ISRCTN16038063 https://doi.org/10.1186/ISRCTN16038063

An evaluation of Ufonia's conversational agent Dora for cataract surgery follow-up

Submission date 08/11/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 11/01/2022	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/07/2024	**Condition category** Surgery	[_] Individual participant data

Plain English summary of protocol

Background and study aims
This project will apply AI technology to meet the gap between increasing demand and the limited capacity of high-volume healthcare services. Ufonia proposes to replace routine clinical follow-up with Dora - a natural-language AI assistant delivered via a regular telephone call. The project will develop evidence that will support the safe deployment of Ufonia's automated telemedicine platform to deliver calls to cataract surgery patients at two large NHS hospital trusts.

Who can participate?
Patients aged 18 years and over who are listed for routine cataract surgery at either Imperial or Oxford NHS Trusts

What does the study involve?
The Dora call doesn't require patients to download any application, be provided with any device or receive any training. They simply receive a call and have a conversation just as they would have done with a human clinician, on top of the care they would receive if not participating in the study. All participants will also be asked to complete a short survey about their experience, and a small group of participants will be randomly selected for an interview to discuss their experience in more depth.

What are the possible benefits and risks of participating?
This safety check is additional to the usual standard of care at the two sites where the study is being conducted. The process will be overseen by a clinician and the system is designed to provide a thorough assessment every time. This study will also benefit future patients through a more convenient follow-up service. Potential disadvantages are that this is a new system so has not been demonstrated to be effective - this is why the system is currently overseen by a clinician.

Where is the study run from?
Oxford University Hospitals and Imperial College Healthcare NHS Trusts (UK)

When is the study starting and how long is it expected to run for?
March 2020 to March 2022

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Dr Eduardo Normando, Chief Investigator (e.normando@imperial.ac.uk)
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Contact information

Type(s)
Scientific

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
297548

ClinicalTrials.gov number
NCT05213390

Secondary identifying numbers
IRAS 297548, CPMS 49658

Study information

Scientific Title
Autonomous telemedicine - cataract surgery follow-up at two NHS trusts

Study objectives
An autonomous conversational agent can identify which patients need clinical follow up after a cataract operation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, Research Ethics Committee (REC) London Centre (2 Redman Place, HRA, E20 1JQ; +44 (0)2071048029, chelsea.rec@hra.nhs.uk), REC ref: 21/PR/0767

Study design
Mixed methods non-randomized study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant infromation sheet

Health condition(s) or problem(s) studied

Clinical follow-up of postoperative symptoms in patients who have undergone routine cataract surgery

Interventions
The autonomous conversational agent (Dora) is configured to deliver calls through a telephone connection as a real-time, stand-alone system: the operator inputs individual patient details to initiate the call and completes a summary in the electronic health record (EHR) afterwards. The entire conversation will be supervised by a clinician who can interrupt if Dora does not collect sufficient information from the patient. All patients who participate in the study will receive the Dora call (one arm).

One of the two clinical trial sites (Imperial) sees all of their postoperative cataract patients at a face-to-face out-patient appointment with an ophthalmologist or specialist nurse. The Dora call will be conducted shortly before this appointment, so the results of the Dora call can be compared with the face-to-face appointment to assess whether any complications were correctly identified and if the management plan remains the same. The Oxford University Hospitals NHS Trust does not conduct routine face-to-face follow-up appointments, so there is no direct comparator for that site. For patients at both clinical sites, however, health records will be examined 90 days after the call to determine whether the patient presented to an eye clinic with any complications from surgery, to enable an assessment of DORA's safety.

Intervention Type
Other

Primary outcome measure
Agreement is measured by inter-rater reliability (the degree of agreement between DORA and the clinician on their assessments of the individual symptoms and the management plan) and whether or not the clinician had to interrupt the call to ask clarifying questions. Measured at 0 days.

Secondary outcome measures
1. Clinical safety measured using complications identified from patients' electronic health records up to 90 days following cataract surgery, congruence between complications identified and management planned in DORA call and face-to-face follow up within a couple of days of the Dora call (Imperial), and comparison to data from patients attending eye casualty (Oxford) at 0 days
2. Feasibility measured by calculating the proportion of autonomous calls that were completed without needing any intervention from the supervising clinician and reviewing the clinician-reported reasons for asking clarifying questions during the call at 7 days
3. Usability measured by the System Usability Scale and the Telehealth Usability Scale, delivered to patients via online or telephone survey within 2 days of the Dora call
4. Usability, acceptability, satisfaction, and appropriateness measured by semi-structured interviews with a small, stratified random sample of participants, conducted through the intervention period
5. Cost-effectiveness measured by a comparison of the costs of implementing Dora and the costs of the usual standard of care over the duration of the intervention delivery period

Overall study start date
01/03/2020

Completion date
24/03/2022

Eligibility

Key inclusion criteria
1. Willing and able to provide informed consent
2. Aged 18 years or older
3. On the waiting list for routine cataract surgery. Cataract surgery as part of a combined procedure with other ocular surgery will not be included
4. No history or presence of significant ocular comorbidities that would be expected to alter the risks of cataract surgery or normal post-operative follow-up schedule. Note that significant ocular comorbidities do not include stable, chronic, or inactive ocular conditions such as amblyopia, drop-controlled stable glaucoma or ocular hypertension, previous squint surgery, inactive macular pathology, previous refractive surgery, or previous vitreoretinal surgery with stable retina

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
591

Total final enrolment
225

Key exclusion criteria
1. Individuals with any condition that could preclude the ability to comply with the study or follow-up procedures
2. Presence of ocular or systemic uncontrolled disease (unless deemed not clinically significant by the Investigator and Sponsor)
3. Involved in current research related to this technology or been involved in related research to this technology prior to recruitment
4. Cognitive difficulties, hearing impairment or non-English speakers
5. History of current or severe, unstable or uncontrolled systemic disease (unless deemed not clinically significant by the Investigator and Sponsor)

Date of first enrolment
17/09/2021

Date of final enrolment

31/01/2022

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Healthcare NHS Trust
Western Eye Hospital
153-173 Marylebone Rd
London
United Kingdom
NW1 5QH

Study participating centre
Oxford University Hospitals NHS Foundation Trust
Oxford Eye Hospital
John Radcliffe Hospital
Headley Way
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Sponsor type
University/education

Website
http://www.imperial.edu/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The project's two clinical sites are leading medical centres with strong reputations for high quality patient care. They have large teams of clinicians, with extensive professional networks and training programmes that involve junior staff from across the globe. These factors mean that their participation in this project will ensure its outputs are communicated to a wide audience.

The project’s academic partners are world renowned institutions with a track record of delivery and publication of high-quality research. Senior clinical academics will ensure the project is conducted robustly and even at this early stage the outputs are presented and published in high impact journals.

Intention to publish date
01/08/2023

Individual participant data (IPD) sharing plan

Audio recordings, transcriptions, and meta-data about the calls will be securely stored in UK data centres with strict role-based access control. The transcription service will only have reference to the unique IDs and the audio recording will be reviewed by the PI to remove any identifying information before being shared. Patient identifiable data will not be sold to any other party and will not be shared with any organisation unless they are a partner in the study and have an appropriate information sharing agreement in place. Records of consent will be kept for 3 years after the publication of final study results, but no other personally identifiable information will be stored beyond the end of the study.

IPD sharing plan summary

Stored in non-publicly available repository, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0		08/11/2021	No	Yes
Protocol file	version 1.0	17/05/2021	08/11/2021	No	No
HRA research summary			28/06/2023	No	No
Basic results			22/11/2023	No	No
Results article		03/07/2024	29/07/2024	Yes	No