

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

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<b>Registration date</b> 22/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/10/2015	<b>Condition category</b> 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

Dr Paola Ceruti

### ORCID ID

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## Additional identifiers

### Protocol serial number

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

**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