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# Effects of message framing on self-management behaviour among patients with type 2 diabetes: a randomised controlled trial protocol

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## ABSTRACT

**Introduction** Accumulating evidence has indicated successful diabetes health education can potentially help to improve blood sugar levels in people with diabetes. However, with a rapid rise in the number of people with diabetes cases and the increasing burden on healthcare, it is often difficult for healthcare providers to find suitable time to provide health education to meet their needs. Thus, more novel and effective ways are needed to conduct education. The message frame provides a new perspective for implementation of a more effective health education in the form of changing information presentation, and the same objective content is described in either positive or negative language or outcomes. Gain framing emphasises the positive consequences of adhering to useful recommendations, while loss framing highlights the negative consequences of the non-adherence. The purpose of our research is to potentially explore the effectiveness of diabetes education based on message framing on the self-management behaviour.

**Methods and analysis** A single-blind, three-arm randomised controlled trial involving 84 participants will be conducted. The participants will be assigned into three groups randomly in a 1:1:1 ratio and will receive 12-week intervention. Patients in group 1 will be provided gain framing education videos about the self-management skills for type 2 diabetes, patients in group 2 will be given education videos based on loss framing and patients in group 3 will receive education with no specific message framing. The primary outcome is self-management behaviour. The secondary outcomes will be self-efficacy, patient activation, diabetes-related knowledge and attitude, quality of life and blood glucose level. All outcomes will be measured at baseline and 12 weeks.

**Ethics and dissemination** This study was approved by the Ethics Committee of School of Nursing, Jilin University (No. 2020101501). The research results will be published in peer-reviewed publications and presented in international conferences.

**Trial registration number** ChiCTR 2100045772; Pre-results.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This randomised controlled trial will focus on the impact of educational interventions based on the message framing on the self-management behaviours of patients with type 2 diabetes.
⇒ This study will assess the effects of the intervention on self-management behaviour, self-efficacy, patient activation, and diabetes-related knowledge and attitudes; and researchers who collect the outcome measures are blinded.
⇒ This study will only assess outcomes after the intervention, without follow-up, and thus the long-term effects will not be explored.

increase to 693 million by 2045.[1] The prevalence of diabetes in China increased rapidly from 0.67% to 11.6%, 3 percentage points higher than the global average, and still continues to exhibit an upward trend.[2 3] There is a high disability rate in people with diabetes and it remains one of the leading causes of blindness and non-traumatic amputation, which can severely impair the quality of life of patients and reduce their life expectancy by 5–10 years.[4] In addition, the expenditures associated with diabetes are large and exert a heavy economic burden on patients and society.[5] The medical expenditure of patients with diabetes has been reported to be 2.3 times that of individuals without diabetes.[6] In 2017, China's medical expenses for diabetics ranked second in the world.[7] Therefore, we need to urgently explore novel effective ways to significantly improve the health status and quality of life of this population of patients.

Successful diabetes self-management education has been reported to exhibit a positive effect on improving diabetes knowledge and patient activation, and promoting patients with diabetes to engage actively and maintain healthy lifestyle changes.[8–10] Moreover, some studies have also reported that

## INTRODUCTION

In 2017, 451 million adults worldwide were diagnosed with diabetes, which is expected to

diabetes self-management education can significantly improve health outcomes, such as glycated hemoglobin A1c (HbA1c) and lipid profiles,[11–15] even reducing the mortality rates.[16] However, previous studies have also shown that diabetes education does not always lead to an effective glucose control.[17] However, the needs of patients for health education remain unmet and additional education might be required to promote the self-management behaviours.[18] In addition, individual health beliefs, such as attitudes towards the self-management behaviour of diabetes, might have positive or negative effects on the self-management behaviour and glycaemic control.[18] Additionally, improving patients' health-related beliefs is also an important goal of diabetes education. At the same time, as the number of diabetes cases increases significantly, it can be difficult for healthcare providers to ensure adequate health education to meet the specific needs of this large patient group.[19] Therefore, it is necessary to explore an effective and economical way of providing health education to significantly improve patients' self-management behaviours and beliefs.

The various changes and persistence of health-promoting behaviours are complex, influenced by multiple factors, and can be difficult to change.[20] The message framing strategy is a method of message tailoring, which can provide a new perspective for facilitating healthy behaviour. Message framing emphasises the adjustment of the presentation of the message, the same objective content is described in either positive or negative language or outcomes, which can markedly affect the behavioural decisions.[21] Positive framing or gain framing emphasises the positive consequences of adhering to useful recommendations, while negative framing or loss framing highlights the negative consequences of non-adherence.[22] Message framing strategies have been successfully applied in a variety of health behaviour change settings. A number of previous studies have reported that message framing might have different powers of persuasion for the different types of behaviour, with positive framing more effective for disease prevention, such as exercise and smoking cessation; whereas the negative framing was found to be more effective for disease detection, such as undergoing a Pap test and screening breast, but only with small effect sizes.[23 24] Moreover, a few studies have applied the message framing strategy for the implementation of health education among patients with diabetes, but there is controversy about the appropriate frame type. For instance, a number of previous studies have shown that negative message framing could significantly improve attitudes and intentions to promote self-management behaviours in people with diabetes,[25 26] while other studies have indicated that patients who received positive-framed messages sustained long-term positive behavioural change.[27] As previously reported in the literature, some types of frames are more persuasive than others, and this may not only depend on the type of behaviour, but also on the process or depth of information processing.[22 28]

The theory of knowledge, attitude/belief and practice is often used to predict the self-management behaviour of patients with diabetes.[29 30] According to this theory, in order to achieve the goal of optimal behavioural change, both knowledge and attitude are required as the primary characteristics. Moreover, based on the ability to acquire knowledge, positive thinking about knowledge and gradually forming positive attitudes and beliefs are possible that can effectively promote the occurrence of productive behaviour.[30] After understanding the self-management knowledge, patients with type 2 diabetes are possibly more likely to form a positive attitude, which might be conducive to actively forming self-management behaviours that can be beneficial for the blood glucose control. Therefore, we aim to explore whether health education based on the message framing could more effectively improve patients' knowledge and attitudes, and thus can significantly promote constructive self-management behaviours.

Patient activation refers to patients having the optimal knowledge, skills, behaviours and confidence needed to manage their own health and care.[31] Patient activation is considered to be the major driver of patient self-management decisions and can potentially determine the process of health information processing.[32 33] Moreover, for patients with chronic diseases such as diabetes, it is more necessary to actively participate in their own health management. Activated patients have also been found to be more aware that they need to take responsibility for their own health, which can motivate them to actively seek information related to their disease or treatment, and are more likely to accept and comply with required self-management behaviours.[31] A systematic review and meta-analysis has previously reported that increased levels of activation in patients with type 2 diabetes mellitus (T2DM) can significantly improve their self-management behaviours and reduce their blood glucose levels.[32] In addition, it has been suggested that presenting advantages of behaviours is more persuasive for activated patients, while messages that present disadvantages are more persuasive for non-activated patients.[34] However, in the study of walking behaviour of patients with T2DM, patient activation did not directly act as a moderator for framing effects.[34] Therefore, it is also necessary to further explore the possible role of patient activation in the influence of message frame to promote the self-management behaviour in patients with type 2 diabetes.

The purpose of our research is to potentially explore the effectiveness of diabetes education based on message framing strategy on the self-management behaviour, and to potentially identify potential moderating effects of patient activation on message framing.

## METHODS
### Study design
A single-blinded, three-arm, randomised controlled trial will be performed to examine the effectiveness of diabetes education based on the message framing on the
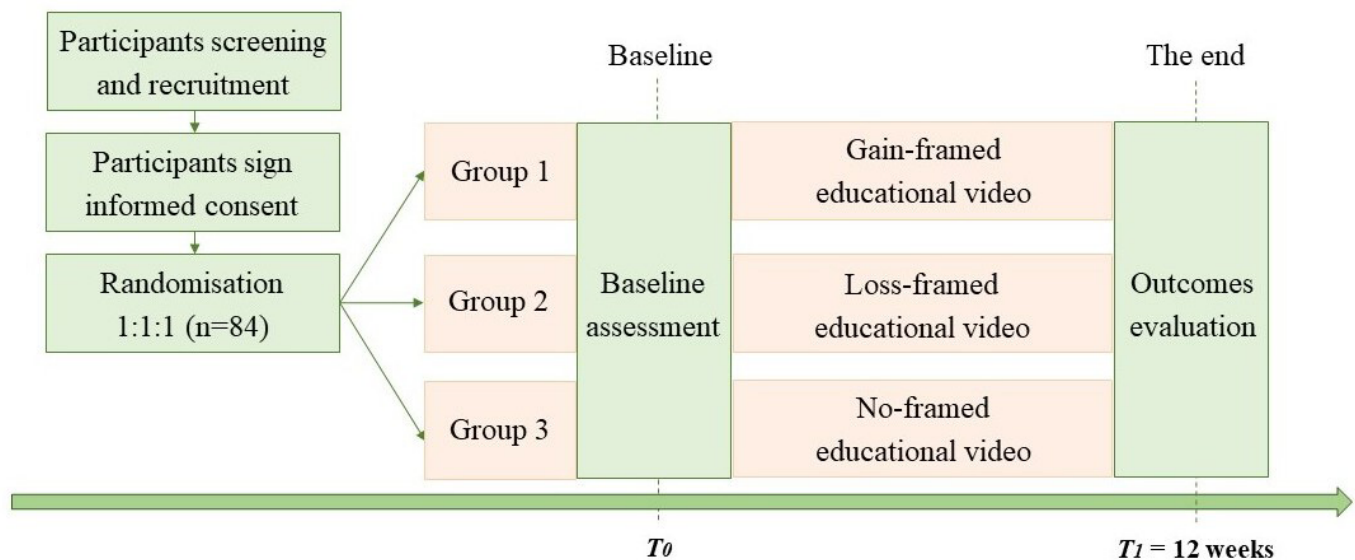
**Figure 1** Illustration of study design.

self-management behaviour, patient activation, knowledge and attitudes, and quality of life in people with type 2 diabetes. In addition, we also aim to explore which frame will be more persuasive, and further to identify the potential moderating effects of patient activation therein. All the participants will be recruited from the endocrinological inpatient setting of a university-affiliated hospital in Changchun, China. A total of 84 participants will be randomly assigned into one of three different groups in a 1:1:1 ratio, and will receive the intervention for 12 weeks. Patients in group 1 will receive gain framing education videos about the self-management skills for type 2 diabetes, patients in group 2 will be provided education videos based on loss framing and patients in group 3 will be given education with no message framing. An illustration of our planned research design has been depicted in figure 1. The trial has been registered at ClinicalTrials. gov, and it has been confirmed to adhere to the Standard Protocol Items: Recommendations for Interventional Trials reporting guidelines.

### Eligibility and recruitment
Participants who will meet the following inclusion criteria will be considered for enrolment in this study: (1) individual with type 2 diabetes was diagnosed clinically under WHO standards; (2) age ≥18 years; (3) diagnosed type 2 diabetes for more than 6 months; (4) HbA1c >7%; (5) able to use a smartphone and have an access to internet at home; (6) proficient in Chinese language; and (7) voluntary participation in the study, and willing to provide informed consent.

Exclusion criteria used will be the following: (1) patients are pregnant or lactating; (2) suffer from combined malignant tumours or severe diabetes complications; (3) have hearing or visual impairment; (4) can perform only limited physical activity; (5) suffer significant cognitive impairment or mental disorders; (6) unavailability of internet access in place of residence and (7) current participants involved in other research projects.

We have a research team that includes experienced endocrinological clinical nurses, endocrinologists and researchers. The eligibility of the potential patients with type 2 diabetes will be carefully evaluated by experienced clinical nurses, and they will introduce patients who meet the inclusion criteria to independent researchers. Thereafter, the independent researcher will present the study in detail to all the participants and invite them to participate in the study. The participants will be asked to sign an informed consent form if they agree to participate in this study.

### Sample size calculation
We have calculated the sample size using the statistical software PASS. For our primary outcome, in order to reach a power of 0.8, a significance level of 0.05, using analysis of variance statistical method, and an estimate effect size of 0.4,[27] a total of 66 participants will be needed, with an equal distribution in three groups and each group will thus have 22 participants. However, after taking into account the 20% rate of dropping out, a total of 84 participants will be required based on calculation using the PASS software, with an average of 28 participants in each group.

### Randomisation, blinding and concealed allocation
Participants will complete the baseline assessment, after they have signed the informed consent form. Thereafter, the participants will be assigned to one of the three groups randomly in a 1:1:1 ratio. A prior randomisation list will be generated by an independent researcher using the statistical software STATA, and patients will be stratified according to high or low patient activation. The random sequence will be concealed in a sealed envelope until the random allocation of the participants has been

fully completed. This assignment will be done by an independent researcher of our team who will not participate in the recruitment process. The researchers who will be collecting the outcome measures will carry it out in a blinded fashion.

## Intervention protocol

The message-framed diabetes self-management informational videos will be delivered as gain-framed for one experimental group (group 1) and loss-framed for the other experimental group (group 2). The control group will receive the standard method of providing health messages about diabetes self-management, which will not contain any particular message framing.

The diabetes self-management content in educational interventions has been designed by endocrinologists, experienced diabetes health education nurses and researchers. The content has been derived from the website of the American Diabetes Association, Guidelines for the prevention and control of type 2 diabetes in China (2017 Edition),[35] and standards of medical care for type 2 diabetes in China 2019,[36] which includes the definition of diabetes, and relevant information about proper diet and exercise, weight control, health teachings about blood glucose monitoring, prevention and identification of hypoglycaemia and hyperglycaemia, foot care, smoking cessation and medication use. The specific intervention arrangements have been shown in online supplemental table 1. Patients in all the three groups will receive equivalent information on diabetes self-management skills, delivered in the form of video, including animation, narrative and text, and only different aspect will be framing of the various outcomes. The gain-framed version will highlight the positive outcomes that can be achieved by adhering to appropriate self-management behaviours, whereas the loss-framed version will address the negative outcomes that may accumulate if the desired behaviours are not followed. For example, for foot care education, the statement in gain-framed group will read as 'If you wear appropriate shoes and socks, which help reduce toe friction, and maintain good foot care, it can definitely help to avoid serious complications such as breakage and blood vessel damage', with a scene showing healthy feet. Its counterpart in the loss-framed version, the statement will be 'If you wear inappropriate shoes or socks, which can increase foot friction, it is possible that poor foot care can increase the risk of breakage, and even lead to serious complications of blood vessel damage', with a picture of an infected and painful foot. In the control group videos, only the self-management skills needed will be emphasised in text and pictures, with no specific message framing.

A total of 90 videos related to diabetes self-management has been designed, with 30 videos for each group, and each video is between 40 and 90 seconds long. The intervention will last for 12 weeks and participants will receive these videos three times a week for the first 6 weeks and two times a week for the next 6 weeks. We will be sending the video to each participant via the mobile communication software WeChat. Each video will follow a specific question about the content of the video, and participants will be asked to answer them to ensure that they are able to watch the video carefully and understand the incorporated contents, which may also facilitate to improve their adherence. The participants who answer the questions correctly will receive a cash reward of 1 Chinese Yuan (RMB), which will be distributed to the participants via WeChat. Moreover, the participants will have the right to request a roll-out at any time.

## Outcome measures

Outcome assessment will be performed by independent investigators who will be unaware of the grouping assignment. The grouping results will be numbered and placed in a sealed envelope. Both the primary and secondary outcome measures will be measured at the baseline and 12 weeks. The summary of outcome measures has been shown in table 1.

The primary outcome will be self-management behaviour in people with type 2 diabetes, which is measured using the Summary of Diabetes Self-care Activities, the most widely used self-assessment tool for diabetes.[37] The secondary outcomes will be self-efficacy for self-management, patient activation, diabetes-related knowledge and attitude, quality of life, fasting blood glucose (FBG) and 2-hour postprandial blood glucose (PBG). Self-efficacy will be measured using the Diabetes Self-efficacy Scale,[38] patient activation will be measured using the Chinese version of the Patient Activation Measurement,[31] diabetes-related knowledge and attitude will be measured using the knowledge and attitude subscale of the simplified Knowledge, Attitude, Behavior (KAB) Evaluation Scale for Self-management of Diabetics.[39] The quality of life will be measured using the Chinese Diabetes Specific Quality of Life Scale.[40] FBG and 2-hour PBG will be obtained from patients' electronic medical records and the various outpatient follow-up records.

Patient engagement, satisfaction and quality of the video will be assessed after the 12-week intervention. Patient engagement will be assessed by the number of questions answered after each video, with more than 75% of questions answered will be considered as good participation. Patient satisfaction will be assessed using a 5-point Likert scale designed for this study. The quality of educational video will be measured by the question: 'In general, to what extent do educational videos focus on the benefits you gain from self-management or the disadvantages of not self-management?' (from 1=emphasised benefits, to 7=emphasised disadvantages).

## Statistical analysis

The statistical analysis of the outcomes will be performed using the 'intention-to-treat' principle. The statistical description of categorical variables will be described as the frequencies and percentages, and the difference

**Table 1** Standard Protocol Items: Recommendations for Interventional Trials diagram for the study

| | Study period | | | |
| --- | --- | --- | --- | --- |
| | Enrolment | Allocation | Post-allocation | Close-out |
| Time point | −t1 | 0 | t1 | t2 |
| Enrolment | | | | |
| Eligibility screen | X | | | |
| Informed consent | | X | X | |
| Randomisation | | X | X | |
| Allocation | | X | X | |
| Interventions | | | | |
| Group 1 | | | | |
| Group 2 | | | | |
| Group 3 | | | | |
| Assessment | | | | |
| Self-management behaviour | | X | X | |
| Self-efficacy | | X | X | |
| Patient activation | | X | X | |
| Diabetes-related knowledge | | X | X | |
| Diabetes-related attitude | | X | X | |
| Quality of life | | X | X | |
| FBG | | X | X | |
| 2-hour PBG | | X | X | |
| Patient engagement | | | X | |
| Satisfaction | | | X | |
| Check of the video | | | X | |

FBG, fasting blood glucose; PBG, postprandial blood glucose; t1, 6 weeks; t2, 12 weeks.

among the three groups will be conducted using the $\chi 2$ test. The continuous variables will be described as mean and SD. Analysis of covariance (ANCOVA) will be used to analyse the differences among the three groups and to further analyse whether the gain frame group or the loss frame group will lead to several advantages. A two-way ANCOVA will be used to analyse the interaction effect between message framing and patient activation level. We will analyse whether there are sociodemographic and clinical data differences between the adherent and non-adherent populations, and also further identify the possible factors that can influence adherence. Statistical significance represents as p-values (two-sided) less than 0.05. SPSS V.26.0 will be used for statistical analysis.

### Patient and public involvement

The involvement of patients and the public played an integral role in this study. During the development of education videos, patients and the public were invited to actively participate in surveys and discussions, thereby helping the research team to effectively design high-quality video text and images based on patients' understanding and preferences. In the pilot study, we had also invited patients to provide constructive feedback, which enabled us to better understand their needs and barriers in accessing the relevant information. We have also invited patients to make recommendations on the possible study design, questionnaire selection and outcome measurement, while considering the burden of intervention.

### Ethics and dissemination

This study was approved by the Ethics Committee of School of Nursing, Jilin University (No. 2020101501). Patients who will be interested in participating in the study will sign an informed consent form. The research results will be published in peer-reviewed publications and reported in international conferences.

### DISCUSSION

Based on the perspective of message framing, this novel study aims to explore the possible effects of gain-framed and loss-framed informational videos on the self-management behaviours, self-efficacy, diabetes-related knowledge and attitude, patient activation and quality of life.

Successful diabetes health education can play an important part in improving self-management behaviour,

promoting quality of life and thereby reducing mortality.[16] While providing health education and training to patients and developing their health behaviours are important parts of healthcare, administering adequate and ongoing health education for such a large number of people with a chronic disease like diabetes remains a huge challenge for the healthcare providers and the whole health service system.[19] Moreover, especially in China, the heavy workload of doctors and nurses makes it difficult for them to spare time to carry out detailed and in-depth strategies to dispense health education among patients. Thus, integrating message frame into diabetes health education is an attempt of low-cost and efficient delivery of health education. Additionally, compared with previous studies that only conducted a single intervention or only measured behavioural intentions,[26 27] our study goes a step further by aiming to conduct the intervention for 12 weeks and will measure actual self-management behaviours.

There are several limitations associated with this planned study. First of all, our study only assesses outcomes after the intervention and is not able to conduct follow-up to determine the long-term effectiveness of the intervention strategy. Second, our home distance education interventions will be limited primarily to patients with smartphones and internet access, which may lead to selection bias. Third, we will only be able to judge whether the patient watches the video through analysing the answers of questions received after the survey, and hence might not necessarily make an accurate judgement.

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