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# Research: Educational and Psychological Aspects The SAD-MEN questionnaire: a new and reliable questionnaire for assessing sexual dysfunction in Asians with diabetes

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# **Abstract**

**Aim** The aim of this study is to construct a new tool for the assessment of sexual dysfunction among men with diabetes that is valid and reliable across different ethnicities, languages and socio-economic backgrounds in South East Asia.

**Methods** Focus group interviews were conducted to determine the construct of the questionnaire. Content and face validity were assessed by a panel of experts. A pilot study was conducted to validate the Sexual Dysfunction in Asian Men with Diabetes (SAD–MEN) questionnaire in English and Malay. The International Index of Erectile Function–5 (IIEF–5) was used for comparison. Construct validity was assessed using exploratory factor analysis, reliability was determined using Cronbach's  $\alpha$  (> 0.700), and test–retest reliability using Spearman's rank correlation coefficient.

**Results** The SAD–MEN questionnaire yielded moderate face and content validity, with high reliability as shown by Cronbach's  $\alpha$  values of 0.949 for sexual performance and 0.775 for sexual desire for the English version. The Malay language questionnaire had a Cronbach's  $\alpha$  value of 0.945 for sexual performance and 0.750 for sexual desire. Test–retest reliability using Spearman's test gave correlation coefficients of r = 0.853, P = 0.000 for the English language questionnaire and r = 0.908, P = 0.000 for the Malay language questionnaire.

**Conclusion** The SAD-MEN questionnaire is a valid and reliable tool by which to assess sexual dysfunction in English-and Malay-speaking Malaysian and South East Asian men with diabetes.

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# Introduction

Diabetes mellitus is highly prevalent in Asia correlating with its rapid socio-economic improvement. In 2010, the prevalence of diabetes in Malaysia was reported to be 22.6% [1]. Diabetes mellitus impairs quality of life, including sexual health, causing reduced life satisfaction, diminished mood and poor relationship quality [2]. Sexual dysfunction (SD) in men encompasses not just erectile dysfunction (ED), but also ejaculatory disorders, orgasmic problems, sexual desire, libido and urge problems [3–6]. Sexual dysfunction in Asian

men with diabetes is commonly under-recognized because Asian men are reluctant to discuss the problem as it involves loss of self-esteem [4].

The World Health Organization (WHO) defined sexual dysfunction as 'the various ways in which an individual is unable to participate in a sexual relationship as he or she would wish'. Men with diabetes develop sexual dysfunction at an earlier age than men without diabetes; the incidence ranging from 20% to 85% [4].

Risk factors for sexual dysfunction such as hypertension, vascular disease and peripheral neuropathy overlap with many of the comorbidities linked with diabetes mellitus [4]. Older men, who had a longer duration of diabetes mellitus and with multiple complications, have a higher incidence of sexual dysfunction and erectile dysfunction [7,8]. Poor glycaemic control is linked to erectile dysfunction with a prevalence of > 48% in men < 40 years of age [9]. The 1994 Massachusetts Male Aging Study demonstrated that men

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#### What's new?

 This study describes the development and validation of a new questionnaire assessing sexual dysfunction in Asian Men with diabetes (SAD–MEN).

- This new tool is culturally acceptable across different ethnic groups, languages and socio-economic backgrounds in South East Asia.
- The SAD-MEN is constructed based on the Malaysian population and is a valid and reliable tool for use in South East Asian populations.

with diabetes are three times more likely to develop erectile dysfunction compared with men without diabetes mellitus, possibly due to autonomic neuropathy [10,11].

Premature ejaculation is defined as 'ejaculation with minimal stimulation and earlier than desired, before or soon after penetration' [12]. Men with diabetes are more likely to have ejaculatory problems and impaired morning and spontaneous erections [13]. Premature ejaculation worsens with chronicity of diabetes mellitus and worsens erectile dysfunction [14,15]. Premature ejaculation was found to be more prevalent in the Asia-Pacific region, as investigated using the Premature Ejaculation Diagnostic Tool (PEDT), Sexual Health Inventory for Men and Index of Premature Ejaculation, but only 40% of men with PEDT-diagnosed premature ejaculation, self-reported premature ejaculation [16]. This warrants a better questionnaire tailored for premature ejaculation in the Asian population with diabetes mellitus. Retrograde ejaculation is a complication of diabetes mellitus due to neuropathic and vascular dysfunction. Other types of sexual dysfunction in men with diabetes mellitus such as anorgasmia are also poorly researched.

Currently, there are limited data on the prevalence of sexual dysfunction in both the general population and men with diabetes in Asia. Most published studies were conducted in the North America and Western European populations, and were mostly on erectile dysfunction. A meta-analysis of the limited available data reported a prevalence rate of erectile dysfunction in Asia ranging widely from 2% to 81.8% [7,17]. This wide range underscores the difficulty in estimating the prevalence of erectile dysfunction among Asian men. In Malaysia, the overall prevalence rate of erectile dysfunction among urban dwellers above the age of 40 was 70.1%, with 32.8% experiencing mild erectile dysfunction, 17.7% mild to moderate erectile dysfunction, 5.1% moderate erectile dysfunction and 14.5% severe erectile dysfunction [18]. The prevalence of severe erectile dysfunction in the general population in Malaysia was 11%, but this study did not distinguish men with diabetes mellitus from those without [19]. One large study on the prevalence of erectile dysfunction was conducted in China, but this does not reflect the multi-ethnic population in South East Asia [7]. The Male Sexual Health Questionnaire addresses the importance of ejaculatory disorders and sexual satisfaction in men with sexual dysfunction [20]. However, important parts of sexual health, such as libido and anorgasmia were not addressed.

The International Index of Erectile Function–5 (IIEF–5) is an internationally validated self-administered questionnaire assessing the severity of erectile dysfunction among men, and is the most commonly used assessment tool for erectile dysfunction [20]. One study found no significant difference in the prevalence of erectile dysfunction between men of South Asian origin and Caucasians with diabetes [21]. However, the IIEF–5 was designed to focus on erectile dysfunction only and not other sexual disorders such as premature ejaculation, which is more prevalent in Asian men compared with Caucasian men [21].

The topic of sex and sexuality is not comfortably discussed and is considered a very sensitive issue to many Asians. A study conducted across China, Taiwan, South Korea, Japan, Thailand, Singapore, Malaysia, Indonesia and the Philippines looking at sexual behaviour, dysfunction and help-seeking patterns among an urban Asian population, found that although sexual dysfunction is prevalent in the middle aged group, sociocultural factors prevented the afflicted individuals from seeking treatment [22]. Self-reported questionnaire is the most appropriate way to obtain such delicate data without causing embarrassment to the patient [22,23]. It is crucial that the tool used cover all the components of sexual dysfunction in order to obtain an accurate reflection of sexual dysfunction.

There is thus a need for a self-administered questionnaire that addresses the issue of sexual dysfunction as a whole, not just erectile dysfunction. Other sexual problems, risk factors like mood disorders, cardiovascular, renal and neuropathic complications of diabetes and medications should also be screened.

The Malaysian population is made up of 60% Malays, 23% Chinese, 7% Indians and 10% others. This ethnic composition is similar to many South East Asian countries such as Singapore, Indonesia, Brunei, southern Thailand and southern Philippines. The different ethnic groups in Malaysia share the same socio-economic background. In Malaysia, the Malays, Chinese and Indians are the three main races that truly reflect the population in Asia because they are ethnically, culturally and socially different from each other. The Chinese originated from China, the Indians are from the Indian subcontinent and the Malays from the Malay Archipelago that includes Malaysia, Singapore, Brunei, southern Philippines, Indonesia and southern Thailand. Although many urban Malaysians of all three races speak English, there are many who are more proficient in the Malay language. The more conservative Asian population would find it hard to relay to healthcare professionals about their concerns regarding sexual dysfunction. Thus, there is a dire need to develop a self-administered questionnaire in English and Malay to cater to the population.

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The primary aim of this study was to develop and validate a reliable self-administered questionnaire encompassing all aspects of sexual dysfunction in English and Malay that is acceptable and stable across the different ethnicities and socio-demographic backgrounds.

#### **Methods**

Ethics approval was obtained from Monash University Human Research Ethics Committee. Written informed consent was obtained from all participants.

### Questionnaire development

Focus group interviews were conducted to determine the construct of the questionnaire. The English language focus group consisted of 10 men with diabetes mellitus and sexual dysfunction of different ethnicities, age group, duration of diabetes mellitus and socio-economic background with English as their lingua franca. The members of the focus group were excluded from the pilot study for validation purposes. The questionnaire consists of three sections. It covers all aspects of sexual dysfunction in men including erectile dysfunction, premature ejaculation, anorgasmia and libido. The development of the questionnaire involved an extensive literature search and advice from endocrinologists and clinical researchers. There were initially 45 questions in the first draft. The questions were on sexual disorders commonly seen such as erectile dysfunction, ejaculatory disorders, anorgasmia and structural deformities causing sexual dysfunction (paraphimosis, phimosis).

The first section details the demographics, diabetes and cardiovascular history, other medical conditions, age, alcohol consumption, hypertension, cigarette smoking, medications used and nerve problems.

The second section explores the history of sexual disorders including poor sexual desire, poor libido, anorgasmia, paraphimosis, phimosis and ejaculatory disorders.

The third section of the questionnaire assesses sexual function. These questions are answered on a scale of 1 to 5, with 1 being the worst score (severe dysfunction) and 5 being the best score, and in terms of various parameters such as frequency, rate of occurrence and degrees of agreement.

A copy of the questionnaire is given in the online Supporting Information.

The first draft of the SAD–MEN questionnaire in English was given to the expert group for face and content validation. The expert group was made up of two endocrinologists, a public health expert, a psychiatrist and a family physician. They provided feedback on the relevance and understanding of the various questions. Seven questions were removed due to repetition and vague structure. The final draft consists of 38 questions, with 12 questions describing the demographics and concomitant medical history, 13 questions on history of sexual disorders and 13 questions

on sexual function assessment. The last section consists of two distinctive components of sexual performance (nine items) and sexual desire (four items).

The final draft of 38 questions was professionally translated by two translators to the Malay language and backtranslated by another two translators to ensure accuracy. The translated Malay version of the questionnaire was given to 30 participants who are literate in the Malay language. These participants were recruited in a government medical clinic and they provided feedback on the language and cultural appropriateness of the questionnaire.

# Validation of the SAD-MEN questionnaire in English Language

A pilot study was conducted and the IIEF-5 in English was co-administered for comparison [19]. In total, 100 participants were recruited. The inclusion criteria were male participants of at least 40 years of age with Type 2 diabetes mellitus who had completed at least six years of education and were able to give written consent. Exclusion criteria were participants with concurrent Parkinson's disease, Alzheimer's disease, dementia, severe visual impairment and with mental illness. Participants were recruited from government (non-paying or subsidized fee) hospital and clinics such as Hospital Sultan Aminah Johor Bahru and Polyclinic Mahmoodiah Johor Bahru and private clinics (selfpaying or third party paying). The participants were Englisheducated of different races, religions and socio-economic backgrounds residing in Malaysia. The basic demographics of the participants are given in Table 1. A doctor researcher assessed the participant's medical history and undertook a

Table 1 Demographic data of the two study groups

Characteristics	English No (%) ( <i>n</i> = 100)	Malay No (%) ( <i>n</i> = 122)	P
Age			
40–50 years	20 (20)	35 (29)	0.12
50-60 years	44 (44)	50 (41)	
61-70 years	25 (25)	32 (26)	
More than 70 years	10 (10)	4 (3)	
Marital status			
Married	92 (93)	226 (89)	1.00
Single	7 (7)	13 (5)	
Ethnicity			
Malay	38 (38)	104 (87)	0.00
Chinese	23 (23)	4 (3)	
Indian	38 (38)	12 (10)	
Duration of diabetes			
1–5 years	29 (29)	51 (42)	0.10
6–10 years	27 (27)	31 (26)	
More than 10 years	44 (44)	39 (32)	
Type of treatment for dia	betes		
Oral pills only	72 (73)	87 (74)	0.90
Insulin only	9 (9)	12 (10)	
Oral pills and insulin	18 (18)	19 (16)	

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physical examination. Participants were given both sets of questionnaires to complete and a private area was provided for this. The questionnaires were given in no specific order. The same questionnaires were completed again given after four weeks to assess test–retest validity.

# Validation of the SAD–MEN Questionnaire in Malay Language

A total of 122 participants of different ethnic groups were recruited for validation of SAD–MEN in Malay language. The participants recruited were different from the English language cohort. The inclusion and exclusion criteria remained the same as for the validation of the English language version. Medical history was recorded and a physical examination was performed. The SAD–MEN and IIEF–5 in the Malay language were given to the participants to complete. The participants were given same set of questionnaires four weeks later to assess test–retest validity.

#### Statistical analysis

Data was analysed using SPSS v. 20.0. Participants who did not complete more than three questions were removed from analysis. A value of P < 0.05 was taken as the level of significance. Demographic data were assessed using frequency-based descriptive analysis. Cross-tabulating the English and Malay versions of the questionnaires was carried out using the chi-square test to determine statistical differences between the two language groups. The validity for the SAD-MEN questionnaire was assessed by face, content and construct validity for both languages. The construct validity was evaluated by factor analysis. Exploratory factor analysis was employed by using principal component analysis. Data suitability was tested using the Kaiser-Meyer-Olkin measure. Factors were extracted using the principal component method with Varimax rotation and a Kaiser's criteria of eigenvalue > 1. Reliability was evaluated using Cronbach's α coefficient, where a value of > 0.7 was taken as indicating high internal consistency. The test-retest reliability was evaluated using the Spearman rank correlation coefficient because preliminary analysis showed the variables were not of normal distribution. Concordant validity was assessed by comparing the reliability coefficient of SAD-MEN with IIEF-5.

# **Results**

Demographic data for the 222 participants recruited for validation are shown in Table 1. The participants were recruited from various clinical sites, viz., Monash Medical Research Centre at Sunway Campus and Johor Bahru Campus, Tropicana Medical Center, Selangor; Poliklinik Mahmoodiah, Johor Bahru; and medical out-patient clinic and medical wards of Hospital Sultanah Aminah, Johor Bahru. The variety of locations facilitated a mixture of urban and suburban popula-

tions of different socio-economic status, ethnicity, lingua franca and diabetes control. There were no significant differences in age and marital status. There was a statistically significant difference between the two languages (P=0.00) because 87% of the Malay language participants were Malays. For the English version, the ethnicity of the participants was equally distributed among the three ethnic groups (Malay, Chinese, Indian). A large percentage of the participants completing the English questionnaire had diabetes for >10 years (44%), whereas most participants completing the Malay questionnaire had diabetes for 5 years or less (42%). More than 70% of the participants took oral hypoglycaemics and only 10% were on insulin; 28% had diabetes complications.

More than 60% of all participants had hypertension and hypercholesterolaemia. Fewer participants suffer from prostate problems (19% for English and 15% for Malay), genital conditions (9% for English and 7% for Malay) and back or spinal trauma (9% for English and 4% for Malay), thus ruling out the other potential causes of sexual dysfunction.

There was a high prevalence of premature ejaculation: 46% of English language participants and 38% of Malay language participants were affected. The most widely accepted definition from the DSM-IV-R and the ICD-10 defines premature ejaculation as a condition of short ejaculatory latency that causes personal distress and is beyond the patient's ability to control [24,25]. The American Urological Association further defined premature ejaculation as ejaculation that occurs sooner than desired, either before or shortly after penetration, causing distress to either one or both partners [26]. The recommended ejaculatory latency time has varied from 1 min to 2 min or less [27]. To date, there is no internationally accepted normal ejaculatory latency time [28]. In our study, premature ejaculation was defined as ejaculation that occurs sooner than desired leading to distress to the patient or his partner.

Nineteen per cent of the English language participants and 21% of the Malay language participants were current smokers, 30% of the English language participants and 28% of the Malay language participants quit for one year or more. More than half (52% for the English language participants and 52% for the Malay language participants) had never smoked. Alcohol consumption was seen in 27% of the English language participants and only 2% of the Malay language participants. There was a statistical difference between the two languages, P = 0.00 because it is prohibited in the Malay/Muslim culture to consume alcohol.

The psychological factors that may affect sexual function were assessed using the questionnaire. More than 80% of participants from both languages do not suffer from stress or insomnia or depression. None of the psychological factors questions showed a statistical difference between the two languages.

The Kaiser–Meyer–Olkin measure for sampling adequacy was 0.860 for the English version of the questionnaire and 0.899 for the Malay version. This indicates that the sample

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size was adequate for factor analysis. Exploratory factor analysis revealed the presence of two components, which explain 55.93% and 13.07% of the variance, respectively for the English version of the questionnaire, and 56.47% and 12.73% for the Malay version of the questionnaire. The rotated component matrix revealed the presence of a good structure of components showing strong loadings in one of the two components, sexual desire and sexual performance (Table 2).

Reliability analysis for the English version, showed component of sexual performance (nine items) yielded a Cron-

Table 2 EFA: principal component analysis

	Rotated Component Matrix (English)		Rotated Component Matrix (Malay)	
	1	2	1	2
Sexual performance				
How much do you enjoy sexual intercourse?	0.780	0.379	0.746	0.341
How satisfied have you been with your sexual life?	0.764	0.374	0.817	0.247
When you attempted intercourse, did you find entering your partner difficult?	0.888	0.043	0.838	0.103
During sexual intercourse, was it difficult to maintain your erection to completion of intercourse?	0.895	0.056	0.879	0.118
Is your confidence high in achieving and maintaining an erection?	0.789	0.285	0.885	0.167
How satisfied were you of your outcome after you have attempted intercourse?	0.901	0.023	0.900	0.049
How often were you able to get an erection during sexual activity (intercourse, foreplay or masturbation)?	0.796	0.358	0.763	0.430
How often did you ejaculate during any sexual activity (intercourse, foreplay, masturbation)?	0.675	0.310	0.605	0.496
How often did you have the feeling of orgasm or climax when you had sexual activity (intercourse, foreplay and masturbation)?	0.727	0.346	0.684	0.539
Sexual desire				
How often is there an urge for sex?	0.438	0.741	0.496	0.607
It doesn't take much for me to get sexually excited	0.068	0.565	0.293	0.672
How frequently do you think about sex?	0.191	0.754	0.097	0.718
I have a strong sex drive	0.127	0.854	0.024	0.814

Table 3 Reliability analysis of the SAD-MEN using Cronbach's alpha

Component	Cronbach's α score (English)	Cronbach's α score (Malay)
Sexual performance (9 items)	0.949	0.945
Sexual desire (4 items)	0.775	0.750

bach's  $\alpha$  value of 0.949, whereas sexual desire (four items) scored 0.775, indicating moderate to high internal consistency and reliability (Table 3). Test–retest reliability, showed a positive and significant correlation between the two questionnaires given at intervals (r = 0.853, n = 61, P = 0.00). There was a strong internal consistency and positive reproducibility when comparing the questions on erectile function with the IIEF–5 (r = 0.881, n = 81, P = 0.000).

For the Malay language version, sexual performance yielded a Cronbach's  $\alpha$  value of 0.945, whereas the value for sexual desire was 0.750, indicating moderate to high internal consistency and reliability (Table 3). The test–retest reliability for the questionnaires given at two intervals showed a Spearman's rank correlation coefficient of r = 0.908, n = 51, P = 0.00. Comparing the component on erectile function of SAD–MEN with the IIEF–5, there was a strong correlation coefficient, r = 0.810, n = 85, P = 0.000.

The scoring system for sexual dysfunction is located in the third section of the questionnaire. It is based on sexual performance and sexual desire and not on demographics or history. The Kolmogorov–Smirnov test for normality shows a non-significant score of 0.200, indicating a normal distribution. The mean score was 42, two standard deviations below the mean was 18, one standard deviation below the mean was 30, one standard deviation above the mean was 55 and two standard deviations above the mean was 67. Based on this, it was decided that the scoring of SAD–MEN was set as severe sexual dysfunction for scores < 18, Moderate sexual dysfunction for scores of 19–42, mild sexual dysfunction for scores of 43–55 and no sexual dysfunction for those who scored 56 and above (Table 4).

A paired-samples *t*–test was conducted to evaluate the scores from the participants who answered in English compared with those who answered in Malay. There was no statistically significant difference in both scores from the first and second administration of the questionnaire in

 Table 4 Scoring system for SAD-MEN

Sexual dysfunction	Score
Severe	≤ 18
Moderate	19-42
Mild	43–55
None	56 and above

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English to Malay. The first administration in English gave a mean of 44.35, with a standard deviation of 12.82 compared with the Malay language (M = 41.11, sD = 11.56), t (90) = 1.86, P < 0.066 (two-tailed). When looking at the second administration of the questionnaire, scores from the English language version (M = 39.96, sD = 14.46) were not significantly different from those for the Malay language version (M = 35.51, sD = 12.41), t(54) = 1.82, P < 0.075 (two-tailed).

# **Discussion**

This questionnaire is the first self-administered assessment tool for the South East Asian population that assesses sexual dysfunction in men with diabetes, is available in English and Malay and which was developed based on a South East Asian population and not translated from a questionnaire developed in Western societies.

The scoring system for sexual dysfunction may aid clinicians in quantifying the severity of sexual dysfunction in men. In addition, because the sexual dysfunction questions are generic, it can be used in not only in men with diabetes, but also in those with other chronic diseases.

From our study of 222 participants of different ethnicities using SAD–MEN questionnaire, clinicians were able to gauge the presence and severity of sexual dysfunction and its cause(s), as well as diabetes control and participants' social and demographical history using a single questionnaire administration.

The questionnaire is able to demonstrate if the underlying sexual dysfunction lies within the sexual desire or sexual performance category. Clinicians are then able to pinpoint and ask in detail about certain risk factors, behaviours and attitudes that may then assist in treating the patient more effectively for both sexual dysfunction and diabetes. In addition, the SAD–MEN considered the cultural sensitivity of the South East Asian population by taking into account the important feedback provided by the participants in the pilot study, and altering the questionnaire accordingly.

The English language version of the questionnaire yielded both high validity and reliability. This questionnaire is effective in its administration to the Asian population and community because they are more reluctant to relay sexual problems and issues to caregivers and their primary health care worker in medical interviews. The SAD–MEN questionnaire was also developed in the local Malay language, and the Malay population was not as forthcoming as those of who answered in English. This version of the questionnaire also obtained a high validity and reliability from our statistical analysis.

The SAD-MEN enquires about sexual problems and evaluates the sexual function and libido. Although erectile dysfunction is highly prevalent among men with diabetes, it is closely related to other sexual disorders such as premature

ejaculation and libido [15], and hence it is important to address these issues. SAD–MEN is the first questionnaire to assess sexual dysfunction comprehensively and not just focus on a particular component of sexual dysfunction such as erectile dysfunction. This questionnaire also took cognizance of the other potential contributors to sexual dysfunction such as duration of diabetes, polypharmacy and the side effects of certain pharmacological agents such as antidepressants, anti-hypertensives, anti-histamines and diuretics by assessing the patient's medical background of having conditions that required these medications for treatment [7,22,23,29–31].

Even though many of the participants reported having hypertension and hypercholesterolaemia, there was no correlation with sexual performance or sexual desire, indicating that these conditions did not affect sexual performance and sexual desire individually. However, the effect of disease duration and progression must be considered before drawing any conclusions. Perhaps a future prospective study will be able to shed more light on this relationship. This also applies to back or spinal trauma and other genital conditions such as prostate problems and prostatic surgeries.

There was a high prevalence of premature ejaculation in the English (46%) and Malay (38%) language participants. Premature ejaculation was associated with sexual performance and sexual desire for the Malay language group (P = 0.004).

The strength of this study is in the ability of SAD–MEN to comprehensively assess all the components of sexual dysfunction. This tool is also available in English and Malay, and is culturally acceptable to the multi-ethnic Malaysian population. However, due to the nature of the tool (self-administration) only literate participants were recruited. In view of the high literacy rate among the urban Malaysian population (93%) [32], the data capture was adequate. The findings of this study were based on a Malaysian population of different ethnicities and cannot be applied to other populations until further studies are done to assess the suitability.

In conclusion, the SAD–MEN questionnaire in English and Malay is a valid and reliable tool for the assessment of sexual dysfunction in men with diabetes. This new tool developed based on South East Asian men has a wide application across Asia and may contribute towards early diagnosis and management of sexual dysfunction to achieve a better quality of life.

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#### Competing interests

None declared.

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# **Supporting Information**

Additional Supporting Information may be found in the online version of this article:

File S1. SAD-MEN questionnaire