Study Protocol

The Protocol of a Clinical Trial on the Effectiveness of Solution-focused Brief Therapy on the Sexual Function of Women With Hypothyroidism

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ABSTRACT

Background and Objective: Hypothyroidism can affect the sexual function of women. This study presents the protocol of a study on the effect of Solution-focused brief therapy (SFBT) on the sexual function of women with hypothyroidism.

Materials & Methods: This is a study protocol for a randomized clinical trial involving 64 women with hypothyroidism in Iran, who will be randomly divided into two groups of control (n=32) and intervention (n=32). To collect data, a sociodemographic/medical form, the general health questionnaire-28 (GHQ-28), the female sexual function index (FSFI), and the female sexual distress scale-revised (FSDS-R) will be used. The individual SFBT will be provided in five sessions of 45 minutes with a one-week interval. Data analysis will be performed in SPSS software, version 22.

Conclusion: The results of the clinical trial on the effect of SFBT for women with hypothyroidism can be highly beneficial.

Keywords: Solution-focused brief therapy (SFBT), Sexual function, Hypothyroidism, Women

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Introduction

Sexual health is a fundamental human right that is influenced by various factors [1]. According to the definition of the fifth edition of the diagnostic and statistical manual of mental disorders (DSM-5), sexual dysfunction is "a heterogeneous group of disorders that are typically characterized by a clinically significant disturbance in a person's ability to respond sexually or to sexual pleasure" [2]. Female sexual dysfunction refers to a group of psychological, individual, and marital problems that manifest as disorders in desire, arousal, orgasm, and pain during intercourse [3]. The prevalence of female sexual dysfunction worldwide is 30-50% [4-9]. Sexual dysfunction can have negative effects on self-esteem, body image, interpersonal relationships, and overall physical health, including fertility [10]. The cause of sexual dysfunction is complex and multifactorial. Medical and psychiatric issues such as medication use, fatigue, stress, and menopausal status, as well as age and relational and environmental factors, may play a role [11].

Thyroid disorders can cause sexual dysfunction in men and women [12]. Hypothyroidism is a chronic disease that is accompanied by a deficiency of thyroid hormones, including thyroxine (T4) and triiodothyronine (T3) [13]. The prevalence of hypothyroidism in the general population varies between 0.3% and 3.7% in the United States and between 0.2% and 3.5% in Europe, depending on the definition used [14]. The Tehran Thyroid Study over a period of six years reported an annual incidence of 2 in 1000 people for overt hypothyroidism in the Iranian population [15]. The Tabari cohort study reported a prevalence of 10.5% for thyroid disorders in Iran (3.4% in men and 15.3% in women) [16]. Hypothyroidism affects women 5-8 times more than men [12]. Sexual function in women with hypothyroidism is worse than in healthy peers [17].

Therapeutic approaches for female sexual dysfunction can be included in four groups of surgical, pharmaceutical, hormonal, and psychological treatments [18]. Solution-focused brief therapy (SFBT) is a psychotherapy approach that focuses on constructing solutions rather than solving problems. It examines current resources and future hopes, rather than current problems and past causes, and typically consists of only three to five sessions [19]. So far, the impact of SFBT on improving women's sexual desire [20], men's erectile dysfunction [21], sexual quality of life in breast cancer survivors [22], violence and quality of life in women exposed to domestic violence [23], and anxiety in pregnant women [24] has been investigated. However, we found no study on the effects of SFBT on the sexual function of women with hypothyroidism. Therefore, since women with hypothyroidism still experience sexual dysfunction even after treatment [25-27] and considering the importance of sexual function in sexual health, the protocol study will determine the effectiveness of SFBT on the sexual function of women with hypothyroidism.

Materials and Methods

Study design and sampling

This is a protocol study outlining a double-blind randomized controlled clinical trial. Considering the sexual function scores of women of reproductive age with hypothyroidism in the study by Sheikh Miri et al. [28], and a test power of 0.9, the sample size was calculated as 26 per group in PASS software, version 2021. Given a dropout rate of 20% in each group, it will increase to 32 per group (total=64). The participants will be selected based on inclusion criteria using a convenience sampling method from among women with hypothyroidism referred to two specialized endocrine clinics of medical centers affiliated with Mazandaran University of Medical Sciences, Iran. Inclusion criteria are: At least one year of marriage, at least a primary education, age 18-49 years, having a smartphone, at least one year of hypothyroidism diagnosed by an endocrine specialist, a female sexual function index (FSFI) score ≤26.5, and a female sexual distress scale-revised (FSDS-R) score >11. Exclusion criteria are: Pregnancy and breastfeeding, menopause, history of infertility, history of pelvic surgeries, sexual dysfunction of husband, smoking, alcohol/hookah use, presence of physical illnesses affecting sexual function (based on the medical records or self-report), use of medications affecting sexual function (based on self-report), psychological disorders (score ≥23 on the general health questionnaire-28 [GHQ-28]), and participation in training and counseling courses related to improving sexual function in the past six months.

The samples will be matched for the duration of hypothyroidism, and the group allocation will be done using a block randomization method (using two blocks of TC and CT, where T is the intervention group and C is the control group). Numbers will be generated randomly using the RANDBETWEEN command in Excel software in the range 1 to 2. According to the generated numbers, one of the blocks (block 1 for CT and block 2 for TC) will be selected, and the samples will be allocated. Participants will be assigned to two groups: Intervention and control (Figure 1). In this study, due to the counseling

Table 1. Time schedule for conducting different parts of the study

Activity	Time to Complete	Timeline (m)										
		1	2	3	4	5	6	7	8	9	10	11
Sampling	Three months	*	*	*								
Intervention	Three months				*	*	*					
Follow-up after intervention	Three months					*	*	*				
Data analysis	Two months								*	*		
Writing the article	Two months										*	*

Current Psychosomatic Research

and therapeutic nature of the intervention, participants will not be blinded to the type of intervention. However, the data analyzer and the one conducting the sampling will be blinded to the group allocation. The schedule for conducting different parts of the study is provided in Table 1.

Data collection tools

The data will be collected before the intervention, immediately after, and four weeks after the intervention from the two groups using four instruments: A sociodemographic/medical form, the FSFI, FSDS-R, and GHQ-28. The sociodemographic/medical form surveys age of the woman and her husband, educational level of the woman and her husband, employment status of the woman and her husband, duration of marriage, number of children, body mass index, ownership type of residential property, sufficiency of monthly income, socioeconomic status, satisfaction level with socio-economic status, duration of disease diagnosis, history of infertility, history of pelvic surgeries, menopausal status, smoking, alcohol/hookah use, name/dosage/method of medications for thyroid dysfunction, history of other physical diseases, history of medications taken, and the information about the sexual dysfunction of the husband.

The FSFI is a questionnaire designed by Rosen et al in 2000. It assesses women's sexual function in six independent domains: Desire (items 1 and 2), arousal (items 3, 4, 5, and 6), lubrication (items 7, 8, 9, and 10), orgasm (items 11, 12, and 13), satisfaction (items 14, 15, and 16), and pain (items 17, 18, and 19). The items are scored on a Likert scale. A higher score indicates better sexual function [29]. Scores ≤26.55 indicate sexual dysfunction [30]. In the study conducted by Mohammadi et al. [31], the internal consistency of the Persian version using Cronbach's α coefficient for the entire scale or domains was 0.70 or higher, consistent with the results of Rosen et al. [29] (0.89 or higher), Wiegel et al. (0.74 or higher), and (0.8 or higher) [30]. Rosen. et al. [29] showed the convergent validity of the FSFI with the marital satisfaction scale. The test re-test reliability for the entire scale was 0.88, and for the sub-scales, ranged from 0.79 to 0.86. Mohammadi et al. [31] found a significant difference between the total scale scores and subscale scores of FSFI in two groups with and without sexual dysfunction, indicating the discriminant validity of the Persian version [31].

The GHQ-28 is a self-report tool developed by Goldberg in 1997. It has 28 items and four domains: Somatic symptoms (items 1-7), anxiety/insomnia (items 8-14), social dysfunction (items 15-21), and depression (items 22-28). The total score of each subscale ranges from 4 to 28. A score >14 indicates higher mental problems. The cut-off point is 23. This means that to the extent that those with higher than 23 should be classified as psychiatric. Goldberg et al [32] reported the classification validity for the entire scale as 0.95. For the Persian version, Nazifi et al. [33] reported Cronbach's α value for the subscales of somatic symptoms, anxiety/insomnia, social dysfunction, and depression, and for the whole scale as 0.86, 0.88, 0.74, and 0.89 and 0.92, respectively.

The FSDS-R, designed by Derogatis et al [34], is a self-report tool with 13 items assessing different aspects of distress related to sexual issues in women. The items are scored on a 5-point Likert scale from 0 (never) to 4 (always), with a higher score indicating greater sexually-related distress. It has acceptable internal consistency with a Cronbach's α ranging from 0.87 to 0.93 and high test/re-test reliability with an interclass correlation coefficient ranging from 0.74 to 0.86. For the Persian version of the FSDS-R, internal consistency and reliability were evaluated by Azimi et al [35], which were

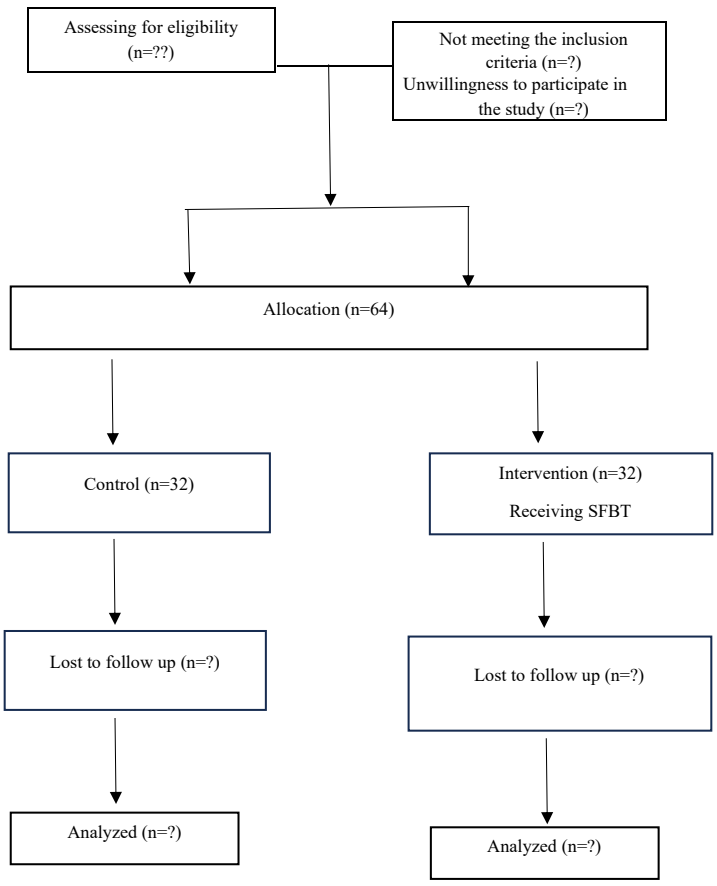

Figure 1. CONSORT diagram of the study

more than 0.7 and thus acceptable, and it can be used as a valid and reliable tool for assessing sexually-related distress in Iranian women.

Intervention

The intervention group will receive individual SFBT in five 45-minute sessions, with a one-week interval between each session. Session 1 includes the client defining the problem, expressing it in one word and transforming that word into a sentence, and discussing and debating the problem to transform it into achievable goals. Session 2 includes prioritizing the goals and examining solutions for problems. Session 3 includes talking about the future and using the exception questions, compatibility questions, and miracle questions. Session 4 includes the use of the key technique for identifying the positive points and capabilities of clients and the scaling questions technique. Finally, session 5 included the use of solution-focused questions and determining whether the client has achieved their goals or not (through scaling questions). Women in the control group will receive routine care in their treatment centers. After the end of the study, a pamphlet containing educational materials about hypothyroidism and its effect on sexual function and solutions to improve it will be provided to the control group. To evaluate the therapists' adherence to the protocol, the evaluation checklist will be marked for each participant, and then the main researcher will check it.

Data analysis

Data will be analyzed in SPSS software, version 22. Qualitative variables will be described using frequency and percentage, while Mean±SD, and interquartile range will be used for quantitative variables. Comparison of the sociodemographic/medical variables between the two intervention and control groups will be done using the chi-square test (if the presumption of Fisher's exact test was not established), independent t-test, analysis of variance (ANOVA), or their non-parametric equivalents (Mann-Whitney U and Kruskal-Wallis tests). Normality will be assessed using the Kolmogorov-Smirnov or Shapiro-Wilk test, and the equality of variances will be assessed using Levene's test. Finally, to compare the mean scores of FSFI between the two intervention and control groups during the study period and also to control the effect of the intervening factors, repeated measures or

mixed ANOVA will be used, and their effect size will be reported. The significance level for all tests will be set at 0.05. To manage missing data in the intention-to-treat analysis, all subjects randomly assigned to the study groups during the randomization process are included in the statistical analysis, regardless of the type of intervention received during the study, their failure to comply with the study instructions, their withdrawal from continuing to participate in the study, or any event that occurred after randomization.

Conclusion

This study outlined the protocol of a clinical trial that will assess the effects of SFBT on the sexual function of women with hypothyroidism in Iran. The session contents will be developed based on a protocol evaluated by experts who are not members of the research team. Given the importance of sexual function and the prevalence of hypothyroidism, the results of the clinical trial can be highly beneficial. The main limitation of this clinical trial will be the use of a convenience sampling method and self-report tools.

Ethical Considerations

Compliance with ethical guidelines

All ethical principles will be considered in this study. This study was approved by the Ethics Committee of Mazandaran University of Medical Sciences, Sari, Iran (Code: IR.MAZUMS.REC.1403.252) and was registered by the Iranian Registry of Clinical Trials (IRCT) Tehran, Iran (Code: IRCT20161126031117N16).

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Authors' contributions

Investigation: Nastaran Salehi and Soghra Khani; Data collection: Zahra Kashi and Nastaran Salehi; Writing and final approval: All authors.

Conflict of interest

The authors declared no conflict of interest.

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