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Developing evidence-based oral healthcare for older Irish adults

Submission date	Recruitment status	[_] Prospectively registered
29/09/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/10/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/01/2017	Oral Health	

Plain English summary of protocol

Background and study aims

The dental health of older patients has changed considerably over the last 30 years around the world. The traditional picture of older patients with no remaining natural teeth and complete replacement dentures is becoming increasingly outdated. Instead, older patients are retaining some of their natural teeth into old age. However many of these patients still require treatment to replace some of their missing natural teeth for functional and aesthetic reasons. Currently the vast majority of these patients receive Removable Partial Dentures (RPDs) to fill spaces and replace some missing teeth. In a number of countries, including the Republic of Ireland and the United Kingdom, RPD is the only treatment offered to older patients to replace teeth as part of state funded healthcare. However, many patients struggle to wear RPDs, particularly those replacing lower teeth, and only wear them infrequently. In addition RPDs are very difficult to keep clean so high levels of tooth decay and gum disease are often found in these patients. Other treatment options do exist including a concept called the Shortened Dental Arch (SDA). These concept aims to only replace teeth towards the front of the mouth using fixed bridges to provide patients with a set of teeth which are aesthetic, functional and easy for them to maintain. Despite the SDA concept originating in the early 1980s, very few studies have ever compared it to traditional RPDs in older patients. This study aims to compare the quality of life, nutritional status and cost effectiveness of these two treatments.

Who can participate?

Patients over 65 years of age, have more than 6 natural teeth remaining and are generally fit and well

What does the study involve?

Patients will be randomly allocated to one of two treatment groups: RPD group and SDA group. Both groups will have a routine dental examination followed by filling of cavities and tooth cleaning. Those in the RPD group will be provided with RPDs to replace all of their missing natural teeth. Those in the SDA group will have fixed bridges fitted to their teeth to replace their front teeth only. All patients will complete a quality of life questionnaire, nutritional status measurement and give a blood sample at the beginning of the study which will be repeated 6 months, 12 months and 24 months after the intervention. The cost of providing the treatment for both groups will be calculated on an ongoing basis throughout the study.

What are the possible benefits and risks of participating?
Patients will receive all treatment within the study free of charge. All blood samples will be taken by a trained specialist who will warn the patients about potential bruising, bleeding, swelling and pain after giving blood.

Where is the study run from?
Cork University Dental Hospital and St Finbarr's Geriatric Day Hospital in Cork City (Ireland)

When is study starting and how long is it expected to run for?
January 2010 to December 2015

Who is funding the study?
Health Research Board (Ireland)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HRB/2008/220

Study information

Scientific Title

Comparison of tooth replacement strategies for partially dentate older patients in the Republic of Ireland: a randomised controlled clinical trial

Study objectives
This study aims to compare two different tooth replacement strategies for partially dentate older patients in the Republic of Ireland, namely conventional treatment with removable partial dentures (RPD) and functionally orientated treatment based on the Shortened Dental Arch concept (SDA). The two strategies will be compared using impact on Oral Health related Quality of Life (OHrQoL), impact on nutritional status and cost-effectiveness as outcome measures. The study will be based on equivalence in outcomes where the null hypothesis stated that there would be no differences observed between the two treatment strategies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University College Cork Clinical Ethics Committee, 07/07/2009, ref: ECM 3 (zzz)

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled 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
Loss of teeth

Interventions
Patients will receive treatment based upon random assignment to one of the treatment arms in the study.

1. Functionally orientated treatment (SDA group)
Following an initial clinical examination by the treating dentist, a functionally orientated treatment plan with minimal intervention will be implemented. Teeth deemed to have a hopeless prognosis (e.g., where affected teeth are deemed unrestorable or grade III mobility is evident) will be extracted. Root canal treatment will not be offered to patients as it could not be provided in both treatment centres.

The following interventions will then be provided:
1. Oral hygiene advice using a standardised protocol
2. Non-surgical periodontal treatment for management of periodontal disease
3. Restoration of carious lesions and/or replacement of defective direct restorations using composite resin for anterior teeth and amalgam for posterior teeth. Class V restorations will be restored with glass ionomer filling material in both anterior and posterior teeth.
4. Restoration of a SDA in both jaws (or one jaw if the patient was edentate in the upper or lower jaw) to provide 10 occluding pairs of natural and replacement teeth using Resin Bonded Bridges (RBB)

Provision of RBB
RBB will be provided using a standardised protocol in each case. Local anaesthetic will not provided as standard unless requested by the patient. Minimal tooth preparation within enamel only will be carried out to produce retentive forms and increase the surface area for bonding. In the anterior dentition tooth preparations include a rest seat in the cingulum area of the abutment tooth with a chamfered finishing line 2-3 mm from the gingival margin. On the posterior teeth (premolars and molars) occlusal seats will be placed on the mesial and distal marginal ridges with a chamfered finishing line 2-3 mm from the gingival margin. No temporary restorations will be provided as preparations were limited to enamel. Impressions will be made of the tooth preparations and the opposing arch using a vinyl polysiloxane impression material (Extrude®, Kerr Corporation, Washington, USA) in stock dentate impression trays. An occlusal record will be taken using a vinyl polysiloxane impression material (Take 1 Bite®, Kerr Corporation, Washington, USA). A shade for the final restoration will be taken using a VITA Classical Shade Guide (Vident, California, USA). Each item of bridgework will be constructed by Southern Cross Dental Laboratory, the Moy, Dungannon, Northern Ireland.

A clear laboratory prescription will be written for each case to provide the technician with information detailing the preparation features, prescribed metal extensions and pontic design for the bridge. The metal used for construction of each bridge will be nickel-chromium (NiCr), which will be sandblasted with 50 μm alumina on the fitting surface by the laboratory. Each bridge will be constructed with a modified ridge lap pontic. In each case the prescribed metal thickness will be 0.7 mm. Cantilever bridge designs will be favoured in all cases. The maximum number of teeth replaced with any single bridge will be two units.

When the RBB returns from the laboratory it will be tried in the patients mouth to check fit prior to cementation. After fit has been deemed satisfactory the fitting surface will again be sandblasted chairside using 50 μm alumina. Panavia™ 21 (Kuraray Co. Ltd, Kita-Ku, Osaka, Japan) will be used to cement each item of RBB with the manufacturers instructions strictly adhered to. An occlusal examination will be carried out on each item of RBB after cementation with modifications as necessary to ensure that the pontic is not involved in any lateral and protrusive excursive movements.

2. Conventional treatment (RPD group)
Following an initial clinical examination by the treating dentist, a treatment plan aimed at restoring a complete dentition will be implemented. Teeth deemed to have a hopeless prognosis (where affected teeth are deemed unrestorable, or grade III mobility is evident) will be extracted. Root canal treatment will not be offered to patients as it can not be provided in both treatment centres.

The following interventions will then be provided:
1. Oral hygiene advice using a standardised protocol

2. Non-surgical periodontal treatment for management of periodontal disease
3. Restoration of carious lesions and/or replacement of defective direct restorations using composite resin for anterior teeth and amalgam for posterior teeth. Class V restorations will be restored with glass ionomer filling material in both anterior and posterior teeth
4. Restoration of a complete dental arch comprising natural teeth and using cobalt-chromium RPDs to replace missing teeth

Provision of Removable Partial Dentures (RPDs)
As with the RBB, each RPD will be provided according to a standardised protocol. Firstly, primary impressions will be made using alginate in stock dentate impression trays. The impressions will be poured on site before they will be sent with a detailed prescription for construction of spaced, perforated special trays and wax record blocks at Southern Cross Dental Laboratory, the Moy, Dungannon, Northern Ireland. An occlusal record and facebow record will be taken of each patient and the primary models mounted on a semi-adjustable articulator. Primary models will be surveyed and the cobalt-chromium denture framework designed. The dentures will be retained using retentive clasps and designed according to best prosthodontic principles. Tooth preparations will be made according to the denture design without local anaesthetic unless specifically requested by the patient. Secondary impressions will be made using the special trays and vinyl polysiloxane impression material (Extrude®, Kerr Corporation, Washington, USA). A denture framework will be requested from the laboratory according to the denture design. Mounted primary models with tripod marks will be sent to the laboratory with the prescription to communicate the chosen path of insertion for the denture.

After a satisfactory try-in of the denture framework, an occlusal record will be taken of each case by direct addition of wax to the framework. At this stage the altered cast technique will be employed to record mucosally-borne saddle areas. A shade for the denture teeth will be taken using a VITA Classical Shade Guide (Vident, California, USA). Each denture will undergo a further try-in stage prior to delivery where the aesthetics, retention and occlusion will be checked and modified as appropriate. At delivery the patient will be issued with careful denture care instructions.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Oral Health related Quality of Life (OHrQOL) is the primary outcome measure in this study. OHrQoL will be measured using the OHIP-14 questionnaire. The questionnaire will be administered by a research nurse at baseline, 6 months, 12 months and 24 months after treatment intervention. The research nurse will read the questionnaire aloud to each of the patients and complete their responses in an answer booklet. Patients record their opinions on 14 statements related to their mouth, teeth or dentures using the OHIP-14 questionnaire. The reference period used in all cases will 1 month i.e. all of the questions asked began with the stem during the last month. Each statement is accompanied with a Likert-type scale which generated a score ranging from 0 to 4 (0 = never; 1 = hardly ever; 2 = occasionally; 3 = fairly often; 4 = very often). These individual scores will be added together to give a summary score ranging from 0 (minimum) to 56 (maximum). As the questionnaire only records negative events,

high scores indicate poor OHrQoL with low scores indicating better OHrQoL. The research nurse administering the questionnaires will be blinded to the treatment group allocation of all participants.

Secondary outcome measures
Nutritional status will be assessed using the full version of the Mini Nutritional Assessment (MNA), which includes a measurement of Body Mass Index (BMI). This measure also includes subjective assessment and dietetic components and has been widely used as an outcome measure in studies of older adults. The MNA involves subjective assessment of appetite, mobility, dietary behaviours in addition to anthropometric data. Using the MNA scoring system, a patient who scored 17 points or less from a possible 30 is considered malnourished. A score of 17-23.5 points indicates that the patient is at risk of malnutrition. The MNA will be administered at baseline, 6 months, 12 months and 24 months after treatment intervention by a research nurse. The research nurse administering the MNA will be blinded to the treatment group allocation of all participants.

In addition, each patient will provide haematological samples which will be screened for biochemical markers of nutritional status. Each sample will be tested in Cork University Hospital for:

1. C reactive protein
2. Serum albumin
3. Serum cholesterol
4. Total lymphocyte count
5. Ferritin
6. Folate
7. Vitamin B12
8. Vitamin D

For each biochemical marker, levels will be compared to normal ranges to indicate the nutritional status for each patient. Haematological samples will be collected from each patient at baseline (pre treatment), 6 months, 12 months and 24 months after the treatment intervention by a research nurse trained in phlebotomy. The research nurse who collected the haematological samples will be blinded to the treatment group allocation of all participants.

Overall study start date
01/01/2010

Completion date
30/12/2015

Eligibility

Key inclusion criteria
In this study, the target population is older partially dentate patients living in Cork city and the surrounding areas in the southwest of Ireland.
1. Partially dentate patients aged 65 years and older
2. Who request treatment to replace missing teeth
3. A minimum of six sound natural teeth in at least one jaw which are suitable for fixed bridges
4.. No medical complications which contraindicate routine dental treatment (e.g., unstable angina; INR level > 4; high risk of infective endocarditis)

5. No evidence of dementia
6. Able to have dental treatment in a dental chair
7. Able to communicate in English

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
130

Key exclusion criteria
1. Less than six sound natural teeth remaining in at least one jaw
2. Medical complications which precluded routine dental care
3. Evidence of dementia
4. Inability to receive dental treatment in a dental chair
5. Inability to communicate in English
6. Unwilling to accept randomised treatment allocation
7. Unwilling to participate with questionnaires
8. Unwilling/unable to provide a haematological sample
9. Unwilling/unable to provide anthropometry measurements for Mini Nutritional Assessment (MNA)
10. Unwilling to attend for follow-up appointments post treatment

Date of first enrolment
01/01/2010

Date of final enrolment
30/12/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Cork University Dental School and Hospital
Cork
Ireland
0

Sponsor information

Organisation
Health Research Board (Ireland)

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Research organisation

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https://ror.org/003hb2249

Funder(s)

Funder type
Research organisation

Funder Name
Health Research Board (Ireland) (HRB/2008/220)

Alternative Name(s)
HRB

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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	preliminary results	01/06/2012		Yes	No
Results article	preliminary results	01/09/2013		Yes	No
Results article	results	01/01/2015		Yes	No
Results article	results	01/11/2015		Yes	No