



Phase II randomized controlled trial of hypnosis versus progressive muscle relaxation for body image after breast or gynecologic cancer

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Abstract

Background Sexual dysfunction, fueled by body image stress, is prevalent in women with a history of breast or gynecologic cancer. Preliminary data support that mind–body connections may improve sexual health outcomes through improving body image.

Objective This randomized controlled trial compared hypnosis to progressive muscle relaxation (PMR). The primary outcome was body image at week 6 as measured by the Impact of Treatment Scale for women who have or have had breast or gynecologic cancer.

Interventions/Methods Consented participants were randomized 2:1 to hypnosis or PMR. Both arms consisted of three face-to-face sessions delivered by a trained therapist. Sessions were every 2 weeks for 6 weeks; participants practiced at home between sessions using an audio recording.

Results Eighty-seven women were randomized, 59 to hypnosis and 28 to PMR. Both groups reported significant improvements on body image over time (within group effect size Cohen’s $d=0.49$ – 0.75) with no significant difference between groups ($p=0.15$). Secondary outcomes were not significantly different between groups. The hypnosis group improved more in sexual satisfaction and sexual interest while the PMR group improved more in positive affect.

Conclusions Interventions facilitating mind–body connections such as hypnosis and PMR may help to improve body image. This study suggests that stress relieving strategies of hypnosis and PMR may contribute to providing a re-connection to one’s body, improved positive affect, and overall better sexual health.

Keywords Body image · Sexual health · Women’s health · Cancer

Background and significance

As the number of cancer survivors continues to rise to nearly 20 million by 2026 [1], it is important to ensure that long-term sequelae of the cancer experience do not negatively

impact important core areas of a meaningful life, such as sexual health. Women diagnosed with breast or gynecologic cancer can experience distressing changes in their sexual health, with body image issues being prevalent [2]. Body image, defined as feelings, thoughts, and/or perceptions about one’s own body, is one of four key predictors of sexual health along with vaginal symptoms, partner issues, and sexual energy/libido [3–7]. Studies support the importance of body image, demonstrating that 77 to 82% of breast cancer survivors score in the “sexual dysfunction” range of the Female Sexual Function Index (FSFI), a widely used self-report measure of female sexual functioning [2, 8], with body satisfaction scoring below published norms [8], and feeling the need to keep one’s body hidden (body stigma) predicting lower total scores on the FSFI indicating worse overall sexual function [2].

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There are limited, yet compelling, data to support that interventions addressing a connection between the mind and the body, such as mindfulness, cognitive behavioral therapy, yoga, and psycho-education can be beneficial to body image [7]. Components of effective interventions included learning to manage stressors, performing body scans, doing muscle relaxation, and managing changes to one's body and perceptions of sexuality [7]. Other components of effective interventions were increasing awareness of reactions, perceptions and feelings, and improving coping strategies.

The extent of the literature on this subject matter is limited in scope, riddled with study design bias, and demonstrates inconsistent or incomplete benefits [7]. In-person group therapy over numerous sessions is a critical limitation to wide dissemination of effective interventions as it is time consuming and costly. Therefore, more efficient options are needed.

An efficient intervention would be able to be delivered in a short period of time, not require a group, and would facilitate the re-connection of mind and body that is often fractured following a diagnosis of cancer [9]. An ideal intervention would improve body image and positively influence the perception of wellbeing in relation to feelings of being a sexual being. Hypnosis could be one such intervention. Hypnotic techniques have a long history of being used for emotional and physical concerns [10]. Hypnosis is defined as a state of consciousness involving focused attention and reduced peripheral awareness characterized by a capacity for response to suggestion [11]. Hypnotic suggestions related to improving body image include (1) increasing one's sense of control, (2) seeing the body as whole, strong, and beautiful, and (3) managing physical and mental tension that can result in fatigue and apathy regarding sexual activity [12]. In addition, imagery techniques assist in re-attaining, or attaining, a positive view of one's body and/or sexual self.

Our feasibility study evaluating the potential for hypnosis to improve sexual health through improvement of body image demonstrated 28% improvement in body image distress measured by the Impact of Treatment Scale (ITS) [13]. What was more striking, however, was that the overall score on the FSFI, which began at a mean of 16 (meaning women were in the "dysfunction" range), improved to a mean of 29 (indicating there was no sexual dysfunction) [13]. The hypnotic intervention was shown to be feasible and its effect measurable. For the present study, slight modifications were made to the number of in-person sessions (decreased from 5 to 3) and the time interval between sessions (increased from 1 to 2 weeks) based on participant recommendations. The purpose of this larger phase II study was to evaluate hypnosis for body image in women with breast or gynecologic cancer, controlling for the effects of relaxation.

Methods

A randomized controlled two-arm design was performed to evaluate the efficacy of hypnosis versus progressive muscle relaxation (PMR) to improve body image in women with breast or gynecologic cancer. The study was approved by the Institutional Review Board of the University of Michigan Medical School (IRBMED) and monitored by the Data and Safety Management Committee of the Rogel Cancer Center at Michigan Medicine. Written informed consent was obtained from all participants after eligibility was confirmed. This study was registered with NIH's clinical trials program (NCT02531997) and was funded by the Breast Cancer Research Foundation.

Eligibility

Women diagnosed with breast or gynecologic cancer at any stage, undergoing or completed treatment, were eligible to participate if they affirmed through two screening questions, a negative change in body image since diagnosis and a desire to improve. Women could not have any mental health diagnosis that would interfere with hypnosis such as psychoses, major depression, schizophrenia, or PTSD. Women could also not have a history of sexual abuse.

Eligible women were consented and randomized 2:1 to a 6-week intervention of hypnosis or progressive muscle relaxation using a computer-generated randomization schedule. Participants were informed of their assigned treatment arm at the baseline study visit. The hypothesis was blinded in that neither group was ever referenced as a control or experimental group.

Measures

Patient-reported outcomes were collected at baseline and 6 weeks except for the Global Impression of Change Scale (GICS) which was measured only at 6 weeks. The primary outcome was the effect of treatment on body image using the Impact of Treatment Scale (ITS). The ITS is a measure of body change stress and was developed in women with breast cancer by investigators at The Ohio State University [14]. ITS is comprised of 13 questions and is scored by summing the items. Higher scores indicate greater body image stress. It has demonstrated good reliability and validity in women with both gynecologic and breast cancer with Cronbach's alphas over 0.90 [14]. ITS can discriminate between women with lower and higher satisfaction with their sexual life.

Secondary outcomes of our randomized study utilized validated tools including measures of perception of sexual

self (Sexual Self-Schema Scale for women) [15], mood (Positive/Negative Affect Scale-PANAS) [16], sexual satisfaction [Patient-Reported Outcome Measurement Information System (PROMIS) sexual health measure] [17], and perceived change (Global Impression of Change Scale-GICS). The Sexual Self-Schema Scale for women was first tested in female undergraduates, later in a group of community women and subsequently in women with gynecologic and breast cancer. It is a measure of 26 trait adjectives that are self-rated from 0 (not descriptive of me) to 6 (very much descriptive of me). Three dimensions have been demonstrated: passionate/romantic; open/direct; and embarrassed/conservative. Cronbach's alpha for this measure is 0.76.

The PANAS and GICS are established measures with well-documented validity and reliability [16, 18, 19]. The PANAS includes 20 items, 10 items each measuring positive and negative affect as two dimensions of mood, in which higher scores indicate more positivity or negativity, respectively. The GICS is a 7-point item in which the participant rates the perceived change in overall status since beginning the study ranging from "very much worse" (−3) to "very much better" (+3). The GICS was included to capture the participants' perception of benefit from the intervention.

The Patient-Reported Outcomes Measurement Information System (PROMIS) sexual function and satisfaction measure has good content, face, discriminant, and convergent validity [17]. In particular, for women, it demonstrates good convergent validity with the FSFI, the gold standard measure in sexual function. PROMIS was selected for this study due to it being nimble in its length and scoring. We used the global satisfaction domain with seven items (correlation of 0.76 with the FSFI satisfaction subscale) and interest domain with four items (correlation of 0.84 with the FSFI desire subscale) with two questions about interfering factors, hot flashes and fatigue, for a total of 13 items. Higher scores indicate higher levels of satisfaction and interest [17].

A study-specific daily log was used by participants to record whether they listened to the assigned audio file that day and to log the number of minutes of listening.

Interventions

Both intervention arms consisted of three sessions delivered face-to-face by a trained therapist, one every 2 weeks, each lasting about 60 min with 15–20 min involving the hypnosis or PMR exercise. Participants practiced at home between sessions at least three times per week using an audio recording of the session, either on a CD or flash drive.

The hypnosis arm consisted of a hypnotic induction with suggestions. The first induction session consisted of focusing on relaxation, feelings of wellness, wholeness, strength, and confidence. The second induction session focused more

specifically on body image related to sexuality and living as a sexual being, as well as sexual desire, passion, and romanticism. The third induction session included suggestions from the previous inductions and added a behavioral component. Women were asked to select and implement a positive behavior for the last 2 weeks of the study. The behavior could be anything consistent with meaningful self-care (e.g., taking time to participate in art, exercise, nature hikes), improving feelings about her body (e.g., getting a massage, looking in the mirror, getting a new hairstyle), or increasing feelings of sexuality (e.g., buying lingerie, planning a romantic getaway, buying a new, flattering outfit).

The progressive muscle relaxation (PMR) sessions consisted of education about and practice of progressive muscle relaxation. The first session centered on assessment of sources of stress, PMR education and demonstration, and education on use of the recording. Session 2 assessed changes in stress, addressed participant questions about using PMR and any barriers to using the recording, and included PMR practice with the research therapist. PMR session 3 was similar to session 2 and included a competency evaluation in the use of PMR. In the PMR sessions, the research therapist utilized a script to focus the conversation on relaxation and planning the implementation of the relaxation behavior. Although participants were given an opportunity to ask questions and express concerns at each session, the therapist did not deliver therapy or provide therapeutic suggestions. Therefore, both groups had very similar face-to-face sessions in terms of length but the PMR session was intentionally not therapeutic.

At the end of session 1, women in both arms chose a CD or flash drive for home practice. The audio files were of comparable lengths, 15 to 25 min. The hypnosis group audio files were tailored to their recorded hypnotic induction session with emphasis on the induction topics previously mentioned while the PMR audio file contained a choice of the following sounds: white noise, ocean waves, running stream, or a waterfall. For the home practice sessions, women in either group could choose from among their audio files, tailoring the practice sessions to what was most meaningful to them. A more detailed accounting of the similarities and differences of each session between arms is shown in Table 1.

Fidelity to each intervention was evaluated through random checks where trained research personnel attended several different sessions in both the hypnosis and the PMR group. This was done so that the interventionist did not know which sessions were being evaluated for fidelity and which were not. A fidelity checklist was completed for 10% of the sessions. The checklist contained all components of the face-to-face session.

Table 1 Content for hypnosis (intervention) and progressive muscle relaxation (control) sessions

	Hypnosis	Progressive muscle relaxation (PMR)
Session 1	<p>Assessment of key concerns/goals related to sexual health and response to induction</p> <p>Ego strengthening and self-esteem focus</p> <p>Perform a hypnotic induction led by research therapist to address self-love and enhance relationship to self</p> <p>Provide a CD/digital recording of hypnotic induction and education for home use at least three times per week</p> <p>Assess CTCAEs</p>	<p>Assessment of sources of stress</p> <p>Education on PMR and use of CD/digital recording</p> <p>Demonstrate relaxation and use of the recording of choice for 15 min led by research therapist</p> <p>Provide a CD/digital recording of white noise/nature sounds and education for home use at least three times per week</p> <p>Assess CTCAEs</p>
Session 2	<p>Individualization: focus on self-image</p> <p>Perform a hypnotic induction led by research therapist to focus on improving self-image related to sexuality</p> <p>Provide a second individualized CD/digital recording of hypnotic induction for home use at least three times per week</p> <p>Assess CTCAEs</p>	<p>Assess stress, changes in stress, and practice the previous 2 weeks</p> <p>Address barriers to using the CD/digital recording</p> <p>Address questions</p> <p>Practice progressive muscle relaxation led by research therapist</p> <p>Encourage practice with audio file at least three times per week</p> <p>Assess CTCAEs</p>
Session 3	<p>Discuss possible, attainable behavior to practice over next 2 weeks</p> <p>Behaviors integrated into the induction and part of home practice</p> <p>Perform a hypnotic induction led by research therapist to empower the participant to embrace herself in an accepting and loving way and to take charge of her sexuality</p> <p>A third CD/digital recording of hypnotic induction provided for home use at least three times per week and completion of final questionnaires</p> <p>Assess CTCAEs</p>	<p>Assess stress, changes in stress, and practice the previous 2 weeks</p> <p>Evaluate competency in use of PMR</p> <p>Practice progressive muscle relaxation led by research therapist</p> <p>Encourage practice with audio file at least three times per week and completion of final questionnaires</p> <p>Assess CTCAEs</p>

CD compact disc, CTCAE common terminology criteria for adverse events, PMR progressive muscle relaxation

Analysis

Descriptive statistics were used to calculate means and standard deviations and to evaluate normality and missing data. Transformation was done to correct for non-normality. Variables were also correlated to evaluate multi-collinearity. *T* tests or χ^2 analyses were used to compare differences in the two groups on all demographic and baseline measures. The primary analysis and most secondary analyses were evaluated using Analysis of Covariance (ANCOVA) with the baseline used as the covariate. The intent-to-treat approach was used for the primary endpoint and missing data were handled using last value carried forward. For analysis of side effects, we used change from baseline, compared the arms with independent *t* tests, and included a description of the means over time. The analysis was conducted using SPSS software® version 24.

Results

Ninety-seven women consented to participate. However, 10 participants withdrew before randomization primarily due to difficulty in scheduling the baseline visit. Eighty-seven women were randomized, 59 to hypnosis and 28 to PMR. Demographic characteristics are described in Table 2. There were no statistically significant differences between groups

at baseline on any demographic characteristics or outcome measures. There was, however, more racial/ethnic diversity in the hypnosis group, albeit not statistically significant. As the CONSORT diagram in Fig. 1 shows, an almost equal number of women withdrew from the study in each arm, mostly due to other time commitments, competing priorities, and issues with their disease and/or treatment.

Baseline means for all outcome measures are shown in Table 3. For most outcome measures, participants scored near the midpoint of the scale. There was no multi-collinearity among variables. At baseline, there was only one demographic variable that was significantly correlated with baseline body image: surgical treatment with bilateral mastectomy. The correlation coefficient was 0.257, $p = 0.016$, indicating greater body image stress in those who reported having had a bilateral mastectomy. No other demographic variable was even moderately correlated with the primary outcome. There was a significant and moderately strong correlation between negative affect and body image stress ($r = 0.48$) and a significant but less strong correlation between positive affect and body image stress ($r = -0.29$), indicating higher negative emotions and lower positive emotions were associated with more body image stress.

Adherence to interventions was good. Participants in both groups reported practicing at least two to three times per week, with the PMR group practicing slightly more (19 days) than the hypnosis group (17 days) over the 6 weeks

Table 2 Sample characteristics

Characteristics	Hypnosis <i>N</i> =59	PMR <i>N</i> =28	χ^2 or <i>T</i> test <i>p</i> value
Age mean (SD)	53 (8.2)	53 (8.9)	0.87
Race/ethnicity	<i>n</i> (%)	<i>n</i> (%)	0.09
Latino/Hispanic/Spanish	1 (2)	0	
Asian	5 (8)	1	
AA/black	3 (5)	0	
White	49 (83)	27	
Other	1 (2)	0	
Diagnosis			1.0
Breast	47	23	
Gynecology	12	5	
Treatment			
Chemo			0.61
Current	5	4	
Previous chemo	35	17	
Radiation therapy			0.81
Current radiation therapy	1	0	
Previous radiation therapy	35	16	
Endocrine therapy current			
Aromatase inhibitor (yes)	20	7	1.0
Tamoxifen (yes)	14	6	0.48
Type of surgery			
Breast surgery			0.32
Mastectomy	4	2	
Mastectomy	4	4	
Mastectomy w/reconstruction	12	1	
Bilateral mastectomy w/reconstruction	14	6	
Lumpectomy	13	9	
Gynecological surgery			0.31
Oophorectomy	20	8	
Hysterectomy no oophorectomy	0	1	
In a relationship			
Yes	46	23	1.0
Has previously tried to address self-image			
Yes	36	15	0.49

PMR progressive muscle relaxation, AA African-American, Chemo chemotherapy

of the study. All participants that did not withdraw early from the study attended all three in-person sessions.

Analysis of covariance did not demonstrate a significant effect of arm assignment on the Impact of Treatment Scale (ITS) (Table 4). In addition, using independent *t* tests, there was no statistically significant difference ($p=0.15$) in the change in ITS between groups at 6 weeks, with both groups significantly improving (within group effect size Cohen's *d* 0.49–0.75). This result did not change when repeated with natural log transformed data due to non-normal distributions. A model including bilateral mastectomy, the only demographic variable significantly correlated to the outcome variable, did not alter the significance of study arm assignment on ITS.

Secondary outcomes

Analysis of covariance did not reveal any significant differences on the secondary outcomes (data not shown). In addition, using independent *t* tests, there were non-significant differences between groups on certain secondary outcomes. Change from baseline for positive affect (PANAS) was 1.7 in the hypnosis group and 3.8 in the PMR group; negative affect change was approximately 2.8 in both groups. Change from baseline for the PROMIS sexual satisfaction scale was 1.5 in the hypnosis group and 1.3 in the PMR group; for sexual interest, change in the hypnosis group was 1.3 while in the PMR group it was 1.1. At 6 weeks, 42% of the

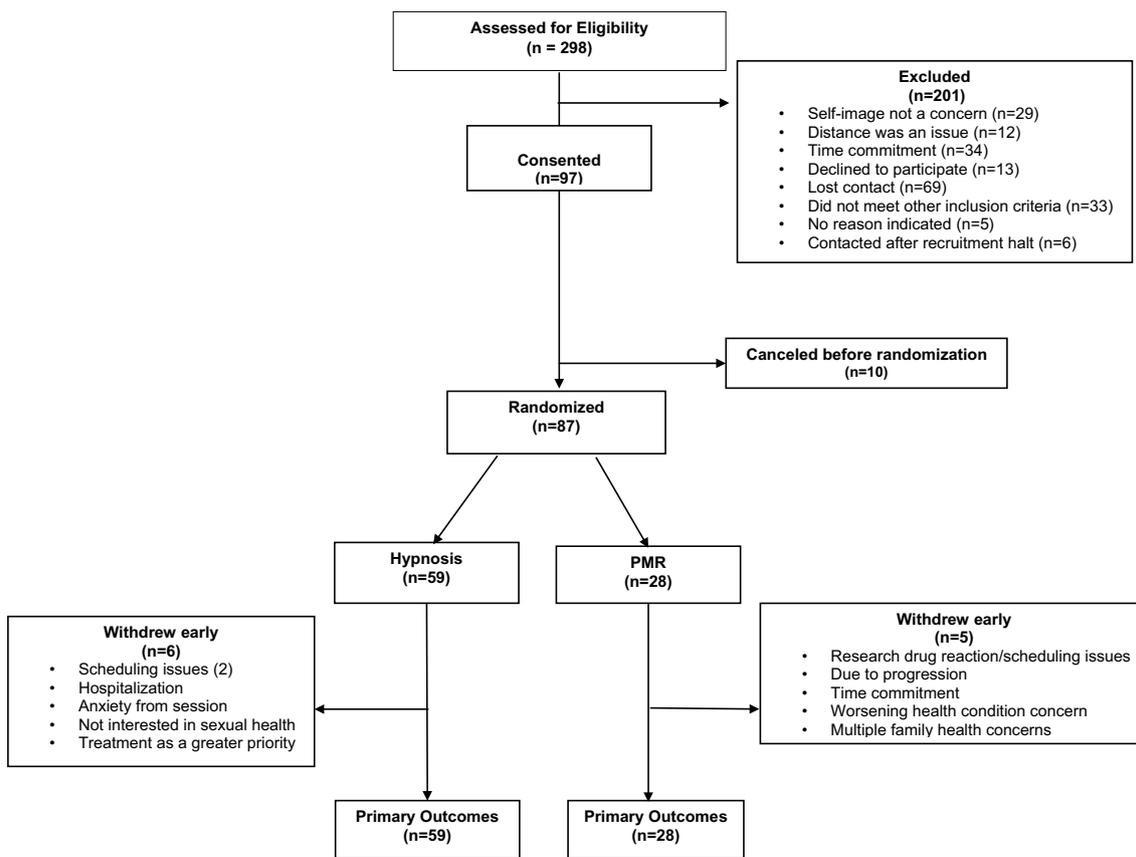


Fig. 1 CONSORT study flow diagram

Table 3 Phase II baseline mean scores on all outcome measures

Group	Impact of treatment scale mean (SD)	PROMIS sexual satisfaction mean (SD)	PROMIS sexual interest mean (SD)	PANAS positive affect mean (SD)	PANAS negative affect mean (SD)	Sexual self-schema sub scale mean (SD)
Hypnosis	36.4 (12.2)	5.9 (2.8)	8.3 (3.2)	32.4 (6.3)	19.9 (7.5)	Romantic: 39.7 (7.7) Open: 33.8 (7.6) Embarrassed: 21.5 (6.1)
PMR control	39.3 (12.8)	5.3 (2.5)	8 (3.3)	31 (6.4)	19.3 (7.3)	Romantic: 42.6 (5.8) Open: 33 (7.9) Embarrassed: 21.4 (7.1)
Scale ranges & score meaning	0–65 High numbers indicate worse body image	3–15 Higher numbers indicate more satisfaction	4–20 Higher numbers indicate more interest	10–50 Higher numbers indicate more positivity	10–50 Higher numbers indicate more negativity	Romantic: 0–60 Higher indicates more romantic Open: 0–54 Higher indicates more open Embarrassed: 0–42 Higher indicates greater embarrassment

PMR progressive muscle relaxation, SD standard deviation, PROMIS patient-reported outcomes measurement information system, PANAS positive/negative affect scale

hypnosis group reported moderate to very much improvement (+2/+3) on body image (GICS) while only 32% of the PMR group reported this level of improvement; 36% of the

hypnosis group versus 11% of the PMR group reported moderate to very much improvement (+2/+3) in their sexuality.

Table 4 ANCOVA primary outcome

Source	Sum of squares	df	Mean square	F	Sig.
Corrected model	6879.598 ^a	2	3439.799	31.472	0.000
Intercept	88.449	1	88.449	0.809	0.371
Baseline ITS	6867.475	1	6867.475	62.834	0.000
Treatment arm	154.654	1	154.654	1.415	0.238
Error	9180.816	84	109.295		
Total	98740.000	87			
Corrected total	16060.414	86			

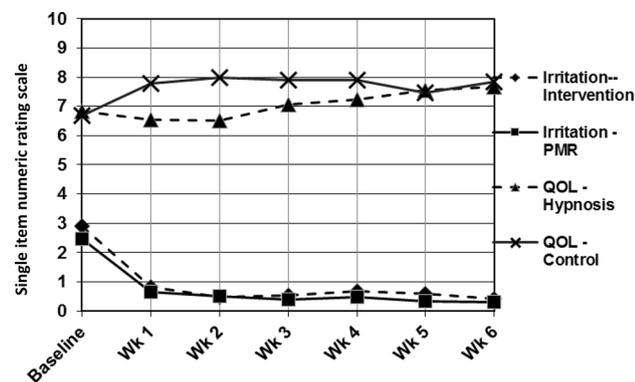
ANCOVA analysis of covariance, ITS impact of treatment scale

^a $R^2=0.428$ (Adjusted $R^2=0.415$)

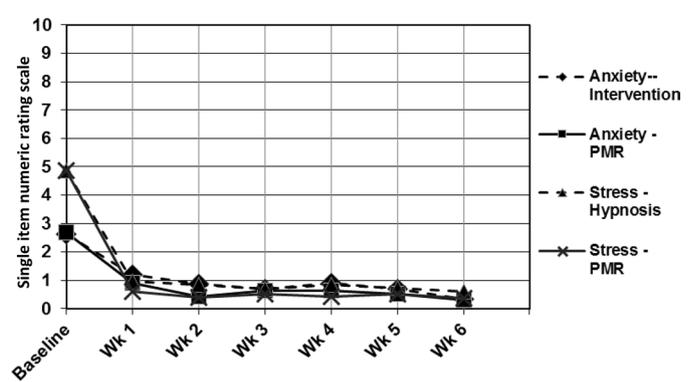
There were no identified issues with the fidelity of the intervention or control group delivery. The scripts were followed in both groups as designed and the fidelity auditors reported that both interventions appeared to be delivered as intended.

Side effects

Self-reported anxiety, irritation, and stress decreased over the 6 weeks of the study in both groups with no difference between arms (Fig. 2a, b). Quality of life increased over the 6 weeks of the study in both groups, increasing from 6.8 to 7.7 in the hypnosis group and 6.7 to 7.9 in the PMR group; these differences were not statistically significantly different (Fig. 2a). Per CTCAE version 4.0, the research therapist reported one participant in the hypnosis arm as having grade 1 agitation at week 4 and one participant with grade 1 restlessness at week 1. There were no AE's reported in the PMR group.



Abbreviations: QOL, quality of life; PMR: Progressive Muscle Relaxation



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Fig. 2 **a** Irritation and QOL—hypnosis and PMR groups. **b** Anxiety and stress—hypnosis and PMR groups. QOL quality of life, PMR progressive muscle relaxation

Discussion

This randomized study of hypnosis and PMR supports the continued exploration of stress reducing and mind–body connecting interventions to improve perceived body image. Participants in both hypnosis and PMR groups reported significant improvements in perception of body image from baseline to 6 weeks and data do not demonstrate a significant benefit of hypnosis over PMR. Adherence was good, and did not appear to impact outcomes, with both groups reporting similar practice rates in between sessions.

There were some differences in the degree to which each group improved on the secondary outcomes. The hypnosis group reported greater improvements than the PMR group in areas more directly related to sexual health such as perceived sexuality, sexual satisfaction, and interest. This may be due to the hypnotic suggestions related to these domains that were incorporated into the recordings.

The benefit of PMR on body image was a bit surprising. There are several hypotheses about why this result occurred. First, PMR was intended to be an active condition to control for the effects of relaxation and stress management. Both stress and anxiety decreased over time with PMR as shown in Fig. 2b. Therefore, low stress and anxiety may be important elements in body image improvement. Secondly, however, since both interventions were delivered by a master's prepared social worker who acknowledged the challenges these women were facing, the fact of normalizing the problem and being empathic may have been the important ingredient. Many descriptive studies and guidelines suggest that education and normalization of the challenges around sexual health after cancer can be helpful [20, 21]. Third, since PMR involves tensing and relaxing the muscles from head to toe, it is in essence connecting the mind and body. Other effective

interventions have integrated both muscle relaxation and mental body scans [7]. The benefit of this mind–body connection is consistent with theoretical frameworks that suggest that a disconnection [4] can occur. Methods to reconnect oneself to one’s body may be critical in improving body image. Finally, it is curious that the PMR group reported twice the improvement on positive affect than the hypnosis group. The study was not powered to look at mediation, but this mechanism would be an important one to evaluate further. Li et al. [22] showed that in women undergoing mastectomy, body image was significantly predictive of affect, suggesting that improving body image could improve affect. Our data support a relationship between positive affect and self-image, but cause and effect in either direction is not known.

Previous literature reports effect sizes of psycho-education and cognitive behavior therapy (CBT) on body image ranging from small (Cohen’s $d=0.15$) to quite large (Cohen’s $d=1.43$) [7]. In our study, within group effect sizes were moderate to large, therefore they are consistent with this literature. Our findings are supported by studies that include interventions that strengthen mind–body connections such as mindfulness, sensate focus, and body imagery and show improved physiological sexual functioning as well as improvement in body image [23, 24].

Mind–body interventions have been evaluated using various delivery methods including in-person, remotely by phone or online, group, and partner-inclusive sessions. Most interventions have required multiple sessions with a provider. Interventions with large effect sizes have been greater than 20 h of content and consisted of up to eight sessions [7] or required the presence of a partner [4]. Our findings suggest that improvement in body image and sexual health may be possible in as few as three sessions with a therapist and not require the presence of a partner. This could allow for dissemination of the intervention to women without partners and to women with schedules that do not allow for numerous outpatient sessions.

Limitations of this study include the small sample size which resulted in a lack of power to evaluate subgroups and multiple variables. In addition, hypnotizability was not evaluated in this particular study. Therefore, it is possible that the hypnosis intervention group did not experience hypnosis to the depth possible.

To advance the science of body image and sexual health, a Phase III study is indicated using an appropriate, neutral control arm in addition to hypnosis and PMR. The inclusion of a neutral control arm allows for a better understanding of natural changes over time. It would be important to power the study to evaluate mediators and moderators in the population with respect to positive changes in body image.

Summary and conclusions

Therapies that include relaxation and use the mind to connect positively with the body, such as hypnosis and PMR, may be helpful in improving body image in women who have or have had breast or gynecologic cancer. More research is needed to better understand the impact of stress reduction and improved mood versus hypnotic suggestion on body image stress and the broader concept of sexual health.

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Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to disclose.

Ethical approval All procedures performed in studies involving human participants were in accordance with ethical standards of the institution and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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