. Piyasena MM, Murthy GV, Yip JL, et al. Systematic review on barriers and enablers for access to diabetic retinopathy screening services in different income settings. *PLoS one* 2019;14(4):e0198979.
30. De Carvalho AB, Ware SL, Belcher T, et al. Evaluation of multi-level barriers and facilitators in a large diabetic retinopathy screening program in federally qualified health centers: a qualitative study. *Implement Sci Commun* 2021;2(1):1-3.
31. Han JED, Liu X, Bunce C, et al. Teleophthalmology enabled and Artificial Intelligence ready referral pathway for community optometry referrals of retinal disease (HERMES): A cluster randomised superiority trial with a linked observational diagnostic accuracy study protocol. *BMJ Open* (forthcoming)
32. Denscombe M. *The Good Research Guide: For Small-Scale Social Research Projects*. Third edition. Maidenhead: McGraw-Hill Education 2007

- 1  
2  
3 616  
4 617 33. Patton, MQ. Qualitative evaluation and research methods. Third edition. London: Sage 2002  
5 618  
6 619 34. Hennink MM, Kaiser BN, Marconi VC. Code saturation versus meaning saturation: how many interviews  
7 620 are enough?. *Qual Health Res* 2017;27(4):591-608.  
8 621  
9 622 35. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical  
10 623 Research Council guidance. *Bmj* 2008;337.  
11 624  
12 625 36. Grol RP, Bosch MC, Hulscher ME, et al. Planning and studying improvement in patient care: the use of  
13 626 theoretical perspectives. *The Milbank Quarterly* 2007;85(1):93-138.  
14 627  
15 628 37. de Wet C, Bowie P, O'Donnell CA. Facilitators and barriers to safer care in Scottish general practice: a  
16 629 qualitative study of the implementation of the trigger review method using normalisation process theory. *BMJ*  
17 630 *open* 2019;9(9):e02991  
18 631  
19 632 38. May C, Finch T. Implementing, embedding, and integrating practices: an outline of normalization process  
20 633 theory. *Sociology* 2009;43(3):535-54.  
21 634  
22 635 39. Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating  
23 636 and implementing complex interventions. *BMC Med* 2010;8(1):1-1  
24 637  
25 638 40. May CR, Mair F, Finch T, et al. Development of a theory of implementation and integration: Normalization  
26 639 Process Theory. *Implement Sci* 2009 Dec;4(1):1-9.  
27 640  
28 641 41. May CR, Cummings A, Girling M, et al. Using normalization process theory in feasibility studies and  
29 642 process evaluations of complex healthcare interventions: a systematic review. *Implement Sci* 2018;13(1):1-27.  
30 643  
31 644 42. McCrorie C, Benn J, Johnson OA, et al. Staff expectations for the implementation of an electronic health  
32 645 record system: a qualitative study using normalisation process theory. *BMC Med Inform Decis Mak*  
33 646 2019;19(1):1-4.  
34 647  
35 648 43. McEvoy R, Ballini L, Maltoni S, et al. A qualitative systematic review of studies using the normalization  
36 649 process theory to research implementation processes. *Implement Sci* 2014;9(1):1-3.  
37 650  
38 651 44. Bouamrane MM, Mair FS. A study of general practitioners' perspectives on electronic medical records  
39 652 systems in NHS Scotland. *BMC Med Inform Decis Mak* 2013;13(1):1-2.  
40 653  
41 654 45. O'connor S, Hanlon P, O'donnell CA, et al. Understanding factors affecting patient and public engagement  
42 655 and recruitment to digital health interventions: a systematic review of qualitative studies. *BMC Med Inform*  
43 656 *Decis Mak* 2016;16(1):1-5.  
44 657  
45 658 46. Holtzblatt, K, Beyer H. Contextual Design. In: Soegaard, Mads and Dam, Rikke Friis (eds.). The  
46 659 Encyclopedia of Human-Computer Interaction. *The Interaction Design Foundation* 2013  
47 660 [http://www.interaction-design.org/encyclopedia/contextual\\_design.html](http://www.interaction-design.org/encyclopedia/contextual_design.html) (accessed 16th of December 2021)  
48 661  
49 662 47. Blandford A, Furniss D, Makri S. Qualitative HCI research: Going behind the scenes. *Synthesis lectures on*  
50 663 *human-centered informatics* 2016 Apr 7;9(1):1-15.  
51 664  
52 665 48. Blandford A. Semi-structured qualitative studies. *Interaction Design Foundation* 2013  
53 666 [https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-](https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/semi-structured-qualitative-studies)  
54 667 [ed/semi-structured-qualitative-studies](https://www.interaction-design.org/literature/book/the-encyclopedia-of-human-computer-interaction-2nd-ed/semi-structured-qualitative-studies) (accessed 16th of December 2021)  
55 668  
56 669 49. Hoffman RR, Crandall B, Shadbolt N. Use of the critical decision method to elicit expert knowledge: A case  
57 670 study in the methodology of cognitive task analysis. *Human factors* 1998 Jun;40(2):254-76.  
58 671  
59 672 50. Blandford A, Wong BW. Situation awareness in emergency medical dispatch. *Int J Hum Comput Stud*  
60 673 2004;61(4):421-52.  
61 674

- 1  
2  
3 675 51. Ericsson KA. Protocol analysis and expert thought: Concurrent verbalizations of thinking during experts'  
4 676 performance on representative tasks. *The Cambridge handbook of expertise and expert performance* 2006;223-  
5 677 241  
6 678  
7 679 52. Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3(2):77-101.  
8 680  
9 681 53. Orlikowski WJ. Knowing in practice: Enacting a collective capability in distributed organizing.  
10 682 *Organization science* 2002;13(3):249-73.  
11 683  
12 684  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46  
47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60

SRQR guidelines\*—recommended items to be included in reports of qualitative studies

	<b>Item No.</b>	<b>Recommendation</b>	<b>Page No.</b>
<b>Title and abstract</b>			
Title	S1	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	The type of the study is included in the title (see the title on page 1)
Abstract	S2	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	Key elements of the abstract as recommended by BMJ open is included in the abstract (see page 1-2)
<b>Introduction</b>			
Problem formulation	S3	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	See page 2-5
Objectives	S4	Purpose or research question	See page 5-6
<b>Methods</b>			
Qualitative approach and research paradigm	S5	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended	See page 6 on details of the design of the qualitative study. See page 9-10 on the theory informing the data collection and analysis
Researcher characteristics and reflexivity	S6	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	This item will be included in future research articles that report results/findings and the potential influence of the researchers' characteristics on data collection and interpretation of the findings.

			A reflective diary will be maintained during the research to aid with this.
Context	S7	Setting/site and salient contextual factors	See page 6
Sampling strategy	S8	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation)	Details on the participants' selection criteria and how they will be selected can be found in Participant Selection section (see page 7-9)
Ethical issues pertaining to human subjects	S9	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Details on ethical approvals and other ethical considerations can be found in Ethics and Dissemination section (see page 15)
Data collection methods	S10	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings	Details on methods of data collection can be found in Data Collection and Methods section (see page 9-13)
Data collection instruments and technologies	S11	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Details on the topic guides that will be used can be found on page 12
Units of study	S12	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Details on the proposed sample can be found in the Sampling subsection on page 7-8
Data processing	S13	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Details on data management can be viewed in the Ethics and Dissemination section (see page 15)

Data analysis	S14	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach	Details on data analysis can be found in the Data Analysis subsection (see page 13-14)
Techniques to enhance trustworthiness	S15	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation)	Data analysis will be conducted by multiple coders/researchers to increase the credibility of the data analysis. Researchers will meet regularly to discuss the coding strategy, analysis and preliminary findings, see the Data Analysis section on 13-14 for more details
<b>Results/findings</b>			
Synthesis and interpretation	S16	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	N/A
Links to empirical data	S17	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	N/A
<b>Discussion</b>			
Integration with prior work, implications, transferability, and contribution(s) to the field	S18	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	N/A
Limitations	S19	Trustworthiness and limitations of findings	N/A
<b>Other</b>			

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28  
29  
30  
31  
32  
33  
34  
35  
36  
37  
38  
39  
40  
41  
42  
43  
44  
45  
46

Conflicts of interest	S20	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	A conflict-of-interest statement is included on page 16
Funding	S21	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	A funding statement is included on page 15

\*Recommended by the EQUATOR NETWORK <https://www.equator-network.org/reporting-guidelines/srq/>

For peer review only