Study Protocol

Official Title: Erectile Dysfunction and the Mind: Evaluating the Influence of Depression and Illness Beliefs on Treatment Progression

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1. Background and Rationale
Erectile dysfunction (ED) is a complex and multifactorial condition...

2. Objectives
Primary Objective: To assess the association between illness perception and depressive symptoms in ED patients.

Secondary Objectives: To evaluate changes in erectile function and depression over 1 month.

3. Study Design
Study Type: Observational

Model: Cohort

Time Perspective: Prospective

Number of Cohorts: 1

Target Follow-Up Duration: 1 month

Enrollment: 120 participants anticipated

Biospecimen Retention: None Retained

4. Study Population
Inclusion Criteria:
- Male, aged 18 or older
- Diagnosed with ED
- Consent to participate

Exclusion Criteria:
- Severe psychiatric disorder
- Hormonal or cancer therapy
- Neurological diseases

5. Procedures
Patients will complete IIEF-5, B-IPQ, and PHQ-9 at baseline and at 1-month follow-up.

6. Statistical Considerations:
Descriptive statistics will be used to summarize baseline characteristics. Paired t-tests or Wilcoxon signed-rank tests will be used to compare baseline and follow-up scores. A p-value < 0.05 will be considered statistically significant.

7. Ethical Considerations

This study was approved by the Ethics Committee of Haseki Training and Research Hospital on March 19, 2025 (Approval No: 23-2025). No amendments were made to the original protocol before submission. The current version has been approved by the ethics committee.

8. Data Management
CRFs and SOPs will guide data entry, quality checks, and confidentiality procedures.