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Patients' satisfaction when wearing different dentures - a pilot study

Submission date
20/02/2017

Recruitment status
No longer recruiting

Registration date
20/03/2017

Overall study status
Completed

Last Edited
21/09/2017

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Around 2.7 million adults in the UK had been reported to suffer from complete tooth loss in 2009. With the years of life expectancy increasing and a sizeable number of people who have no natural teeth, there is a demand to restore teeth (albeit with the use of a dental prosthesis) to provide an acceptable quality of life. The biting surfaces of denture teeth can have an impact on the function and comfort of these dentures. This aim of this study is to assess if denture teeth which has a shape based on natural teeth provide higher patient satisfaction compared to the current denture teeth shape being used.

Who can participate?
Generally healthy adults who have complete tooth loss and require new dentures.

What does the study involve?
Each participant has two sets of dentures made for them. One set are dentures with a classic denture teeth shape and the other set of dentures use an enhanced denture teeth shape. Each patient is asked to wear each set for a period of two months. After wearing each set of dentures, participants are asked to filled in two patient satisfaction questionnaires.

What are the possible benefits and risks of participating?
Participants benefit from receiving the treatment that they need (i.e. the need to have new dentures as their current ones are not functional). The patient would also receive an extra set of dentures to use. There are no notable risks involved with participating.

Where is the study run from?
The Royal London Dental Hospital (UK)

When is study starting and how long is it expected to run for?
June 2016 to September 2018

Who is funding the study?
Queen Mary University of London (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.05 date 25/01/2017

Study information

Scientific Title
Patients satisfaction and quality life assessment when wearing complete dentures with teeth of different anatomical designs: a randomised controlled crossover pilot study

Study objectives
The aim of this study is to assess and compare patients' satisfaction and quality of life when wearing dentures with teeth of more detailed tooth morphology with teeth copying natural tooth morphology, and whether the enhanced denture provide better comfort and chewing ability than the classic denture.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Westminster Research Ethics Committee, 06/04/2017, REC ref: 17/LO/0518

Study design
Pilot randomised controlled cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Complete tooth loss (edentulism)

Interventions
The patients will be randomised into 2 groups via a computerised block envelope process. This was done by using the website www.sealedenvelope.com . The two groups are named Group A and Group B. Group A will wear the the classic shaped dentures first for 2 months and after will wear the enhanced shaped dentures for a further 2 months. Group B will wear the enhanced shaped dentures first for 2 months and after will wear the classic shaped dentures for a further 2 months.

The treatment provided from the study is the construction of 2 complete dentures. The fabrication of these dentures involves making the first set first: taking moulds of the patients

mouths, ensuring the general outline of the denture shape is correct on a template, adding denture teeth to this template and converting this template to a definitive plastic denture. So far this is the fabrication to make the first set of dentures.

To construct the second set of dentures, a mould is taken of the first set of dentures to have a copy template for the second dentures. The teeth on the copy template is then changed and converted to a definitive plastic denture. This would produce our second set of dentures.

Patients are then provided with their first dentures as dictated by which group they have been randomised into. They will wear these dentures for two months, attending a review appointment one week into this period to ensure there are no clinical concerns. At the end of the two months, patients will be asked to fill in a patient questionnaire (Prof. Fenlon's validated questionnaire) and a quality of life questionnaire (OHIP-EDENT).

The first set of dentures is then taken away and patients are provided with the second set of dentures to wear for two months, attending a review appointment one week into this period to ensure there are no clinical concerns. At the end of the two months, patients will be asked to fill in a patient questionnaire (Prof. Fenlon's validated questionnaire) and a quality of life questionnaire (OHIP-EDENT). At this point the patient is entitled to keep both sets of dentures and the study would have ended for them.

The total duration of the study is one year and 5 months. The total time involved for each participant will be approximately 8 months.

Intervention Type
Device

Primary outcome measure
Patient satisfaction is assessed using Professor Fenlon's patient satisfaction with dentures questionnaire at the start and end of each two-month treatment period.

Secondary outcome measures
1. Quality of life is measured using the OHIP-EDENT questionnaire at the start and end of each two-month treatment period
2. Self-assessed chewing ability is measured using a questionnaire at the start and end of each two-month treatment period
3. Self-assessed aesthetics of each set of dentures is rated by patients using a questionnaire at the end of each two-month treatment period

Overall study start date
19/06/2016

Completion date
30/09/2018

Eligibility

Key inclusion criteria
1. Informed consent
2. Age 18-100 years
3. Any gender

4. Any ethnicity
5. Successful denture wearers (i.e. previous denture wearing experience – 3+ years) who need new dentures
6. No mental health issues
7. No problems of Xerostomia (dry mouth).

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Any inclusion criteria not met
2. Under 18 years
3. The shape and size of the jaw bones - Any Cawood and Atwood classification that is other than Class 2 or 3 or 4:
Class 2 = a bone shape that is well rounded and of good height but with the remnants of a socket due to tooth being recently removed
Class 3 = a bone shape that is well rounded and of good height.
Class 4 = a bone shape that is knife edged and of reasonable height.
4. Unable to consent
5. Pregnant patients.
6. Patients unable to attend easily due to locality or occupation limitations.
7. Large skeletal base discrepancies. This relates to the positioning of the upper and lower jaw to each other. A large skeletal discrepancy would include the lower jaw being too far forward in relation to the upper jaw. Also the contrary where the lower jaw is too far back in relation to the upper jaw. These are called Class 3 and Class 2 Skeletal base relationships respectively.
8. Severe fibrous replacement. This means that there is an area of the oral tissue upon which the denture may be seated on where it has excess fibrous/scar tissue.
9. Maxillo-facial defects. The subject may have undergone surgery or have existing defects to the jaws or face due to multiple reasons such as tumours, cysts, trauma to the face and developmental facial defects. These can change the anatomy of the area where the dentures rely on heavily and can influence the trial.

Date of first enrolment
01/04/2017

Date of final enrolment

31/12/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Dental Hospital
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Sponsor information

Organisation
Queen Mary University of London, Barts & The London Dental School

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Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
University/education

Funder Name
Queen Mary, University of London

Alternative Name(s)
QMUL

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
30/09/2019

Individual participant data (IPD) sharing plan
The current 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?
HRA research summary			28/06/2023	No	No