

## ORIGINAL RESEARCH—OUTCOMES ASSESSMENT

**Using an FSDS-R Item to Screen for Sexually Related Distress: A MsFLASH Analysis**

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**ABSTRACT**

**Introduction.** The Female Sexual Distress Scale-Revised (FSDS-R) was created and validated to assess distress associated with impaired sexual function, but it is lengthy for use in clinical practice and research when assessing sexual function is not a primary objective.

**Aim.** The study aims to evaluate whether a single item from the FSDS-R could be identified to use to screen midlife women for bothersome diminution in sexual function based on three criteria: (i) highly correlated with total scores; (ii) correlated with commonly assessed domains of female sexual functioning; and (iii) able to differentiate between women reporting high and low sexual concerns during the prior month.

**Methods.** Data from 93 midlife women were collected by the Menopause Strategies Finding Lasting Answers to Symptoms and Health (MsFLASH) research network.

**Main Outcome Measures.** Women completed the FSDS-R, Female Sexual Function Index (FSFI), and Menopausal Quality of Life Scale (MENQOL). Those who reported a change in the past month on the MENQOL sexual were categorized into a high sexual concerns group, while all others were categorized into a low sexual concerns group.

**Results.** Women were an average of 54.6 years old (SD 3.1) and mostly Caucasian (77.4%), college educated (60.2%), married/living as married (64.5%), and postmenopausal (79.6%). The FSDS-R item number 1 “Distressed about sex life” was: (i) highly correlated with FSDS-R total scores ( $r = 0.90$ ); (ii) moderately correlated with FSFI total scores ( $r = -0.38$ ) and FSFI desire ( $r = -0.37$ ) and satisfaction domains ( $r = -0.40$ ); and (iii) showed one of the largest mean differences between high and low sexual concerns groups ( $P < 0.001$ ). Other FSDS-R items met one or two, but not all three of the prespecified criteria (i, ii, iii).

**Conclusions.** A single FSDS-R item may be a useful screening tool to quickly identify midlife women with sexually related distress when it is not feasible to administer the entire scale, though further validation is warranted.

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**Key Words.** Menopause; Sexual Behavior; Female Sexual Distress Scale Revised; Quality of Life; Adult; Female

## Introduction

Sexual function is an important aspect of quality of life for most women, but is known to be of particular importance for midlife women as hormonal changes may result in untoward skin, vascular and neuronal changes [1,2]. Practitioners rarely ask their patients about sexual function at midlife, and women rarely volunteer that they are distressed or affected by diminishing sexual function [3]. A single item question that could screen women for bothersome diminution in sexual function could provide direction for more in-depth clinical conversations and greatly improve health care for women receiving primary care by family practitioners, internists, and gynecologists. It may also be beneficial for use in research studies where assessing sexual function is not a primary objective.

Current definitions of female sexual dysfunction from the *Diagnostic and Statistical Manual of Mental Disorders*, Fifth Edition (*DSM-V*) include problems with desire, arousal, orgasm, or pain that cause marked distress or interpersonal difficulty [4]. Current diagnostic criteria require an assessment of both symptoms and symptom-associated distress. One of the most commonly used instruments used to diagnose sexual dysfunction in clinical gynecologic and urogynecologic practices and in research settings is the Female Sexual Function Index (FSFI) [5]; however, it does not assess distress and it is somewhat lengthy, with a total of 19 items. Many women have distress around diminishing sexual function, but do not screen positive for one of the *DSM-V* sexual function disorders. Starting conversations around sexual function with a single screening question that identifies women “bothered” by their sexual function would be of value.

The Female Sexual Distress Scale-Revised (FSDS-R) was created and validated to assess sexually related distress—that is, distress associated with inadequate or impaired sexual function. An evaluation of the original scale (FSDS) among 500 women showed a final 12-item version to be a psychometrically sound, unidimensional measure [6]. Subsequently, a revised 13-item scale (FSDS-R) was devised that also showed strong psychometric properties, including the ability to assess sexually related distress in women with hypoactive sexual desire disorder or serve as a screening tool to identify women with high and low sexual function [7]. The FSDS and/or FSDS-R have been widely adopted and are available in 10 different languages, with translated

scales also demonstrating strong internal consistency, reliability, and validity [7–9]. However, its multiple items can be lengthy for use in research where assessing sexual function is not the primary objective of the clinical trial. In these studies, sexual function typically is only one of multiple end points assessed, and subjects are completing a large number of questionnaires. In addition to its utility in research, a validated single item to assess sexually related distress could be very helpful in clinical practice to standardize quick identification of women who would benefit from a more comprehensive assessment and/or referral to practitioners with expertise in assessing and treating sexual dysfunction.

## Aims

The purpose of this analysis was to evaluate whether a single item from the FSDS-R could be identified to use to screen women for bothersome diminution in sexual function based on three criteria: (i) highly correlated with total scores; (ii) correlated with commonly assessed domains of female sexual functioning; and (iii) able to differentiate between women who reported high and low sexual concerns on a validated questionnaire during the prior month.

## Methods

### Design

This was a cross-sectional analysis of baseline data collected from the second trial conducted by the Menopause Strategies: Finding Lasting Answers to Symptoms and Health (MsFLASH) research network. Study methods and findings are published elsewhere [10–14]. Briefly, the trial compared yoga, exercise, and omega-3 fatty acid supplements to placebo for the treatment of menopausal hot flashes in symptomatic women. Although the study was conducted at three sites, only women at the Seattle site completed the FSDS-R, as investigators at the other sites believed the questionnaire was too lengthy for subjects already completing a large battery of questionnaires related to the study’s principal objectives, including assessments of vasomotor symptoms, sleep, and mood. At the Seattle site, recruitment occurred between November 9, 2010 and February 8, 2012, and data collection occurred between February 16, 2011 and May 1, 2012.

### Setting and Participants

Participants were recruited primarily by mass mailings. Eligible participants were 40–62 years

old, postmenopausal ( $\geq 12$  months since the last menstrual period or bilateral oophorectomy) or in the late menopausal transition (amenorrhea  $\geq 60$  days in the past year), in good general health according to medical history, and reporting  $\geq 14$  hot flashes per week and rated as severe or bothersome on  $\geq 4$  days or nights per week. Women were excluded for use of any hot flash treatments, current severe medical illness or major depressive episode, conditions that interfered with ability to tolerate the interventions, such as physical limitations, high fish consumption, or serious medical illnesses.

### Procedures

Following a telephone screening that included verbal consent, women maintained hot flash diaries for 2 weeks. Those who continued to be eligible provided written informed consent and took part in two baseline assessments 1 week apart. Questionnaires used in this analysis were completed at the first or second baseline visit by the Seattle participants. Study staff were available to address questions or concerns, but did not otherwise direct participants in filling out the questionnaires.

### Main Outcome Measures

Demographic data collected on a form included menstrual history to determine menopausal status, age, race/ethnicity, education, and marital status. Height and weight were measured by a clinic staff to determine body mass index. Women were also asked to rate their current health status from 1 (poor) to 5 (excellent).

For the 13-item FSDS-R, women rated each item in terms of frequency from 0 (never) to 4 (always). Items were summed to create a total score ranging from 0 to 52, with higher scores indicating more sexually related distress. Cronbach's alpha for the scale in our participants was 0.95.

Two other questionnaires were used in the analysis. The FSFI is a 19-item assessment of sexual function over the past 4 weeks [5]. The scale includes six domains (desire, subjective arousal, lubrication, orgasm, satisfaction, and pain). Individual domain scores are as follow: 1.2–6 for desire; 0–6 for arousal, lubrication, orgasm, and pain; and 0.8–6 for satisfaction. Total scores range from 2 to 36, with lower scores indicating higher symptom burden. Cronbach's alpha was 0.91. In addition, the three items that comprise the sexual

domain from the 30-item Menopausal Quality of Life Scale (MENQOL) were used in this analysis [15]. Women were categorized as having high sexual concerns if they responded yes to all three MENQOL sexual domain items: (i) experiencing diminished sexual desire; (ii) avoidance of intimacy; and (iii) vaginal dryness. All other respondents were categorized as having low sexual concerns.

### Data Analysis

Sample demographics were summarized using descriptive statistics ( $n = 93$ ). Frequencies for individual FSDS-R items were calculated. Pearson correlations were calculated for: FSDS-R item to FSDS-R total, FSDS-R item to FSFI total, and FSDS-R item to FSFI domain scores. Then based on MENQOL scores, women were divided into high ( $n = 20$ ) and low ( $n = 72$ ) sexual concerns groups. FSDS-R item means were compared between groups via two-sample  $t$ -tests.

A total sample size of 93 participants provided 83% power to detect a correlation coefficient as small as 0.3, based on a two-sided 0.05 significance level. In addition, sexual concerns subgroups of 20 and 72 provided 80% power to detect an effect size of 0.72 standard deviation (SD) unit difference between groups, based on a two-sample  $t$ -test with two-sided 0.05 significance level. An effect size is defined as the difference between the groups' means, divided by their common SD. Observed effect sizes, calculated as Glass' delta due to inequality in variances between groups, ranged from 0.5 to 1.6 SD.

### Results

The 93 participants at the Seattle site completed the FSDS-R, the FSFI, and both MENQOL items. There were 20.4% who were missing one or more items on at least one of the three questionnaires: FSDS-R (2.2%), FSFI (3.2%), and MENQOL (19.4%). All available data were included in each individual analysis. While FSFI total and satisfaction scores had a 19.4% rate of missing data, only 3.3% or fewer participants were missing data for all other outcome variables.

Demographic characteristics were as follows. Participants' mean age was 54.6 years old ( $SD = 3.1$ ). Women were Caucasian (77.4%), African American (9.7%), or other ethnicities (12.9%). Most held a college degree (60.2%) and were married or living as married (64.5%). Women were postmenopausal (79.6%) or perimenopausal

**Table 1** Distribution of responses to the Female Sexual Distress Scale-Revised (FSDS-R) items (n = 93)

	Never 0		Rarely 1		Occasionally 2		Frequently 3		Always 4	
	n	%	n	%	n	%	n	%	n	%
1. Distressed about sex life	28	30	33	36	20	22	7	8	5	5
2. Unhappy about sexual relationship	28	30	28	30	22	24	10	11	4	4
3. Guilty about sexual difficulties	43	46	26	28	10	11	11	12	3	3
4. Frustrated by sexual problems	44	47	23	25	15	16	7	8	4	4
5. Stressed about sex	46	50	24	26	12	13	9	10	2	2
6. Inferior because of sexual problems	62	67	17	18	8	9	4	4	1	1
7. Worried about sex	47	51	22	24	16	17	7	8	1	1
8. Sexually inadequate	50	54	18	19	16	17	6	7	3	3
9. Regrets about sexuality	56	60	15	16	14	15	6	7	2	2
10. Embarrassed about sexual problems	57	61	20	22	10	11	3	3	3	3
11. Dissatisfied with sex life	31	33	19	20	27	29	9	10	7	8
12. Angry about sex life	66	71	16	17	8	9	1	1	2	2
13. Bothered by low sexual desire	36	39	15	16	22	24	13	14	7	8

(20.4%). Most had a body mass index below 30 (67.3%), and most self-reported their health as very good or excellent (69.9%).

Table 1 shows the distribution of responses on the FSDS-R. Women most frequently endorsed 0 or 1, indicating no or little sexually related distress for the majority of items. The median score for all participants was 10.0 (interquartile range = 2 to 17). Women were least likely to endorse being “angry about sex life” or feeling “inferior because of sex problems.”

Table 2 depicts correlations between FSDS-R items and FSDS-R total, FSFI total, and FSFI domains. Item 1, distress about sex life, was the FSDS-R item most highly correlated with FSDS-R total scores. Distress about sex life was tied with item 2, “unhappy about sexual relation-

ship,” as the FSDS-R items most highly correlated with FSFI total scores. FSDS-R items were generally not as highly correlated with FSFI domain scores as with FSFI total scores. FSDS-R items were modestly correlated with FSFI domains of desire and satisfaction, and poorly correlated with other FSFI domains. However, distress about sex life was one of the three items most highly correlated with FSFI desire and satisfaction domain scores.

Shown in Table 3 are differences in FSDS-R items between high and low sexual concerns groups, classified based on the MENQOL sexual domain scores. Of note is that all but one FSDS-R item was significantly higher in the high sexual concerns group compared with the low sexual concerns group. The largest mean differences were for

**Table 2** Pearson correlation coefficients between FSDS-R items and FSDS-R total scores, FSFI total scores, and FSFI domain scores

	FSDS-R		FSFI Domains					
	Total	FSFI Total	Desire	Arousal	Lubrication	Orgasm	Satisfaction	Pain
Distressed about your sex life	0.90***	-0.38***	-0.37***	-0.15	-0.09	-0.06	-0.40***	-0.06
Unhappy about your sexual relationship	0.76***	-0.38***	-0.23*	-0.15	-0.08	-0.03	-0.52***	-0.15
Guilty about sexual difficulties	0.79***	-0.34***	-0.38***	-0.21	-0.05	-0.15	-0.29*	-0.05
Frustrated by your sexual problems	0.86***	-0.33**	-0.35***	-0.15	-0.09	-0.11	-0.31**	-0.09
Stressed about sex	0.81***	-0.22**	-0.21*	-0.07	-0.01	-0.01	-0.24*	-0.03
Inferior because of sexual problems	0.81***	-0.23	-0.28**	-0.17	-0.06	-0.11	-0.25*	-0.07
Worried about sex	0.81***	-0.28*	-0.34***	-0.22*	-0.08	-0.14	-0.36**	-0.11
Sexually inadequate	0.82***	-0.30*	-0.34**	-0.18	-0.12	-0.12	-0.29*	-0.12
Regrets about your sexuality	0.69***	-0.12	-0.18	-0.01	-0.04	0.03	-0.09	-0.01
Embarrassed about sexual problems	0.79***	-0.34**	-0.36***	-0.24*	-0.14	-0.18	-0.29*	-0.16
Dissatisfied with your sex life	0.74***	-0.32**	-0.23*	-0.09	-0.02	-0.01	-0.52***	-0.09
Angry about your sex life	0.72***	-0.30**	-0.17	-0.17	-0.10	-0.13	-0.36**	-0.10
Bothered by low sexual desire	0.71***	-0.30**	-0.40***	-0.08	-0.05	-0.03	-0.29*	0.07

\* $P < 0.05$ , \*\* $P < 0.01$ , \*\*\* $P < 0.001$ .

FSDS-R = Female Sexual Distress Scale-Revised, high scores = greater frequency of problems, n = 93.

FSFI = Female Sexual Function Index, lower scores = higher symptom burden, n = 93.

**Table 3** Mean with 95% confidence interval of FSDS-R items between MENQOL high and low sexual concerns groups\*

	High concerns (n = 20)	Low concerns (n = 72)	Effect size <sup>†</sup>	P <sup>‡</sup>
1. Distressed about your sex life	2.1 (1.5, 2.7)	1.0 (0.8, 1.2)	1.1	<0.001
2. Unhappy about your sexual relationship	2.1 (1.5, 2.7)	1.1 (0.8, 1.3)	1.0	<0.001
3. Guilty about sexual difficulties	1.8 (1.2, 2.4)	0.8 (0.5, 1.0)	1.0	<0.001
4. Frustrated by your sexual problems	2.0 (1.4, 2.5)	0.7 (0.5, 0.9)	1.3	<0.001
5. Stressed about sex	1.6 (0.9, 2.3)	0.7 (0.5, 0.9)	1.0	0.012
6. Inferior because of sexual problems	1.1 (0.4, 1.7)	0.4 (0.2, 0.6)	0.9	0.044
7. Worried about sex	1.4 (0.8, 2.0)	0.7 (0.5, 0.9)	0.8	0.036
8. Sexually inadequate	1.8 (1.1, 2.4)	0.6 (0.4, 0.8)	1.3	<0.001
9. Regrets about your sexuality	1.3 (0.7, 1.9)	0.6 (0.4, 0.8)	0.7	0.009
10. Embarrassed about sexual problems	1.4 (0.7, 2.1)	0.5 (0.3, 0.6)	1.3	0.013
11. Dissatisfied with your sex life	2.1 (1.6, 2.6)	1.2 (0.9, 1.5)	0.8	0.004
12. Angry about your sex life	0.8 (0.4, 1.2)	0.4 (0.2, 0.6)	0.5	0.053
13. Bothered by low sexual desire	2.8 (2.3, 3.2)	1.0 (0.7, 1.3)	1.6	<0.001

\*High sexual concerns defined as "Yes" to experiencing a change in sexual desire, avoiding intimacy, and vaginal dryness in past month on Menopausal Quality of Life Scale (MENQOL).

<sup>†</sup>Effect size (Glass' delta).

<sup>‡</sup>P values from a two-sided two-sample t-test.

FSDS-R = Female Sexual Distress Scale-Revised.

FSDS-R items of distress about sex life, sexual inadequacy, frustrated about sex life, and bothered by low desire.

### Conclusions

This analysis was undertaken in an effort to identify a potential single-item screening question to quickly identify women who may be experiencing sexually related distress, in hopes of increasing the likelihood that this important end point is assessed in both clinical practice and research. In research, a simple assessment could be very valuable when sexual function is not the primary focus of a clinic visit or a study. For example, an assessment of sexually related distress is currently not included in large randomized controlled trials of new drugs for hypertension, diabetes, or cancer treatments. A validated single item could easily be added to the large battery of questionnaires completed in these trials without increasing subject burden. If a significant effect on sexual distress was identified, more extensive and detailed investigation then would be required to determine what aspects of sexual function were affected. In clinical practice, clinicians rarely ask women about sexual problems, despite a high prevalence of distressing sexual problems, especially in midlife women [3,16]. The availability of a validated single item to standardize quick identification of sexually related distress would be very helpful in general clinical practice to identify women who would benefit from further evaluation or referral to practitioners with expertise in sexual dysfunction.

Results demonstrate that a single FSDS-R item pertaining to distress about sex life (item 1) per-

formed well based on prespecified criteria. This item was most highly correlated with FSDS-R total scores, among the most highly correlated items with FSFI total and domain scores, and was among the top items showing the greatest mean difference between high and low sexual concerns groups. It is not surprising that the FSDS-R distress item 1 emerged as a central item, given the importance of the construct in the definition of sexual function [4,6]. Other FSDS-R items met one or two of our prespecified criteria, but not all three criteria.

To our knowledge, prior studies have not evaluated a single-item screening question for sexual function distress. Research has focused on evaluating the FSDS-R single item related to sexual desire bother (item 13) rather than distress about sex life (item 1) among women with *DSM-V* sexual dysfunction disorders [17]. Using data from 738 women from the United States, Canada, and Europe, FSDS-R total scores and responses to FSDS-R item 13 were found to differentiate between groups with and without hypoactive sexual desire, but not between groups with other different types of sexual dysfunction. Similar analyses for distress about sex life (item 1) were not reported. In our study, item 13 did not perform as well as item 1, probably because we wished to identify an item that assessed global sexual function rather than disorders of desire. While item 13 did differentiate between high and low sexual concerns groups, it was less highly correlated with FSDS-R total, FSFI total, and FSFI domain scores in comparison with item 1. Further analyses in larger populations would be needed to determine

whether FSDS-R item 1 differentiates women with different types of sexual dysfunction and whether the FSDS-R item 1 would be useful in clinical settings, opening up patient-provider discussions that otherwise rarely occur.

Correlations within the FSDS-R and between the FSDS-R and FSFI total and domain scores are somewhat difficult to interpret due to the lack of comparable published data. Several prior psychometric analyses did not report FSDS-R item to total correlations [5–8,17] or FSDS-R to FSFI correlations [5–8,17]. However, correlations were reported for the Farsi version of the FSDS-R among 1,966 Iranian women, most of whom did not report female sexual dysfunction (67%). Farsi FSDS-R item to total correlations ranged from 0.67 to 0.82 ( $P < .001$ ) [18], which are lower than in our study using the English language version. In addition, correlations between the Farsi FSDS-R total and FSFI dimensions were  $-0.16$  to  $0.40$  ( $P < .001$ ) [18], which are comparable with our results.

It is possible that the strength of correlations we observed may have varied based on a woman's sexual activity. For example, correlations between the Sexual Health Outcomes in Women Questionnaire (SHOW-Q) and health-related quality of life, body image, and symptom scales varied based on whether or not a woman was sexually active [19].

Limitations include the following. We did not collect data on sexual frequency, partner gender, or history of physical or sexual abuse. The number of study subjects was relatively small and limited to a single geographic area. Only women at a single MsFLASH site completed the FSDS-R due to concerns from principal investigators at all other research sites about subject burden. In addition, the sample was predominantly Caucasian, college educated, and married/living as married. The sample was (i) limited to menopausal women with hot flashes and other symptoms; and (ii) not specifically selected based on sexual dysfunction, so we relied on MENQOL items to differentiate high and low sexual concerns groups based on desire and symptoms, important aspects of *DSM-V* criteria. The MENQOL is a validated, widely used measure of menopausal symptoms, and the sexual function domain is a validated subscale. The FSFI is a more comprehensive measure of sexual function, but it was not used to determine high and low sexual concerns groups in this study, as then it could not have been used in the assessment of construct validity.

In summary, the single FSDS-R item “distress about your sex life” (item 1) may serve as a useful single item in screening women for sexually related distress when time or subject burden is an issue. Replicating our analyses in larger and more diverse populations of all ages and with attention to evaluating sensitivity to change or intervention effects occurring over time is warranted.

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*Conflict of Interest:* Jan L. Shifren is a Consultant at New England Research Institutes. All other authors report no disclosures.

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