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Heart rate variability biofeedback increases sexual arousal among women with female sexual arousal disorder: Results from a randomized-controlled trial



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ABSTRACT

Low resting heart rate variability (HRV) has been associated with poor sexual arousal function in women. In a recent study, a single session of autogenic training increased HRV and facilitated improvements in both sexual arousal and perceived genital sensations among women experiencing decreased arousal. The current study expands upon these findings by examining the efficacy of HRV biofeedback, with and without autogenic training, as a treatment for sexual arousal dysfunction in an at-home setting. Participants (N = 78) were randomized into one of three conditions: HRV biofeedback, HRV biofeedback + autogenic training, or waitlist control. Each condition included three laboratory sessions; participants in the two active conditions completed 4–6 biofeedback sessions at home, and participants in the HRVB + A condition listened to a 14-min autogenic training recording before completing the biofeedback. Across the three laboratory visits, participants in the three conditions singficinally differed in their genital arousal, subjective sexual arousal, and their perceived genital sensations. Compared to women in the control group, women who engaged in HRV biofeedback at home, with and without additional autogenic training, experienced increases in genital arousal, subjective sexual arousal, and perceived genital sensations. These results provide preliminary support for the contribution of heart rate variability level to female sexual arousal function and for the use of either of these interventions in the treatment of sexual arousal concerns.

1. Introduction

Sexual arousal dysfunction affects one out of every four women in the United States (Shifren, Monz, Russo, Segreti, & Johannes, 2008). Although the number of women distressed by their arousal concerns is considerably smaller than the number of women who report arousal problems, the age-stratified prevalence rates of arousal dysfunction with distress are not trivial; 3.3% of women between the ages of 18 and 44, 7.5% of women aged 45 to 64, and 6% of women above the age of 65 experience low arousal coupled with distress (Shifren et al., 2008). Arousal concerns are linked to relational difficulties, physical health problems, and some mental health conditions. Women who experience arousal difficulties and related distress have lower quality of life, less relationship satisfaction, and poor sexual communication with their partners compared to women without distress (Hendrickx, Gijs, Janssen, & Enzlin, 2016). Both low sexual arousal and overall sexual dysfunction are correlated with markers of increased cardiovascular risk (Veronelli, Mauri, Zecchini, & Peca, 2009), and distressing arousal problems are strongly associated with depression and anxiety (Shifren et al., 2008). Given the scope of the condition as well as its interpersonal and health implications, the availability of a new psychosocial intervention that effectively increases arousal among women with female sexual arousal disorder (FSAD) would be clinically meaningful.

Few treatments explicitly target sexual arousal in women. Those that have done so have either led to only marginal improvements in some arousal indices (Brotto, Basson, & Luria, 2008; Brotto et al., 2012; Brotto, Seal, & Rellini, 2012) or have failed to measure critical components of sexual arousal (Brotto & Basson, 2014; Paterson, Handy, & Brotto, 2017). Psychological treatment studies have focused primarily on testing cognitive behavioral therapy (CBT) protocols and mindfulness-based protocols on women with low desire, though a few of the mindfulness-based studies have included women with low arousal (Brotto et al., 2008; Paterson et al., 2017). The results of the CBT-based studies have not been particularly promising; in the two experiments

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that examined the efficacy of CBT for low desire, a sizeable portion of the samples did not benefit from the treatment (McCabe, 2001; Trudel et al., 2001). Another study compared two sessions of CBT to two sessions of a mindfulness-based treatment for women with sexual distress and a history of childhood sexual abuse (Brotto et al., 2012). Although women in both groups experienced significant decreases in sexual distress, there were no significant increases in subjective sexual arousal or genital sexual arousal in either group. Mindfulness-based treatments, which train participants to focus on their thoughts, emotions, and sensations without judgment (Kabat-Zinn, 2003), have been comparatively more successful at mitigating symptoms of female sexual dysfunction. In one of the first mindfulness-based treatment studies, women with low desire and/or arousal experienced significant increases in desire and decreases in distress, but only marginally significant improvements in subjective arousal and perceived genital sensations (Brotto et al., 2008). In the one study that compared a mindfulness-based treatment against a delayed treatment control group, the intervention led to significant increases in desire, perceived lubrication, sexual satisfaction, subjective arousal, and overall sexual functioning, but the authors did not directly measure genital arousal (Brotto & Basson, 2014).

Furthermore, all of the mindfulness protocols that have been adapted for women with sexual dysfunction are group-based, which may not be feasible, accessible, or desirable for all women who are distressed by their level of arousal. For example, Brotto and Basson (2014) developed four, 90-min group sessions that included mindfulness meditation, cognitive therapy, and psychoeducation; these four sessions were spaced two weeks apart, lasting eight weeks in total. Similarly, a separate study that adapted mindfulness-based cognitive therapy to treat the combination of low desire and arousal included eight weekly group sessions (Paterson et al., 2017). The group-based treatments not only require a significant time commitment from participants, they also require access to trained facilitators. Women who are unable to commit eight weeks to the treatment of their sexual concerns or who live in areas that lack skilled providers or specialty sexual medicine clinics will likely will not benefit from mindfulnessbased interventions.

Heart rate variability. Mindfulness-based treatments are not the only promising interventions for treating sexual arousal problems in women. Heart rate variability (HRV), defined as the degree of variation in the lengths of time between successive heart beats, may also be an appropriate treatment target. Mental health disorders that are characterized by autonomic imbalance, including depression, anxiety, and female sexual arousal disorder (Kemp, Quintana, Felmingham, Matthews, & Jelinek, 2012; Licht, de Geus, van Dyck, & Penninx, 2009; Stanton, Lorenz, Pulverman, & Meston, 2015), have been associated with low HRV. As a marker of autonomic balance (Xhyheri, Manfrini, Mazzolini, Pizzi, & Bugiardini, 2012), HRV is likely relevant to the etiology of genital arousal. HRV has also been associated with emotional regulation, which depends on an individual's ability to adjust physiological arousal on a momentary basis (Gross, 1998). Higher HRV, which is indicative of a more flexible autonomic nervous system, allows for rapid generation and/or modulation of both physiological and emotional states in order to meet situational demands. In contrast, autonomic rigidity compromises one's ability to adjust bodily responses in tandem with environmental changes.

We surmise that HRV level might be related to subjective sexual arousal due to its role in the regulation of physiological and emotional responses because subjective sexual arousal reflects positive engagement during sexual activity (Althof et al., 2017). Consider a woman who is not seeking to engage in sex when her partner approaches her and initiates sexual activity. If this woman is receptive to her partner's advances and has a relatively high degree of autonomic flexibility, her body will adapt physiologically to meet the demands of the sexual situation. This adaptive response will likely facilitate feelings of mental arousal or psychological excitement, which might then contribute to a positive feedback loop. A woman with a lower level of autonomic flexibility may not as readily adjust her body in accordance with the sexual situation, leaving her physiologically and emotionally unprepared, and perhaps ultimately compromising her subjective arousal.

Our understanding of this cycle is informed by Basson's cyclical model of the female sexual response (Basson, 2001). According to her model, women's sexual function is motivated both by the biological urge to experience arousal and by various non-sexual outcomes, including emotional closeness with a partner, affection, and acceptance. Acknowledging the complex associations between subjective and genital sexual arousal, Basson explains that women can move from a state of sexual neutrality to a state of receptivity. If psychological factors facilitate positive associations with the stimulus and trigger the neurological signals that enable genital and other somatic arousal responses, women experience increased arousal and desire, leading to increased satisfaction and intimacy, which then reinforces receptivity and openness (Basson, 2001). Higher HRV may positively influence subjective arousal through increased psychological flexibility and receptivity to sexual cues.

Importantly, research has shown that HRV can be increased acutely using autogenic training (Mishima, Kubota, & Nagata, 1999; Miu, Heilman, & Miclea, 2009), a psychophysiological relaxation technique that requires verbal self-suggestions invoking specific sensations in the body (Kanji, 1997). Relevant to the current research, autogenic training has also been found to increase both genital sexual arousal and subjective sexual arousal in sexually functional women (Stanton & Meston, 2016) and subjective arousal in women with sexual arousal problems (Stanton, Hixon, Nichols, & Meston, 2018). The results of these studies revealed that, in small samples of women, autogenic training effectively increased HRV, subjective sexual arousal, and genital sexual arousal. However, the autogenic training intervention did not lead to improvements in genital arousal among women with FSAD, and these studies did not follow up with participants after their laboratory visits to determine if the treatment resulted in long-term effects on their sexual arousal function.

Instead of using autogenic training alone as the method to increase HRV, we chose HRV biofeedback and a combination of HRV biofeedback with autogenic training as the two active arms of the current intervention. A method of controlling one's breathing to the resonant frequency of about five to six breaths per minute, HRV biofeedback consists of feeding back beat-by-beat heart rate data to the participant as she follows the paced breathing protocol for the purpose of maximizing respiratory sinus arrhythmia (RSA) and matching RSA to heart rate patterns. HRV biofeedback has been linked to improvements in overall autonomic function (Lehrer et al., 2003; Vaschillo, Vaschillo, & Lehrer, 2006). The procedure is designed to improve autonomic reactivity and increase voluntary control over the physiological processes that are otherwise outside of one's awareness.

In recent years, HRV biofeedback has also shown promise in the treatment of several disorders that are specifically associated with autonomic imbalance, including depression, anxiety, and PTSD (e.g., Beckham, Greene, & Meltzer-Brody, 2013; Henriques, Keffer, Abrahamson, & Horst, 2011; Siepmann, Aykac, Unterdörfer, Petrowski, & Mueck-Weymann, 2008; Tan, Dao, Farmer, Sutherland, & Gevirtz, 2011). The key mechanism believed to be responsible for the beneficial effects of HRV biofeedback is an increase in baroreflex gain (Lehrer et al., 2003). Some researchers have suggested that the positive effects of HRV biofeedback may also be driven by stimulation of the vagal afferent pathways (Brown & Gerbarg, 2005; Brown, Gerbarg, & Muench, 2013; Porges, 2011). These pathways affect brain areas known to be involved in affect regulation and mood, specifically the locus coeruleus, orbitofrontal cortex, hippocampus, insula, and amygdala (Grundy, 2002). Biofeedback protocols have been tested on a variety of clinical populations, and in general, findings suggest that this practice improves psychomotor performance, cognitive and psychological states, and physiological functioning.

It is evident that HRV biofeedback is particularly helpful for clinical populations whose autonomic balance shifts too far toward a sympathetic-predominant state. Depression, anxiety, and PTSD are all associated with over-activation of the sympathetic nervous system (SNS; e.g., Blechert, Michael, Grossman, Lajtman, & Wilhelm, 2007; Carney, Freedland, & Veith, 2005), and these conditions have also been linked with low sexual arousal in women (Kennedy, Dickens, Eisfeld, & Bagby, 1999; Shifren et al., 2008; Yehuda, Lehrner, & Rosenbaum, 2015). Among sexually functional women, there is an optimal level of SNS activation that facilitates increases in genital arousal. Too much (or too little) activation inhibits genital arousal, whereas moderate levels of activation increase genital arousal (Lorenz, Harte, Hamilton, & Meston, 2012; Meston & Gorzalka, 1996). However, women who have overactive SNS activity at baseline (e.g., women with a history of childhood sexual abuse and/or PTSD) do not experience increases in sexual arousal after SNS activation (Rellini & Meston, 2006). Moreover, the most common sexual problem among women with a history of sexual abuse and related PTSD is low sexual arousal (Laumann, Paik, & Rosen, 1999). Women with high state anxiety also show lower increases in physiological sexual arousal in response to an erotic film compared to women with state anxiety scores in the moderate range (Bradford & Meston, 2006). If exaggerated SNS activity is related to genital sexual arousal difficulties in some women, a potential treatment for women with these concerns may be parasympathetic stimulation via HRV biofeedback.

The aim of the current study was to examine the effects of HRV biofeedback on sexual arousal function among women who report problems with genital and/or subjective sexual arousal. We hypothesized that one month of HRV biofeedback, with and without autogenic training, would improve subjective sexual arousal and perceived genital arousal, possibly leading to clinically relevant improvements in sexual arousal function. We also hypothesized that women receiving both HRV biofeedback and autogenic training would experience the greatest gains in arousal compared to the women randomized to the other two groups. Finally, we hypothesized that HRV biofeedback, with and without autogenic training, would lead to marginal increases in genital sexual arousal.

2. Method

2.1. Participants

Participants were recruited from the local community via brochures, fliers, and online advertisements. These materials instructed potential participants to call the laboratory to complete a phone screen with a trained research assistant. After receiving information about the study, participants were offered the opportunity to complete a confidential verbal phone screen to assess inclusion and exclusion criteria. Phone screeners used an adapted version of the Female Sexual Dysfunction Diagnosis (FSDD) questionnaire to determine if callers meet criteria for female sexual arousal disorder (FSAD). Women who identified experiencing at least two types of genital sensations in the past and stated that these sensations were currently diminished or absent (for at least six months) and/or reported diminished or absent subjective arousal (for at least six months) were eligible to participate.

During the phone screen, the research assistant also assessed the caller's overall sexual function using the Female Sexual Function Index (FSFI; Rosen et al., 2000). Only premenopausal women who scored below a 26.55 on the FSFI, the clinical cut-off for sexual function, were eligible. Other inclusion criteria were as follows: fluency in English; heterosexual or bisexual sexual orientation; sexually active with a partner; and ownership of a mobile device or tablet that is compatible with the at-home biofeedback software. Exclusion criteria included: currently pregnant or breastfeeding, history or current diagnosis of a sexually transmitted infection; history of sexual abuse; history of major pelvic surgery; currently taking any androgens/estrogens (other than hormonal contraceptives) or any other medical treatments to enhance sexual response; currently taking benzodiazepines or beta blockers; if

currently taking antidepressants or anti-hypertensives, must be stabilized on the medications for at least 3 months; and current psychosis.

If eligible, participants were invited to the laboratory for their first sessions. They were asked to refrain from unaccustomed or strenuous exercise for at least 6 h prior to every study session, given that sympathetic nervous system activation via acute exercise has been shown to facilitate genital sexual arousal in women (e.g., Lorenz et al., 2012; Meston & Gorzalka, 1996). Eligible participants were also asked to refrain from consuming caffeine, a central nervous system stimulant, for at least 5 h prior to every study session, as the range of the half-life of caffeine in non-pregnant females is 2–5 h (Knutti, Rothweiler, & Schlatter, 1982).

Recruitment took place over approximately one year (October 2016–December 2017). The target sample size for this study was 65 women (25 for the HRVB condition, 25 for the HRVB + A condition, and 15 for the wait-list control condition), According to sample size guidelines for multilevel modeling, 50 participants is a reasonable minimum for multilevel analyses (Maas & Hox, 2005). A sample size of less than 50 participants has been shown to lead to biased estimates of second-level standard errors (Maas & Hox, 2005). Based on this guideline, we determined that a sample size of 65 women was appropriate.

The final sample included 78 adult women, aged 18–50 (M = 25.42, SD = 7.96), split among the three conditions. There were no statistically significant differences in age, age of sexual debut, baseline FSFI scores, relationship status, race/ethnicity, educational attainment, dropout rates, or follow up rates among the three groups (see Table 1). Nine women dropped out of the study after the first laboratory visit. Of the 69 women who completed all three laboratory visits, 29 did not complete the one month follow up assessment (see Fig. 1) (see Table 2).

2.2. Stimulus materials

Three 10-min audiovisual films were used as stimulus materials; they were counterbalanced and matched for content. The three films included a 4-min neutral segment followed by a 6-min erotic segment. The neutral segments depicted different images of natural landscapes paired with classical music, and the erotic segments featured different heterosexual couples engaging in 2 min of foreplay, 2 min of cunnilingus, and 2 min of penetrative sexual intercourse.

2.3. Measures

Overall sexual function and arousal function. The FSFI was used to quantify overall sexual function at baseline and at the third laboratory visit. A 19-item self-report questionnaire, the FSFI assesses overall sexual function and six specific domains; desire, arousal, lubrication, pain, orgasm, and satisfaction. Total scores range from 2 to 36, with higher scores indicating greater sexual function. The FSFI has good internal reliability (r = 0.89-0.97), test-retest reliabilities ($\alpha = 0.79-0.88$), and has been shown to discriminate between women with and without sexual problems.

Arousal function was assessed at baseline using an adapted version of the Female Sexual Dysfunction questionnaire, which was developed for use in our laboratory. The adapted FSDD briefly assesses participants' levels of both genital arousal and subjective arousal by referencing five specific genital responses typically experienced during sexual activity (e.g., pleasurable sexual feeling in your genitals; genital/clitoral fullness, pressure, or engorgement; genital pulsing or throbbing; genital warmth; genital wetness or lubrication) and by inquiring about mental engagement (i.e., the degree to which one is mentally "turned on" during sex). The measure also asks participants to rank how important it is for them to experience these specific responses during sexual activity.

Heart rate variability. Baseline heart rate was measured at a rate of 200 samples/sec via electrocardiography (ECG) during the neutral segment of each neutral-erotic film. The signal from the ECG leads was detected using an MP100 data acquisition unit that was equipped with AcqKnowledge 3.9.1 software (Biopac Systems, Inc., Santa Barbara,

Table 1

Participant characteristics.

	$\mathrm{HRVB}(n=31)$	HRVB + A(n = 26)	WL(n = 21)	F	Entire Sample($n = 78$)
	M (SD)	M (SD)	M (SD)		M (SD)
Age	25.10 (8.15)	25.46 (8.15)	25.86 (7.72)	.06 ^a	25.42 (7.96)
Age of sexual debut	16.91 (2.49)	19.30 (3.29)	17.33 (1.98)	.31 ^a	16.99 (2.46)
Baseline FSFI score	19.49 (3.12)	19.30 (4.84)	18.50 (3.76)	.43 ^a	19.16 (3.90)
	n	n	n	χ^2	n
Relationship status				5.99 ^a	
Single (not dating)	7	6	3		16
Single (casually dating)	8	6	8		22
In a committed relationship	11	9	10		30
Married	5	5	0		10
Race/Ethnicity				6.12^{a}	
African American/Black	6	1	4		11
Asian	3	5	3		11
Caucasian/White	14	9	6		29
Hispanic/Latin American	7	10	7		24
Other	1	1	1		3
Highest level of education				6.71 ^a	
High school degree/GED	3	4	6		13
Some college	17	14	10		41
College degree	8	4	5		17
Advanced degree	3	4	0		7
Drop out status				2.30^{a}	
Completed all lab visits	26	25	18		69
Follow up status				.90 ^a	
Completed all lab visits and follow up survey	14	15	11		40

a = p > .05.

CA). The ECG data was extracted to Microsoft Excel for processing and artifact removal. The final Excel files were converted to text files and analyzed by Kubios HRV Analysis Software (Biosignal Analysis and Medical Imaging Group, University of Kuopio, Kuopio Finland). The standard deviation of the normal heart beat interval lengths (SDNN), a time domain measurement, was used as the index of HRV in this study. SDNN is considered one of the most widely used measures of HRV (Xhyheri et al., 2012); it provides information about all components contributing to HRV during the recording period.

Genital sexual arousal. Genital sexual arousal was assessed via vaginal photoplethysmography (Sintchak & Geer, 1975), which produces two measurements: vaginal blood volume (VBV) and vaginal pulse amplitude (VPA). Vaginal pulse amplitude, which reflects shortterm changes in the engorgement of blood in the vaginal tissue (Rosen & Beck, 1988), is considered to be the more sensitive of the two indices (Heiman, 1977) and has been shown to be a reliable index of women's genital arousal (Laan, Everaerd, Van Aanhold, & Rebel, 1993). Vaginal pulse amplitude data was sampled at a rate of 200 samples/sec throughout the erotic films during each laboratory session. These data were recorded in millivolts and collected by an MP100 data acquisition unit equipped with AcqKnowledge 3.9.3 software (Biopac Systems, Santa Barbara). These data were then exported to Microsoft Excel for processing, and movement artifacts were removed from the data using an automated processing procedure (Pulverman, Meston, & Hixon, 2015) that was built in the R software environment (R Foundation, 2014) using the MGCV package for generalized additive modeling (Wood, 2011). After the artifacts were removed, the vaginal pulse amplitude data were binned into 5-s segments, representing mean peakto-peak VPA response, and the data within each segment were averaged into a single value.

Subjective arousal. Discrete subjective arousal was assessed via three items on the modified version of the Film Scale (Heiman & Rowland, 1983), which measures perception of physiological arousal and psychological arousal in response to a sexual film. Participants completed the Film Scale after watching the erotic film during each of the three laboratory sessions. Continuous subjective arousal was

measured with the Arousometer (Rellini, McCall, Randall, & Meston, 2005). The arousometer is a computer mouse attached to a lever, which is numbered from 0 to 7. During the erotic films at each of the three laboratory sessions, participants were instructed to move the mouse up or down as they felt their mental sexual arousal changing.

Perceived genital arousal. Perceived genital arousal was assessed via five items on the modified version of the Film Scale (Heiman & Rowland, 1983). Participants completed the Film Scale after watching the erotic film during each of the three laboratory sessions.

2.4. Procedure

The study involved three laboratory sessions and a one-month follow up survey. Eligible participants were randomized into one of three conditions: HRV biofeedback (HRVB), HRV biofeedback plus autogenic training (HRVB + A), and a wait-list control condition (WL). Participants were roughly matched on age and stratified across the three groups based on baseline FSFI scores, which were determined during the phone screen.

During each study session, the experimenter explained how to use the vaginal photoplethysmograph, ECG, and the Arousometer. The experimenter then placed the ECG electropads on the participants' bodies and then left the room, locking it from the inside so that the participants enjoyed complete privacy during the session. After completing some questionnaires, participants were instructed to attach the ECG wires to the electropads and insert the vaginal probe. They then watched a 10min film composed of first neutral (4 min) and then erotic (6 min) content. Baseline HRV was measured *only* during the neutral segment of the film; genital and subjective sexual arousal were measured continuously during both the neutral and the erotic stimuli. Then, participants in all three conditions completed the Film Scale to retrospectively assess their subjective sexual arousal and perceived genital sensations during the erotic stimulus.

At the end of the first laboratory session, women in the WL condition were informed that their sexual arousal needed to be monitored while they waited for availability in the experimental condition.

Approximate study timelin	ь.					
	Day 1	Days 2–11	Day 12–13	Days 14–27	Day 28	Day 58
Phone screen and Randomization	Laboratory Visit 1 (90 min for HRVB and HRVB + A groups, 50 min for WL group)	At-home biofeedback (HRVB and HRVB + A groups only)	Laboratory Visit 2 (50 min for all three groups)	At-home biofeedback (HRVB and HRVB + A groups only)	Laboratory Visit 3 (50 min for all three groups)	1-month follow up (online survey; 20–30 min for all three groups)

Table 2

Women in the two active conditions (HRVB, HRVB + A) were also given a Polar H7 Bluetooth Heart Rate Sensor & Fitness Tracker, as well as access to the Elite HRV app on their mobile devices or tablets. The experimenter helped the participants set up the Elite HRV app and ensured that the app connected to the sensor. Participants were then provided with a brief introduction to paced breathing; the experimenter explained the connection between the pace of the breath and the baroreflex and guided participants through a paced breathing exercise (See Appendix A for biofeedback procedure). After some paced breathing practice, participants were instructed to follow along with the circle, Elite HRV's visual breathing aid, by breathing in as the circle expanded and breathing out as the circle shrank. After 5 min of biofeedback practice, women in the HRVB condition were asked to complete athome HRV biofeedback two-three 20-min biofeedback sessions per week. Women in the HRVB + A condition were asked to complete the same number of biofeedback sessions as their counterparts in the HRVB condition, but they were instructed to listen to a specific 14-min autogenic training recording, which was provided by the experimenter, before doing so. The experimenter did not offer explicit instructions on how to engage in autogenic training; women were simply asked to follow along with the recording at home. Finally, the participants in these two conditions were informed that they should complete the biofeedback in a non-sexual context. That is, participants were asked to avoid doing their biofeedback immediately prior to becoming aroused/ attempting to engage in sexual activity. The experimenter informed women in the HRVB and HRB + A conditions that they would receive \$5 for every self-guided HRV biofeedback session completed between laboratory visits one and two (a maximum of \$30) and \$5 for every selfguided HRV biofeedback session completed between laboratory visits two and three (again, a maximum of \$30). Participants were also told that their biofeedback session would be tracked online by the experimenter. All participants were compensated \$25 for this visit and provided with a handout outlining their required home practice. Participants in the HRVB and HRVB + A conditions were also given a handout of instructions for using the Elite HRV app.

The second laboratory session took place approximately 14 days after the first laboratory session. During this second session, all participants watched a neutral-erotic film sequence; similar to laboratory session 1, resting state HRV was measured during the neutral segment of the film; genital and subjective sexual arousal were measured continuously during both the neutral and the erotic segments. Participants did not engage in biofeedback during the measurement period. Following the film, participants completed the Film Scale. To incentivize women in the HRVB and HRVB + A conditions to complete the study and return the biofeedback sensors (valued at \$50), they were not compensated for this laboratory session until laboratory session three. Women in the WL condition were compensated \$25 for this session.

The third laboratory session took place approximately two weeks after the second laboratory session. Again, resting state HRV was measured during the neutral segment of the film, and both genital and subjective arousal were measured during the erotic segment of the film. Women in the WL condition were compensated \$25 for this session. Upon returning the biofeedback sensor, women in the HRVB and the HRVB + A conditions were compensated \$50 for this session (\$25 for laboratory visit two and \$25 for laboratory visit three); they were also compensated for their at-home biofeedback.

At laboratory session three, participants were told that they would receive an email in one month with a link to several online measures. Participants were asked to complete a battery of self-report questionnaires one month after their third laboratory visit. Once they completed the online measures, women who were in the WL condition were invited back to the laboratory for one session of experimenterguided HRV biofeedback. Although two women expressed interest in this option, they did not respond to follow up requests. The study was registered with ClinicalTrials.gov (NCT02958176).



Fig. 1. Consort diagram.

2.5. Data analysis

Primary outcome measures. There were four primary arousal outcome measures in this study: genital sexual arousal, continuous subjective sexual arousal, discrete subjective arousal, and perceived genital sensations. Following the "intent to treat" approach, all participants who were enrolled and randomly allocated to a treatment condition were included in the analyses and were analyzed in the groups to which they were randomized. For the analyses involving two of the primary outcome measures, genital sexual arousal and continuous subjective sexual arousal, participants with missing data were not excluded. In general, hierarchical linear modeling (HLM) accommodates missing data well. For example, if a participant forgot to use the Arousometer to document her continuous subjective arousal during one of her laboratory visits, her VPA data from that visit as well as her Arousometer data from her other laboratory visits were included in the model.

First, both raw change and percent change in HRV were analyzed by condition via a one-way ANOVA. These analyses assessed differences in SDNN between laboratory visit one and laboratory visit two, as well as between laboratory visit one and laboratory visit three, among the three conditions.

Second, HLM was used to assess changes in genital sexual arousal (VPA) and continuous subjective arousal due to the treatment. These analyses were conducted using the NLME package (Pinheiro, Bates, DebRoy, Sarkar, & Team, 2017) in the R Software environment (R Foundation, 2014). The effects of time, condition, and visit on genital sexual arousal were evaluated in a model that included a three-way interaction term and a random intercept term. Similarly, the effects of time, condition, and visit on continuous subjective sexual arousal were evaluated in a separate model that included a three-way interaction term and a random effect for subject ID. Consistent with standard practices in the analysis of VPA data, observations wherein participants exhibited a negative VPA slope over the 10 min neutral-erotic film at a

given laboratory visit were excluded from the HLM analyses, as VPA may decrease over time due to poor or inconsistent placement of the vaginal photoplethysmograph. In total, 57 observations were dropped; 30 participants had at least one visit excluded; 5 participants had two visits excluded, and 3 participants had all three visits excluded.

The following two models assessed the relationship among time, condition, visit and either VPA or continuous subjective arousal during the film sequences:

 $\begin{aligned} &Y(VPA)_{ij} = \beta_0 + \beta_1(time)_{ij} + \beta_2(condition)_{ij} + \beta_3(visit)_{ij} + \beta_4(time * condition)_{ij} + \beta_5(time * visit)_{ij} + \beta_6(condition * visit)_{ij} + \beta_7(time * condition * visit)_{ij} + r_{ij} \end{aligned}$

 $\begin{aligned} &Y(\text{Arousometer})_{ij} = \beta_0 + \beta_1(\text{time})_{ij} + \beta_2(\text{condition})_{ij} + \beta_3(\text{visit})_{ij} \\ &+ \beta_4(\text{time} * \text{condition})_{ij} + \beta_5(\text{time} * \text{visit})_{ij} + \beta_6(\text{condition} * \text{visit})_{ij} + \beta_7(\text{time} * \text{condition} * \text{visit})_{ij} + r_{ij} \end{aligned}$

Y(VPA)_{ij} and Y(Arousometer)_{ij} are the _ith participant's VPA and continuous subjective arousal, respectively, at the _jth time point. In these models, β_1 represents the main effect of time on either genital or subjective sexual arousal, β_2 represents the main effect of condition (where 1 = HRVBF, 2 = HRVBF + A, and 3 = WL), β_3 highlights the main effect of visit (where 1 = laboratory visit 1, 2 = laboratory visit 2, and 3 = laboratory visit 3), and $\beta_{5.7}$ represent the various two-way interactions effects and the three-way interaction effect among time, condition, and visit. The time variable refers to the course of each of the neutral-erotic film segments; all three neutral-erotic film segments were 10 min (600 s) in length. Finally, β_0 represents the participant-specific intercept and r_{ij} are the individual error terms.

Third, HLM was used to analyze differences in discrete subjective arousal and perceived genital sensations among the three conditions across the three visits.

Mediation analyses. Heart rate variability was analyzed as a mediator of treatment-related increases in all four arousal variables (genital arousal, continuous subjective arousal, discrete subjective arousal, and perceived genital sensations) using the mediation package (Tingley, Yamamoto, Hirose, Keele, & Imai, 2013) in R. These analyses were univariate, not multivariate; separate models were run for each of the arousal outcome variables. All variables included in these analyses were standardized via z-scoring. The mediation package allows for causal mediation analysis of multilevel data, where individual observations are clustered within groups (Tingley, Yamamoto, Hirose, Keele, & Imai, 2014). In this study, the treatment was assigned at the group level, whereas the mediator and outcome variables were measured at the individual level. The mediation package dissects total effect of a treatment into direct and indirect effects, and the indirect effect is transmitted via the mediator to the outcome (Zhang et al., 2016). The user specifies which variable should be treated as the predictor and which variable should be treated as the mediator. In this case, condition served as the predictor variable, and SDNN was the mediator. By design, the analyses compared (1) the HRVB condition against the WL condition and (2) the HRVB + A condition against the WL condition. The output produced by the package includes the average causal mediation effect (ACME), which is total effect minus the direct effect, and the average direct effect (ADE), or the direct effect of X on Y after taking the effect of M into account.

Because the mediation package does not provide output for the traditional "A" and "B" paths described by Baron and Kenny (1986), separate linear mixed effects models were run when the magnitude of the ACME was significant to estimate the relationships between the predictor and HRV (the "A" path) and between HRV and the arousal measure (the "B" path).

Importantly, the mediation analyses were only conducted on the data of participants who were compliant with the treatment. Participants in the HRVB condition were required to complete at least eight at-home biofeedback sessions, and participants in the HRVB + A condition were also required to couple autogenic training and HRV

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Table 3				
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Mean	law	change	and percer	it change	шпки	Dу	condition.

Condition	М	SE	F
Percent change in SDNN, v1-v2			
HRVB	8.35	5.81	1.37
HRVB + A	15.99	7.29	
WL	51	6.70	
Raw change in SDNN, v1-v2			
HRVB	2.99	2.15	2.28
HRVB + A	7.13	3.35	
WL	-1.87	2.81	
Percent change in SDNN, v1-v3			
HRVB	15.40	8.10	3.68*
HRVB + A	39.26	11.24	
WL	3.64	6.37	
Raw change in SDNN, v1-v3			
HRVB	6.20	3.61	5.49*
HRVB + A	17.14	3.91	
WL	.57	1.91	

Note. HRV = heart rate variability; SDNN = standard deviation of the N–N intervals; v1 = laboratory visit one; v2 = laboratory visit two; v3 = laboratory visit three; HRVB = HRV biofeedback condition; HRVB + A = HRV biofeedback plus autogenic training condition; WL = wait list condition. *p < .05.

biofeedback at least eight times. Therefore, those participants (n = 9) who completed seven or fewer at-home biofeedback sessions were excluded.

3. Results

3.1. Target engagement

The Elite HRV app recorded HRV measures as participants completed their biofeedback at home. For the majority of participants in the HRVB and HRVB + A conditions (78%), SDNN increased with each additional biofeedback session, which suggests that, for the most part, participants were breathing at the assigned frequency.

A one-way ANOVA revealed that raw change in HRV (indexed by SDNN) from laboratory visit one to laboratory visit three significantly differed among the three conditions, F(2, 66) = 5.49, p = .006. Percent change in SDNN between these two laboratory visits also significantly different among the conditions, F(2, 66) = 3.68, p = .031. There were no statistically significant differences in SDNN raw change or SDNN percent change among the three groups from laboratory visit one to laboratory visit two. Between laboratory visits one and three, women randomized to the HRVB + A condition had the greatest average raw change and percent change, followed by women randomized to the HRVB condition. On average, women randomized to the WL condition experienced little change (see Table 3). These analyses indicate that the two active conditions effectively targeted HRV as intended.

3.2. Primary outcomes

Genital sexual arousal. The HLM analyses revealed that the interaction of cubic time, condition, and visit significantly predicted changes in genital arousal (measured by VPA), $\beta = 0.00$, t (26067) = 2.14, p < .05 (see Table 4, Fig. 2). This model was compared to a model that included a linear term for time, and the cubic model had a lower AIC (196,854.80 vs. 196,6917.10), so it was retained. Fig. 2 highlights the VPA trajectories of the women in the HRVB, HRVB + A, and WL conditions over the three 10-min film clips at each of the laboratory visits. It is evident in Fig. 2, which represent the raw data, that women who were randomized to the waitlist control condition experienced the least positive change in VPA during the course of the neutral-erotic film across the three visits. Women in the HRVB condition had the greatest increases in VPA from the first laboratory

Table 4

Results from an HLM analysis examining centered time, condition, and visit as predictors of genital arousal (VPA).

Predictor	β	SE	df	t-ratio	p-value
(Intercept)	12.04	3.34	26057	3.60	0.0003
Time	0.006	0.006	26057	0.96	0.34
Condition	0.79	1.64	76	0.47	0.64
Visit	3.35	0.30	26057	11.09	0.000
Time ²	000001	0.00002	26057	08	0.93
Time ³	0.00	0.00	26057	-0.57	0.57
Time*Condition	0.01	0.003	26057	3.47	0.0005
Time*Visit	0.01	0.003	26057	4.99	0.000
Condition*Visit	-0.67	0.15	26057	-4.51	0.000
Condition*Time ²	0.000003	0.00	26057	0.45	0.66
Visit*Time ²	0.000004	0.00	26057	0.49	0.62
Condition*Time ³	0.00	0.00	26057	-1.78	0.07
Visit*Time ³	0.00	0.00	26057	-2.40	0.02
Time*Condition*Visit	-0.006	0.001	26057	-4.03	0.0001
Time ² *Condition*Visit	-0.000001	0.00	26057	-0.23	0.82
Time ³ *Condition*Visit	0.00	0.00	26057	2.15	0.03

Time = -300-300 s, binned in 5 s intervals; Condition = HRVB (1), HRVB + A (2), and WL (3); Visit = laboratory visit 1, 2, or 3; SE = standard error; df = degrees of freedom.

visit to the third laboratory visit. Women in the WL condition experienced an increase in their VPA from their first laboratory visit to their third laboratory visit, but a decrease from their first visit to their second visit. **Continuous subjective sexual arousal.** The HLM analyses revealed that the interaction of cubic time, condition, and visit significantly predicted changes in continuous subjective arousal (measured by the Arousometer), $\beta = 0.000$, t(25946) = -2.46, p < .005 (see Table 5, Fig. 3). This model was compared to a model that included a linear term for time, and the cubic model had a lower AIC (-11869.41vs. -9958.797), so it was retained. Fig. 3 presents the Arousometer trajectories of the women in the HRVB, HRVB + A, and WL conditions over the three 10-min film clips at each of the laboratory visits. Based on Fig. 3, it is clear that women who were randomized to the WL experienced decreases in continuous subjective arousal during the course of the neutral-erotic film across the three visits. In contrast, women in the HRVB and HRVB + A conditions demonstrated increases in their subjective arousal from the first laboratory visit to the third laboratory visit.

Discrete subjective arousal. Changes in discrete subjective arousal were analyzed via HLM. interaction of condition and visit significantly predicted changes in discrete subjective arousal (measured by the Film Scale), $\beta = -0.82$, t(25959) = -38.14, p < .0001. Post-hoc analyses did not indicate any significant differences in discrete subjective arousal among the three conditions at specific laboratory visits. Participants in the two active conditions experienced the greatest increases in subjective sexual arousal throughout the course of the intervention (see Fig. 4).

Perceived genital sensations. Changes in perceived genital sensations were also analyzed via HLM. The interaction of condition and visit significantly predicted changes in perceived genital sensations



Fig. 2. Smoothed representation of the raw VPA data for women in the HRVB condition (left), HRVB + A condition (middle), and WL condition (right). across all laboratory visits. The solid line represents the raw VPA data during the 10-min neutral-erotic film presented at visit 1, the dotted line represents the raw VPA data during the 10-min neutral-erotic film presented at visit 2, and the dashed line represents the raw VPA data during the 10-min neutral-erotic film presented at visit 3.



Fig. 3. Smoothed representation of the raw Arousometer data for women in the HRVB condition (left), HRVB + A condition (middle), and WL condition (right). across all laboratory visits. The solid line represents the raw Arousometer data during the 10-min neutral-erotic film presented at visit 1, the dotted line represents the raw Arousometer data during the 10-min neutral-erotic film presented at visit 2, and the dashed line represents the raw Arousometer data during the 10-min neutral-erotic film presented at visit 3.

Table 5

Results from an HLM analysis examining centered time, condition, and visit as predictors of continuous subjective arousal.

Predictor	β	SE	df	t-ratio	<i>p</i> -value
(Intercept)	0.24	0.04	25946	5.92	0.000
Time	0.002	0.0001	25946	18.77	0.000
Condition	-0.001	0.02	76	-0.04	0.96
Visit	0.04	0.006	25946	7.15	0.000
Time ²	-0.000002	0.000	25946	-0.64	0.52
Time ³	-0.0000002	0.000	25946	-10.60	0.000
Time*Condition	-0.00003	0.000	25946	-0.64	0.52
Time*Visit	0.00001	0.000	25946	0.23	0.82
Condition*Visit	-0.03	0.003	25946	-9.59	0.000
Condition*Time ²	0.0000004	0.000	25946	2.81	0.005
Visit*Time ²	0.0000006	0.000	25946	4.14	0.000
Condition*Time ³	0.000	0.000	25946	2.11	0.035
Visit*Time ³	0.000	0.000	25946	3.44	0.001
Time*Condition*Visit	-0.00009	0.000	25946	-3.35	0.001
Time ² *Condition*Visit	-0.0000001	0.000	25946	-1.74	0.08
Time ³ *Condition*Visit	0.000	0.000	25946	-2.46	0.004

Time = -300-300 s, binned in 5 s intervals; Condition = HRVB (1), HRVB + A (2), and WL (3); Visit = laboratory visit 1, 2, or 3; SE = standard error; df = degrees of freedom.

(measured by the Film Scale), $\beta = -0.90$, t(25959) = -25.98, p < .0001. Post-hoc analyses did not indicate any significant differences in perceived genital sensations among the three conditions at specific laboratory visits. Collectively, these results indicate that participants in the two active conditions experienced the greatest increases in subjective sexual arousal throughout the course of the intervention (see Fig. 5).

Post-hoc analysis of continuous measures. Post-hoc contrast analyses were conducted to assess the possibility of between-group differences in both VPA and continuous sexual arousal slopes as a function of treatment condition assignment across laboratory visits. Helmert contrasts (Fox, 2002) revealed no consistent, meaningful differences between the HRVB/HRVB + A conditions and the WL condition with regard to either continuous measure. While the arousometer slopes for visit three showed statistically significant differences between the active and the control conditions (p < .05), all other contrasts showed no significant differences (all ps > .10).

3.3. Causal mediation

HRV, indexed by SDNN, was assessed as a causal mediator of changes in the four arousal variables (genital arousal, continuous subjective arousal, discrete subjective arousal, and perceived genital



Fig. 4. Changes in discrete subjective arousal, measured via the Film Scale, by condition.



Fig. 5. Changes in perceived genital sensations, measured via the Film Scale, by condition.

sensations). Compared to women who were randomized to the WL condition, women in the HRVB condition demonstrated significant indirect effects of condition on perceived genital sensations that were mediated through SDNN, ACME = 0.17 [0.002, 0.42], p = .04. The direct path from the HRVB condition to perceived genital sensations was also significant, ADE = 0.54 [0.02, 1.05], p = .04. These results indicate that, compared to the WL condition, the HRVB condition facilitated an increase in SDNN, which then led to an increase in perceived genital sensations. Again, compared to women in the WL condition, women who were randomized to the HRVB condition experienced a trend toward significant indirect effects of condition on discrete subjective arousal that were mediated through SDNN, ACME = 0.15 [-0.0009, 0.41], p = .06, and a trend toward significant direct effects from the HRVB condition to discrete subjective arousal, ADE = 0.42 [-0.06, 0.87], p = .08. Though the magnitude of the ACME did not reach statistical significance, the HRVB condition led to increases in SDNN, which then caused increases in discrete subjective arousal over the course of the intervention. Note that the modeling approach employed by the mediation package is considerably more complex than the traditional Baron and Kenney method (Baron & Kenny, 1986). Nevertheless, our results are consistent with those provided by such an approach. See the supplementary materials for more information.

Increased SDNN did not mediate the relationship between the HRVB condition and continuous genital arousal (p > .10), nor did it mediate the relationship between the HRVB condition and genital arousal (p > .10). Finally, SDNN did not mediate the relationship between the HRVB + A condition and any of the arousal variables (all ps > .10).

4. Discussion

This randomized-controlled trial examined the effect of targeting and increasing heart rate variability on several indices of sexual arousal in women with FSAD. Building on previous research, which indicated that increasing heart rate variability via autogenic training in the laboratory facilitated increases in both genital arousal and subjective arousal, we designed a month-long, three-armed intervention for women with genital and/or subjective arousal concerns. Participants were randomized to one of three conditions: HRVB, HRVB + A, or WL. The two active conditions (HRVB, HRVB + A) required two to three 20min HRV biofeedback sessions per week. Participants in the HRVB + A condition listened to a 14-min autogenic training recording prior to engaging in the biofeedback. The intervention led to increases in HRV as well as increases in genital arousal, continuous subjective arousal, discrete subjective arousal, and perceived genital sensations among women in the two active conditions; this was not the case for women in the WL condition. For women in the HRVB condition, increases in HRV significantly mediated the relationship between condition and perceived genital sensations. That is, randomization to this specific condition led to increases in SDNN, which then led to increases in perceived genital sensations. In addition, there was a trend toward statistically significant indirect effects of SDNN on the relationship between the HRVB condition and discrete subjective arousal. Again, only for women in HRVB condition, increases in HRV partially accounted for increases in subjective arousal. To our knowledge, this study was the first randomized controlled trial of HRV biofeedback, with and without autogenic training, in a population of women with sexual arousal problems.

It is particularly notable that the intervention facilitated increases in genital arousal and increases in perceived genital arousal. Not only did participants experience increased blood flow to the genitals, they improved in their ability to perceive this physiological change. To date, no published randomized-controlled trials of psychosocial interventions for FSAD have demonstrated significant increases in VPA alongside increases in perceived sensations. Mindfulness-based protocols have led to increases in perceived genital sensations and subjective arousal, but not in VPA (Brotto, Chivers, Millman, & Albert, 2016; Brotto et al., 2008). Some pharmacologic agents (e.g., L-arginine glutamine plus yohimbine, gingko biloba, tibolone, and sildenafil), have increased genital arousal relative to placebo (Laan et al., 2002; Laan, van Lunsen, & Everaerd, 2001; Meston, Rellini, & Telch, 2008; Meston & Worcel, 2002), but others have not (Chivers & Rosen, 2010; Foster, Mears, & Goldmeier, 2009). For the most part, the drugs that do increase vasocongestion do not increase women's self-reported genital sensations, nor do they lead to improvements in women's mental engagement during sexual activity. Unlike these existing treatments, the HRV-based intervention seems to have positive effects on both perceptions of arousal and objective indices of arousal. While the results should be considered tentatively as preliminary evidence, the current intervention may be appropriate for women who have compromised genital blood flow due to neurovascular or other organic factors and women who have appropriate levels of vaginal vasocongestion but may not be attending to their genital sensations.

Even though increases in the four arousal measures were observed in women randomized to the HRVB and HRVB + A conditions compared to women in the WL condition, the role that HRV played with respect to these increases is somewhat unclear. Indeed, the evidence for increased HRV as a mediator of change in arousal was relatively weak. Specifically, increasing SDNN facilitated improvements in only one index of arousal (perceived genital sensations) and only among randomized to only one of the two active conditions (HRVB). Interestingly, women who randomized to the other active condition, HRVB + A, experienced the greatest gains in HRV, but these gains were not strongly related to any of the arousal indices. We can only speculate as to what accounts for these seemingly divergent findings. It is possible, for example, that the purported mechanism of action only emerges in training that exclusively focuses on attending to and manipulating the breath and that adding sensory activation (evident in the HRVB + A condition) may engage alternative mechanisms underlying increases in arousal.

As is true for all interventions, the two active conditions examined in this study engaged multiple mechanisms critical to sexual arousal. We focused on and measured HRV as a mediator. It is possible, however, that the combination of HRV biofeedback and autogenic training, while engaging this putative mediator, also activated an alternative or complementary (unmeasured) mechanism that overrode the hypothesized mediational effects of HRV. For example, autogenic training increases sensory acuity; HRV biofeedback does not direct participants to engage with the senses, nor does it direct participants to actively increase their sensations. When a practitioner listens to an autogenic training recording, she mentally repeats certain phrases that target specific sensations, such as muscular relaxation, feelings of warmth, and feelings of heaviness (Kanji, 1997). Although HRV is an excellent measure of autonomic nervous system function, it only indexes one aspect of autonomic function: the variation in the lengths of time between adjacent heartbeats. Autogenic training may have facilitated autonomic balance in a way that was not picked up by HRV. It is possible that attention to sensations of warmth may have manipulated blood flow, leading to changes in blood pressure, which would have impacted genital arousal and possibly emotion regulation (potentially affecting subjective arousal). Attention to sensations in general may have also increased attendance to erotic cues, which could have led to increases in subjective arousal. The combination of HRV biofeedback and autogenic training clearly increases sexual arousal, but the mechanism or group of mechanisms driving that effect have yet to be determined.

The HRVB condition was the "purer" of the two active conditions in that it aimed to exclusively increase HRV by training women to attend to and adjust their autonomic arousal via their breath; it is perhaps unsurprising, then, that increases in HRV were associated with increased genital sensations, another component of autonomic arousal. Women in this condition slowed down the pace of their breath following Elite HRV's breathing guide and then used their breath to increase their HRV, which was graphically demonstrated for them on their mobile devices. Unlike the women in the HRVB + A condition, participants in the HRVB condition were not asked to activate sensations like warmth or heaviness in different areas of the body. This intense, exclusive focus on the breath was intended to regulate their autonomic arousal. It is well known that the amplitude of HRV is systematically related to breathing frequency; higher amplitudes are achieved with slower respiration (Lehrer & Gevirtz, 2014). During normal breathing, the phase relationship between breathing and heart rate is not synchronous (Vaschillo, Lehrer, Rishe, & Konstantinov, 2002). At rest, most people breathe at a rate between 0.15 and 0.4 Hz, or about 9-24 breaths per minute (Lehrer, 2007); heart rate increases tend to follow inhalation at the mid-point of the breath, and heart rate decreases also occur in the middle of exhalation (Vaschillo et al., 2002). When paced breathing is facilitated by biofeedback, the relationship between heart rate and respiratory rate changes dramatically. The amplitude of heart rate oscillations increases, and heart rate oscillates in phase with respiration (Lehrer & Gevirtz, 2014). That is, heart rate and breathing are exactly in sync. After a month of training their breath (i.e., training their non-sexual, autonomic arousal) in a non-sexual context, women in the HRVB condition were better able to perceive another aspect of their autonomic arousal, namely their genital arousal. Although perceived genital sensations may not be the most appropriate clinical outcome measure for all women with sexual arousal concerns (especially not for women who report a lack of mental arousal), it is the measure that is most relevant to the mechanism that was targeted in the HRVB condition.

This study had several limitations that warrant mention. First, baseline HRV was measured during the neutral segment of the neutralerotic film at each laboratory visit, as in previous studies (Stanton et al., 2018; Stanton & Meston, 2016). It is arguable that measuring HRV during the film is not a true baseline measurement, as women had already inserted the vaginal photoplethysmograph and were therefore anticipating the start of the erotic segment of the film. To avoid additional participant burden, we did not ask women to come to the lab for a separate visit to measure their baseline HRV. Limiting our measurement of baseline HRV to three "snapshots" in the laboratory may also have missed the effect of increasing HRV on some of the arousal indices. Baseline HRV could have been measured more times throughout the trial (e.g., at home every morning or every couple of days), though that might have been challenging for participants given the length of the trial. Second, three neutral-erotic films were prepared for this study, and the order of their presentation was randomized. Though extreme efforts were taken to match the films for content, some women likely found certain films more arousing than others. It is possible, though

unlikely, that preferences for certain settings or certain actors contributed to changes in genital or subjective arousal over time. Third, few participants completed the one-month follow up survey, which made it impossible to conduct any moderated mediation analyses. Such analyses would have helped us identify certain characteristics or demographic variables that make specific groups of women more likely to benefit from the intervention than others. The follow up survey was sent via email, and participants were not paid to complete it. In the future, dedicating additional monetary resources to the follow up protocol would help ensure that more data is collected.

Finally, we were unable to measure the pace of participants' breathing as they watched the films during the second and third assessment sessions. Though the participants did not engage in biofeed-back while viewing the films, it is possible that they intentionally decreased the pace of their breath to influence their sexual arousal. If this did occur, the mediation effect may be due to the use of acute paced breathing rather than to changes in underlying autonomic flexibility. However, given that participants already had another task to complete while watching the films (continuously report their subjective arousal using the arousometer), it is unlikely that they would have been able to maintain the six breaths per minute pace (or a similarly slow breathing rate) throughout the films.

The results of this study suggest several targets for future experiments that examine the relationship among female sexual arousal, HRV, and autonomic balance. It will be crucial to establish the ways in which increased HRV influences female sexual arousal in the positive direction. It is clear that increased HRV facilitates increases in perceived genital sensations and that larger increases in HRV drive greater changes in subjective sexual arousal, but it is not yet evident how increased HRV catalyzes these effects. A more nuanced examination of the mechanisms underlying the relationship between HRV and sexual arousal may reveal the importance of additional variables to isolate during treatment for arousal concerns, such as sensory acuity, interoceptive awareness, and other physiological indices of autonomic regulation that may be related to but distinct from HRV. These examinations will be particularly important with respect to genital arousal, which increased as a result of the intervention, but the increases were unrelated to changes in HRV.

After the underlying relationship between HRV and the two components of female sexual arousal is elucidated, researchers and clinicians can begin to focus on treatment matching. It is unlikely that an intervention will be a good match for all women with arousal dysfunction, so particular care must be taken to identify the women who would most benefit from HRV biofeedback, autogenic training, or a combination of the two. Increasing HRV via HRV biofeedback may be particularly appropriate for women with decreased genital sensations. Given that women who present with low arousal may not identify their concerns as primarily subjective or primarily genital, it is important that researchers ask participants to describe the nature of their arousal problem via direct, standardized questions that inquire about the presence of genital sensations as well as the level of mental engagement during sexual activity. If they continue to develop treatments that do not specifically target one or both types of arousal, new interventions may fail to improve women's specific symptoms. We also encourage clinicians to engage in the same thorough assessment of their patients' arousal concerns. When both researchers and clinicians address the two components of sexual arousal in their work and acknowledge that some interventions may be more applicable to women with certain symptoms, we will ultimately increase the number of treatment options and adequately meet the needs of these women.

One of the greatest strengths of this study is the privacy and portability of the intervention. App-based, at-home HRV biofeedback with and without autogenic training will be clinically useful for the women who find group-based sexual health interventions unappealing and the women who are unable to access these groups. With some initial guidance from a therapist or health professional, women who are not interested in disclosing their arousal problems to a group will be able to access and engage in treatment from the privacy of their homes. Women living in rural areas can guide themselves through treatment without weekly visits with a provider. In the future, it may be clinically beneficial to increase the availability of mobile interventions for FSAD and other sexual problems both to reach the widest possible audience and to potentially circumvent sexual health-related stigma.

In summary, our intervention had meaningful effects on genital arousal, subjective arousal, and perceived genital sensations. There is some evidence that the effects are indeed mediated by increased HRV, but it appears likely that there are multiple mechanisms at play. This intervention may particularly appropriate for women with FSAD secondary to high SNS activity and low parasympathetic cardiac control, such as women with a history of childhood sexual abuse, sexual anxiety, and PTSD. Future research aimed at shedding light on the mechanisms of action of HRVB and HRVB + A should include multiple mediators at multiple levels assessed frequently throughout the intervention, which would allow testing of specific and causal effects (Kazdin & Nock, 2003). In the meantime, clinicians should consider offering HRV biofeedback or the combination of HRV biofeedback and autogenic training to female patients with both genital and subjective arousal concerns.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2018.10.016.

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