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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