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IMPRESSeD: IMproving facial PRosthesis construction with contactlESs Scanning and Digital workflow

Submission date	Recruitment status	[X] Prospectively registered
19/02/2021	No longer recruiting	[X] Protocol
Registration date	Overall study status	[ ] Statistical analysis plan
08/06/2021	Completed	[ ] Results
Last Edited	Condition category	[ ] Individual participant data
04/07/2023	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Some people may be missing a facial part e.g. an eye or nose. This can be due to a number of reasons including trauma or surgery for head and neck cancer. This affects a patient's appearance, function, and wellbeing. The missing part can be replaced with a bespoke removable silicone facial prosthesis. Patients attend multiple hospital visits so that highly trained healthcare staff can recreate the missing part. There is an ongoing patient and healthcare burden as prostheses are replaced every 6-24 months.

The current standard of making facial prostheses has significant drawbacks. Patient and public involvement contributors selected three priority improvement areas:
1. Get rid of uncomfortable/painful facial moulds (impressions) used to make prostheses
2. More closely match the way they looked before surgery
3. Receive their prosthesis sooner after surgery

Digital technology could change the way prostheses are made. Facial scanning could offer a contactless and comfortable alternative to impressions, prostheses could be designed using computers to recreate the missing part, and the process could be made quicker using 3D printing technology.

This feasibility study aims to assess the possibility of conducting a future full-scale trial that will compare patient preference, costs, and benefits of using digital technology to make facial prostheses compared with the current standard of care.

Who can participate?
Adult patients across two NHS hospitals who require a replacement eye or nose facial prosthesis

What does the study involve?
Each patient will receive two new prostheses which will be made at the same time (one made digitally and one made by current standards). Patients will not know how each prosthesis was made. Patients will be reviewed four weeks after receiving each prosthesis. They will be asked

which prosthesis they prefer. Information will be collected on costs and benefits through surveys.

What are the possible benefits and risks of participating?
Research like this helps to continually improve the treatments and care provided to patients. By taking part, it will help us to design a larger study that will find out if making prostheses by hand or using digital technology is better for patients and healthcare services. In addition, if the healthcare team is happy with the performance of both facial prostheses, participants will be able to keep both prostheses at the end of the study. There are no extra risks involved with having the prostheses made compared with normal care. Appointments may take longer than normal and participants will be asked to attend 2 additional review visits above normal care. Participants will be recompensed for reasonable direct travel expenses incurred during these 2 additional review visits (such as train fares or car parking) up to a limit as outlined in the Participant Information Sheet.

Where is the study run from?
The University of Leeds (UK)

When is the study starting and how long is it expected to run for?
October 2019 to September 2023

Who is funding the study?
The National Institute for Health Research (UK) and funding for a digital scanner and colour matching equipment from Leeds Hospitals Charity (UK)

Who is the main contact?
Miss Rachael Jablonski
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
283502

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 48262, IRAS 283502

Study information

Scientific Title
IMPRESSeD: IMproving facial PRosthesis construction with contactlESs Scanning and Digital workflow. A feasibility cross-over randomised controlled trial of digital versus conventional manufacture for facial prostheses.

Acronym
IMPRESSeD

Study objectives
Is it feasible to conduct a definitive randomised controlled trial to evaluate the clinical and cost effectiveness of digitally manufactured facial prostheses versus conventionally manufactured facial prostheses (current standard of care) in patients with orbital and nasal facial defects? The study aims to assess the possibility of conducting a future full-scale trial that will compare patient preference, costs and benefits of using digital technology to make facial prostheses compared with current standard of care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/03/2021, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0) 2071048103; leedseast.rec@hra.nhs.uk), ref: 21/YH/0028

Study design
Feasibility cross over randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Facial defect following surgery for head or neck cancer. The trial management group may also widen participation to participants with facial trauma.

Interventions
The intervention is a facial prosthesis produced through digital manufacturing. The manufacturing process will involve 3D facial scanning, computer aided design, and computer aided manufacturing. The control is a facial prosthesis produced through conventional manufacturing (current standard of care). This will involve a facial impression, hand carving a wax pattern and traditional manufacturing techniques. All trial participants will receive 2 new facial prostheses in a sequential manner. Participants will be randomised remotely on the order of receiving the intervention and control prostheses using simple randomisation with a 1:1 allocation ratio.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
-

Primary outcome measure
1. Eligibility rate measured as the proportion of people that were approached who were eligible for participation at baseline
2. Recruitment rate measured as the proportion of people that were invited that were successfully recruited at baseline
3. Conversion rate measured as the proportion of those who were eligible that consented to participate at baseline
4. Attrition rate measured as the proportion of those that dropped out of the trial at 4-week review following delivery of the second prosthesis

Secondary outcome measures
Current secondary outcome measures as of 23/06/2022:

1. Participant preference measured using a question at the final review visit (4-week review following delivery of the second prosthesis)
2. Condition-specific quality of life measured using the Toronto Outcome Measure for Craniofacial Prosthetics (TOMCP-27) at baseline, 4-week review following delivery of the first prosthesis, and 4-week review following delivery of the second prosthesis
3. Quality of life measured using the Short Form 12 item version 2 (SF-12v2) and EQ-5D-5L at

baseline, 4-week review following delivery of the first prosthesis, and 4-week review following delivery of the second prosthesis
4. Resource use measured using questionnaires during all clinical visits and laboratory stages
5. Qualitative substudy (semi-structured interviews)

Previous secondary outcome measures:

1. Participant preference measured using a question at the final review visit (4-week review following delivery of the second prosthesis)
2. Condition-specific quality of life measured using the Toronto Outcome Measure for Craniofacial Prosthetics (TOMCP-27) at baseline, 4-week review following delivery of the first prosthesis, and 4-week review following delivery of the second prosthesis
3. Quality of life measured using the Short Form 12 item version 2 (SF-12v2) at baseline, 4-week review following delivery of the first prosthesis, and 4-week review following delivery of the second prosthesis
4. Resource use measured using questionnaires during all clinical visits and laboratory stages

Overall study start date
01/10/2019

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Acquired orbital or nasal facial defects
2. Require a replacement orbital or nasal facial prosthesis
3. Capable of giving informed consent
4. Available for follow-up
5. Aged ≥16 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 30; UK Sample Size: 30

Key exclusion criteria
1. Receiving active cancer therapy or have plans for major reconstructive surgery
2. Have not received a removable facial prosthesis previously

3. Facial defects due to an underlying congenital aetiology
4. Known hypersensitivity to the materials used in the research
5. Pre-existing skin conditions that require intervention and prevent the delivery of a new prosthesis
6. Unable to give informed consent

Date of first enrolment
01/12/2021

Date of final enrolment
31/01/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Teaching Hospitals NHS Trust
St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
4th Floor, Gassiot House
St. Thomas's Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
University of Leeds

Sponsor details

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Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

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

Funder Name
Leeds Hospitals Charity

Results and Publications

Publication and dissemination plan
Planned conference presentation by 30/09/2024. Planned publication in a high-impact peer reviewed journal by 30/09/2024. Reports for research funders based on funder deadlines.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (Research Data Leeds; https://archive.researchdata.leeds.ac.uk/) for a period of 10 years unless there is a legal or ethical reason for destruction. The data will be available upon request after an embargo period (after the trial manuscripts have been published). Anonymised participant level data will only be shared for participants who have consented for their data to be used in future research or shared anonymously with other researchers. Data sharing agreements will be agreed before data is released. This will outline the purposes for which the data is to be released, conditions under which it may be used in relation to obligations for ethical approval, confidentiality, data security, archiving/destruction, onward transfer and acknowledgements.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol article		03/07/2023	04/07/2023	Yes	No