Randomized Comparison of Mindfulness versus Group Support for Treatment of Low Sexual Desire in Women

Study Protocol and Statistical Analysis Plan

Note: No separate study protocol exists. This attachment includes a description of the study and data analysis plan.

Proposal for "Randomized Comparison of Mindfulness versus Group Support for Treatment of Low Sexual Desire in Women"

JUSTIFICATION:

Population-based studies suggest that difficulties with low sexual desire and insufficient sexual arousal are extremely common in women across the life cycle. Our understanding of the precise mechanisms that control female sexual response is at present incomplete. Sexual response, which includes sexual motivation, interest, and arousal, has been conceptualized as a complex interaction between physiological and psychological components (Everaerd, Laan, Both, van der Velde, 2000; Rosen & Beck, 1988), and mounting evidence suggests that sexual desire and arousal may be two aspects of the same sexual response process. Several studies have found a high degree of comorbidity between Hypoactive sexual desire disorder (HSDD) and Female sexual arousal disorder (FSAD; Brotto 2011; Fugl-Meyer& Fugl-Meyer, 2002). Moreover, scores on desire and arousal domains, using different instruments, are typically highly correlated with one another (Brauer, Lakeman, van Lunsen, and Laan 2010; Laan, Termeer, van Lunsen, Zimmerman, Coelingh Bennink, 2010; Nobre, Pinto-Gouveia, Gomes, 2006; Rosen et al., 2000; ter Kuile, Brauer, and Laan, 2006). This high correlation was found both in women with and without FSAD (Wiegel, Meston, and Rosen, 2005). In their longitudinal research on mid-life women, which contributed to the development of a model of women's sexuality, Dennerstein and colleagues found that items tapping into women's sexual arousal and responsiveness could not be separated from items tapping into sexual desire (Dennerstein, Lehert, and Burger, 2005). A central tenet of the Incentive Motivation Model for sexual response is that sexual desire and sexual arousal emerge, together, in response to effective sexual cues. Sexual desire and sexual arousal may even represent different sides of the same sexual coin. If desire and arousal are to be distinguished, it is likely only at a phenomenological level, with desire defined as the willingness to behave sexually and sexual arousal reflecting the subjective experience of genital changes (Laan and Both, 2008).

In one of the most recent examinations of population prevalence of low desire, the "Prevalence of Female Sexual Problems Associated with Distress and Determinants of Treatment Seeking" (PRESIDE) study examined 31,581 American women aged 18-102 (mean age 49; Shifren et al. 2008). The Female Sexual Distress Scale (FSDS; Derogatis et al., 2002) was used to measure sex-related distress and the item "How often do you desire to engage in sexual activity" was used to capture low desire. Low desire, defined as a response of "never" or "rarely" to this item, was found in 38.7% of the sample and distress, defined as a score > 15 on the FSDS, was found in 22.8%. The overall estimate of HSDD, taking into account both criteria, was found to be 10.0%. Even considering the drop in prevalence when low desire and distress together are assessed, this continues to be the most frequent complaint seen in sex therapy clinics, and the majority of women with any sexual difficulty (i.e., desire, arousal, orgasm, or pain-related) state that their low sexual desire is the cause of their sexual difficulties (Hayes, et al., 2006).

Population-based estimates suggest that lubrication difficulty, as a specific symptom of Female Sexual Arousal Disorder (FSAD), affects from 11-19% of women younger than 30, up to 24-27% of women older than 50 (Fugl-Meyer & Fugl-Meyer, 1999; Laumann, Paik, & Rosen, 1999), and may be as high as 75% for those women seeking routine gynecological care (Nusbaum et al., 2000). Lack of subjective (sometimes called cognitive or mental) sexual arousal during the sexual experience, especially when intercourse frequency is more tuned to the higher needs of the partner, is a more common complaint among women presenting clinically. Despite the fact that complaints of sexual arousal difficulty and associated distress are extremely common in the clinical setting, evidence based treatments to address FSAD are non-existent.

Despite their high prevalence, sexual interest, desire, and arousal concerns remain without effective treatment today. Moreover, there are no Food and Drug Administration (FDA) or Health Canada approved pharmaceutical products available to treat these highly distressing symptoms.

Our laboratory has published evidence showing the efficacy of a mindfulness-based cognitive behavioural therapy for the treatment of distressing loss of desire/arousal in women (Brotto, Basson, Luria, 2008; Brotto, Heiman, et al., 2008; Brotto, Erskine, Carey, et al., 2012; Brotto, Seal, & Rellini, 2012). Our protocol included four sessions delivered in group format with two facilitators and was based on empirically supported techniques in other areas of female sexual dysfunction (e.g., sensate focus, challenging maladaptive cognitions and sexual myths). The ingredients were adapted from a variety of sources including (1) *Becoming Orgasmic* by Heiman and LoPiccolo (1988), which is an empirically-supported behavioural treatment for women with lifelong orgasmic disorder, (2) *Seven principles for making marriage work* by Gottman (1999); (3) *The Miracle of Mindfulness* by Thich Nhat Hahn (1976); (4) *Full Catastrophe Living* by Jon Kabat-Zinn (1990) and (4) *Progressive Relaxation* by Edmund Jacobson (1938). It involved in-session didactic material as well as in-session mindfulness practices followed by daily homework activities between sessions.

In our clinical experience, mindfulness techniques, with the aim of guiding attention into the present, can be a very effective component of care among women with sexual difficulties and we have been using mindfulness techniques for women with loss of desire and arousal. The proposed study, "Randomized Comparison of Mindfulness versus Group Support for Treatment of Low Sexual Desire in Women" compares the effectiveness of group mindfulness-based cognitive therapy (MBCT) and support. The MBCT group expands on our previous 4-session intervention by incorporating a larger proportion of mindfulness practice and information in session, and expanding the sessions to eight weekly sessions to make it more in line with other mindfulness based interventions for depression that have received widespread empirical attention and support.

PURPOSE:

This study utilizes a mindfulness-based psychoeducational treatment approach that is based on our 4-session effective treatment protocol. As with the 4-session treatment, the currently proposed 8-session MBCT group is based on a variety of empirically supported techniques, and integrates elements of education, mindfulness skills, and sex therapy. The purpose of this study is to determine whether an 8-session intervention is effective in reducing women's sexual distress, improving their sexual response, and increasing their mindful skills. To date, many women who have received our 4-session intervention have indicated that having more than 4 sessions would be beneficial. As well, other integrated mindfulness/cognitive behavioral treatments (e.g., Mindfulness-Based Cognitive Therapy for depression; Segal, Williams, & Teasdale, 2002) are 8-sessions in length and provide increased opportunity for participants to practice the skills they are learning in session.

HYPOTHESES:

1. Compared to baseline, the MBCT group will have significant post-treatment improvements in self-report measures of: (a) sexual distress; (b) sexual desire, subjective sexual arousal, perception of genital arousal, and sexual pleasure; (c) relationship satisfaction; (d) depressive symptoms and rumination; (e) perceived stress, general anxiety, anxiety sensitivity, and sexuality-related situational anxiety (as self-reported at the sexual arousal assessment); and (f) mindfulness, self-compassion, non-attachment, and interoceptive awareness.
2. Compared to baseline, the MBCT group will have significant post-treatment improvements in laboratory physiological measures of: (a) genital sexual response as measured by a vaginal photoplethysmograph, (b) interoceptive awareness, as measured

by a heart rate perception task, (c) cortisol:DHEA ratio as measured by hormonal assays of saliva samples, and (d) a significant decrease in C-reactive protein as measured by hormonal assays of saliva samples.

3. We hypothesize that the changes in the endpoints listed in #1 or #2 will be significantly greater in the MBCT group than in the support group.
4. We hypothesize that participation in the MBCT group will significantly increase concordance.
5. Mindfulness, self-compassion, and interoceptive awareness will significantly mediate improvements in sexual distress and desire in the MBCT group at all post-treatment assessment points.
6. Expectations of change with treatment will not significantly moderate improvements in sexual distress and desire in the MBCT group.
7. Participants' impressions of change will be significantly greater in the MBCT group compared to the support group at all post-treatment assessment points.
8. We hypothesize that participants with sexual desire issues will see an improvement (fewer breaks in the cycle) throughout the course of the eight-week treatment.

OBJECTIVES:

The main objective for this study is to test the MBCT group with women who are currently seeking treatment for low sexual interest/desire and/or arousal and compare it to a support group.

RESEARCH METHOD:

Recruitment: Women who are currently seeking treatment at the BC Centre for Sexual Medicine, who have participated in other studies in our laboratory and expressed interest in being contacted for future research, and who see our advertisements in the community (including public transit advertising) will be candidates for this study. Patients from BC Women's Hospital and Health Centre's Complex Chronic Diseases Program who have provided permission to be contacted for future research will be candidates for the study. Those who are seen for an initial assessment by one of the Co-Investigators, or any of the clinicians at the BC Centre for Sexual Medicine will be informed about the study at the conclusion of their assessment if they are determined to meet inclusion criteria. After briefly mentioning the study, the clinician will give interested women a handout (one-page information sheet) that briefly outlines the methods of the study and the criteria for inclusion, as well as contact information for the study coordinator. A copy of the consent form will be included with the handout to allow the woman to review the consent prior to contacting the study coordinator about the study. Specific instructions will be included informing women that the consent form provided at this time is for information purposes and should not be returned until the woman has spoken to the study coordinator. For women in our database of former participants, the study coordinator of the study in which they participated will contact them by phone or email, inform them about the study, and email them the handout with instructions to contact the study coordinator if they are interested in participating. For women in the "permission to be contacted for research" database from the Complex Chronic Disease program at BC Women's Hospital, they will be contacted by the coordinator from the program and interested women can contact the DESIRE study coordinator. Interested candidates from the community will contact the study coordinator directly. She will perform a detailed telephone screen for all potential participants that further assesses study eligibility and explains the methods in more detail, and then mail/email a copy of the consent form to participants. If, after reading the consent form, the woman is interested in taking part, she will contact the Study Coordinator to set up an in-person meeting with a trained graduate student in clinical or counselling psychology at UBC who will carry out the in-person assessments under the supervision of the PI. At this time, her eligibility will be confirmed and she will sign the

consent form. Following enrolment, she will be randomized to either group mindfulness-based therapy or support group therapy and will be registered for the next study group. Arrangements will also be made to complete the saliva sampling, pre-treatment questionnaires, and the sexual psychophysiological assessment.

Inclusion criteria for treatment group includes: any woman between the ages of 19-65, fluent in English, and who experiences distressing sexual interest/desire and or sexual arousal concerns. Exclusion criteria include: a psychiatric or medical condition precluding group attendance or homework completion, and Borderline Personality Disorder (for which mindfulness meditation may cause dissociation and is therefore counter-indicated; Sachse, Keville, & Feigenbaum, 2011).

Procedures: Participants will be randomly assigned to either the MBCT group or the support group (control condition). The purpose of the support group is to control for any effect of the sexuality education, discussion, and support provided in the MBCT group.

All participants will meet in-person with a trained graduate student in clinical or counselling psychology to ask any further questions about the study, to review study protocol, and discuss participant remuneration- $55/assessment ($25 per questionnaire package plus $30/ per laboratory-based assessment and at-home saliva sample collection) for each of the four times completed. Participants will receive their saliva sampling kit (which includes all necessary sampling equipment) and detailed written and verbal instructions on how to collect their samples.

After saliva samples have been collected, participants will return their saliva sampling kits to the Study Coordinator when they take part in an individual sexual psychophysiological assessment in the PI's laboratory (UBC Sexual Health Lab) located in the Diamond Health Care Centre at Vancouver Hospital. Women will be asked to undergo a heartbeat perception task and a sexual arousal assessment.

The Heartbeat Perception task, performed according to the Mental Tracking Method proposed by Schandry (1981), involves the silent counting of perceived heartbeats during four intervals of varying duration (25, 35, 45, and 55 seconds) separated by a 30 second resting period. After each counting period participants will be asked to report the number of counted heartbeats. Electrocardiogram measurements will be taken to determine actual heart rate. Participants will wear non-polarized Ag-AgC1 electrodes attached to two points on the body (mid right clavicle and lower left ribcage). Signals will be recorded and analyzed by a computer-based data acquisition system (MP150; Biopac Systems, Inc.) The Heartbeat Perception task is a well-validated measure of the ability to detect changes within the body known as Interoceptive Awareness (Dunn et al., 2007; Jones, 1994; Wildmann & Jones, 1982).

The sexual arousal assessment will involve exposure to brief audiovisual films which include erotic content. While viewing the film, a woman's vaginal pulse amplitude (VPA) will be measure with a Vaginal Photoplethysmograph which has been found to be a sensitive and specific measure of genital arousal (Laan & Everaerd, 1995). Participants will indicate their levels of subjective arousal while viewing the film by using a device manufactured for the UBC Sexual Health Lab called the “arousometer”- a computer mouse mounted on a metal track divided into 10 equally spaced intervals corresponding to “sexually turned off” (-2) to “the most sexually aroused you have ever been or could imagine being” (7). This device allows continuous self-report measurement of subjective sexual arousal while viewing the erotic films. Immediately before and after watching the films, participants will complete a pre and post film questionnaire that assess mood and reactions to the erotic film (Heiman & Rowland, 1983). This assessment is performed pre-treatment, 2-4 weeks post treatment and 6 and 12 months post treatment. Women who enroll in the study and complete their pre-treatment physiological assessment more than 2.5 months before their group starts will undergo an additional sexual arousal assessment

prior to the group. Each woman will be provided with an individualized link to online questionnaires to be completed before their assessments.

Each group will have between 6-8 women and we hope to run approximately four groups per year. The group will be led by the PI, the Co-Investigator (Dr. Paterson), and/or the team of trained clinicians at the BC Centre for Sexual Medicine who have been involved in designing and carrying out similar groups over the past six years. Groups will have at least 2 facilitators. All groups will take place in a private group room at the Diamond Health Care Centre, located at Vancouver General Hospital, at 2775 Laurel Street, Vancouver.

The 8-session MBCT group is based on a variety of empirically supported techniques, and integrates elements of education, mindfulness skills, and sex therapy. It consists of eight, two-hour long sessions spaced one week apart. Each woman will participate for 16 hours of group time. In addition, participants are also given handouts and asked to complete approximately 10-60 minutes/day of at-home practice/skills, which may include reading material, mindfulness exercises, and behavioural exercises between sessions. The treatment in the MBCT group is very similar to that of the 4-session PED previously tested and found effective in our centre; participants who receive the expanded version will, however, be given more time to practice the various exercises (e.g., mindfulness exercises) in session, and more time will be devoted to inquiry about participants' in-session practice experiences. The support group will include all of the same material except for the mindfulness practice in session and at home. Approximately 10% of the group sessions will be audio-recorded to ensure facilitator adherence to the treatment manual.

Participants will complete brief questionnaires online and over the telephone between sessions 4 and 5 of their therapy group, in order to establish the temporal sequence of changes in the main outcome variable and hypothesized mediators.

After the conclusion of group session 8, women will be provided with an individualized link to online questionnaires, which will be nearly identical to those completed prior to their first assessment, and a second saliva sampling kit. In addition, women will repeat their sexual psychophysiological assessment at the UBC Sexual Health Lab. Women will also be asked about their experience with the mindfulness practices and/or sexuality worksheets at each post-treatment assessment. Questionnaires, at-home saliva sample collection, and the in-lab psychophysiological assessments will also be done 6 and 12 months after completing the 8-session group treatment.All online questionnaires for women in both treatment groups will be administered with SurveyMonkey™.

Participants who have completed the study will be invited to take part as a "patient partner," which will involve attending a focus group meeting with the study investigators to provide insight and feedback on their experience living with Sexual Interest/Arousal Disorder, as well as get their feedback on what they would find most interesting and relevant to viewers regarding the findings of another study called MODEST (Mood, Stress, and Sexual Desire in Women, CREB number = H10-02067), which also examined women's low sexual desire. This will help to develop a script to create a knowledge translation infographic video in the future. This meeting would take approximately 2 hours and patient partners would receive $50 for their time and cost of parking. This is not a required study procedure but rather an invitation if former participants would like to share their experience. The meeting will be a single 2 hour session with up to three women with low desire, two facilitators, and a note-taker from the study team. The entire session will be audio-recorded and later transcribed. No individual names will be used in the transcript. Patient Partners will be asked to respect the confidentiality of those who attend this focus group meeting, and will be told that facilitators cannot control what other participants do with the information discussed, so that they can make an informed decision about whether or not to participate in the focus group.

Specification of Endpoints: The primary endpoint in this study will be sexual distress given that distress associated with impaired sexual functioning is the reason that women provide for

seeking treatment. Sexual distress will be measured with the revised version of the Female Sexual Distress Scale-R (Derogatis et al., 2008). Measurement of sexual interest/desire, arousal (both self-report and psychophysiological), stress hormone ratios, and Interoceptive Awareness represent secondary endpoints. Psychophysiological sexual arousal will be measured with a vaginal photoplethysmograph in the UBC Sexual Health Laboratory. Stress hormone ratios will be measured through calculating the cortisol:DHEA slope within participants' saliva samples. This will be done by measuring the change in cortisol:DHEA secretions over the course of the day, and calculating a simple difference score (PM minus AM values). Interoceptive Awareness will be measured using the Heartbeat Perception task (Schandry, 1981) at the time of the sexual arousal assessment and with the Multidimensional Assessment of Interoceptive Awareness (MAIA; Mehling et al., 2012) questionnaire. Self-reported sexual desire and arousal will be assessed with the Female Sexual Function Inventory (FSFI; Rosen et al., 2000), the Sexual Pleasure Questionnaire (a two-question supplement to the FSFI developed for this study), and the Sexual Interest and Desire Inventory (SIDI; Clayton et al. 2006). Other endpoints include: relationship satisfaction, which will be measured with the Relationship Assessment Scale (Hendrick, 1988); motivations for sex, which will be measured with the Motivations for Sex Measure (Muise et al., 2013); disruptions to the sexual response cycle, which will be measured using the Sexual Response Cycle Worksheet (Basson, 2000); perceived stress, which will be measured with the Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983); depression, which will be measured with the Beck Depression Inventory-II (BDI-II; Beck, Steer, & Brown, 1996) or the Hamilton Depression Scale – Short Form (McIntyre et al., 2005); rumination, which will be measured with the Ruminative Responses Scale (Treynor, Gonzalez, & Nolen-Hoeksema, 2003) or the Rumination-Reflection Questionnaire – Adapted Rumination Subscale (adapted from Trapnell & Campbell, 1999 to inquire about sexuality-related rumination); trait anxiety and situational anxiety at the sexual arousal assessments, which will be measured with the State-Trait Anxiety Inventory (Spielberger, Gorsuch, & Lushene, 1970); and anxiety sensitivity, which will be measured with the Anxiety Sensitivity Index – 3 (Taylor et al., 2007). Mindfulness, self-compassion, and non-attachment will be measured with the Five Factor Mindfulness questionnaire (Baer, Smith, Hopkins, Krietemeyer & Tony, 2006), Self-Compassion Scale (Neff, 2003), and Non-Attachment Scale (Sahdra, Shaver, & Brown, 2010), respectively. We will assess socially desirable responding (impression management and self-deceptive enhancement) with the Balanced Inventory of Desirable Responding-6 (BIDR-6; Paulhus, 1998), expectations of change with treatment with the Expectations Measure [a two-item questionnaire completed following the session 1, designed for and used in our approved mindfulness-based treatment study for provoked vestibulodynia (H12-02358)], and participants' impressions of change with treatment with the Patient Global Impression of Change Scale – Revised (adapted from Hurst & Bolton, 2004; as used in H12-02358).

Measures: Questionnaires to be included in this study will be administered to women online. Women choosing to have a hard copy of the questionnaire will be provided with such questionnaires at the time of their in-person sexual arousal assessment. The following instruments will be used at all testing times: (1) Beck Depression Inventory-II (Beck et al., 1996) or the Hamilton Depression Scale – Short Form (McIntyre et al., 2005); (2) Female Sexual Distress Scale-Revised (Derogatis et al., 2008); (3) Female Sexual Function Index (Rosen et al., 2000); (4) Five Facet Mindfulness Questionnaire (Baer et al., 2006); (5) Sexual Interest and Desire Inventory (Clayton et al., 2006); (6) State-Trait Anxiety Inventory – State Form (Spielberger et al., 1970); (7) Sexual Pleasure Questionnaire; (8) Multidimensional Assessment of Interoceptive Awareness (Mehling et al., 2012); (9) Ruminative Responses Scale (Treynor et al., 2003) or Rumination-Reflection Questionnaire – Adapted Rumination Subscale (adapted from Trapnell & Campbell, 1999); (10) Anxiety Sensitivity Index – 3 (Taylor et al., 2007); (11) Self-Compassion Scale (Neff, 2003); (12) Non-Attachment Scale (Sahdra, Shaver, & Brown, 2010); (13) Perceived Stress Scale (Cohen, Kamarck, & Mermelstein, 1983); (14) Relationship

Assessment Scale (Hendrick, 1988); (15) Film Scale Before and After -1983 (Heiman & Rowland, 1983).

The following questionnaires will be used at baseline only: (16) Balanced Inventory of Desirable Responding-6 (Paulhus, 1998); (17) State-Trait Anxiety Inventory – Trait Form (Spielberger et al., 1970); and (18) Expectations Measure (following session 1).

The following questionnaires will be used at post-treatment (approximately 4-6 weeks after session 8), and at 6- and 12-month follow-ups only: (19) Patient Global Impression of Change Scale – Revised (adapted from Hurst & Bolton, 2004). For post-treatment assessments only, participants will complete an investigator-derived MIND or STEP Follow-Up Form in order to assess completion of group homework, which will be administered by a trained research assistant at each assessment point.

All questionnaires for the study will be completed online using Survey Monkey, except for the Hamilton Depression Scale – Short Form, which will be administered by a trained research assistant at each assessment point. Women who prefer to receive a hard copy of the questionnaires will be sent the questionnaire package via mail.

At baseline, participants will complete an investigator-derived Dysmenorrhea Questionnaire in order to assess painful menstruation. This questionnaire is being used in the COMFORT study (H12-02358) with women with provoked vestibulodynia, as dysmenorrhea has been linked to the development of chronic pain conditions. When the COMFORT study's data are analyzed, rates of dysmenorrhea in the two different studies will be compared.

The following questionnaires will be used at pre-treatment and post treatment (approximately 4-6 weeks after session 8) only: (20) Pelvic Floor Distress Inventory – short form 20 (Barber, Walters, & Bump, 2005); (21) Pelvic Floor Impact Questionnaire – short form 7 (Barber, Walters, & Bump, 2005).

For the control group, data collected from the VENUS study will be used in the DESIRE Study from participants who consent to participating. Demographic information and the following validated measures will be analyzed from the VENUS Study: (1) Female Sexual Interest and Desire Inventory (SIDI-F; Clayton et al, 2006); (2) Female Sexual Distress Scale (Derogatis, Rosen, Leiblum, Burnett, & Heiman, 2002).

For control group participants recruited from the community, demographic information and the following validated measures will be analyzed: (1) Female Sexual Interest and Desire Inventory (SIDI-F; Clayton et al, 2006); (2) Female Sexual Distress Scale (Derogatis, Rosen, Leiblum, Burnett, & Heiman, 2002).

Data analyses

Analyses of measures of sexual distress, sexual functioning (sexual desire, subjective sexual arousal, perception of genital arousal, sexual pleasure, and VPA), relationship satisfaction, mood and anxiety (depressive symptoms, rumination, perceived stress, general anxiety, anxiety sensitivity, and sexuality-related situational anxiety), stress hormone ratios, mindfulness, self-compassion, non-attachment and interoceptive awareness will be carried out with a repeated measures ANOVA with group (MBCT vs. support) entered as a between-subjects variable, time (waitlist, pre-group, post-group, and 6- and 12-month follow ups) entered as the within-subjects variable, and age entered as a between subjects covariate. We will attempt to control for socially desirable responding and degree of homework completion in these analyses. Multiple regression analyses will be used to determine effects of predictor variables on treatment efficacy (including participants' impressions of change). These might include: depression scores and mindfulness scores at pre-treatment, and demographic variables such as relationship duration and menopausal status. We will conduct mediation analyses of mindfulness, self-compassion, and interoceptive awareness, and moderation analyses of

treatment expectations. We will examine (1) the number of breaks in their sexual response cycle, and (2) the locations of the breaks in their sexual response cycle. We will also carry out a qualitative analysis comparing the themes arising from reasons for sex, as well as the factors that impair information processing. These analyses will be repeated during the initial completion of the sexual response cycle, and again during week 5.

References

Baer, R. A., Smith, G. T., Hopkins, J., Krietemeyer, J., & Toney, L. (2006). Using self-report assessment methods to explore facets of mindfulness. *Assessment, 13*(1), 27-45.

Barber, M. D., Walters, M. D., & Bump, R. C. (2005). Short forms of two condition-specific quality-of-life questionnaires for women with pelvic floor disorders (PFDI-20 and PFIQ-7). American Journal of Obstetrics and Gynecology, 193(1), 103-113.

Basson, R. (2000). The female sexual response: A different model. *Journal of Sex & Marital Therapy, 26(1), 51-65.*

Beck, A. T., Steer, R. A., & Brown, G. K. (1996). *Manual for the Beck Depression Inventory-II*. San Antonio, TX: Psychological Corporation. Brauer, M., Lakeman, M., van Lunsen, R. H. W., & Laan, E. (2010). Inadequate pain behavior in women with dyspareunia and primary vaginismus. Manuscript under review.

Brotto, L.A., Basson, R., & Luria, M. (2008). A mindfulness-based group psychoeducational intervention targeting Sexual Arousal Disorder in women. *Journal of Sexual Medicine, 5*, 1646-1659.

Brotto, L.A., Graham, C.A., Binik, Y.M., Segraves, R.T., & Zucker, K.J. (2011). Should sexual desire and arousal disorders in women be merged? A response to DeRogatis, Clayton, Rosen, Sand, and Pyke. *Archives of Sexual Behavior, 40,* 221-225.

Brotto, L.A., Heiman, J.R., Goff, B., Greer, B., Lentz, G., Swisher, E., Tamimi, H., & Van Blaricom, A. (2008). A psychoeducational intervention for sexual dysfunction in women with gynecological cancer. *Archives of Sexual Behavior, 37*, 317-329.

Brotto, L.A., Erskine, Y., Carey, M., Ehlen, T., Finlayson, S., Heywood, M., Kwon, J., McAlpine, J., Stuart, G., Thomson, S., & Miller, D. (2012). A brief mindfulness-based cognitive behavioral intervention improves sexual functioning versus wait-list control in women treated for gynecologic cancer. *Gynecologic Oncology, 125,* 320-325.

Brotto, L.A., Seal, B.N., & Rellini, A.H. (2012). Pilot study of a brief cognitive behavioral versus mindfulness-based intervention for women with sexual distress and a history of childhood sexual abuse. *Journal of Sex and Marital Therapy, 38,* 1-27.

Clayton, A.H., Segraves, R.T., Leiblum, S., Basson, R., Pyke, R., Cotton, D., Lewis-D'agostino, D, Evans, K., Sills, T.L., & Wunderlich, G.R. (2006). Reliability and validity of the sexual interest and desire inventory-Female (SIDI-F), a scale designed to measure severity of female hypoactive desire disorder. *Journal of Sex and Marital Therapy, 32*, 115-135.

Cohen, S., Kamarck, T., and Mermelstein, R. (1983). A global measure of perceived stress. *Journal of Health and Social Behavior, 24,* 386-396.

Dennerstein, L., Lehert, P., & Burger, H. (2005). The relative effects of hormones and relationship factors on sexual function of women through the natural menopausal transition, *Fertility and Sterility*, *84*, 174-180.

Derogatis, L., Clayton, A., Lewis-D'Agostino, D., Wunderlich, G., & Fu,Y. (2008). Validation of the female sexual distress scale-revised for assessing distress in women with hypoactive sexual desire disorder. *Journal of Sexual Medicine, 5,* 357-364.

Derogatis, L.R., Rosen, R., Leiblum, S., Burnett, A., & Heiman, J. (2002). The Female Sexual Distress Scale (FSDS): Initial Validation of a Standardized Scale for Assessment of Sexually Related Personal Distress in Women. *Journal of Sex & Marital Therapy, 28,* 317-330.

Dunn, B. D., Dalgleish, T., Ogilvie, A. D., & Lawrence, A. D. (2007). Heartbeat perception in depression. *Behaviour Research and Therapy*, 45, 1921–1930.
Everaerd, W., Laan, E., Both, S., van der Velde, J. In Szuchman, L.T., Muscarella, F, Eds. *Psychological perspectives on human sexuality*. John Wiley & Sons Inc: New York, 2000, pp. 101-148.
Fugl-Meyer, A.R., & Fugl-Meyer, K.S. (1999). Sexual disabilities, problems and satisfaction in 18-74 year old Swedes. *Scandinavian Journal of Sexology, 2,* 79-105.
Fugl-Meyer, K.S & Fugl-Meyer, A.R. (2002). Sexual disabilities are not singularities. *International Journal of Impotence Research, 14,* 487-493.
Gottman, J.M. & Silver, N. (1999). *The Seven Principles for Making Marriage Work*. New York: Three Rivers Press.
Hahn, T.N. (1976). *The Miracle of Mindfulness: A Manual on Meditation*. Boston: Beacon Press.
Hayes, R.D., Bennett, C.M., Fairley, C.K., & Dennerstein, L. (2006). What can prevalence studies tell us about female sexual difficulty and dysfunction? *Journal of Sexual Medicine, 4,* 589-595.
Heiman, J. R., & LoPiccolo, J. (1988) *Becoming Orgasmic: A sexual and personal growth program for women (rev. and expanded ed.).* New York: Simon & Schuster.
Heiman, J.R., & Rowland, D.L. (1983) Affective and physiological response patterns: The effects of instruction on sexually functional and dysfunctional men. Journal of Psychosomatic Research; 27, 105-116.
Hendrick, S. S. (1988). A generic measure of relationship satisfaction. *Journal of Marriage and the Family, 50,* 93–98.
Hurst, H., & Bolton, J. (2004). Assessing the clinical significance of change scores recorded on subjective outcome measures. *Journal of Manipulative and Physiological Therapeutics, 27,* 26-3.
Jacobson, E. (1938) *Progressive Relaxation*. Chicago: University of Chicago Press.
Jones, G. E. (1994). Perception of visceral sensations: Areview of recent findings, methodologies, and future directions. In J. R. Jennings & P. K. Ackles (Eds.), *Advances in Psychophysiology* (Vol. 5, pp. 55–192) London: Jessica Kingsley.
Kabat- Zinn, J. (1990) *Full Catastrophe Living: Using the Wisdom of Your Body and Mind to Face Stress, Pain, and Illness*. New York: Random House.
Laan, E., & Both, S. (2008). What makes women experience desire? *Feminism and Psychology, 18,* 505-514.
Laan, E., Everaerd, W., & Evers, A. (1995). Assessment of female sexual arousal: Response specificity and construct validity. *Psychophysiology, 32,* 476-485.
Laan, E., Termeer, H. J. M. M., van Lunsen, R. H. W., Zimmerman, Y., & Coelingh Bennink, H. J. T. (2010). Effect of OCPs on sexual function. Manuscript in preparation.
Laumann EO, Paik A, Rosen RC. (1999). Sexual dysfunction in the United States: prevalence and predictors. *Journal of the American Medical Association. 281,* 537-544.
McIntyre, R. S., Konarski, J. Z., Mancini, D. A., et al. (2005). Measuring the severity of depression and remission in primary care: validation of the HAMD-7 scale. *CMAJ, 173,* 1327–34.
Mehling, W. E., Price, C., Daubenmier, J. J., Acree, M., Bartmess, E., & Stewart, A. (2012). The Multidimensional Assessment of Interoceptive Awareness (MAIA). *PLoS ONE, 7,* e48230. doi:10.1371/journal.pone.0048230
Muise, A., Impett, E. A., & Desmarais, S. (2013). Getting it on vs. getting it over with: Approach-avoidance sexual motivation, desire and satisfaction in intimate bonds. *Personality and Social Psychology Bulletin, 39,* 1320-1332.
Neff, K. D. (2003). The development and validation of a scale to measure self-compassion. *Self and Identity, 2,* 223-250.

Nobre, P., Pinto-Gouveia, J., & Gomes, F.A. (2006). Prevalence and comorbidity of sexual dysfunctions in a Portuguese clinical sample. *Sex & Marital Therapy, 32,* 173-182.
Nusbaum, M. R., Gamble, G., Skinner, B., Heiman, J. (2000). The high prevalence of sexual concerns among women seeking routine gynecological care. *Journal of Family Practice, 49,* 229-232.
Paulhus, DL. (1998). *Manual for Balanced Inventory of Desirable Responding (BIDR-6).* Toronto: Multi-Health Systems.
Rosen, R.C., & Beck, J.G. (1988) *Patterns of sexual arousal.* The Guildford Press: New York.
Rosen, R., Brown, C., Heiman., Leiblum, S., Meston, C., Shabsigh, R., Fergson, D., & D'Agrostino, R. (2000). The Female Sexual Function Index (FSFI): A multi-dimensional self-report instrument for the assessment of female sexual function. *Journal of Sex and Marital Therapy, 26,* 191-208.
Sachse, S., Keville, S., & Feigenbaum, J. (2011). Feasibility study of mindfulness-based cognitive therapy for individuals with borderline personality disorder. *Psychology and Psychotherapy: Theory, Research and Practice, 84,* 184-200.
Sahdra, B. K., Shaver, P. R., & Brown, K. W. (2010). A scale to measure non-attachment: A Buddhist complement to Western research on attachment and adaptive functioning. *Journal of Personality Assessment, 92,* 116-127.
Schandry, R. 1981. Heartbeat perception and emotional experience. *Psychophysiology, 18,* 483-488.
Segal, Z.V., Williams, J.M.G., & Teasdale, J.D. 2002. *Mindfulness-based cognitive therapy for depression.* Guilford Press; NY, NY.
Shifren, J.L., Monz, B.U., Russo, P.A., Segreti, A., Johannes, C.B. (2008). Sexual problems and distress in United States women: prevalence and correlates. *Obstetrics and Gynecology, 112*, 970-978.
Spielberger, C. D., Gorsuch, R. L., & Lushene, R. E. (1970). *Manual for the State-Trait Anxiety Inventory*. Palo Alto, CA: Consulting Psychologists Press.
ter Kuile, M.M., Brauer, M., & Laan, E. (2006). The Female Sexual Function Index (FSFI) and the Female Sexual Distress Scale (FSDS): Psychometric properties within a Dutch population. *Journal of Sex & Marital Therapy, 32,* 289- 304.
Taylor, S., Zvolensky, M. J., Cox, B. J., Deacon, B.; Heimberg, R. G.; Ledley, D. R., et al. (2007). Robust dimensions of anxiety sensitivity: Development and initial validation of the Anxiety Sensitivity Index-3. *Psychological Assessment, 19,* 176-188.
Trapnell, P. D., & Campbell, J. D. (1999). Private self-consciousness and the five-factor model of personality: Distinguishing rumination from reflection. *Journal of Personality and Social Psychology, 76,* 284-304.
Treynor, W., Gonzalez, R., & Nolen-Hoeksema, S. (2003). Rumination reconsidered: A psychometric analysis. *Cognitive Therapy and Research, 27,* 247-259.
Wiegel, M., Meston, C., & Rosen, R. (2005). The Female Sexual Function Index (FSFI): Cross-validation and development of clinical cutoff scores. *Journal of Sex & Marital Therapy; 31,* 1-20.
Wildmann, H. E., & Jones, G. E. (1982). Consistency of heartbeat discrimination scores on the Whitehead procedure in knowledge-of-results-trained and untrained subjects. *Psychophysiology, 19*, 592.