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Original Research

The effectiveness of "prompt sheet" in initiating a discussion of sexual dysfunction among male patients with diabetes in a primary care setting: an open-label control trial

Nazihah Mohd Khalid[1,2], Seng Fah Tong[2,*], Ezura Madiana Md Monoto[2]

[1]Klinik Kesihatan Jalan Perak, Ministry of Health Malaysia, 11600 Penang, Malaysia
[2]Department of Family Medicine, Faculty of Medicine, National University of Malaysia, 56000 Kuala Lumpur, Malaysia
*Correspondence: tsf@ppukm.ukm.edu.my (Seng Fah Tong)
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Abstract

Background: Erectile dysfunction (ED) affects millions of men worldwide yet many are undiagnosed and untreated. Both doctors and men may have a miscommunication that ED is taboo to be brought up in the consultation. This study determined the effectiveness of prompt sheet in initiating a discussion of sexual dysfunction in a primary care setting. **Methods**: This was an open label control trial done at two government primary care clinics, one as a control and the other, an intervention group. All doctors in the participating clinics were given education on diagnosis and management of ED. Participants who came for their diabetes mellitus follow-up were approached. Those who consented to the study had their sociodemographic data recorded and erectile function evaluated using International Index of Erectile Function (IIEF-5). The patients in the intervention group (n = 69) received a prompt sheet allowing participants to indicate their decision, prior to consultation, of whether to discuss about erectile dysfunction. The prompt sheet was presented to their treating doctors during consultation. The control group (n = 65) received usual care. All participants would provide a written feedback whether there was any discussion about erectile dysfunction after the consultation. **Results**: A total of 134 participants completed the study. Ethnic distributions in intervention group differed significantly from the control group with 46.4% Chinese, 44.9% Malay, 7.2% Indian and 53.8% Chinese, 15.4% Malay, 29.2% Indian respectively. Other baseline characteristic of both groups (age, body weight, education level, employment, smoking, marital status, duration of diabetes and prevalence of ED) were similar. The prevalence of ED in both groups was about 80%. In the intervention group, only 59% of participants opted to discuss their sexual problems and among them, 80.5% of them had it discussed during the consultation. Thus, in the intervention group, 47.8% of total participants discussed about erectile dysfunction, compared to 4.6% in the control group (Odds Ratio (OR) 18.4, 95% Confidence Interval (CI): 5.4–66.2, $p < 0.001$). Sub-analysis did not reveal any relationship between either ethnicity or severity of ED and participant's option to discuss ED. **Conclusions**: Prompt sheet is a simple and inexpensive tool to cue a discussion of erectile dysfunction during consultation. More importantly, prompt sheet provides patients an opportunity to indicate their interest of discussing ED to bridge the gap of miscommunication between men and doctors.

Keywords: Erectile dysfunction; Primary care; Men's health

1. Introduction

Erectile dysfunction (ED) is defined as the inability to attain or maintain or both penile erection sufficient for satisfactory sexual performance [1]. It affects millions of men worldwide. The reported prevalence of erectile dysfunction in Malaysia is about 70% for those above 40 years old, ranging from mild to severe ED [2,3]. However, many of these patients are untreated [4]. Globally, prevalence of ED in diabetic patients for those 18 years and above was 52.5% [5]. ED is common in diabetes with a prevalence odd of about 3.5 times more than the healthy men, which was 25.5% [5].

Detection of erectile dysfunction is challenging mainly because patients are not open to discussing the symptoms during a consultation in primary care settings [6–9]. In China, only 1 in 10 would discuss ED with their doctors [6]. Other Asian countries showed similar trend. In MALES study, a multinational Asian study, reported that less than half of men with self-reported ED sought treatment for their problem [9]. Japan reported only 43% of men sought help, Malaysia 33%, Korea 30%, Taiwan 30%, and China 17%. In Turkey, the prevalence of moderate to severe ED in men 40 or more years old was 36%, however this number did not represent the exact burden of the problem as it remained under-screened, under-diagnosed and under-treated mainly because of the delay in seeking help [8]. The factors causing low rate of help-seeking for ED includes low level of awareness [8], low level of socio-economic status [7,8], culturally embarrassing [7,8], ED posing a negative masculine image [10]. From health care providers perspective, a significant proportion of primary care doctors in Malaysia were noted to perceived men as not being receptive of discussing sexual health [11]. Thus, the challenges of having to discuss ED in a consultation involving not only patients' values, culture, awareness and socio-economic circumstances, but also healthcare providers' beliefs, value and culture of discussing ED. In the setting of

a busy primary care setting, where doctors often have other competing interests and agenda besides ED, discussing ED may be more easily overlooked. Further, consultation environment may not be entirely conducive for discussing sensitive issues like ED.

Thus, a communication tool may be helpful to overcome fear, embarrassment and misunderstanding receptivity of men in discussing ED in primary care setting. Prompt sheet is one of many such tools available that may be able to help conveying a men's desire to discuss ED with their doctors. It also offers doctors a way to acknowledge men's desired without the need to guess men's receptiveness in talking about erectile dysfunction. It acts as a communication tool by giving a cue from both parties, the patients and the doctors. Prompt sheet was evaluated in a range of medical consultations. Among oncology patients, it was shown to be effective in significantly increased the total number of questions asked by patients attending oncology clinic, although the psychological outcomes did not differ among the groups [12]. In settings of breast cancer genetic counseling, prompt sheet was shown to have a positive impact on increasing patients' active participation in consultations compared to control group [13]. The prompt sheet helped the patients to communicate more assertively and the information provided was more patient specific, without affecting the visit duration [13]. Thus, prompt sheet has the potential to permit both doctors and patients on opportunity to initiate the discussions on sexual dysfunction. It is an inexpensive, non-confrontational and worth investigating. This study aimed to determine the effectiveness of a prompt sheet in initiating the discussion of sexual dysfunction among male patients with diabetes in a primary care setting. This specific group of patients was chosen because their higher prevalence of ED compared to the general population.

2. Methodology

2.1 Study design and setting

This was an open label cluster control trial done in two primary care clinics in Malaysia between August and October 2018. The two clinics were chosen because of their proximity and similarity in their profile. Both clinics are in the urban city of Penang and have similar number of staff and clinic attendees. The study focused on male diabetic patients attending clinics for their follow-ups. This is because patients with diabetes were at high risk of erectile dysfunction and follow-up visits offer a setting for discussion of this complication as oppose to walk-in visits where the agenda of acute consultation was more relevant than discussing erectile dysfunction. Those who were eligible were invited to participate in this study. The inclusion criteria were aged 18 years and above. Although the ED was common among men with diabetes over 40 years old, diabetes patients are getting younger from the recent National Health and Morbidity Survey Malaysia 2015 (1 in 5 adults aged 18 years and above) [14]. Thus, we have decided to include men above 18 years old. Those with cognitive impairment, active psychiatric disorders and emergency cases such as diabetic ketoacidosis (DKA) and hypoglycemia were excluded.

2.2 Intervention and control

Before the initiation of the data collection, a continuous medical education (CME) was conducted for all doctors from both clinics. The CME focused on management of erectile dysfunction and they were also briefed regarding the flow of the study. The aim of CME was to aim to clarify the usual care, which was based on local management guidelines and protocol.

In the intervention group, the participants were given a prompt sheet and an IIEF-5 questionnaire, which was available in three main languages in Malaysia, i.e., Malay, English and Mandarin version prior to consultation. These are common languages used in Malaysia. The prompt sheet provided brief information about ED and list of participants' desired options of issues that would like to discuss about ED (**Supplementary Table 1**). The basic information of ED was referenced from the Malaysian Clinical Practice Guidelines [15] for ED. The guidelines were developed by a team of consultant urologist. The design of information delivery was based on concepts of Health Belief Model (HBM) and Theory of Planned Behavior (TPB). HBM attempts to predict health related behavior in terms of belief patterns, whereas TPB is a model used to understand a person's behavior to initiate and maintain health behavior. The desired four options, which participants need to indicate their choice were: (1) I do not want to discuss about ED, (2) I want to discuss about risk of ED, (3) I want to discuss about treatment of ED, and (4) I want to discuss about severity of ED'. Choosing any of later 3 (option 2, 3 or 4) was considered desired to discuss about ED. After completing the prompt sheet, the participants went into the consultation room and presented only the prompt sheet to the attending doctor. Then, no further intervention in the consultation, where the doctor would conduct the consultation in a usual manner. After the consultation, the participants were instructed to return to the researchers at a data collection station to provide feedback whether there was any discussion about sexual dysfunction during the consultation.

In control group, they were not given the prompt sheet, but they would complete an IIEF-5 questionnaire prior to consultation. Their result of IIEF-5 was interpreted to patients. No further instruction was given whether to show it to the treating doctors and the decision to discuss about erectile dysfunction was entirely by the patients or the treating doctors without any active prompt. Nevertheless, the patients were told to return to common station to have their feedback as in the intervention group after the consultation.

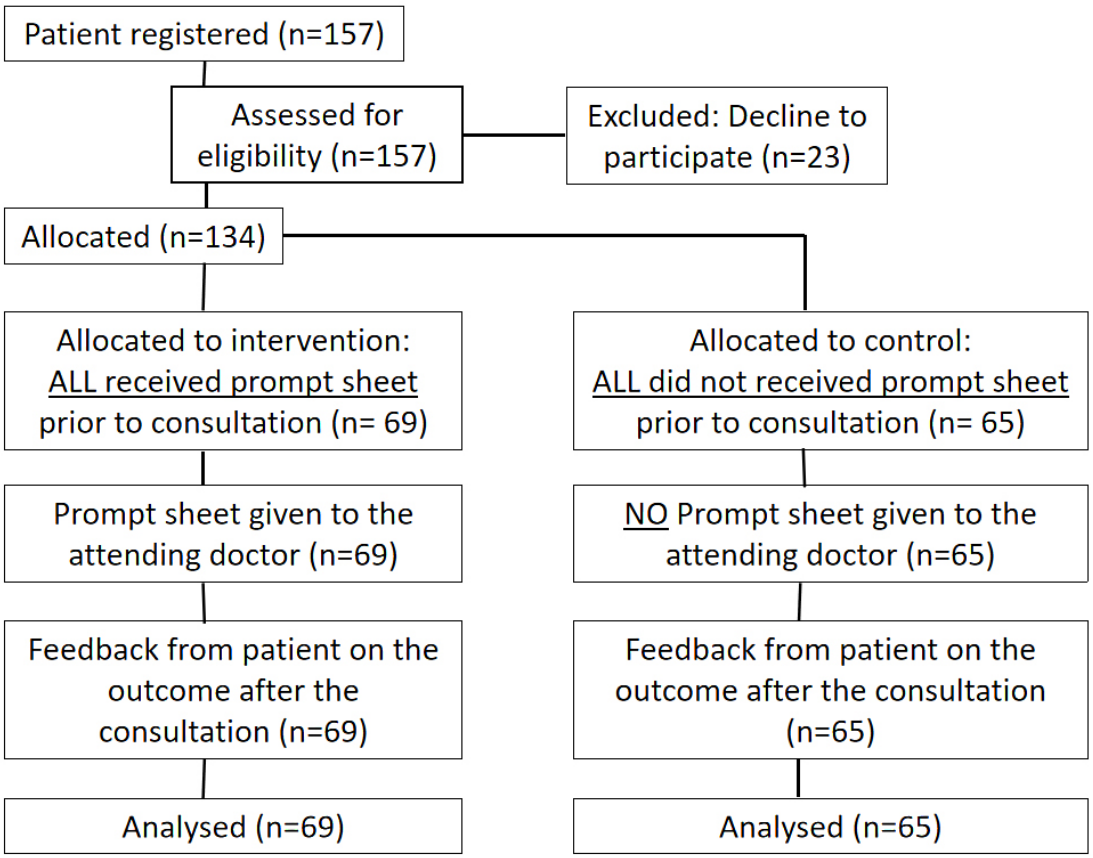

Fig. 1. Study flow diagram.

2.3 Study outcome

The outcome of study was based on the feedback from all the participants on whether there was any discussion about sexual dysfunction during the consultation. The initiation of discussion was defined as any communication occurred during consultation on any agenda related to ED. We did not document any sequelae of the consultation, whether any prescription or referral for ED treatment, because our study focused on bridging the gap on non-communication. The content of the consultation was private between the participants and doctors.

2.4 Sample size, sampling and participant allocation

The sample size was calculated using Power and Sample Size Calculator (Dupont and Plummer 1997). Based on previous study [3], at baseline, we estimated 20% of patients in usual care settings would discuss sexual dysfunction during follow up in primary care settings. We estimated that the prompt sheet would increase this proportion to 60%. Therefore, taking a power of 80% to detect the difference in the outcome of 40% between intervention and control group, an alpha of 0.05, dropout rate of 20% and a design effect of cluster sampling in two primary care clinics, we would need 60 patients for each group.

As usual clinic flow, after the patients registered at the main counter, they were seen at a common station in the clinic for routine pre-consultation vital sign evaluation. At this station, patients were approached to participate in the study and were given the patient information sheet by the same researcher for both clinics. Those who agreed to participate signed a consent form.

Upon consent, a self-administered questionnaire was given to all the participants. The participants with visual difficulties were assisted appropriately throughout the answering process. There were four sections of the questionnaire. The first section was the demographic data, and the second section was the 5-Item version of the International Index of Erectile Function (IIEF-5). The IIEF-5 and its validated Malay and Mandarin versions were used for diagnostic evaluation of ED severity [16–18]. They were then classified based on the total score into no ED (score 22–25), mild ED (score 17–21), mild to moderate ED (score 12–16), moderate ED (score 8–11) and severe ED/not sexually active (score 1–7). The third section was the prompt sheet, which was only available to intervention group. All three initial sections were filled in prior to consultation. The fourth section was the feedback, which was completed after participants' consultation.

All patients were reminded to return the feedback form after their consultation with the doctor at the pre-

consultation station. The return of the feedback was ensured because patients needed to collect their next appointment dates at this station prior to leaving the clinic. This was the normal flow of patient flow in the clinic.

As mentioned, this was an open label trial. Doctors and participants of both clinics were aware of a study concerning erectile dysfunction. The intervention was allocated to one of the two selected clinics at random flip of a coin. This was to avoid contamination and confusion among the treating doctors, which could happen if randomization was at the level of participants of both clinics. This was because doctors might unintentionally ask for prompt sheet in control group. In control group, doctors still had the freedom to initiate discussion of ED as deemed necessary. One researcher carried out all the data collection. Outcome evaluation was also done by the same researcher. We did not think this would create significant bias in the assessment of outcome because the outcome was self-reported by the participants. For participants, they were informed of an intervention being carried out without specifying the use of prompt sheet in participant information sheet. If they seek clarification, prompt sheet would be mention. This was to mimic usual consultation as much as possible in control group.

2.5 Data analysis

All data were analyzed using the Statistical Package for Social Sciences (SPSS) version 23 (IBM Corp., Armonk, NY, USA). The profile of the participants, IIEF score and the choices of option of the prompt sheet were described using descriptive analysis. The difference between the profile of intervention and control, and the association between prompt sheet given with the outcome were analyzed with either chi-square, Fisher's exact, independent *T* test or Mann Whitney U test depending on the types and skewness of the data. The analysis on the outcome was analyzed using chi-square and odds ratio was calculated to determine the impact of intervention on study outcome. The *p* value of less than 0.05 indicates statistically significant association. We noted significant difference in the distribution of ethnicity between intervention and control group. Multiple logistic regression was used to adjustment for baseline difference between intervention and control groups.

3. Results

A total of 157 patients were approached, of which, 72 patients were from control clinic and 85 from intervention clinic. Finally, 65 and 69 agreed to join the study respectively (Fig. 1). Those refused did not consent to be enrolled. The sociodemographic data and medical profile for both groups did not differ significantly except for the ethnic group (Table 1). The mean age of subjects was 57 and 58 years old in the control and intervention group respectively, with range age from 30 years old to 84 years old. The majority of participants in the control group were Chinese (53.8%) and followed by Indian, Malay and others. This reflected the race profile of the clinic attendees. However, the majority of participants in the intervention group were Malay (44.9%) and Chinese (46.4%), followed by Indian and others. This did not reflect the actual ethnicity profile of the clinic, which was supposed to be similar to the control clinic. This was due to the approached patients refused to join the study after the study information was given. The duration of being diagnosed to have diabetes, and the comorbid profile of both groups were similar. The prevalence of ED was similar in both groups which was 81.3% for the control group and 84.1% for the intervention group (Table 1). There was no statistically significant difference of ED severity between the participants in both groups.

Table 1. Sociodemographic, baseline characteristics and prevalence of erectile dysfunction.

Characteristics	Control (n = 65)	Intervention (n = 69)
Age, years (mean ± sd)	57.11 (8.50)	58.13 (11.4)
Weight, kg (median, IQR)	75.0 (16.0)	74.0 (16.5)
Ethnicity groups, n (%)[#]		
Malay	10 (15.4)	31 (44.9)
Chinese	35 (53.8)	32 (46.4)
Indian	19 (29.2)	5 (7.2)
Others	1 (1.5)	1 (1.4)
Education level, n (%)		
Primary	9 (13.8)	12 (17.4)
Secondary	45 (69.2)	51 (73.9)
Tertiary	11 (16.9)	6 (8.7)
Employment, n (%)		
Yes	39 (60.0)	38 (55.1)
No	26 (40.0)	28 (40.6)
Missing data	0 (0.0)	3(4.3)
Smoking status, n (%)		
Yes	21 (32.3)	19 (27.5)
No	44 (67.7)	50 (72.5)
Marital status, n (%)		
Married	55 (84.6)	60 (87.0)
Divorced	4 (6.2)	4 (5.8)
Widowed	1 (1.5)	3 (4.3)
Single	5 (7.7)	2 (2.9)
Duration of DM, years (median, IQR)	6.0 (7.5)	6.0 (9.0)
Prevalence of Erectile Dysfunction (ED)		
No significant ED		
No abnormality (22–25)	1 (1.6)	2 (2.9)
Mild (17–21)	11 (17.2)	9 (13.0)
Significant ED		
Mild/moderate (12–16)	31 (48.4)	26 (37.7)
Moderate (8–11)	4 (6.2)	12 (17.4)
Severe (1–7)	17 (26.6)	20 (29.0)

#$p < 0.001$.

Among the participants in the intervention group, 59% of them opted to discuss their sexual problems with the doctor during the consultation (Table 2a). They could choose

Table 2a. Intervention group response to prompt sheet (n = 69).

		Choice of discussion ED from prompt sheet	
		Not wanting to discuss	Opted to discuss
		28 (41%)	41 (59%)
Participant's options of discussion	1. Treatment of ED	-	56%
	2. Risk of ED	-	51%
	3. Severity of ED	-	32%
Discussed ED during consultation	Yes	0	80.5%
	No	100%	19.5%

Table 2b. Comparison of primary study outcome.

	Discussed sexual dysfunction during consultation	Odds ratio	95% confidence interval	*p**
Control group	4.6%	18.4	5.4–66.2	<0.001
Intervention group	47.8%			

*chi square.

Table 3a. Factors associated with option to discuss or not about erectile dysfunction.

Factor	Crude OR	95% CI	*p*	Adjusted * OR	95% CI	*p*
Age (year)	1.051	(1.002; 1.103)	0.04	1.077	(0.990; 1.173)	0.084
Employment						
Yes	1.0					
No	2.832	(1.020; 7.865)	0.046	1.434	(0.376; 5.472)	0.598
Education						
Tertiary	1.0		0.248			
Primary	7.0	(0.613; 79.871)	0.117			
Secondary	3.226	(0.351; 29.683)	0.301			
Ethnicity						
Malay	1.0		0.613			
Chinese	1.231	(0.451; 3.364)	0.685			
Indian	0.396	(0.039; 3.977)	0.431			
Marital status						
Married	1.0		0.548			
Divorced	1.727	(0.227; 13.139)	0.598			
Widowed	3.455	(0.296; 40.322)	0.323			
Severity of Erectile Dysfunction						
No Abnormality	1.0					
Mild	0.500	(0.023; 11.088)	0.661			
Mild/Moderate	0.444	(0.025; 8.031)	0.583			
Moderate	0.714	(0.036; 14.347)	0.826			
Severe	1.222	(0.067; 22.401)	0.892			

OR, Odds Ratio; CI, Confidence Interval. Simultaneous multiple logistic regression was applied.

*Adjusted for age, employment status, level of education, ethnicity and marital status.

Table 3b. Association of severity of ED and option of wanting to discuss or not about their sexual dysfunction (intervention group).

Severity of ED	Opted to discuss	Opted not to discuss	*p*
No abnormality, n = 2	1 (50%)	1 (50%)	0.540
Mild, n = 9	6 (66.7%)	3 (33.3%)	
Mild to moderate, n = 6	18 (69.2%)	8 (30.8%)	
Moderate, n = 12	7 (58.3%)	5 (41.7%)	
Severe, n = 20	9 (45%)	11 (55%)	
Total	41	28	

more than one option if they choose to discuss ED. The most popular option chosen was discussion about treatment of ED (56%), followed by the risks of ED (51%) and the severity of ED (32%). Among those who opted to discuss on the sexual problems, 80.5% had it discussed during the consultation. The remaining 19.5% of men, despite opted to discuss ED, the discussion was not reported to occur. Nevertheless, their concern was addressed by the researcher during the feedback session. All the participants who opted not to discuss on the sexual problem did not have any discussion of the matter during the consultation. Comparing the study outcome regardless of their choice of discussing

ED, the intervention group had an OR of 18.4 (95% CI: 5.4–66.2, $p < 0.001$) of having ED discussed ED during consultation compared to control group, where 33 (47.8%) of men in the intervention group discussed ED during consultation compared to only 3 (4.6%) (Table 2b). We took note that it would be inappropriate to discuss ED if patients had indicated not to do so in the consultation. We also noted a significant number of patients (n, 41%) with ED opted not to discuss ED.

We found there was an ethnicity difference in the baseline and therefore we attempted to explore the effect of ethnicity on the reported option to discuss ED. We found there was no difference in odds of choosing to discuss ED between the different baseline characteristics (Table 3a). In the intervention group, we also noted that there was no association between severity of ED and patients' intention to discuss ED (Table 3b).

4. Discussion

This study has shown that prompt sheet was effective in bringing about ED discussion among men who indicated their interest to discuss sexual dysfunction with the attending doctors. This effect was independent of ethnicity and ED severity. A local study has shown that the primary care doctors had difficulties in initiating health check-ups with men especially regarding the sensitive issues such as sexual matters [19]. This strategy may help to assist doctors to identify patients who were receptive to discuss this sensitive issue [19]. We also found a significant number of participants in the intervention group (41%) opted not to discuss about the treatment and their risks of getting ED.

As in the demographic characteristics, there was significant difference in the ethnicity distribution for both groups. All the participants from both groups were approached in a similar manner at the recruitment stage, however, more the Chinese patients in the intervention group refused to join the study after given the information. This could be due to the discomfort answering prompt sheet or it could be their intention not wanting to discuss sexual health matters. The other demographic profiles reflected the local population characteristics of patients with diabetes, where the mean age of them (patients with diabetes) from the registry was 56.6 years old [20]. We did not collect other comorbidity data of the patients, as they would have been similar with our national data. From Malaysian National Diabetic Registry of 2018, 65% had been diagnosed with hypertension, 55% with dyslipidaemia, 4% ischemic heart disease and 1% cerebrovascular disease [20].

Previous study revealed that sending an anonymous questionnaire about sexual dysfunction increased awareness of the matter and subsequently increased the number of consultations discussing about their sexual issues [21]. In that study, the questionnaire was sent to the study population of men aged 40 years and over with ED (reviewed from the patient files), and they were invited to discuss and manage further at their visits to the family doctor. In the following 2 months after the questionnaire was sent, the visits were monitored for complaints of sexual dysfunction and it was found that 9.3% patients in the intervention group consulted their family doctor compared to 1% in the control group. Both our study and this study shown that prompting patients about this sensitive issue helped in breaching the patient's agenda or wanting to discuss about it or not, albeit this study showed a larger impact, 47.8% as opposed to 9.3%. The difference of timing of prompt sheet (given immediately before the consultation compared to about 2 months before clinic visits) could have been a significant factor. Patients may forget about the prompt sheet when given earlier as compared to immediate prompt before the consultation.

There may be some elements of embarrassment and discomfort upon answering the questionnaires and discussing about the sexual issues among the participants. The prompt in this study avoided the embarrassment during consultation. This is because the prompt asked patients to indicate their intention to discussing ED, which is not a prompt to enquire about their ED status. This approach is gentler and more appealing to most men. Asking men directly of ED may create tension in the consultation [19]. Confidentiality of their response was assured. The prompt sheet provided an opportunity for the patients to express their intention to discuss about their sexual problems without having to say it out loud, which may be embarrassing to them. On the other hand, the doctors preferred that the patients to bring up the matter of their sexual health [22,23], because doctors were also noted to be unsure of men's receptivity to discuss about ED [19]. This cue then alerted the doctor about the patient's wish and assisted appropriately. Our other findings also supported the argument on the need to allow patients to express their intention to discuss ED, rather than doctors having to breach the topic. A total of 23 out of 157 invited men decline to participate. This refusal could mean they would not like to discuss ED in this consultation. Further, 41% of the intervention arm indeed expressed their intention of not wanting to discuss ED. These findings emphasized the important of having this prompt sheet as more appropriate approach rather than having doctors proactively asking every diabetic patient of their ED status regardless of patients' readiness to discuss ED.

We acknowledge ED and cardiovascular disease particularly heart disease are related [24]. Further, these participants have diabetes which makes their risks higher. Thus, with this volunteered discussion, the doctors may use this opportunity to emphasize on healthy lifestyle to reduce future vascular risks and improve erectile function [25].

5. Limitations and strength

There were few limitations identified in our study. One of them was our convenient selection of clinics where these clinics were situated in an urban community, and the

findings may differ from other communities, mainly the semi-urban and rural communities. Some of the participants did not understand some of the terms in the prompt sheet and they were guided minimally during the answering process, but the numbers of participants needed guidance was small. There was also sample bias on the ethnicity of the patients recruited in the study, nevertheless, we have further analyzed the impact of ethnicity and found no impact of ethnicity on discussing ED.

We estimated 20% of patients in the usual care would discuss ED and expected this would increase to 60% with intervention, with a difference of 40%. From this study, the rate of discussion ED in the control group was 4.6%, which was much lower than expected. Nevertheless, comparing to intervention group of 47.8%, the difference between usual care and intervention group was 43.2%, which was within the expected effect size. Thus, this study achieved the expected power to make our conclusion. Furthermore, we had a refusal rate of 18.8% with no drop out, which add further to our power of study.

The doctors in both clinics were not blinded of the intervention because it involved a process in the clinic that was not possible to be blinded to the staff in the clinic. The participating doctors in both clinics were informed of the changes occurred in the clinics, either an intervention or control. The doctors in the intervention group may be more alerted to the decision to discuss ED, but the difference in the rate of discussing sexual dysfunctions between two groups was too big to ignore the impact of prompt sheet on the initiation of discussing sexual dysfunction. Thus, we believed the difference observed between intervention and control was most likely due to the prompt given rather the effect of the unblinding process.

Further similar studies should be conducted in the future at multicenter involving public and private primary care settings. The target population can be extended to others such as walk-in patients, patients with hypertension and many more. Further, the outcome could include the impact of the discussion, i.e., resulting in prescribing, treatment satisfaction, time taken in the clinic, doctors' feedback. Prompt sheet is a simple cue to initiate communication. This cue to initiate communication is important as health seeking behavior of male Asian patients, as they tend to be passive and indirect. This study has shown that the prompt sheet has overcome the barrier of communication regarding problems of sexual dysfunction.

6. Conclusions

We know that ED and cardiovascular disease particularly heart disease are related [24]. Further, these participants have diabetes which makes their risks higher. Thus, with this volunteered discussion, the doctors may use this opportunity to emphasize on healthy lifestyle to reduce future vascular risks and improve erectile function [25].

Author contributions

NMK, SFT and EMMM designed the study. NMK and SFT analyzed the data. NMK wrote the initial draft and all authors contributed, commented, and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by Human Research Ethics Committee University Kebangsaan Malaysia (FF-2016-343) and Medical Research and Ethics Committee (NMRR-16-1327-31539 IIR). The informed consent was obtained from the participants.

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Conflict of interest

The authors declare no conflict of interest.

Supplementary material

Supplementary material associated with this article can be found, in the online version, at https://doi.org/10.31083/j.jomh1806125.

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