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The effect of improved oral prostheses on the nutritional state of elderly edentulous individuals

Submission date 20/10/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2005	**Overall study status** Completed	
Last Edited 29/10/2013	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Jocelyne Feine

Contact details
Oral Health and Society Research Unit
Suite #101
Faculty of Dentistry
McGill University
3550 University Street
Montreal, Quebec
Canada
H3A 2A7
+1 514 398 7203 ext. 00052
jocelyne.feine@mcgill.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UCT-36052

Study information

Scientific Title
The effect of improved oral prostheses on the nutritional state of elderly edentulous individuals: a randomised controlled trial

Acronym
SIN II

Study objectives
Null Hypothesis:
That there will be no difference in nutritional status measured by serum homocysteine levels in elderly edentulous males and females wearing mandibular 2-implant overdentures and those wearing mandibular conventional dentures at six months following delivery of the prostheses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
McGill University Faculty of Medicine IRB, original approval received November 15, 2002; renewed yearly; latest renewal approved 29 August 2006 (study number A08-M75-02B).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Edentulism (lack of all teeth)

Interventions
Control: Complete conventional dentures

Experimental: Mandibular 2-implant overdenture with ball attachments and maxillary conventional denture

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Serum level of homocysteine.

Secondary outcome measures
1. Patient satisfaction
2. Vitamin status
3. Changes in serum albumin
4. Changes in dietary habits
5. Changes in function
6. Cost effectiveness

Overall study start date
01/09/2002

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Male and female seniors aged 65 and older
2. Completely edentulous for a minimum of five years
3. Wishing to replace existing conventional dentures
4. An adequate understanding of written and spoken English or French
5. Able to understand and respond to questionnaires used in the study
6. Willing and able to accept the protocol and give informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
254

Key exclusion criteria

1. Insufficient bone to place two implants in the anterior mandible
2. Other oral conditions that preclude immediate prosthetic treatment
3. Acute or chronic symptoms of temporomandibular disorders
4. History of radiation therapy to the orofacial region
5. Systemic or neurological disease that contraindicate implant surgery
6. Any neoplasia diagnosed less than five years previously
7. Body mass index (BMI) less than 20 or greater than 32 kg/m^2
8. Score of 20 or less on the Mini-Mental State Evaluation
9. Taking any of the following which will affect blood nutrient concentrations:
9.1. Dietary supplements
9.2. Anti-neoplastic medication
9.3. Phenytoin or corticosteroids
9.4. Insulin
10. Other conditions that jeopardise surgical treatment (e.g. alcoholism)
11. Psychological or psychiatric conditions that could influence diet and reaction to treatment

Date of first enrolment
01/09/2002

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Canada

Study participating centre
Oral Health and Society Research Unit
Montreal, Quebec
Canada
H3A 2A7

Sponsor information

Organisation
McGill University (Canada)

Sponsor details
845 Sherbrooke Street West
James Administration Bldg., Suite 429
Montreal, Quebec
Canada

H3A 2T5
+1 514 398 4455
jacques.hurtubise@mcgill.ca

Sponsor type
University/education

Website
http://www.mcgill.ca/

ROR
https://ror.org/01pxwe438

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: UCT-36052)

Funder Name
Straumann Canada (Canada)

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	etiological factor results	01/05/2008		Yes	No
Results article	sex differences results	01/05/2008		Yes	No

Other publications	research approaches	01/12/2008	Yes	No
Other publications	methodological issues	01/04/2009	Yes	No
Results article	mandibular bone height results	01/11/2010	Yes	No
Results article	implant overdentures and nutrition results	01/01/2012	Yes	No
Results article	treatment satisfaction results	01/08/2012	Yes	No
Results article	dietary intake results	01/12/2013	Yes	No