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Research Article

A PLISSIT-Model Intervention in People with Type 2 Diabetes with Sexual Problems: Results from a Cluster-Randomized Controlled Trial in Primary Care

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Keywords

- PLISSIT
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Abstract

Introduction: Sexual problems are prevalent among people with type 2 diabetes, but often remain unaddressed in primary care. We hypothesized that the use of a stepped-care sexual counseling strategy, such as PLISSIT (Permission, Limited Information, Specific Suggestions, Intensive Therapy), would lead to improved (sexual) well-being.

Aim: To evaluate the effectiveness of a PLISSIT-model-based intervention on sexual functioning, sexual satisfaction, and quality of life in men and women with type 2 diabetes aged 40-75 years who indicated to be dissatisfied about their sexual functioning.

Methods: In a cluster-randomized clinical trial, participants were randomly allocated to the intervention or the control group in 44 general practices using block randomization. Participants in the intervention group were offered discussion of sexual issues with a PLISSIT-trained primary care physician (PCP); the control group received standard care.

Main outcome measures: The main outcome measures included subjective reports of sexual function, satisfaction with sexual function, and quality of life. Male sexual functioning was measured with the International Index of Erectile Function. Female sexual function was assessed with the Female Sexual Function Index. Satisfaction with sexual function was measured using a Visual Analogue Scale. Quality of life was measured with the Short Form-12 item survey. Outcomes were measured at baseline and after three and twelve months of follow-up in 44 general practices between January 2015 and February 2017. Longitudinal multilevel linear regression analyses were conducted, adjusted for age and sex.

Results: In total, 150 participants with type 2 diabetes (78.7% men, mean age 62.7 (± 8.5) years) were included (87 intervention; 63 control). Female sexual functioning significantly improved at three months follow-up (P=0.036): women in the intervention versus the control group had a 5.87 (SE 2.80) higher score on the Female Sexual Function Index, however after 12 months these differences disappeared. No other statistically significant effects were observed. Nevertheless, PLISSIT-trained PCP's reported a significant improvement in their competence to discuss sexual issues.

Conclusions: Compared to standard care, the PLISSIT-model intervention improved short-term female sexual functioning in women. More intensive, specialized treatment may be necessary to improve male sexual functioning. The PLISSIT-framework may help PCP's to discuss sexual health in diabetes care.

Trial registration: Dutch Trial Registry (NTR4807

ABBREVIATIONS

BSSC: Brief Sexual Symptom Checklist; CONSORT: Consolidated Standards of Reporting Trials; ED: erectile dysfunction; FSDS-R: Female Sexual Distress Scale-Revised; FSFI: Female Sexual Function Index; ICC: Intra-cluster Correlation Coefficient; IIEF: International Index of Erectile Function; MCS: Mental Component Summary; PCP: Primary Care Physician; PCS: Physical Component Summary; PHQ-9: Patient Health Questionnaire; PLISSIT: Permission, Limited Information, Specific Suggestions, Intensive Therapy; RCT: Randomized

Controlled Trial; SD: Standard Deviation; SF-12: Short Form-12 Item Survey; VAS: Visual Analogue Scale; WHO-5: World Health Organization-Five Well-Being Index

INTRODUCTION

Sexual dysfunction among men and women with type 2 diabetes is common, with erectile dysfunction (ED) being the most frequently reported sexual dysfunction (85%) in men with type 2 diabetes [1], followed by premature ejaculation (32-67%) [2,3] and low sexual desire (25-40%) [2,4,5]. In women with type 2 diabetes, high prevalence estimates of sexual dysfunction have been reported as well [6-8], including: low sexual desire (50-82%), low sexual arousal (34-68%), problems with orgasm (36-84%), and dyspareunia (10-46%). Sexual dysfunction has a negative effect on a person's psychological well-being and health-related quality of life [9,10] and therefore warrants clinical attention.

In the Netherlands, the majority of people with type 2 diabetes are treated in primary care. According to the Dutch clinical guideline for primary care physicians (PCP's), sexual problems should be reviewed by the PCP at least once a year [11]. However, sexual problems appear to be one of the most frequently neglected complications in diabetes care [12], possibly due to a lack of time and training of PCP's, but also because patients as well as professionals find it difficult to talk about sex [13]. The use of a stepped-care sexual counseling model, such as PLISSIT, has frequently been recommended to improve the discussion of sexual health in diabetes care [14]. PLISSIT is an acronym referring to the four stages of the model: Permission, Limited Information, Specific Suggestions, and Intensive Therapy [15]. It has shown promising results in improving sexual functioning in women with sexual problems [16-18] and in various somatic patient populations with sexual dysfunction [19-23]. Thus far, the effectiveness of the PLISSIT-model in improving the (sexual) well-being of people with type 2 diabetes has not been examined. We, therefore, conducted a cluster-randomized controlled trial (RCT) in people with type 2 diabetes treated in Dutch primary care settings to examine the PLISSIT model's effectiveness compared to standard care.

MATERIAL AND METHODS

Study design

A detailed description of the study methods has been published previously [24]. This study was designed as a cluster RCT (Dutch Trial Registry (NTR4807)) implying that randomization took place at the level of general practice. Data were collected in 44 participating general practices in the Netherlands between January 2015 and February 2017. The study was approved by the Medical Ethics Committee of the VU University Medical Center in Amsterdam, The Netherlands.

Participants and procedures

Recruitment took place in 45 practices between January 2015 and March 2016, of which one general practice did not manage to recruit eligible participants and was done by trained practice nurses. Eligible participants were identified by the practice nurse based on screening with the Brief Sexual Symptom Checklist (BSSC) [25] during routine three-monthly control meetings. Eligible participants were men and women with type 2 diabetes aged 40-75 years old who indicated to be dissatisfied about their sexual functioning and who expressed a wish to talk about their sexual problem(s) with their PCP. After filling out the baseline questionnaire, eligible participants received an information leaflet on diabetes and sexuality from the Rutgers Knowledge Center Sexuality (https://www.rutgers.nl/producten/diabetes-en-seksualiteit). In the intervention group, all participants were scheduled for an appointment with the PCP to discuss sexual problems two weeks post-baseline. In the control group, the practice nurse asked whether the information leaflet was of sufficient help, and, if not, whether the participant would like to have an appointment with his/her PCP.

Intervention group

PCP's were instructed to adopt the PLISSIT-model as a dynamic approach to consultation, tailored to the participants' sexual problems and (possible) care needs, including, when necessary, returning to or skipping steps [26]. In short, the PCP first set the agenda and inquired if the participant had a wish to talk about his or her sexual health and sexuality during step 1 (Permission). After permission had been given by the participant, the PCP provided general information during step 2 (Limited Information), such as explaining the effects of diabetes on sexual functioning [26]. To be able to provide Specific Suggestions in step 3, PCP's were trained in taking a short sexual history to understand the participant's particular complaint. Examples of specific suggestions include the use of lubricants and medication adjustment. Step 1-3 were aimed at directly helping the participants within a relatively short period of time [15]. For complex sexual problems or problems that could not sufficiently be addressed in the previous steps, step four of the model was applied (Intensive Therapy) [26]. This step will normally have consisted of referring the patient to specialized care, for which an overview of local referral possibilities was provided to each PCP [24].

The training of practice nurses and PCP's was described in detail before [24]. In short, practice nurses received an one-day training session especially focused on an appropriate attitude and skills needed for introducing sexual issues and recruitment for the study. PCP's in the intervention group received a one-day training with general information about sexuality and type 2 diabetes and role-playing to get aware of attitudes towards sexuality. Also, a thorough explanation of the steps of the PLISSIT model was discussed, followed by practical training with role-playing. The training was delivered by an experienced and certified sexologist (PL). A questionnaire to measure the PCP's knowledge and self-perceived competence with discussing sexual problems in people with type 2 diabetes was administered before and 3-4 weeks after the training. Knowledge was evaluated by scoring eight true-or-false statements, (score range 0-8). Competence with discussing sexuality in primary care was evaluated by scoring five statements, as measured on a five point scale ranging from completely agree to completely disagree (score range 5-25). To check for attention bias, PCP's in the control group filled out the questionnaire at recruitment and after 3-4 weeks.

Control group

In the control group, PCP's provided standard care [11]. In order to establish equal referral options for both study arms, PCP's in the control condition received the same overview of local referral possibilities.

Measures

Self-reported data was captured at baseline and after three and twelve months follow-up using validated questionnaires [27-32]. Participants were informed that they could skip items on sexuality if perceived as too personal. To evaluate the execution of the study protocol, care use among participants was assessed with a questionnaire at three months follow-up.

Primary outcome measures included sexual function, satisfaction with sexual function, and quality of life. Male sexual functioning was measured with the International Index of Erectile Function (IIEF) (cut-off ≤ 25 on ED domain score) [27]. The Dutch version of the IIEF-5 showed to be a reliable and valid measure to determine severity of symptoms of ED [28]. Moreover; the IIEF can also detect treatment-related changes in men with erectile dysfunction [29]. The Female Sexual Function Index (FSFI) is a widely used measurement tool to assess female sexual function along the six dimensions of desire, arousal, lubrication, orgasm, satisfaction, and pain [30,31]. It showed to have a high internal consistency and test-retest reliability in women with type 2 diabetes [32]. A Dutch study supports the reliability and psychometric validity of the FSFI in the assessment of dimensions of female sexual functioning and sexual distress in women with and without sexual complaints [33]. The index also showed to be a valid method for diagnostic classification, specifically with a total scale score of 26.6 or less [29]. Satisfaction with sexual function was measured using a Visual Analogue Scale (VAS) (range 0-10). Quality of life was measured with the Short Form-12 item survey (SF-12) with scores summated for the Physical Component Summary (PCS) and Mental Component Summary (MCS) scales, using population norm scores [34].

Secondary outcome measures included depressive symptoms, sexual distress, and emotional well-being. Depressive symptoms were assessed with the Patient Health Questionnaire (PHQ-9) (cut-off ≥ 10) [36]. Sexual distress was assessed with the Female Sexual Distress Scale-Revised (FSDS-R) (cut-off ≥ 11) [35]. Although the FSDS-R was originally developed for women, the items are considered to be gender neutral [38]. Emotional well-being was assessed with the World Health Organization-Five Well-Being Index (WHO-5) (cut-off <50) [37]. Also frequency of referral to a sexologist and the use of PDE5i in men was calculated.

Randomization and blinding

Forty general practices were initially enrolled and randomly allocated to one of the study arms by block randomization (19 intervention; 21 control). Practices were matched in blocks of equal size based on their location and number of patients. During the recruitment phase, five additional control practices were recruited to improve the inclusion of participants in the control group of which four included eligible participants. Thus, in total 19 intervention and 25 control practices participated in the study. Patients were blinded to the randomization status; PCP's and practice nurses could not be blinded due to the nature of the RCT intervention.

Statistical methods

For both men and women, the sample size was based on a 25% improvement in sexual functioning between the intervention and control group. With 90% power and a 5% significance level, and taking into account cluster-randomization by assuming an intra-cluster correlation coefficient of 0.05, and 20% drop-out, we calculated that we needed 195 participants.

Baseline data were described as mean (standard deviation (SD)) or N (%) stratified for intervention status. Normality assumptions were checked for continuous variables. Baseline data were tested for differences by allocation with independent T-tests and Chi-square tests. To evaluate the effect of the training of the care providers, knowledge and competence change scores were constructed. A positive change score indicated improvement. Independent T-tests of the change score were performed between care providers of the intervention and control group. Multilevel linear regression analyses were conducted to determine the effectiveness of the PLISSIT-model intervention. Data were analyzed longitudinally to study the overall and time-specific intervention effects. All data were analyzed as intention-to-treat. The intervention effect was evaluated in a model with a three-level structure (level 1 (lowest level): individual observations within a participant at baseline, three and twelve months follow-up; level 2: participants; and level 3: practices) and with a random intercept on the two lowest levels. All crude analyses were corrected for their respective baseline outcome score; analyses were additionally adjusted for age and sex. People with missing data during follow-up were tested for differences in baseline characteristics. Independent T-tests and Chi-square tests were performed between participants with and without missing data during follow-up, stratified for allocation of treatment.

The following sensitivity analyses were conducted to test the robustness of our data: 1) an analysis without the participants (N=8) recruited from the four additional control practices that were included after randomization; 2) a per protocol analysis, excluding intervention participants (N=18) who reported to not have had a consultation with their PCP; 3); an analysis to study people with imputed partner satisfaction scores on the FSFI (item 14, 15) and IIEF (item 14); these participants originally scored 'not applicable' for partner satisfaction; 4) an analysis of the FSFI and IIEF that included solely people who reported to have been sexually active in the last 4 weeks. Sexual activity is a prerequisite for evaluating these questionnaires, but due to low numbers, we decided to include every participant in our main analysis. A P-value <0.05 was considered to be statistically significant. Descriptive statistics were performed with IBM SPSS Statistics (Version 22.0, IBM Corp). Multilevel analyses were performed using MLwiN (version 2.22, Centre for Multilevel Modelling, University of Bristol, UK) [39].

RESULTS

Participants

In total, 150 participants were included: 87 in the intervention and 63 in the control group (Figure 1). All participants were

original Dutch men and women, no people from other ethnicities participated. Baseline characteristics of all participants are shown in Table 1. Most participants were men (78.7%) and mean age of participants was 62.7 (± 8.5) years. The IIEF sum scores for men were slightly different for people in the control versus the intervention group (37.8 versus 33.2). The FSFI sum scores for women were almost not different between the control and the intervention group (respectively 19 and 18.5) (Table 2). At three months post-intervention, overall loss to follow-up was 15.3%, with 18.4% in the intervention and 11.1% in the control group (P=0.222). In the intervention group, people with missing data at three months follow-up were more often treated with oral diabetes medication at baseline. At 12 months post-intervention, overall loss to follow-up was 21.3%, with 25.3% in the intervention and 15.9% in the control group (P=0.165). In the intervention group, people with missing data at twelve months more often were treated with oral diabetes medication and more often had comorbid conditions at baseline. No significant differences in loss to follow-up were observed in the control group.

PCP training

Competence change scores of PCP's significantly differed between the intervention group (3.6 (± 3.0)) and the control group (0.0 (± 1.8); P<0.001). Knowledge change scores of PCP's did not significantly differ between the intervention group and control group (0.1 (± 1.1) vs. 0.3 (± 0.7); P=0.472).

PLISSIT

The outcomes of the participants at baseline and at three and twelve months follow-up are presented in Table 2. No harms or unintended effects were reported in either arm of the trial.

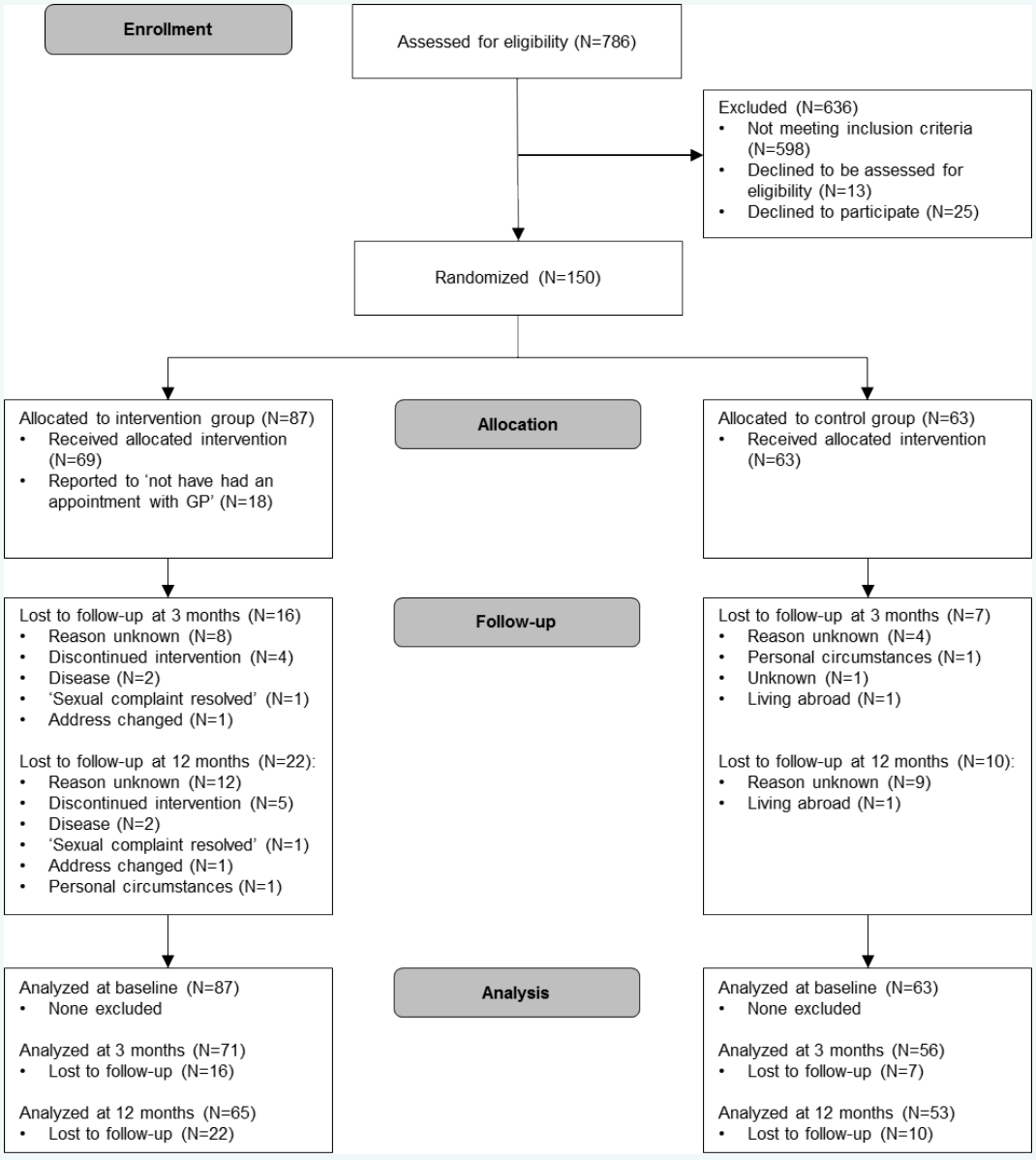

Figure 1 Flowchart diagram according to CONSORT statement.

Table 1: Baseline characteristics of the participants, stratified for allocation of treatment.

	Total population	Intervention group	Control group	P-value
Socio-demographic characteristics	**N=150**	**N=87**	**N=63**	
– Sex (% men)	118 (78.7%)	64 (73.6%)	54 (85.7%)	0.073
– Age (mean years (±SD))	62.7 (±8.5)	63.5 (±8.4)	61.7 (±8.5)	0.184
– Educational level (% low education)*	80 (53.3%)	45 (51.7%)	35 (55.6%)	0.761
– Ethnicity (% Dutch native)†	114 (76.0%)	66 (75.9%)	48 (76.2%)	0.478
– Marital status (% married/cohabiting)	124 (82.7%)	71 (81.6%)	53 (84.1%)	0.457
Medical characteristics	**N=150**	**N=87**	**N=63**	
– BMI (mean BMI kg/m ^{2} (±SD))	29.7 (±4.3)	29.4 (±4.2)	30.1 (±4.4)	0.333
– Smoking status (% current smoker)	26 (17.3%)	13 (14.9%)	13 (20.6%)	0.572
– Diabetes duration (mean years (±SD))	8.8 (±6.0)	9.0 (±5.6)	8.6 (±6.5)	0.690
– Oral medication (% yes)‡	121 (80.7%)	70 (80.5%)	51 (81.0%)	0.940
– Insulin use (% yes)‡	25 (16.6%)	13 (14.8%)	12 (19.0%)	0.486
– Diabetes complication(s) (% yes) ‡	61 (40.7%)	35 (40.2%)	26 (41.3%)	0.950
– Other types of medications (mean number (±SD))	2.3 (±1.3)	2.3 (±1.4)	2.2 (±1.1)	0.546
– Other diseases (mean number (±SD))	1.0 (±1.0)	1.1 (±0.9)	0.9 (±0.9)	0.214
– Menopausal status (women only)	**N=32**	**N=23**	**N=9**	
- % post-menopause	17 (53.1%)	12 (52.2%)	5 (55.6%)	0.233
Sexual-health related characteristics	**N=150**	**N=87**	**N=63**	
– Sexual orientation (% heterosexual)	147 (98.0%)	85 (97.7%)	62 (98.4%)	0.678
– Important to be sexually active (% yes)	108 (72.0%)	62 (71.3%)	46 (73.0%)	0.783
– Sexual partner in the past 4 weeks (% yes)	102 (68.0%)	57 (65.5%)	45 (71.4%)	0.620
– Sexual activity in past 4 weeks (% yes)§	102 (68.0%)	58 (66.7%)	44 (69.8%)	0.896
– Infection of the glans of the penis (men only)	**N=118**	**N=64**	**N=54**	
- % yes	4 (3.4%)	3 (4.7%)	1 (1.9%)	0.390
– Infection of the vagina (women only)	**N=32**	**N=23**	**N=9**	
- % yes	8 (25.0%)	7 (30.4%)	1 (11.1%)	0.288

Data are shown as N (%) or mean (±SD). Abbreviations: BMI: body mass index; SD: standard deviation. * Level of education was categorized as: no education or low education (elementary education, low vocational education, lower general secondary education), middle education (intermediate vocational education, higher general secondary education and pre-university education) and high education (higher vocational education, university). † Ethnicity was coded based on the country of birth of the participant and parents. If the participant and both parents were born in the Netherlands, the participant was coded as Dutch native. If the participant and one or both of the parents were born outside the Netherlands, the participant was coded as 1st generation migrant. If the participant was born in the Netherlands and one or both of the parents were born outside the Netherlands, the participant was coded as 2nd generation migrant. If the participant was born outside the Netherlands and both parents were born in the Netherlands, the participant was coded as Dutch native. ‡ Multiple answers possible. § Sexual activity referred to 'every activity that turns you on sexually, including masturbation'.

Table 2: Outcomes at baseline, 3 months and 12 months, stratified for allocation of treatment.

	Intervention group			Control group		
	Baseline	**3 months**	**12 months**	**Baseline**	**3 months**	**12 months**
Primary outcome measures	**N=87**	**N=71**	**N=65**	**N=63**	**N=56**	**N=53**
Male sexual dysfunction	**N=64**	**N=53**	**N=47**	**N=54**	**N=48**	**N=46**
IIEF sum score (range 5-75)	**N=47**	**N=40**	**N=34**	**N=41**	**N=40**	**N=33**
– Mean (±SD)	33.2 (±14.1)	37.8 (±16.0)	35.0 (±15.4)	37.8 (±15.3)	39.9 (±16.0)	37.4 (±16.7)
– Erectile dysfunction based on cut-off score of 25 (%yes)	56 (96.6%)	48 (94.1%)	40 (90.9%)	44 (89.8%)	38 (86.4%)	39 (90.7%)
Female sexual dysfunction	**N=23**	**N=18**	**N=18**	**N=9**	**N=8**	**N=7**

FSFI sum score (range 2-36)	N=16	N=12	N=12	N=7	N=6	N=4
– Mean (±SD)	18.5 (±7.8)	21.6 (±4.9)	23.5 (±7.9)	19.0 (±7.8)	18.4 (±6.1)	15.5 (±10.3)
– Female sexual dysfunction based on cut-off score of 26.6 (%yes)	14 (87.5%)	10 (83.3%)	8 (66.7%)	6 (85.7%)	5 (83.3%)	4 (100%)
Satisfaction with sexual functioning						
VAS scale 0-10	**N=83**	**N=70**	**N=64**	**N=59**	**N=52**	**N=49**
– Mean (±SD)	2.8 (±2.1)	3.7 (±2.2)	3.8 (±2.3)	3.2 (±2.3)	4.0 (±2.2)	3.8 (±2.3)
– Unsatisfied (0-4)	63 (72.4%)	42 (59.2%)	39 (60.0%)	42 (66.7%)	27 (48.2%)	26 (49.1%)
– Neutral (5)	12 (13.8%)	10 (14.1%)	8 (12.3%)	7 (11.1%)	12 (21.4%)	11 (20.8%)
– Satisfied (6-10)	8 (9.2%)	18 (25.4%)	17 (26.2%)	10 (15.9%)	13 (23.2%)	12 (22.6%)
– Missing	4 (4.6%)	1 (1.4%)	1 (1.5%)	4 (6.3%)	4 (7.1%)	4 (7.5%)
Quality of life (SF-12)						
PCS (range 0-100)	**N=81**	**N=61**	**N=58**	**N=54**	**N=51**	**N=46**
– Mean (±SD)	46.3 (±10.5)	46.8 (±9.7)	46.6 (±9.6)	45.2 (±9.1)	45.8 (±8.9)	45.5 (±9.3)
MCS (range 0-100)	**N=81**	**N=61**	**N=58**	**N=54**	**N=51**	**N=46**
– Mean (±SD)	51.1 (±9.2)	50.7 (±8.9)	51.8 (±8.4)	48.3 (±10.1)	47.2 (±10.8)	49.0 (±9.7)
Secondary outcome measures						
Depressive symptoms						
PHQ-9 sum score (range 0-27)	**N=78**	**N=62**	**N=60**	**N=50**	**N=45**	**N=42**
– Mean (±SD)	4.3 (±4.8)	4.6 (±5.3)	3.7 (±3.6)	5.4 (±5.5)	5.6 (±5.7)	5.6 (±4.9)
– Depression based on cut-off score (% yes)	10 (12.8%)	8 (12.9%)	3 (5.0%)	11 (22.0%)	10 (22.2%)	9 (21.4%)
Sexual distress						
FSDS-R sum score (range 0-52)	**N=78**	**N=68**	**N=60**	**N=60**	**N=54**	**N=48**
– Mean (±SD)	22.0 (±9.9)	22.0 (±11.5)	20.0 (±12.3)	22.5 (±12.3)	21.2 (±13.3)	20.2 (±12.9)
– Sexual distress based on cut-off score (%yes)	66 (84.6%)	58 (85.3%)	48 (80.0%)	50 (83.3%)	42 (77.8%)	37 (75.5%)
Emotional well-being						
WHO-5 sum score (range 0-100)	**N=80**	**N=66**	**N=62**	**N=58**	**N=55**	**N=49**
– Mean (±SD)	61.1 (±23.1)	61.3 (±22.9)	63.0 (±21.9)	57.2 (±22.6)	55.6 (±24.9)	57.6 (±22.5)

Data are shown as N (%) or mean (±SD). Abbreviations: FSDS-R: Female Sexual Distress Scale-Revised; FSFI: Female Sexual Function Index; IIEF: International Index of Erectile Function; MCS: Mental Component Summary; PCS: Physical Component Summary; PHQ-9: Patient Health Questionnaire; SD: standard deviation; SF-12: Short Form-12 item survey; VAS: Visual Analogue Scale; WHO-5: World Health Organisation-Five Well-Being Index.

Table 3 shows the results of the longitudinal linear multilevel regression analysis of the intervention effect. For our primary outcomes, a significant intervention effect was observed for female sexual functioning as measured by the FSFI at three months follow-up, nevertheless, the majority of the women still reported sexual dysfunction at three months follow-up (83.3%). In adjusted analyses, women in the intervention group scored 5.87 (standard error 2.80) points higher compared to the control group (P=0.036). No other significant effects in men or women were observed at three or twelve months follow-up. Sensitivity analyses 1 and 2 showed similar results (data not shown). Analysis 3 and 4 showed similar results for male sexual function (data not shown), but the intervention effect for female sexual function disappeared (Appendixes 1,2).

Care provision

As shown in Table 4, significantly more participants in the intervention group received an information leaflet on diabetes and sexuality compared to the controls (70.4% vs. 57.1%; P=0.024). In addition, intervention participants more often had an appointment with their PCP to discuss sexuality (70.4% vs. 33.9%; P<0.001). In both groups, only one person was referred to a sexologist. In the intervention group 11.3% of men received a PDE5i compared to 6.8% in the control group.

DISCUSSION

We aimed to evaluate the effectiveness of a PLISSIT-model intervention in people with type 2 diabetes who indicated to be dissatisfied and expressed a wish to talk about their sexual functioning. Only a statistically significant improvement in female sexual functioning was observed at three months follow-up. PLISSIT-trained PCP's reported a significant improvement in their self-perceived competence to discuss sexual issues after the training with a sexologist, compared to control group PCP's.

This is the first randomized controlled trial that studied the effectiveness of the PLISSIT-model on sexual functioning and

Table 3: Longitudinal multilevel linear regression analysis on the intervention effect of the trial.

	Intervention effect					
	Overall	**P-value**	**3 months**	**P-value**	**12 months**	**P-value**
Primary outcome measures						
Male sexual dysfunction (IIEF, range 5-75)						
– Crude	1.45 (1.95)	0.457	1.01 (2.57)	0.695	1.97 (2.35)	0.401
– Adjusted	1.56 (1.95)	0.424	1.09 (2.57)	0.670	2.10 (2.36)	0.374
Female sexual dysfunction (FSFI, range 2-36)						
– Crude	3.11 (2.52)	0.216	**6.15 (3.06)**	**0.045**	1.87 (2.91)	0.520
– Adjusted	2.87 (2.20)	0.192	**5.87 (2.80)**	**0.036**	1.47 (2.64)	0.577
Satisfaction with sexual function (VAS, range 0-10)						
– Crude	0.15 (0.29)	0.612	0.17 (0.35)	0.631	0.12 (0.34)	0.717
– Adjusted	0.20 (0.29)	0.507	0.22 (0.35)	0.532	0.17 (0.34)	0.618
Quality of life (SF-12): physical component score (PCS, range 0-100)						
– Crude	-0.98 (0.95)	0.302	-1.02 (1.22)	0.403	-0.94 (1.17)	0.422
– Adjusted	-1.07 (0.97)	0.272	-1.13 (1.24)	0.363	-1.01 (1.18)	0.392
Quality of life (SF-12): mental component score (MCS, range 0-100)						
– Crude	0.87 (1.08)	0.419	0.24 (1.42)	0.864	1.44 (1.36)	0.290
– Adjusted	0.98 (1.04)	0.347	0.45 (1.41)	0.751	1.46 (1.33)	0.272
Secondary outcome measures						
Depressive symptoms (PHQ-9, range 0-27)						
– Crude	0.21 (0.51)	0.676	0.35 (0.61)	0.569	0.10 (0.59)	0.868
– Adjusted	0.02 (0.51)	0.967	0.12 (0.62)	0.843	-0.06 (0.59)	0.923
Sexual distress (FSDS-R, range 0-52)						
– Crude	-0.49 (1.45)	0.733	-1.30 (1.73)	0.450	0.18 (1.66)	0.915
– Adjusted	-0.79 (1.49)	0.594	-1.62 (1.76)	0.358	-0.12 (1.69)	0.944
Emotional well-being (WHO-5, range 0-100)						
– Crude	3.95 (2.36)	0.095	2.31 (3.07)	0.453	5.39 (2.94)	0.067
– Adjusted	3.58 (2.40)	0.138	1.95 (3.10)	0.529	4.95 (2.96)	0.095

Data are shown as regression coefficient (standard error). Abbreviations: FSDS-R: Female Sexual Distress Scale-Revised; FSFI: Female Sexual Function Index; IIEF: International Index of Erectile Function; MCS: Mental Component Summary; PCS: Physical Component Summary; PHQ-9: Patient Health Questionnaire; SF-12: Short Form-12 item survey; VAS: Visual Analogue Scale; WHO-5: World Health Organisation-Five Well-Being Index. Analyses were adjusted for age at baseline and sex; analyses with male and female sexual dysfunction were corrected only for age at baseline. All models consisted of a three-level structure: level 1: observations within patients; level 2: patients in practices; level 3: practices in intervention/control group. All models were fitted with a random intercept on level 1 (observations) and level 2 (patients).

Table 4: Three months post-intervention care use among study participants, stratified for allocation of treatment.

	Total	Intervention group	Control group	P-value
	N=127	**N=71**	**N=56**	
Received an information leaflet (% yes)	82 (64.6%)	50 (70.4%)	32 (57.1%)	0.024
Appointment with PCP (% yes)	69 (54.3%)	50 (70.4%)	19 (33.9%)	<0.001
Follow-up appointment(s) with PCP	**N=69**	**N=51**	**N=19**	0.374
– 1 follow-up appointment	18 (26.1%)	12 (23.5%)	6 (31.6%)	
– 2 follow-up appointments	2 (2.9%)	1 (2.0%)	1 (5.3%)	
– No	37 (53.6%)	26 (52.0%)	11 (57.9%)	
– Missing	12 (17.4%)	12 (23.5%)	1 (5.3%)	
Referral to sexology specialist (% yes)	13 (10.2%)	8 (11.3%)	5 (8.9%)	0.854
Type of sexology specialist* (%yes)	**N=13**	**N=8**	**N=5**	NT
– Urologist	5 (38.5%)	2 (25.0%)	3 (60.0%)	
– Psychologist	3 (23.1%)	2 (25.0%)	1 (20.0%)	
– Sexologist	3 (23.1%)	1 (12.5%)	2 (40.0%)	
– Gynecologist	1 (7.7%)	1 (12.5%)	0 (0%)	
– Internist	1 (7.7%)	0 (0%)	1 (20.0%)	
– Physiotherapist	1 (7.7%)	1 (12.5%)	0 (0%)	
– Unknown	1 (7.7%)	1 (12.5%)	0 (0%)	

Data are shown as N (%). Abbreviations: PCP: Primary Care Physician; NT: not tested due to low numbers. * Multiple answers possible

sexual satisfaction in men and women with type 2 diabetes in routine primary care, adding to the external validity.

Patients as well as professionals may find it difficult to talk about sex. It can be a sensitive and awkward topic that raises feelings of embarrassment, shame or inadequacy [40,41]. However, asking patients about sexual matters is universally recognized as an important part of collecting a patient's medical history. But evidence suggests that many physicians do not take sexual histories from their patients [42,43,44]. PCP's have previously indicated that a lack of training impedes the discussion of sexual issues [13]. So, in the end two problems need to be tackled, firstly the hesitation of patients to talk about their sexuality and secondly hesitation of doctors to open such a discussion. We hypothesized that. the PLSSIT-model would help PCP's to overcome the many challenges to talk about sexuality, while acknowledging that in this specific patient group sexual dysfunction may be at least partly due to irreversible pathophysiological changes caused by ageing and/or diabetes with limited somatic therapeutic options. Still, helping patients achieve acceptance of the dysfunction and/or finding alternative ways to enjoy sexuality are worthwhile goals. This applies to both men and women, although it is thought that a woman's sexuality is more capable to adapt to changing circumstances, which is also known as 'erotic plasticity' [45]. Our findings did show only an improvement of female sexual functioning which is in line with this theory. Improving male sexual function may require more intense or specialized treatment than what was offered in this trial [1]. It is positive to see that we were able to help doctors, based on their self-report to improve communication about sexual functioning with patients due to the training received prior to the study and the steps defined in the PLISSIT-model itself. We have unfortunately no data from patients regarding the PCP's communication, which should be investigated in future studies.

Our results must be interpreted with caution. Although at three months follow-up a significant improvement in female sexual functioning was observed, the majority of the women still reported some degree of sexual dysfunction (83.3%). Second, based on sensitivity analyses, it seemed that the PLISSIT-approach was only effective in improving sexual functioning of women who had a partner. For women without a partner, it could be that PCP's had less options to improve sexual function during counseling, however only about 17% of the study participants had no partner, so this result can also be due to lack of power. Moreover, there were few women in the study compared to men. Third, the significant intervention effect among women was not observed at twelve months follow-up. This could indicate waning of the intervention effect or that the regression analysis may have been underpowered due to lower numbers at twelve months follow-up. Moreover, despite our best efforts, we were unable to reach the necessary sample size of 195. However, we do not expect in view of the results of our analysis that this would have changed our conclusions. We included fewer female than male participants. Even though practice nurses were instructed

to recruit both sexes, some expressed that it was easier for them to approach men than women [46]. Moreover, women were less often eligible to participate: women less often reported to be sexually dissatisfied or to have a need for care, compared to men [41]. Fourth, we have no data to indicate which PLISSIT-steps providers actually carried out, however the competence training for the care providers showed a relevant competence improvement. Fifth, we do not have information which of the PCP's in a group practice delivered the intervention; therefore we could not analyze the effect of sex of the PCP on the intervention results.

CONCLUSION

To conclude compared to standard primary diabetes care, the PLISSIT-model based intervention only improved short-term sexual functioning in women, with no effects in men with type 2 diabetes who were dissatisfied about their sexual functioning. Nevertheless, the PLISSIT-model was valued by PCP's as a useful tool that enables discussing sexual health issues in primary diabetes care.

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