Scale for Quality of Sexual Function (QSF) as an Outcome Measure for Both Genders?

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ABSTRACT

Background. For years, there has been interest in sexual dysfunction and its impact on quality of life but usually focused on one gender. Therapeutic options that became available raised the interest to evaluate effects on the other partner but there is no standardized instrument applicable for both genders. This paper reports first data regarding the development of a new general "Quality of Sexual Function" (QSF) scale.

Methods. The raw scale was based on our own gender-specific scales and the pertinent literature. The scale was applied in over 700 persons of a cross-sectional survey in Germany. Factorial analyses were performed to describe the internal structure (domains) of the scale and for item reduction. Internal consistency reliability and some aspects of validity were analyzed with the same community sample preliminary reference values determined.

Results. The scale consists of 32 specific items and eight general questions. Four dimensions were identified: "psycho-somatic quality of life," "sexual activity," "sexual (dys)function—self-reflection," and "sexual (dys)function—partner's view." The internal consistency reliability coefficients of the total scale and the subscales were good as were the total–domain correlations. Content validity was promising.

Conclusion. This self-administrable 40-item QSF scale can measure and compare quality of sexual function for both genders. The scale was well accepted by the respondents. It is easy to answer and the evaluation is simple. Only a few results of reliability and validity have been established in this early stage of the development of the new instrument. Further research is needed to complete many missing aspects of reliability and the construct validity, particular its sensitivity to treatment effects.

Key Words. Sexual Functioning; Quality of Life; Aging; Questionnaire; Diagnostics; Validation

Introduction

The development of psychological and somato-vegetative complaints as well as urogenital and sexual dysfunctions in the aging process has been discussed for many decades for both genders. To some extend this was embedded in the debate on male and female "menopause" [1–5] and the impact on quality of life (QoL). Several scales were developed to measure the health-related quality of life (HRQoL) in the (aging) population [6–13].

Sexual dysfunction and its treatment in males and females became a separate issue in recent years and led to the development of many scales [14–20]. Sexual dysfunction has an impact on QoL which is a reason to measure it in addition.

Indicators of HRQoL—among them urogenital or sexual dysfunction—are not as different between the genders as one might believe. On the contrary, there is considerable overlap [1–4,21,22]. In addition, if sexual dysfunction is treated this has an impact on the respective partner. This involvement of the respective partner is a central aspect

of the paradigm of sexual medicine to assess and treat sexual disorders by involving both partners, that is, by treating the couple as the real patient [23]. Therefore, we became interested to consider the development of a unique QoL scale applicable to both genders.

This paper describes the development of a new scale to measure sexual functioning and HRQoL for both genders and to present first psychometric characteristics of the scale.

Materials and Methods

Concept

It was our objective to develop a scale that measures HRQoL with a special focus on sexual functioning in aging males and females, using one single instrument.

This plan originated from the practical experience with, and the validation of, two successful scales for aging men and women: the Menopause Rating Scale (MRS [12,13]) and the Ageing Males' Symptom Scale (AMS [6–8]). It became obvious that both scales had very similar dimensions: psychological, somato-vegetative, and urogenital/sexual domain. Deriving from these observation thoughts developed about a uniform HRQoL scale for both genders and this seems to be logically valid. In addition, reviewing some existing scales for male and female dysfunction created again the impression that similar facts and experiences were inquired from patients. Moreover, there are almost always two partners who define the quality of functioning in sexual life. This was another argument in favor of a uniform scale for males and females together.

All the same, the aim of the construction was to get a new instrument that [1] is applicable for both males and females to permit direct comparisons [2], measures QoL associated with sexual function [3], is short enough and easy to complete as self-report [4], enables inter- and intraindividual comparisons of results, that is, between persons (groups) and different points in time the same persons [5], facilitates reliable comparisons before vs. after therapeutic intervention, that is, being sensitive to therapeutic intervention [6], tries to estimate the effect on the partner or the perceived view of the partner [7], could possibly be used also as screening instrument, and [8] has favorable psychometric test characteristics. Obviously, this is a long list of desirable objectives and it will need time to be completed in a process of thorough testing of various aspects of reliability and construct validity.

Compilation of the Raw Scale

Existing standardized scales were analyzed to demarcate the array of interesting features for the analysis of HRQoL with particular focus on sexual dysfunction in men and women: the MRS [12,13], the AMS [6–8], the Female Sexual Function Index (FSFI) [14], the Derogatis Interview for Sexual Functioning (DISF) [15,16], the Female Sexual Distress Scale (FSDS) [17], and the Brief Sexual Function Questionnaire (BSFQ) for men [18,19].

Altogether 40 specific items, and additionally eight general questions were selected trying to cover the dimensions of well-being and satisfaction with life (psychological and somatic aspects), urogenital and sexual dysfunction, sexual desire (libido), sexual arousal or responsiveness to sexual stimulation, sexual activity and satisfaction from own perspective and perceived partner's view, and in addition sociodemographic variables, partnership, importance of sexuality, and number of sexual events in the last month. The content of the selected items is not new, that is, they have been used before in a similar form in established and internationally recognized scales for HRQoL or sexual dysfunction. Therefore, we could assume significance for the new questionnaire, that is, no further expert ratings/discussions were required.

Testing of the Raw Scale in a Community Sample

The raw scale was applied in an existing population panel in Germany (Healthcare Access Panel) aged from 45 to 70 years. This panel mirrors the German population concerning age, sex, regional structure, but also regarding health and health care indicators with good correlation [24]. The fieldwork was performed from June 11 to July 2, 2003, by means of a postal, self-completion questionnaire. This method was chosen to support the necessary privacy of answers, and which is, supposedly, the usual method of application in clinical settings in the future. Altogether, 1,200 men and women were invited to complete the questionnaire, stratified in three age groups with similar frequency. The overall response rate was 68%, and 738 questionnaires were sufficiently complete to be entered into the database.

Item Reduction and Characteristics of the Final Scale

The item reduction was performed on the basis of a factorial analysis (Principal Component Method

with Varimax rotation). Items that were not associated with the main factors were eliminated from the final questionnaire unless there was good reason to expect that the study sample chosen was inappropriate to decide upon the importance of certain items, for example, items that are related to adverse effects of treatment—which could not be tested with the community sample. In total, eight items were excluded resulting in a final scale with 32 specific items and eight general questions (Appendix 1).

Questionnaire and Scoring Guideline

Each question (item) of the Quality of Sexual Function (QSF) scale was presented in a five-point Likert scale (cf. Appendix 1). Following our general intention to develop a simple instrument for practical use, we decided to give each intensity grade one extra scoring point. If items were not applicable "Null" was coded, for example, if no sexual partner is available.

Once the respondent completed the QSF questionnaire, a simple form (Appendix 1) can be used if an evaluation on paper is intended.

The questionnaire has for each of the 32 items an option to check one of five degrees of severity concerning the degrees of impairment from "no" to "very severe/strong/often." The scoring points of each of the items into the form should be entered in the form in Appendix 1. However, it is important to note that the coding schemes for the last questions are orientated opposite to the direction of all other questions (cf. questionnaire in Appendix 1). The correct domain that the item belongs to is where the arrow ends. The composite scores for each of the four dimensions (subscales) are based on adding up the scores of the items of the respective dimensions. The composite score (total score) is the sum of the four-dimension scores.

Dimensions of the Scale

To put the various aspects of symptoms or complaints, sexual desires, responsiveness, satisfaction, and other experiences into perspective with aging and gender, we analyzed the data set with statistical methods that allow meaningful clustering of parameters/complaints. The type of the data set suggested "factor analysis" as the most appropriate tool to describe the dimensions of the QSF scale. We applied the Principal Component Method of the factorial analysis with Varimax rotation and Kaiser normalization to get independent (orthogonal) factor solutions.

Reference Values in the Population

Based on the dimensions found with factor analysis, we defined norm values for the scores of each of the dimensions from the answers of the community sample. Each dimension consists of an intensity profile of a number of specific questions (cf. Results).

Internal Consistency Reliability

Cronbach's alpha coefficient for internal consistency was used. Item–total correlations were considered as acceptable if about 0.8. We also calculated how much the scale mean values changed if items were deleted—as an indicator of the importance of the items.

Validity

Content or face validity was assumed acceptable if the theoretically expected domains of the scale were found in the multivariate analysis of internal structure (factor analysis).

Analysis Tools

All analyses were conducted with the statistical packages SPSS for Windows, release 9.0, and STATA. Frequency tabulations and factor analysis (see above) as well as reliability analysis were used as main analyses in this descriptive paper. Missings were list-wise deleted.

Results

Characteristics of the Study Sample

Table 1 describes briefly the available characteristics of the community sample used to standardize the scale. Analyzable data were available for 738 persons. About half of the sample were female, and the three 10-year age groups were about one-third each. The majority of study participants were married or living together. About 80% reported to have a sexual partner; of those, about two-thirds reported duration of the relationship of more than 10 years. About three-quarters had sexual contacts during the recent month before completing the questionnaire; however, 16% left this question unanswered. Sexuality had an important or very important role for the majority of the respondents.

Dimensions of the "Quality of Sexual Function" Scale

To get characteristic profiles of complaints, symptoms, desires, and other sexual issues of interest, we analyzed the data set with the factor analysis (Principal Component Method). Symptoms or

Table 1 Description of the community sample. Frequency distribution of selected characteristics

Variable	n	%
Gender		
Men	379	51.4
Women	359	48.6
Age (years)		
40–49	222	30.1
50–59	253	34.3
60–69	257	34.8
70+	6	0.8
Marital status		
Single	64	8.7
Married/cohabiting	500	67.8
Divorced	123	16.7
Widowed	51	6.9
Sexual partner		
No	128	17.3
Yes	607	82.2
Missing	3	0.4
Sexual partner for how long		
More than 10 years	490	66.4
7–10 years	33	4.5
4–6 years	34	4.6
1–3 years	32	4.3
6–12 months	11	1.5
Less than 6 months	22	3.0
No sex	58	7.9
Missing	58	7.9
Sexual contacts during last month		
No	93	12.6
Yes	530	71.8
Missing	115	15.6
Role of sexuality		
Less important	202	27.4
Important	401	54.3
Very important	125	16.9
Missing	10	1.4

complexes of intercorrelating items/symptoms formed "dimensions," that is, it was intended to aggregate all relevant symptoms into a few "dimension or domains."

Table 2 summarizes the findings. The most relevant, that is, interpretable variant of factors (domains) was found when forced to build four factors or domains—these factors explained about 50% of the total variance in the database. Approaches to accept up to 10 domains or less than four resulted in less clear interpretability (data not shown). For easy recognition, only factor weights over 0.5 are displayed in Table 2 with a few exceptions where we consider that therapeutic intervention may have an impact. The effect of therapeutic intervention could not be studied in this first stage of development.

Domain 1: "Psycho-Somatic Quality of Life"

This factor aggregates features of psychological and somato-vegetative nature in men and women determining more general aspects of the QoL. Altogether 13 items are associated with this dimension. Since items related to sexual (dys)function dominate the questionnaire, these aspects of QoL are detailed in three additional factors [2–4].

Domain 2: "Sexual Activity"

This dimension describes features of sexual activity and satisfaction, such as taking the initiative in sexual life, normal reaction of relevant organs to sexual stimuli, and different aspects of sexual satisfaction. It is important to realize that due to the phrasing of the item the coding goes into the opposite direction compared to that in other items, that is, "impairment/complaints" are on the other side of the Likert scale (see questionnaire, Appendix 1). Seven items of the QSF belong to this domain.

Domain 3: "Sexual (Dys)function—Self-Reflection"

This domain clusters complaints concerning sexual function, perceived as own, personal problems rather than as problems of the partner (see factor 4). This factor describes aspects of perceived dissatisfaction with sexual life and eight items form this dimension.

Domain 4: "Sexual (Dys)function—Partner's View"

The highest loadings on this factor are related to perceived problems of the partner regarding sexual life. However, the loadings of only four items were sufficient to allocate them to this dimension. This will be revisited once data on treatment effect are available for analysis.

Reference Values of the Population

The community sample was also used to preliminarily determine norm—or reference—values for the degree of reported impairment in each of the four dimensions.

For this purpose, the self-reported severity of "impairment or complaints" of all 32 items (see scoring scheme in Appendix 1) was added up to a total score. The same was performed for the four subscales.

We arbitrarily classified the severity of complaints/impairment according to the frequency distribution of the total score in the community sample: no/little complaints, mild, moderate, and severe complaints/problems. The majority of respondents showed no/little or mild complaints/problems, and a small proportion only severe problems—concerning the total scale score and the domain scores (Table 3).

Table 2 The Quality of Sexual Function (QSF) scale. Factor matrix: loadings in the four subscales. Only loadings above 0.5 were depicted (exceptions are explained in the text)

	Psycho-somatic quality of life	Sexual activity	Sexual (dys)function—self-reflection	Sexual (dys)function—partner's view
1. Well-being declined	0.71			
2. Pain in chest	0.65			
3. Heart discomfort at rest	0.68			
4. Joint and muscular ache	0.58			
5. Episodes of sweating	0.68			
6. Feeling dizzy	0.61			
7. Sleep problems	0.65			
8. Irritability and nervousness	0.71			
9. Depressive mood	0.79			
10. Physical exhaustion	0.83			
11. Memory, concentration impaired	0.70			
12. Muscular strength decreased	0.72			
13. Problems with urination	0.47			
14. Unhappy with sexual life			0.69	
15. Partner unhappy with sex				0.62
16. Problems during sex			0.26	
17. Partner problems during sex			0.45	
18. More sexual contacts desired			0.79	
19. Partner desires more sex				0.77
20. Partner wishes less sex			0.72	
21. Desire for sexual activity decreased		0.50		
22. Desire for sexual activity increased			0.45	
23. More sexual dreams, fantasies			0.66	
24. Partner sexual dreams				0.58
25. Sexual self-satisfaction			0.63	
26. Refuse sexual intercourse				0.57
27. Sex organs respond to desires		0.63		
28. Sexual initiative		0.56		
29. Great sexual excitement		0.81		
30. Satisfaction with sexual excitement		0.79		
31. Sufficient moisture during sex		0.71		
32. Sexual satisfaction achieved		0.70		

Above four factors explained 49% of the total variance: Factor 1: 19%; Factor 2: 12%; Factor 3: 11%; Factor 4: 7%.

The cut-off points of the total group were copied for both genders to permit simple comparisons. Males perceive for themselves obviously more frequently problems than women do. The latter report more often partner problems. Sexually related problems of women seem to be more often "mild" in their own perception, whereas men report more often "moderate and severe impairment" according our results.

Reliability Measures

Reliability investigates to what extent measures are internally consistent and results of the scale more or less identical if the scale is repeatedly administered (test–retest reliability). Table 4 describes all items of the total scale (32 items) with relevance for this first reliability analysis. It can be seen that the mean of the total scale did not change very much if items were deleted.

The internal consistency reliability—measured with Cronbach's alpha—was 0.8 for the total scale. It remained consistently high if certain items were deleted from the analysis (cf. Table 4).

The internal consistency is also acceptable for the four subscales with one exception. The values were 0.90, 0.82, 0.75, and 0.57 for the subscales "psycho-somatic quality of life," "sexual activity," "sexual (dys)function—self-reflection," and "sexual (dys)function—partner's view," respectively.

Validity Measures

Validation is a very complex and long-lasting process and we were only able to present a few early results in this paper.

Internal Structure of the Quality of Sexual Function Scale

The first step of validation is usually to demonstrate multivariately the internal structure ("dimensions/domains") of a given scale through factor analysis (cf. Table 2). The four domains found in the above analysis do fit theoretical

Table 3 The Quality of Sexual Function (QSF) scale norm values and gender. Reference scores derived from a community sample of 738 persons aged over 45 years (379 males and 359 females). The categories of severity were *only* defined for the total group (both gender together) and applied to both gender groups

Points	Complaints/ problems	Percent of the population		
		Males	Females	Both genders
Total sum-score				
–54	No, little	15.8	21.1	17.9
55–68	Mild	50.7	48.0	49.7
69–79	Moderate	24.3	21.2	23.0
80+	Severe	9.2	9.7	9.4
Psycho-somatic quality of life				
–15	No, little	15.9	17.2	16.5
16–24	Mild	61.6	44.2	53.4
25–34	Moderate	16.8	23.4	19.9
35+	Severe	5.7	15.2	10.2
Sexual activity level				
–17	No, little	8.8	24.4	15.6
18–23	Mild	45.9	50.0	47.6
24–26	Moderate	29.1	17.4	24.1
27+	Severe	16.2	8.2	12.7
Sexual (dys)function—self-reflection				
–9	No, little	22.1	30.0	25.4
10–15	Mild	44.5	52.6	47.9
16–19	Moderate	20.6	11.3	16.7
20+	Severe	12.8	6.1	10.0
Sexual (dys)function—partner's view				
–5	No, little	30.9	16.7	25.0
6–8	Mild	43.2	47.5	45.0
9–11	Moderate	18.8	23.7	20.8
12+	Severe	7.1	12.1	9.2

expectations: sexual function has a significant impact on QoL and consists of satisfactory activity and good functioning of the two partners. Concluding from this consideration, the face validity seems to be given.

Subscores and Total Score Correlations

Another structural validity aspect is the total–domain correlation, that is, the correlation of the total score with the scores of the subscales. Ideally, there should be significant and high correlations between the total scale and all subscales forming the total scale. In contrast, the correlations among the individual subscales should be smaller, because the subscales are supposed to be "independent" according the factor-analytic model we used.

The correlations with the total scale were the highest, as expected, ranging from 0.30 to 0.77. The correlations among subscales oscillate in the majority well under 0.2 and many were not significant despite the large sample size (Table 5).

Discussion

Interest in sexual dysfunction and its impact on QoL has been increasing steadily for years, but investigations and thinking were usually focused on either the male or female gender [14–20]. Therapeutic options that became available raised interest to evaluate the effect on the other partner but there is no standardized instrument applicable for both genders—as far as we know. It seems that the interrelation of sexual dysfunction and the HRQoL could benefit from combined therapy and this would need evaluation, that is, including the partners view. Therefore, we consider it as a significant methodological contribution if a unique instrument with identical wording for males and females could be established, even though it is clear that identical wording will not completely eliminate disparity based on gender-specific context and understanding. Clearly, the gap can be smaller with a unified instrument.

The literature search in addition to our own experiences with gender-specific QoL scales [7,12] led to a list of items that have shown to be relevant for QoL in general and sexual function in particular in aging persons. That means, the array of potentially interesting items/complaints came from own gender-specific scales and information derived from the pertinent literature. Thus, the items selected can be considered as significant and valid for testing in a different context of a new scale.

Table 4 The Quality of Sexual Function (QSF) scale. Reliability for the total scale: reliability coefficients for 32 items: Cronbach's alpha = 0.80; standardized item alpha = 0.80. Scale mean if items were subsequently deleted (scale variance not depicted)

Quality of life and sexual dysfunction	Scale mean if item deleted	Alpha if item deleted
1. Well-being declined	63.15	0.78
2. Pain in chest	63.43	0.79
3. Heart discomfort at rest	63.37	0.79
4. Joint and muscular ache	62.04	0.79
5. Episodes of sweating	63.10	0.78
6. Feeling dizzy	63.40	0.79
7. Sleep problems	62.84	0.78
8. Irritability and nervousness	63.04	0.78
9. Depressive mood	62.11	0.78
10. Physical exhaustion	62.72	0.78
11. Memory, concentration impaired	63.01	0.78
12. Muscular strength decreased	62.93	0.78
13. Problems with urination	63.49	0.79
14. Unhappy with sexual life	62.78	0.79
15. Partner unhappy with sex	62.97	0.80
16. Problems during sex	63.55	0.80
17. Partner problems during sex	63.50	0.80
18. More sexual contacts desired	62.51	0.78
19. Partner desires more sex	62.81	0.80
20. Partner wishes less sex	63.17	0.79
21. Desire for sexual activity decreased	62.81	0.80
22. Desire for sexual activity increased	63.34	0.79
23. More sexual dreams, fantasies	62.76	0.78
24. Sex organs respond to desires	61.75	0.79
25. Partner sexual dreams	62.40	0.80
26. Sexual self-satisfaction	63.17	0.79
27. Sexual initiative	61.95	0.80
28. Refuse sexual intercourse	63.24	0.80
29. Great sexual excitement	61.23	0.80
30. Satisfaction with sexual excitement	61.23	0.80
31. Sufficient moisture during sex	61.17	0.80
32. Sexual satisfaction achieved	60.96	0.80

More than 40 items were considered for the new scale such as well-being and satisfaction with life (psychological and somatic aspects), urogenital and sexual complaints, sexual desire (libido), sexual arousal or responsiveness, sexual activity and satisfaction from own perspective and perceived partner's view, including partnership and number of sexual events in the last month. These patterns were condensed in a raw scale. The raw scale was administered to over 700 males and females in a cross-sectional survey in Germany.

Our first practical experience was that the QSF scale was well accepted from respondents although intimate questions are sometimes a hurdle for good response. Possible reasons for the good performance are the self-administrative nature, the easily understandable items, and that the completion of the questionnaire takes less than 10 minutes—normal intelligence or vigilance assumed. That's what respondents fed back; but they also fed back that a basic hesitation to answer intimate questions has to be overcome in the beginning.

Factorial analyses of the data set from the survey were performed to describe the internal structure (domains) of the scale and to reduce the number of items that showed not sufficient relevance. Finally, a four-factor model was the one that was most easy to interpret and detailed enough to distinguish important characteristics that might be relevant for the practice of diagnosis and treatment. A problem, however, was that the community sample was obviously fairly healthy. It would be helpful for the interpretation to get data from persons with known sexual dysfunction with or without prior treatment to check for potential differences in the factor structure of the scale.

The domains of the scale were: "psychosomatic quality of life," "sexual activity," "sexual (dys)function—self-reflection," and "sexual (dys)function—partner's view." All items are related to QoL but describe different aspects. The most general domain describes the first factor, which explains the largest part of the total variance. It can be assumed that all four factors together, that is, the total score, form a HRQoL measure. This assumption, however, needs to be empirically confirmed by comparing with other HRQoL scales.

We observed that two domains related to "sexual dysfunction," what fitted our primary working

Table 5 Domain score–total score correlations of the Quality of Sexual Function (QSF) scale

	QSF_TOT	QSF_QOL	QSF_ACT	QSF_SDFS	QSF_SDFP
QSF_TOT	1.00				
QSF_QOL	0.77*	1.00			
QSF_ACT	0.30*	−0.14*	1.00		
QSF_SDFS	0.65*	0.21*	0.15*	1.00	
QSF_SDFP	0.33*	0.07	−0.07	0.17*	1.00

* $P < 0.01$, statistically significant.
QSF_QOL, psycho-somatic quality of life; QSF_ACT, QSF–sexual activity; QSF_SDFS, QSF–sexual (dys)function—self reflection; QSF_SDFP, QSF–sexual (dys)function—partner's view.

hypothesis that sexual dysfunction is a two-sided coin and successful therapy of one partner might create undesired side-effects for the other partner, if the other partner is not included in the treatment setting. All the same, this issue will be revisited once data of the first therapy study are available.

Another issue that cannot be decided in the absence of therapy-related data are two sets of items: the items "problems during sex—self or partner" and "desire for sexual activity increased/decreased." They showed low correlations with the two factors of sexual dysfunction—but nevertheless they were not eliminated from the final scale. Again, this decision will be revisited once data from intervention studies are available.

The final QSF scale consists of 40 items: 8 general questions, and 32 specific questions in four domains, that is, "psycho-somatic quality of life" (13 questions), "sexual activity" (7 questions), "sexual (dys)function—self-reflection" (7 questions), and "sexual (dys)function—partner's view" (5 questions). Each of the specific items in the scale can get 0 (no partner), 1 (no/none)—up to 5 scoring points (most problematic category) depending on the box ticked in the questionnaire (cf. Appendix 1). The scoring scheme is simple, that is, the score increases point by point with increasing severity of subjectively perceived symptoms in each of the 11 items [severity 0 (no/little problems/complaints) . . . 4 scoring points (very severe problems)]. The composite scores for each of the four dimensions (subscales) are based on adding up the scores of each item of the respective domains. The composite score (total score) is the sum of the dimension scores. The four domains, their corresponding questions and the evaluation are detailed and summarized in Appendix 1. The questionnaire, originally German, was preliminary adapted to English (translation/back-translation/consensus). This will be reviewed again in a more formal way in the context of the linguistic and cultural adaptation to other languages than English.

The population reference values estimated from the same sample where the analysis of items and dimensions was performed are useful in the practice, that is, one can compare how far a certain subgroup of patients is from the normal pattern of a healthy population in the same age group. However, it would have been an advantage if a new community sample could be used to determine norm values but this was not possible due to budgetary reasons. Thus, we will revisit reference values as soon as possible. There might be also suggestions from future investigations to alter the current, arbitrarily defined categories of severity of impairment.

It might be considered as problematic that the severity of problems/complaints was arbitrarily defined. According to a normal distribution one would expect that the majority of normal, healthy persons have no important (no/little) complaints, the majority mild and moderate complaints, and only few experience a severe impairment of their QoL and sexual function. This underlying assumption for arbitrarily setting the cut-off points can be challenged. However, it is possible, of course, to use the continuous scores points, if one do not accept the arbitrary cut into four categories of severity.

With regard to sex-specific norm values, we do recommend to use only one norm value for both genders but to be fully aware of differences that exist among genders. Therefore, the differences in the frequency distribution between males and females of the community sample were described.

For all scientific measurements it is required to give evidence of replicability (consistency). In contrast to systematic and random variation, *reliability* gives an estimate of method-related measurement errors, which should be low not to cover intended changes—due to treatment for example.

Internal consistency reliability and some aspects of validity were analyzed with the same community sample as well as reference values of the scale. We found quite promising results: the internal consistency reliability—measured with Cronbach's alpha—was good for the total scale of 32 items (0.8 on average) and also for the four subscales. Internal consistency of about 0.8 is generally accepted as good reliability for the measurement of intraindividual changes pre/post therapy. The least good reliability coefficient was found for the domain "sexual (dys)function—partner's view." This, however, may well be explained by the lack of treatment-influenced data. However, one important aspect of reliability is still missing. The test–retest reliability will be determined in the next future in order to propose the scale as an outcome measure for therapeutic intervention (see further down: next steps).

Similar to reliability that assesses the consistency of measurement, the *validity* estimates whether a scale measures what it intends to measure. But whereas reliability can be determined straightforward with very few indicators, the pro-

cess of establishing validity is almost always a continuous process (construct validation).

As a first step we demonstrated with the multivariate internal structure ("dimensions") of the scale that the four extracted factors fitted the theoretical expectation: sexual "well functioning" is part of the QoL and concerns two partners. Our interpretation is that the content validity is given.

Another aspect of validity that can be checked at this early stage is that the total scale–domain correlations are substantial whereas the correlation coefficients among subscales are much lower. This fits with the requirement that all subscales should contribute to the total scale but are not very much interrelated with each other.

For the time being we can conclude that the reliability and validity—as far as elucidated yet—gives a promising outlook. However, many investigations are still required before a final conclusion can be drawn concerning construct validity of the new instrument.

In addition to the already mentioned open questions of the new scale are additional limitations.

All patient-reported information needs validation particularly in a sensitive field associated to sexual behavior or dysfunction. The magnitude of this problem can be estimated by a rigorous testing of various aspects of reliability and validity. It seems not to be avoidable that patients not motivated to tell the truth about their problems tick the box "Null" although this means "no partner, or they leave the question unanswered and this will be coded as "null" in the analysis or they pretend to have no problems. Further test–retest investigations have to provide evidence if this is a real problem or not.

Since the scale contains no item directly focusing on orgasm, but only phrases associated with satisfaction with sexual life, specific analyses on anorgasmia cannot be performed although indirect conclusions might be drawn.

A problem that was mentioned above is that the standardization of the scale and the determination of reference values were performed in the same community sample. The latter will be repeated in one of the next investatigations.

The next steps of the complex validation envisaged are: firstly the full linguistic and cultural adaptation of the scale in a few "world languages" (French, Spain, Portuguese, and a final check of the current English version—also for North-American English). This will be accompanied by (small) test–retest investigations.

In parallel or successive, the scale will be applied patients with sexual dysfunction to compare results with "normal persons."

It may take a bit longer to get funding for an empirical comparisons of the QSF scale with other scales devoted to measure generic QoL, with HRQoL scales, and scales that measure sexual dysfunction in men and women. An very important issue is the validity of the scale as clinical utility: sensitivity (specificity) to measure therapeutic effects in patients with sexual dysfunction (clinical studies/trials). Later, the internal structure of the scale and of reference values across cultures/countries will be compared.

All these steps follow the logical procedure of construct validation as we have worked through in other instruments developed by our group [8,25]. This will take approximately 2 years.

Conclusion

This self-administrable 40-item QSF scale can measure and compare quality of sexual function for both genders. The scale was well accepted by the respondents. It is easy to answer and the evaluation is simple. Only a few results of reliability and validity have been established in this early stage of the development of the new instrument. The need for further research has been listed to complete many missing aspects of reliability and the construct validity.

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Appendix

Final version of the scale
(Original in German; translated/back-translated into English)

Quality of Sexual Function (QSF) Scale

With increasing age, minor or major problems or even complaints occur frequently. This questionnaire deals with the aging of both females and males.

Which of the following statements describe your personal situation when considering the last month?

Please, mark for each statement whether it applies to you or not, and if yes, to what extent. For symptoms that do not apply, please mark "NONE."

A. Below you will find a list of general symptoms. Please, mark for **each** of the statements whether it applies to you or not, and if yes, to what extent you are affected.

	Degree of intensity/severity				
Description of impairments/symptoms	No, none	Mild	Moderate	Severe	Very severe
Coding	(1)	(2)	(3)	(4)	(5)
1. My feeling of general well-being has declined (physically or mentally).	☐	☐	☐	☐	☐
2. Pain in my chest has occurred.	☐	☐	☐	☐	☐
3. I have got heart discomfort at rest (unusual awareness of beating, racing, skipping, tightness).	☐	☐	☐	☐	☐
4. I sometimes have joint pain and muscular ache (lower back pain, joint pain, pain in a limb, general back ache).	☐	☐	☐	☐	☐
5. Unexpected episodes of sweating occur, sometimes also at night (without any previous physical or mental load).	☐	☐	☐	☐	☐
6. I suffer from feeling dizzy.	☐	☐	☐	☐	☐
7. Sometimes I have got sleep problems (difficulty in falling asleep or sleeping through, poor sleep, sleeplessness).	☐	☐	☐	☐	☐
8. Irritability and nervousness have increased (inner tension, inner restlessness, easily upset about little things, aggressiveness).	☐	☐	☐	☐	☐
9. Sometimes I am in a depressive mood (feeling down, sad, on the verge of tears, lack of drive, mood swings).	☐	☐	☐	☐	☐
10. I feel physical exhaustion sometimes, and lacking vitality	☐	☐	☐	☐	☐
11. My memory and concentration are impaired.	☐	☐	☐	☐	☐
12. My muscular strength has clearly decreased.	☐	☐	☐	☐	☐
13. Sometimes I have got problems with urination.	☐	☐	☐	☐	☐

B. Many people are not happy with their sexual relations in general and with their sexual intercourse in particular. For this reason, we would like to ask you some even more private questions and to also ask you to tell us about your current situation, your desires, and your problems by marking the respective boxes. These questions refer to the last month.

If you answer the questions, please, do so totally openly and honestly—this questionnaire will be treated absolutely confidentially. However, if you are not willing to answer these questions, please leave the following part blank.

	Degree of intensity/severity					
Sexual function	No partner	No	Slightly	Moderately	Strongly	Very strongly
Coding	(0)	(1)	(2)	(3)	(4)	(5)
14. Are you yourself unhappy with your common sexual life?		☐	☐	☐	☐	☐
15. Is your partner unhappy with your common sexual life?	☐	☐	☐	☐	☐	☐
16. Do you personally experience pain or other problems during sexual intercourse?	☐	☐	☐	☐	☐	☐
17. Does your partner experience pain or other problems during sexual intercourse?	☐	☐	☐	☐	☐	☐
18. Would you like to have sexual contacts more often?		☐	☐	☐	☐	☐
19. Does your partner wish for sexual intercourse more often than you do?	☐	☐	☐	☐	☐	☐
20. Does your partner wish for sexual intercourse less often than you do?	☐	☐	☐	☐	☐	☐
21. Has your desire for sexual activity (sexual intercourse or masturbation) ***de***creased?		☐	☐	☐	☐	☐
22. Has your desire for sexual activity (sexual intercourse or masturbation) ***in***creased?		☐	☐	☐	☐	☐

	No partner	No	Rarely, little	Moderately	Often	Very often
Coding	(0)	(1)	(2)	(3)	(4)	(5)
23. Do you often have sexual dreams, fantasies or desires?		☐	☐	☐	☐	☐
24. Does your partner have sexual dreams, fantasies or desires about you?	☐	☐	☐	☐	☐	☐
25. Do you frequently do sexual self-satisfaction (masturbation)?		☐	☐	☐	☐	☐
26. Do you occasionally refuse sexual intercourse with your partner, though desired?	☐	☐	☐	☐	☐	☐

	No partner	No	Rarely, little	Moderately	Often	Very often
Coding	(0)	(5)	(4)	(3)	(2)	(1)
27. Do your sexual organs respond to sexual desires or dreams as usual?		☐	☐	☐	☐	☐
28. Do you take the initiative to have sexual intercourse with your partner?	☐	☐	☐	☐	☐	☐
29. Do you experience great sexual excitement before and during sexual intercourse?	☐	☐	☐	☐	☐	☐
30. Are you happy with your state of excitement before and during sexual intercourse?	☐	☐	☐	☐	☐	☐
31. Is sufficient moisture achieved during the entire sexual intercourse?	☐	☐	☐	☐	☐	☐
32. Do you reach full satisfaction during sexual activities (orgasm)?		☐	☐	☐	☐	☐

C. Now a few more general questions to better understand the above answers:

33. What is your gender? Male ☐ Female ☐
34. What is your age? ☐☐ years
35. What is your weight (kg)? ☐☐ kg
36. How tall are you? ☐.☐☐ meter
37. Did you have a partner for sexual relations last month? No ☐ Yes ☐
38. If Yes: Did you have sexual contacts last month? No ☐ Yes ☐
39. For how long have you been intimate with your current partner?
    No intimate intercourse ☐
    Less than 6 months ☐ 6–12 months ☐ 1–3 years ☐
    4–6years ☐ 7–10 years ☐ More than 10 years ☐
40. Does sexuality play an important role in your life?
    Less important ☐ Important ☐ Very important ☐

Thank You for Your Cooperation

The Quality of Sexual Function (QSF) Scale: Evaluation Scheme

Once the QSF questionnaire is completed by the respondent, the following form can be used if a evaluation on paper is intended. However, we recommend a computerized evaluation.

The scoring scheme of the QSF scale is simple: the questionnaire has for each of the 32 item an option to check one of five to six boxes (coding points 0, 1, . . . 5). Put these coding points of each of the items into the form below.

The composite scores for each of the four dimensions (subscales) is based on adding up the scores of the items of the respective dimensions. The composite score (total score) is the sum of the four-dimension scores. The four dimensions, that is, psycho-somatic quality of life, sexual activity, sexual (dys)function—self-reflection, and sexual (dys)function—partner's view, and their corresponding question numbers are detailed in the form.

This form explains how the total sum-score and the sum-scores of the subscales are determined: add up the points from each of items belonging to one of the subscales (indicated by an arrow into a blank field) to get the sum-score for the respective subscale.

The "total score" is the sum of the sum-scores of the three subscales.


Four subscales
Psycho-somatic quality of life
Sexual activity
Sexual (dys)function—self-reflection
Sexual (dys)function—partner's view
1. Well-being declined
2. Pain in chest
3. Heart discomfort at rest
4. Joint and muscular ache
5. Episodes of sweating
6. Feeling dizzy
7. Sleep problems
8. Irritability and nervousness
9. Depressive mood
10. Physical exhaustion
11. Memory, concentration impaired
12. Muscular strength decreased
13. Problems with urination
14. Unhappy with sexual life
15. Partner unhappy with sex
16. Problems during sex
17. Partner's problems during sex
18. More sexual contacts desired
19. Partner desires more sex
20. Partner wishes less sex
21. Desire for sexual activity decreased
22. Desire for sexual activity increased
23. More sexual dreams, fantasies
24. Partner's sexual dreams
25. Sexual self-satisfaction
26. Refuse sexual intercourse
27. Sex organs respond to desires
28. Sexual initiative
29. Great sexual excitement
30. Satisfaction with sexual excitement
31. Sufficient moisture during sex
32. Sexual satisfaction achieved