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The Impact of Psychosexual Counseling in Women With Lichen Sclerosus: A Randomized Controlled Trial

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Introduction: Lichen sclerosus (LS) can affect sexuality and quality of life (QoL).

Objective: The aim of the study was to evaluate the impact of psychosexual counseling in women with LS.

Materials and Methods: One hundred fifty-eight women 18 years or older, newly diagnosed with LS, and referred to North Denmark Regional Hospital from January 2018 to November 2019 were included. The women were randomized in a 1:1 ratio to usual care or an intervention group receiving usual care and up to 8 individual consultations with a specialist in sexual counseling. Spouses or partners were encouraged to participate. The women filled out the questionnaires Female Sexual Function Index (FSFI), Dermatology Life Quality Index, and the WHO-5 Well-Being Index at baseline and after 6 months.

Results: The controls presented a mean score of 14.8 ± 8.7 and the intervention group presented a mean score of 12.8 ± 8.9 at FSFI. At follow-up, the controls had an FSFI score of 15.2 ± 9.2 and the intervention group revealed an FSFI score of 18.3 ± 9.5 . Both groups experienced improved sexual functioning and for the intervention group the increase was significant ($p < .001$).

At baseline, the Dermatology Life Quality Index mean score was 8.9 ± 5.6 for the control group and 9.3 ± 6.1 for the intervention group. At follow-up, the controls revealed a score of 8.6 ± 5.5 and the intervention group a score of 6.8 ± 5.8 . The intervention group reached a significantly higher degree of QoL than the controls ($p = .008$).

Conclusions: Psychosexual counseling has a significant impact on sexual functioning and QoL in women with LS.

Key Words: vulvar lichen sclerosus, sexual dysfunction, sexual behavior, quality of life, sexual counseling, intervention

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Lichen sclerosus (LS) is a chronic inflammatory skin disorder, which primarily affects the anogenital skin in women of all ages and is mostly seen in prepubertal girls and in perimenopausal and postmenopausal women. A positive family history in women with LS has been reported in up to 12%–17% of cases.^{1,2} Ultrapotent topical steroids are recommended as a first-line treatment, and

most patients get symptomatic relief after having followed a standard regime, but there is no definitive cure for LS.^{2–4} Lichen sclerosus is associated with increased risk of vulvar squamous cell carcinoma with a life-time risk of approximately 5%.^{5,6}

Lichen sclerosus causes substantial discomfort (eg, itching and soreness) and architectural changes (eg, scarring, phimosis, whitening, and narrowing of the vaginal introitus).^{1,2,7} Women with LS often experience pain, and in cases with advanced LS, the introitus may become narrow, which results in painful sexual intercourse or prevents sexual penetration altogether.^{8,9}

Lichen sclerosus is a significant impairment in many different aspects of a woman's life. Lichen sclerosus negatively impacts overall quality of life (QoL), particularly in the arenas of sexuality, intimate relationships, and mental health.^{1,5,8,10}

Because of the architectural changes in the vulva, some women are ashamed, embarrassed, and potentially uncomfortable and insecure being intimate with a sexual partner.^{6,7} Women with LS who seek care have considerable QoL impairment and report both sexual problems and an impact on their general happiness. These women also report trying to avoid and withdraw from sexual intimacy.^{1,2,8,11,12}

A number of studies documented that the QoL and sexuality of women with LS are affected, such that they should have been offered counseling by a sexologist in line with the European guideline for the management of vulvar conditions.^{5,8,12} The effect on women with LS' QoL and sexuality was confirmed in a previous study, which also included the population of the present study.¹⁰

However, there are no studies that document the effect of such interventions. The aim of the present study is to evaluate the effect of a psychosexual intervention focusing on QoL and sexuality.

METHODS

This randomized controlled study was conducted according to the Declaration of Helsinki. It took place from January 2018 to November 2019 in the North Denmark Regional Hospital, Hjoerring, Denmark. The local data authorities and local ethical committee approved the study protocol (N-20170082), and the study was registered at ClinicalTrials.gov under the identifier NCT03419377. Oral and written informed consent was obtained from all participants.

Participants

One hundred fifty-eight women diagnosed with LS in the outpatient vulvar unit at the Department of Obstetrics and Gynecology, North Denmark Regional Hospital, were included. Inclusion criteria were 18 years of age or greater and newly diagnosed with LS. Exclusion criteria were women who could not speak and understand Danish and women with an untreated psychiatric disorder. A gynecologist that specialized in vulvar diseases diagnosed the women based on their history and on clinical findings. If the clinical diagnosis was uncertain or dysplasia/carcinoma suspected, biopsies were taken.⁴

A specialized nurse informed the women about the project and ensured written informed consent was given before

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The authors have declared they have no conflicts of interest.

This study was performed in compliance with the Declaration of Helsinki. The North Denmark Regional Committee on Health Research Ethics (N-20170082), and the Danish Data Protection Authority (2008-58-0028) approved the protocol. The study is registered in ClinicalTrials.gov NCT03419377.

The data presented in this study were previously mentioned in Vittrup et al.¹⁰ Copyright © 2022 The Author(s). Published by Wolters Kluwer Health, Inc. on behalf of the ASCCP. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.

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participation. From such population, the baseline data, the demographic, and the data found in the questionnaires outlined in the following section were presented in the previously mentioned previous article documenting the participating women's QoL and sexuality.¹⁰

All eligible women were randomized 1:1 to either an intervention group or a control group. The women completed the questionnaires electronically using Research Electronic Data Capture (REDCap) tools hosted in the North Denmark Region before participation. After 6 months, they received an email with the questionnaires again and were sent reminders if they did not respond.

Measures

For assessment of the women's experience in relation to sexuality, dermatology, and QoL in general, the following 3 standardized and validated questionnaires were filled by the women; Female Sexual Function Index (FSFI),¹³ Dermatology Life Quality Index (DLQI),¹⁴ and the WHO-5 Well-Being Index (WHO-5).¹⁵

Female Sexual Functioning Index

The FSFI is a self-reporting measure of sexual functioning that has been validated through a clinically diagnosed sample of women with female sexual arousal disorder and women with vulvodynia.^{16,17} The total score ranges from 2 to 36; a higher score indicates better sexual functioning. Sexual inactivity was defined as women answering “no sexual activity” to any question where this was an option.¹³

Dermatology Life Quality Index

The DLQI is a questionnaire with 10 questions used to measure the impact of skin disease on QoL. It has been validated for dermatology patients.¹⁸ The DLQI is calculated by scoring each of the 10 questions with 0–3 points, with a maximum score of 30, in accordance with the guidelines; a lower score indicates better QoL.¹⁴

WHO-5 Well-Being Index

The WHO-5 is a generic global rating scale measuring subjective well-being. Each of the 5 areas is scored from 0 to 5, where 5 is “all the time” and 0 is “none of the time.” The raw scores range from 0 (no well-being) to 25 (maximal well-being). Because scales measuring health-related QoL are conventionally translated to a percentage scale from 0 (none) to 100 (maximal), it is generally recommended that the raw score is multiplied by 4. A cutoff score of 50 or less on the WHO-5 indicates signs of depression.¹⁵

Management—Usual Care

When diagnosed, the women received oral information individually, as well as general written information about LS, including symptoms and treatment, the prognosis, and good advice on how to deal with a chronic vulva disorder. The first-line treatment of LS is the use of an ultrapotent topical corticosteroid in combination with a fatty cream and oil massage of the vulva.⁴ They were taught that LS is not a curable disease but that the treatment is given primarily to reduce symptoms, reduce scarring, and avoid malignancy. Three months after initiating treatment, each woman had a consultation by phone with a nurse specialized in vulva diseases to adjust the treatment regimen, to strengthen compliance and medication adherence, and finally to provide support to the women. The women were then encouraged to be reviewed annually by their general practitioner.

Management—Intervention

As well as the above, the women in the intervention group were offered up to 8 individual sessions of psychosexual counseling within 6 months after inclusion. The sessions were based on individual needs and problems. Each session lasted 45 minutes. Women in established relationships were encouraged to invite their partners to participate.

The psychosexual counseling (see Figure 1) was tailored and based on biological, psychological, and social aspects, considering religious and cultural background. When the mutual aims of treatment were reached, the patient was discharged.

The aim of the psychoeducative approach and support was to ensure that the women and their partners obtained sufficient knowledge about LS, including the importance of optimal treatment of LS to strengthen compliance, and that they gained motivation to be responsible and secure in treatment.

Through prescription of structured behavioral assignment, sensate focus was performed at home either by the women alone or with their partner. Sensate focus aimed to restore pleasurable sexual activities and for that reason intercourse and breast and genital touching were initially prohibited. When feeling ready and willing to continue, the activities were enriched with genital touching, gradually working up to full intercourse.¹⁹

In cases where a phobic response to a certain sexual stimulus, for example, painful intercourse, was evident, desensitization treatment was introduced. The woman and/or their partner was encouraged to list the level of distress for the various types of exposure to sexual situations. The intervention was performed by teaching relaxation skills and by gradual exposure, beginning with the least distressing sexual situation. When the women and their

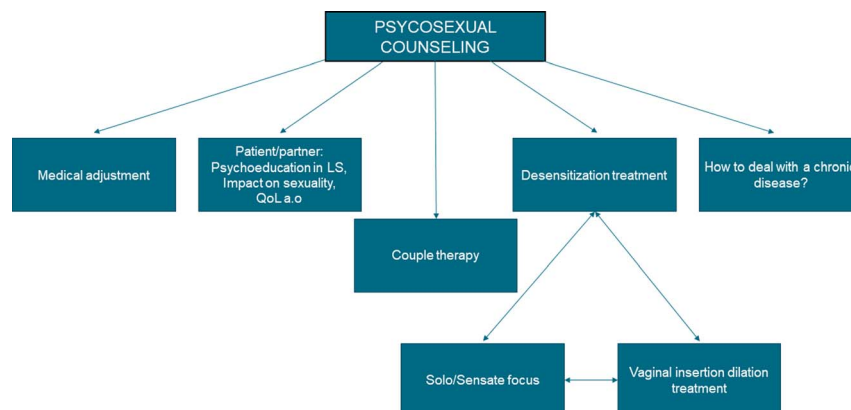


FIGURE 1. Structure and content of psychosexual counseling.

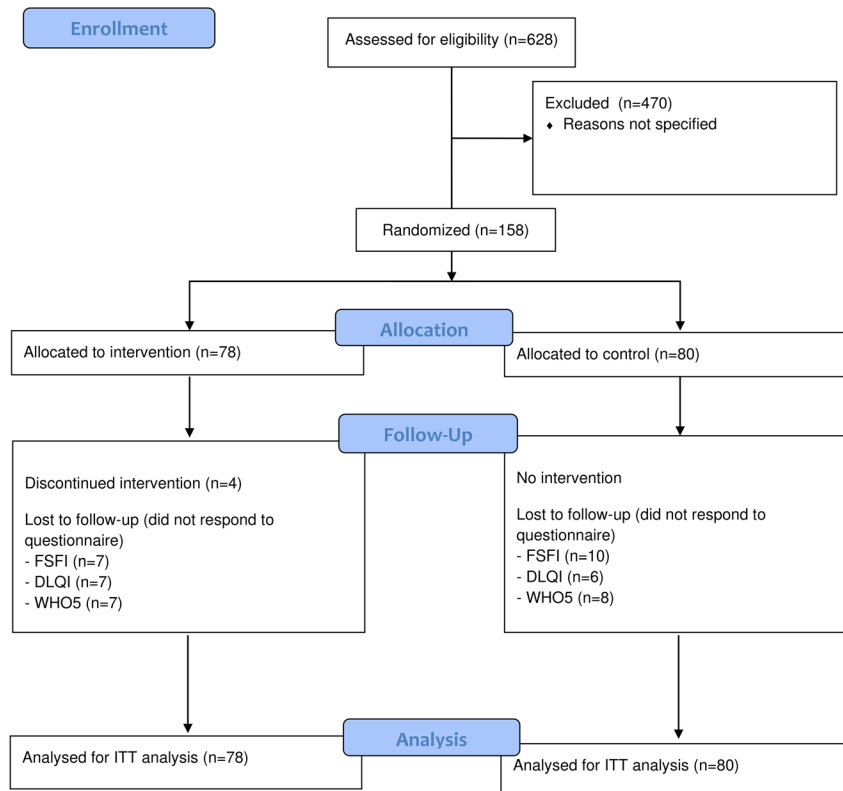


FIGURE 2. Inclusion process and flow of participants.

partners agreed on having intercourse, vaginal insertion dilation treatment, either with the fingers or dilators in increasing sizes was thoroughly introduced.

STATISTICAL METHODS

We based our a priori sample size calculations on available evidence for the DLQI, giving a minimal important difference of 2.97 and an SD of 5.5.²⁰ To detect this difference at 90% power and an α level of 5% we determined that a total of 144 participants (72 in each group) were needed to complete the trial.

Baseline characteristics were reported as numbers and percentages for categorical data and, for continuous data, as means and SDs if normally distributed, or medians and interquartile range if not normally distributed.

All analyses of results after the intervention period were performed as intention to treat analyses. Missing outcome data were set to baseline values, assuming no difference from baseline. To compare the differences between control and intervention groups, as well as across subgroups, we used analysis of covariance (ANCOVA) adjusted for the baseline value of the relevant outcome. A *p* value less than .05 was considered statistically significant. The mean difference from baseline with 95% CIs within respective groups was determined using paired *t* tests. Subscale results for the FSFI and DLQI were presented graphically as means and standard error. Results for changes in sexual activity between the control group and intervention group were determined using logistic regression, adjusted for baseline sexual activity status.

All statistical analyses were performed using R version 3.5.1 (R Core Team [2020], R: A language and environment for statistical computing; R Foundation for Statistical Computing, Vienna, Austria; <https://www.R-project.org/>).

RESULTS

A total of 158 women were randomized to the study as illustrated in Figure 2, and at a 6-month follow-up, 78 women in the intervention group and 80 women in the control group were analyzed in the intention to treat analysis. A total of 7 participants in

TABLE 1. Demographic Data

	Intervention (n = 78)	Control (n = 80)	<i>p</i>
Age, median (IQR)	53 (33.2–60.5)	50.5 (30.8–57.0)	NS
Waistline, mean ± SD	87.2 ± 11.8	86.2 ± 12.0	NS
Alcohol consumption, >7 U/wk	5 (6.4%)	11 (13.7%)	NS
Smoking, current/prior	27 (34.6%)	34 (42.5%)	NS
Relationship status, with partner	65 (83.3%)	67 (83.8%)	NS
Employment			NS
Employed	48 (61.5%)	45 (56.2%)	
Student	6 (7.7%)	13 (16.2%)	
Retired	20 (25.6%)	15 (18.8%)	
Other	4 (6.2%)	7 (8.7%)	
Educational level			NS
High school or less	19 (24.4%)	29 (36.3%)	
Some college or associate's degree	17 (21.8%)	13 (16.3%)	
Bachelor's degree or higher	42 (53.8%)	37 (46.3%)	
Other	0 (0.0%)	1 (1.2%)	

IQR indicates interquartile range; NS, non significant.

TABLE 2. Results

	<i>n</i>	Baseline, Mean ± SD	Follow-up, Mean ± SD	Effect size, Difference (95% CI)	<i>p</i> , ANCOVA
FSFI (higher score better)					
Control	80	14.8 ± 8.7	15.2 ± 9.2	0.4 (−1.2 to 2.0)	.0001 ^a
Intervention	78	12.8 ± 8.9	18.3 ± 9.5	5.4 (3.2 to 7.7)	
DLQI (lower score better)					
Control	80	8.9 ± 5.6	8.6 ± 5.5	−0.4 (−1.5 to 0.8)	.008 ^a
Intervention	78	9.3 ± 6.1	6.8 ± 5.8	−2.5 (−3.7 to −1.3)	
WHO-5					
Control	80	55.4 ± 20.5	56.4 ± 16.5	1.0 (−3.2 to 5.1)	.005 ^a
Intervention	78	57.9 ± 20.4	64.4 ± 18.9	6.4 (2.3 to 10.5)	

^a Comparing likelihood of being sexually inactive at follow-up between treatment group and controls adjusted for baseline values.

the intervention group and 10 participants (different between questionnaires) in the control group did not give full responses to follow-up questionnaires, and they were analyzed as a carry forward from baseline assuming no effect of intervention as a worst-case scenario.

As illustrated in Table 1, the intervention group and the control group were similar at the start of the trial.

The women in the intervention group experienced a strongly significant effect of the psychosexual counseling on their FSFI, DLQI, and WHO-5 scores (see Table 2). At baseline, 33 of the women (42.3%) in the intervention group were not sexually active, compared with 30 of women (37.5%) in the control group. After 6 months, this number was reduced to 19 (24.4%) and 27 (33.8%), respectively. This difference is nonsignificant ($p = .09$).

Table 3 illustrates the significant difference according to the FSFI score in women who are sexually active versus women who are not sexually active at baseline and at follow-up. Both groups were significantly affected by the intervention, although the largest effect was seen in nonsexually active women.

Table 4 shows intervention group characteristics associated with the effect of treatment on the FSFI in this group. It is shown that a greater number of counseling sessions, counseling with a partner, and vaginal insertion dilation treatment were all associated with greater improvement in the FSFI. However, because treatment was tailored to individual needs, the intervention group, nevertheless, still showed low scores at baseline compared with the control group.

The FSFI contains of 6 subgroups as illustrated in Figure 3. The effect of psychosexual counseling is significant for all subgroups for orgasm ($p = .02$) and for desire ($p = .002$), arousal ($p = .01$), lubrication ($p = .002$), satisfaction ($p = .001$), and pain ($p = .008$).

There is a significant difference in the score of sexual difficulties according to the DLQI ($p = .034$), but no significant difference is demonstrated in symptoms ($p = .056$), embarrassment ($p = .057$), shopping and home care ($p = .23$), clothes ($p = .098$), social and

leisure time ($p = .83$), sport ($p = .73$), work or study ($p = .12$), partners, close friends, or relatives ($p = .15$), and treatment ($p = .14$).

DISCUSSION

The present study is the first study examining the effect of psychosexual counseling on sexuality and QoL in women with LS. The results show a significant effect on sexuality, QoL, and well-being. Despite the significant positive effect of the intervention, however, it is worth noting that the majority of the participating women still score less than 26.55 on the FSFI, showing that these women have a need for sexual treatment.²¹

We showed that psychosexual counseling in combination with usual care significantly improved QoL (measured by the DLQI) compared with usual care alone. It should be mentioned that the only DLQI question that was significant different between groups was related to sexual functioning. This supports the view that the primary gain of psychosexual counseling in the treatment of LS is improved sexual functioning and thereby QoL. As we have previously documented, the sexual functioning of women with LS is severely impacted, and thus, improvement in this domain may also be assumed to improve overall QoL. To further support this, we also showed improved overall well-being as measured by the WHO-5.

The usual care management of LS is a topical treatment according to the European guidelines, and it is well documented that this is effective for symptoms control in women with LS.⁴ However, the treatments may not result in improved sexual function.⁸ In accordance with these findings, the present study documents that while both groups of women reported lower degrees of itching, soreness, pain, and stinging on the DLQI (see Figure 4), the women who were only treated with an ultrapotent topical corticosteroid in combination with fatty cream still experienced almost unchanged pain during sexual intercourse after 6 months of treatment according to the FSFI (see Figure 3). In comparison, the women in the intervention group experienced significantly less pain during sexual intercourse and improved overall sexual function after

TABLE 3. Effect of Sexual Counseling on FSFI in Subgroups

	<i>n</i>	Baseline, Mean ± SD	Follow-up, Mean ± SD	Effect size, Difference (95% CI)	<i>p</i> , ANCOVA
Sexual activity at baseline					
Control, sexually active	50	19.4 ± 6.6	18.8 ± 8.2	−0.6 (−2.7 to 1.6)	Reference
Intervention, sexually active	45	18.5 ± 7.1	22.0 ± 8.3	3.5 (0.5 to 6.4)	.03
Control, nonsexually active	30	7.2 ± 6.0	9.2 ± 7.5	2.0 (−0.5 to 4.4)	Reference
Intervention, nonsexually active	33	5.0 ± 3.4	13.2 ± 8.7	8.2 (4.8 to 11.5)	.02

TABLE 4. Intervention Characteristics

No. counseling sessions					
Controls, 0 sessions	80	14.8 ± 8.7	15.2 ± 9.2	0.4 (−1.2 to 2.0)	Reference
Intervention 1–2 sessions	16	18.2 ± 9.9	19.9 ± 10.0	1.7 (−4.8 to 8.2)	NS
Intervention, 3–4 sessions	21	12.0 ± 9.5	15.6 ± 10.4	3.5 (−0.5 to 7.8)	NS
Intervention, 5–6 sessions	15	12.2 ± 7.5	17.8 ± 9.0	5.6 (1.8 to 9.4)	.01 ^a
Intervention, 7–8 sessions	26	9.2 ± 7.1	21.1 ± 8.3	11.9 (8.5 to 15.3)	<.0001 ^a
Partnered sessions					
Controls	80	14.8 ± 8.7	15.2 ± 9.2	0.4 (−1.2 to 2.0)	Reference
Intervention, no partner	12	12.8 ± 9.6	15.5 ± 10.1	2.7 (−2.2 to 7.7)	NS
Intervention, only solo sessions	22	14.5 ± 9.5	16.7 ± 10.3	2.3 (−2.6 to 7.1)	NS
Intervention, solo and partnered sessions	44	12.0 ± 8.4	19.8 ± 8.8	7.8 (5.0 to 10.6)	<.0001 ^a
Intervention with dilators					
Controls (no dilators)	80	14.8 ± 8.7	15.2 ± 9.2	0.4 (−1.2 to 2.0)	Reference
Intervention, no dilator	51	14.9 ± 9.4	18.9 ± 9.4	4.0 (1.1 to 7.0)	.006 ^a
Intervention, dilators	27	8.8 ± 6.2	17.0 ± 9.8	8.2 (5.0 to 11.3)	.003 ^a

^a Comparing likelihood of being sexually inactive at follow-up between treatment group and controls adjusted for baseline values.

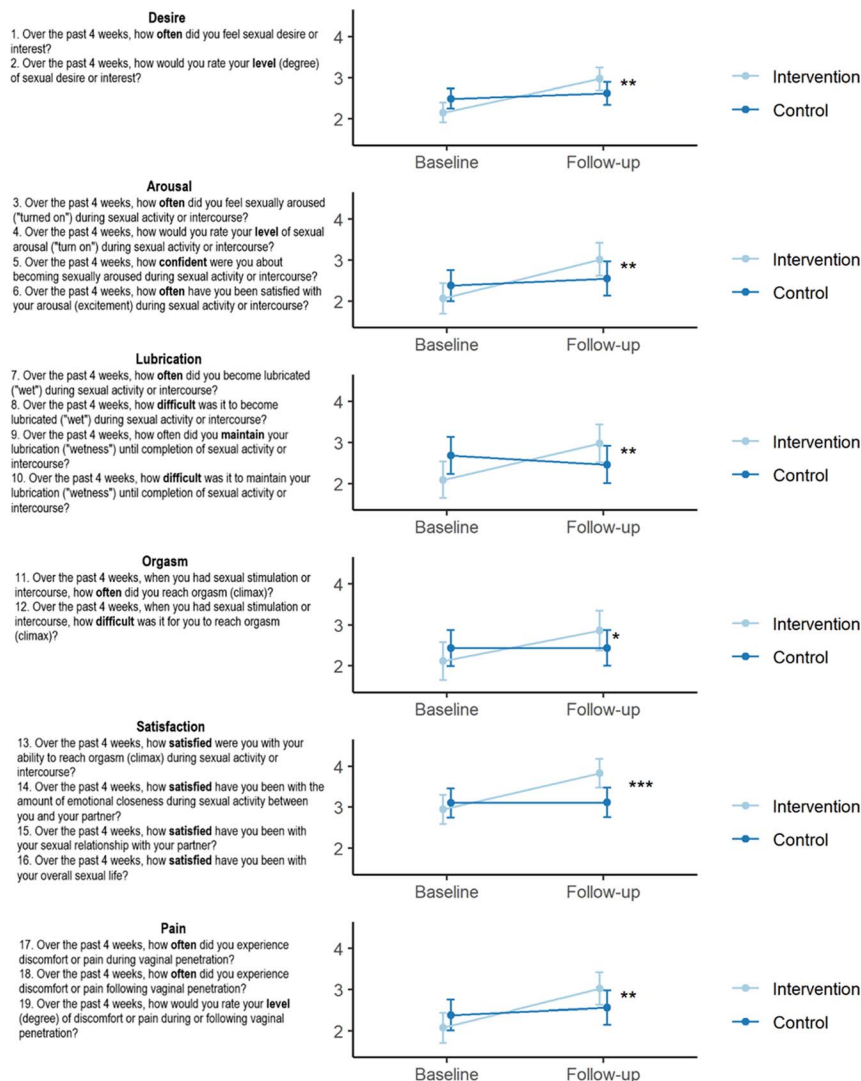


FIGURE 3. Effect of intervention compared with control on subscales of the FSFI questionnaire. Specific questions defining each subscale are shown to the left.

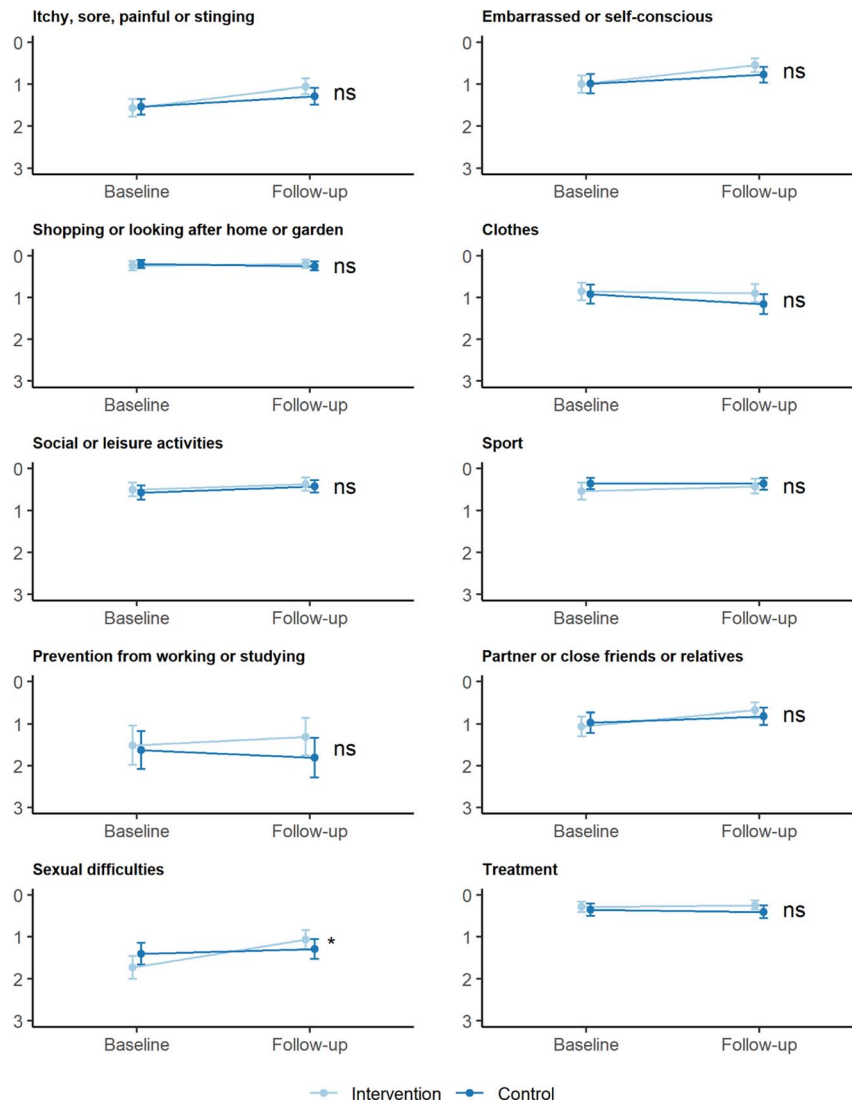


FIGURE 4. Figure shows effect of intervention compared with control on questions of the DLQI.

6 months of psychosexual counseling. No other studies examining the effect of psychosexual counseling in women with LS have been identified, but a cognitive behavioral approach for reducing vulvovaginal pain in women with sexual dysfunction has been found to be beneficial, especially in women with vulvodynia.^{22–24} Intimacy seems to be an important factor for the well-being among couples or individuals who are struggling with sexual dysfunction and health problems.²⁵

We found an association between the number of sessions and overall effect on sexuality, indicating a dose-response relationship of psychosexual counseling. Furthermore, we found no signs of ceiling effects and it is possible that some women might continue to benefit even beyond 8 sessions. However, as the number of sessions was tailored to individual needs, this secondary analysis is only exploratory, and results need to be confirmed in future randomized controlled trials. Our results do not allow us to establish the optimum number of sessions or whether the number of sessions should be individually tailored or standardized, and we have found no previous literature exploring this, thus underlining the need for future research.

Partners were encouraged to participate in the intervention in this study, and it is documented that women who involved their

partners in the treatment found that the treatment was significantly more effective than women who did not involve their partners. This result was confirmed by a former study documenting that for couples experiencing sexual dysfunction or sexual health problems, intimacy appeared to facilitate communication and the ability to express sexual needs, and thereby helped renew and renegotiate their sexuality.²⁵

A combination of sexual therapy and vaginal dilation treatment has been found to be beneficial, especially in women with vulvodynia who became able to regain the confidence to engage in sexual intercourse.²⁴ This present study confirmed that vaginal dilation treatment was associated with greater improvement in sexual function than psychosexual counseling alone. Another approach that seemed to enhance treatment was an explicit and systematic approach focusing on exposure to stimuli that had been feared.²⁶ A Canadian study of women with provoked vestibulodynia showed that higher pain self-efficacy was associated with lower pain experience during sexual intercourse and with better sexual function.²⁵ Both woman and partner have a role in the experience of painful sexual intercourse, and increasing partner involvement in treatment may serve to diminish feelings of guilt, and it may help in raising motivation toward changes and redefinition of their mutual sexual

relationship.²⁷ The reason why the partner should be involved is that he or she gains more knowledge of the many causes of pain, and this communication has been found to have a positive impact on the overall coping strategies.²⁸ Even when the partner was not directly participating in the intervention process, the woman was encouraged to improve her communication regarding her pain experience and to negotiate changes in her partner's behavior when it comes to pain.²⁸ Women without a partner could easily benefit from solo sensitization treatment, aiming to increase a positive relationship with their bodies and the erogenous zones.²⁵

There are several strengths of the present study. The randomization of the patients and the fact there was a very high response rate to the questionnaires is one strength. Another strength is the use of standardized and validated questionnaires. One of the limitations in the present study is the missing information around reasons for women not included in the study. Another limitation is that sexually related personal distress was not measured. Knowledge about a possible diagnostic delay of LS, the severity of the disease, or a possible sexual dysfunction before the onset of LS is also not assembled but was discussed during the sessions and as a basic part of the sexual history. Finally, it is important to consider that results exploring treatment effects based on number of sessions, partner involvement, and dilation treatment are all secondary analyses not benefiting from the initial randomization. Although we adjusted all analyses for baseline values, these results may still be subject to residual confounding and should be interpreted as associations rather than as causation. Therefore, these results also warrant confirmation through further research.

CONCLUSIONS

The present study documents the significant effect of psychosexual counseling on the experiences of women with newly diagnosed LS. The results confirm the recommendation in the European guidelines: that sexual dysfunction should be considered in all patients with vulvar conditions, either as the cause of the symptoms, or developed secondary to the symptoms, and assessed whether appropriate. The psychosexual counseling practiced in the present study included more interventions, like medical adjustment, couples therapy, desensitization treatment, etc. This study does not provide knowledge about whether it is individual elements in the treatment that have an effect or whether it is the overall course where the many elements are included. We suggest that the present study, in addition to the positive findings, leads to more studies documenting a possible effect of psychosexual counseling in women with LS.

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