ISRCTN85921622 https://doi.org/10.1186/ISRCTN85921622

A small-scale study to investigate whether it is possible to conduct a large study comparing digitally printed artificial eyes to hand-painted eyes

Submission date
15/06/2021

Recruitment status
No longer recruiting

Registration date
17/06/2021

Overall study status
Completed

Last Edited
04/11/2025

Condition category
Eye Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
After operations to remove a diseased or blind, painful eye many patients suffer from anxiety and depression. The physical and mental trauma of losing an eye is challenging. Returning to normal family, social and work life can be difficult. Artificial eyes have been hand-painted at the National Artificial Eye Service since 1948. Each eye can take over 6 weeks to make. However, advances in technology mean that alternatives are now possible. One such method involves taking a digital photograph of the unaffected eye and printing the image onto special adhesive paper. Although the digitally printed eye appears to be more life-like, there is no research evidence to show whether patients prefer it or whether this process can be replicated on a larger scale and save the NHS money. Researchers want to do a large study comparing digitally-printed artificial eyes with handpainted artificial eyes, but first they need to run a smaller study to see if the larger study can be done. They will look at whether they can get people to take part, collect information about their health, and ask what they liked and did not like about taking part.

Who can participate?
Patients aged 18 years or older who have worn an artificial eye for more than 12 months and require a replacement artificial eye

What does the study involve?
Participants will be asked to attend the Leeds Artificial Eye Service (LAES) to be seen by a Prosthetist who will check eligibility (Appointment 1). Participants will be asked to fill in a questionnaire (which should take about 30 minutes), their eye socket will be checked and they will be asked some questions about their current artificial eye.
After the paperwork is completed, participants will be randomly allocated (similar to flipping a coin) to receive either the hand-painted or a digitally-printed artificial eye first. The clinical staff have no control over this. The Prosthetist will start then the process of manufacturing whichever eye the participant has been allocated to receive first. The participant will then return to clinic

after about 2-3 weeks for this process to be finished (Appointment 2) and for the eye to be fitted.
After wearing it for 2 weeks, participants will return to clinic to complete another questionnaire, have a photograph taken of their eyes and the Prosthetist will start manufacturing the second eye (Appointment 3). Participants will then return to clinic about 2 - 3 weeks later for this process to be finished and the second eye to be fitted (Appointment 4). After 2 weeks, participants will return to clinic to complete a final questionnaire and another photograph of their eyes (Appointment 5). They may also be asked to take part in an interview about their experiences.

What are the possible benefits and risks of participating?
Participants will be contributing to knowledge about what patients think about digitally-printed artificial eyes and hand-painted artificial eyes. This knowledge will be used to inform a much larger study and help guide practice for future patients. Participants will be able to keep both artificial eyes manufactured for them. They may find that they prefer one of the eyes which may improve how they feel and their quality of life.
There are minor risks associated with using the new artificial eyes, which would be the same as for using their current artificial eye (e.g. infection, irritation of the eye socket, inflammation, pain). Being in the study means that participants will be closely monitored and any complications would be identified early on. All participants involved in the study will experience some additional burden by having to complete some questionnaires and some additional clinic visits. Being interviewed by the researcher will take up some time. In addition, they might be asked questions about certain topics which are sensitive or may upset them. Participants can refuse to answer any questions which they feel uncomfortable with and can stop the interview at any time.

Where is the study run from?
Leeds Teaching Hospitals NHS Trust (UK)

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

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

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
294610

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 49292, IRAS 294610, NIHR201559

Study information

Scientific Title
A novel, high-definition PERSONALised artificial EYE Service (PERSONAL-EYE-S): a cross-over, randomised feasibility study of digitally printed versus hand-painted artificial eyes in adults

Acronym
PERSONAL-EYE-S

Study objectives
This study aims to determine the feasibility of conducting a randomised controlled trial (RCT) of the effectiveness and cost-effectiveness of digitally printed artificial eyes compared to hand-painted eyes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/06/2021, North West - Haydock Research Ethics Committee (3rd Floor - Barlow House, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)2071048211; haydock.rec@hra.nhs.uk), REC ref: 21/NW/0150

Study design
Randomized; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Artificial eyes

Interventions
PERSONAL-EYE-S is a cross-over randomised controlled, open feasibility study. The researchers will randomise people with a longstanding artificial eye who require a replacement artificial eye to:
A: receive a digitally printed artificial eye first (intervention), followed by a hand-painted artificial eye (control)
B: receive a hand-painted artificial eye first, followed by a digitally printed artificial eye.
The study has a 3-month recruitment period. Follow-up will be conducted after the participant has used each type of eye. Participants will wear each eye for 2 weeks before follow-up.

Sample size:
The proposed research is a feasibility study and therefore does not have a primary outcome measure to inform a sample size calculation. One of the aims of this cross-over trial is to estimate the within-subject standard deviation for each outcome measure, in order to inform the sample size calculation for a future study. It has been recommended in the pilot and feasibility trial literature that a sample size of between 24 and 70 is required for standard deviations to be reliably estimated. The researchers aim to recruit 35 eligible patients, which, assuming a 15% attrition rate, would allow for 30 patients in the final analysis.

Recruitment and randomisation:
Prospective participants will be identified via three main methods: during a routine ophthalmology clinic visit, via screening of the patient database by the ophthalmology clinic, or via notification placed on the websites of two relevant organisations (Blind Veterans UK, and Royal National Institute of Blind People).

Participants will be given an information pack including a consent to contact form. If they return the consent to contact form, they will be phoned and offered an appointment to attend clinic for a final eligibility assessment by the Prosthetist or member of the clinical team (e.g. to ensure socket suitability, no infections etc) aided by completion of a screening form.

The potential participant will be allowed as much time as they wish to consider the information, and given the opportunity to ask questions to decide whether they will participate in the study.

During this process, patients interested in participating will be asked to approach a close contact with the intention of them participating as well. A specific information sheet, consent form and consent to contact form will be provided for these close contacts. For the purposes of this study, a 'close contact' is defined as someone who can give their opinion of the participant's artificial eye, for example, a spouse, family member, or close friend. If a patient does not have a close contact to approach, or does not want to approach someone, their eligibility to participate in the study will not be affected.

Close contacts, if they consent, will be asked to participate in an interview to explore how each artificial eye impacts patients' quality of life and wellbeing. Where possible, close contacts will be interviewed separately from the participant to allow them to freely express their opinions

Outcomes:
Participants will be asked to complete questionnaires in clinic visits at three time points: i) at baseline, ii) after wearing their first allocated eye, and iii) after wearing their second allocated eye.

At baseline, data will be collected related to demographics and contact details of the participant and their GP, past medical and artificial eye history, medications, family history relating to eyes, and eye socket health. At each time point, participants will be asked to fill out the following questionnaires:
• Short Form -36 (SF-36)
• EuroQol-5 dimensions-5 levels (EQ-5D-5L)
• Vision Quality of Life Index (VisQoL)
• Connor-Davidson Resilience Scale-10 (CD-RISC-10)
• Derriford Appearance Scale short form (DAS24)
• Participant satisfaction
• Resource use
Close contacts at baseline will be asked for their contact details.

A subset of patients, and their close contacts, will be asked to participate in interviews to gain a more in-depth understanding of the acceptability of the study design and procedures, as well as how each artificial eye impacts patients' quality of life and wellbeing.

In addition, a small number of staff will be interviewed to explore healthcare professionals' opinion on the different artificial eyes, including views on delivery times and patient satisfaction. These interviews can be conducted at any time during the later parts of the study.

Feasibility outcomes include the number of patients screened, eligible, consenting and randomised, and reasons for ineligibility and non-consent given where possible. All participant and close contact data, along with questionnaire return rates and adverse event data, will be summarised overall and by randomised group, and treatment period as appropriate.

Continuous variables will be summarised descriptively using the mean, standard deviation, median, minimum and maximum. Categorical data will be summarised as counts and percentages. As this is a feasibility trial, statistical hypothesis testing for effectiveness will not be carried out. No interim analyses will be carried out.

Project duration:
The project will run for a total of 18 months. The recruitment period will be 3 months long (approximately months 5-7) with participants' time in the study varying from 8 to 24 weeks, depending on clinic attendance. All study data (questionnaires and interviews) should be collected by month 16.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Digitally printed artificial eye, hand-painted artificial eye

Primary outcome(s)
Feasibility outcomes relating to the acceptability of the trial intervention and procedures, resource use; Timepoint(s): After each intervention:
1. Recruitment rate is defined as the proportion of eligible participants who are randomised onto the trial. Data will be collected on:
1.1. Number of eligible patients
1.2. Proportion of eligible patients approached for consent
1.3. Proportion of eligible patients not approached for consent and reasons why
1.4. Proportion of patients approached who provide consent
1.5. Proportion of patients approached who do not provide consent and reasons why
Feasibility will be assessed based on whether the study consent/retention rates and proposed sample size indicates recruitment for the full-scale RCT is plausible within a reasonable time frame
2. Attrition rate is defined as the proportion of patients dropping out between randomisation and follow-up. Data will be collected on:
2.1. The proportion of randomised participants withdrawing from the study
2.2. The proportion of randomised participants lost to follow-up
2.3. Where possible, reasons for withdrawal from the study
Feasibility will be assessed based on the attrition rate, where an attrition rate of <=15% is feasible as is, 20-25% is feasible with additional measures in a full trial, and >25% is infeasible.
3. Missing outcome data will be used to assess the feasibility of gathering patient-reported outcome measures and other outcome measures at baseline and follow-up. Measures with over 10% missing data may be modified/replaced prior to the main trial.

Key secondary outcome(s))
Measured at baseline, after wearing the first allocated eye (T1 - clinic visit 3) and after wearing the second allocated eye (T2 - clinic visit 5):
1. Health-related quality of life and utility data measured by:
1.1. Short-form 36
1.2. The EuroQol-5 dimensions-5 levels (EQ-5D-5L)
1.3. Impact of vision loss on quality of life: Vision Quality of Life Index (VisQol)

2. Resilience measured by Connor-Davidson Resilience Scale-10 (CD-RISC-10)
3. Distress and difficulties in living with a disfigurement measured by Derriford Appearance Scale short form (DAS24)
4. Participant satisfaction measured using a brief, bespoke study-specific questionnaire
5. Resource use data measured by a participant-reported bespoke questionnaire
6. Feasibility data collected by qualitative methods which include interviews with participants and close contacts. This will be conducted only after participants have completed both interventions

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Longstanding artificial eye user (at least 12 months post-operation)
3. Requires a replacement artificial eye (can be due to a variety of reasons such as wear and tear; damage; loss, change in fitting, clinician opinion; unhappy with their current artificial eye)
4. Be able to self-complete the English language outcome measure tools (or can complete with assistance)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
35

Key exclusion criteria
1. Ongoing clinical concerns with respect to their artificial eye use, such as poor eye socket healing, infections, extrusion, dehiscence
2. Lacks capacity or willingness to provide consent to participate in the study
3. Pregnant women or persons currently shielding (due to ongoing COVID-19 pandemic, to avoid unnecessary visits to the clinic)
4. Is currently participating in another study evaluating their artificial eye
5. Has been previously recruited for this study
6. Has bilateral artificial eyes
7. Is deemed to be not clinically appropriate to take part in the study (at clinician discretion)

Date of first enrolment
01/10/2021

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
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Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR201559

Results and Publications

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/08/2024	06/08/2024	Yes	No
Protocol article		15/03/2023	17/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Health economic findings	03/11/2025	04/11/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes