Clinical Trial Protocol

Date: 1 June 2022

Ref: CT-5-ED-TT-DAD

Title: The effect of Thermobalancing therapy and Dr Allen's Device for Prostate Treatment on erectile dysfunction, prostate volume, and health-related quality of life in men with chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) and benign prostate enlargement (BPE) or benign prostatic hyperplasia (BPH)

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

Acronym: TT-DAD-ED-CP-BPE

Research Parties: Fine Treatment (13 Station Road, Borough Green, Sevenoaks, Kent, TN15 8ES, United Kingdom) and Government College University Faisalabad (Kotwali Road, Faisalabad, Punjab, 38000, Pakistan)

Key contacts:

Principal Investigator	Dr Simon Allen, Director and Head of Medical Research, Fine Treatment, Oxford, UK; +44-7958878300; info@finetreatment.com
Investigator I	Professor Dr Abid Rashid, Dean, Faculty of Medical Science, Government College University Faisalabad, Pakistan; +92-3336503578; drabidrashid37@gmail.com
Investigator II	Dr Muhammad Akram, Associate Professor, Chairperson, Department of Eastern Medicine, Government College University Faisalabad, Pakistan; +92-3452888394; makram_0451@yahoo.com
Research Manager	Ariana Adjani, MPhil Oxon, Senior Researcher, Fine Treatment, Oxford, UK; +44-7905057023; ariana.adjani@finetreatment.com
Lead Investigator and Statistician	Professor Dr Shahid Kamal, Vice Chancellor, Government College University Faisalabad, Pakistan; +92-419200670; adminofficertovc@gcuf.edu.pk
Co-Investigator as Consultant I	Dr Akram Malik, MBBS, FCPS (Urology), FCPS (Surgery) Urologist, General Surgeon, Madinah Teaching Hospital, Faisalabad, Pakistan; +92-418869862; akrammlk@yahoo.com
Co-Investigator as Consultant II	Dr Muhammad Tahir Bashir Malik, MBBS, FACS (USA), FCPS (Urology), FRCS (U.K), Urologist, Assistant Professor of Urology, Faisalabad Medical University / Allied Hospital Faisalabad, Pakistan; +92-3004403770; drtahirbasheer@gmail.com

Co-Investigator as Statistician	Dr Rehan Ahmed Khan, Associate Professor, College of Statistical and Actuarial Science, University of Punjab Lahore, Pakistan; +92-3344118684; srat4u@gmail.com
Co-Investigator as Research Associate	Dr Muhammad Talha Khalil, MPhil Scholar, Department of Eastern Medicine, Government College University Faisalabad, Pakistan; +92-3211335107; talhakhalil49@gmail.com

Background: Chronic prostatitis / chronic pelvic pain syndrome (CP/CPPS) and benign prostate enlargement (BPE) – also known as an enlarged prostate or benign prostatic hyperplasia (BPH) – are common health conditions among men. CP/CPPS affects 8.2% of men. The prevalence of histologically diagnosed BPE increases from 8% in men aged 40, to 40-50% in men aged 51 to 60, to over 80% in men older than age 80. These health problems are often accompanied by erectile dysfunction (ED).

It has been confirmed that novel Thermobalancing therapy and Dr Allen's Device for Prostate Treatment reduce prostate inflammation in patients with CP/CPPS, decrease the size of benign prostate enlargement, and ease lower urinary tract symptoms (LUTS) associated with BPE. Also, this treatment has a positive impact on the health-related quality of life in men with CP/CPPS and BPE. Moreover, no complications associated with the use of Dr Allen's Device have ever been observed in patients with BPH and chronic prostatitis [1,2].

Many studies show that commonly used medications and surgeries for CP/CPPS and BPE have a negative effect on the quality of life, and lead to ED. Standard treatment options with drugs can cause side effects, especially in the long-term use [3,4]. Surgical interventions are associated with irreversible complications [5,6]. Most of these side effects and complications affect erectile and sexual function causing emotional problems and depression [7,8]. Solving these problems is, therefore, extremely important for men's long-term health and wellbeing.

Therefore, new research on risk-free Thermobalancing therapy for ED and health-related quality of life in men with CP/CPPS and BPE is needed.

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 erectile function, the size of the inflamed or enlarged prostate gland, urinary symptoms, and health-related quality of life (HRQoL) in men with ED linked to CP/CPPS or BPE.

Study Hypothesis: The out-of-hospital treatment with Thermobalancing therapy and Dr Allen's Device for Prostate Treatment is expected to improve erectile function, reduce the size of the inflamed or enlarged prostate gland, reduce urinary symptoms, and improve health-related quality of life (HRQoL) in men with CP/CPPS or BPE.

Medical Innovation Description: In essence, Thermobalancing therapy improves blood circulation in the affected prostate gland by means of temperature regulation locally for a prolonged period of time. It is achieved with the continuous use of wearable Dr Allen's Device. Dr Allen's Device for Prostate Treatment is designed as a soft belt with a thermoelement made from a special wax-based material. It maintains the required temperature when retained on the body; it needs to be placed correctly with the thermoelement covering the coccyx area of the back.

Condition: Treatment of erectile dysfunction in patients with benign prostate enlargement or chronic prostatitis / chronic pelvic pain syndrome

Study Design: Single-centre prospective interventional randomised controlled trial

Time Frame: The clinical trial is expected to run for approximately a year. The duration of treatment with Dr Allen's Device for each participant will be 6 months.

Participants: The recruited participants will be men aged between 40 and 55 with ED due to CP/CPPS or BPE. Exclusion criteria: 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.

Methods: Thermobalancing therapy with Dr Allen's Device will be used as a monotherapy. Every participant in the treatment groups will be investigated during the clinical trial 3 times: before the start of the treatment, 3 and 6 months after the start of the treatment. Every participant in the control groups will be investigated during the clinical trial also 3 times: at the start of the observation period, 3 and 6 months later.

Patients in the treatment groups will use Dr Allen's Device. Patients in the control groups will be under watchful waiting and will not receive treatment with Dr Allen's Device.

The dynamics of the symptoms and indicators in each group will be assessed 3 times, before, during and at the end of the treatment period, by:
(1). The International Index of Erectile Function (IIEF-5) Questionnaire – to investigate the severity of ED symptoms;
(2). Ultrasound – to determine the volume of the prostate gland (PV);

(3). AUA Symptom Score Questionnaire – to investigate the severity of urinary symptoms (UrS);
(4). Short Form Survey Instrument (SF-36) – to determine the health-related quality of life (HRQoL);
(5). The serum levels of PSA, total testosterone, and 17β-estradiol (E2) – to assess the impact of the treatment on key patient parameters.

The data collected from the treatment groups will be compared to the control groups under watchful waiting. No other interventions, including medications and surgical procedures, will be used.

Statistical Analysis: A statistical analysis will be performed. Sample size is calculated using G*Power software and the details are included in the Statistical Analysis Plan (SAP).

Informed Consent: Informed Consent will be obtained from all participants by signing the Informed Consent form before any trial specific procedures are performed.

Approvals and Safety: Dr Allen's Device is registered with The Medicines and Healthcare products Regulatory Agency (MHRA) in the UK as a Class 1 medical device. All previously conducted clinical trials involving Dr Allen's Devices received Research Ethics Committee (REC) approvals and demonstrated total safety of this treatment. Written approval of the Ethics Review Committee of the Government College University Faisalabad will be obtained for this trial.

Data Management: Source documents will include medical history, hospital records, laboratory records, questionnaires, and correspondence. Data access will be granted to authorised representatives from the Sponsor, the Investigator Team, host organisation, REC, and the regulatory authorities. All documents will be stored confidentially.

Expected Outcomes: It is anticipated that Dr Allen's Device and Thermobalancing therapy will treat ED and improve erectile function; reduce PV; reduce UrS; and improve HRQoL. The findings may allow us to recommend this novel out-of-hospital treatment as a new safe solution for ED.

Principal Investigator and Sponsor:

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Dr Simon Allen, MD, PhD, Director and Head of Medical Research,
Fine Treatment,
Oxford, United Kingdom

Chief Investigator:

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Dr Muhammad Akram, Associate Professor, Chairperson, Department of Eastern Medicine, Government College University Faisalabad, Pakistan

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