Statistical Analysis Plan (SAP)

Date: 1 June 2022

Short Study Title: The Effect of Dr Allen's Device and Thermobalancing Therapy on Erectile Dysfunction in Men with Chronic Prostate Diseases

Objectives: The purpose of this clinical trial is to investigate the effect of the out-of-hospital treatment with Thermobalancing therapy and Dr Allen's Device for Prostate Treatment on the erectile function, the size of the inflamed or enlarged prostate gland (PV), urinary symptoms (UrS), and health-related quality of life (HRQoL) in men with erectile dysfunction (ED) linked to chronic prostatitis (CP/CPPS) or benign prostate enlargement (BPE).

Study Design: Single-centre prospective interventional randomised controlled clinical trial

Participants: Study participants will be recruited in Faisalabad, the 3rd largest city in Pakistan, with the population of over 3 million people. The recruited participants will be men aged between 40 and 55 with ED due to CP/CPPS or BPH.

Exclusion criteria: Participants will be excluded in cases of previous prostate surgeries, infectious diseases, severe comorbidities, such as cancer, heart failure, and end-stage chronic diseases, patients who are cognitively impaired, and those with mental illness.

Target Number of Participants: The target sample size is 100 patients.

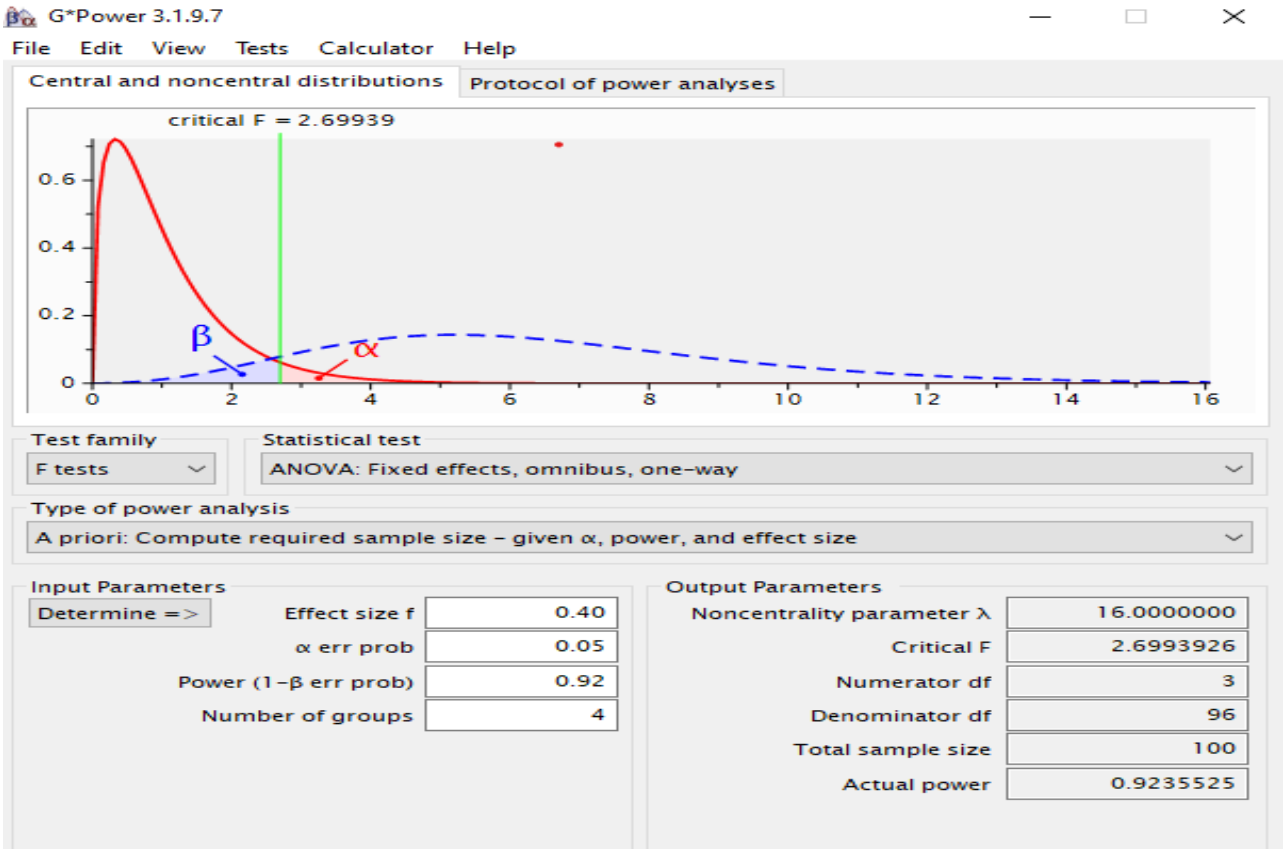
Randomisation: A total of 100 participants will be recruited for the study: 50 participants with ED due to CP/CPPS and 50 participants with ED due to BPH. Every participant in each of these 2 groups will be randomly assigned to either the treatment group or the control group in equal numbers of 25 participants in each group.

Sample Size Calculation: Sample size is calculated using G*Power 3.1.9.7 software. A total of 100 participants (25 ED due to CP/CPPS in treatment group & 25 ED due to CP/CPPS in control group, 25 ED due to BPH in treatment group & 25 ED due to BPH in control group) will be required to conduct the study, based on the following assumptions:

	tests - ANOVA: Fixed effects, omnibus, one-way		
Analysis:	A priori: Compute required sample size		
Input:	Effect size f	=	0.40
	α err prob	=	0.05
	Power (1-β err prob)	=	0.92
	Number of groups	=	4
Output:	Noncentrality parameter λ	=	16.0000000
	Critical F	=	2.6993926

Numerator df	=	3
Denominator df	=	96
Total sample size	=	100
Actual power	=	0.9235525

Screenshot for G-Power calculation is as follows:



Study participants to be analysed: All randomised study participants completing the whole study period (complete cases) will be included into the analysis. This will be seen as the primary population for the analysis. For a specific analysis, study participants with missing data on any of the variables in the model will be excluded from the analysis.

Analyses: All outcomes will be presented using descriptive statistics.

Principal Investigator:

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