BMJ Open Effectiveness of diabetes little helper video intervention on medication adherence among elderly patients with type 2 diabetes mellitus in Henan, China: study protocol for a randomised controlled trial

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ABSTRACT

To cite: Wang M, Lim PY, Lee K, *et al.* Effectiveness of diabetes little helper video intervention on medication adherence among elderly patients with type 2 diabetes mellitus in Henan, China: study protocol for a randomised controlled trial. *BMJ Open* 2025;**15**:e093191. doi:10.1136/ bmjopen-2024-093191

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/ bmjopen-2024-093191).

Received 02 September 2024 Accepted 04 April 2025



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Correspondence to Dr Hui Zhu Thew; jothew@upm.edu.my **Introduction** In the management of medication adherence in elderly patients with type 2 diabetes mellitus (T2DM), traditional methods such as verbal guidance and written materials may have certain limitations. Therefore, the development of digital intervention measures may play a key role in addressing these shortcomings. The objective of this study is to investigate the effects of Diabetes Little Helper (DLH) video intervention in improving medication adherence among elderly patients with T2DM in Henan province, China.

Methods and analysis A parallel cluster randomised controlled trial will be applied in the current study. The two hospitals will be randomly divided into a control group and an intervention group, with 68 patients in each arm. Both groups will receive standard care, meanwhile the intervention group will receive an additional DLH video intervention. Data collection is planned at baseline, 1 month after intervention and at 3-month follow-up. Once the study is completed, the control group will also receive the similar video as in the intervention arm to uphold the ethical issues.

Ethics and dissemination This study has obtained ethical approval from the Institutional Review Board of University Putra Malaysia (JKEUPM-2023-1279) and Henan Provincial People's Hospital (20240107). The research results will also be submitted for publication in peer-reviewed journals.

Trial registration number Chinese Clinical Trial Registry, ChiCTR2400083282.

BACKGROUND

Diabetes mellitus (DM) is a chronic endocrine disorder characterised by abnormal insulin production or utilisation.¹ The global prevalence of DM among the elderly is steadily increasing, projected to reach 192.5 million by 2030 and 276.2 million by 2045.^{2 3} DM can lead to systemic complications affecting vital organs, including retinopathy, neuropathy,

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Based on the information-motivation-behavioural skills model, the intervention content design is systematic and targeted to address the lack of knowledge, insufficient motivation and skill deficiencies in elderly patients.
- ⇒ Video intervention meets the preference of the elderly population for intuitive and repeatable learning methods and may overcome the time and space limitations of traditional health education.
- ⇒ The elderly T2DM patients included in this study are from only two hospitals in Henan province, China, and may not be representative of populations in other regions, with different cultural backgrounds or in other countries.
- ⇒ The study is not a double-blind design, which may introduce potential bias in outcome assessments.

cardiovascular events and nephropathy.4 5 The cornerstone of DM management lies in consistent medication adherence, essential for mitigating complications, reducing healthcare costs and enhancing patients' quality of life.⁶⁻⁸ Type 2 DM (T2DM) is the predominant form, representing around 90.0%-95.0% of all DM with a primary incidence among the elderly population.⁹ Numerous research studies have underscored medication adherence levels among T2DM individuals, particularly in China, where the poor prevalence of medication adherence surpasses 50.0%.⁶ ¹¹⁻¹³ Interventions such as message reminders, educational brochures and telephonic reminders have been introduced to enhance medication adherence among DM.¹⁴⁻¹⁶ However, these methods are not entirely applicable to elderly patients. Elderly individuals commonly experience

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issues with declining vision, hearing and memory, which may affect the effectiveness of health education through information and telephone channels. Additionally, due to varying levels of educational background among elderly patients, there is no guarantee that they have the ability to understand the contents of educational manuals.

Currently, there is a lack of effective educational approaches specifically tailored for elderly patients and most studies have not taken into account the characteristics of the elderly, resulting in reduced intervention effectiveness. Therefore, it is necessary to develop appropriate intervention measures targeting elderly patients with DM. It is worth noting that research in this area is still relatively limited. Furthermore, most research studies lack robust theoretical frameworks to support their intervention strategies.^{14 15 17} The information-motivation-behavioural skills (IMB) model is a theory of behaviour change that emphasises the role of information interpretation, motivational factors and behavioural skills as fundamental factors influencing individual behaviour change.¹⁸ This model has been used to predict medication adherence in elderly and DM patients,^{19 20} and studies have shown that it helps improve medication adherence in patients with various diseases, thereby enhancing their quality of life.^{21 22} Therefore, this study formulated intervention measures based on the IMB theory model to improve medication adherence in elderly patients with T2DM from multiple aspects. Additionally, this study will disseminate the intervention through WeChat, which is the most popular social application in China and has been proved to be an effective tool for chronic disease management.²³ This protocol is for a randomised controlled trial to develop the Diabetes Little Helper (DLH) video intervention based on IMB theory to improve medication adherence in elderly patients with T2DM in Henan province, China.

Hypotheses

- 1. At baseline, there were no significant differences between the control group and intervention group in terms of sociodemographic characteristics, diseaserelated characteristics, knowledge, attitudes, behaviours, medication beliefs, social support and medication adherence.
- 2. Compared with the control group, elderly patients with T2DM who received intervention through DLH videos have positive improvements in medication knowledge, attitudes, behaviours, medication beliefs, social support and medication adherence during the intervention and the 3-month follow-up period.

METHODS

Study design

The study design is a cluster parallel randomised controlled trial. Ethical approval was obtained from the Universiti Putra Malaysia Ethics Committee (JKEUPM-2023–1279) and Henan Provincial People's Hospital



Figure 1 Participant flow diagram of Diabetes Little Helper video intervention for medication adherence in elderly patients with type 2 diabetes mellitus.

(20240107) for research involving human subjects and registered for clinical trials in China: ChiCTR2400083282. The study duration is from April 2024 to June 2025, including recruitment, intervention, data collection and analysis. The study will be conducted and reported following the Consolidated Standards of Reporting Trials statement guidelines for cluster randomised controlled trials. The parallel design will be implemented until the study is completed (figure 1), and the Standard Protocol Items: Recommendations for Interventional Trials checklist is presented in online supplemental file 1.

Participants

This study will select two tertiary grade A hospitals in Zhengzhou city as the research sites. Zhengzhou city, as the capital city of Henan province, is home to 45% of the tertiary hospitals in the entire province. It is a pilot city for the construction of 'National Regional Medical Centers' and has a complete DM prevention and treatment system. The two selected hospitals meet the following criteria: (1) both are affiliated with Zhengzhou University Hospital, with highly consistent management models and medical team training systems, (2) both are national DM prevention and treatment bases designated by the National Health Commission and (3) neither has previous experience participating in similar digital health education projects. The inclusion criteria to be fulfilled by the patient are: (1) age ≥ 60 years old and meet the diagnostic criteria for T2DM (at least 6 months), (2) Chinese citizen, able to understand Chinese, (3) treatment with at least one oral hypoglycaemic agent and control of HbA1c at



Figure 2 Conceptual framework of the effectiveness of the Diabetes Little Helper video intervention on medication adherence in elderly patients with type 2 diabetes mellitus based on information-motivation-behavioural (IMB) theory model.

a level \geq 7.0%, (4) no cognitive impairment (the confirmation will be based on the patients' medical records) and (5) the patient or a family member has a smartphone with internet access and can use WeChat. Meanwhile, the exclusion criteria are: (1) patients with multimorbidities including serious heart disease (myocardial infarction and heart failure) and lung, kidney and other diseases, (2) there are obvious barriers of consciousness and the inability to communicate effectively and (3) those who are participating in other clinical trials.

Development and intervention of DLH video

The intervention design of this study is grounded by the IMB theory model, highlighting information, motivational factors and behavioural skills as key drivers of individual behaviour change (figure 2).¹⁸ These modules have five themes: theme one is knowledge of medication adherence; theme two is medication adherence attitude; theme three is medication belief; theme four is perceived social support on medication adherence; theme five is behaviour on medication adherence. Based on the five themes, a total of eight different educational topics will be developed (table 1).

After the establishment of different themes and content for DLH video intervention, the materials were sent to supervisor teams and four experts via email for validation. The mentoring team conducted three meetings to discuss the intervention content, continuously making modifications and improvements to ensure its content validity. Subsequently, an animation video was produced using the 'Wancai Animation Master' software. After the completion of video production, five clinical experts in the nursing field were invited to assess its face validity using a questionnaire.²⁴ The assessment criteria included the appropriateness of the video's title, audiovisual effects, the suitability of language used, the appropriateness and comprehensibility of the content and the appropriate duration of the video. Based on the feedback from the experts, revisions were made to ensure that the video possessed good face validity. DLH intervention module will be delivered through an official WeChat account. Participants in the intervention group will receive eight videos in a month, every Tuesday and Friday at 8:00. Each video is about 2-5 min, allowing patients to choose their viewing time. If patients encounter any issues while watching the videos, they will be able to contact the researchers for assistance via WeChat or phone.

Outcomes

This study will assess outcome measures at three time points: baseline, 1 month postintervention and at 3-month follow-up. We will distribute a self-administered questionnaire to the patients, which includes sociodemographic

 Table 1
 Diabetes Little Helper video intervention for elderly patients with type 2 diabetes mellitus—video schedule and content

| oontent | | | |
|--|--------------------|--|---|
| Week | IMB | Theme | Торіс |
| First week | Information | Knowledge of medication adherence | Storage and travelling methods for hypoglycaemic medications. |
| | | | How to check your medications? |
| Second week | | | What you should do during sick days? |
| | Motivation | Medication adherence attitude | The importance of taking your hypoglycaemic medication on time. |
| Third week | | Medication belief | Precautions for taking hypoglycaemic medication. |
| | | | Correct understanding of hypoglycaemic medications. |
| Fourth week | | Perceived social support on medication adherence | Self-empowerment and support for elderly diabetes mellitus patients. |
| | Behavioural skills | Behaviour on medication adherence | Regular blood glucose monitoring. |
| IMB, information-motivation-behavioural. | | | |

characteristics, disease-related variables, medication adherence, medication knowledge, medication attitudes, medication behaviours, medication behaviour beliefs and social support.

The first part, sociodemographic characteristics, includes the information on age, gender, residence, living arrangement, marital status, educational level, smoking status, household income, medical payment method, body mass index and smartphone usage.

Next, the disease-related variables are duration of T2DM and family history of T2DM, combined with other chronic disease, type of medication, number of medications used and adverse medication reaction.

Self-Efficacy for Appropriate Medication Use Scale (SEAMS) is adopted to assess the level of medication adherence.²⁵ This scale contains 13 items, each item was rated on a 3-point Likert scale and participants were asked to select the level of confidence they had in taking their medication correctly in different situations (1=no confidence, 2=some confidence and 3=confidence). The score range of the scale is 13-39, calculated by summing the scores of individual items. A higher total score indicates a higher level of medication adherence. Dong *et al*²⁶ translated the scale into Chinese and conducted a study to assess its reliability and validity. The results showed a Cronbach's alpha value of 0.934 and a content validity index of 0.913.^{25 26} The Chinese version of SEAMS has been used to measure medication adherence in elderly patients with different chronic illnesses in China.^{27 28}

Medication knowledge, medication attitude and medication behaviour are adopted from a previous study.²⁹ The knowledge questionnaire comprised 17 items with three options (yes, no and uncertain). Correct responses earn one point, and incorrect responses earn zero points. The total score ranges from zero to 17 points, where higher scores indicate a greater level of knowledge regarding safe medication use. Medication attitude questionnaire had 10 items, assessed using a 5-point scale, with total scores from 10 to 50 points. Elevated scores signify a more favourable attitude towards safe medication usage. Medication behaviour questionnaire included 13 items, with the initial nine items graded on a 4-point scale (never, sometimes, often and always) and items one, three, six, seven and eight are inversely scored. Scores range from nine to 40 points, with higher scores indicating safer medication behaviour. Each dimension displayed a testretest reliability between 0.854 and 0.920, while the overall questionnaire's test-retest reliability was 0.868.²⁹

The Chinese version of the Medication Belief Questionnaire is adopted to assess the personal medication beliefs of DM patients.³⁰ The questionnaire comprises 10 items, categorised into two dimensions: medication necessity and medication concern, with scores ranging from 1 (strongly disagree) to 5 (strongly agree). Increased scores signify more profound medication beliefs. The Cronbach's alpha for the Medication Beliefs Questionnaire was 0.724, with respective Cronbach's alpha values of 0.749 and 0.796 for the two dimensions.³⁰ The Chinese version of the social support scale is adopted to assess the support received by patients in multiple dimensions.³¹ The scale consists of four dimensions with a total of 19 items and a 5-point scale (never to always), with a total score range from 19 to 95. A higher score indicates a higher level of social support among the elderly. The questionnaire demonstrated good reliability and validity, with a Cronbach's alpha value of 0.803 and a content validity of 0.958.³¹

The content validity and facial validity of the questionnaire were evaluated by the evaluation group in the field, respectively, to verify whether the design of the questionnaire is appropriate, whether the wording is simple and understandable and whether it can meet the requirements of all aspects and domains of the research purpose.

The evaluation group consists of five members, including one clinical medical expert, one pharmaceutical expert, two nursing experts and one public health expert. These experts need to meet the following criteria: (1) have a minimum of 5 years of work experience in the field of DM management, elderly care or health behaviour intervention, (2) hold a mid-level or higher professional title or a doctoral degree and (3) have published relevant research or participated in the development of similar scales in the past 3 years. Modifications and improvements were made based on the suggestions of the experts. After calculation, both the Item Content Validity Index and Scale Content Validity Index of the questionnaire were found to be 1.

Sample size calculation

Based on the two-mean sample size formula³² (as follows) and mean±SD of medication adherence of the control group and intervention group at different time periods in the studies (29.15±3.10, 31.27±3.35 and 26.25±2.01, 30.19 ± 2.41),²⁷ ²⁸ the sample size was calculated by adopting 80% response rate^{33 34} and the design effect was determined to be 1.5, taking into account the formula design effect =1+(m-1)×ICC and similar studies^{35 36}; thus, the required total sample size that will be needed is 136, with 68 per group.

$$n = \frac{2\sigma^2 \left[z_{1-\frac{\sigma}{2}} + z_{1-\beta} \right]^2}{\left(\mu_1 - \mu_2 \right)^2}$$

Randomisation and allocation concealment

Two hospitals will be selected and numbered, and a random number generator will be used to randomly assign these two hospitals to the control and intervention groups (https://www.randomizer.org/). After obtaining the list of elderly T2DM patients and informed consent forms (online supplemental file 2), 68 elderly T2DM patients will be selected from each hospital to participate in the study using a simple random sampling method. The study will be conducted using a parallel design and will continue until its completion. The allocation task will be completed by an independent randomisation expert who has no association or vested interest in the participants. The random group assignments will be allocated

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and maintained by a dedicated staff member who is not involved in the study.

Blinding

Given the visibility nature of video intervention, blinding could not be implemented on both the research executors and the participant groups in this study. In order to control potential biases, the evaluators and statistical analysts remained blind throughout the entire process, focusing solely on the quantification and modelling of outcome measures and completely separated from the participant recruitment and intervention implementation phases.

Data collection

Data will be collected at baseline, 1 month postintervention and at 3-month follow-up to comprehensively understand the participants' situation. During the baseline survey, eligible patients need to sign a paper informed consent form and scan the QR code to follow our WeChat public account 'Diabetes Little Helper' to fill out an electronic questionnaire that has been uploaded in advance to the WeChat platform. As for the data collection after intervention and the 3-month follow-up, an electronic questionnaire will be used. During the process of completing the paper questionnaire, if patients encounter any problems, the researcher will remain neutral and provide assistance, as well as inspect the quality and completeness of the questionnaire on the spot. Before participants fill out the electronic questionnaire, they will receive instructions and notes on questionnaire completion through WeChat or phone. For elderly people who are unable to independently complete the online questionnaire, they can seek assistance from their family members. Additionally, the electronic questionnaire supports the 'freeze and restore' technology, which allows for continuing from the breakpoint in case of accidental exit. To ensure the integrity of the questionnaire, we have set a requirement for every question to be answered. Participants will be unable to submit the questionnaire if any question is left unanswered. The researcher will also remind or assist participants in filling out the questionnaire through WeChat and phone to ensure timely completion.

Data analysis

All analyses will follow the intention-to-treat approach, meaning all participants assigned to a specific intervention group will be included, regardless of adherence to the protocol. Data analysis for this study will be conducted using IBM SPSS Statistics V.29.0. The primary outcome is medication adherence, and secondary outcomes are knowledge, attitudes and behaviours about medication, beliefs about medicines and social support among elderly patients with T2DM. The categorical data will be described using frequency and percentage (%). Continuous data that follow a normal distribution will be described using mean and SD. Independent samples t-test and χ^2 test will be used for comparing baseline data between both groups. Significant variables at baseline will be adjusted in the final model as covariates. Generalised estimating equations will be used to analyse the changes of primary outcome and secondary outcomes across time points between groups, adjusted with covariates. The significance level is set as 0.05.

Patient and public involvement

This study invited clinical medicine experts, pharmaceutical experts, nursing experts and public health experts to evaluate the titles, audio-visual effects, language expressions and duration of the survey questionnaire and DLH videos used. Based on their feedback, improvements were made to ensure their accuracy and ease of understanding. In addition, there was no involvement of patients or the public in the design, execution, reporting and dissemination plans of this study.

DISCUSSION

This study proposed a randomised controlled trial aimed at improving medication adherence in elderly T2DM patients by sending DLH videos through the WeChat platform. The intervention was developed based on the IMB model, as previous studies have demonstrated the effectiveness of the IMB model in elucidating and predicting medication adherence in DM patients.¹⁹ Given the unique challenges that the elderly face in medication adherence, such as memory decline and multiple medications, the intervention module based on the IMB model could help the elderly to understand and adhere to their medication treatment plans. Currently, there have been studies in China that apply the IMB model to the health management of stroke patients, knee replacement surgery and gestational DM patients,³⁷⁻³⁹ but no research has yet been conducted on the effectiveness of the module using IMB theory in improving medication adherence in the elderly with T2DM. Meanwhile, research has shown that the IMB model can be used to study medication adherence factors in elderly patients.⁴⁰ There are also studies that use the IMB model to predict medication adherence in elderly patients with heart failure.⁴¹ Therefore, this study is based on the IMB model and formulates targeted intervention strategies for the unique characteristics of elderly individuals.

To improve medication adherence in patients with DM, various intervention modes have been used including face to face interviews,^{42,43} educational brochures,¹⁴ telephone reminders¹⁵ and message reminders.¹⁶ These interventions have shown some improvements in medication adherence, but they have their limitations. For example, face to face interviews require patients and healthcare professionals to meet at a specific time and location, which may be inconvenient for patients to arrange their schedules and travel. Producing educational brochures requires financial and material resources, resulting in relatively high costs and paper wastage. Additionally, this is not very user-friendly for elderly individuals with a lower level of

education and declining evesight. Telephone reminders may be interrupted by other patient obligations, leading to distractions and difficulties in ensuring that patients receive the reminders adequately. This study aims to deliver the intervention module through the dissemination of videos on the widely used Chinese social platform (WeChat). This mode of information delivery is not only cost-effective but also facilitates rapid information dissemination and sustainable education.^{23 44 45} Previous studies have indicated that WeChat serves as an effective platform for managing chronic diseases, positively influencing the health outcomes of patients with conditions like hypertension, DM and chronic obstructive pulmonary disease.⁴⁶⁻⁴⁸ This study converts the information to video format which combines visual and auditory elements to present information through a combination of images and sound, thereby enhancing the vividness of knowledge. Existing research has demonstrated the effectiveness of video-based health education across diverse populations.^{49–51} However, there is a lack of direct evidence of uploaded videos via WeChat on improving medication adherence among elderly patients with T2DM. Should this intervention prove to be feasible and showcase preliminary evidence of effectiveness, it has the potential to lead to larger-scale clinical trials, ultimately benefiting a larger number of T2DM patients.

The intervention measures explored in this study are in line with the trend of the times. In addition, this intervention scheme is constructed with the support of theory models, which enhances the integrity, scientific nature and explanatory power of the research content. This intervention approach also, to some extent, overcomes the shortcomings of previous methods to improve medication adherence. Moreover, the adoption of rigorous randomised controlled trial research design helps to ensure the reliability of intervention effects and assess the authenticity and effectiveness of intervention outcomes more accurately.

Ethics and dissemination

This study has obtained ethical approval from the Institutional Review Board of University Putra Malaysia (JKEUPM-2023-1279) and Henan Provincial People's Hospital (20240107) and has been registered in the Chinese Clinical Trial Registry (ChiCTR2400083282). Participants were ensured to sign written informed consent, allowing them to withdraw from the study at any stage without any reason. All patient data need to be anonymised and stored in an encrypted database, with access restricted to the research team only. It is explicitly stated that the control group will receive intervention resources after the research concludes to avoid ethical controversies caused by delayed treatment. The research team declares no affiliation with any commercial interests (such as collaboration with video platforms) to ensure the objectivity of the results. The research results will also be submitted for publication in peer-reviewed journals and disseminated through presentations at local, national or international conferences.

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Acknowledgements The author expresses gratitude to Universiti Putra Malaysia and two hospitals in Henan province, China, for their support in this research. We sincerely appreciate the guidance, professional expertise and valuable feedback provided by all the experts throughout the entire process. Their assistance has enabled us to improve this intervention research programme and enhance its overall quality.

Contributors Each author has made significant contributions to the conception and design of this study. MW and HZT were involved in the overall research design, protocol development and manuscript drafting. PYL, LK, SNS, HZT and QJ participated in the formulation of the intervention plan, review of the video production and important revisions of the manuscript. In addition, all authors contributed to the manuscript revision process, providing intellectual input and professional knowledge to enhance the clarity and accuracy of the final proposal. All authors have read and approved the final version of the manuscript. Guarantor: HZT.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, conduct, reporting or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s).

Provenance and peer review Not commissioned; externally peer reviewed.

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