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Improving dentures for patient benefit

Submission date 11/11/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/01/2010	**Overall study status** Completed	
Last Edited 24/08/2016	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Improving dentures for patient benefit: a single centre randomised, controlled, crossover clinical trial comparing materials for complete dentures

Acronym
IMPROVDENT

Study objectives
The aim of this study is to significantly impact on the quality of denture production within NHS dentistry. To achieve this objective, we aim to provide evidence of effectiveness and cost-

effectiveness of a development in denture impression materials. The aim is to ask the patients to provide the outcome assessments for the trial; a user-centered approach which will give clinically significant results, empower research participants and facilitate a deeper understanding of patients' denture wearing problems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Single-centre randomised controlled cross-over clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Quality of denture production

Interventions
Patients should be assessed for their suitability to participate in this study before they give their consent and are registered into the trial.

Denture construction:
The Prosthodontic Research Team at the Leeds Dental Institute has developed and published a method of producing two or more sets of dentures which are clinically identical apart from the one deliberate alteration which is to be the subject of this trial. This methodology will be used to produce two sets of dentures which are clinically identical apart from the impression material that was used to provide the mould for the fitting surface of each denture.

Habituation:
Patients will be given both sets of dentures for a 2-week habituation period. During the 2 weeks the patients will be provided with a diary and asked to record the wearing of each set of dentures. They will then be asked to score each denture for comfort, mobility and chewing efficiency using a 5-point Likert scale. Both sets of dentures will be returned and re-marked for the adjustment stage. The code will be blind to clinicians and patients, and kept confidential until the end of the trial.

Adjustment:
Dentures will be given back to patients, one at a time over two adjustment periods (8 weeks each), in random order. If any adjustment or remedial work is required to make the dentures comfortable, retentive and useful this will be carried out by an experienced clinician. Within the limits of the LDI appointment system there will be no restriction on the number of appointments the patients can request during these two 8-week periods. Every appointment requested by the patient will be noted and a detailed record of the work required will be kept. At the end of each 8-week adjustment period the patient will be asked to attend and report the impact the dentures have had on their quality of life by the completion of a OHIP-EDENT and EQ-

5D questionnaires and will rate the denture for comfort, mobility and chewing efficiency using 5-point Likert Scales.

Confirmation:
After the two adjustment periods of 8 weeks it is to be expected that each set of dentures will be as good as it is possible to make them. The patient will be asked to take both sets of dentures away for a 2-week confirmation period and return for a final visit to express any preference for the dentures and perform a Likert assessment of comfort, mobility, and chewing efficiency.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Patient preference for unadjusted dentures and overall cost-effectiveness, measured at the end of the habituation period. Patient preference will be established by asking whether one or other denture is preferred, or whether there is no preference. Those expressing no preference will be further asked whether both dentures were satisfactory or unsatisfactory.

Key secondary outcome(s)
Measured at the end of the secondary impressions, habituation, adjustment and confirmation periods:
1. Comfort, Mobility, Chewing Efficiency using 5-point Likert Scales
2. Oral Health-Related Quality of Life using OHIP-EDENT
3. Patient preference for adjusted dentures
4. Patient perception of comfort, taste and ease of use of each impression material using a 5-point Likert scale
5. Qualitative interviews to gain insight into the impact of oral health status on daily lives

Patient preference for adjusted dentures will be established by asking whether one or other denture is preferred, or whether there is no preference. Those expressing no preference will be further asked whether both dentures were satisfactory or unsatisfactory. Patients will be asked to reflect on the whole process of receiving the final denture (including initial comfort, amount of adjustment needed) when expressing preference.

Completion date
15/01/2012

Eligibility

Key inclusion criteria
1. Patients of either sex who are edentulous
2. Subject is available for follow up
3. Subject requires replacement complete dentures
4. Subject is able and willing to sign the Informed Consent Form
5. Aged 18 years or over at the time of signing the Informed Consent Form

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Presence of an oral tumour
2. Requirement for an obturator
3. Extreme xerostomia (e.g. Sjogren's Syndrome)
4. Patients who would benefit from selective pressure impressions
5. Known hypersensitivity to silicone or alginate

Date of first enrolment
15/01/2010

Date of final enrolment
15/01/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Dental Institute
Leeds
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Sponsor information

Organisation
University of Leeds (UK)

ROR

https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) programme (ref: PB-PG-0408-16300)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2014		Yes	No
Results article	results	01/08/2014		Yes	No
Protocol article	protocol	31/08/2012		Yes	No