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A multicenter randomized controlled trial for evaluating timing and clinical outcomes of the technique in making complete dentures

Submission date
06/10/2015

Recruitment status
No longer recruiting

Registration date
22/10/2015

Overall study status
Completed

Last Edited
21/10/2015

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Denture treatment can be a very complex and long-lasting process, involving many steps. Many simplified procedures have been introduced to shorten the process and to improve comfort for patients. The aim of this study was to compare two different techniques: a traditional, long-lasting technique that involves 6 clinical sessions, and a new, simplified and shorter technique that involves 2 to 3 sessions.

Who can participate?
Patients who need complete dentures (i.e., a full set of false teeth).

What does the study involve?
Participants are randomly allocated to receive either traditional treatment or the new simplified shorter treatment. For each patient we record the time spent during clinical procedures, the time spent during laboratory procedures, and the number of clinical sessions. The clinical quality of the dentures and the patients' satisfaction are assessed using questionnaires.

What are the possible benefits and risks of participating?
Patients may benefit from receiving a shorter treatment but will have to spend some more time for the study procedures and questionnaires. There are no risks related to the treatment.

Where is the study run from?
Universities of Torino, Ferrara and Siena (Italy).

When is the study starting and how long is it expected to run for?
September 2011 to July 2013.

Who is funding the study?
Università degli Studi di Torino (Italy).

Who is the main contact?
Dr Paola Ceruti

Contact information

Type(s)
Scientific

Contact name
Dr Paola Ceruti

ORCID ID
http://orcid.org/0000-0001-7240-8126

Contact details
v. Nizza, 230
Turin
Italy
10126

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Simplified Edentulous Treatment: a multicenter randomized controlled trial in edentulous patients for evaluating timing and clinical outcomes of the technique

Acronym
SET

Study objectives
The hypothesis was that there are between-group differences in clinical and laboratory timing, number of clinical sessions and number of exchanges, and no between-group differences in patient satisfaction and denture quality, among the two treatment groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Ethics Committee of the Province of Ferrara, 25/11/2010, protocol number 9/2010

Study design
Interventional multicentre parallel single-blind controlled randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel 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
Edentulism

Interventions
Patients were randomly assigned to two groups:
1. The traditional treatment group (control group) receive traditional rehabilitation
2. The SET group (study group) receive the innovative, simplified rehabilitation

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Time (minutes) spent during clinical procedures
2. Time (minutes) spent during laboratory procedures
3. Number of clinical sessions
4. Number of laboratory returns

Secondary outcome measures
1. At delivery, clinical quality of the dentures was assessed by means of a questionnaire filled by a blinded expert
2. Six months after the delivery, patient satisfaction was assessed by means of a specific questionnaire
3. Patients were also asked to express a judgment on the treatment modalities

Overall study start date
01/09/2011

Completion date
01/07/2013

Eligibility

Key inclusion criteria
Edentulous patients requiring rehabilitation by means of maxillary and mandibular complete dentures

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
64

Key exclusion criteria
Presence of temporo-mandibular disorders, xerostomia, orofacial motor disorders, systemic diseases with oral manifestations, psychological or psychiatric conditions that could influence their response to treatment

Date of first enrolment
01/02/2011

Date of final enrolment
31/07/2011

Locations

Countries of recruitment
Italy

Study participating centre
University of Turin
Turin
Italy
10124

Study participating centre
University of Ferrara
Italy
44121

Study participating centre
University of Siena
Siena
Italy
53100

Sponsor information

Organisation
Università degli Studi di Torino (Italy)

Sponsor details
v. Nizza, 230
Torino
Italy
10126

Sponsor type
University/education

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Torino

Alternative Name(s)
University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request