

Health Service Research

The development of an integrated behavioural model of patient compliance with diabetes medication: a mixed-method study protocol

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Abstract

Background. There has been a shift in worldwide disease burden from infections to non-communicable diseases, especially type 2 diabetes (T2D). Behavioural change and self-management are key to optimal T2D control. Several universal models of diabetic care have been proposed to help explain the dimensions of T2D self-care such as medication adherence, physical activity, diet and patient–doctor interaction. These models do not allow an objective and quantifiable measurement of the problems faced by patients in terms of medication compliance.

Objective. To create a comprehensive conceptual model of behavioural change related to T2D medication compliance.

Methods. A cross-sectional study will be conducted at a regional primary care clinic using a mixed-method technique. First, a Grounded Theory qualitative inquiry will be used to investigate predictors of medication adherence in T2D patients. Consequently, the elements derived from the interview will be incorporated into the Theory of Planned Behaviour framework to generate an integrated behavioural model. This model will then be used to quantify the factors related to compliance with medication amongst T2D patients.

Discussion. The framework developed here could help in the design of policies to optimize T2D control by identifying lapses in patients' intake of diabetic medications. This can be done by exploring the patients' fundamental and unarticulated belief system via a naturalistic approach adopted in this study. The properties of the framework can be replicated in other settings to serve as a benchmark for quality improvement in T2D patient care.

Keywords: Compliance, Grounded Theory, medication adherence, non-communicable diseases, Theory of Planned Behaviour, type 2 diabetes.

Introduction

Background and rationale

Type 2 diabetes mellitus (T2D) and its management have captured the attention of policymakers, clinicians, dietitians and the general population worldwide. With the remarkable reduction in infectious diseases

in the last century, there has been a paradoxical global increase in non-communicable diseases (NCDs) such as T2D (1). T2D has now become a common lifestyle epidemic that is closely linked with other NCDs such as cancer, heart disease and hypertension (1). T2D is now a major contributor to 'death by diseases' in many countries (1).

The prevalence of T2D in Malaysia has been rising and is the second most common chronic illness in the country (2). There has been an 80% increase in cases over a span of just a decade (3). The prevalence of diabetes in the nation now stands at a rate of 17.5%, higher than most South-East Asian countries (4,5). Diabetes is also one of the biggest contributors to both disability adjusted life-years (DALY) and deaths in Malaysia (3).

Self-management of T2D remains one of the cornerstones of optimal diabetes care. Self-management in T2D plays a vital role in determining adherence to medication, physical activity, dietary measures and glucose self-monitoring practices (6). The lack of self-management in Malaysian diabetic patients is well documented (7). Lapses are seen in the three major facets of care that determine optimal blood glucose control—healthy diet, adequate physical activity and adherence to medical treatment (7). Diabetic patients also have high rates of medication non-adherence (46%) (8). Concurrently, they appear to have higher fasting blood glucose levels. (8).

Internationally, many studies have examined the compliance of diabetic medication amongst patients with T2D (6,9–14). However, most studies related to diabetic medication compliance appear to focus on the descriptive, epidemiological and multivariate aspects of compliance which are not driven by psychological frameworks (6,9,10,12–14). On the other hand, most qualitative research has explored the phenomenon of medication adherence as seen from the perspective of healthcare providers and patients living with T2D (11). While there is an abundance of research related to this issue, more effort should be made to unify both quantitative and qualitative findings to explain medication compliance, especially by using pre-existing theories related to health behaviour.

Objectives

We plan to conduct two independent but interrelated studies on patients suffering from T2D. First, a qualitative inquiry approach will be undertaken, followed by a large-scale quantitative study. The initial study would explore variables that are likely to be related to patients' compliance with diabetic medication at a primary care clinic through in-depth interviews (IDIs) and focus-group discussions (FGDs).

The second study would evaluate the relative contributions of various predictors of intention in line with the Theory of Planned Behaviour (TPB) and Integrated Behavioural Model (15,16). Factors mediating medication compliance in the first phase of the study would also be incorporated into the model of care in the second study for quantitative testing (Fig. 1). The goal of the study is to develop an integrated behavioural model for the patient's compliance with diabetic medication.

This study will be designed to answer the following research questions on diabetes medication compliance:

1. Do variables such as (1) knowledge and skill facilitating compliance to medication (16), (2) the salience of this behaviour (16), (3) environmental constraints (16), (4) inherent habits (17), (5) unrealistic optimism (18,19), (6) learned helplessness (20), (7) attitude (15) subjective norm (15) and (9) perceived behavioural control (15), contribute to the compliance of patient towards T2D medication compliance?
2. Does attitude, subjective norm and perceived control significantly predict the intentions to comply with T2D medication?
3. Does intention correlate well to other variables derived from the earlier qualitative assessment?
4. Does the overall integrated behavioural model have an acceptable goodness-of-fit as determined through structural equation modelling (SEM)?

Methods

Phase 1: Factors contributing to patient compliance to diabetic treatment: a grounded theory approach Philosophical and theoretical underpinnings to this qualitative inquiry

An axiological philosophical assumption underpins the qualitative inquiry intended for this study (21). This assumption means that we have assumed the value-laden nature of the study due to the 'positionality' of the researcher in relation to the context and setting of the research. This 'positionality' refers to the professional experience

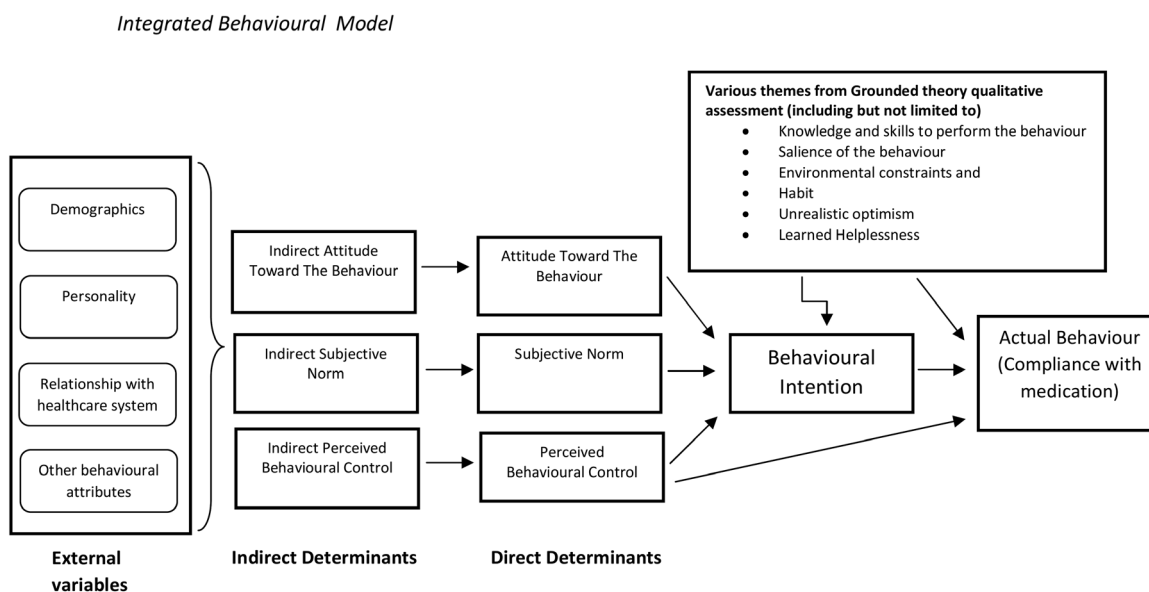


Figure 1. Path diagram of TPB + Grounded Theory model of patient's intention to adhere to diabetic management at a primary care setting

of the researcher working with patients with diabetes for more than 10 years. From an interpretive framework standpoint, we assume that our study will follow a combination of post-positivist (proving causality in human behaviour is often shrouded with uncertainty, thus, a robust behavioural theory can only be generated by employing multiple methods of inquiry and testing) and social constructivism (the analysis of what influences participants to construct meanings and actions in a specific situation) approach to research (21). This study will also use a Grounded Theory approach, which is a qualitative procedure to discover an all-encompassing theoretical explanation for a process or action (21–23).

Participants and setting

This study will be carried out at a primary care setting with a dedicated NCD department in the state of Negeri Sembilan, Malaysia. Purposeful sampling strategy will be employed to recruit a range of patients with varied socio-demographic background. Theoretical sampling will be used to gather information-rich cases to aid saturation of emergent constructs that help explain the behaviour of medication compliance.

Study participants will be (1) citizens above 18 years of age, (2) proficient in Malay or English language, (3) diagnosed with T2D, (4) currently on medication (insulin, oral hypoglycaemics or both), (5) has been a patient at the NCD clinic for at least two years (to allow a time period for patients to engage in self-care behaviour) and (6) do not have any T2D-related complications. Patients who decline to participate will be excluded from the study.

The details of the study will be conveyed to the participants personally by the researcher during their routine appointment for a consultation session. After obtaining informed consent, the participants will be given a scheduled appointment depending on their convenience. An IDI will involve an initial number of 20 participants (or until there is a scarcity of the emergence of new information). Later, two FGDs involving five patients per session will be conducted. However, the number of participants remains emergent and is subject to adjustments based on what is learned as the field-work is conducted (24).

On the other hand, selected healthcare providers (four diabetic educator nurses, four general practitioners and two diabetic clinic pharmacists) will be interviewed with regards to (1) their experiences

and perceptions about treating patients with T2DM and (2) patients' attitude and behaviour towards treatment and management of diabetes. The co-ordination of the interview sessions will be assisted by designated NCD nurses. The nurses will brief the participants about the objectives of the project and help mediate FGDs.

Data collection

Data will be collected from June 2018 to May 2019. We will obtain data through face-to-face IDIs and FGDs. Initially, IDIs will be guided by research questions to elicit their understanding of medication compliance and their intention towards compliance (Table 1). However, the interview will also be unstructured enough to allow discovery of new ideas and themes. An interview or topic guide has been developed containing a list of questions to be asked during the interview with patients (Supplementary Table S1) (23). These research questions will be modified in tandem with the information that is gathered during the data collection process. This step serves to refine questions that are not generating the needed information and to clarify relevant concepts within categories that might benefit from further exploration.

When the interviews and the preliminary data analysis are complete, FGDs will be held (lasting 1 h) to disseminate and gather feedback from the participants to ensure that the findings reflect their experience related to medication adherence. Newer insights acquired from exchange of information during these interviews will guide the refinement of the questions in the topic guide and the overall behavioural framework. All IDIs and FGDs will be tape-recorded with the permission of the participants and transcribed verbatim.

English and Malay language will be used as the primary medium of communication in this study based on the linguistic preference of the participant. As a token of appreciation, all participants will be given RM30 (equivalent to 7.20 US dollars) after completion of the interview or FGD sessions. All identifiers to the participants will be coded to preserve anonymity in the transcripts. A sample size of 20 will be used as a baseline, and theoretical saturation will be employed to determine final sample size.

Data management and analysis

Transcribed interviews and field notes will be entered into the Atlas.ti qualitative analysis software (Version 7, Cincorn Systems Inc.,

Table 1. Themes to be explored via qualitative inquiry

Category	Possible codes in categories
Knowledge and skills to perform the behaviour (16)	Sufficient information to comply with medical prescription Understanding of how/when to take medication
Saliency of the behaviour (16)	Seeking the correct person for advice if unsure about managing diabetes
Environmental constraints (16)	The importance of compliance to medication Problems faced in complying with medication regime Factors preventing compliance Strategies to overcome these failures
Habit (based on Verplanken and Orbell (17), Measure of habitual strength: the self-report habit index)	Fundamental belief system in daily ritual of taking medications
Unrealistic optimism (based on indirect measure of optimistic bias (18,19)	The understanding of the relationship between complications and vulnerability
Learned helplessness (20)	The perceived control over the disease, ability to use innate coping strategies, perception in relation to other diabetics
Attitude (15)	Overall evaluation of the behaviour of medication compliance.
Subjective norm (15)	Participant's own estimate of the social pressure to perform or not perform the target behaviour of medication compliance.
Perceived behavioural control (15)	The extent to which the participant feels able to perform the behaviour of medication compliance.

2008). The responses from the qualitative study will be evaluated by the first author, followed by scheduled discussion with the second author in order to categorize the data according to relevant emerging themes. The data will be coded in accordance with the classical and constructivist Grounded Theory methods (22,23).

The coding process will be divided into three main stages: open coding, axial coding and selective coding (22). In the open coding phase, the main investigator will perform an initial coding of the obtained data by observing the actions in each segment of data without applying pre-existing categories to the data (25). A line-by-line coding technique will be employed to help decipher the implicit and explicit concerns as well as statements (23,25). This phase of the coding procedure will also be jointly performed by a second coder who is unfamiliar with the current objectives of the research.

In the axial coding stage, the main investigator will employ a focused coding strategy to sift through large amounts of data seen in the initial coding phase to identify a core phenomenon (22). Finally, in the selective coding phase, all investigators will attempt to conceptualize a theory based on the relationships between various themes/categories that were discovered in the previous step.

The development of specific themes will be determined by an expert panel comprising authors and independent advisors. This panel will decide on the consensus of the themes derived from the open-ended questions. The interviews conducted in the Malay language will be transcribed without translation. The analysis will be done in the Malay and English in order to preserve contextual validity. Subsequently, the text will be read in its original language and coded in English. Quotes in the Malay language will be translated into English for publication purposes.

Phase 2: Factors contributing to patient compliance to diabetic management in a primary care facilities: a quantitative exploration

Theoretical framework to quantitative assessment

A proper understanding and application of a theoretical framework are essential to any research designed to change patient behaviour (16). The TPB is useful for acquiring information about behavioural change interventions at the level of the individual (16). Three principal TPB constructs determine behavioural intentions: attitude towards a behaviour, subjective norm and perceived behavioural control (15,16).

Methods

Participants

A survey will be conducted between January 2019 and June 2019. Evidence from literature suggests that a minimum sample size of 160 participants is necessary for most studies employing the TPB framework (26). So, we plan to randomly recruit 200 T2D patients from the annual patient appointment registry of the clinic. All patients at the participating primary healthcare clinic should have a diagnosis of T2D for at least 2 years prior to the date of recruitment. As mental health issues are quite common among T2D patients, participants will not be merely excluded on the basis of their mental health conditions as that might lead to the reduced representation of the population. Any patient who is capable of giving consent and communicating with the researchers will be included in the study.

Study design and tools

We will employ a cross-sectional study design. Standardized TPB manuals will be used as a guide to develop the questionnaire for both

direct and indirect measures (15,26). The 'Hba1c and compliance to medication construct' and 'intention' are the dependent variables of this analysis. While, attitude, subjective norm and perceived control are dependent variables (i.e. the 3 primary constructs of TPB determining actual behaviour and intention). These constructs (inclusive of 2 dependent outcome variables) are described as follows.

Intentions on compliance to diabetic medication

The items in this construct will be developed by asking the respondent's about their intention to comply with T2D medication as prescribed by the doctor. For example, 'I plan to comply with my diabetic medication until my next consultation (1 = strongly disagree, 7 = strongly agree)'. The average score obtained from the response to each of these items will reflect the measure of intention. The scores for this measurement will range between 1 to 7.

Attitudes influencing medication compliance

The following items will be tested in this construct: 'Complying with the prescribed medications is harmful/beneficial, good/bad, pleasant (for me)/unpleasant (for me), worthless/useful; I trust the intentions of doctor who provides diabetic management or advice during consultations (strongly disagree/strongly agree). The scores for both measurements will range from 1 to 7.

The indirect measure of this construct will be developed from the information obtained from a structured interview during the pilot phase of the study. A formula will be used to compute the sum score of the belief-based measures and the corresponding outcome evaluations (seven-point dimension). These scores will be used to calculate the indirect measure of attitude. The scores for this measurement will range between -84 to 84.

Subjective norm

Four items will be used to determine the direct measure of subjective norm. For example, 'People who are important to me think that I (1 = should not to 7 = should) comply to the medication as discussed with the doctor during consultation'. The scores for this measurement will range from 1 to 7.

A belief-based measure of subjective norm will be calculated by analysing the responses to six items on normative beliefs (the extent to which important individuals endorse being compliant with medications) and motivations to comply (willingness to act based on the opinions of others). A summed product of these items will provide a composite score for belief-based measures and the corresponding outcome evaluations. The minimum and maximum scores for this measurement will be -84 and 84, respectively.

Perceived behavioural control

This construct measures the extent to which the participant will be able to perform the behaviour of medication adherence. The direct measure of perceived behavioural control is a composite score generated by summing up responses to items under the construct, inclusive of an item evaluating the adherence to behaviour related to self-efficacy. The scores for this measurement will range from 1 to 7.

The indirect measure of perceived control will also be calculated. This measure of behavioural belief will comprise summed up responses related to control over behaviour and confidence to perform. The items in the 'control over behaviour' construct evaluate external influences that may affect the respondent's act of compliance with diabetic management as recommended by the doctor. A composite score will be generated by calculating the arithmetic sum of the belief measures and

behavioural outcome of this construct. The minimum and maximum scores for this measurement will be -84 and 84, respectively.

HbA1c and compliance to medication

The average HbA1c levels obtained from patients' records will serve as a surrogate marker of actual behaviour towards compliance to medication over the past 2 years.

Procedure

Data would be gathered from a regional primary healthcare clinic in Negeri Sembilan. Participants will be chosen from an adult population aged 18 and older seeking consultation at the primary care clinic. A nominal list of eligible participants will be generated from the annual clinic appointment list for 2017 and 2018. This step ensures the random selection of patients with diabetes. Patients who decline participation will be randomly replaced with other available participants on the nominal list.

At first, approximately 30 participants will be selected to participate in a pilot survey (15,26). During the pilot stage of questionnaire development, participants will be tested on items related to the direct measures of TPB (15,26). Consequently, an explorative phase will be conducted to elicit salient beliefs in relation to the TPB constructs using self-administered open-ended questions, followed by structured interviews. Participant feedback will be solicited to supplement the findings from this qualitative study. Their responses will be categorized according to relevant themes. Inter-rater reliability will be jointly established between authors to obtain consensus on development of these themes.

Concurrently, themes discovered from the qualitative assessment using Grounded Theory will be incorporated into the TPB framework to form the integrated behavioural model. The model will assess participant relationship to intention to adhere to diabetic management and the factors that the patients thought were preventing them from complying with diabetic treatment.

Data management and analysis

The statistical interpretation of the data will be performed using Statistical Package for Social Sciences program (SPSS version 20; IBM Corp., USA) and STATA (version 15.0, IC Edition 64-bit). The scores for items with negative endpoints will be converted to represent actual observed values (15,26). The dataset will be vetted to identify any missing or invalid values within the dataset that might hinder statistical analysis.

Reliability of constructs

The internal consistency of all the scales developed in the study (TPB constructs and also scales generated from the initial qualitative inquiry phase) will be assessed. A Cronbach's α -value above 0.6 will be considered as a benchmark of acceptable consistency (26). Subsequently, inter-relationships between these theoretical constructs will be evaluated via bivariate correlation analysis. These results will be reported as Pearson's r , with a P -value of <0.05 considered statistically significant.

Descriptive analysis

This step will involve the description of participant characteristics (age, gender, average HbA1c parameters, income range, education level and marital status), psychometric item endorsement rates, mean and standard deviation of all the measures.

Validity and the predictability of the integrated model

SEM will be used to test the overall integrity of the conceptual model by (1) determining the strength of the regression weights of variables that predict intentions and (2) confirming the validity of all the latent components developed from this study (TPB constructs and other Grounded Theory-derived scales). Finally, an equation-level goodness-of-fit will be assessed through path analysis. The explanatory power of the model will be expressed by the adjusted r^2 value of the model. A P -value of <0.05 will be interpreted as statistically significant for all analysed parameters.

Discussion

T2D medication adherence in Malaysia has not been assessed well. Several qualitative studies assessing this topic have been done recently but 'niche area' qualitative inquiry appear to dominate mainstream research (27-30). These qualitative assessments of patient behaviour appear arbitrary, intending to focus on isolated areas of diabetes care such as blood glucose self-monitoring, barriers to optimal diabetes control and 'experimentation' in the selection of medications (27-30). Fewer still research efforts are dedicated towards the discovery of a more comprehensive explanation of diabetes care that is built upon a robust psychological framework.

Researchers have attempted to synthesize all existing conceptual models of medication adherence into a single explicative model (31). Similarly in Malaysia, a comprehensive chronic disease model has been devised to help bridge the gap between the various mediators of diabetes care in the country (7). Nevertheless, these generic models have been conceptualized without taking into account crucial psychological aspects, primarily in relation to behavioural change amongst diabetic patients. Furthermore, these frameworks do not allow a quantifiable, objective evidence-based assessment of problems faced by patients in terms of medication compliance. Hence, such an approach does not allow targeted intervention that could help identify problems in terms of health behaviour among diabetic patients.

We recognize several limitations in our study design. Our study will be conducted in a single, large-scale primary care clinic, thus generalizability of our findings to other types of healthcare organizations, such as secondary and tertiary care centres, may be limited. However, much of the task of managing of T2D patients has already been devolved to primary care clinics throughout the country. Hence, the relevance of the possible findings from this study could be widely extended to other primary healthcare clinics. As mentioned earlier, we will not exclude any patients just because they have mental health conditions because suffering from anxiety and depression is quite common among T2D patients. The exclusion of this kind of patients would lead to the lack of representativeness of the population, thus potentially reducing the generalizability of the model under construction. Any patient will be eligible to participate as long as (1) proper consent can be obtained and (2) the data collection process is unimpeded and does not lead to any ethical violation.

In conclusion, this study uses a step-wise mixed-method approach to build a suitable model that could help explain why patients do not comply with T2D medical prescription. Unlike recent studies (27-30), we use a qualitative and quantitative approach to find an explanation for this critical behavioural pattern in T2D patients. The replicable and operational properties of this framework could see the model being used as a benchmark for quality improvement in T2D medication adherence in many other clinical settings.

Acknowledgements

We would like to thank Monash University of Malaysia for granting us the opportunity and technical support requisite to carry out this project. Secondly, this study would have not possible without the unwavering encouragement of Dr. Goh Pik Pin from the National Clinical Research Centre, Malaysia. We are also indebted to Dr. Ananth Kumar, Dr. Salmiah Sharif and Dr. Siti Zubaidah Ali for always being there in our hour of need.

Declaration

Funding: This study was funded by the MOH-NIH grant (Grant No.: 91000440) received from the Ministry of Health Malaysia.

Ethical approval: This study protocol received approval from the Medical Research and Ethics Committee, Ministry of Health Malaysia (NMRR-18-151-39886) on the 30th of May 2018 and also Monash University Human Research Ethics Committee (Project ID: 17062) on 1 November 2018.

Conflict of interest: none declared.

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