Study protocol
NCT03232801
Title: A Mindfulness-Based Intervention for Older Women with Low Sexual Desire
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Study Rationale

Sex is a fundamental component of overall well-being for many adults. Individuals who maintain a healthy sex life with aging live longer and gave high quality of life. However, sexual function problems are common, particularly among midlife women; 39% of this population struggles with low sexual desire. This can affect not only a women's sex life, but also negatively impact on psychosocial functioning and relationships.
Despite success in developing treatment for men, there has been a lack of treatment options for women. An increasingly accepted model of female sexual response emphasizes both physiologic and psychologic aspects of female sexual function. Pharmacologic treatments that only target physiologic response will only help a subset of women. In contrast, behavioral interventions have the potential to target both physiologic and psychological aspects of female sexual function. Using this rationale, this study will look at the use of a mindfulness study to improve sexual function in midlife women. Female sexual dysfunction is associated with sexually-related anxiety, autonomic nervous system imbalance, negative body image, discursive negative thoughts that distract during sex, and poor sleep.
Using this rationale, this study will look at the use of a mindfulness study to improve sexual function in midlife women. Mindfulness, a concept that emphasizes in-the-moment focus and non-judgmental bodily awareness, can target all these aspects of sexual dysfunction simultaneously by decreasing anxiety, improving autonomic imbalance, enhancing body image, reducing distracting thoughts, and improving sleep.
Treating sexual dysfunction will result in improvements in women's sexuality and can have the opportunity to go beyond sex to improve relationships and overall quality of life in aging adults. At least 85% of women in the intervention group will indicate somewhat or very satisfied on a measure of the intervention satisfaction.

A multi-component, mindfulness-based intervention, developed by Dr. Lori Brotto at the University of British Columbia, has shown preliminary efficacy in smaller studies for the treatment of desire, arousal, and sexual pain disorders (1-6). However, these studies lacked control groups or used wait-list controls. Additionally, this intervention was developed and tested primarily among women in their 30s and 40s. Whether and how this intervention works in older women is not known. Older women have unique physical and psychological sexual health needs that are not adequately addressed by the existing intervention. Older women are more likely to have medical conditions, such as hypertension (7,8) or diabetes (9), or to be using medications, such as antidepressants (10) or antihypertensives (11), that can affect sexual function. Women over 50 may also have musculoskeletal pain and orthopedic issues that can negatively impact sexual function. Additionally, older women are more likely to experience problems with vaginal dryness and dyspareunia than younger women, as these changes are most prevalent for women in their 50s, 60s and beyond (13-15, 18). Further, the sexual outcomes that are most important to older women differ from those of younger women; while younger women prioritize physical outcomes, older women may consider emotional outcomes more important (16-18). Cohort effects may influence the acceptability of the intervention between younger and older women, such as openness to mindfulness-based approaches (19). Finally, older women may have different social roles – such as caregiver – that may affect their relationship with their partners, sexual function, and overall wellbeing (20)(21). The adapted intervention should ensure that we address these unique sexual health needs of older women.

Known Risks and Benefits

Benefits

- Increased awareness of sexual genital sensations, attributed to increased awareness of present moment in their own bodies and decreased distraction
- May allow women to tap in to their physical arousal to enhance overall sexual arousal, desire, and satisfaction
- Decreasing anxiety, depression, and negative affect
- Improved body image
- Enhanced sleep quality

Risks

- Loss of confidentiality

- Injury during light yoga sessions
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To minimize risk, participant information is kept on a password protected computer behind a firewall. Additionally, through Zoom, participants can participate and give as much information as they feel comfortable with. Additionally, all participants have the opportunity to change their name on Zoom and allow them to decide whether they would like to keep their camera on or not.
To reduce the risk of injury during yoga sessions, everyone is encouraged to only complete what they feel comfortable doing. Additionally, the yoga practice is kept as simple as possible and feasible for people of all ages and abilities.

Recruitment
Inclusion Criteria
In order to be eligible to participate in this study, an individual must meet all of the following criteria:

1. Provision of signed and dated informed consent form
2. Stated willingness to comply with all study procedures and lifestyle considerations/availability for the duration of the study
3. Females; Age 45 and older
4. Self-reported diagnosis of low sexual desire/decrease in sexual desire
5. Willingness to adhere to the 6-week program regimen

Exclusion Criteria
An individual who meets any of the following criteria will be excluded from participation in this study:

1. Does not have a sexual partner who they would like to be sexually active with
2. Requires assistance with bathing, dressing, toileting, and/or eating
3. Experiencing symptoms of depression
4. User of recreational drugs (excluding marijuana)
5. Consumes more than 7 alcoholic beverages in one week
6. Started a new medication for anxiety, depression, or other mental health problem in the past 3 months
7. Currently in a relationship with a romantic partner that has pushed or slapped them, or threatened them with violence
8. Very dissatisfied with their current romantic partner
9. Experienced high or very high levels of pain during or following vaginal penetration

Screen Failures
Screen failures are defined as participants who consent to participate in this study but are not subsequently assigned to the study intervention or entered in the study. Individuals who do not meet the criteria for participation in this trial (screen failure) because of meeting one or more exclusion criteria are thanked for their time and given the opportunity to ask any questions. Examples of exclusions are those that have severe pain with vaginal penetration, more than 7 drinks in a week, or those who do not have a partner with whom they would like to be sexually active.

Strategies for Recruitment and Retention
Each group (control and experimental) will have roughly 12-15 people in order to keep the group size comfortable. If participant number is fewer than 12 people per group, the sessions can still be held. As long as participants are willing to join and participate, the sessions can still go on. We are limiting our recruitment only women who are 45 years and older. Due to the nature of this study, participants must be proficient in English.

Women will be recruited via: (a) flyers placed at local internal medicine, gynecology, and sex therapy clinics; (b) advertisements in University of Pittsburgh and UPMC staff e-mail newsletters, in newspapers, and on buses; (c) presentations to UPMC providers that care for midlife women; (d) social media advertisements such as Facebook; (e) the CTSI Research Participant Registry; and (f) Pitt + Me. The advertisement used for Facebook will only be posted on the personal pages of study staff, and we will not encourage others to "Share" the posting.

We will obtain verbal consent to perform telephone screening procedures, which involve minimal risk to the potential participant using the screening survey on RedCap. After telephone screening procedures, women who are eligible can be mailed or emailed detailed information on the study, if they are interested.

For participants, the study will initially be described over the phone. Participants will have the opportunity to ask questions about the study at this time. The Research Assistant will review the consent form and any risks associated with the study. Participants will be given the opportunity to verbally consent at that time or to read over more information that will be sent by email or snail mail. This will take about 20 minutes.

If uncomfortable with the study requirements, the participant may choose not to enroll in the study at this time. If the person decides to participate, they will be asked to complete a verbal consent over the phone. All documents specifically state that participation in the study is voluntary and the decision NOT to participate in the study will not have negative consequences for the participant.

In order to increase retention and keep participants interested, women will receive $25 for completing each of the three assessments. An extra $25 will be given for completing all three assessments, for a total of $100 per participant. If interested, participants can complete an optional interview about the study at the completion of the sessions for a bonus of $20.

STUDY INTERVENTION OR EXPERIMENTAL MANIPULATION DESCRIPTION

Women will be randomized into two separate groups. The active control group will attend six, two-hour sessions over six weeks in groups of approximately 12-15 women. The content of these sessions will focus on general health and aging (e.g., cardiovascular health, osteoporosis) and will include only limited information on sexual health. The use of an active control allows the study to control for group support and attention. It will also allow the study to explore women's willingness to be randomized.

Intervention will be given in the form of in person mindfulness training, including self-observation, meditation techniques, gentle yoga, and attention to breath. Additional content will include general sex education, sensate focus, and couples therapy, such as information on potential etiologies of sexual function and sexual response, bodily exploration exercises, and communication training.

Both women in the control group and the experimental group will be lead by the PI and a trained expert in mindfulness-based stress reduction. Women in both groups have the opportunity to complete an optional phone interview with a RA at the completion of the sessions on their experience.

Administration

Following the screening, participants will be sent a survey link to complete all the baseline activities. Once the intervention starts, participants will attend a weekly virtual session with other members of their group (control vs variable). These sessions will last for six weeks at approximately two hours each. In these sessions, they have the possibility of interacting with members of their group and with the leaders of each group. However, group participation is up to the participant; they are able to share as little or as much as they feel comfortable. Following the completion of the sessions, a survey will be sent to participant. These surveys will be identical to the baseline surveys, excluding the surveys on Demographics, Relationship Variables, Frequency of Sexual Activities, and Medical Variables. There will also be an Acceptability of Intervention survey sent out at the finish of the sessions. Participants will have one week to fill out and return the surveys, which will be tracked through RedCap.

At the 12 week mark, a final set of surveys will be sent out, identical to the baseline surveys, excluding the surveys on Demographics, Relationship Variables, Frequency of Sexual Activities, and Medical Variables. Participants will have one week to fill out and return the surveys, which will be tracked through RedCap.

Interventionist Training and Tracking

To ensure the completion of all surveys, in the week the survey is disseminated, progress will be monitored using RedCap. All surveys need to be returned within the week they are sent out so if progress is not being made by a participant, the RA will reach out up to three different times to send reminders and check in. The three contact points can be made via different methods, including through email and phone call.

Discontinuation/Withdrawal

An investigator may discontinue a participant from the study for the following reasons:

- Significant study intervention non-compliance, unless varying compliance is an aspect of the study objectives
- Lost-to-follow up
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that would confound the interpretation of the study
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation

Participants are allowed to withdraw at any time for any reason. Data up until the point a participant discontinued the study will be included in the study. Participants will not to continue with surveys when participation is discontinued.
If a participant misses more than 2 meetings, they are withdrawn from the study. They are still eligible for payment if they completed the first survey. If there are further six-week sessions, a participant can move to a later session that may fit their schedule.

Loss to Follow-Up
The following actions must be taken if a participant fails to return their surveys in the correct amount of time:

- The site will attempt to contact the participant, remind them of the studies they have left to complete, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain if the participant wishes to and/or should continue in the study
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant. The investigator or designee will make up to 3 different attempts at contact with the participant. These attempts will include reaching out via phone or email.
- Should the participant continue to be unreachable, they will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

Weekly Meetings
Meetings for each group will be held on separate days. Following recruitment, a survey will be sent out to the participants to each group. Any survey system can be used to generate the surveys to gauge interest in the best day and time for the group (Qualtrics was used). Make sure that each group has a separate survey (i.e. an availability survey for both the mindfulness (experimental) and educational (control) group).
Give the groups around one week to answer, sending out 1-2 reminders. Once a day and time is decided on, meetings can begin. An email can be sent to participants with the upcoming dates and the Zoom link. To ensure participants remember the meeting, an email should be sent every week, 12-24 hours before the meeting with the zoom link.
Meetings are held every week for six weeks total. Meeting length is variable, but participants should prepare for a two-hour meeting.
At each meeting, a research assistant should take attendance and keep track of who is coming to the meetings. This is important to record to ensure participants are making it to at least 4 meetings.

Payment
Payment will be made through The University of Pittsburgh's Research Study payment system, Vincent. Information for payment includes Name, Address, and Birthdate. Participants are eligible to give their Social Security Number if they feel comfortable. If they would rather not include that information, 24% of their total will be taken. To help participants make the decision on whether to include their SSN or not, explain that it is needed for tax purposes. If a participant makes over $600 in studies per year, it becomes taxable income.
Following the completion of the Zoom sessions, an email will be sent out with information on payment and for the opportunity to schedule a quick phone call to go over all the information. As with loss to follow-up, three contact attempts will be made to participants. If they do not answer following the three attempts, they are not paid.
All Vincent cards are requested on the Vincent website. Each card in your inventory can be assigned to a participant. Some participants may have an existing account and card. If that is the case, have the participant

verify their account by asking for their birthdate or address. If they match, make sure to ask whether they would prefer to keep their old card or if they would like a new card.
After the completion of the twelve-week survey, cards are sent out or money is added the existing card (in the case of a participant having a pre-existing account).

References

1. Brotto LA, Seal BN, Rellini A. Pilot study of a brief cognitive behavioral versus mindfulness-based intervention for women with sexual distress and a history of childhood sexual abuse. Journal of sex & marital therapy. 2012;38(1):1-27. Epub 2012/01/25. doi: 10.1080/0092623X.2011.569636. PubMed PMID: 22268979.

2. Brotto LA, Heiman JR, Goff B, Greer B, Lentz GM, Swisher E, et al. A psychoeducational intervention for sexual dysfunction in women with gynecologic cancer. Archives of sexual behavior. 2008;37(2):317-29. Epub 2007/08/08. doi: 10.1007/s10508-007-9196-x. PubMed PMID: 17680353.

3. Brotto LA, Erskine Y, Carey M, Ehlen T, Finlayson S, Heywood M, et al. A brief mindfulness-based cognitive behavioral intervention improves sexual functioning versus wait-list control in women treated for gynecologic cancer. Gynecologic oncology. 2012;125(2):320-5. Epub 2012/02/02. doi: 10.1016/j.ygyno.2012.01.035. PubMed PMID: 22293042; PubMed Central PMCID: PMC3438201.

4. Brotto LA, Basson, R., Carlson, M. & Zhu, C. Impact of an integrated mindfulness and cognitive behavioural treatment for provoked vestibulodynia (IMPROVED): A qualitative study. Sexual and Relationship Therapy. 2013;28(1-2):3-19.

5. Brotto LA, Basson R, Luria M. A mindfulness-based group psychoeducational intervention targeting sexual arousal disorder in women. The journal of sexual medicine. 2008;5(7):1646-59. Epub 2008/05/30. doi: 10.1111/j.1743-6109.2008.00850.x. PubMed PMID: 18507718.

6. Brotto LA, Basson R, Smith KB, Driscoll M, Sandownik L. Mindfulness-based group therapy for women with provoked vestibulodynia. Mindfulness. 2014:1-16.

7. Manolis A, Doumas M. Sexual dysfunction: the 'prima ballerina' of hypertension-related quality-of-life complications. Journal of hypertension. 2008;26(11):2074-84. Epub 2008/10/16. doi: 10.1097/HJH.0b013e32830dd0c6. PubMed PMID: 18854743.

8. Doumas M, Tsiodras S, Tsakiris A, Douma S, Chounta A, Papadopoulos A, et al. Female sexual dysfunction in essential hypertension: a common problem being uncovered. Journal of hypertension. 2006;24(12):2387-92. Epub 2006/11/04. doi: 10.1097/01.hjh.0000251898.40002.5b. PubMed PMID: 17082720.

9. Erol B, Tefekli A, Ozbey I, Salman F, Dincag N, Kadioglu A, et al. Sexual dysfunction in type II diabetic females: a comparative study. Journal of sex & marital therapy. 2002;28 Suppl 1:55-62. Epub 2002/03/20. doi: 10.1080/00926230252851195. PubMed PMID: 11898710.

10. Serretti A, Chiesa A. Treatment-emergent sexual dysfunction related to antidepressants: a meta-analysis. Journal of clinical psychopharmacology. 2009;29(3):259-66. Epub 2009/05/15. doi: 10.1097/JCP.0b013e3181a5233f. PubMed PMID: 19440080.

11. Thomas HN, Evans GW, Berlowitz DR, Chertow GM, Conroy MB, Foy CG, et al. Antihypertensive medications and sexual function in women: baseline data from the SBP intervention trial (SPRINT). Journal of hypertension. 2016;34(6):1224-31. Epub 2016/04/01. doi: 10.1097/HJH.0000000000000911. PubMed PMID: 27032074; PubMed Central PMCID: PMC4859426.

12. Castelo-Branco C, Cancelo MJ, Villero J, Nohales F, Julia MD. Management of post-menopausal vaginal atrophy and atrophic vaginitis. Maturitas. 2005;52 Suppl 1:S46-52. Epub 2005/09/06. doi: 10.1016/j.maturitas.2005.06.014. PubMed PMID: 16139449.

13. Dennerstein L, Dudley EC, Hopper JL, Guthrie JR, Burger HG. A prospective population-based study of menopausal symptoms. Obstetrics and gynecology. 2000;96(3):351-8. Epub 2000/08/29. PubMed PMID: 10960625.

14. Woods NF, Mitchell ES. Symptoms during the perimenopause: prevalence, severity, trajectory, and significance in women's lives. The American journal of medicine. 2005;118 Suppl 12B:14-24. Epub 2006/01/18. doi: 10.1016/j.amjmed.2005.09.031. PubMed PMID: 16414323.

15. Avis NE, Brockwell S, Randolph JF, Jr., Shen S, Cain VS, Ory M, et al. Longitudinal changes in sexual functioning as women transition through menopause: results from the Study of Women's Health Across the Nation. Menopause. 2009;16(3):442-52. Epub 2009/02/13. doi: 10.1097/gme.0b013e3181948dd0. PubMed PMID: 19212271; PubMed Central PMCID: PMC2908487.

16. Winterich JA. Sex, menopause, and culture: Sexual orientation and the meaning of menopause for women's sex lives. Gender & Society. 2003;17(4):627-4. doi: 10.1177/0891243203253962.

17. Thomas HN, Hamm M, Hess R, Borrero S, Thurston RC. Patient-Centered Sexual Function Outcomes among Midlife Women. Journal of Women's Health. 2016;25(4):A1-A35. Epub 3-31-2016. doi: 10.1089/jwh.2016.20996.abstracts.

18. Ginsberg TB, Pomerantz SC, Kramer-Feeley V. Sexuality in older adults: behaviours and preferences. Age and ageing. 2005;34(5):475-80. Epub 2005/07/27. doi: 10.1093/ageing/afi143. PubMed PMID: 16043445.

19. Morone NE, Greco CM, Weiner DK. Mindfulness meditation for the treatment of chronic low back pain in older adults: a randomized controlled pilot study. Pain. 2008;134(3):310-9. Epub 2007/06/05. doi: 10.1016/j.pain.2007.04.038. PubMed PMID: 17544212; PubMed Central PMCID: PMC2254507.

20. Martire LM, Stephens MA, Townsend AL. Centrality of women's multiple roles: beneficial and detrimental consequences for psychological well-being. Psychology and aging. 2000;15(1):148-56. Epub 2001/02/07. PubMed PMID: 10755296.

21. Martire LM, Stephens MA, Atienza AA. The interplay of work and caregiving: relationships between role satisfaction, role involvement, and caregivers' well-being. The journals of gerontology Series B, Psychological sciences and social sciences. 1997;52(5):S279-89. Epub 1997/10/06. PubMed PMID: 9310100.