

Mindfulness in sex therapy and intimate relationships: a feasibility and randomized controlled pilot study in a cross-diagnostic group

Julie Fregerslev Krieger, MD^{1,*}, Ellids Kristensen, MD^{1,2}, Mikkel Marquardsen, MD¹, Shlomy Ofer, BSc¹, Erik Lykke Mortensen, PhD³, Annamaria Giraldi, MD, PhD^{1,2}

¹Sexological Clinic, Mental Health Centre Copenhagen, Mental Health Services - Capital Region of Denmark 2200, Denmark ²Department of Clinical Medicine, University of Copenhagen, Copenhagen 2200, Denmark

³Department of Public Health, University of Copenhagen, Copenhagen 1353, Denmark

*Corresponding author: Sexological Clinic, Mental Health Centre Copenhagen, Ole Maaløes Vej 14, 2200 Copenhagen N. Email: juliekfa@hotmail.com

Abstract

Background: Mindfulness facets can be trained with structured mindfulness interventions, but little is known regarding application on a broader level within sex therapy (e.g. men, partners and different sexual dysfunctions).

Aim: To evaluate the feasibility and preliminary efficacy of an 8-week intervention—specifically, mindfulness for sex and intimacy in relationships (MSIR)—as a supplement to treatment as usual (TAU) as compared with only TAU in a clinical sample of men and women referred for sexual difficulties with or without a partner.

Methods: In this randomized controlled feasibility pilot study, 34 participants were randomized to MSIR + TAU (n = 15) or TAU (n = 19). Six healthy partners were also included in the study. MSIR was administered as 2 individual evaluations and six 2-hour group sessions of mixed gender and different types of sexual dysfunction.

Outcomes: The primary outcome measures were as follows: (1) feasibility, defined as the implementation of recruitment, acceptance, and attendance of intervention in daily clinical practice and the MSIR completion rate; (2) sexual functioning, as measured on a visual analog scale ("bothered by problem") and by validated questionnaires (Changes in Sexual Function Questionnaire for Females and Males, Female Sexual Function Index, Female Sexual Distress Scale, International Index of Erectile Function).

Results: MSIR was feasible and well received by patients, with high rates of acceptance and intervention completion. As compared with pretreatment, the MSIR + TAU group and TAU control group were significantly less bothered by their sexual problems at the end of treatment, but the change was significantly larger in the MSIR + TAU group (P = .04). Participants in the MSIR + TAU group did not receive fewer TAU sessions than the TAU group (MSIR + TAU mean, 6 sessions; TAU mean, 8 sessions).

Clinical Implications: MSIR could be effectively used in a clinical setting as an add-on to TAU in the treatment of female and male sexual dysfunction and healthy partners.

Strengths and Limitations: The major strength of the study is that it is a randomized controlled study. This study is novel in the sense that it included men and women with different types of sexual dysfunction in the same mindfulness group. Limitations include the pilot nature of the study (e.g. a small sample size), and statistical conclusions should be made with caution. More accurate results may be found in a larger sample. **Conclusion:** Results from this study support already existing evidence that mindfulness-based interventions are feasible and effective for targeting sexual dysfunctions in men and women.

Keywords: female sexual dysfunction; male sexual dysfunction; mindfulness; sexual therapy; biopsychosocial; psychological treatment.

Introduction

Sexual problems are prevalent among men and women, but the exact level of problems can vary across gender and age.¹ When a sexual problem causes distress, it can be considered a sexual dysfunction.² Sexual dysfunction is often associated with impaired quality of life, general well-being problems,³⁻⁵ and relationship problems.^{5,6} Thus, effective treatments are needed.⁷

Sexual dysfunction can be caused and maintained by physiologic and psychological factors in accordance with the biopsychosocial model, and the etiology is often multifactorial.⁸⁻¹⁰ Evidence on psychosocial treatment options indicates that psychological interventions to target impairment in sexual functioning are effective, especially in women, but also

in men where the etiology underlying the problem is primarily psychological.¹¹⁻¹³

One of the first psychological interventions in sexology was sex therapy, as introduced by Masters and Johnson.¹⁴ Sex therapy includes psychoeducation, counseling, and sensate focus training to reduce judgmental self-focus and anxiety concerning sexual intimacy. This program was later refined and combined with other elements from behavioral and psychodynamic approaches. In addition, cognitive behavioral therapy (CBT) is used in sexology to help patients challenge potentially unrealistic thoughts and unpleasant emotions in a sexual situation and initiate behavioral changes that can lead to improved sexual functioning. In recent years, mindfulness has been introduced into the treatment of sexual

Received: May 6, 2022. Revised: May 16, 2023. Accepted: May 21, 2023

[©] The Author(s) 2023. Published by Oxford University Press on behalf of The International Society of Sexual Medicine

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (https://creativecommons.org/lice nses/by-nc/4.0/), which permits non-commercial re-use, distribution, and reproduction in any medium, provided the original work is properly cited. For commercial re-use, please contact journals.permissions@oup.com

dysfunction, where it has been suggested to mitigate sexual problems.¹⁵⁻¹⁷

In mindfulness, one cultivates the ability to notice feelings, sensing the body and being in the present moment nonjudgmentally.¹⁸ Mindfulness has been proposed to enhance interoceptive awareness, which can lead to improved attention to sexual stimuli by lowering some of the known barriers to sexual functioning (ie, impaired attention to bodily sensations, self-judgment, and clinical symptoms such as depression and anxiety).¹⁹ A recent systematic review on mindfulness and sexual dysfunction by Selice and Morris concluded the existence of an inverse association between the cultivation of mindfulness and different types of sexual dysfunction in men and women.¹⁵

The available research encompasses few randomized studies, and the treatment was often given in combination with other treatments. Studies have shown that mindfulness combined with other treatments, such as psychoeducation, CBT, sensate focus, and pelvic floor exercises, can increase desire, arousal, satisfaction, and orgasm in women with desire, arousal, orgasm, and pain disorders.²⁰⁻²² The studies on women were primarily carried out by Brotto and colleagues, who examined women with sexual desire and arousal disorder^{23,24} and women with gynecologic cancer.²⁵ In a recent study, women with sexual interest/arousal disorder were randomized to a mindfulness cognitive therapy program or supportive sex education and therapy-with mindfulness being the only distinction between the treatment arms. Both treatments showed similar improvements in sexual desire and arousal, whereas the mindfulness groups had a significantly larger effect size for decreased sexual distress.²⁶ Similar findings were reported by Banbury et al in the latest meta-analysis on mindfulness-based interventions for men and women in sexology.²⁷ In addition, they found gender inequality in this research area, as all clinical trials were predominately in women, with a 6:1 ratio as compared with men, which is why more studies including men with sexual dysfunction are needed. Only 1 minor study, by Bossio et al²⁸ (n = 10), has evaluated mindfulness in the treatment of men with a sexual dysfunction. Performance anxiety is one of the main psychological reasons for sexual dysfunction in men,²⁹ and studies have indicated that trait/dispositional mindfulness in men is the mediating factor between anxiety and low sexual desire,³⁰ which supports the need to better investigate the role of mindfulness in samples of men with sexual dysfunction.

Learning mindfulness skills has been shown to benefit couples in populations without a diagnosed sexual problem.^{31,32} However, Selice and Morris¹⁵ pointed out that research has focused on improving sexual functioning on an individual level without any partner context. Considering the beneficial effects of mindfulness on couple's sexuality and due to the often dyadic nature of sexual functioning, it seems relevant to include partners in the therapy and therefore in clinical research.

Many aspects of mindfulness resemble the sensate focus training introduced by Masters and Johnson, such as nonevaluative exploration of bodily sensations, being present in the moment, and not having specific expectations. Mindfulness can be seen as complementing Masters and Johnson's sensate focus, as both focus on becoming more aware of one's physical sensations with an attitude of nonstriving.³³

The former research on mindfulness in patients with sexual dysfunction investigated trait/dispositional mindfulness, but recent studies on mindfulness in sexual and relational

well-being have introduced sexual mindfulness, which means the capability of remaining aware and nonjudgmental in a sexual context.³⁴ To address sexual mindfulness, the mindfulness for sex and intimacy in relationships (MSIR) protocol³⁵ was developed for patients with sexual dysfunction by directly addressing sexual issues to make the patients more aware and nonjudgmental in their sexual experiences. There have not been any randomized controlled trials exploring the proposed effects of the MSIR program to date. The MSIR protocol was developed to include men and women because mindfulness is not gender specific. Furthermore, the MSIR practices are not aimed at 1 particular dysfunction; they are directed at common characteristics across different diagnoses of sexual dysfunction, making it a cross-diagnostic intervention. This approach is in line with the original mindfulness-based stress reduction program, which was designed not for any specific diagnosis or gender but to alleviate suffering no matter the circumstances.^{36,37} This alleviation can diminish the mental and emotional distress regarding a sexual dysfunction.²⁸

The present pilot study aimed to evaluate whether it is feasible and acceptable to apply an 8-week MSIR as a supplement to treatment as usual (TAU) in a clinical setting. Secondarily, this study evaluated the preliminary effect of MSIR alone and MSIR + TAU on sexual function and distress as compared with TAU alone in the treatment of mixedgender groups and whether participation in the MSIR program would result in requiring fewer TAU treatment sessions afterward.

Methods

The present study is a randomized controlled pilot study performed at Sexological Clinic, Mental Health Centre Copenhagen, Mental Health Services - Capital Region of Denmark in the period from September 2018 to March 2020. The study was approved by the National Committee on Health Research Ethics in Denmark (H-18017600) and the Danish Data Agency in the Capital Region of Denmark (RHP-2017-056, I-Suite: 05968) and registered at ClinicalTrials.gov (NCT03775239).

Participants and procedures

The feasibility study followed the recommendations for feasibility and pilot studies by Lancaster³⁸ and Bell et al.³⁹ Feasibility was defined as implementation in daily clinical practice, whether it was possible to recruit patients and partners in daily clinical practice, acceptance and attendance of the intervention, and the MSIR completion rate.

All patients were referred as usual to the clinic, primarily from their general practitioner as a part of the public health care system. As part of the standard procedure, men and women had an extensive initial assessment when referred to the clinic. At the initial assessment, a thorough clinical interview was performed with a focus on the patients' disposing, precipitating, and maintaining factors for their sexual complaint, focusing on biopsychosocial factors. Sexual complaints and distress were assessed, and the patient's potential sexual dysfunction was evaluated and diagnosed according to *ICD*-10 criteria. Furthermore, whether the patient's partner should be included was determined. After the initial assessment, each case was discussed within the multidisciplinary team in the clinic; a final decision was made on the diagnosis and the treatment that the patient should be offered; and patients'



Figure 1. CONSORT flow diagram of participants.

eligibility for the current feasibility study was determined (Figure 1). Patients and partners who were not eligible were offered treatment following usual procedures in the clinic.

Participants who were considered eligible were contacted by phone, briefed on the purpose of the study, and invited to a one-on-one introductory meeting with 1 of the study investigators to have the procedures explained in detail. Before the meeting, written information was sent to the participants.

At the introductory meeting, potentially eligible participants were assessed with respect to the inclusion and exclusion criteria. The inclusion criteria were as follows: men and women with referral to the Sexological Clinic, Mental Health Centre Copenhagen; a diagnosis of a sexual dysfunction, such as decreased desire, erectile dysfunction, or orgasmic/ejaculatory dysfunction; age 20 to 65 years; and fluency in Danish. If relevant for the therapy, the partner was also included. Including the partner was relevant if, for example, the sexual problem had evolved in the current relationship or it was judged that the partner played a crucial role in the problem and/or the process to solve it. Partners did not necessarily have a sexual dysfunction. People referred to individual therapy were those without a partner, those whose problem had repeatedly occurred independent of the partner, and those whose partner could not or would not attend therapy. Participants were excluded if they had been referred to group therapy; had past sexual trauma; had a severe mental and/or somatic disease; or had a current addiction. As a part of the standard procedure in the clinic, people who experienced sexual traumas were referred to more specialized treatments, as the trauma needs to be integrated into the treatment. Severe mental disease was defined as ongoing mental health problems, such as depression, anxiety, severe personality disorder, schizophrenia, or ongoing pharmacologic or nonpharmacologic treatment for a mental health problem. Severe somatic disease was diabetes or other endocrine disease, cardiovascular disease, neurologic disease, dermatologic disease, or other medical condition that could be the main cause of the sexual problem. Participants

were also excluded if they could not participate in the scheduled MSIR sessions due to practical reasons. Partners had to fulfil the same inclusion criteria.

Written informed consent was obtained from participants who were eligible and willing to participate. The enrolled participants were randomized to either TAU or a 6-week mindfulness intervention followed by TAU (MSIR + TAU). Randomization was done electronically through the REDCap system. Block randomization was organized into clusters of 4 to ensure an equal number in each treatment group. The randomization list was stratified by gender to ensure equal allocation of men and women in each group. When partners were included, they followed the randomization of the patient. Pretreatment data were collected at the introductory meeting after randomization.

Participants randomized to receive TAU were scheduled for 6 individual or couple appointments with the first available therapist. Participants randomized to receive MSIR + TAU were assigned to 1 weekly group mindfulness session for 6 weeks in addition to 1 individual midway and end-oftreatment evaluation (8 weeks total). Following the completion of the MSIR program, participants continued with TAU, which was scheduled as 6 individual or couple appointments with the first available therapist. The therapy followed the normal procedure at the clinic, and the number of treatment sessions was not fixed; that is, the therapist could determine, on the basis of clinical evaluation and treatment progress, if more or fewer than 6 scheduled sessions were necessary.

At the midway and final individual evaluations, the therapists could address any potential adverse effects experienced by the participants. Furthermore, all patients received TAU, where any adverse events could be discussed in the subsequent therapy. We did not observe any adverse events.

The flow of participants is shown in Figure 1. Data were collected at pretreatment; after 3 and 6 sessions of MSIR, allowing us to measure the effect of MSIR alone after 3, 6, and 9 sessions of TAU; and at end of treatment (in both

groups). Six months after end of treatment, the participants were contacted by mail and phone to collect follow-up data. These latter data are not included in this article. In addition, specific mindfulness scales were collected after each mindfulness session. These data are also not included in this article.

Interventions

Treatment as usual

TAU is anchored in the biopsychosocial model acknowledging that all aspects of the patient's life have to be taken into account when attempting to understand and manage one's sexual dysfunction.¹¹ The offered TAU was individual or couple (marital) therapy based on the assessment and discussion with the patient. The treatment is eclectic and incorporates different therapy elements, such as CBT, psychodynamic therapy, systemic therapy, Master and Johnson's sensate focus training, pelvic floor exercises, and, if necessary, the introduction of sexual aids and/or pharmacologic treatment, depending on the patient's complaints and whether it was individual or couple therapy. The cornerstone in the treatment was sensate focus training for couples and exercises exploring one's sexuality for individuals. This eclectic psychotherapy was conducted by medical doctors and/or psychologists who worked at the clinic at the time of the study. As some of the therapists in the clinic normally use mindfulness in their sessions, they were instructed to omit this when having participants randomized to the TAU group.

Mindfulness for sex and intimacy in relationships

The mindfulness intervention was based on an MSIR protocol from the Jane Wadsworth Clinic at St Mary's Hospital, London.³⁵ The MSIR protocol was based on the theoretical framework of mindfulness-based cognitive therapy and has been adapted to treat patients with sexual dysfunction. In collaboration with the 2 psychologists who designed the original protocol, a Danish protocol was developed and implemented in a Danish context by 2 of the study investigators after practical training at the Jane Wadsworth Clinic. To ensure the applicability of the protocol in a new clinic and culture, any changes needed prior to implementation were considered. In this respect, the considerations did not give rise to any changes.

The sessions primarily concentrated on mindfulness theory and exercises, with a maximum of 12 patients in each group, and focused first on the more general aspects and then on sexual aspects in later sessions. The sessions always started with mindful body movements based on yoga, with a focus on one's experience in the present moment and not judging the performance as good or bad-one of the key teachings throughout the course. There were also general discussions on cognitive behavioral aspects of sexual dysfunction and psychoeducation, but the participants were not to share information about their diagnoses or private histories. Participants were sent links after each session with audio-recorded mindfulness exercises for home exercises. The groups were mixed gender and had different types of sexual dysfunction. Each group session lasted 2 hours, and the individual interviews (weeks 4 and 8) each lasted 30 minutes. An overview of the content of each session is described in Table 1.

The MSIR groups were administered as conjoint therapy by a senior psychiatrist and a psychomotor therapist, the former with extensive expertise in psychotherapy and sex therapy and the latter in mindfulness. In the present study, the 2 facilitators were not permitted to deliver any of the TAU to the participants.

Measures

Demographic information

The demographic questionnaire entailed questions concerning date of birth, gender, relationship status, medication, education, and occupation.

Bothered by problem

A single-item distress scale was used to measure how much distress was caused by the problem. The patient was asked to use a visual analog scale (VAS) from 0 (not distressed at all) to 100 (maximum distress) when asked, "How bothered are you right now by the sexual problem you are/were seeking help for?"

Changes in Sexual Function Questionnaire for Females and Males

The Changes in Sexual Function Questionnaire for Females and Males (CSFQ_F/M) is a self-reported inventory that measures sexual functioning on a 5-point Likert scale. The questionnaire is available in female and male versions, which both comprise 14 items and 5 domains: desire/frequency, desire/interest, arousal/excitement, orgasm/completion, and pleasure. The questionnaire has a high degree of internal consistency overall (Cronbach alpha = 0.90 for females and 0.89 for males) and for the individual scales (between 0.68 and 0.84; except the male orgasm/completion scale, which is 0.59).⁴⁰ A total score <41 for women and <47 for men is seen as impaired sexual function and thus indicates sexual dysfunction. Similarly, each subdomain has a separate cutoff. The questionnaires have been validated in Danish (https://eprovide.mapi-trust.org/instruments/changes-in-se xual-functioning-questionnaire).

Female Sexual Function Index

The Female Sexual Function Index (FSFI) is a validated 19item multidimensional self-report instrument for the assessment of female sexual function that comprises a total score and 6 subscales (desire, arousal, lubrication, orgasm, satisfaction, and pain).⁴¹ The FSFI measures the items of sexual function with Likert scales of either 0 to 5 points or 1 to 5 points. A higher total score represents better sexual function. A score ≤ 26.55 represents a risk of sexual dysfunction. The FSFI has test-retest reliability (r = 0.75-0.86, Cronbach alpha = 0.94). The scale is recommended for clinical practice as a measure of symptom severity in women who have been sexually active in the prior 4 weeks⁴² and is the gold standard when measuring sexual function in women.⁴³ The scale has been translated to Danish and used in other studies on Danish populations.^{44,45}

Female Sexual Distress Scale

The Female Sexual Distress Scale (FSDS) is a validated 12item self-administered questionnaire developed to measure sexually related personal distress in women. Lower scores represent less sexual distress, and scores \geq 15 indicate sexually related distress.⁴⁶ The Cronbach alpha is 0.94. The scale has been translated to Danish and used in other studies of the Danish population.^{44,45}

Table 1.MSIR intervention.

Week 1 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful inquiry and listening
	Raisin exercise: eating a raisin slowly and mindfully
	Lying body scan: sensing successive body areas
	Home exercise: lying body scan
Week 2 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful inquiry and listening
	Pair exercise: sensory awareness, choosing an object for partner to explore and describe, initially with eyes
	closed
	Seated body scan: sensing successive body areas
	Home exercise: seated body scan
Week 3 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful inquiry and listening
	Pair exercise: mindful movement back to back
	Seated body scan: sensing successive body areas
	Home exercise: seated body scan and mindful exploration of own body
Week 4 (30 m)	Individual interview of participants: feedback and clarification of problem areas
Week 5 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful inquiry and listening
	Seated meditation: exploring sexual self
	Pair exercise: sensory awareness, choosing a picture from a selection for partner to explore and describe
	Small group exercise: "opinion game" to discuss alternative meanings to sexual/relationship-based
	situations presented on paper
	Home exercise: lying body scan and sensual touch of own body and mindful exploration of movement
Week 6 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful inquiry and listening
	Seated meditation: exploring sexual discomfort
	Pair exercise: intimate questions with mindful listening
	Pair exercise: walking, one guiding, the other with eyes closed
	Home exercise: seated mindfulness, mindful movement, and mindful intimacy exercise for participants in a
	couple
Week 7 (2 h)	Mindful body movement based on yoga
	Pair exercise: mindful enquiry and listening
	Seated meditation: future intentions
	Group exercise: mindful feeling for own and others' boundaries
	Letter with future message to myself
Week 8 (30 m)	Individual interview of participants: feedback, pros and cons, motivation to continue mindfulness

Abbreviation: MSIR, mindfulness for sex and intimacy in relationships.

International Index of Erectile Function

The International Index of Erectile Function (IIEF) is a validated 15-item self-administered questionnaire that assesses male sexual function. The IIEF seeks to detect treatmentrelated changes in patients with erectile function and is considered the gold standard. The questionnaire comprises a total score and 5 subdomains with separate cutoffs (erectile function, orgasmic function, sexual desire, intercourse satisfaction, and overall satisfaction). A high degree of internal consistency has been observed for each of the 5 domains and for the total scale (Cronbach alpha ≥ 0.73 and ≥ 0.91 , respectively) in the populations studied.⁴⁷ A low score represents worse sexual function. As the men in this study had a variety of sexual dysfunction, only analysis from the subdomain "overall satisfaction" is presented in this article. The scale has been translated and validated in Danish48 and used in other studies in Danish populations.49

Statistical analysis

Differences between the TAU and MSIR + TAU groups in pretreatment characteristics were analyzed through exact tests because of the small sample frequencies. A mixed model was used to analyze the mean scores of the MSIR + TAU group before treatment, after 3 MSIR sessions, and after 6 MSIR sessions. The model included the 3 assessment times as a fixed effect and the subject as a random effect. A mixed model was also used to compare development over time in the TAU and MSIR + TAU groups. For each outcome, this model included the intervention group, rating time (pre- vs posttreatment), and the interaction between the intervention group and time as fixed effects. Using this model, we tested group differences in pre- and posttreatment scores separately and differences between pre- and posttreatment scores in each group. Finally, group differences between pre- and posttreatment scores were tested (ie, corresponding to the interaction between intervention group and rating time). Because of the small samples, statistical tests were conducted with t statistics instead of large-sample z tests; degrees of freedom were estimated via the Satterthwaite approximation.

As this was a feasibility study, no power calculation was performed. The estimated needed number in each arm was 15 based on the target effect size and a medium standard difference as described by Bell et al³⁹ All statistical analyses were performed with SPSS Statistics for Windows (version 25.0; IBM). All data were stored electronically in REDCap.

Results

Recruitment and feasibility

An overall 34 participants were randomized in this study: 15 women (mean \pm SD age, 30.96 ± 10.01 years) and 19 men (37.55 \pm 11.71 years). In addition, 6 healthy partners were

Table 2.	Participants'	sociodemographic	information	at pretreatment.a
----------	---------------	------------------	-------------	-------------------

Characteristic	MSIR + TAU	TAU (n = 19)	Total (N=34)
	(11-13)		
Sex, women:men, No.	6:9	9:10	15:19
Age, y, mean \pm SD	38.42 ± 11.50	33.29 ± 11.68	35.55 ± 11.71
Regular partner			
Yes	11 (73.33)	15 (78.94)	26 (76.47)
No	4 (26.67)	4 (21.05)	8 (23.52)
Sexual orientation			
Same sex	1 (6.67)	0 (0.00)	1 (2.94)
Opposite sex	14 (93.3)	19 (100.00)	33 (97.06)
Highest education			
Youth education	2 (13.33)	3 (15.79)	5 (14.71)
Academy profession program (>1 to <3 y)	2 (13.33)	5 (26.32)	7 (20.59)
Undergraduate $(3-4 y)$	4 (26.67)	7 (36.84)	11 (32.35)
Graduate or postgraduate (≥ 5 y)	7 (46.67)	4 (21.05)	11 (32.35)
Occupation status			
Enrolled in education	4 (26.67)	4 (21.05)	8 (23.53)
Employed full-time	5 (33.33)	9 (47.37)	14 (41.18)
Employed part-time	3 (20.0)	1 (5.26)	4 (11.76)
Self-employed	2 (13.33)	1 (5.26)	3 (8.82)
Other	1 (6.67)	4 (21.05)	5 (14.71)
Diagnosis at sexological clinic			
Erectile dysfunction	5 (33.33)	6 (31.58)	11 (32.35)
Premature ejaculation	1 (6.67)	2 (10.53)	3 (8.82)
Orgasmic disorder	2 (13.33)	6 (31.58)	8 (23.53)
Sexual desire disorder	4 (26.67)	5 (26.32)	9 (26.47)
Sexual genital pain disorder	3 (20.0)	0 (0.0)	3 (8.82)

Abbreviations: MSIR, mindfulness for sex and intimacy in relationships; TAU, treatment as usual. ^aData are presented as No. (%) unless noted otherwise. No significant differences were found between groups (P > .05).

included and followed the randomization of the patient. See Table 2 for pretreatment sociodemographics.

One primary aim of this study was to investigate the feasibility and acceptability of the MSIR intervention in the natural environment of Sexological Clinic, Mental Health Centre Copenhagen. Treatment was easily implemented in clinical practice as a weekly 2-hour session following the MSIR protocol before initiation of TAU. It was possible to apply the MSIR program to men and women and a mixed group of sexual dysfunctions (Table 2).

The eligibility for the study was 95% (patients and healthy partners): 65 patients were screened and 62 met the inclusion criteria. The acceptance rate of the study was 73% (45 participants randomized out of 62 eligible and approached). The intervention completion rate was 78% (18/23) in the MSIR + TAU arm and 100% in the TAU arm. In the MSIR + TAU arm, the reasons for not completing the intervention were scheduling conflicts realized after baseline/randomization (n = 3) and inclusion errors (n = 2). The latter 2 patients were taken out of the MSIR group by the study investigators. Therefore, 34 patients and 6 healthy partners received the allocated intervention.

Mean attendance was 4 of 6 possible sessions in the MSIR group (range, 1-6).

Number of TAU sessions

No significant difference was found between the interventions (TAU and MSIR + TAU) regarding the number of TAU sessions. Participants in the TAU group received a mean 8 treatment sessions (range, 2-18) before they had completed treatment at the Sexological Clinic. Participants in the MSIR + TAU group received a mean 6 TAU treatment sessions (range, 1-16) in addition to the 8 MSIR sessions.

Healthy partners

It was possible to recruit 6 healthy partners who received the allocated intervention with their partners (MSIR + TAU or TAU). Data measuring sexual distress and function were removed from the analysis presented in this study, as the number of partners was too small for any analysis. Therefore, data presented here are based on 15 patients from the MSIR + TAU group and 19 patients from the TAU group, who all were diagnosed with a sexual dysfunction.

Effects of MSIR

Table 3 summarizes the results of linear mixed modeling of the primary outcomes in the MSIR group before treatment, after 3 MSIR sessions, and after 6 MSIR sessions and the differences among these time points. For men and women, a significant decrease was found on the VAS measuring how bothered the patient was by the problem from pretreatment to 6 MSIR sessions (P = .002). The significant improvement on the VAS was first established after 6 MSIR sessions. A significant improvement in sexual function was measured by the CSFQ_M after 3 MSIR sessions, which improved after 6 MSIR sessions, whereas no significant change in sexual function was measured by the CSFQ_F. The other outcome measures (FSFI, FSDS, and IIEF) did not show any significant changes (Supplementary Material A).

Differences in effects between TAU and MSIR + TAU $\,$

Table 4 presents the results of the mixed linear model for the TAU arm and MSIR + TAU arm and the differences from pretreatment to end of treatment. The table presents the mean group differences in pre- and posttreatment scores, which

Table 3. MSIR linear mixed modeling of scores at 3 assessment p	points
---	--------

	Score, mean (SE)			Difference from pretreatment (SE)		<i>P</i> value	
Measure	Pretreatment	$3 \times MSIR$	$6 \times MSIR$	$3 \times MSIR$	$6 \times MSIR$	$3 \times MSIR$	$6 \times MSIR$
$VAS^a (n = 15)$	80 (3.75)	72.11 (7.41)	60.15 (8.74)	-7.89 (5.49)	-19.85 (7.53)	.174	.020*
$CSFQ_F (n = 6)$	42.67 (3.50)	44.33 (3.13)	44.67 (4.05)	1.66 (1.58)	2 (2.11)	.341	.387
$CSFQ_M (n = 9)$	49.56 (2.15)	52.76 (1.85)	52.44 (2.42)	3.20 (1.01)	2.88 (1.23)	.014*	.051*

Abbreviations: CSFQ_F/M, Changes in Sexual Function Questionnaire for Females and Males; MSIR, mindfulness for sex and intimacy in relationships; VAS, visual analog scale. ^a "How bothered are you right now by the sexual problem you are/were seeking help for?" $*P \le .05$.

Table 4. Linear mixed modeling comparing the 2 interventions: TAU and MSIR + TAU.

	Score, mean (SE)			P value	
Measure	Pretreatment	End of treatment	Difference (SE)		
$\overline{VAS^a (n = 34)}$					
MSIR + TAU (n = 15)	80 (3.46)	38.22 (8.03)	-41.78(7.33)	<.001**	
TAU (n = 19)	76.10 (3.07)	56.51 (7.89)	-19.59 (7.33)	.013*	
Difference	3.89 (4.63)	18.29 (11.26)	22.18 (10.37)	.043*	
$CSFQ_F (n = 15)$					
MSIR + TAU (n = 6)	42.67 (3.58)	49.77 (2.66)	7.19 (2.94)	.036*	
TAU $(n = 9)$	41 (2.92)	44.33 (2.50)	3.32 (2.70)	.244	
Difference	1.67 (4.62)	5.44(3.65)	3.77 (3.99)	.366	
$CSFQ_M (n = 19)$					
MSIR + TAU (n = 9)	49.56 (1.87)	52.75 (2.63)	3.20 (2.24)	.177	
TAU $(n = 10)$	48.6 (1.77)	53.65 (2.72)	5.05 (2.39)	.054	
Difference	0.96 (2.57)	0.90 (3.78)	1.85 (3.28)	.582	

Abbreviations: CSFQ_F/M, Changes in Sexual Function Questionnaire for Females and Males; MSIR, mindfulness for sex and intimacy in relationships; TAU, treatment as usual. ^a "How bothered are you right now by the sexual problem you are/were seeking help for?" $*P \le .05$. $**P \le .01$.

corresponds to the interaction between the group and time factor.

Significant improvements were found on the VAS for both groups, with a difference in means of -19.59 in the TAU arm and -41.78 in the MSIR + TAU arm. This indicates that patients in both groups were less bothered by their sexual problems at the end of treatment than at pretreatment. A significant group difference was also found between TAU and MSIR + TAU on the VAS, indicating that the MSIR + TAU arm improved significantly more than the TAU arm. A significant difference occurred on the CSFQ_F in the MSIR + TAU group, as the women reported less impaired sexual function at the end of treatment, but no significant difference was noted on the CSFQ_M. On the FSDS for women, a significant decrease was seen in both groups but with no significant difference between groups, and at end of treatment the mean score for both groups was <15, indicating no sexual distress. The mixed model did not show significance for the FSFI and IIEF scores (Supplementary Material B).

Discussion

This small study examined the feasibility, and provides preliminary data on the efficacy, of an 8-week MSIR intervention followed by TAU as compared with a TAU control. Overall, we found that the MSIR intervention was feasible and well accepted by patients, with a high rates of acceptance (73%) and intervention completion (78%). Furthermore, the MSIR intervention could be applied to men and women with different types of sexual dysfunction. In addition, when relevant, the partners could be included. This study is the first to evaluate the effect sizes of the MSIR program developed by Kocsis and Newbury-Helps³⁵ and adds new knowledge to how mindfulness can be used in groups of mixed-gender patients with different types of sexual dysfunction. Only 1 other study has applied mindfulness to men with sexual dysfunction. Bossio et al examined 10 men with erectile dysfunction and, similar to the present study, showed that it was feasible to implement mindfulness in men with sexual dysfunction.⁵⁰ The present study also included patients' partners. In a recent article, Selice and Morris emphasized the need for studies of mindfulness in couples to collect and analyze dyadic data.¹⁵ The present study has shown that it is possible to include the partner, but it does not provide data on differences in outcomes between individuals and couples due to the small number of participants. Interestingly, participants in the MSIR + TAU group did not attend fewer TAU sessions than the TAU group. One possible interpretation of this finding is that the mindfulness intervention made the patients more motivated for the subsequent TAU and influenced their participation. Larger-scale studies are needed to explore this further.

Preliminary data were collected on the efficacy of the treatment. The present study investigated a mindfulness intervention in combination with TAU, whereas other studies investigated a mindfulness intervention vs CBT⁵¹ or wait-list control groups.^{22,26,52} Due to the small number of participants, the results of the present study need to be interpreted with caution but are highly relevant before a larger-scale study is conducted, as they showed that it is feasible to implement the MSIR intervention in a mixed-gender group with varying sexual dysfunction.

The patients in the MSIR intervention group were significantly less bothered by their sexual problems after the 8week MSIR intervention. Regarding their responses on the VAS from pre- to posttreatment, the MSIR + TAU group was bothered significantly less by its sexual problems than the TAU control group. Both groups improved significantly on the VAS from pre- to posttreatment, but the reduction was twice as great in the MSIR + TAU group than the TAU group. These findings suggest that MSIR itself may induce a decrease in how bothered the patients are with their sexual dysfunctions, which may have an immediate effect on them. This study did not investigate mechanisms of change. However, an explanation may be that mindfulness in general works on accepting the moment without judging.⁵³ There is a tendency for men and women with sexual problems to have a judgmental and negative attitude toward their sexual experience.⁵⁴ Therefore, patients may be less bothered by their sexual problems after MSIR because they learned nonjudgmental awareness of one's present experience. In accordance with our findings, the standardized mindfulness-based stress reduction program, which is well investigated in the treatment of physiologic and psychological conditions,⁵⁵ has been shown to reduce perceived stress and/or psychological distress in a clinical population as compared with a control group.⁵⁶ No significant improvement in sexual functioning was measured by validated sexual functioning measures, except the CSFQ_M for men, after the MSIR intervention alone. Previous studies, which mainly focused on females with desire/arousal disorders or pain disorders, found a significant improvement in sexual functioning when pretreatment measures were compared with posttreatment measures.¹⁷ Significant effects were improvement of sexual desire, arousal, lubrication, sexual distress, orgasm satisfaction, and concordance between genital and subjective arousal. However, the methodology of the studies differed in, for example, the length and content of intervention,¹⁷ which precludes a comparison of the studies. Many of the interventions combined mindfulness with several elements, such as psychoeducation, communication skills, muscle relaxation, and sex therapy. Therefore, it is difficult to conclude whether the results were due to a specific component in the mindfulness treatment or synergistic effects. Furthermore, many of the studies were not randomized controlled studies with an active control group. A possible explanation for the missing significant effects on sexual functioning measures in our study, apart from sample size, could be that the MSIR mainly focused on general mindfulness principles to make it easier to profit from the following TAU sessions. As the participants in the MSIR groups had various sexual problems and were of mixed gender, it is possible that they did not experience the MSIR program addressing their particular sexual problems sufficiently. In previous studies, participants were more homogenous with regard to sexual dysfunction and/or gender. In a recent study, Leavitt et al⁵⁷ compared trait mindfulness with sexual mindfulness and found that sexual mindfulness leads to higher sexual awareness as compared with mindfulness alone. They then validated the Sexual Mindfulness Measure (SMM),58 which focuses on mindfulness within a sexual context: those who are more sexually mindful tend to be more satisfied with their relationships and sex lives, in combination with higher self-esteem. This conclusion was replicated in a French-speaking population.⁵⁹ As the SMM was published after the present study was performed, it was not utilized here even though nonspecific measures for mindfulness were used, but future randomized controlled trials on the MSIR would benefit from using the SMM.

The significant improvement in sexual functioning observed in men by the CSFQ_M after the MSIR intervention is in line with the only previously published study investigating a mindfulness-based intervention in a group of men diagnosed with erectile dysfunction, though it was a noncontrolled study.²⁸ More studies are needed that include control groups to investigate mindfulness in the treatment of men with sexual dysfunction. Concerning sexual functioning, significant improvements were found from pre- to posttreatment on the CSFQ_F for women in the MSIR + TAU group. In addition, we noted improvements from pre- to posttreatment for women in sexual distress (FSDS) in the mindfulness intervention group and the control group. However, no significant group differences were found, indicating that the addition of MSIR to TAU did not change the effect of the treatment.

Brotto et al⁶⁰ investigated sexually related distress in women with provoked vestibulodynia, as measured by the FSDS, and found that sexual distress decreased after a brief mindfulness-focused group treatment. Furthermore, sexrelated distress decreased after a mindfulness intervention in a population of women with a history of sexual abuse.⁵¹ However, the effect might seem greater in these studies because they did not have an active control group. As previously mentioned, it may also improve the effect to target a specific sexual dysfunction because these groups included only women. It is important to state that, even though we did not find a significant difference between groups, we can conclude that the mindfulness intervention in combination with TAU and the TAU sessions alone improved sexually related distress in women, which is important clinically.

Hucker and McCabe conducted a study that included partners' sexual function in the investigation of mindfulness in the treatment of sexual dysfunction.⁵² They found that women had a significant reduction in sexual distress when compared with a wait-list control group. In addition, the male partners of women with sexual problems demonstrated significant improvements in sexual functioning from preto posttest vs the male partners of women in the wait-list control group. However, the mindfulness intervention was online and not in a clinical setting and therefore is difficult to compare with the present study. Even though this study included partners when relevant for the therapy, the sample size was too small to investigate any potential changes. Due to the dyadic nature of sexual functioning, future research on mindfulness in sexology would benefit from including potential partners. In addition, learning mindfulness skills has been shown to benefit couples in a population without a diagnosed sexual problem.31,32

Strengths and limitations

The present study is a feasibility study. Therefore, the primary focus was to evaluate the feasibility and acceptability, instead of calculating effect sizes. The major strength of this study is that it is a randomized study. This study is the first in this area to include men and women with different types of sexual dysfunction in the same mindfulness group. However, this pilot study has several limitations worth discussing. First, the sample size of the current study was small; therefore, statistical conclusions should be made with caution, and more significant results may be found in a larger sample. Our sample consisted of cis-gender adults, predominantly heterosexual, and all Caucasian. In addition, it is possible that our sample with sexual problems is not representative of the larger population of individuals with sexual problems/concerns.

The MSIR protocol lasted 8 weeks and comprised 6 mindfulness sessions and 2 individual evaluations, midway and after the final session. In general, standardized 8-week mindfulness-based stress reduction/cognitive therapy programs have been found to be more effective than shorter or modified versions in other therapeutic contexts.⁶¹ As

Table 5. Recommendations for future studies.

MSIR is feasible and safe to implement in everyday clinical practice. MSIR is feasible to apply to a mixed-gender group. MSIR is feasible to apply to individuals with different sexual dysfunctions.

Future research would benefit from

- Larger-scale randomized controlled trial
- Include the validated Sexual Mindfulness Measure
- Collect data on homework exercises
- Include men
- Include potential partners
- Investigate follow-up data
- Investigate how MSIR can be combined with other treatment modalities and how it can stand alone

Abbreviation: MSIR, mindfulness for sex and intimacy in relationships.

compared with evidence-based protocols for mindfulnessbased stress reduction and cognitive therapy, the MSIR protocol has several differences that may influence the results, such as shorter sessions, fewer sessions, and content of the intervention. However, since the MSIR protocol is a shorter modified version, it might be more feasible for participants and easier to implement in everyday clinical practice, thus translating into greater adherence.

As it is an intervention study with mindfulness, double blinding could not be implemented, which leads to the risk of bias. Patients who were willing to participate in this pilot study may have hoped to receive the mindfulness treatment, and if they were allocated to the TAU group, their disappointment could have influenced their treatment at the Sexological Clinic. Furthermore, it is possible that patients allocated to TAU have been doing mindfulness at home, which is a confounding risk. The study investigators did not complete an exhaustive screening to evaluate whether participants were suited for a group mindfulness intervention, and unsuited patients could result in smaller treatment effects. There is also a risk that any placebo effect may be stronger in the MSIR intervention group, though the use of an active control group is likely to minimize such bias. Moreover, this program had daily home exercises, and we did not collect data on the amount that participants practiced. This is an important limitation for the interpretation of our results, as a relationship is known to exist between the frequency of formal mindfulness practice and clinical outcomes.62

As pointed out by Van Dam et al,⁶³ mindfulness therapy may have adverse effects. In worst cases, these have been reported to be psychosis, mania, depersonalization, anxiety, panic, traumatic memory reexperiencing, and other forms of clinical deterioration.⁶³ Mindfulness-based interventions in general are relatively safe.⁶⁴ However, research on the adverse effects of meditation practices is lacking and remains an area of improvement.⁶³ To overcome the risk of any potential adverse effects, we excluded patients with any psychiatric diagnosis, as recommended by Crane and Kuyken⁶⁵ and Santorelli,⁶⁶ and the thorough assessment determined whether the patient was eligible for a psychotherapeutic intervention.

Last, as in all psychotherapeutic research, it can be difficult to conclude whether results are influenced by the ability of a specific therapist. However, only therapists with a minimum of 6 months of experience at the clinic conducted the therapy, and due to the randomization, this should not lead to bias.

Clinical implications

Given the results of the current feasibility study, we conclude that it is feasible to implement the mindfulness intervention in the treatment of sexual problems in men and women and to expect a high acceptance rate. The intervention also seemed feasible and acceptable for the healthy partners, as they attended the same number of mindfulness sessions as their partners with diagnoses of sexual dysfunction. Results from this study add to the growing body of evidence suggesting the use of mindfulness in the treatment of sexual impairment, and we learned that MSIR has a positive effect in combination with TAU. The mindfulness intervention was group based, which leads to less waiting time until treatment starts; yet, the intervention could have been administered individually, and this should be investigated further. In opposition to sensate focus training, mindfulness does not require a partner; therefore, patients can train either alone or in a group setting. However, the intervention has not yet been tested in an individual context. In addition, the mindfulness intervention may give the patient some relevant tools to incorporate in the following TAU at the Sexological Clinic or in sex therapy in general. Last, it will be relevant to investigate the 6-month follow-up data to see whether these findings remain.

We used experiences from the current feasibility study to collect a set of recommendations for future studies on mind-fulness in sexology and present them here in Table 5.

Conclusion

This feasibility study is among the first to implement a mindfulness protocol in the natural setting of a sexological clinic with a mixed group of patients, including men and women with different types of sexual dysfunction and healthy partners when relevant. As compared with the TAU control group, the MSIR + TAU group was bothered significantly less by their sexual problems post- vs pretreatment. However, it did not attend fewer TAU sessions afterward.

Results from this feasibility study support already existing evidence that mindfulness-based interventions are feasible and effective for targeting sexual impairment in men and women. However, more studies are needed, especially in men, due to the limitations of the methodology of the available studies.

Acknowledgements

We are grateful and want to thank Dr. A. Kocsis and J Newbury-Helps, Jane Wadsworth Clinic at St. Mary's Hospital, London, for sharing their expertise in the MSIR program with us.

Supplementary material

Supplementary material is available at *Sexual Medicine* online.

Funding

The study was partly funded by The Owesenske Foundation.

Conflicts of interest: None declared.

References

- McCabe MP, Sharlip ID, Lewis R, *et al.* Incidence and prevalence of sexual dysfunction in women and men: a consensus statement from the Fourth International Consultation on Sexual Medicine 2015. *J Sex Med.* 2016;13(2):144–152. https://doi.org/10.1016/j. jsxm.2015.12.034.
- McCabe MP, Sharlip ID, Atalla E, *et al.* Definitions of sexual dysfunctions in women and men: a consensus statement from the Fourth International Consultation on Sexual Medicine 2015. *J Sex Med.* 2016;13(2):135–143. https://doi.org/10.1016/j. jsxm.2015.12.019.
- Rosen RC, Bachmann GA. Sexual well-being, happiness, and satisfaction, in women: the case for a new conceptual paradigm. J Sex Marital Ther. 2008;34(4):291–297. https://doi.o rg/10.1080/00926230802096234.
- Dogan T, Tugut N, Golbasi Z. The relationship between sexual quality of life, happiness, and satisfaction with life in married Turkish women. Sex Disabil. 2013;31(3):239–247. https://doi.org/10.1007/s11195-013-9302-z.
- Sánchez-Fuentes M D M, Santos-Iglesias P, Sierra JC. A systematic review of sexual satisfaction. *Int J Clin Heal Psychol*. 2014;14(1): 67–75. https://doi.org/10.1016/S1697-2600(14)70038-9.
- Fallis EE, Rehman US, Woody EZ, Purdon C. The longitudinal association of relationship satisfaction and sexual satisfaction in long-term relationships. *J Fam Psychol.* 2016;30(7):822–831. https://doi.org/10.1037/fam0000205.
- Nappi RE, Cucinella L, Martella S, Rossi M, Tiranini L, Martini E. Female sexual dysfunction (FSD): prevalence and impact on quality of life (QoL). *Maturitas*. 2016;94(1):87–91. https://doi.o rg/10.1016/j.maturitas.2016.09.013.
- Sørensen T, Giraldi A, Vinberg M. Sexual distress and quality of life among women with bipolar disorder. *Int J Bipolar Disord*. 2017;5(1):29. https://doi.org/10.1186/s40345-017-0098-0.
- Christensen BS, Grønbæk M, Osler M, Pedersen BV, Graugaard C, Frisch M. Sexual dysfunctions and difficulties in Denmark: prevalence and associated sociodemographic factors. *Arch Sex Behav.* 2011;40(1):121–132. https://doi.org/10.1007/s10508-010-9599y.
- McCabe MP, Sharlip ID, Lewis R, et al. Risk factors for sexual dysfunction among women and men: a consensus statement from the Fourth International Consultation on Sexual Medicine 2015. J Sex Med. 2016;13(2):153–167. https://doi.org/10.1016/j. jsxm.2015.12.015.
- Berry MD, Berry PD. Contemporary treatment of sexual dysfunction: reexamining the biopsychosocial model. J Sex Med. 2013;10(11):2627–2643. https://doi.org/10.1111/jsm.12273.
- Frühauf S, Gerger H, Schmidt HM, Munder T, Barth J. Efficacy of psychological interventions for sexual dysfunction: a systematic review and meta-analysis. *Arch Sex Behav.* 2013;42(6):915–933. https://doi.org/10.1007/s10508-012-0062-0.
- Berner M, Günzler C. Efficacy of psychosocial interventions in men and women with sexual dysfunctions—a systematic review of controlled clinical trials. J Sex Med. 2012;9(12):3089–3107. https://doi.org/10.1111/j.1743-6109.2012.02970.x.
- Renshaw DC. Masters and Johnson on sex and human loving. JAMA. 1987;257(11):1528.
- 15. Selice L, Morris KL. Mindfulness and sexual dysfunction: a systematic research synthesis. J Sex Marital Ther.

2022;48(4):323–342. https://doi.org/10.1080/0092623X.2021. 1991536.

- Ost L-G. Efficacy of the third wave of behavioral therapies: a systematic review and meta-analysis. *Behav Res Ther.* 2008;46(3): 296–321. https://doi.org/10.1016/j.brat.2007.12.005.
- Jaderek I, Lew-Starowicz M. A systematic review on mindfulness meditation-based interventions for sexual dysfunctions. *J Sex Med.* 2019;16(10):1581–1596. https://doi.org/10.1016/j. jsxm.2019.07.019.
- Kabat-Zinn J. Full Catastrophe Living: Using the Wisdom of your Body and Mind to Face Stress, Pain, and Illness. Rev ed. Bantam Books Trade Paperbacks; 2013.
- Silverstein RG, Brown A-CH, Roth HD, Britton WB. Effects of mindfulness training on body awareness to sexual stimuli: implications for female sexual dysfunction. *Psychosom Med*. 2011;73(9): 817–825. https://doi.org/10.1097/PSY.0b013e318234e628.
- Brotto LA, Yong P, Smith KB, Sadownik LA. Impact of a multidisciplinary vulvodynia program on sexual functioning and dyspareunia. J Sex Med. 2015;12(1):238–247. https://doi.org/10.1111/ jsm.12718.
- 21. Bober SL, Recklitis CJ, Bakan J, Garber JE, Patenaude AF. Addressing sexual dysfunction after risk-reducing salpingo-oophorectomy: effects of a brief, psychosexual intervention. *J Sex Med*. 2015;**12**(1):189–197. https://doi.org/10.1111/JSM.12713.
- 22. Brotto LA, Basson R. Group mindfulness-based therapy significantly improves sexual desire in women. *Behav Res Ther.* 2014;57(1):43–54. https://doi.org/10.1016/j.bra t.2014.04.001.
- Paterson LQP, Handy AB, Brotto LA. A pilot study of eight-session mindfulness-based cognitive therapy adapted for women's sexual interest/arousal disorder. J Sex Res. 2017;54(7):850–861. https:// doi.org/10.1080/00224499.2016.1208800.
- Brotto LA, Erskine Y, Carey M, et al. A brief mindfulness-based cognitive behavioral intervention improves sexual functioning versus wait-list control in women treated for gynecologic cancer. *Gynecol Oncol.* 2012;125(2):320–325. https://doi.org/10.1016/j. ygyno.2012.01.035.
- Brotto LA, Zdaniuk B, Chivers ML, *et al.* A randomized trial comparing group mindfulness-based cognitive therapy with group supportive sex education and therapy for the treatment of female sexual interest/arousal disorder. *J Consult Clin Psychol.* 2021;89(7): 626–639. https://doi.org/10.1037/ccp0000661.
- 26. Banbury S, Lusher J, Snuggs S, Chandler C. Mindfulnessbased therapies for men and women with sexual dysfunction: a systematic review and meta-analysis. *Sexual and Relationship Therapy*. Published online February 27. 2021; https://doi.o rg/10.1080/14681994.2021.1883578.
- Brotto LA, Chivers ML, Millman RD, Albert A. Mindfulnessbased sex therapy improves genital-subjective arousal concordance in women with sexual desire/arousal difficulties. *Arch Sex Behav.* 2016;45(8):1907–1921. https://doi.org/10.1007/ s10508-015-0689-8.
- Bossio JA, Basson R, Driscoll M, Correia S, Brotto LA. Mindfulness-based group therapy for men with situational erectile dysfunction: a mixed-methods feasibility analysis and pilot study. J Sex Med. 2018;15(10):1478–1490. https://doi.org/ S1743609518311548.
- McCabe MP, Connaughton C. Psychosocial factors associated with male sexual difficulties. J Sex Res. 2014;51(1):31–42. https:// doi.org/10.1080/00224499.2013.789820.
- Déziel J, Godbout N, Hébert M. Anxiety, dispositional mindfulness, and sexual desire in men consulting in clinical sexology: a mediational model. J Sex Marital Ther. 2018;44(5):513–520. https://doi.org/10.1080/0092623X.2017.1405308.
- Khaddouma A, Coop Gordon K, Strand EB. Mindful mates: a pilot study of the relational effects of mindfulness-based stress reduction on participants and their partners. *Fam Process.* 2017;56(3): 636–651. https://doi.org/10.1111/famp.12226.
- 32. Leavitt CE, Maurer TF, Clyde TL, et al. Linking sexual mindfulness to mixed-sex couples' relational flourishing, sexual harmony,

and orgasm. Arch Sex Behav. 2021;50(6):2589–2602. https://doi.org/10.1007/s10508-021-02054-0.

- Weiner L, Avery-Clark C. Sensate focus: clarifying the Masters and Johnson's model. Sexual and Relationship Therapy. 2014;29(3): 307–319. https://doi.org/10.1080/14681994.2014.892920.
- Leavitt CE, Whiting JB, Hawkins AJ. The Sexual Mindfulness Project: an initial presentation of the sexual and relational associations of sexual mindfulness. *J Couple Relatsh Ther.* 2021;20(1): 32–49. https://doi.org/10.1080/15332691.2020.1757547.
- Kocsis A, Newbury-Helps J. Mindfulness in sex therapy and intimate relationships (MSIR): clinical protocol and theory development. *Mindfulness (N Y)*. 2016;7(3):690–699. https://doi.o rg/10.1007/s12671-016-0506-z.
- Reibel DK, Greeson JM, Brainard GC, Rosenzweig S. Mindfulnessbased stress reduction and health-related quality of life in a heterogeneous patient population. *Gen Hosp Psychiatry*. 2001;23(4): 183–192. https://doi.org/10.1016/s0163-8343(01)00149-9.
- Grossman P, Niemann L, Schmidt S, Walach H. Mindfulness-based stress reduction and health benefits: a meta-analysis. J Psychosom Res. 2004;57(1):35–43. https://doi.org/10.1016/S0022-3999 (03)00573-7.
- Lancaster GA. Pilot and feasibility studies come of age! *Pilot Feasibility Stud.* 2015;1(1):1–4. https://doi.o rg/10.1186/2055-5784-1-1.
- Bell ML, Whitehead AL, Julious SA. Guidance for using pilot studies to inform the design of intervention trials with continuous outcomes. *Clin Epidemiol*. 2018;10(1):153–157. https://doi.o rg/10.2147/CLEP.S146397.
- Keller A, McGarvey EL, Clayton AH. Reliability and construct validity of the Changes in Sexual Functioning Questionnaire shortform (CSFQ-14). J Sex Marital Ther. 2006;32(1):43–52. https:// doi.org/10.1080/00926230500232909.
- Rosen R, Brown C, Heiman J, et al. The Female Sexual Function Index (FSFI): a multidimensional self-report instrument for the assessment of female sexual function. J Sex Marital Ther. 2000;26(2):191–208. https://doi.org/10.1080/009262300278597.
- 42. Giraldi A, Rellini A, Pfaus JG, *et al.* Questionnaires for assessment of female sexual dysfunction: a review and proposal for a standardized screener. *J Sex Med.* 2011;8(10):2681–2706. https://doi.org/10.1111/j.1743-6109.2011.02395.x.
- 43. Meston CM, Freihart BK, Handy AB, Kilimnik CD, Rosen RC. Scoring and interpretation of the FSFI: what can be learned from 20 years of use? J Sex Med. 2020;17(1):17–25. https://doi.o rg/10.1016/j.jsxm.2019.10.007.
- 44. Petersen CD, Giraldi A, Lundvall L, Kristensen E. Botulinum toxin type A—a novel treatment for provoked vestibulodynia? Results from a randomized, placebo controlled, double blinded study. J Sex Med. 2009;6(9):2523–2537. https://doi.org/10.1111/ j.1743-6109.2009.01378.x.
- 45. Wåhlin-Jacobsen S, Pedersen AT, Kristensen E, *et al.* Is there a correlation between androgens and sexual desire in women? *J Sex Med.* 2015;12(2):358–373. https://doi.org/10.1111/jsm.12774.
- 46. Derogatis LR, Rosen R, Leiblum S, Burnett A, Heiman J. The Female Sexual Distress Scale (FSDS): initial validation of a standardized scale for assessment of sexually related personal distress in women. J Sex Marital Ther. 28(4):317–330.
- Rosen RC, Riley A, Wagner G, Osterloh IH, Kirkpatrick J, Mishra A. The International Index of Erectile Function (IIEF): a multidimensional scale for assessment of erectile dysfunction. Urology. 1997;49(6):822–830.
- Rosen RC, Cappelleri JC, Gendrano N 3rd. The International Index of Erectile Function (IIEF): a state-of-the-science review. *Int J Impot Res.* 2002;14(4):226–244. https://doi.org/10.1038/sj.i jir.3900857.
- Karlsen RV, Bidstrup PE, Hvarness H, *et al.* Feasibility and acceptability of couple counselling and pelvic floor muscle training after operation for prostate cancer. *Acta Oncol (Madr)*. 2017;56(2): 270–277. https://doi.org/10.1080/0284186X.2016.1267397.
- 50. Bossio JA, Basson R, Driscoll M, Correia S, Brotto LA. Mindfulness-based group therapy for men with situational erectile

dysfunction: a mixed-methods feasibility analysis and pilot study. J Sex Med. 2018;15(10):1478–1490.

- Brotto LA, Seal BN, Rellini A. Pilot study of a brief cognitive behavioral versus mindfulness-based intervention for women with sexual distress and a history of childhood sexual abuse. J Sex Marital Ther. 2012;38(1):1–27. https://doi.org/10.1080/0092623 X.2011.569636.
- 52. Hucker A, McCabe MP. Incorporating mindfulness and chat groups into an online cognitive behavioral therapy for mixed female sexual problems. *J Sex Res.* 2015;52(6):627–639. https://doi.org/10.1080/00224499.2014.888388.
- Kabat-Zinn J. Mindfulness-based interventions in context: past, present, and future. *Clin Psychol Sci Pract*. 2003;10(2):144–156. https://doi.org/10.1093/clipsy.bpg016.
- Nobre PJ, Pinto-Gouveia J. Emotions during sexual activity: differences between sexually functional and dysfunctional men and women. Arch Sex Behav. 2006;35(4):491–499. https://doi.o rg/10.1007/s10508-006-9047-1.
- 55. Gotink RA, Chu P, Busschbach JJV, Benson H, Fricchione GL, Hunink MGM. Standardised mindfulness-based interventions in healthcare: an overview of systematic reviews and meta-analyses of RCTs. *PLoS One*. 2015;10(4):1–17. https://doi.org/10.1371/jou rnal.pone.0124344.
- 56. Fjorback LO, Arendt M, Ornbol E, Fink P, Walach H. Mindfulnessbased stress reduction and mindfulness-based cognitive therapy—a systematic review of randomized controlled trials. *Acta Psychiatr Scand*. 2011;124(2):102–119. https://doi.org/10.1111/ j.1600-0447.2011.01704.x.
- Leavitt CE, Allsop DB, Gurr J, et al. A couples' relationship education intervention examining sexual mindfulness and trait mindfulness. Sexual and Relationship Therapy. Published online January 24, 2022. https://doi.org/10.1080/14681994.2021.2024802
- Leavitt CE, Lefkowitz ES, Waterman EA. The role of sexual mindfulness in sexual wellbeing, relational wellbeing, and selfesteem. J Sex Marital Ther. 2019;45(6):497–509. https://doi.o rg/10.1080/0092623X.2019.1572680.
- 59. Dussault É, Lafortune D, Canivet C, Boislard MA, Leavitt CE, Godbout N. Validation of the French Sexual Mindfulness Measure and its links with psychosexual well-being. *Sexual and Relationship Therapy*. Published online December 16, 2021. https://doi.o rg/10.1080/14681994.2021.2009794
- Brotto LA, Basson R, Smith KB, Driscoll M, Sadownik L. Mindfulness-based group therapy for women with provoked vestibulodynia. *Mindfulness (N Y)*. 2015;6(3):417–432. https:// doi.org/10.1007/s12671-013-0273-z.
- Khoury B, Sharma M, Rush SE, Fournier C. Mindfulness-based stress reduction for healthy individuals: a meta-analysis. *J Psycho*som Res. 2015;78(6):519–528. https://doi.org/10.1016/j.jpsychore s.2015.03.009.
- 62. Parsons CE, Crane C, Parsons LJ, Fjorback LO, Kuyken W. Home practice in mindfulness-based cognitive therapy and mindfulnessbased stress reduction: a systematic review and meta- analysis of participants' mindfulness practice and its association with outcomes. *Behav Res Ther.* 2017;2017(95):29–41. https://doi.o rg/10.1016/j.brat.2017.05.004.
- 63. Van Dam NT, van Vugt MK, Vago DR, et al. Mind the hype: a critical evaluation and prescriptive agenda for research on mindfulness and meditation. Perspect Psychol Sci. 2018;13(1):36–61. https://doi.org/10.1177/1745691617709589.
- Wong SYS, Chan JYC, Zhang D, Lee EKP, Tsoi KKF. The safety of mindfulness-based interventions: a systematic review of randomized controlled trials. *Mindfulness (N Y)*. 2018;9(5):1344–1357. https://doi.org/10.1007/s12671-018-0897-0.
- Crane RS, Kuyken W. The implementation of mindfulness-based cognitive therapy: learning from the UK health service experience. *Mindfulness (N Y)*. 2013;4(3):246–254. https://doi.org/10.1007/ s12671-012-0121-6.
- 66. Santorelli S. *Mindfulness-Based Stress Reduction (MBSR): Standards of Practice.* Center for Mindfulness in Medicine, Health Care and Society, University of Massachusetts Medical School; 2014.