IJPHCS
Open Access: e-Journal

International Journal of Public Health and Clinical Sciences
e-ISSN : 2289-7577. Vol. 7:No. 4
July/August 2020

PSYCHOLOGICAL INSULIN RESISTANCE AMONG INSULIN NAÏVE TYPE 2 DIABETES MELLITUS PATIENTS IN PENANG, MALAYSIA: A MIXED METHODS STUDY PROTOCOL

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ABSTRACT

Background: The insulin usage among the type 2 diabetes mellitus (T2DM) patients in Malaysia is low despite of majority of them have poorly controlled glycaemic level. Studies also found that high prevalence of insulin initiation refusal among these patients. In this study context, psychological insulin resistance (PIR) is referred to patients reluctant to initiate insulin therapy. This study is to determine the predictors of PIR among the insulin naïve T2DM patients and to understand the barriers of insulin initiation among them.

Methods: This is an explanatory sequential mixed methods study conducted in the primary care health clinics of Penang. The first quantitative phase is conducted through interviewer-assisted questionnaire among the adult insulin naïve T2DM patients in the studied clinics. Simple random sampling methods is used to select the participants. The dependent variable is PIR which is assessed using Insulin Treatment Appraisal Scale (ITAS). Multiple linear regression analysis is conducted to determine the predictors of PIR. Using the quantitative results, the informants of qualitative phase are purposively selected to recruit those who are indicated but refuse insulin initiation. The second qualitative phase is conducted through in-depth interview using semi structured interview protocol. Thematic analysis is conducted to identify the themes of PIR. Both the quantitative and qualitative findings are integrated and interpreted in the discussion to explain the factors of PIR.

Conclusion: Using mixed methods approach, the complex and multifaceted PIR issue is comprehensively assessed. The richness of the evidences will imply to the current practice.

Keywords: ITAS, mixed methods study, psychological insulin resistance, refuse insulin initiation, Social Ecological Model, study protocol, type 2 diabetes mellitus

International Journal of Public Health and Clinical Sciences
e-ISSN : 2289-7577. Vol. 7:No. 4
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1.0 Introduction

1.1 Background

In year 2019, International Diabetes Federation (IDF) reported that 1 in 5 people with aged above 65 years old were living with diabetes globally and 1 in 2 people with diabetes were undiagnosed (International Diabetes Federation, 2019). Majority (90%) of the people living with diabetes were diagnosed to have type 2 diabetes mellitus (T2DM) (International Diabetes Federation, 2019). The prevalence of diabetes is increasing in worldwide, predominately noted in those countries transit from low income to middle income countries (International Diabetes Federation, 2019). Based on the National Health Morbidity Survey (NHMS), the increasing trend in prevalence of diabetes is also seen in Malaysia. Using the definition of diabetes if fasting blood glucose ≥ 7mmol/L, the prevalence of diabetes in Malaysia had been increased from 11.2% (2011), 13.4% (2015) to the latest 18.3% (2019) (Institute for Public Health, 2011, 2015, 2020).

To have good glycaemic control and to prevent the risk of developing diabetes complications remain the main goals of the diabetes management. However, based on the National Diabetes Registry Report (NDR) 2009-2012, in year 2012 there were 76.2% of the T2DM patients with uncontrolled diabetes with HbA1c ≥6.5% (Mustapha & Azmi, 2013). In Malaysia, the target of diabetes treatment is to keep the HbA1c 6.5% and below (Ministry of Health Malaysia, 2015). The insulin usage at the year 2012 was only 21.4%, this showed that many of the uncontrolled T2DM patients did not have optimum intensified diabetes treatment.

One of the reasons of low insulin usage could be due to the refusal of the T2DM patients to initiate insulin therapy. This can be seen in the two studies conducted in Federal Territory of Putrajaya and Kedah revealed that 51% and 74.2% respective T2DM patients refused to be started on insulin therapy (Nur Azmiah et al., 2011; Tan et al., 2015). The prevalence in Malaysia is higher if compared to the countries such as Hong Kong (47.2%), Saudi Arabia (34.6%), and Netherlands (39%) (Batais & Schantter, 2016; Kam, 2015; Woudenberg et al., 2011). Psychological insulin resistance (PIR) is the term used to describe the diabetes patients or the physicians refuse to initiate or intensify insulin therapy (Polonsky & Jackson, 2004). In this study context, PIR is referred to the reluctant of the T2DM patients to initiate insulin therapy.

There are many factors contributing to refuse insulin initiation among the T2DM patients. Transitional to insulin involves many psychological aspects, psychological fear is one of the factors. Many patients have the phobia in injection, they related the insulin injection with pain (Abu Hassan et al., 2013; Taylor Jr. et al., 2017). Besides worried about the side effect of insulin injection especially hypoglycaemia is another barrier (Petrak et al., 2013). Having negative perceptions towards insulin therapy hindered the patients to accept insulin therapy, some felt that initiating insulin therapy indicated the increased severity of the diabetes, others perceived insulin therapy as lifelong treatment (Ng et al., 2015). Besides, lack of family support also leads to insulin refusal (Ng et al., 2015). Worried about the social stigma on insulin users also concerned the T2DM patients (Fu & Cheung, 2017).

Above literatures clearly showed that PIR is a complex and multifaceted issue. Hence Social Ecological Model (SEM) would be a suitable model to guide the variables development in this

study (McLeroy et al., 1988). SEM proposed that an individual's health behaviour is determined by interaction of individual with the social environmental factors. Hence, it approaches a health issue from the individual, interpersonal, organizational, community and public policy aspects. Using SEM in this study enables the PIR issues to be dissected from various aspects, not just focusing on individual factors.

Mixed methods approach is a study design that involves collection, analysis, interpretation and integration of the quantitative and qualitative data in a study (Creswell & Plano Clark, 2007). The quantitative study able to provide statistically significant information however PIR is a complex issue that involves psychological and emotional appraisal that is unable to be completely assessed using quantitative study. Hence qualitative study which able to explore the emotional and experiences of the individuals provides a deeper understanding regarding the PIR issue. Mixed methods approach highlights the strengths and counterbalance the weakness of both quantitative and qualitative studies (Creswell & Plano Clark, 2007).

1.2 Study objectives

In view of the high prevalence of insulin refusal on top of the low insulin usage despite of poorly controlled diabetes mellitus among T2DM patients in Malaysia, it is timely for us to understand the underlying factors that lead to psychological insulin resistance in the local context. With the new inputs of the factors contributing to PIR, the practitioners will be alerted and focus on dealing with specific factors to smoothen the insulin transition process. Hence this study aims to identify the predictors of PIR among the insulin naïve T2DM patients and to explore the barriers of insulin initiation among the patients who are indicated for insulin therapy but refuse initiation.

2.0 Methods

2*.1 Study design*

This is an explanatory sequential mixed methods study. The first phase is the quantitative phase in which quantitative data is collected through interviewer-assisted questionnaire. After the analysis of the quantitative data, the quantitative results are used to purposively select the qualitative informant who are indicated but refuse insulin initiation. The second qualitative phase is conducted through in-depth-interview. After the thematic analysis of the qualitative data, both the quantitative and qualitative findings are integrated in discussion. The qualitative data helps to explain the quantitative findings in a deeper manner.

2.2 Settings

This study is conducted in four governments health clinics in a district of Penang, Malaysia. The government health clinic is selected as the site of study as majority of the T2DM patients in Malaysia are follow up in the government primary care facilities (Institute for Public Health, 2011).

2.3 Ethics approval

Ethical approval for this study was obtained from Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia (NMRR-18-2654-42289) and Ethics Committee for Research Involving Human Subjects, Universiti Putra Malaysia (JKEUPM).

2.5 Quantitative phase

2.5.1 Sampling population

The sampling population is the T2DM patients who have registered in the four studied health clinics and attend diabetes follow up in the respective health clinics during the data collection period. The sampling frame is the name list retrieved from diabetes appointment books.

2.5.2 Inclusion and exclusion criteria

The inclusion criteria are T2DM patient aged ≥18 years old, insulin naïve patients and at least on one type of oral anti-diabetic agent (OAD). Those T2DM patients who are pregnant and non-Malaysian are excluded from the study.

2.5.3 Sampling methods

Based on the name list retrieved from diabetes appointment books, the list of patients is filtered based on the eligible criteria. Then from the eligible list, simple random sampling method via random number generator online version are used to select the patients for survey.

2.5.4 Sample size

Sample size is calculated based on the multiple linear regression sample size formula as shown below (Milton, 1986).

$$n = k + 1 + \frac{t^2(1 - R^2)}{\Delta r_j^2}$$

n = sample size
k = number of predictors = 21
t = 2 for $p < 0.05$
R^2 = adjusted R^2 from previous literature = 0.154
Δr^2 = minimum addition to r^2 when the variable is entered last = 0.01

The R^2 above is based on the study conducted in Netherlands with 0.154 in the multiple linear regression analysis of predictors in PIR (Woudenberg et al., 2011). The calculated minimum sample size is 361, with the assumption of 20% non-respondents and missing data, 361 is divided by 0.8 and becomes 452 participants. Using G*Power 3.1.9.2 software, with 361 sample size, medium effect size Cohen's f^2 of 0.15, level of significant α at 0.05, and 21 predictors, a power of 0.99 is achieved (Cohen, 1988; Faul et al., 2009).

International Journal of Public Health and Clinical Sciences
e-ISSN : 2289-7577. Vol. 7:No. 4
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2.5.5 Variables

The dependent variable of this study is the total score of psychological insulin resistance, measured by Insulin Treatment Appraisal Scale (ITAS). The independent variables of this study are Social Ecological factors which include individual, interpersonal, organizational and community factors as showed in the Figure 1 below. Based on SEM, individual factors are the individual characteristics which include knowledge and self-concept (McLeroy et al., 1988). Interpersonal factors are the social network and social support whereas organizational factors include the organizational operational rules and regulations. Community factors in this study context mainly refer to family, friends, neighbourhood as well as community norms and values.

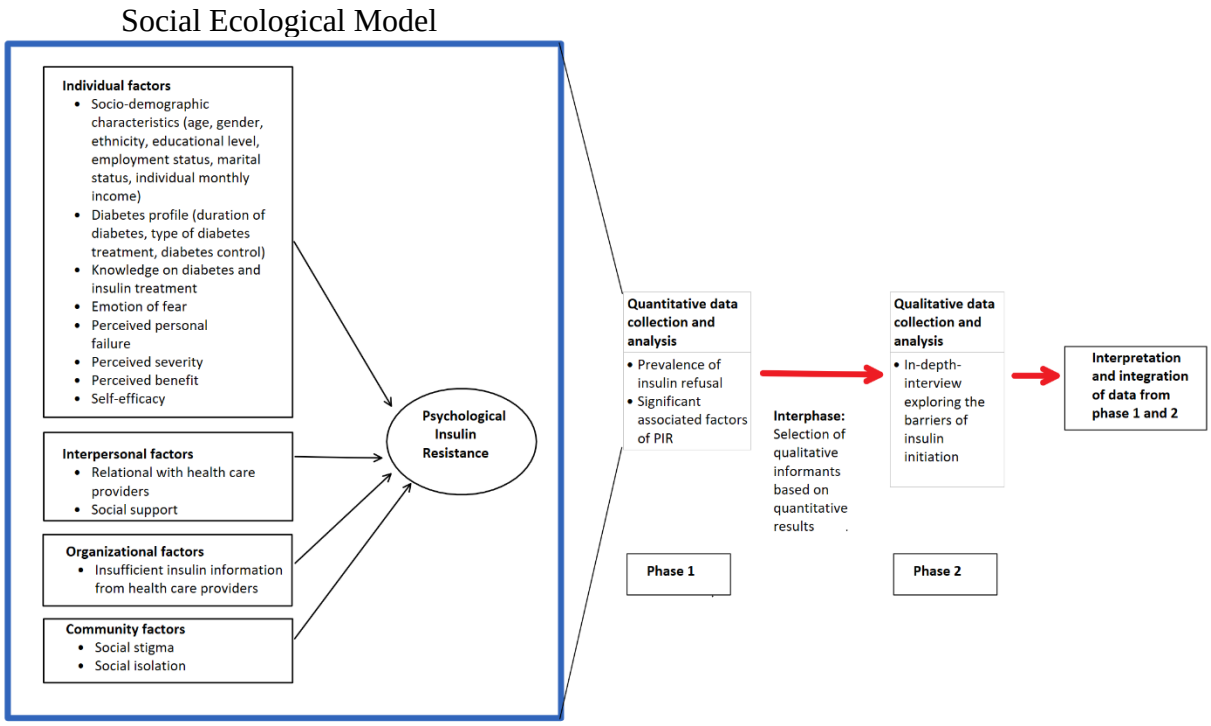

Figure 1. Quantitative and Qualitative Exploration of Psychological Insulin Resistance among Insulin Naïve T2DM Patients

2.5.6 Instruments

The quantitative data collection is through a structured questionnaire which contains 6 sessions.

A. Socio-demographic characteristics (7 items): age, gender, ethnicity, educational level, employment status, marital status, and individual monthly income
B. Diabetes profile (3 items): duration of diabetes mellitus, type of diabetes treatment, diabetes control (latest HbA1c level)
C. Willingness of initiating insulin (1 item): one question to assess the willingness of starting insulin. The four options of "strongly unwillingly" to "strongly willingly" are given. Those who response as "strongly unwillingly" and "unwillingly" are considered as insulin refusers.
D. Insulin Treatment Appraisal Scale (ITAS): a validated 20 items instrument to assess the PIR. There are 16 negative and 4 positive perceptions in the scale. Each statement is given the 5 options of "strongly disagree" to "strongly agree". The Cronbach's alpha of this total scale was 0.89 (Snoek et al., 2007). The negative perceptions are graded as "strongly

disagree"–1 and "strongly agree"-5, the positive perceptions are recorded vice versa. The sum of scores in 20 items is calculated in which the higher the ITAS score, the higher the PIR where the participant is more likely to refuse insulin initiation.

E. Knowledge on diabetes and insulin treatment (14 items): self-developed questionnaire based on the literatures. Each item is given the options of "yes", "no" and "unsure". The correct answer will score one mark whereas the wrong answer and "unsure" will score zero. The higher the scores indicate the higher knowledge on diabetes and insulin treatment.
F. Social Ecological constructs: individual factors (emotion of fear, perceived personal failure, perceived severity, perceived benefit, self-efficacy); interpersonal factors (relational with health care providers, social support); organizational factor (insufficient insulin information from health care providers); community factor (social stigma, social isolation). These constructs are self-developed questionnaire based on literatures. Each item is given 5 options ranged from "strongly disagree" to "strongly agree". The score is given as "strongly disagree"-1 and "strongly agree"-5, recoded are performed for the positive statements. The higher the score in that construct indicates the higher perceptiveness of that construct.

2.5.7 Data collection

The eligible and selected patients are approached during their diabetes follow up clinic visit. Researcher and enumerators introduce and explain the study to them, once they agree to participate, written consent will be obtained prior to data collection. Data is collected through interviewer-assisted questionnaire. The enumerators are trained prior to data collection to have a standard interaction with the participants to prevent interviewer bias. Pilot-testing are conducted by the enumerators prior to data collection. The questionnaire takes about 15-20 minutes to complete answering. All parts of the questionnaire are answered by participants via interviewer assisted except for diabetes profile section in which the data is obtained from the diabetes medical record.

2.5.8 Quality control

As part of the questionnaire is self-developed, validation of the quantitative instrument was conducted through content, face and construct validity. The reliability of the instrument was checked by internal consistency reported as Cronbach's alpha. This questionnaire was pilot-tested among the population not from the studied population. The content validity is conducted by six experts in the area of study who are the public health specialists and family medicine specialists prior to pilot-testing. They reviewed each item in the questionnaire and evaluated based on four options of "not relevant", "somewhat relevant", "quite relevant" and "highly relevant". The first two options were considered that the expert disagreed with the item. Item-content validity index (I-CVI) was used to assess the content validity. If one expert out of six experts disagreed with the item, the I-CVI would be 5/6 = 0.83. The item would be removed if two or more expert disagreed with the item. The questionnaire was modified based on experts advises.

Total of six T2DM patients not from the studied sites were invited to conduct the face validity of the questionnaire. Their understanding of the items and the appropriate words used were evaluated. The necessary modifications were made based on their recommendations. The construct validity was conducted for all the items except for socio-demographic characteristic and diabetes profile in the questionnaire using exploratory factor analysis (EFA) via SPSSS 23.0 software. Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was used to assess

the sufficient sample size to perform satisfactory factor analysis, with the KMO of 0.5 as minimum requirement (Kaiser, 1974). Kaiser's criterion with Eigenvalue >1 was used to determine the optimum number of factors (Kaiser, 1960). Items loading more than 0.40 in one factor and not more than 0.32 in another factor was considered as good scale (Snoek et al., 2007).

2.5.9 Data analysis

Data entry and analysis are conducted using SPSS 23.0 software. All the filled questionnaires are checked after each participant to ensure that there is no missing data. After data cleaning, normality distribution of each variables is examined statistically and graphically. Both the univariate and multivariate normality are checked to determine whether the transformation of skewed data is needed. For the descriptive analysis; the frequency, percentage, mean with standard deviation or median with interquartile range will be presented. In term of inferential analysis, Pearson correlation and simple linear regression are used to determine the association of the independent variable with PIR. The two-sided *p* value of < 0.05 and 95% confidence interval (CI) not including zero were considered as statistically significant. All the variables with significant association with PIR will be included in multiple linear regression to determine the predictors of PIR.

2.6 Qualitative phase

2.6.1 Informants selection

In order to get the key information regarding barriers of insulin initiation, the informants who are indicated but refuse insulin initiation are purposively selected. The informants of this qualitative phase are selected based on the quantitative results. The selection is based on the four criteria, (a) the participant who answers "strongly unwillingly" and "unwillingly" in the quantitative questionnaire, (b) have ITAS total score at or above the cut-off point, the cut-off point will be calculated using Receiver Operating Characteristic (ROC) curve, (c) on at least two type of OADs, (d) have latest HbA1c level of $\geq 7\%$. The criteria (a) and (b) are to identify those who refuse insulin initiation whereas the criteria (c) and (d) are to identify those who are indicated of insulin therapy, the criteria are based on the Malaysia Clinical Practice Guidelines Management of Type 2 Diabetes Mellitus (Ministry of Health Malaysia, 2015).

2.6.2 Sampling method

Purposively sampling method is used to select qualitative informants. As mentioned above, the informants who are indicated but refuse insulin initiation are selected. In order to obtain the data from different perspectives, the informants from various social demographic backgrounds are selected by age, gender, ethnicity, educational level, employment status, marital status, and individual monthly income.

2.6.3 Sample size estimation

In the qualitative phase, there is no specific sample size determination. The data collection will be stopped once the thematic saturation point is reached. Thematic saturation point is reached when there is no new input or new point emerges during the interview of the informant, the informant's input is similar to the inputs of previous interviews. Usually after the thematic

saturation point is reached, the researchers will continue the interviews for one or two more informants to ensure no new code emerge in the following interviews.

2.6.4 Instruments

Semi structured in-depth-interview protocol is used to guide the researchers during the interview with informants. This interview protocol is designed based on the results obtained in the quantitative phase, which is in line with the explanatory sequential mixed methods study design in which the qualitative findings are used to explain the quantitative findings in depth. There were four main questions in the interview protocol which consist of exploration of patient's experience in being initiated insulin therapy, the barriers of insulin initiation, the main sources of patient's perception towards insulin therapy and the facilitators of insulin initiation. The audio recorder and field notes are used during the interview sessions.

2.6.5 Data collection

The qualitative data is collected through in-depth-interview that are conducted at the studied health clinics. The purposively selected eligible informants are contacted via phone to inform and arrange for the interview. The written consent is taken on the day on interview, audio recording and field note are taken throughout the interview with the informant's consent. Each interview takes about 30 to 60 minutes.

2.6.6 Quality control/ Ensuring rigour

Validity of the qualitative data is maintained by member check, after the transcription of the interview recording, the summary of the findings is informed to the informants and seek for validation whether the findings reflect their views during the interviews. Besides, the interview content is verified by triangulation of data with patient's diabetes medical records especially the offer of insulin therapy by the HCP.

Reliability of the data is obtained through 2 coders independently code the transcripts. The inter-coder agreement is performed and achieved with comparison of coding of different coders. In addition, audit trail is used to keep track on the processes and decision-making points throughout the qualitative phase. In term of reflexivity, the researcher aware of her experiences, biases and values have certain influence on the quality study (Creswell & Plano Clark, 2017).

2.6.7 Data analysis

The data collection and data analysis are conducted concurrently in qualitative study (Merriam & Tisdell, 2009). The audio recording of the interview is transcribed and open coded with the aid of NVivo 12 plus. Inductive and deductive thematic analysis is used to identify patterns within the data. Inductive approach is data driven whereas the deductive approach is based on the theoretical interest (Braun & Clarke, 2006). The six steps thematic analysis is used (Braun & Clarke, 2006). After transcribing the audio recording, the transcript is repeatedly being read to familiarize with the data, next is to generate the initial codes. Then is to sort the codes accordingly to categories and potential themes. Then the themes are reviewed for coherency and matched with the similar predictors in quantitative findings. This is in line with the explanatory sequential mixed methods design in which the qualitative findings further explain

International Journal of Public Health and Clinical Sciences
e-ISSN : 2289-7577. Vol. 7:No. 4
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the quantitative results. Next is to define and name the themes, this is to ensure the essence of themes are captured. Finally, is to produce the report of the findings.

2.7 Integration of data

In this explanatory sequential mixed methods study, the quantitative phase is to identify the predictors of PIR whereas the second qualitative phase is to explain further the quantitative findings. These two sets of data will be integrated in the discussion to provide a comprehensive understanding on factors of PIR among the insulin naïve T2DM patients and draw a cohesive conclusion.

3.0 Discussion

One of the key strengths of this study is we are using mixed methods approach to dissect this complex PIR issue. As compared to prior work, we understand that there are numerous literatures regarding PIR were available in overseas as well as in Malaysia. Most of the studies were conducted either in quantitative or qualitative approach. There were limited studies approach PIR issue using mixed methods approach. As PIR involved emotional and cognitive appraisal, using solely quantitative approach might not able to dissect the issue in the deeper meaning. Hence qualitative approach will increase the richness of findings and allow a deeper understanding in this complex issue. Using mixed methods approach allow us to dissect this issue in a broader and deeper manner among the same group of participants. It also allows us to unveil the mask of the underlying problems contributing to the factors of refusing insulin initiation among the insulin naïve T2DM patients.

Explanatory sequential mixed method design is chosen in this study as we need to know what are the predictors that bother the insulin naïve T2DM patients during insulin transition period. Conducting the quantitative study in the first phase unable us to identify the statistically significant factors that lead to PIR. The quantitative findings would help us to identify the key informants in the qualitative phase who can provide the fundamental concepts of PIR. As in qualitative phase, we were looking for those who are indicated for insulin therapy but refuse to initiate the therapy. We purposively select the informant who answers refuse insulin initiation based on the quantitative findings, from there we expect to explore their experiences and perceptions towards insulin therapy. We believe that since PIR involves psychological aspects, by conducting the in-depth-interview in the second qualitative phase, it helps us to have a better appraisal regarding patients' inner emotions and beliefs towards insulin therapy.

In line with the mixed methods pragmatism paradigm that emphasizes on "What works in reality?", the richness of the findings in this study would have the implications on the practical world (Creswell & Plano Clark, 2007). By understanding the factors of PIR, the T2DM patients' concerns will be better understood and taken into account during the insulin transition period. These findings provide a direction for the HCP during the counselling of insulin initiation. The HCP can address the T2DM patients' concerns and worries, focusing mainly on the main factors that contributing to insulin refusal. In term of implication to the policy, the policy makers can use the evidences to plan and implement health education and health intervention. All these will

contribute to the increase uptake of insulin therapy and improve the glycaemic control of T2DM patients.

Theory is a collection of interrelated concepts that provide a systematic view of the situations by specifying the relationship between variables to explain and predict the situation (Glanz et al., 2008). Model on the other hand is a mixture of concepts based on few theories (Glanz et al., 2008). By including theory or model in the research, it allows us to understand and explain a health behaviour. As PIR is a multifaceted issue, using model in this research allows us to understand the factors T2DM patients refuse insulin initiation in a systematic manner. Besides, interventions can be developed based on model to improve the insulin acceptance. Using Social Ecological Model in this study allows us to approach the issue from the individual, interpersonal, organizational, community and public policy aspects (McLeroy et al., 1988). As many studies on PIR mainly focus on the individual factors that lead to PIR, we would like to explore more on the interaction of social environmental factors with the T2DM individuals that contributing towards the insulin refusal among them.

Some parts of the questionnaire used in the quantitative phase are self-developed questionnaire based on literatures. Self-developed questionnaire is used as the validated questionnaire regarding the PIR issue on these constructs is unavailable. However, it is not an easy task to include all the study variables of SEM in one set of questionnaires taken into account of the time and patience needed for the participants to complete the questionnaire. If we have plenty of items to assess one construct, the participants will have to answer a long list of questions. Their interest of answering might be loss throughout the process and the accuracy of answering might be reduced towards the end of the questionnaire. Besides, interviewer-assisted method is used instead of the self-administered questionnaire method in this study as the interviewers can facilitate and keep the participants' attention throughout the quantitative data collection process.

One of the limitations in our study is this study is only conducted on the T2DM patients, since initiating insulin therapy involves both T2DM patients and HCP, HCP context is not explored in current study. It would provide a broader picture of PIR issue if the HCP context in PIR is studied as well. Besides, this study is only conducted in the four health clinics in a district of Penang, Malaysia. Hence the study findings might not able to generalize to other population in Malaysia. Using interviewer assisted during quantitative data collection might cause interviewer bias, hence training and pilot testing are conducted to ensure the standard technique of interview is commenced during the data collection.

In conclusion, if the study successfully conducted, it will provide rich evidences regarding the factors of insulin initiation refusal among the insulin naïve T2DM patients in Malaysia. These findings will contribute to the improvement of insulin acceptance among the T2DM patients in Malaysia.

Acknowledgement

We would like to express our gratitude for the approval of Penang State Health office and the studied district to conduct our study. We would like to thank the Director General of Health Malaysia for his permission to publish this article.

Declaration

The authors received no specific funding for this study. There is no conflict of interest.

Authors contribution

Author 1: designed the study, drafted the proposal and manuscript; Author 2 and Author 3: provided guidance in the study, reviewed the methodology, revised the manuscript

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