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ABSTRACT

Introduction Multimorbidity is highly prevalent among older patients and has been shown to be associated with poor health outcomes and lower quality of life. Adherence to medication treatments is essential in order to maximise the efficacy of treatments and improve health outcomes. However, nearly half of the older patients with multimorbidity fail to adhere to their medications, which can result in an increased risk of adverse health events, lower quality of life and higher healthcare cost. Only a few studies have explored the underlying mechanism and influencing factors of medication adherence among older patients with multimorbidity, which are inadequate to provide robust evidence for the development and evaluation of the medication adherence interventions. This study aims to examine and adapt the information–motivation–behavioural skills (IMB) model, a widely used social behaviour theory, to explain the medication adherence behaviour among community-dwelling older patients with multimorbidity.

Methods and analysis A cross-sectional study will be conducted in community settings in China. Around 309 older patients with multimorbidity will be recruited to complete questionnaires on adherence knowledge, adherence motivation, adherence self-efficacy, medication adherence, medication treatment satisfaction, depressive symptoms, treatment burden, disease burden and basic demographic information. Structural equation modelling will be used to analyse and validate the relationships among variables in the IMB model.

Ethics and dissemination This study has been approved by the Survey and Behavioral Research Ethics Committee of the Chinese University of Hong Kong (reference number SBRE-18-675). The study results will be published in peer-reviewed journals and presented in academic conferences and workshops.

Trial registration number ChiCTR1900024804.

INTRODUCTION

Multimorbidity, that is, the existence of multiple medical conditions in a single

Strengths and limitations of this study

- This study is the first to test, adapt and validate the information–motivation–behavioural skills (IMB) model to explain the medication adherence among older patients with multimorbidity in community settings.
- This study will extend the IMB model by adding new variables to make it more fit for older patients with multimorbidity.
- The cross-sectional study design precludes conclusions about the causal effects between variables, a longitudinal study is required to evaluate the causal relationships among constructs of the IMB model.
- Constructs of the IMB model will be measured by self-reported questionnaires, which may have a risk of recall bias.

individual,¹ is common among older patients. A large survey found that the prevalence of multimorbidity in Chinese older adults was 47.5%.² Medications are one of the most effective treatments for multimorbidity and adherence to medication treatments is, therefore, the key factor to reach potential maximum benefits of medications. Medication adherence is the extent to which a patient acts in accordance with the prescribed interval, and dose of a dosing regimen.³ Older patients with multimorbidity are usually at a high risk of poor adherence to medication. They have to contribute much effort and time to manage and adhere to numerous medications.⁴ Also, the single condition-oriented and poorly coordinated healthcare system can further increase patients' medication burden and negative experience with medication taking. Medication non-adherence has been reported to be associated with adverse

health outcomes,⁵ increased risk of hospitalisation,⁶ poor quality of life⁷ and high healthcare cost.^{8,9}

As medication taking is a complex behaviour,⁹ health behaviour theories and models can help researchers to understand the mechanism of action and refine medication adherence interventions. The information–motivation–behavioral skills (IMB) model is one of the established social behaviour theories. This model has been widely used in understanding and improving health behaviour in various populations and chronic diseases since it was proposed in 1992 by Fisher and Fisher.¹⁰ It adequately captures three essential constructs (information, motivation and behavioural skills) to improve health-related behaviours. Each construct can have a direct influence on health-related behaviours, but the behavioural skills mainly mediate the effects of information and motivation on behaviours. The model proposes that individuals who are well informed, highly motivated and having skills to perform health-related behaviours are more likely to enact and maintain health-related behaviours. The IMB model is not only providing a relatively simple explanation for complex health behaviours but also identifying the key factors to implement and maintain the adherence behaviour.

Although the IMB model has been used to explain and understand patients' medication adherence behaviour across a variety of patients,^{11,12} it has not been tested among community-dwelling older patients with multimorbidity. The relationships between the IMB constructs and the contribution of each construct may be different among different groups of patients. Furthermore, the model can be improved as previous studies have found that the IMB model with extended variables explained more variance in health behaviour than the original non-extended model.^{13,14} Several frequently reported predictors of medication adherence including depressive symptoms, treatment burden, disease burden and

medication treatment satisfaction are not included in the IMB model. The IMB model with extended variables may increase the fitness of the model in explaining medication adherence.

The present study aims to test the IMB model in explaining medication adherence among community-dwelling older patients with multimorbidity and to adapt the model by incorporating new variables. We hypothesise that the IMB model of medication adherence is fit for community-dwelling older patients with multimorbidity, and the IMB model with extended variables is more suitable than the original model.

Conceptual framework: IMB model of medication adherence

Overview of the IMB model of medication adherence

Based on the original IMB model and previous studies, the IMB model of medication adherence is proposed (figure 1). In this model, adherence information, adherence motivation (including adherence personal motivation and adherence social motivation) and adherence behavioural skills can have an impact on patients' medication adherence. Consistent with the original IMB model assumptions, adherence information, adherence personal motivation and adherence social motivation are interrelated and can directly and positively affect medication adherence. Adherence information and adherence motivation can positively affect adherence behavioural skills, which can in turn affect medication adherence. Patients who are well informed, motivated and have behavioural skills can enact and maintain medication adherence. The hypothesised extended IMB model includes four inter-related potential predictors of medication adherence, as shown in figure 2. Based on the previous research, it is hypothesised that depressive symptoms, treatment burden and disease burden have negative effects on original IMB constructs, as shown in figure 1, while high medication treatment satisfaction would produce a positive effect.

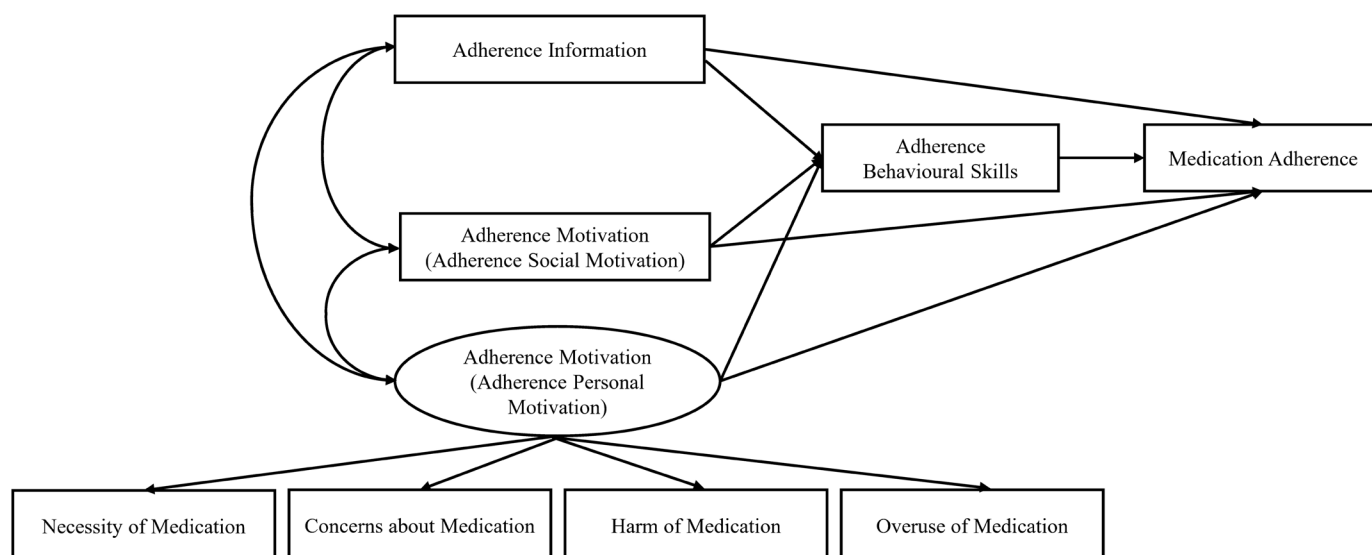


Figure 1 The proposed information–motivation–behavioural skills model of medication adherence, adapted from Fisher *et al*¹⁵ and Mayberry and Osborn.²²

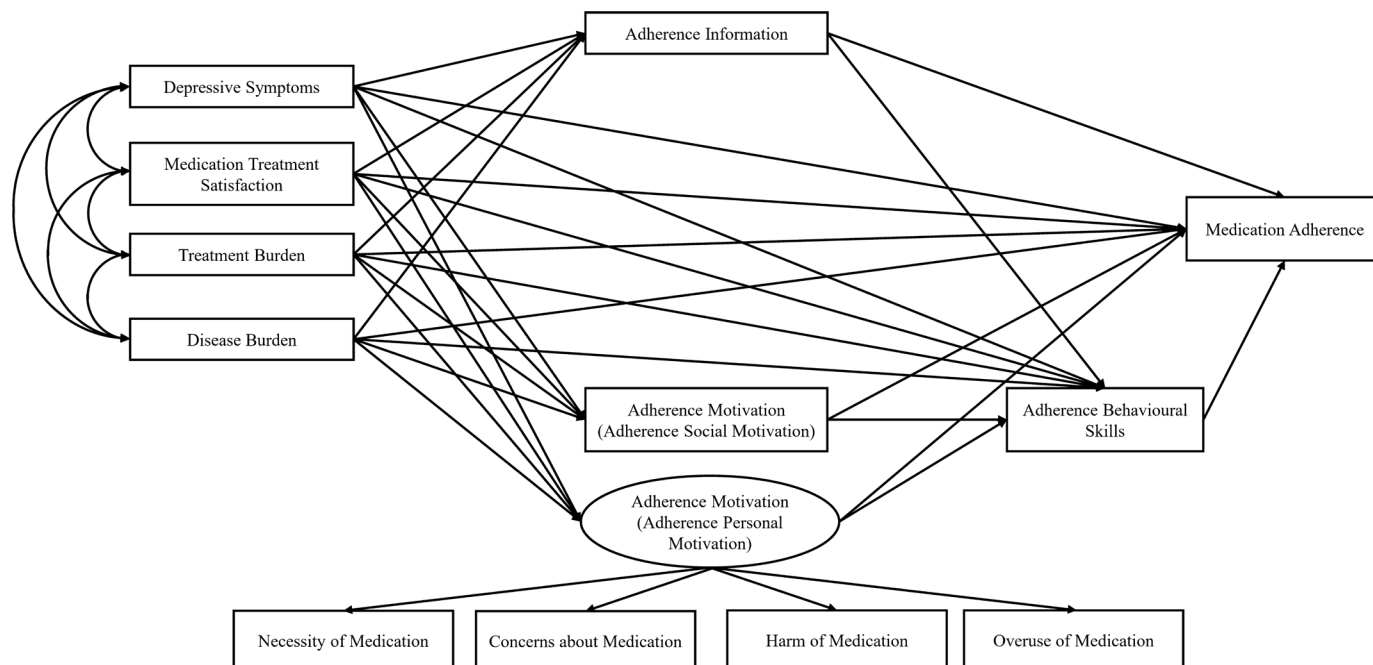


Figure 2 The proposed extended information–motivation–behavioural skills model of medication adherence.

The key constructs and empirical support of the model are discussed below.

Adherence information

Adherence information is the prerequisite of consistent and correct use of medications.¹⁵ It contains patients' information, which is relevant to medication taking in terms of dosage, timing, frequency, purpose and side effects. Some studies have found a significant correlation between medication knowledge and adherence in various chronic diseases.^{16–17} However, some other studies have shown that medication knowledge is not associated with medication adherence in some chronic conditions.^{18–19} A systematic review on the effectiveness of medication informational/educational interventions on medication adherence in chronic diseases also reported mixed results.²⁰ Therefore, information alone does not seem to be adequate in fully explaining and improving medication adherence, which is consistent with the proposition of the original IMB model.

Adherence motivation

Individual's adherence motivation, which is based on the one's adherence personal and social motivation, is another fundamental factor of adherence to medications. In the original model, personal motivation and social motivation are two sub-areas of the motivation construct. Some researchers have identified that personal motivation and social motivation are independently interrelated and associated with various health behaviours.^{21–22} Therefore, the adherence personal and social motivation will be separated in the proposed IMB model of medication adherence, and their relationships with other variables will be explored respectively.

Adherence personal motivation is the individual's attitude and belief toward medication adherence. Four constructs (necessity of medication, concerns about medication, harm of medication and overuse of medication), which were extracted by Horne *et al*²³ from literature review and interviews with chronically ill patients, can represent patients' key beliefs and motivation underpinning patients' decisions about medication treatment. The necessity of medication indicates patients' perceptions of the necessity of medications for controlling conditions and maintaining health. The concerns about medication indicate patients' concerns about the medications' potential adverse consequences. The harm of medication is patients' beliefs about how harmful medications are and the overuse of medication is patients' beliefs about how medications are overused by doctors. Studies have demonstrated that patients perceiving higher necessity of medication and lower concerns about medication treatments are more likely to have better medication adherence among patients with various chronic conditions.^{23–25} Patients who believe that medications in general are harmful substances, which are overused by doctors are more likely to report lower medication adherence.²³

Adherence social motivation is patients' perceptions of social norms of medication taking and social support for enactment of medication adherence. Patients can receive support from their family, friends and healthcare providers. A great number of studies have identified a positive relationship between social support and medication adherence in various chronic diseases.^{26–28}

Adherence behavioural skills

Behavioural skill is the key construct of the IMB model to determine whether a well-informed and highly motivated

individual can adhere to medication. Behavioural skills are patients' abilities including their confidence (self-efficacy) to perform medication adherence behaviours.¹⁵ Various abilities are needed for patients to complete complex medication-taking tasks, including integrating complex medication treatment into one's daily life, identifying and coping with adverse drug events and communicating effectively with healthcare providers.^{15 22} Patients' self-efficacy, which is the core concept of several behaviour change theories, is individual's belief and confidence that he or she can successfully perform a specific behaviour to achieve a desired outcome.²⁹ A systematic review has identified that higher self-efficacy is associated with better medication adherence in hypertension.³⁰ Also, self-efficacy has been found to play a key role in mediating the relationships between medication adherence and other variables, such as patients' personality,³¹ depression³² and social support.^{33 34}

Other potential predictors of medication adherence

Depressive symptoms

Depressive symptoms are common among older patients and can reduce patients' physical activity, impair abilities to communicate with clinicians and directly limit their adherence to medications.³⁵ A meta-analysis found that patients with depression were 1.76 times more likely to have medication non-adherence.³⁶ Cross-sectional studies have also identified that depressive symptoms could directly or indirectly affect medication adherence.^{37 38}

Treatment burden

Treatment burden is a relative new patient-centred concept considering its complexity for patients with chronic diseases. In general, the tasks that patients with chronic conditions must perform to respond to the requirements of their healthcare providers and the impact that these practices have on their functioning and well-being are defined as treatment burden.³⁹ It is fundamentally distinct from disease burden, which is concerned with the physical and emotional impact of one or more diseases on patients.⁴⁰ Treatment burden focuses on patients' negative experiences in the procedure of undertaking or engaging in treatment. High medication regimen complexity, financial burden and numerous chronic diseases self-management tasks can contribute significantly to patients' treatment burden.

A survey found that high treatment burden was associated with low medication adherence.⁴¹ Several factors with medication treatment have also been identified as the predictors of medication non-adherence, including a great number of medications, presence of drug side effects, and a heavy burden of drug costs.⁴²

Disease burden

Patients with multimorbidity usually have a heavy disease burden. The impact of chronic conditions on patients' functioning can further impair their ability to adhere to medications.⁴³ Longer duration of chronic diseases,

a great number of co-existing conditions and higher severity of diseases have been found to be associated with lower medication adherence.^{25 44}

Medication treatment satisfaction

Medication treatment satisfaction is patients' evaluation of the process of taking the medication and the outcomes associated with the medication.⁴⁵ The effectiveness of medication efficacy, side effects and convenience can influence patients' satisfaction and experience with medication treatments. Available evidence has confirmed the positive relationship between medication treatment satisfaction and medication adherence.⁴²

Moderators

The IMB model proposes that certain situational and personal characteristics can moderate the relationships between the constructs of the model.¹⁵ In this study, demographic factors will be tested as potential moderators. Variables including age,^{37 46} gender,^{47–49} income,⁴⁸ marital status,⁴⁹ education⁴⁶ and medical insurance⁴⁶ are found to be associated with medication adherence. However, the relationships are not found to be consistent in previous studies. One large cross-sectional study found that age and gender were not associated with medication adherence.⁴² Another study also reported that there was no effect of gender, age and education on medication adherence in older patients with multiple diseases.⁵⁰ The role of demographic factors will be explored how these factors influence the direction and magnitude of the relationships between the constructs of the IMB model in the proposed study.

Objectives

The objectives of the study are to (1) explore whether the IMB model can explain medication adherence among community-dwelling older patients with multimorbidity and examine the associations among adherence information, adherence personal motivation, adherence social motivation, adherence behavioural skills and medication adherence; (2) evaluate whether other potential predictors (depressive symptoms, treatment burden, disease burden and medication treatment satisfaction) can influence the effect of the IMB model of medication adherence and extend the model by incorporating associated factors and (3) explore the demographic factors that may moderate the relationships between the constructs of the IMB model of medication adherence.

METHODS AND ANALYSIS

Study design and setting

A cross-sectional study will be conducted at two community health centres (CHCs) in Changsha of Hunan province, China. CHCs are the major primary care providers in urban China, which provide various primary care services to community-dwelling populations including

health education, medical treatment services and chronic disease management.⁵¹

Participants

The participants of the study are community-dwelling older patients with multimorbidity. Multimorbidity is defined as the co-occurrence of three or more chronic conditions as patients with three or more chronic conditions are more likely to have complex needs and higher utilisation of healthcare services.⁵² Participants will be asked an open-ended question ‘what chronic diseases have you ever been told by a doctor that you have?’ Chronic diseases will be coded, based on a list of 38 chronic diseases adapted from a previous large Chinese-based survey.²

The inclusion criteria are 60 years old or over, having at least 3 chronic conditions of the 38 chronic diseases, having at least 1 chronic prescription medication, independently managing their medications, able to speak and understand Chinese, capable to provide a written informed consent to participate in the study.

The exclusion criteria are being institutionalised in a nursing home or in any other long-term care facility, currently participating in research involving chronic disease management, cognitive impairment, having severe mental diseases or deafness.

Sample size

The power analysis approach proposed by MacCallum *et al.*⁵³ is adopted to estimate the sample size required to test the hypothesised model on the basis of the root mean square error of approximation (RMSEA) assessment. According to MacCallum *et al.*,⁵³ the minimum sample size depends only on the degree of freedom if the alpha level, desired level of power, null and alternative values of RMSEA are established. The required sample size would increase as the degree of freedom decreases. Therefore, the hypothesised non-extended model (figure 1), which has less degree of freedom than the extended model (figure 2), is used to guide the sample size calculation for this phase of the study. For this structural model (figure 1), there are 8 manifest variables with 22 parameters to be estimated. The degree of freedom of the model is thus 14. Using the SAS V.9.4 program of MacCallum,⁵³ a sample size of $n=250$ is adequate to assure 80% statistical power to reject the null hypothesis of good fit (RMSEA ≤ 0.05) to the data at 5% level of significance for the hypothesised model, if the observed RMSEA is more than 0.1 (larger than this level is considered to be poor fit).⁵⁴ The required total sample size will be 309 taking account for a non-response rate of 19%.⁵⁵

Recruitment procedures and data collection

Participants will be recruited in CHCs using a convenience sampling method by physician referrals and approaching patients in waiting rooms from July to September 2019. Interested patients will be informed of the study objectives and their eligibility will be verified. Researchers will

describe the procedure, potential benefits and risks of the study to eligible participants. Medical conditions will be interviewed and recorded by trained research nurses. Participants will complete self-administered questionnaires on obtaining written informed consent. Investigators will provide assistance with questionnaire completion as required. The questionnaires are to be completed in approximately 30–45 min, and participants who complete the survey will be given a small gift (approximately 0.6 US\$ in value) for their participation.

Measurements

Social-demographic information

Participants will answer the one-item question about age in years (60–69=1, 70–79=2, $\geq 80=3$), gender (male=1, female=2), education levels (illiteracy=1, elementary school=2, junior high school=3, senior high school=4 and technical school or college=5), marital status (married=1, widowed/divorced=2), monthly income in Chinese Yuan ($<1000=1$, 1000–2999=2, 3000–4999=3, 5000–6999=4, $\geq 7000=5$), insurance status (basic medical insurance for urban employees and residents=1, new rural cooperative medical system=2 and not covered by medical insurance=3) and the number of medications.

Adherence information

The adherence information will be measured by using Patients’ Perceived Knowledge in Medication Use Questionnaire, which was developed by Okere *et al.*⁵⁶ The questionnaire contains five items covering two dimensions: general knowledge in medication use and drug interaction knowledge. Responses are on a 5-Likert scale from 1=strongly disagree to 5=strongly agree and the individual item scores are summed to give a total score ranging from 5 to 25, with a higher score indicating a higher level of medication knowledge. The Cronbach’s alpha of the Chinese version of this scale among kidney transplant recipients was 0.647 for the whole scale, 0.912 and 0.861 for two subscales, respectively.⁵⁷

Adherence motivation: adherence personal motivation

Adherence personal motivation will be measured by using the Beliefs about Medication Questionnaire (BMQ), which assesses people’s beliefs and concerns about taking medications. BMQ has two subscales: the BMQ-Specific that evaluates representations of medications prescribed for personal use and BMQ-General that evaluates beliefs about medications in general.⁵⁸ BMQ-Specific subscale assesses beliefs about the necessity of medications (five-item Specific-Necessity) and concerns about the medications (five-item Specific-Concerns). BMQ-General contains eight items that include two four-item subscales: the General-Harm that evaluates beliefs about harm of medication and the General-Overuse that evaluates beliefs about overuse of medication by doctors.⁵⁹ All items have a 5-point Likert answer ranging from 1=strongly disagree to 5=strongly agree. Points of each individual item in each subscale are summed to give a subscale score. A higher



score indicates stronger beliefs about the corresponding concepts in each subscale.

BMQ is a widely used instrument in China. A recent systematic review which included 58 articles that used the Chinese-version of BMQ concluded that the BMQ is a reliable tool for assessing medication beliefs in the Chinese population. The Cronbach's alpha of overall Chinese-version questionnaire and each subscale ranged from 0.67 to 0.94 (overall), 0.60–0.92 (Specific-Necessity), 0.58–0.91 (Specific-Concerns), 0.55–0.73 (General-Harm) and 0.47–0.79 (General-Overuse).⁶⁰

Adherence motivation: adherence social motivation

The eight-item Medication-Specific Social Support Questionnaire (MSSS) will be administered to participants to measure adherence social motivation. MSSS was developed to identify how often others help participants with their medications over a 3-month period.⁶¹ Participants reported their perceived medication social support on a scale from 0=never to 4=very often. A mean item score is calculated as the sum of each item score divided by the number of items. A higher score indicates more medication social support. The Chinese-version of MSSS has been tested among patients with HIV and the Cronbach's alpha was 0.92.⁶²

Adherence behavioural skills

The Self-Efficacy for Appropriate Medication Use Scale (SEAMS) will be used to measure patients' medication behavioural skills.⁶³ The SEAMS assesses medication self-efficacy in patients with chronic diseases. It has been identified as the most appropriate measure of self-efficacy for medication self-management considering its high psychometric properties in a recent systematic review.²⁹ The SEAMS has 13 items that require participants to identify their level of confidence in taking medications under various circumstances. Response options range from 1=not confident to 3=very confident and are summed to create a score ranging from 13 to 39, with a higher total score indicating higher medication self-efficacy. The Chinese version of SEAMS has been tested in patients with stroke and has demonstrated very good internal reliability (Cronbach's alpha=0.915).⁶⁴

Medication adherence

Medication adherence will be measured by the five-item Medication Adherence Report Scale,⁶⁵ which has been demonstrated to be a reliable and valid measure of medication adherence in various chronic conditions. It contains five items of unintentional and intentional non-adherent behaviours with a 5-point scale that ranges from 1=always to 5=never. The total score is based on the sum of the points in each item and ranges from 5 to 25. Patients with higher scores have better medication adherence. It has been translated into Chinese (Cronbach's alpha=0.762) and has been used in Chinese patients with various chronic conditions.^{59 66}

Depressive symptoms

Depressive symptoms will be measured by the Patient Health Questionnaire-9 (PHQ-9), which is the most commonly used instrument for screening depression.⁶⁷ The PHQ-9 contains nine items and each item evaluates the frequency of a depressive symptom experienced in the previous 2 weeks. PHQ-9 is rated based on a 4-Likert answer option that ranges from 0=not at all to 3=nearly every day. A total score is obtained by summing responses to each of the nine individual items. The total score ranges from 0 to 27 with 10 commonly recommended as the cut-off score.⁶⁸ A higher score indicates a higher level of depression. The PHQ-9 has been tested in the general Chinese population with good internal reliability (Cronbach's alpha=0.86).⁶⁹

Treatment burden

Treatment burden will be measured by using the Treatment Burden Questionnaire (TBQ).^{41 70} The TBQ evaluates patients' global treatment burden in multiple chronic diseases, which takes into account the patients' burden associated with medication taking, self-care activities, financial burden and the impact of healthcare on social relationships. The TBQ is composed of 15 items that are rated on an 11-Likert scale ranging from 0=not a problem to 10=big problem. A sum score is calculated ranging from 0 to 150 with higher scores indicating a higher level of treatment burden. It has been shown to be a reliable instrument for patients with chronic conditions across several countries with the Cronbach's alpha=0.89.^{41 70} The Chinese version of TBQ has been validated among patients with chronic conditions.⁷¹

Medication treatment satisfaction

Medication treatment satisfaction will be measured by using the Treatment Satisfaction Questionnaire with Medication (TSQM). There are three existing versions of the TSQM and the TSQM V. II will be used in this study because it has been demonstrated good psychometric properties among the Chinese population.⁷² TSQM V. II consists of 11 items across 4 domains: effectiveness, convenience, side effects and global satisfaction. Each item is rated on a 5-Likert scale or 7-Likert scale that ranges from 'extremely dissatisfied' to 'extremely satisfied'. Item scores can be summed into a total score ranging from 0 to 100 with a higher score indicating higher convenience, better effectiveness, higher global satisfaction and fewer side effects. The Chinese version of TSQM V. II has been tested among patients with kidney transplant recipients. The Cronbach's alpha for the whole scale was 0.707 and ranged from 0.847 to 0.961 for each subscale.⁵⁷

Disease burden

Disease burden will be measured by using Cumulative Illness Rating Scale-Geriatric (CIRS-G). The CIRS was originally developed by Linn *et al*⁷³ and later revised by Miller *et al*⁷⁴ specifically for older people. The scale rates the severity of diseases across 14 organ systems

on a 5-Likert point that ranges from 0=no problem to 4=extremely severe. The total score is the sum of each of the individual system score, with a higher score indicating a higher multimorbidity burden. The severity of diseases in each system will be rated by trained assessors according to the guidelines for scoring the CIRS-G developed by Salvi *et al*⁷⁵ in 2008. The scale and scoring guideline have both been translated into Chinese and validated among Chinese older people.⁷⁶

Patient and public involvement

Patients were not involved in the development of the research question, study design or the outcome measures. Participants' phone number or email will be recorded after obtaining their permission during the survey. Participants who might have severe depression or very poor medication adherence will be contacted to provide appropriate healthcare recommendations after data analysis, such as suggesting a further psychiatric test or educating participants on the importance of medication adherence.

Data analyses

All data will be analysed in IBM SPSS Statistics V.25.0 and Mplus V.7.4. The SPSS V.25.0 will be used for data entry and performing the descriptive statistical analyses. Normality of continuous data will be examined by skewness statistic and normal probability plot, and appropriate transformations will be made on skewed variables before being subjected to inferential analysis. Pearson correlation will be used to examine the associations among variables.

Structural equation modelling (SEM) approach will be used to examine the path model derived from the hypothesised model. Mplus V.7.4 will be used to estimate the parameters of the path model. The relationships between the potential predictors of medication adherence and IMB constructs will also be examined using SEM. The IMB model will be extended and adapted by incorporating associated variables into the original model (figure 2). Guided by Schermelleh-Engel *et al*,⁷⁷ the goodness of fit of the path model will be assessed by the χ^2 test and several goodness-of-fit indices, including the RMSEA, the standardised root mean square residual, the comparative fit index and the non-normed fit index. The relationships between the model variables will be assessed by the direction and magnitude of the path coefficients and relative coefficients. Furthermore, the path model will be refined on the basis of the modification indices by adding theoretically plausible paths and variables with non-significant loading or pathways will be omitted from the model. Moderators will be tested by multigroup analysis. Missing data will be imputed by using multiple imputation methods. All statistical tests will be two sided and $p \leq 0.05$ will be considered significant.

Ethics and dissemination

This study is approved by the Survey and Behavioral Research Ethics Committee of the Chinese University of

Hong Kong (reference number SBRE-18-675). Informed consent will be obtained from all participants before the administration of the survey. Patients will be informed of the purpose and procedures of the study and their right to withdraw from the study at any time without any impact on their present and future medical treatments and care. Data will be collected by an anonymous questionnaire. Patients are free to take short breaks during the survey if they experience some fatigue and discomforts. To protect the privacy of the participants, no identifying information will be collected in the survey. The study results will be published in peer-reviewed journals and presented in academic conferences and workshops.

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Patient consent for publication Not required

Provenance and peer review Not commissioned; externally peer reviewed.

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