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**A controlled Pilot Study to test the Online Intervention Self:Cervix focusing on cervical
Pain, Numbness, sexual Pleasure and Well-being**

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Abstract

There is a need for more holistic and multidisciplinary approaches to treat female sexual dysfunction disorders. New programs to improve female sexual experiences or help with sexual dysfunctions have been created. In a controlled pilot study, we evaluated *Self:Cervix*, an online intervention aimed to increase women's sexual pleasure and reducing genital pain and/or numbness through guided self-massage, mindfulness techniques to increase pleasure, and learning about consent.

To this end, 36 women in the intervention group and 25 in an untreated control group (CG) filled in online questionnaires twice across a 6-month interval. In this period, *Self:Cervix* participants took part in three 21-day online courses. Outcome criteria were genital numbness, sexual functioning, and pain during intercourse in addition to attitudes towards women's genitals and psychological well-being. There were no significant effects on numbness and pain in the repeated measures analysis of variance. However, compared with the control group, women in the intervention group showed significantly increases in *desire* ($p \leq .010$, $\eta^2 = .122$), *arousal* ($F = 7.114$, $p \leq .010$, $\eta^2 = .122$), and psychological well-being (anxiety: $F = 12.227$, $p < .001$, $\eta^2 = .172$; depression: $F = 4.887$, $p \leq .031$, $\eta^2 = .076$; somatization: $F = 5.465$, $p \leq .023$, $\eta^2 = .086$) and more positive attitudes towards women's genitals. To conclude, participants benefited from *Self:Cervix* in some areas, but more research is needed with more sensitive measures to capture more subtle changes in genital sensitivity and numbness.

Keywords

Female sexuality, cervix, evaluation, controlled study, online intervention

1 Introduction

Sexual health plays an integral part in overall health, well-being and quality of life according to the World Health Organization (World Health Organization, 2018). But still there is a high prevalence of sexual function disorders which may limit the quality of life of the affected persons (Khajehei, Doherty, & Tilley, 2015). Up to 43% of women and 31% of men suffer from sexual dysfunction in the USA (Laumann, Paik, & Rosen, 1999). Although prevalence of sexual dysfunction is higher for women, far more research has been carried out on male sexuality (Komisaruk, Beyer-Flores, & Whipple, 2006). The high prevalence rate for women in particular might be interpreted as a societal mirror of phallogocentric scripts of sexuality which encourages women to disregard their own sexual needs and instead prioritize their (mostly male) partner's sexual interests (Fahs, 2014; Willis, Jozkowski, Lo, & Sanders, 2018) even at the cost of pain or sexual dissatisfaction (Elmerstig, Wijma, & Swahnberg, 2013; Fahs, 2014). Additionally, female gender roles placing a high emphasis on women's appearance may be detrimental to women's positive sexual experiences (Peixoto, Amarelo-Pires, Pimentel Biscaia, & Machado, 2018; Woertman & van Den Brink, 2012).

In contrast with the obvious need for evidence based interventions, even the most popular approaches to help women with sexual dysfunctions were not consistently supported by research or showed small effects (Pereira, Arias-Carrión, Machado, Nardi, & Silva, 2013), for instance $d = 0.46$ for female orgasmic disorders (Frühauf, Gerger, Schmidt, Munder, & Barth, 2013) leaving room for improvement or innovative approaches. Recommended treatments focus, for instance, on sensate focus, the PLISSIT approach (Providing Permission, Limited Information, followed by Specific Suggestions if the problem is not resolved, followed by Intensive Therapy), cognitive behavior therapy (CBT), directed masturbation, couple therapy, or mindfulness based approaches (Laan, Rellini, & Barnes, 2013). Apparently, there is a link of mindfulness with greater awareness of bodily sensations

and hence higher levels of sexual desire and arousal (Brotto, Chivers, Millman, & Albert, 2016; Pepping, Cronin, Lyons, & Caldwell, 2018). In an overview of treatment recommendations, Basson et al. conclude that “there remains a need for more research and scientific reporting on the optimal management of women’s sexual dysfunctions including multidisciplinary approaches” (2010; p. 314).

Thus, current interventions may be enhanced by incorporating a more holistic view of female sexuality beyond the focus on functioning. Parallel to this, scholarly attention towards the complexity of female sexuality is only currently developing (Basson, 2000; Komisaruk et al., 2006), challenging the notion of the linear sequential model of desire, arousal, peak orgasm, and resolution of Masters und Johnson’s human sexual response cycle (Masters & Johnson, 1966). To date, there still seems to be a lot of miseducation and disagreement in the area of female sexuality with misperceptions about the female genitals and sexual experiences. For instance, Kinsey and colleagues (1953) have considered the cervix “numb” based on early studies. It took decades before this was scientifically challenged. Today we know that the cervix is an organ with highly erogenous abilities (Jannini et al., 2012; Komisaruk & Whipple, 2011; Komisaruk et al., 2004).

If we were to complement current standard treatments, we may turn to the field of sex and body therapy approaches that are developed in practice and based in Tantric school of thought (Lousada & Angel, 2011) as one potential source for new multidisciplinary and holistic techniques. These approaches are, for instance, online courses with instructions and inspirations for women on how to focus more on their own pleasure and to develop a more individual expression of their sexuality (to name a few: <https://start.omgyes.com/>, <http://mariahfrea.com/reconnect-with-vagina>, <http://gettingnaked.com.au/2015/02/20/genital-numbness-vagina-asleep/>). However, the evidence base as well as the theoretical foundation of many of these approaches is not clear.

If women with clinical or sub-clinical levels of sexual dysfunctions turn to these offers, the medical sector should be aware of this and encourage scientific tests not only to protect the consumers but also to be aware of potential effective approaches, which could enhance the limited effects of current mainstream treatments.

One of these online courses is Self:Cervix (S:C; <https://selfcervix.com>) created by sex therapist Olivia Bryant. The program aims to alter and intensify sexual pleasure in women. S:C is taught as an online course conceived as a 21-day cycle with daily video input and recommended practices as well as a closed facebook group to share experiences and get support. The pillars of S:C are anatomical and sexual education, self-massage to release pain and numbness in the genital area especially the cervix (called “de-arming”), and mindfulness techniques to increase pleasure and learn about consent. The focus on the cervix as an organ of pleasure is based on Komisaruk’s findings (Jannini et al., 2012; Komisaruk et al., 2011) and Tantric bodywork (Lousada & Angel, 2011) which offers a holistic view of interpersonal, intrapersonal, and transpersonal aspects of sexual experiences. So far, about 3,000-4,000 women participated in varying forms of the S:C program. Participants are mostly 35-45 years of age. Women hear about S:C mainly via social media and media coverage and pay a fee to participate. “De-arming” is supposed to increase sensitivity comparable to myofascial release in manual therapy (Barnes, 1997; Schleip, 2003). It should be noted that the S:C program is constructed for all women who are interested in their sexuality and not specifically for women affected by sexual dysfunction. Still many exercises in the S:C course are similar to interventions used for the treatment of sexual dysfunction and Olivia Bryant also refers to the course as a treatment option for numbness and pain.

The aim of the current study is to explore the efficacy of the S:C course, since this approach is innovative in focusing on the cervix, linking research findings from Komisaruk and tantric knowledge (Lousada & Angel, 2011). Thus, this pilot trial could potentially

inform and enrich mainstream interventions for female sexual functioning. We chose to evaluate an online program, because there are a number of non-evidence based online interventions available, which need scientific scrutiny. It is necessary to test these interventions critically to protect users from potential harm. We hypothesize, that S:C will have a positive effect on the participants' sexual functioning, psychological well-being, numbness and pain in the cervix and other genital areas, attitudes towards women's genitals compared with the control group.

Methods

Procedure

The current study used a controlled repeated measures design to assess the effects of the S:C program with two groups of women: participants of the S:C program vs. an untreated control condition. Both groups filled in online questionnaires (in English language) at two time-points approx. six months apart (t1 and t2). The S:C program tested here consisted of three 21-day periods of intensive practice every other month with time in between stretching over approximately six months. During the 21-day period, women can access video tutorials and interviews daily. In the videos women are guided through the "de-arming" technique, learn about dealing with intense emotions that may arise, about consent, mindfulness techniques, and female sexual anatomy. Women are encouraged to set aside an hour of their day within this period for the "de-arming" practice in a stepped approach which women can do at their own pace. Additional support is given if necessary via online communication and exchange in the closed Facebook group. The survey was in English and online via Unipark, an academic, secure online survey tool.

Inclusion criteria were women identifying as female, sufficient command of the English language, age ≥ 18 years, as well as pain and/or numbness in the vaginal/cervical

area during sexual penetration or gynecological examination. Since we did not have any professional screening for the inclusion criteria of pain or numbness, we relied on the self-assessment of the potential participants. Participants had the chance to enter into a raffle to win one of four 20€ gift vouchers at each measurement point. We ensured participant's anonymity via an individual code created by participants. Participants gave their informed consent. The study received an ethics approval by the ethics board of the (omitted for blinded review). Data collection took place between January and December 2017.

Participants

108 women participated in the control condition, 107 women participated in the S:C group. Dropout rates were high (66.7% and 76.6%). Thus, only data from 36 control participants and 25 from S:C participants were available for the longitudinal analyses. To control for potential dropout bias, comparisons of drop-out and continuers were analyzed. The analyses yielded no significant differences at t1 in any of the sociodemographic or sexual functioning variables.

Participants were on average 32.53 years of age (SD=7.24) in the control condition and 39.84 years (SD=36) in the S:C condition. Most of the women in both groups lived in stable, long-term relationships (control: n=24, 66.7%; S:C: n=16, 64%) and about a quarter had children (control: n= 9, 25%; S:C: n=7, 28%). Overall, women came from twelve Western countries. The majority of participants lived in Germany followed by Australia. IG and CG differed significantly only in terms of age (IG was older) and country of origin (IG more from Australia). Table 1 shows a detailed description of the sample.

--- *Insert Tab. 1 about here.* ---

To control for potential dropout bias, comparisons of dropout and continuers were analyzed. The analyses yielded no significant differences at t1 in age, level of education, sexual functioning, depression, somatization, anxiety, aggressiveness, attitudes towards women's genitals, or child and relationship status of the women.

Instruments

Numbness in the cervical and vaginal area

Numbness and sensitivity in the cervical and vaginal area were assessed with the Self-Assessment of Genital Anatomy and Sexual Function (SAGASF-F) by Schober et al. (2004). The SAGASF-F is a questionnaire designed to assess the sexual functioning of women. In the original test, women are asked to indicate one of several options of size, position and appearance of their *clitoris, outer and inner lips, opening of the vagina, inside vagina, cervix and area of the anus*. For these areas, participants are asked to rate discomfort pain, sexual pleasure, orgasmic intensity, and the effort for achieving orgasms in the past twelve months. In the current analysis, we examined numbness, effort required to orgasm and reaction to touch for each area. The timeframe was reduced to "last month". Reliability of the SAGASF-F was satisfactory, re-test reliability between $r=.42$ to $r=.70$ (Meyer-Bahlburg, Dolezal, & Schober, 2006).

Sexual Functioning

The Female Sexual Function Index (FSFI) (Rosen et al., 2000) is a self-report instrument, measuring female sexual functioning. The test consists of 19 items, which provide scores on six domains and a total score. Domains include *desire, arousal, lubrication, orgasm, satisfaction and pain*. The questions concern the past four weeks prior to the completion of the test. Answers are given on a 5-point scale from *almost never or never*

to *almost always or always* with the option *no sexual activity* added for some items.

Reliability coefficients of the FSFI range from $r=.79$ to $.86$ and Cronbach's alpha for internal consistency values are $\alpha=.89$ and higher. A high construct validity of the questionnaire could be shown by significant differences in scores in women with sexual dysfunction disorders and control groups. Cut-off score for sexual dysfunctions is set at ≤ 26 (Wiegel, Meston, & Rosen, 2005).

Psychological well-being

The Symptom Checklist (SCL-90 R) (Derogatis and Unger, 2010) measures the subjective impairment by psychological and physical symptoms within the duration of 7 days on a 5-point scale from *not at all* to *extremely*. The SCL-90-R comprises nine dimensions with a total of 90 items. The SCL-90-R shows a good reliability of Cronbach's $\alpha=.97$ to $.98$ (Derogatis & Unger, 2010). For the current study, we used the dimensions *somatization*, *depression*, *anxiety*, and *aggression*. Cut-off scores are T-values ≥ 63 .

Attitudes towards female genitalia

The Attitudes Towards Women's Genitalia Scale (ATWGS) (Herbenick, 2009) consists of 10 items concerning women's perception of female genitals. Responses are given on a 4-point scale from *strongly disagree* to *strongly agree*. The internal consistency of the ATWGS was shown to be in the acceptable range with a Cronbach's alpha $\alpha=.85$. Likewise, the convergent validity was shown to be satisfactory (Herbenick, 2009).

Adherence and participant evaluation

We collected data on adherence, Facebook group participation, and recommendation to a friend.

Statistical Analysis

For the comparison of the groups across time, we calculated repeated measures ANOVA with the factor time and group. Dependent variables were sexual functioning, attitudes towards women's genitals, anxiety, somatization, depression, and aggression.

For the ordinal scales (pleasure, orgasm, and discomfort/pain ratings for different genital regions), we calculated non-parametric Wilcoxon signed-rank tests. For the dropout analyses we compared age, sexual functioning with a ANOVA between the groups and relationship status and having children with a χ^2 -test. All test assumptions were checked prior to the analyses. Violations of assumptions were only noted for the anxiety scale. For the sake of consistency, we still carried out ANOVAs. However, these results need to be interpreted with caution. Alpha level was set to .05 and effect sizes were interpreted according to common standards. Data were analyzed using SPSS 24.0. In view of the high dropout rates, we calculated a post-hoc power analysis using G*Power (Faul, Erdfelder, Lang, & Buchner, 2007). For a repeated measures analysis of variance with two groups and two measurement time points and moderate effect sizes ($f=.025$), the test power was .93 for $n=25$ of the (smaller) control group.

Results

Changes across time

Changes from beginning to the end of the intervention interval were analyzed with analyses of variance with repeated measures and group as a second factor. Overall, there were no significant changes in terms of global **sexual functioning** (FSFI) for both the intervention and the control group. Table 2 shows means and standard deviations. However, on the

subscale level the intervention group had a significant increase in *arousal* and *desire* compared with no change/decrease in the control group (time*group: *arousal* ($M_{t1-IG} = 4.00$, $M_{t2-IG} = 4.45$, $M_{t1-CG} = 4.45$, $M_{t2-CG} = 4.06$, $F = 7.114$, $p \leq .010$, $\eta^2 = .122$; *desire* $M_{t1-IG} = 3.08$, $M_{t2-IG} = 3.65$, $M_{t1-CG} = 3.72$, $M_{t2-CG} = 3.35$, $F = 7.739$, $p \leq .008$, $\eta^2 = .132$). These effects were in the range of moderate effect sizes. Neither *pain*, *satisfaction*, *orgasm*, nor *lubrication* changed significantly across time.

--- Insert Tab. 2 about here. ---

Changes in the **sensitivity in genital regions** were tested with Wilcoxon's signed rank test for intervention and control group separately across time. There were no significant changes for the cervix, the labia, and the clitoral area in terms of pleasure, orgasm, or discomfort/pain. However in the intervention group, discomfort/pain was reduced deep inside the vagina and pleasure increased (pain: $Z = 3.660$; $p < .001$; pleasure: $Z = 2.138$; $p \leq .033$). For the control group orgasm experience was reduced in this area ($Z = 2.287$; $p \leq .022$). Secondly, for the vaginal opening pleasure increased significantly in the intervention group ($Z = 2.054$; $p \leq .040$) but not in the control group.

In terms of **mental health**, there was a significant decrease in anxiety (time*group: $F = 12.227$, $p < .001$, $\eta^2 = .172$), depressive time*group: ($F = 4.887$, $p \leq .031$, $\eta^2 = .076$), and somatization symptoms (time*group: $F = 5.465$, $p \leq .023$, $\eta^2 = .086$) in the intervention group compared with no change in the control group (see Tab. 2). These effect sizes were moderate to large. Aggressiveness did not change significantly across time in any of the two groups.

The **attitudes towards women's genitals** improved significantly in the intervention group compared with no change in the control group (see Tab. 2). The difference was in the magnitude of a large effect size.

Adherence and participant evaluation

The women participating in S:C practiced on average $M = 3.92$ (range 0-18) per 21-day period. Sixty-eight percent reported that they watched most/all of the accompanying videos. When asked, how closely they followed the S:C recommendations, 28% said closely/very closely, 48% said fairly closely. Mostly, the women said they listened to their own impulses, changed the pace (e. g. take more time) or continued with clitoral stimulation. Sixty per cent of the participants reported that they checked on or contributed to the Facebook group chat often/very often (8% not at all). Eighty per cent of the participants will definitely continue with the S:C work, the rest probably will. Sixty per cent would definitely recommend S:C to a friend (36% probably, 4% might not).

Discussion

We aimed to test the effects of the S:C online course compared with a control group. Contrary to the S:C rationale, the women in the IG did not report significant improvements of the level of numbness around the cervix and inner vagina. Whether this finding is due to a lack of practice (women applied the self-massage only four times during a 21-day period instead of daily as recommended) or a lack of sensitivity to detect change in the measures used cannot be answered here. Likewise, it is possible that some kind of sleeper effect of the Self:Cervix program would become apparent only a couple of months after the program, provided participants keep practicing. Alternatively, the “de-armoring” approach may not be suitable to reduce pain and numbness in the cervical region as hypothesized (when practiced at the low rate that the women reported).

However, there were significant changes in some genital regions, namely a reduction in discomfort/pain and an increase of pleasure deep inside the vagina as well as an increase of pleasure in the vaginal opening. This seems to underpin the notion that myofascial release is possible for women in the genital area (Barnes, 1997; Schleip, 2003). Women were encouraged to work at their own pace and individually on the regions that they felt needed attention. Since the cervix is located deep inside the vagina, other areas may have been tended to first with the “de-armor” practice. This could explain the lack of change in the cervical region. Another explanation might be that “de-armor” at the cervix needs more time and ‘learning’ for sensitization to happen.

However, there was a significant increase in the experience of desire and arousal similar to other mindfulness interventions for sexual functioning (Brotto et al., 2016). Both aspects of sexual functioning seem to be more psychological in nature than lubrication, pain and orgasm and may thus have benefited more from the mindfulness and self-care/-love focus of S:C. This is in line with evidence suggesting that women’s level of mindfulness is related to an increased experience of sexual pleasure due to an improved ability to focus the mind during sexual activities (Adam, Géonet, Day, & de Sutter, 2015).

Interestingly, S:C seemed to have a greater impact on the psychological well-being of the women than on the actual sexual functioning as rated with the FSFI. Drawing on the empirical results of the qualitative study that we carried out in parallel (omitted for blind review), women reported that through the intensive focus on their genitals and the “practical self-love” through the self-massage, they developed a greater sense of empowerment and satisfaction with their bodies and themselves allowing to taking better care of themselves and treating themselves in a more loving way. This stronger connection to their genitals and thus their femininity might have led to the strong improvements in psychological well-being.

Additionally, the results of the current analysis indicated a significant improvement in the participants' attitudes towards female genitalia. This may be due to the encouragement in S:C of taking time for oneself, taking care of oneself, developing a more intimate relationship with their own genitals with a mindful, non-judgmental, and loving attitude. Since there seems to be an association of a positive body image with the experience of sexual pleasure, this might increase pleasurable sexual interactions, too (Fredrickson & Roberts, 1997; Masters & Johnson, 1970; Quinn-Nilas, Benson, Milhausen, Buchholz, & Goncalves, 2016; Robbins & Reissing, 2018).

Another aspect of S:C was the optional group chat, which the women seemed to appreciate. Being able to listen to or participate in conversations about topics that are usually not talked about or even considered taboo (for instance vaginal odor or negative experiences with gynecologic procedures), may be another catalyst in helping women feel more positive about their femininity and their genitals. Even though, S:C may be a challenging intervention, the women who were followed-up would recommend it to a friend and would like to continue with the process.

Limitations

We would like to mention a number of limitations that need to be considered. First, we relied on subjective report only – more objective measures of sensitivity could be explored in future studies. The increases in tactile sensitivity of the participants of the current analysis could be present but too small to be quantified accordingly. The *FSFI* as a measure for sexual pleasure may not have been sensitive enough to capture subtle changes in numbness or pain. Additionally, the focus on functioning might have been too narrow to fully capture the range of experiences of female sexuality that may have changed in the course of S:C (Lousada & Angel, 2011). Furthermore, participants' adherence was low in terms of

frequency. The women reported practicing on average only 4 times. This might not have been sufficient to evoke detectable changes in numbness or sensitivity. Another issue that needs to be considered is the high dropout rate. We do not know whether this happened due to the lack of commitment in participating in an online survey or because of the potentially overly demanding nature of S:C, where some women might have been confronted with their insecurities or former traumatic experiences. This limits the external validity of the current study. Another limitation is the non-randomized group allocation, which weakens the internal validity of this study. In future studies, a more rigorous study design with more sensitive measures should be followed.

Conclusions and practical implications

The evaluation of S:C yielded some promising results, even though women practiced only 4 times on average per each 21-day period. To conclude, S:C is a promising new approach which might be helpful in the treatment of sexual function disorders in women, incorporating scientifically marginalized but potentially beneficial techniques of Tantric practice (Lousada & Angel, 2011). As a practical implication, cautiously drawn from this pilot study, there seems to be a considerable link between female sexual experience and psychological well-being. In terms of the low rate of adherence to the recommended daily practice during a three-week period, a more flexible design spread over a longer period may be more beneficial. In addition, this would then potentially lead to the expected changes in sensitivity. Future research should utilize more sensitive measures of sexual functioning and study a group of participants that practiced S:C on a more regular basis. With a more rigorous research design, we may gain insights whether the benefits of S:C indeed are to be found more on the psychological level than the physiological, like sensitivity, numbness, and pain.

Declaration of interests

The authors declare that they have no conflict of interest. No funding was received for this study.

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Table 1:

Characteristics of the S:C and control group (means and standard deviations or frequencies in percent)

	Intervention	Control
	n=25	n=36
	M (SD)	M (SD)
Age	39.84 (9.91)	32.53 (7.24)
	n (%)	n (%)
Gender		
Female	24 (96%)	36 (100%)
Other	1 (4%)	-
Country		
Australia	5 (20%)	1 (2.8%)
Austria	2 (8%)	-
Canada	-	1 (2.8%)
Germany	7 (28%)	27 (75%)
Netherlands	3 (12%)	-
New Zealand	-	5 (13.9%)
Portugal	1 (4%)	-
Sweden	1 (4%)	-
Switzerland	2 (8%)	-
United	-	-
Kingdom		
United States	2 (8%)	-

University education	21 (84%)	33 (91.7%)
Relationship status		
Long-term/stable	16 (64%)	24 (66.7%)
Single	9 (36%)	12 (33.3%)
Gender sex partner		
Male	23 (92%)	32 (88.9%)
Female	1 (4%)	-
Both	1 (4%)	3 (8.3%)
Other	-	1 (2.8%)
Children	7 (28%)	9 (25%)

Table 2:

Repeated measures analysis of variance with means and standard deviations of sexual functioning, attitudes towards women's genitals, depression, somatization, anxiety, and aggression for intervention and control group

	Self:Cervix		Control		F	<i>p</i>	η^2	
	t1	t2	t1	t2				
	<i>M</i>	<i>M</i>	<i>M</i>	<i>M</i>				
	(<i>SD</i>)	(<i>SD</i>)	(<i>SD</i>)	(<i>SD</i>)				
FSFI total	23.73	25.33	26.96	26.23	Time	0.393	.534	.008
	(7.43)	(7.07)	(5.26)	(6.43)	Time*group	2.781	.102	.052
SCL depression	14.68	9.32	15.28	14.69	Time	7.565	.008	.114
	(7.87)	(5.79)	(9.56)	(7.66)	Time*group	4.887	.031	.076
SCL somatization	8.29	5.96	8.53	9.19	Time	1.687	.199	.028
	(5.66)	(3.78)	(6.15)	(6.27)	Time*group	5.465	.023*	.086
SCL anxiety	7.12	3.40	6.58	6.61	Time	11.867	.001*	.167
	(4.32)	(2.80)	(5.34)	(5.76)	Time*group	12.227	.001*	.172
SCL aggression	4.04	3.32	4.42	5.06	Time	.008	.930	.000
	(3.10)	(3.58)	(4.42)	(4.72)	Time*group	2.168	.146	.035
ATWGS	34.36	37.44	33.78	32.53	Time	6.275	.015	.096
	(3.15)	(3.11)	(3.99)	(4.58)	Time*group	35.129	<.001*	.373

Note: ATWGS = Attitudes Towards Women's Genitals Scale; FSFI = Female Sexual Function Index; SCL = Symptom Checklist, * $p \leq .05$