

# Medical Biostatistics Unit review report for sample size calculation

## Individual details:

First Name: Ahmed

Surname: Jassim Alsubaya

Email address: [ahmed.alsubaya@dentistry.cu.edu.eg](mailto:ahmed.alsubaya@dentistry.cu.edu.eg)

## Your status \*

-- Please select --

Master postgraduate student ✓

PhD postgraduate student

Academic Staff

Other (Please specify below)

## Department \*

Oral and Maxillofacial Surgery

## Main Supervisor details (if applicable)

Title: Associate Professor

First name: Mohamed

Surname: Atef Abdelrasoul

Email address: [mohammedatef@dentistry.cu.edu.eg](mailto:mohammedatef@dentistry.cu.edu.eg)

## Research information:

### Research title:

**Transoral Fixation of Mandibular Angle Fracture using 3D Titanium Miniplate versus Standard Two Plate Fixation: Randomized Clinical Trial**

### Research question:

**Does transoral fixation mandibular angle fracture using 3D titanium miniplate provide better occlusal bite force than the standard two plate fixation?**

## Complete items used in sample size calculated \*

- The outcome used (State 1ry or 2ry): **primary (occlusion force measurement at the end point 6 months)**
- Values used for outcome (e.g. mean difference, percentage, proportion..... etc ): **mean difference and standard deviation**
- Entry 1: (mean difference between 2 groups, mean and standard deviation of group 1, proportion 1 or estimated prevalence): **mean and SD of control group = 596.8± 70.578**

- **Mean of Group 1 = 596.8**
- **SD of Group 1 = 70.578**
- Entry 2: (standard deviation of control group, mean and standard deviation of group 2, proportion 2 or clinically important difference): **minimal clinical important difference estimated to be 105**
- Alpha level of significance: **(5%) (0.05)**
- Effect size used in calculation:
- Power of the study: **(80%) (0.8)**
- Statistical test used: **Independent t-test**
- The calculated sample size: **8 patients per group with the total sample size 16 patients (2 groups).**
- Increased number for anticipated missing data: **10 subjects in each group to compensate for a drop-out rate of 25%. (total sample size 20).**
- Sample size calculation was performed using PS power

#### **Upload\***

- Applicant's protocol written based on Faculty templates.
- Article used by applicant for sample size calculation.

#### **Decision of MBU:**

- Accepted ☒
- Needs modifications ☐

What to be modified:

- A meeting is needed ☐

Date of meeting:    /    /                      Time of meeting:                      Place of meeting:

N.B. If you couldn't attend the meeting, show up to apologize or contact your reviewer by e-mail to set up another convenient time.

MBU member: Associate Professor Dr. Weam Elbattawy

MBU Director: Professor Dr. Noha Ghallab

\* Date of submission 04 / 01 / 2025

Date of approval: 21 / 01 / 2025  
Vice Dean for Postgraduate affairs and research