

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/10/2015	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request