Validation and Reliability of a Thai Version of the International Index of Erectile Dysfunction (IIEF) for Thai Population

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Background: *The International Index of Erectile Function 5 (IIEF5) is a standard questionnaire used for the evaluation of men with erectile dysfunction (ED). The Thai language version of this questionnaire is still lacking.*
Objective: *To develop and validate the Thai version of the IIEF5 (IIEF5-Th) questionnaire for clinical use in the Thai population.*
Material and Method: *The original IIEF5 questionnaire was translated into the Thai language by three experienced urologists working independently. The final version of the IIEF5-Th was obtained after consensus was reached among the three urologists and an experienced psychiatrist. The internal consistency and validity of this questionnaire was tested using Cronbach's alpha coefficient and the weighted kappa statistic (phase 1). The test-retest reliability was checked using the intraclass correlation coefficient (ICC) for agreement (phase 2).*
Results: *Fifty participants with good knowledge of the English language enrolled in phase 1 and 123 participants enrolled in phase 2 of the study. The IIEF5-Th demonstrated adequate internal consistency, with a Cronbach's alpha of 0.99. There was excellent agreement between the Thai and English versions of the IIEF5 questionnaire (weighted kappa >0.75), and the ICC for test-retest reliability was 0.92.*
Conclusion: *The Thai version of the IIEF5 questionnaire has a high internal consistency, and it is a valid, reliable, and useful tool for the evaluation of Thai men with ED.*

Keywords: *Erectile dysfunction, IIEF5, Questionnaire*

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Erectile dysfunction (ED) is a common problem worldwide. The prevalence of ED is 30.7% among 57 to 64-year-old men[1], increasing to 44.6% among 65 to 74-year-old men, indicating that age is one of the most important risk factors of ED. There is limited data on the incidence of ED in the Thai population, but the estimated overall prevalence is 37.5%[2,3]. ED has a known negative impact on patients and their partners, as well as a negative correlation with the overall cardiovascular health of the patients.

Sexual symptoms are highly subjective and sometimes difficult for patients to explain. Furthermore, some patients feel uncomfortable discussing their sexual symptoms with doctors. To improve diagnosis, a severity assessment, and patient monitoring after treatment, a number of sexual function questionnaires have been developed to help physicians evaluate their ED patients, including the Erection Hardness Score (EHS), Brief Male Sexual Function Inventory (BSFI), and Male Sexual Health Questionnaire (MSHQ)[4-6]. Among these questionnaires, the International Index of Erectile Function (IIEF) is one of the standard questionnaires that has been developed by Dr. Rosen in 1997[7]. The original IIEF questionnaire is composed of 15 questions, while the modified version (IIEF5) has five questions that focus mainly on ED and intercourse satisfaction[8]. This questionnaire has been translated into more than 32 languages and has served as a primary endpoint in more than 50 clinical studies of sexual medicine[9]. However, the validated Thai version of the IIEF5 is still lacking. ED in the Thai population is a

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common condition. The objective of this study is to develop a standard Thai version of the IIEF5 (IIEF5-Th) questionnaire to help Thai physicians treat their ED patients. Furthermore, this questionnaire would be a self-reported tool and would help in research on sexual medicine in the Thai population.

Material and Method

The present study was conducted after approval from the ethical committee board in human research of Ramathibodi Hospital, Mahidol University. Men who are 18 years or older and met the inclusion criteria were invited to take part in the present study. All participants signed the informed consent before data collection. Baseline demographic data (age, body weight, education, income, and underlying disease, etc.) were recorded. Exclusion criteria were participants having dementia, mental retardation, Alzheimer's disease, or the inability to answer the questionnaire.

The same protocol was used as previously described in the validation of the Thai version of the International Prostate Symptoms Score (IPSS) questionnaire[10]. The original version of the IIEF5 questionnaire was translated into the Thai language by three experienced urologists working independently. The final version of the IIEF5-Th questionnaire was developed after a comparison of each Thai version at the end of three meetings. A psychiatrist with experience in the translation and validation of medical questionnaires was involved in this process before completing the final Thai version.

Phase 1

To test the validity of the IIEF5-Th questionnaire, 50 Thai men with good knowledge of the English language were asked to complete the IIEF5-Th questionnaire. None of the participants viewed the questionnaire before enrollment. Two weeks later, all participants were asked to complete the English version of the IIEF5 questionnaire; this two-week period is long enough to prevent recall bias. The internal consistency of the IIEF5-Th was calculated using Cronbach's alpha coefficient. The answers to each question were compared to measure pairwise agreement using the weighted kappa statistic.

Phase 2

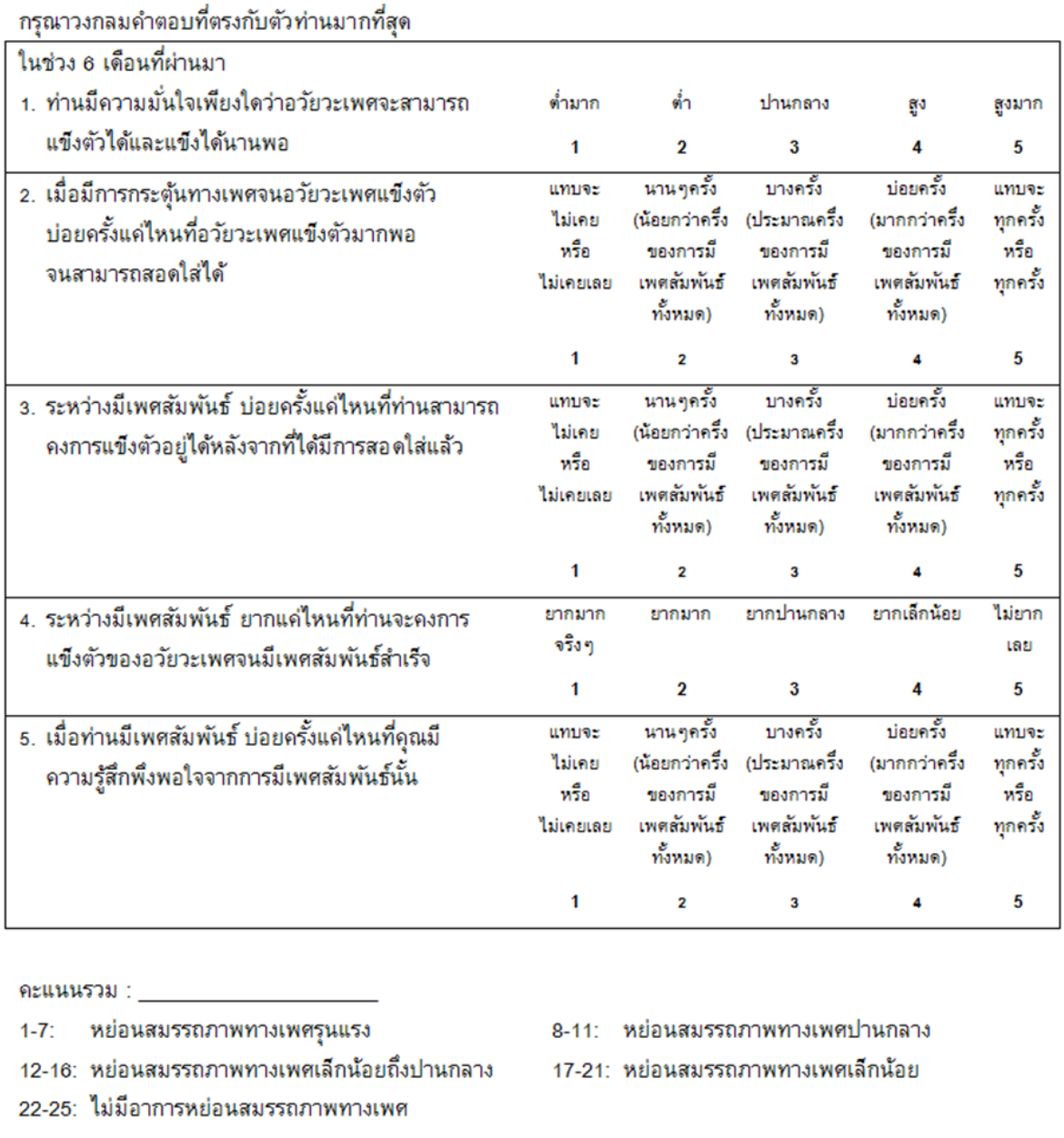
The test and retest reproducibility of the IIEF5-Th questionnaire were checked, a process that was necessary to assess the reliability of the questionnaire. Male patients who presented at the Andrology Clinic at Ramathibodi Hospital were asked to participate in the present study. Most patients have at least some degree of ED and/or lower urinary tract symptoms and/or testosterone deficiency. At the initial visit, the research team explained the objectives of the study and asked all participants to sign the consent form. The participants were asked to complete the IIEF5-Th twice. The first questionnaire was completed immediately at the initial visit. The second questionnaire was completed two weeks later, at the clinic if the patient had an appointment, or by telephone. Participants who did not complete two questionnaires were excluded from the analysis. The reliability of the IIEF5-Th questionnaire was evaluated using the intraclass correlation coefficient (ICC) for agreement, where ICC values were reported from 1 (perfectly reliable) to 0 (totally unreliable)[11,12]. All statistical analyses were performed using Stata version 14.1 (Stata Crop, College Station, Texas, USA).

Results

Two hundred twenty-two participants were invited to participate in the present study. At the end of the study, 51 participants were excluded from analysis because of incomplete questionnaire responses, so 50 participants in phase 1 and 123 participants in phase 2 were included for data analysis. The mean ages of the patients were 43 and 63 years in phase 1 and phase 2, respectively. Phase 1 participants included men with a good understanding of both the English and Thai languages, whereas phase 2 participants had a good understanding of only the Thai language. Overall, 74% of participants in phase 1 had at least a Bachelor's degree, and participants in phase 1 were younger and healthier than those in phase 2. The IIEF5-Th questionnaire used in this study is shown in Fig. 1, and the demographic characteristics of the participants in both groups are shown in Table 1.

Phase 1

The IIEF5 scores of each item are shown in Table 2. The internal consistency was calculated using Cronbach's alpha, where a high score (>0.7) means a high correlation among multiple questions[12]. The IIEF5-Th demonstrated adequate internal consistency, with a Cronbach's alpha of 0.99, as shown in Table 3. The pairwise agreement between the English and Thai versions of the IIEF5 questionnaire was evaluated using the weighted kappa statistic. The excellent agreement between the English and Thai versions was documented when the weighted kappa value was



กรุณาวงกลมคำตอบที่ตรงกับตัวท่านมากที่สุด

ในช่วง 6 เดือนที่ผ่านมา					
1. ท่านมีความมั่นใจเพียงใดว่าอวัยวะเพศจะสามารถแข็งตัวได้และแข็งได้นานพอ	ต่ำมาก 1	ต่ำ 2	ปานกลาง 3	สูง 4	สูงมาก 5
2. เมื่อมีการกระตุ้นทางเพศจนอวัยวะเพศแข็งตัว บ่อยครั้งแค่ไหนที่อวัยวะเพศแข็งตัวมากพอจนสามารถสอดใส่ได้	แทบจะไม่เคย หรือ ไม่เคยเลย 1	นานๆครั้ง (น้อยกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 2	บางครั้ง (ประมาณครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 3	บ่อยครั้ง (มากกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 4	แทบจะทุกครั้ง หรือ ทุกครั้ง 5
3. ระหว่างมีเพศสัมพันธ์ บ่อยครั้งแค่ไหนที่ท่านสามารถคงการแข็งตัวอยู่ได้หลังจากที่ได้มีการสอดใส่แล้ว	แทบจะไม่เคย หรือ ไม่เคยเลย 1	นานๆครั้ง (น้อยกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 2	บางครั้ง (ประมาณครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 3	บ่อยครั้ง (มากกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 4	แทบจะทุกครั้ง หรือ ทุกครั้ง 5
4. ระหว่างมีเพศสัมพันธ์ ยากแค่ไหนที่ท่านจะคงการแข็งตัวของอวัยวะเพศจนมีเพศสัมพันธ์สำเร็จ	ยากมากจริงๆ 1	ยากมาก 2	ยากปานกลาง 3	ยากเล็กน้อย 4	ไม่ยากเลย 5
5. เมื่อท่านมีเพศสัมพันธ์ บ่อยครั้งแค่ไหนที่คุณมีความรู้สึกพึงพอใจจากการมีเพศสัมพันธ์นั้น	แทบจะไม่เคย หรือ ไม่เคยเลย 1	นานๆครั้ง (น้อยกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 2	บางครั้ง (ประมาณครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 3	บ่อยครั้ง (มากกว่าครึ่งของการมีเพศสัมพันธ์ทั้งหมด) 4	แทบจะทุกครั้ง หรือ ทุกครั้ง 5

คะแนนรวม : _____

1-7: หย่อนสมรรถภาพทางเพศรุนแรง
8-11: หย่อนสมรรถภาพทางเพศปานกลาง
12-16: หย่อนสมรรถภาพทางเพศเล็กน้อยถึงปานกลาง
17-21: หย่อนสมรรถภาพทางเพศเล็กน้อย
22-25: ไม่มีอาการหย่อนสมรรถภาพทางเพศ

Fig. 1 Thai version of 5 International index of erectile function (IIEF5).

greater than 0.75, according to Fleiss's criteria[11]. The statistical analysis was evaluated in each question of the IIEF5-Th. In the present study, excellent agreement was found among questions one, two, and three. The results also showed good agreement among questions four and five (weighted kappa between 0.4 to 0.75). There was no poor agreement (Kappa <0.4) documented in the present study. These results confirmed the validity of the IIEF5-Th when compared to the original English version.

Phase 2

In phase 2, 123 participants completed the IIEF5-Th questionnaire. The mean age was 63 years, and more than half of the participants reached an educational level of at least a bachelor's degree, as shown in Table 1. There were no differences among the individual questions in terms of test and retest scores.

Table 1. Demographic characteristics of participants in both groups

Variable	Phase 1 (control)	Phase 2
Number (n)	50	123
Age (mean ± SD)	43.00±14.40	63.42±11.26
Height (mean ± SD)	168.64±7.22	165.73±6.42
Weight (mean ± SD)	74.04±13.22	68.38±9.80
Smoking (%)	5 (10.00)	5 (10.00)
Drinking (%)	14 (28.00)	23 (18.70)
Religion (%)		
Buddhism	49 (98.00)	123 (100)
Christ	0 (0.00)	0 (0.00)
Muslim	1 (2)	0 (0.00)
Education (%)		
Under primary	0 (0.00)	0 (0.00)
Primary	2 (4.00)	10 (8.13)
High school	11 (22.00)	27 (21.95)
Bachelor's degree	27 (54.00)	62 (50.41)
Master degree	9 (18.00)	20 (16.26)
More than master's degree	1 (2.00)	4 (3.25)
Occupation (%)		
Government officer	27 (54.00)	18 (14.63)
Company officer	3 (6.00)	4 (3.25)
Own business	9 (18.00)	21 (17.07)
Retired	2 (4.00)	61 (49.59)
Unemployed	0 (0.00)	4 (3.25)
Other	9 (18.00)	15 (12.20)
Income (%)		
<15,000 bath	8 (16.00)	31 (25.20)
15,000 to 30,000 bath	30 (60.00)	49 (39.84)
30,000 to 50,000 bath	10 (20.00)	34 (27.64)
>50,000 bath	2 (4.00)	9 (7.32)
Underlying disease (%)		
Diabetes mellitus	8 (16.00)	19 (15.45)
Dyslipidemia	5 (10.00)	50 (40.65)
Hypertension	15 (30.00)	57 (46.34)
Heart disease	6 (12.00)	6 (4.88)
Benign prosthetic hyperplasia	0 (0.00)	40 (32.52)
Overweight	0 (0.00)	5 (4.07)
Testosterone deficiency	0 (0.00)	24 (19.51)
None	27 (54.00)	19 (15.45)
Other	13 (26.00)	27 (21.95)

There was adequate internal consistency, with a Cronbach's alpha of 0.96, as shown in Table 4, and the test-retest reliability of the IIEF5-Th was calculated using the ICC for agreement, with a value of 0.92. This mean the IIEF5-Th questionnaire was considered adequately reliable.

Discussion

The objective of the present study was to validate the Thai version of the IIEF5 questionnaire, composed of five questions adapted from the original IIEF questionnaire, created by Dr. Rosen. This questionnaire is also known as the Sexual Health Inventory for Men (SHIM)[8,13]. After completing all questions, the results will be classified into five severity grades, no ED[22-25], mild ED[17-21], mild to moderate ED[12-16], moderate to severe ED[8-11], and severe ED[1-7]. Among sexual function questionnaires, the IIEF5 has been widely accepted and used in worldwide clinical trials on sexual medicine. This questionnaire is easy

Table 2. Agreement between IIEF5-Th and English version in phase 1 and between first and second questionnaire response in phase 2

Variable	Phase 1			Phase 2		
	Kappa	Thai version (mean score ± SD)	English version (Mean score ± SD)	Kappa	Thai version (first) (Mean score ± SD)	Thai version (second) (Mean score ± SD)
Question 1	0.9030	3.90±1.13	3.86±1.18	0.5493	2.54±0.98	2.63±1.10
Question 2	0.9579	3.76±1.35	3.82±1.34	0.8063	2.92±1.26	2.78±1.21
Question 3	0.9309	3.74±1.38	3.76±1.32	0.7461	2.92±1.34	2.85±1.28
Question 4	0.8577	3.96±1.18	3.90±1.23	0.6819	3.08±1.25	2.89±1.25
Question 5	0.7726	3.74±1.29	3.88±1.15	0.6646	3.07±1.39	3.00±1.32

Table 3. Internal consistency and reliability of phase 1 study

	Internal consistency (Cronbach's alpha)	Test-retest reliability Patients (n = 50)		
	Reference group (n = 50)	Intra-class correlation coefficient (n = 50)	$Mean_{change} \pm SD_{change}$	Limits of agreement[a]
IIEF-total score (1-25)	0.9922	0.9846	0.12±0.05	0.02 to 0.22

[a] Limits of agreement described by Bland and Altman = $mean_{change} \pm 1.96 * SD_{change}$ [17]

Table 4. Internal consistency and reliability of phase 2 study

	Internal consistency (Cronbach's alpha)	Test-retest reliability Patients (n = 123)		
	Reference group (n = 123)	Intra-class correlation coefficient (n = 123)	$Mean_{change} \pm SD_{change}$	Limits of agreement[a]
IIEF-total score (1-25)	0.9615	0.9262	0.4±0.15	0.08 to 0.66

[a] Limits of agreement described by Bland and Altman = $mean_{change} \pm 1.96 * SD_{change}$ [17]

for patients to understand, and patients need only a few minutes to complete all questions. It can be used for self-reporting, screening, severity evaluations, and monitoring after treatment for ED. In addition, this questionnaire is recommended by the International Consultation on Sexual Medicine to be used routinely as part of sexual problem evaluations in all patients (Level 1, Grade A)[14].

Based on the literature review in this study, this is the first validated Thai version of the IIEF5 questionnaire. After phase 1 and 2 data collection and evaluation, positive evidence to support this questionnaire was identified, and the internal consistency, validity, and reliability (test-retest) of the Thai version were evaluated. Those parameters are considered standard tools for questionnaire translation validation[15,16]. The results from the calculation documented the adequate internal consistency, excellent agreement, and good test-retest reliability. When compared to the Dutch version of the IIEF5, the researchers found that the Dutch version has an adequate internal consistency, with a Cronbach's alpha

of 0.94, and the ICC agreement was 0.88[15]. Our study showed a Cronbach's alpha of 0.99 and the ICC agreement was 0.92. This evidence supported the suitability of the IIEF5-Th as a standard questionnaire for the evaluation of Thai patients with sexual dysfunction. However, the authors believe the IIEF5-Th still needs further evaluation of its effectiveness in routine clinical practice for Thai-speaking patients who have sexual dysfunction.

There are some limitations of this study. A two-week timeframe was used for each questionnaire evaluation to prevent recall bias, but most participants had a high educational level, so there is a potential for recall bias. However, if the timeframe was extended past two weeks, patient symptoms may change over time and affect reliability. Most studies typically still use a one-to-two-week period to avoid recall bias. The number of sexual activities may affect the results, as well as the types of sexual activity (sexual intercourse or masturbation). This issue was not explored further because of a cultural barrier.

Conclusion

This Thai version of the IIEF5 questionnaire has a high internal consistency, and it is a valid, reliable, and useful tool for the evaluation of male sexual dysfunction in Thai patients. We encourage the use of this questionnaire in Urology, Andrology, or men's health clinics as an objective measurement in routine clinical practice and future research in the Thai population.

What is already known on this topic?

Sexual symptoms are highly subjective symptoms. The International Index of Erectile Function (IIEF) is one of the standard questionnaires that has been developed by Dr. Rosen in 1997. It has been translated into more than 32 languages. This questionnaire is widely used for patient evaluation during clinic visit and serves as monitoring tool in clinical studies. However, there is no validated Thai version of this questionnaire.

What this study adds?

We developed a standard Thai version of the IIEF5 questionnaire to help Thai physicians treat their ED patients. This questionnaire can be used as a reliable self-reported tool during clinic visit for the patients. Furthermore, this questionnaire would help in research on sexual medicine in the Thai population.

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Potential conflicts of interest

None.

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การตรวจสอบความถูกต้องและความน่าเชื่อถือแบบสอบถามฉบับภาษาไทยของ International Index of Erectile Function 5 เพื่อใช้สำหรับประชากรไทย

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ภูมิหลัง: *แบบสอบถาม International Index of Erectile Function 5 (IIEF5) เป็นแบบสอบถามที่เป็นมาตรฐานในการประเมินผู้ป่วยชายที่มีอาการหย่อนสมรรถภาพทางเพศ ปัจจุบันยังไม่มีแบบสอบถามนี้ในฉบับภาษาไทย*

วัตถุประสงค์: *เพื่อพัฒนาและตรวจสอบความถูกต้องของแบบสอบถาม IIEF5 ฉบับภาษาไทย สำหรับใช้ในการดูแลผู้ป่วยที่เป็นคนไทย*

วัสดุและวิธีการ: *แบบสอบถาม IIEF5 ฉบับดั้งเดิมถูกแปลเป็นแบบสอบถามฉบับภาษาไทยโดยศัลยแพทย์ระบบทางเดินปัสสาวะสามคนทำการแปลแยกกันและแบบสอบถามถูกทบทวนร่วมกันระหว่างศัลยแพทย์ระบบปัสสาวะทั้งสามคนและจิตแพทย์ที่มีประสบการณ์ จนได้แบบสอบถามภาษาไทยฉบับสมบูรณ์ ค่าความสอดคล้องภายในและค่าความถูกต้องถูกตรวจสอบด้วยค่า Cronbach's alpha และ weight kappa statistic ค่าความน่าเชื่อถือถูกทดสอบด้วย intraclass correlation coefficient (ICC)*

ผลการศึกษา: *มีผู้เข้าร่วมการศึกษาที่มีความรู้ดีในภาษาอังกฤษ 50 คน เข้าร่วมในการศึกษาระยะที่ 1 และมีผู้เข้าร่วมการศึกษา 123 คน เข้าร่วมการศึกษาในระยะที่ 2 แบบสอบถาม IIEF5 ฉบับภาษาไทยมีความสอดคล้องภายในที่เพียงพอจากค่า Cronbach's alpha 0.99 มีความสอดคล้องเป็นอย่างดีระหว่างแบบสอบถามฉบับภาษาไทยและภาษาอังกฤษ (weighted kappa >0.75) และค่าความน่าเชื่อถือ ICC คือ 0.92*

สรุป: *แบบสอบถาม IIEF5 ฉบับภาษาไทย มีความสอดคล้องภายในที่สูง ถูกต้อง เชื่อถือได้ และเป็นเครื่องมือที่เป็นประโยชน์ในการประเมินผู้ชายไทยที่มีปัญหาหย่อนสมรรถภาพทางเพศ*