COUPLES

Couples' Use of Online Stress Management and Resiliency Training for Sexual Health Concerns: A Randomized Controlled Trial

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ABSTRACT

Introduction: Mindfulness is a promising intervention for female sexual dysfunction (FSD); however, of the mindfulness interventions studied, few treat the woman and her partner.

Aim: We developed a brief online mindfulness, resilience, and psychoeducation intervention, Stress Management and Resiliency Training for Sexuality (Sex SMART), for women with sexual health concerns and their partners.

Methods: Women with female sexual interest/arousal disorder and their partners were recruited between February 24, 2015, and October 6, 2016, and randomized to treatment or control groups (received educational pamphlets). The treatment intervention comprised of an online SMART and sexual health psychoeducation module.

Main Outcome Measures: The Female Sexual Function Index (FSFI), Female Sexual Distress Scale-Revised (FSDS-R), Sexual Desire Inventory-2 (SDI-2), Revised Dyadic Adjustment Scale (RDAS), International Index of Erectile Function (IIEF), and other subjective measures were used to assess sexual function and sexual distress at baseline and 12 weeks.

Results: The study included 60 women and their partners (30 couples in each group). In both groups, sexual function by total FSFI scores and sexual distress scores significantly improved at 12 weeks compared with baseline, with no significant between-group differences (FSFI effect estimate for Sex SMART vs control = +1.4 (90% CI [−0.6 to +3.4]; P=.13). Both participants and partners randomized to the intervention reported significantly improved attitude and feelings, comfort as a sexual person, and subjective sexual functioning at 12 weeks. The findings provide preliminary evidence for efficacy of an online intervention for couples with sexual health problems.

Conclusions: A brief online mindfulness, resilience, and psychoeducation–based intervention showed no significant improvement in many outcomes (FSFI, FSDS-R, SDI-2, RDAS) of sexual health versus controls. Although this is the first online randomized controlled trial to evaluate a mindfulness-based therapy intervention, it was limited by its lack of population diversity and high attrition rate. Significant improvements in subjective sexual health and partner sexual function by the International Index of Erectile Function were reported only in the intervention group. **Rullo JE, Sood R, Fokken SC, et al. Couples' Use of Online Stress Management and Resiliency Training for Sexual Health Concerns: A Randomized Controlled Trial. Sex Med 2021;9:100404.**

Abbreviations: ANCOVA, analysis of covariance; CBT, cognitive behavioral therapy; CD-RISC2, Connor-Davidson Resilience Scale-2; CONSORT, Consolidated Standards of Reporting Trials; DSM-5, *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; EF, erectile function; FSD, female sexual dysfunction; FSDS-R, Female Sexual Distress Scale-Revised; FSFI, Female Sexual Function Index; FSIAD, female sexual interest/arousal disorder; GAD, generalized anxiety disorder; GAD-7, Generalized Anxiety Disorder-7; GQ-6, Gratitude Questionnaire Six-Item Form; IIEF, International Index of Erectile Function; MBCT, mindfulness-based cognitive therapy; MBT, mindfulness-based therapy; PSS-4, Perceived Stress Scale-4; RCT, randomized controlled trial; RDAS, Revised Dyadic Adjustment Scale; SDI-2, Sexual Desire Inventory-2; Sex SMART, Stress Management and Resiliency Training for Sexuality; SHS, Subjective Happiness Scale; SMART, Stress Management and Resiliency Training; SWLS, Satisfaction With Life Scale

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INTRODUCTION

Mindfulness is commonly defined as intentional, present moment, nonjudgmental awareness.[1] Staying in and being nonjudgmental about the present moment may be an oxymoron for persons with sexual dysfunction and distress. Persons with sexual distress are often overwhelmed with negative thoughts, judgments, and unrealistic sexual expectations (eg, "I hate my body"; "It's taking me too long to orgasm"; "He's not attracted to me"), and they are often unable to be present in their bodies, let alone present in their sexual experiences. They may monitor their sexual performance as a success or failure, known as *spectatoring*.[2] This cognitive distraction is one reason women consistently demonstrate discordance between their subjective and their physiologically measured sexual arousal.[3,4] Instruction in mindfulness shifts the focus away from negative thoughts and judgments and back to present-moment sensations and experiences, and to awareness of the body.[2,5]

Resilience is a multifaceted construct that comprises several personal resources, such as self-esteem, optimism, flexibility, coping strategies, and good social relations.[6,7] In intimate relationships, resilience is the ability of couples to thrive despite adversity. It involves the relational capacity to adapt, grow, and recover from challenges.[8] Mindfulness interventions are one of the key components of resilience-building programs. However, there is minimal existing literature on mindfulness- and resilience-based interventions for female sexual dysfunction (FSD).

Brotto[2] and Paterson and colleagues[9] were the first to systematically study mindfulness-based therapy (MBT) as a treatment for FSD. The consistent components of this therapy include mindfulness, sexual psychoeducation, and elements of cognitive therapy. In 3 wait-list controlled trials, Brotto and Basson[10] and Brotto et al[11,12] showed that a mindfulness program significantly improved women's sexual desire, arousal, satisfaction, vaginal lubrication, genital pain, and overall sexual functioning (as indicated by a validated measure of sexual function). Their findings related to improved sexual desire and sexual pain were subsequently supported by 2 randomized controlled trials (RCTs) on MBT for sexual dysfunction.[13,14] An additional pilot study (N=20) by Brotto et al[15] showed that MBT was more effective in increasing women's subjective sexual arousal than a cognitive behavioral therapy (CBT) intervention. Further, a comparison study of mindfulness-based cognitive therapy (MBCT) versus CBT for the treatment of provoked vulvodynia found that, for a subsample of sexually active women, MBCT was more effective than CBT in reducing self-reported sexual pain over time.[16] A 12-month follow-up of this study indicated that both CBT and MBCT were effective in the reduction of sexual pain and sexual distress, with no significant differences noted in outcome measures between groups.[17]

The concept of MBT has now been extended to online interventions. Brotto and colleagues[18] incorporated MBT into a 12-week online psychoeducational intervention for sexual dysfunction in gynecologic cancer survivors and in male and female colorectal cancer survivors. Findings indicated significant improvement for women with sexually related distress and sexual dysfunction at the completion of the program and at 6-month follow-up. Men reported a significant improvement in intercourse satisfaction, which was not maintained at 6-month follow-up. Hucker and McCabe[19] incorporated mindfulness in a 6-module online CBT program for women with self-reported sexual difficulties (desire, arousal, orgasm, and pain). This wait-list controlled trial was primarily tailored to women, but included couples' activities, such as communication and sensate-focus exercises. Women reported significant improvements in all domains of sexual function except pain, and benefits were maintained at 3-month follow-up. Male partners reported significant improvements in erectile function (EF), sexual desire, and overall sexual satisfaction, which were mostly maintained at 3-month follow-up. The expansion of mindfulness-based interventions to an online format is an important step toward removing geographical and emotional barriers to in-person treatments.

In addition, MBT is particularly well suited as a couple's intervention. Mindfulness has repeatedly been shown to improve relationship satisfaction.[20,21] Specifically, 2 facets of mindfulness, awareness, and acceptance, have been identified as the mechanisms for increased relationship satisfaction.[22,23] Research has shown that awareness-enhancing practices (eg, sitting meditation, body scan, mindful eating), which improve mental health and the ability to regulate stress and emotions, may help partners better manage interpersonal conflict.[24] Acceptance-oriented practices (eg, loving kindness, gratitude, forgiveness) enhance acceptance of one's partner and improve empathic responding, which in turn may improve relationship satisfaction.[25-27] Given the robust literature demonstrating that mindfulness improves sexual functioning and relationship satisfaction, it is a natural next step to explore the impact of mindfulness on sexual functioning in couples.

Existing studies on MBT for sexual health concerns have some important limitations. Only one study to date[19] has included the woman's partner, yet the existing literature supports that couple's sexual health interventions are superior to

individual interventions for FSD.[28,29] A recent meta-analysis of MBT for the treatment of FSD reported that participants currently in a romantic relationship had greater sexual-function benefit from MBT than those not in a current romantic relationship.[30] Further, lack of higher quality trials is another limitation of existing studies, with only 2 RCTs investigating MBT for sexual dysfunction.[13,14]

The current study addresses these limitations. The study was designed as an online randomized controlled MBT, resilience enhancement, and psychoeducation intervention for women with sexual health concerns and their partners. The primary aim of the study was to assess the feasibility and potential efficacy of using Stress Management and Resiliency Training for Sexuality (Sex SMART) to improve sexual function in women who reported sexual health concerns and distress associated with these concerns and to include their partners in the treatment. With this aim in mind, a randomized phase II trial was designed to assess the potential feasibility of delivering an online intervention to women with sexual health concerns and their partners and to test its efficacy, with the additional goal of providing preliminary data for a larger phase III trial in the future. We hypothesized that it would be feasible to offer an online mindfulness, resilience, and psychoeducation program to couples with sexual health concerns. We also hypothesized that such a program would improve women's and their respective partners' sexual health function.

METHODS

Study Overview

The present study was a randomized, wait-list controlled clinical trial. Women with self-reported sexual dysfunction (participant) and their partners were randomized as a couple to receive either the Sex SMART intervention or usual care followed by the Sex SMART intervention (control). The institutional review board at our institution approved this study.

Setting and Participants

On the basis of a report by Brotto and Basson[10] we determined that with 30 patients per group (control vs intervention), we would have 90% power to detect a 0.7 SD difference in the primary outcome (change in FSFI total score from baseline to week 12) between the 2 groups, with a one-sided significance level of 0.10. Therefore, we sought to recruit a total of 60 couples, 30 per group. Potential participant couples were recruited from loco-regional and distant sites between February 24, 2015, and October 6, 2016, via print, radio, and newspaper advertisements. This was a couple's study, and eligible participants had to be in a partnered relationship where the female participant reported sexual dysfunction. Hence, the study identified women with sexual dysfunction as *participants* and their respective male or female sexual companions as *partners*. The participant had to meet the criteria for female sexual interest/arousal disorder (FSIAD) according to the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition* (DSM-5),[31] with symptoms persisting for a minimum of 6 months and causing distress. Eligibility criteria were verified via a phone screening conducted by the study coordinator. Participants were asked whether they endorsed each of the DSM-5 symptoms of FSIAD. They needed to endorse at least 3 symptoms for a minimum of 6 months and report significant distress related to these symptoms, in order to be eligible for this study. Both participant and partner had to be over 18 years of age and willing to participate in an online intervention, have reliable internet access, and speak fluent English. Couples were excluded if a participant reported dyspareunia not relieved by use of a personal lubricant, was taking flibanserin within the 3 months before enrolling, had an unstable psychiatric disorder in the 3 months before enrolling, or was taking a psychotropic or antidepressant medication and was not on a stable dose.

The study adhered to the CONSORT (Consolidated Standards of Reporting Trials) guidelines on reporting clinical trials.[32] Figure 1 shows participant flow regarding enrollment into the study. Interested individuals called a central number and underwent a 10-minute telephone prescreen interview with the study coordinator (S.C.F.). Those who passed the prescreen interview were invited to attend a face-to-face consent visit. During the consent visit, details of the study were discussed, and a written informed consent document was signed. The couples were told the difference between the 2 groups (ie, the intervention group would receive the educational information and active intervention immediately, whereas the control group would receive educational information to review for 3 months before receiving the active intervention).

Interventions

Sex SMART consisted of 2 online modules for couples to complete together. From module 1, the participant and her partner learned stress management and resiliency training through 12 brief online videos (approximately 120 minutes in total) and read corresponding book chapters before each online module from *The Mayo Clinic Guide to Stress-Free Living* (a Stress Management and Resiliency Training [SMART] self-help book).[33-36] Each video in this module began with a brief quiz to pretest knowledge followed by a video presentation (about 8-10 minutes). Finally, each session ended with a posttest. The daily practice in this program was not ritualized and required minimal time commitment because the practices were designed to be integrated into the individual's life. After the couples completed module 1 (ideally within 2 weeks), they were instructed to practice incorporating the SMART practices into their daily routines for the next 2 weeks.

Couples were then emailed the link for module 2, the sexual health education module. Module 2 provided couples with information for enhancing their sexual and overall relationship by utilizing SMART skills specifically for sexual health. Couples were to complete 7 sessions (30 minutes each) consisting of brief videos and worksheet exercises (ideally within 2 weeks). The participant and her partner learned sexual health psychoeducation, which

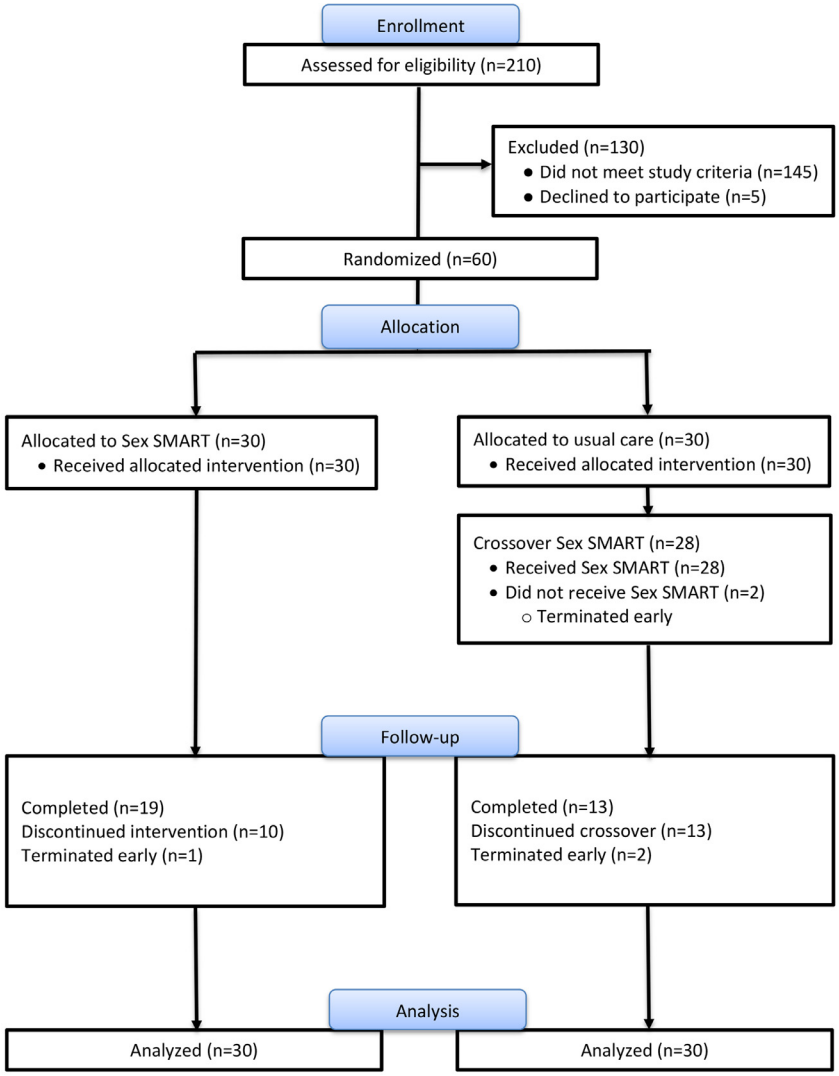


Figure 1. Study flow diagram. Sex SMART indicates Stress Management and Resiliency Training for Sexuality.

included information about FSD, nonpenetrative sensual/sexual pleasuring, the circular and linear sexual response models,[37,38] reasons for engaging in sex,[39] the relationship between mindfulness and sexual function, [10-12] and sensate-focus training.[40]

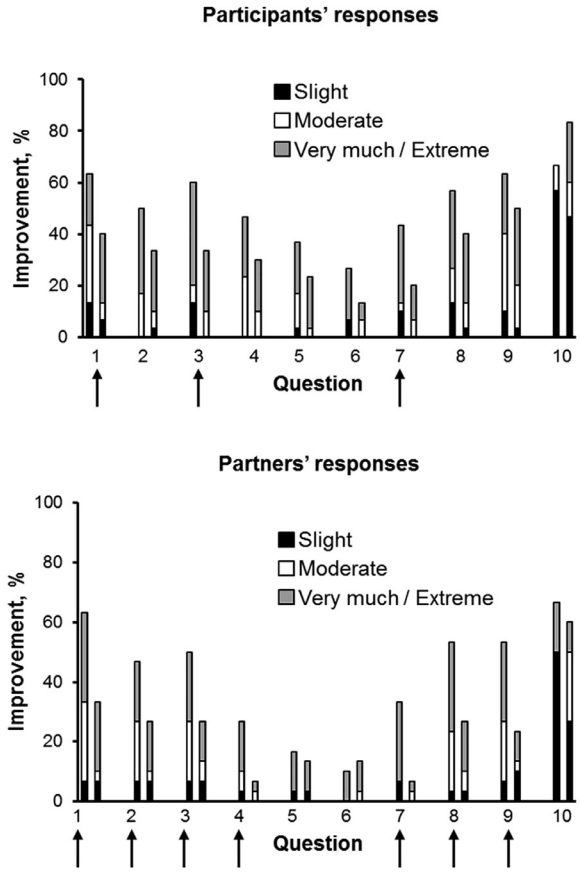
The study included a wait-list control group with a crossover to the Sex SMART modules. Couples randomized to the control group were sent 2 pamphlets and a link to a video on intimacy, which were attached to the introductory study email. The pamphlet topics included information on stress management and sexual health to assist with improving their sexual relationships, which the couple was instructed to discuss. After 3 months, the couples in the control group received online links for the Sex SMART intervention, as described above.

Outcome Measures

Outcome measures were assessed for both study groups via online questionnaires at baseline and at 3 months, 6 months, and 12 months after completion of the intervention. In addition, the control group was assessed 3 months after receiving the pamphlets and before beginning the active intervention.

Primary End Point

The primary end point was change in sexual function as assessed by the Female Sexual Function Index (FSFI) total score from baseline to week 12. The FSFI is a validated questionnaire that measures self-reported sexual function over the past 4 weeks with a total score in addition to the following domains: sexual desire, vaginal lubrication, sexual arousal, orgasm, sexual pain, and sexual satisfaction. Scores for each domain range from 0 to 6, and total sexual function scores range from 2 to 36, with higher scores indicating better sexual function.[41] Total scores of less than or equal to 26.55 indicate clinically significant sexual problems.[42] The FSFI has been shown to have high test-retest reliability (r=0.79-0.86)



Questions:

1. Have your attitudes or feelings improved since your participation in this program?
2. Has your mood on a day-to-day basis improved since completing this program?
3. Are you more comfortable as a sexual person since completing this program?
4. If sexual desire was a concern, has the experience of your sexual desire improved since the beginning of this program?
5. If sexual arousal was a concern, has the experience of your sexual arousal improved since the beginning of this program?
6. If orgasm was a concern, has the experience of your orgasm improved since the beginning of this program?
7. Has your overall sexual functioning improved from the beginning of this program until now?
8. Has your satisfaction with your current sexual relationship improved since the beginning of this program?
9. Has the experience of your overall relationship with your partner changed since the beginning of this program?
10. Was your partner supportive and engaged during this program?

Figure 2. Subjective assessment of women and their partners. For each of the questions (1-10), the possible response options were none, slight, moderate, very much, and extreme. The first bar for each question represents the percentage of participants reporting improvement, and the second bar represents the percentage of controls reporting improvement. Arrows indicate questions with responses showing significant differences between groups.

and high internal consistency, with a Cronbach α of 0.82 or higher for all domains.[41]

Secondary End Points

The secondary end points were self-reported change in sexual function, comfort with sexuality, satisfaction with sexual function, and satisfaction with partner participation, as assessed with subjective questions developed by the authors (Figure 2). These questions provided Likert-response options over a 5-point scale from "not at all" to "extremely" and were adapted from the qualitative interview questions utilized by Brotto et al[43] in their study on MBT for provoked vestibulodynia. Questions included: (1) Have your attitudes or feelings improved since your participation in this program? (2) Has your mood on a day-to-day basis improved since completing this program? (3) Are you more comfortable as a sexual person since completing this program? (4) If sexual desire was a concern, has the experience of your sexual desire improved since the beginning of this program? (5) If sexual arousal was a concern, has the experience of your sexual arousal improved since the beginning of this program? (6) If orgasm was a concern, has the experience of your orgasm improved since the beginning of this program? (7) Has your overall sexual functioning improved from the beginning of this program until now? (8) Has your satisfaction with your current sexual relationship improved since the beginning of this program? (9) Has the experience of your overall relationship with your partner changed since the beginning of this program? (10) Was your partner supportive and engaged during this program? These questions were developed and used as an adjunct to the usual quantitative assessment measures, which, despite strong reliability and validity, may offer a limited viewpoint of the participants' experience and in many cases (eg, FSFI and International Index of Erectile Function [IIEF]) provide limited information if the participant has not recently been sexually active with a partner.[43]

Sexual desire was measured by the Sexual Desire Inventory-2 (SDI-2),[44] a 14-item questionnaire that assesses self-reported levels of sexual desire and desired (versus actual) frequency of both solo and dyadic sexual behavior. Dyadic sexual behavior was measured by Likert-scale responses ranging from "either not at all" to "more than once a day." Solitary sexual behavior was

measured by Likert-scale responses ranging from "no desire" to "strong desire." Scores range from 0 to 112, with higher scores indicating stronger sexual desire. The SDI-2 has been found to have high reliability (Cronbach α=0.86, dyadic-desire scale; 0.96, solitary-desire scale).[44]

Relationship satisfaction was measured by the Revised Dyadic Adjustment Scale (RDAS).[45] The RDAS is a 14-item questionnaire that assesses overall relationship satisfaction and 3 relationship domains: consensus, satisfaction, and cohesion. Response items are based on 5- to 6-point Likert scales, with total scores ranging from 0 to 69. Higher scores indicate greater relationship satisfaction, with a total score of less than 48 indicating relationship distress.[46] The RDAS has been found to have high reliability (Cronbach α=0.90).[45]

Sexual distress was measured by the Female Sexual Distress Scale-Revised (FSDS-R). Only female participants received this questionnaire. The FSDS-R assesses intensity and frequency of sexual distress on 13 items. Responses are based on a 5-point Likert scale (from 0, "never," to 4, "always") with scores ranging from 0 to 52. Higher scores indicate more sexual distress. A score of 11 or greater indicates FSD. The FSDS-R has been shown to have both high internal consistency (0.92) and test-retest reliability (0.69-0.83) among women with hypoactive sexual desire disorder.[47]

EF was measured by the IIEF. Only male participants received this questionnaire. The IIEF is a 15-item self-report questionnaire that measures EF over the past 4 weeks. Responses are Likert scales, with scores ranging from 5 to 75. There are 5 subscales: EF (scores range from 0-30), orgasmic function, sexual desire, intercourse satisfaction, and overall sexual satisfaction. Higher scores indicate better sexual function. Scores less than 14 on the EF domain suggest that a sexual health intervention is warranted. The IIEF has been shown to have both high internal consistency (0.73-0.95) and test-retest reliability (0.64-0.84).[48]

Additional Outcomes

Anxiety was measured by the Generalized Anxiety Disorder-7 (GAD-7).[49] This 7-item measure has 4-item Likert scale responses and measures presence and severity of generalized anxiety disorder (GAD). Scores of 5, 10, and 15 correspond with mild, moderate, and severe anxiety, respectively. A score of 10 or greater indicates the likely presence of GAD. The GAD-7 has been found to have both high internal consistency (α=0.92) and test-retest reliability (interclass correlation=0.083).[49]

Resilience was measured by the Connor-Davidson Resilience Scale-2 (CD-RISC2),[50] which is composed of 2 items from the original 25-item CD-RISC. These 2 items (1, "able to adapt to change"; and 8, "tend to bounce back after illness or hardship") have been found to have good test-retest reliability and convergent validity with the CD-RISC.[50]

Stress was measured by the Perceived Stress Scale-4 (PSS-4), a psychological instrument for measuring stress.[51] The global measure of stress has 14 items, of which items 2, 6, 7, and 14 are used for the PSS-4 scale. Items are rated from 0 to 4, with the total score ranging from 0 to 16. The psychometric properties of the PSS-4 have been tested and found to be acceptable.[52] The PSS has shown adequate reliability and good convergent validity with the *number of life events* and *impact of life events* measures.[51]

Happiness was measured by the Subjective Happiness Scale (SHS).[53] The SHS is a 4-item scale that measures self-reported happiness with response items based on a Likert scale. The SHS has been found to have good convergent validity (0.52−0.72), test-retest reliability (0.55-0.90), and adequate reliability (α=0.79−0.94).[53]

The Satisfaction With Life Scale (SWLS) was developed to assess whole-life satisfaction.[54, 55] The SWLS is a 5-item questionnaire that measures what a person believes makes their life satisfactory. Responses are based on a 7-item Likert scale, from "strongly disagree" to "strongly agree." This scale has good convergent validity with other measures of subjective well-being.[56]

Gratitude was measured by the Gratitude Questionnaire Six-Item Form (GQ-6).[57] The GQ-6 measures the disposition to experience gratitude. Responses are based on a 7-item Likert scale, from "strongly disagree" to "strongly agree." The GQ-6 has been found to have good internal reliability (α=0.82−0.87).

Partner engagement was measured with the following question: Is your partner still engaging in this study with you? The response options were binary, "yes" or "no."

Study Schedule

Study visits were divided into 3 phases: screening, intervention, and follow-up. Couples' participation in the study varied depending on their randomization. Couples were in the study for either 12 months (intervention group) or 15 months (control group). The screening phase included the participants completing a prescreening phone interview and an in-person consent with a screening visit. After completing the screening procedures, participants were given a sealed envelope containing a letter explaining the study, a mail-in version of the consent document, and a contact form for their partners. Once a partner agreed to participate, the partner signed the consent document and returned it by mail with contact information. Using this information, the partner received a link to complete the screening procedure and the online demographic survey. Once the participant and her partner completed the consent and screening procedures, the couple was assigned a couple-identifier and randomized by the study coordinator (S.C.F.) by opening a corresponding sealed envelope that contained the treatment assignment. The randomization envelopes were prepared by the division of biomedical statistics and informatics using a blocked randomization schedule with blocks of size N=4. After this envelope was opened, the study coordinator (S.C.F.) was aware of treatment randomization. All other co-investigators remained blinded to the treatment randomization.

Once randomization was determined, the study coordinator emailed all couples a 10-minute video developed at Mayo Clinic entitled "Intimacy Through Life's Changes" and the additional materials needed to begin their randomized participation. They were also instructed to participate in study procedures together, complete their own online surveys when received, and complete compliance phone visits throughout the study according to study design. If randomized to the intervention group, couples received email links to the online SMART module 1 with a username and password. They were mailed copies of the book *The Mayo Clinic Guide to Stress-Free Living*[36] and a SMART journal, a companion piece for documenting SMART practices if couples wished to do so. These couples continued the active intervention for approximately 6 weeks. Couples randomized to the control group were emailed the video link and the 2 usual care pamphlets pertaining to stress management and sexual health to begin the first 3 months of their participation in the study. Approximately 3 months into the study, or for the intervention group, once the couple completed the active intervention, the participant and her partner were each sent links to the online 3-month questionnaire set to complete. They also completed a subjective questionnaire (Figure 2) adapted from a qualitative study by Brotto et al[43] to assess the intervention impact and barriers to treatment.

Once the couple completed the 3-month survey, they began the next part of study participation. The intervention group began the follow-up phase of the study, and the control group was sent the link to begin the crossover participation with the study intervention. Once the control group completed the active intervention (approximately 6 months after beginning the study), they began the follow-up phase.

The follow-up phase included compliance phone calls, reminder calls as needed, and surveys. For the intervention group, this phase began once the couples had completed participation in the active intervention and the 3-month questionnaires, and it ended 12 months from the start of the study. For the control group, the follow-up phase began once the couple completed the crossover intervention and ended 15 months from the start of the study.

The participants and their partners were individually sent online questionnaires pertaining to sexual function (FSFI, SDI-2, and FSDS-R for women and IIEF for male partners), relationship quality (RDAS), and additional measures of mood (GAD-7), resilience (CD-RISC2), stress (PSS-4), happiness (SHS), satisfaction with life (SWLS), and gratitude (GQ-6). These surveys were sent to the intervention group at screen/baseline, at 3 months (or at completion of intervention), and at approximately 6 and 12 months. The control group received the surveys at baseline and 3 months, and then at approximately 6 months (after completion of active study intervention/crossover treatment), 9 months, and 15 months.

To keep participants engaged in study participation, co-intervention phone calls and a reminder protocol were incorporated into the study schedule. Co-intervention phone calls with the participant were completed 2 to 4 weeks after completion of the intervention and addressed compliance and answered participant questions. The phone calls assisted with understanding whether the couples were reading *The Mayo Clinic Guide to Stress-Free Living*,[36] watching the videos, practicing Sex SMART and intimacy education skills, and using the optional SMART journal. Phone calls to participants also occurred approximately 2 weeks before each survey set would be sent, to prompt questionnaire completion. The reminder protocol was developed to be used as necessary to determine a participant's intent and interest in continued participation. If certain milestones (ie, consent, online questionnaires, online modules) were not completed, the participants received 2 weekly email reminders and then a phone call after 3 weeks. If the participant did not respond or requested to stop participation, the couple was withdrawn from the study. If at any time the participant requested an extension, it was at the investigator's discretion to keep the couple in the study. The phone contacts were to encourage continued study progression, to determine desire to continue with study participation, and to ascertain participant and partner engagement.

Statistical Analysis

Baseline participant and partner characteristics were summarized using mean±SD for continuous variables and frequency counts and percentages for categorical variables. In all cases, intention-to-treat analyses were performed, with all participants included in the analysis according to the group to which they were randomized. The primary outcome of interest was the FSFI total score, and secondary outcomes included the subjective questionnaires, SDI-2, RDAS, FSDS-R, and IIEF. Additional outcomes related to resilience, stress, and well-being included the GAD-7, CD-RISC2, PSS-4, SHS, SWLS, and GQ-6.

In the treatment group, 10 (33%) participants discontinued the study before week 12 compared with only 2 (7%) participants in the control group (Fisher exact test, P=.021). Among the 28 control group participants who remained in the study after week 12, 13 (46%) discontinued the study before completing the crossover SMART intervention (Figure 1). Because of the high percentage of missing data for the 6- and 12-month assessments, these time points were not included in any analyses. For the primary analysis, the baseline value was carried forward for participants and partners who had missing information at 12 weeks. A supplemental analysis of the primary and secondary end points was also performed without using the carry-forward approach for those with missing data (complete case analysis).

For each outcome, the within-treatment group change from baseline to week 12 was assessed using the paired t test. Because the primary outcome (FSFI) was only relevant for the female participants, separate analyses were performed for these participants and their partners. For these analyses, the change from baseline to week 12 was compared between groups using analysis of covariance (ANCOVA), with the baseline value included as a covariate. For primary and secondary outcomes that were assessed consistently in both the female participants and their

Table 1. Baseline participant and partner characteristics[a]

Characteristic	Participants			Partners		
	Overall (N=60)	Sex SMART (n=30)	Control (n=30)	Overall (N=60)	Sex SMART (n=30)	Control (n=30)
Age, y						
Mean±SD	44.1±10.4	44.1±10.3	44.1±10.7	45.7±10.9	45.8±10.6	45.6±11.3
Median (25th, 75th)	44 (36, 53)	44 (36, 55)	43 (36, 52)	45 (39, 54)	46 (39, 56)	44 (36, 53)
Highest level of education						
HS graduate (with/without some college)	12 (20)	6 (20)	6 (20)	17 (28)	7 (23)	10 (33)
4-year college degree	30 (50)	14 (47)	16 (53)	18 (30)	12 (40)	6 (20)
Graduate/professional degree	18 (30)	10 (33)	8 (27)	25 (42)	11 (37)	14 (47)
Race/ethnicity						
White/not Hispanic	56 (93)	28 (93)	28 (93)	57 (95)	29 (97)	28 (93)
Other	4 (7)	2 (7)	2 (7)	3 (5)	1 (3)	2 (7)
Sexual orientation						
Lesbian, gay, or homosexual	1 (2)	1 (3)	0 (0)	1 (2)	1 (3)	0 (0)
Straight or heterosexual	57 (95)	28 (93)	29 (97)	58 (97)	28 (93)	30 (100)
Bisexual	2 (3)	1 (3)	1 (3)	1 (2)	1 (3)	0 (0)
Relationship status						
Married	55 (92)	27 (90)	28 (93)	55 (92)	28 (93)	27 (90)
Partnered	4 (7)	2 (7)	2 (7)	4 (7)	2 (7)	2 (7)
Multiple partners	1 (2)	1 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Other	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	1 (3)
Prior treatment for sexual difficulties						
No	43 (73)	20 (69)	23 (77)	57 (95)	29 (97)	28 (93)
Yes	16 (27)	9 (31)	7 (23)	3 (5)	1 (3)	2 (7)

HS = high school; Sex SMART = Stress Management and Resiliency Training for Sexuality.
[a]Data are presented as No. (%) unless otherwise indicated.

partners, an additional analysis was performed that included data from both participants and their partners. This analysis was performed using a mixed linear model with the couple identifier included as a random effect. For all within-group comparisons, a 2-tailed P value <.05 was considered statistically significant. For the between-group comparison of the primary outcome (FSFI total score), a one-tailed P value of <.10 was determined a priori to be considered evidence suggesting that additional studies would be warranted. For consistency, the results of all between-group comparisons were summarized by presenting the effect estimate (Sex SMART vs control) along with a 90% confidence interval and one-tailed P value. In addition to the validated scales, at 12 weeks the participants and their partners were asked 10 additional subjective questions (Figure 2). For each question, the response options were as follows: 0, "not at all"; 1, "slightly"; 2, "moderately"; 3, "very"; and 4, "extremely." For each question, the responses were compared between treatment groups using the rank sum test.

RESULTS

Baseline characteristics of study participants and their partners are shown in Table 1. The mean±SD age was 44.1±10.4 years for participants and 45.7±10.9 for partners. The majority (92%) of couples were married. All participants and partners had at least a high school education, and most (80% participants, 72% partners) had a 4-year college degree or higher. Prior treatment for sexual problems was reported by 27% of the participants and 5% of the partners. At baseline, the participant and partner characteristics were similar between treatment groups. The baseline assessments of the primary and secondary end points were found to have high internal consistency (Cronbach α = 0.89, 0.94, 0.80, 0.92, and 0.95 for FSFI, SDI-2, RDAS, FSDS, and IIEF-EF, respectively).

Primary End Point

Although the FSFI total score increased significantly form baseline to week 12 for both treatment groups, the change from baseline did not differ significantly between groups (effect estimate for Sex SMART vs control = +1.4 [90% CI, −0.6 to +3.4], P=.13). The FSFI domain scores for desire and satisfaction increased significantly from baseline to 12 weeks, but they did not differ between groups (Table 2). Similar results were obtained for the primary end point (FSFI total score change from baseline) when the analysis was performed without using the carry-forward approach for participants who discontinued the study before week 12 (effect estimate for Sex

Table 2. Primary outcome measures: Female Sexual Function Index[a]

Scale	Participants	
	Sex SMART (n=30)[b]	Control (n=30)[b]
Total Score		
Baseline	17.2±5.4	16.4±5.4
Week 12	20.2±4.3	18.4±5.9
Delta	+3.0±6.1[c]	+2.1±4.9[c]
Effect estimate[d]	+1.4 (−0.6 to +3.4); *P*=.13	
Desire		
Baseline	2.0±0.8	2.0±0.9
Week 12	2.6±0.9	2.6±1.2
Delta	+0.5±0.8[c]	+0.5±0.9[c]
Effect estimate[d]	+0.0 (−0.4 to +0.4); *P*=.50	
Satisfaction		
Baseline	3.1±1.3	2.8±1.0
Week 12	3.9±1.1	3.3±1.4
Delta	+0.8±1.1[c]	+0.6±1.4[c]
Effect estimate[d]	+0.3 (−0.1 to +0.8); *P*=.12	

FSFI = Female Sexual Function Index; Sex SMART = Stress Management and Resiliency Training for Sexuality.
[a]In all cases, higher scores on FSFI scales are better.
[b]There were 17 participants (11, Sex SMART; 6, control) who had missing information from the FSFI at week 12. For analysis purposes, the baseline FSFI values were carried forward to week 12 for these participants.
[c]*P*<.05, paired *t* test comparing week 12 versus baseline.
[d]The change from baseline was compared between treatments using analysis of covariance, with the baseline value included as a covariate. The point estimate (90% CI) is presented for the estimated treatment effect (Sex SMART vs control) along with the one-tailed *P* value assessing whether a significant beneficial effect existed for Sex SMART compared with control.

SMART vs control = +1.9 [90% CI, −0.7 to +4.6], *P*=.11) (Supplemental Table 1).

Responses to the 10 subjective questions assessed at week 12 are summarized in Figure 2. For participants, those assigned to Sex SMART reported significantly more improvement than controls for questions related to attitudes/feelings, comfort as a sexual person, and overall sexual functioning. For partners, those assigned to Sex SMART versus control reported significantly more improvement for questions related to attitudes/feelings, daily mood, sexual desire, overall sexual functioning, overall sexual satisfaction, and overall relationship experience.

Secondary End Points

Secondary end points included the SDI-2, RDAS, FSDS-R, and IIEF (Table 3). For participants, the SDI-2 and FSDS-R total scores were significantly improved at 12 weeks compared with baseline for both treatment and control groups. The RDAS total score did not change significantly from baseline in either group. In all cases, the change from baseline was not found to differ significantly between groups (*P*=.57 for SDI-2, *P*=.28 for RDAS, and *P*=.33 for FSDS-R). For partners in the treatment group, the IIEF-EF score increased from baseline to 12 weeks (25.8±8.8 vs 28.2±5.5, *P*=.06). Additionally, the IIEF-EF score change from baseline differed significantly between groups (effect estimate for Sex SMART vs control = +2.6 [90% CI, +0.3 to +4.9], *P*=.04). The SDI-2 and RDAS did not change significantly from baseline to 12 weeks in either group and did not differ significantly between treatment and control groups (*P*=.69 for SDI-2; *P*=.33 for RDAS). Similar results were obtained when secondary end points were analyzed without using the carry-forward approach for participants who discontinued the study before week 12 (Supplemental Table 2).

Additional Outcomes

Additional outcomes included the GAD-7, CD-RISC2, PSS-4, SHS, SWLS, and GQ-6. For participants, the SHS improved significantly from baseline to week 12 in both treatment and control groups. No other measures were found to change significantly from baseline to 12 weeks among participants or partners, and no significant differences between treatment and control groups were observed (Supplemental Tables 3-5).

To determine participants' overall experiences for the trial, they were asked questions about the most burdensome and the most helpful elements of the intervention. The intervention group indicated that the greatest barrier to completing the intervention included the time burden of the daily Sex SMART practice (29%), the time burden of the online modules (29%), and other reasons (29%). Half (50%) of participants who indicated "other" emphasized the difficulty in making time for this intervention given work/life demands. Despite their reporting the daily Sex SMART practices as one of the greatest burdens, the participants (28%) reported that these practices were also one of the most helpful aspects of the intervention. One-third (33%) of intervention participants indicated "other" as the most helpful aspect of the intervention, and many described the connection between the stress management education and sexual health materials as enlightening. Control group participants (27%) reported that the stress management pamphlet was the most helpful element. Participants were asked, "Overall, do you believe this program was helpful?" Response options ranged on a 5-point Likert scale from "extremely" to "not at all." The intervention group reported the intervention to be significantly more helpful than did the control group (*P*<.001). Finally, by week 12, 6 of the 17 (35%) Sex SMART participants who reported their partner's compliance with the study indicated that their partner was no longer engaging in the study.

DISCUSSION

To our knowledge, this is the first online RCT to examine a mindfulness, resilience, and psychoeducation–based intervention in women with sexual health concerns and their partners. Our primary aim was to determine the feasibility of offering an online mindfulness, resilience, and psychoeducation program to couples with sexual health concerns. Support for the feasibility of

Table 3. Secondary sexual function and relationship outcomes for participants and partners

Scale	Participants		Partners	
	Sex SMART (n=30)[a]	Control (n=30)[a]	Sex SMART (n=30)[a]	Control (n=30)[a]
SDI-2 total score				
Baseline	31.2±15.3	27.2±16.0	61.7±14.7	66.1±15.3
Week 12	37.8±13.7	35.2±18.7	62.0±14.1	66.1±13.9
Delta	+6.6±12.7[b]	+8.0±10.6[b]	+0.3±6.9	−0.1±8.9
Effect estimate[c]	−0.5 (−5.4 to +4.4); *P*=.57		−0.5 (−3.8 to +2.9); *P*=.69	
Overall estimate[d]	−0.6 (−3.5 to +2.4); *P*=.87			
RDAS total score				
Baseline	48.8±6.7	45.6±8.0	48.7±5.7	45.3±6.7
Week 12	48.0±6.5	44.9±8.3	48.6±6.3	45.1±7.6
Delta	−0.8±6.2	−0.8±5.1	−0.1±3.6	−0.2±5.2
Effect estimate[c]	+0.9 (−1.6 to +3.3); *P*=.28		+0.5 (−1.5 to +2.6); *P*=.33	
Overall estimate[d]	+0.7 (−0.8 to +2.3); *P*=.22			
FSDS total score			NA	NA
Baseline	27.9±9.5	27.7±10.9	…	…
Week 12	23.4±9.9	24.9±10.9	…	…
Delta	−4.5±7.0[b]	−3.6±6.6[b]	…	…
Effect estimate[c]	−0.8 (−3.7 to +2.1); *P*=.33			
IIEF-EF	NA	NA		
Baseline	…	…	25.8±8.8	25.8±8.8
Week 12	…	…	28.2±5.5	25.9±8.6
Delta	…	…	2.4±6.6	−0.1±5.8
Effect estimate[c]	…		+2.6 (+0.3 to +4.9); *P*=.04	

FSDS = Female Sexual Distress Scale (lower scores are better); IIEF-EF = International Index of Erectile Function—Erectile Function subscale; NA = not applicable; RDAS = Revised Dyadic Adjustment Scale (higher scores are better); SDI-2 = Sexual Desire Inventory-2 (higher scores are better); Sex SMART = Stress Management and Resiliency Training for Sexuality.

[a]Baseline values were carried forward to week 12 for participants who had missing information for a given scale at week 12. For participants, FSDS was missing for 3 (2, Sex SMART; 1, control) at baseline and 15 (11, Sex SMART; 4, control) at week 12; SDI-2 was available for all participants at baseline but missing for 13 (11, Sex SMART; 2, control) at week 12; RDAS was missing for 3 (1, Sex SMART; 2, control) at baseline and 13 (10, Sex SMART; 3, control) at week 12. For partners, SDI-2 was missing for 2 (1, Sex SMART; 1, control) at baseline and 11 (11, Sex SMART; 0, control) at week 12; RDAS was missing for 2 (2, Sex SMART; 0, control) at baseline and 9 (9, Sex SMART; 0, control) at week 12. IIEF-EF was missing for 3 partners at baseline (1, Sex SMART; 2, control) and missing for 13 (13, Sex SMART; 0, control) at week 12.

[b]*P*<.05, paired *t* test comparing week 12 versus baseline.

[c]Change from baseline was compared between treatments using analysis of covariance, with the baseline value included as a covariate. The point estimate (90% CI) is presented for the estimated treatment effect (Sex SMART vs control) along with the one-tailed *P* value assessing whether a significant beneficial effect existed for Sex SMART compared with control.

[d]Analysis was performed using a mixed linear model with the couple identifier included as a random effect.

implementing this intervention is limited. First, the attrition rate was high among couples receiving the intervention. Given that this was a feasibility study, the high attrition rate is concerning and needs to be explored further. Second, we hypothesized that this program would improve women's and their respective partners' sexual health function versus controls. These hypotheses were only partially supported. The improvements in sexual function reported in the primary (FSFI) and many secondary outcomes (SDI-2 and FSDS-R) did not significantly differ from the control group, which also reported significant improvement. However, the intervention group did report significant subjective improvement in sexual attitudes, feelings, comfort, and functioning versus the control group. Further, partners in the intervention group also reported significant improvement in the IIEF-EF scores versus the control group.

Regarding the attrition rate, despite measures taken to maintain study compliance (which included regularly scheduled compliance phone calls),[58] there was a high attrition rate among couples receiving the intervention immediately (33%) and among couples in the waitlist-control group after crossing over to the intervention (46%). The attrition rate in the current study is comparable to those of other internet-based dyadic interventions, which tend to be higher than in-person interventions.[59-61] Internet-based *couple* interventions may even have higher attrition rates (eg, up to 52% reported from a systematic review[62]).[19]

The high attrition rate highlights engagement as 1 of the primary difficulties in conducting online couple interventions. Given the importance of treating the couple in sexual health interventions, future research focused on exploring potential barriers associated with online dyadic interventions, in addition to

identifying the subset of participants who would most benefit from such an intervention, would be beneficial.[58,63,64] In the present study, the majority of participants identified time (or lack thereof) as the greatest burden associated with the intervention. This is consistent with feedback from participants undergoing low-intensity psychotherapy internet-based interventions.[65]

Regarding our hypotheses, our study findings showed that women with sexual health concerns randomized to the Sex SMART intervention had significant improvements from baseline to week 12 in several validated measures, including FSFI, SDI-2, and FSDS-R scores, but there were no statistically significant differences in the FSFI, SDI-2, and FSDS-R scores between the intervention and control groups. The lack of between-group differences may have been due to the nature of the intervention provided to the control group. Per the study design, partners needed to engage in a conversation for both to agree to participate in this study, which likely facilitated communication regarding sexual health issues. Further, control group participants had to attend an informed-consent session with the study coordinator before receiving their care pamphlets on sexual health and stress management. This interactive consent session and mutual agreement to participate, the stress management and sexual health pamphlets received, and even the follow-up study questionnaires are likely to have led to increased communication between partners regarding their sexual health, which may have had a therapeutic effect on sexual functioning. This finding is consistent with those of prior studies linking sexual communication with improved sexual desire and arousal, orgasm, sexual pain, and overall sexual function, particularly for married women.[66] Thus, both the Sex SMART intervention and control groups received interventions that resulted in improvements in sexual functioning on the validated measures. However, although we did not detect a statistically significant difference between groups, the upper bound of the confidence interval includes a clinically relevant difference, and, therefore, we cannot rule out the possibility that the SMART intervention could be beneficial. Future controlled trials might benefit from including a control group that does not encourage sexual communication and an intervention group that specifically teaches healthy communication skills.[29]

Despite no statistically significant findings with the abovementioned validated measures, women with sexual health concerns randomized to the Sex SMART intervention reported significantly improved sexual attitudes and feelings, increased comfort as a sexual person, and increased sexual functioning compared with the control group. Additionally, male partners randomized to the intervention group reported significant improvements in EF, as indicated on the IIEF. Further, partners (men and women) randomized to the intervention group also reported significantly improved sexual desire, overall sexual function, and increased satisfaction with their sexual and overall relationship with their partner versus partner controls. These significant improvements suggest some degree of promise for this online dyadic intervention, particularly for male partners. However, further research with particular attention to increasing engagement is needed to confirm these findings.

Our study had several limitations. The study sample lacked diversity and was predominantly educated, white, married, and employed, which may limit the generalizability of the findings to other populations. For example, participants from different sociocultural backgrounds may have received different cultural messages around sexual values, sexual behaviors, and sexual health, which may have affected their receptivity of the psychoeducation intervention.[67,68] Participants from lower socioeconomic backgrounds may not have had the means (eg, time, childcare, privacy, internet) to engage in an online couple intervention.[69] In addition, given the high attrition rate, it is likely that the couples who completed this intervention were highly motivated and may not reflect the behavior of other couples who report sexual health concerns. Further, we did not require that participants be sexually active to participate in this trial. A small number of women reported no sexual activity in the last 4 weeks at baseline (2 [7%] participants in the SMART group; 3 [10%] in the control group). Of those who completed the 12-week assessment, 0 (0%) in the SMART group and 2 (7%) in the control group indicated that they were not sexually active in the prior 4 weeks. For these sexually inactive women, the FSFI may have overestimated sexual dysfunction. Finally, because this was a feasibility trial with the eventual goal of providing preliminary data for a future, larger phase III trial, many secondary and exploratory end points were analyzed, which increases the likelihood of type I errors.

CONCLUSION

The findings of this study provide only limited support for the feasibility of implementing an online mindfulness, resilience, and psychoeducation program for couples with sexual health concerns. Special attention needs to be focused on how to mitigate attrition when providing an online couples' intervention. While this program significantly improved the sexual function of women and their respective partners, the primary outcome (FSFI) and several important secondary outcomes (SDI-2 and FSDS-R) did not significantly differ from those reported by the control group. Future controlled trials would benefit from minimizing inadvertent therapeutic effects of being in the control group, such as enhancing communication.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.esxm.2021.100404.