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Clinical trial to evaluate 3D-printed dentures

Submission date
17/09/2021

Recruitment status
No longer recruiting

Registration date
22/07/2022

Overall study status
Completed

Last Edited
05/03/2024

Condition category
Oral Health

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There is a new way to manufacture dentures using a technology called 3D printing. This technology may be more accurate and consistent than traditional denture manufacture. It is hoped that this new method can be used to manufacture better fitting dentures. To find out if 3D printing the dentures is better researchers are running clinical trials. The aim of this study is to determine if 3D-printed dentures are better for patients than traditional dentures and to find out the study participants' opinion of the new dentures.

Who can participate?
NHS patients aged over 60 years who have no natural teeth of their own and need new dentures

What does the study involve?
Once the participant consents to the study, the dentists in the research team will make two sets of dentures for them. One set of dentures will be manufactured in the normal way and the other set of dentures will be manufactured by the new method using 3D printing technology. The participants will need to approve the appearance before the dentures go through the final manufacturing process. Once the dentures have been made, participants will be given both dentures for 2 weeks along with a diary containing instructions as to which dentures to wear on which days. After these 2 weeks, participants will be asked for their opinion of both sets of dentures and specific questions about the fit, comfort and chewing ability whilst wearing each denture. Next, they will be asked to bring both sets of dentures back to the dentist, and will be given one set back for a period of 8 weeks. After 8 weeks, participants will return to the clinic to swap the denture for the other set, which they will wear for the next 8 weeks. During these two 8-week periods, participants will be able to return to see a dentist as often as they need to have any adjustments made that are necessary. Finally, participants will return to the clinic and be given both sets of dentures for a further 2 weeks. After these 2 weeks, they will be asked again for their opinion on the dentures and specific questions about the fit, comfort and chewing ability. The order in which participants will wear the dentures manufactured in the normal way and 3D-printed dentures will be decided by a process called randomisation. This is so that neither the participant nor the research dentist and nurse know which denture is the 3D-printed denture.

What are the possible benefits and risks of participating?
Participants will be given two sets of dentures to keep and wear. Their participation will help in

developing an evidence-based procedure for the benefit of people who need new dentures. To construct the dentures, dentists usually take a minimum of 5 visits. In this study participants are asked to return for an additional four visits to tell the researchers about their dentures. There are no anticipated disadvantages of taking part in this study other than the potential inconvenience of four additional visits.

Where is the study run from?
1. Leeds Dental Institute (LDI) (UK)
2. University Dental Hospital of Manchester (UK)
3. Birmingham Dental Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2020 to January 2023

Who is funding the study?
The Dunhill Medical Trust (UK)

Who is the main contact?
1. Mrs Gillian Dukanovic, G.Dukanovic@leeds.ac.uk
2. Ms Catherine Porter, C.E.Porter@leeds.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
246584

Protocol serial number
CPMS 46375, Grant Codes: RPGF1802/33, IRAS 246584

Study information

Scientific Title
A pilot randomised controlled clinical trial of 3D-printed dentures

Study objectives
This pilot randomized controlled trial is indicated to enable a calculation of the sample size that would be required to detect clinically significant differences between the traditional method of manufacturing complete dentures and a new manufacturing process by 3D printing.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/10/2020, South West – Cornwall & Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)2071048071; cornwallandplymouth.rec@hra.nhs.uk), ref: 20/SW/0123

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preference for type of dentures

Interventions
In conjunction with their integrated PPI group, the research team developed the “IMPROVDENT” RCT protocol for the patient-centred assessment of two sets of dentures. The PPI group consists of patients who are denture wearers. Two previous trials have used the “IMPROVDENT” protocol in ethically approved RCTs. The first was funded by Dunhill (DMT Grant R19/0506). The second RCT was funded by an NIHR grant (PB-PG-0408-16300). The protocol has been recognised as internationally excellent by the award of the Senior Clinical Hatton Prize of the International Association of Dental Research (IADR). The protocol has a track record; it has proved sufficiently sensitive and specific to detect clinically and statistically significant differences in patient-centred RCTs of dentures. In order to be able to calculate the sample size required for the envisaged future investigation (main RCT), this pilot RCT will use the full IMPROVDENT protocol.

A pilot, multi-centre, cross-over, double-blind, randomised, controlled clinical trial (RCT) is proposed. The NIHR provides a useful definition for both “Pilot” and “Feasibility” studies. (See: https://www.nihr.ac.uk/funding-and-support/documents/funding-for- research-studies/research-programmes/RfPB/Guidance%20Documents/Guidance_on_feasibility_studies.pdf). Under these definitions, this is a full protocol pilot study, “a version of the main study that is run in miniature”.

In order to gain the maximum input from experienced clinicians, the pilot RCT is taking place in three centres of excellence within leading UK Dental Schools (Manchester, Birmingham and Leeds). The researchers will recruit 18 participants for this study.

All the patients who have been accepted for treatment for the provision of complete dentures at the three research sites will be identified as potential participants. They may be approached and offered the opportunity to discuss the research and take part in the study.

Following informed consent they will proceed with the routine clinical stages of denture production; moving on directly to primary impressions. At this first clinical visit (CV1) primary impressions will follow the normal clinical routine. However, study participants will also be asked to fill in the validated OHIP-Edent questionnaire to assess their baseline Oral Health-Related Quality of Life.

At the next visit (CV2), the participant will have the normal definitive impressions taken using a standardised procedure. Following the definitive impression, after the participant has left the clinic, the impressions will be optically scanned to produce a 3D digital 'map' of the surface. The impressions will then be cast in dental stone in the usual way. Following the casting of the impression the resultant cast will be optically scanned to produce another map of the denture-bearing area. From these two scans (of impression and cast) a 'hybrid' file will be produced which 'fills in' discrepancies in the impression scan with patches from the model scan. This hybrid scan will be used later when printing the fitting surface of the 3D-printed dentures

At the next clinical visit (CV3) the normal routine treatment is continued. The position of the lower jaw relative to the position of the upper jaw is recorded using traditional wax 'jaw registration blocks'.

Following 'jaw registration', in the dental laboratory, two sets of conventional wax trial dentures will be produced for the participant. At the next clinical visit (CV4) the wax trial dentures will be tried in the participant's mouth. The clinical procedures to check the wax dentures will follow the normal routine and no extra research procedures will be undertaken. It is normal routine for the wax dentures to be adjusted and altered until both participant and clinician are satisfied with the dentures. When both are satisfied the wax dentures are returned to the dental laboratory for processing.

Following the routine appointment, when the participant has left the clinic, the upper surfaces of wax trial dentures will be scanned. This scan of the wax denture will be merged/combined with the hybrid scan of the fitting surface of the denture. The teeth are then digitally removed from the combined digital file and the resultant toothless file printed. Following printing, the teeth are re-attached. The resultant 3D-printed denture is returned to the clinic for fitting. The conventional denture for the participant will be produced in the traditional way and be returned to the clinic alongside the printed denture.

Before the dentures are returned to the clinic both the conventional denture and the 3D printed denture will be scanned. The scans of the fitting surface of the dentures will be compared to the scans detailed above using color-coded contour maps which highlight any distortions. In this way, for each participant, we will be able to assess the trueness of both the fitting surface and the occlusal (tooth) surface of each denture (both conventional and 3D printed). The null hypothesis for this section of the project is that there is no difference in the accuracy of production of the surfaces.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
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Primary outcome(s)
Patient's preference for the dentures measured using a participant questionnaire (non-validated) at the clinical visit which occurs 2 weeks after delivering both sets of dentures

Key secondary outcome(s))
1. Participant preference for the unadjusted dentures measured using a non-validated participant preference assessment of dentures questionnaire at visit 6
2. Participant preference after the dentures have been fully adjusted measured using a non-validated participant preference assessment of dentures questionnaire at visit 9
3. Participant assessment of comfort, stability and chewing ability of each of the dentures, before and after each adjustment period measured using a 5-point Likert assessment questionnaire (visits 6, 7, 8 & 9)
4. Oral Health-Related Quality of Life (OHRQoL) assessed using an established and validated OHIP-Edent questionnaire at the 1st impression visit and at the end of each adjustment period (visits 1, 7 & 8)

Completion date
16/01/2023

Eligibility

Key inclusion criteria
Patients who:
1. Have no natural teeth
2. Are available for follow up
3. Require replacement complete dentures
4. Are able and willing to complete the informed consent process
5. Are aged over 60 years at the time of signing the Informed Consent Form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
60 years

Sex
All

Key exclusion criteria
Patients who:
1. Have (or have had) an oral tumour
2. Require an obturator
3. Have extreme xerostomia (e.g. Sjögren's syndrome)
4. Have a denture stomatitis
5. Have known hypersensitivity to dental materials used in the research
6. Are incapable of providing written informed consent

Date of first enrolment
25/05/2021

Date of final enrolment
15/02/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Dental Institute (LDI)
Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU

Study participating centre
University Dental Hospital of Manchester
Higher Cambridge Street
Manchester
United Kingdom
M15 6FH

Study participating centre
Birmingham Dental Hospital
5 Mill Pool Way

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B5 7EG

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research organisation

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, Dunhill Medical Trust, DunhillMedical, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

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
Available on request, Published as a supplement to the results publication, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 2.0	11/09/2020	22/07/2022	No	No