Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Exploring the Lived Experiences of Women with Husbands Suffering from Premature Ejaculation: Improvement, Feasibility, and Efficacy of an Individual Cognitive-Behavioral Treatment Package into a Couple-Oriented Package Based on the Findings of a Qualitative Study

Protocol summary

Study aim

Evaluating the efficacy of the couple-oriented protocol on premature ejaculation symptoms, sexual quality of life of affected men, couples' sexual satisfaction and marital adjustment, sexual function, and sexual quality of life of the wives of affected men.

Design

Type: Single-case with multiple baselines, no classical control group. Groups: Intervention group (4 couples + 1 pilot); each couple serves as their own control. Randomization: None; order of initiation based on baseline scheduling (random determination of baseline length). Sample size: 4 couples + 1 pilot. Phase: Pilot Duration: 10-week intervention + 1.5-month follow-up.

Settings and conduct

Setting: Family Health Clinic Four-phase study (qualitative, package development, feasibility, single-case). In Phase 4: 4 couples + 1 pilot; 3 baseline measurements; 10-week intervention; assessments at the end of sessions 3, 6, and 9; post-test after session 10; 1.5-month follow-up.

Participants/Inclusion and exclusion criteria

nclusion Criteria:Age 25–45 years, at least 2 years of marital life, confirmed PE (PEDT), no major psychiatric/personality disorders (SCL-27, PID-5-BF), no major marital conflicts, no PE-affecting medications in the past 3 months, willingness to participate. Exclusion Criteria: Unwillingness to continue cooperation.

Intervention groups

Group 1: Couples receiving the couple-oriented CBT package (4 couples + 1 pilot); single-case with multiple baselines (each couple serves as their own control).

Main outcome variables

Premature ejaculation symptoms in men, men's sexual quality of life, couples' sexual satisfaction, couples' marital adjustment, women's sexual function, and women's sexual quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261012071397N1**
Registration date: **2026-10-16, 1405/07/24**
Registration timing: **prospective**

Last update: **2026-10-16, 1405/07/24**
Update count: **0**

Registration date

2026-10-16, 1405/07/24

Registrant information

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zahra khaksari
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2027-02-20, 1405/12/01

Expected recruitment end date

2027-05-05, 1406/02/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Exploring the Lived Experiences of Women with Husbands Suffering from Premature Ejaculation: Improvement, Feasibility, and Efficacy of an Individual Cognitive-Behavioral Treatment Package into a Couple-Oriented Package Based on the Findings of a Qualitative Study

Public title
Exploring the Lived Experiences of Women with Husbands Suffering from Premature Ejaculation: Improvement, Feasibility, and Efficacy of an Individual Cognitive-Behavioral Treatment Package into a Couple-Oriented Package Based on the Findings of a Qualitative Study
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Couples with a husband diagnosed with premature ejaculation Confirmed diagnosis of the husband's premature ejaculation based on clinical interview and the PEDT questionnaire Absence of major psychiatric disorders (based on SCL-27) and personality disorders (based on PID-5-BF) in either spouse Absence of major marital conflicts No use of psychiatric medications affecting premature ejaculation within the past three months Willingness to participate and ability to communicate verbally At least two years of marital life Age 25 years and older for both spouses
Exclusion criteria:
Presence of other sexual dysfunctions (e.g., erectile dysfunction) requiring independent treatment
Age
From **25 years** old to **45 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **8**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Unique Design Features of the Study: 1. Multi-Phase Design: This study consists of four distinct phases: (a) a qualitative phenomenological study exploring the lived experiences of women with husbands suffering from premature ejaculation; (b) development and improvement of an individual CBT package into a couple-oriented package based on qualitative findings; (c) feasibility assessment of the developed package based on experts', therapist's, and couples' opinions; (d) efficacy evaluation of the final package using a single-case experimental design. 2. Single-Case Experimental Design (SCED): The fourth phase employs a single-case design with multiple baselines. In this design, each couple serves as their own control, and data are collected during baseline, intervention, and follow-up phases. Classical randomization is not used; instead, phase assignment is based on baseline scheduling. 3. Couple-Oriented Nature of the Intervention: Unlike conventional individual- and symptom-focused treatments for premature ejaculation, this study designs a couple-oriented intervention, actively involving wives in treatment and addressing women's sexual needs and expectations. This approach is based on Phase 1 qualitative findings and women's lived experiences. 4. Mixed-Methods Approach: The present study employs a mixed-methods approach, in which the qualitative findings of the first phase inform the development of the treatment package in the second phase, which is then evaluated quantitatively in the third and fourth phases (feasibility and single-case). 5. Absence of Full Blinding: Due to the nature of the psychological intervention (couple-oriented CBT), full blinding of participants and therapists is not feasible. 6.Presence of a Male Research Collaborator: Given cultural considerations and the necessity of observing religious boundaries in sexual health interventions, male-specific sessions and joint couple sessions are conducted with the presence of a male therapist (Dr. Seyed Kazem Foroutan, Urologist and Head of the Family Health Clinic at Shahed University. 7.Emphasis on Theoretical Saturation in the Qualitative Study: The sample size in the first study is determined based on theoretical saturation (estimated 12–20 participants), and purposive sampling is employed. 8. Limited Sample Size in the Efficacy Study: The fourth study is conducted with 4 couples (plus 1 pilot couple), which is consistent with the nature of the single-case design and the goal of in-depth examination of the change process.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahd University of Medical Sciences
Street address
Khalij-e Fars Highway (Beginning of Tehran-Qom Freeway), Opposite the Holy Shrine of Imam Khomeini, Shahed University

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Tehran
Province
Tehran
Postal code
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Approval date
2026-09-01, 1405/06/10
Ethics committee reference number
IR.SHAHED.MED.REC.1405.062

Health conditions studied

1

Description of health condition studied
Premature ejaculation
ICD-10 code
F52.4
ICD-10 code description
Premature ejaculation

Primary outcomes

1

Description
Severity of premature ejaculation symptoms in men
Timepoint
Severity of premature ejaculation symptoms in men is measured at the following time points: 1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively). 3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.
Method of measurement
Tool: Premature Ejaculation Diagnostic Tool (PEDT) and Intravaginal Ejaculatory Latency Time (IELT) measurement.Method: The PEDT questionnaire is completed by the affected man. The IELT is measured based on the couples' self-report.

2

Description
Men's Sexual Quality of Life
Timepoint
Men's sexual quality of life is measured at the following time points:1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively). 3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.
Method of measurement
Sexual Quality of Life Questionnaire for Men (SQOL-M) by Abraham et al. (2008)

3

Description
Couples' sexual satisfaction
Timepoint
Couples' sexual satisfaction is measured at the following time points:1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively). 3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.
Method of measurement
Golombok-Rust Sexual Satisfaction Questionnaire

4

Description
Couples' marital adjustment
Timepoint
Couples' marital adjustment is measured at the following time points:1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively). 3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.
Method of measurement
Revised Dyadic Adjustment Scale (RDAS) by Busby et al.

5

Description
Female sexual function
Timepoint
Female sexual function is measured at the following time points:1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively).3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.
Method of measurement
Female Sexual Function Index (FSFI) self-report questionnaire by Rosen et al

6

Description
Sexual Quality of Life-Female

Timepoint
Sexual Quality of Life-Female is measured at the following time points:1. Baseline: At least three measurements before the start of the intervention, at one-week intervals, to establish the baseline trend and symptom stability. 2. During Intervention: After the start of the intervention, assessments are conducted at the end of sessions 3, 6, and 9 (i.e., weeks 3, 6, and 9, respectively). 3. Post-Intervention (Post-test): Immediately after the completion of the 10-week sessions. Follow-up: 1.5 months after the end of the intervention.

Method of measurement
Sexual Quality of Life-Female questionnaire (SQOL-F) by Symonds et al (2005)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention name: Couple-oriented cognitive-behavioral therapy based on qualitative findings for premature ejaculation. **Intervention type:** Psychological – Cognitive/Behavioral (CBT). **Therapeutic method:** This intervention is based on a cognitive-behavioral treatment package initially developed in an individual format and then improved into a couple-oriented package using qualitative research findings (women's lived experiences) and active participation of couples. The main approach is a combination of cognitive techniques (correcting dysfunctional sexual thoughts and beliefs), behavioral techniques (exposure exercises, stop-start, communication), and couple-oriented techniques (increasing intimacy, communication skills, attention to women's sexual needs). **Number and duration of sessions:** Total sessions: 10. Duration per session: 60 to 90 minutes. Course duration: 10 weeks (one session per week). **Session content and structure:** Includes cognitive-behavioral education on premature ejaculation, ejaculation control techniques (stop-start, squeeze), anxiety management, and correcting dysfunctional sexual beliefs. Introductory education on sexual anatomy and physiology of men and women, communication and sexual dialogue skills, foreplay and intimacy exercises, attention to women's sexual needs and expectations, and couple-based homework. **Setting:** Family Health Clinic, Shahed University. **Equipment:** Private counseling room, printed questionnaires and worksheets, and educational materials. **Homework and worksheets:** Couple-based homework and in-session/out-of-session worksheets.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Family Health Clinic, Shahed University

Full name of responsible person
Zahra Khaksari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahed University

Full name of responsible person
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Grant name
-

Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahed University

Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Zahra Khaksari
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Latest degree
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Seyed Kazem foroutan
Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Zahra khaksari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Primary and Secondary Outcome Data Qualitative Data (Interviews) Protocol and Treatment Package Analytical Data and Results

When the data will become available and for how long

Access start date: 6 months after publication of the main results in a reputable scientific journal. Time frame: Unlimited.

To whom data/document is available

Academic and Scientific Institution Researchers Clinical Specialists and Therapists Ethics Committees and Scientific Reviewers

Under which criteria data/document could be used

Request Conditions: Official request form + introduction letter + practice license + ethics approval + confidentiality agreement + DUA. Permitted analyses: Descriptive, inferential, statistical, qualitative. Not permitted analyses: Commercial, re-identification, destructive. Permitted use of documentation: Scientific, educational, clinical with citation. Not permitted use: Reproduction, sale, ownership claims, commercial use. Governing mechanisms: PI supervision, reporting, citation, no third-party transfer, specified validity period. Qualitative data: Key quotes only, without identifying information.

From where data/document is obtainable

Applicants may request access to data or documentation through the following channels, in order of priority: 1. Principal Investigator (First Priority): Name: Zahra Khaksari Role: Principal Investigator Email: zahra.khaksari@shahed.ac.ir Mobile:00989046466233 Postal Address: Tehran, Palestine Street, Italia Street, Next to Shahid Mostafa Khomeini Hospital, Family Health Clinic, Shahed University 2. Supervisor (Second Priority): Name: Dr. Seyed Kazem Foroutan Role: Supervisor, Urologist Email: foroutan@shahed.ac.ir Postal Address: Tehran, Beginning of Tehran-Qom Freeway, Opposite the Holy Shrine of Imam Khomeini, Shahed University, Family Health Clinic

What processes are involved for a request to access data/document

Request Process: Submit form + introduction letter (1 week) PI review (1-2 weeks) Ethics approval (2-4 weeks) Sign confidentiality agreement + DUA (1 week) Data preparation and delivery (1-2 weeks) Post-use reporting

Comments