

BMJ Open Effects of an exercise intervention based on the COM-B model among community-dwelling prefrail older adults with diabetes: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Prefrailty is common among community-dwelling older adults with diabetes and can lead to adverse health outcomes. With effective exercise interventions, prefrailty is reversible. However, there is a paucity of evidence regarding the effects of exercise interventions for prefrail older adults with diabetes.

This study presents a study protocol for evaluating the effectiveness of an exercise intervention based on the Capacity, Opportunity and Motivation Behaviour (COM-B) model among community-dwelling prefrail older adults with diabetes.

Methods and analysis Using a randomised controlled trial design, a total of 100 community-dwelling prefrail older adults with diabetes will be allocated to either an intervention or a control group in a 1:1 ratio.

Participants in the intervention group will receive a 16-week multicomponent exercise intervention based on the COM-B model, while those in the control group will receive usual diabetes care and general advice on physical activity. The primary outcome is frailty status, and the secondary outcomes include physical function, quality of life, depressive symptoms, self-efficacy for exercise and fasting blood glucose. Assessments will be conducted at baseline, week 8 and week 16.

Ethics and dissemination This study has been approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University (approval number: K2023-320). The findings will be submitted to a peer-reviewed journal for publication.

Trial registration number ChiCTR2400082831.

INTRODUCTION

The number of people suffering from diabetes is rising, and the proportion of older adults with diabetes relative to the total population with diabetes has reached 34.0%.^{1 2} As an observable global public health issue, diabetes has emerged as an important challenge associated with ageing populations. Previous studies have demonstrated that diabetes is closely associated with frailty.³ According to

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study will be the first randomised controlled trial to assess the effectiveness of a theory-based exercise intervention among community-dwelling prefrail older adults with diabetes.
- ⇒ The application of the Capacity, Opportunity and Motivation Behaviour model will help to identify the key components of behaviour change in relation to exercise.
- ⇒ Due to the nature of the intervention, blinding of the researchers and participants will not be possible.
- ⇒ Loss to follow-up may occur during the 16-week intervention period, which will decrease the power of the study.

the Fried criteria, frailty is defined by the presence of three or more phenotypes, including weakness, unintentional weight loss, slow walking speed, exhaustion and low physical activity.⁴ Prefrailty is defined by the presence of one or two phenotypes and is regarded as an intermediate state between frailty and robustness.⁵ A meta-analysis showed that the prevalence of prefrailty among community-dwelling older adults with diabetes (49.1%) was higher than frailty (20.1%).⁶ Prefrailty has also been found to increase the risk of long-term mortality and cardiovascular events in older adults with diabetes, leading to greater healthcare utilisation.⁷ Moreover, older adults with diabetes in a prefrail state are prone to transition to a frail state.⁸ Notably, prefrailty is potentially reversible and is considered a window of intervention.^{5 9} With appropriate intervention, prefrail individuals are more likely to return to a robust state.¹⁰ Hence, it is necessary to develop effective interventions to prevent or treat frailty in its early stage in older adults with diabetes. Exercise intervention is considered an important aspect of both

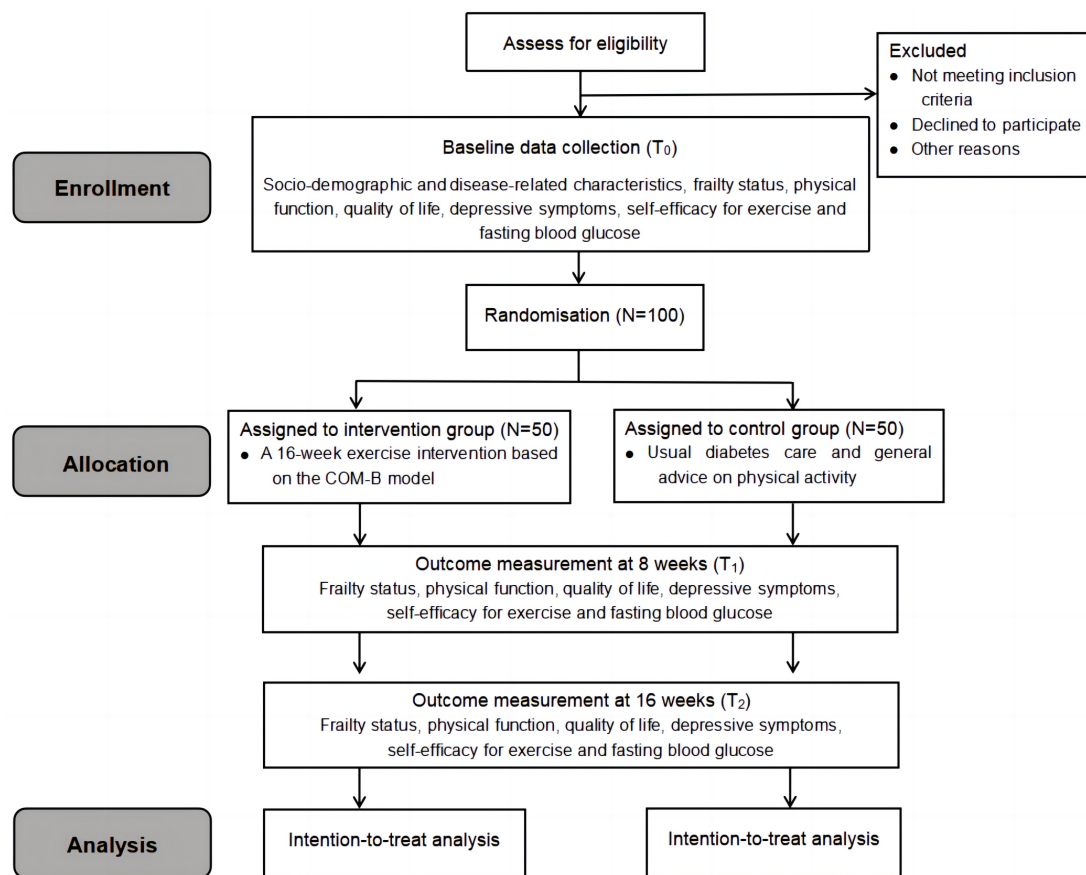


Figure 1 The flow diagram of this study. COM-B, Capacity, Opportunity and Motivation Behaviour.

frailty and diabetes management.¹¹ Evidence shows that exercise interventions have promise in reversing frailty by improving muscle strength, muscle mass and physical function in frail older adults with diabetes.¹² However, limited studies have focused on the effects of exercise interventions in prefrail older adults with diabetes. There is a pressing need to implement exercise interventions as a strategy for managing frailty in prefrail older adults with diabetes.

Previous studies have developed exercise interventions for prefrail older adults and found that exercise interventions have benefits in improving frailty status.⁹ In order to improve older adults' participation in exercise interventions, these studies have used diverse strategies and techniques, such as education, goal setting and supervision of exercise.^{13 14} For older adults, the change and maintenance of exercise behaviour is a complicated process. The Medical Research Council has suggested that theory-based interventions are more effective in behaviour change.¹⁵ A systematic review also recommended developing exercise interventions based on behaviour change theory to achieve long-term benefits of exercise interventions for frail older adults.¹⁶

The Capacity, Opportunity and Motivation Behaviour (COM-B) model is a theoretical framework for understanding and supporting behaviour change, consisting of six components that are hypothesised to drive behaviour change, namely capacity (physical capability and

psychological capability), opportunity (physical opportunity and social opportunity) and motivation (reflective motivation and automatic motivation).¹⁷ The COM-B model offers an overarching framework that encompasses all components related to behaviour change and can help formulate comprehensive strategies and techniques to support behaviour change.¹⁸ Previous studies have shown that the COM-B model is effective in developing exercise interventions to change individuals' beliefs and healthy behaviours in patients with multiple sclerosis and sarcopenic obesity.^{19 20} Therefore, the COM-B model can provide a systematic framework for designing and implementing exercise interventions in prefrail older adults with diabetes to increase the effectiveness of intervention programmes. In this study, the COM-B model will be used to select the components of the intervention. Additionally, under the guidance of this theory model, multiple strategies and techniques will be designed and applied to optimise the exercise intervention programme and provide practical evidence.

This study aims to implement an exercise intervention based on the COM-B model among community-dwelling prefrail older adults with diabetes, and to evaluate its effects on frailty status and other health outcomes. We hypothesise that participants who receive the exercise intervention based on the COM-B model will report better improvement in frailty status, physical function, quality of life, depressive symptoms, self-efficacy for exercise and fasting blood glucose.

Table 1 The schedule of trial enrolment, intervention and assessment

Time point	Baseline (T ₀)	8 weeks intervention (T ₁)	16 weeks intervention (T ₂)
Inclusion/exclusion criteria			
Informed consent	×		
Demographic characteristics	×		
Flexibility exercise	×		
Randomisation and allocation	×		
FFP	×	×	×
SPPB	×	×	×
SF-12	×	×	×
GDS-15	×	×	×
SEE	×	×	×
Fasting blood glucose	×	×	×
Adherence and adverse event		×	×

FFP, Fried Frailty Phenotype; GDS-15, 15-item Geriatric Depression Scale; SEE, Self-Efficacy for Exercise scale; SF-12, Short Form-12; SPPB, Short Physical Performance Battery.

METHODS AND ANALYSIS

Study design, setting and participants

This is a two-arm, parallel design, assessor-blinded, randomised controlled trial that will be conducted in community settings targeting prefrail older adults with diabetes in Chongqing, China. Community sites will be selected based on local community consent and availability of eligible older adults.

The inclusion criteria for participants are: (1) aged ≥ 60 years old; (2) defined as prefrail based on the Fried Frailty Phenotype (FFP) (score 1–2 points); (3) diagnosed with diabetes for at least 6 months and (4) consent to participate. Exclusion criteria for participants are: (1) having severe cognitive impairment (based on previously diagnosed Alzheimer's disease or other types of dementia) or any mental illnesses; (2) being hospitalised in the past 6 months; (3) having severe visual or hearing problems; (4) unable to walk independently (Short Physical Performance Battery (SPPB) score ≤ 6 points or using gait aids) and (5) currently participating in any other intervention programme. The flow diagram of this study can be seen in [figure 1](#). The schedule for trial enrolment, intervention and assessment is presented in [table 1](#).

Sample size

The sample size estimation is based on the primary outcome (frailty status). Assuming an equal sample size

for the two arms, with an estimated two-tailed alpha of 0.05 and G Power of 0.90, calculated with respect to similar previous research on the frailty status of exercise interventions,²¹ the required sample size is 34 participants per arm. In consideration of a 20% attrition rate, with 50 participants in each group, the total number of participants required is 100.

Randomisation and blinding

An independent researcher, who will not be involved in the recruitment of participants or any subsequent contact with potential participants, will randomise all eligible participants using a computer-generated random number sequence with a 1:1 allocation ratio. Each allocated sequence will be recorded on a small card and placed in a sealed envelope. Subsequently, the envelopes will be opened in sequence, following the completion of the baseline questionnaire by the participants. Then the research assistant will inform the participants of the intervention allocation and follow-up procedure.

Given the nature of the exercise intervention and trial design, blinding is not possible for the participants and intervention providers. To reduce the occurrence of measurement bias, the outcome assessors and statisticians will be unaware of the generation of allocation serial numbers and intervention allocation, and will not be involved in the implementation of the intervention.

Intervention

Intervention group

Participants assigned to the intervention group will receive usual diabetes care (regular blood glucose monitoring, and assessment and management of the diabetes treatment plans, etc), and a 16-week exercise intervention based on the COM-B model. The exercise intervention is developed following a comprehensive literature review of exercise intervention studies for prefrail older adults and comprises four components. (1) Preparation: during the initial 3-week period, two health lectures and one exercise instruction session will be held, with each session lasting between 30 and 45 min. The detailed information will be presented in specific instruction manuals and videos, which are delivered by a trained research assistant. (2) Home-based exercise programme: from week 4 to week 15, a 12-week multicomponent home-based exercise intervention programme will be conducted. This programme includes aerobic, resistance, balance and flexibility exercise, delivered three times a week for sessions lasting 40–60 min each ([table 2](#)). (3) Group sessions: at weeks 7, 11 and 16, three face-to-face sessions will be conducted to monitor progress towards exercise goals, address emerging concerns and provide guidance on subsequent steps in the exercise regimen. (4) Follow-up: during the multicomponent home-based exercise intervention period, the WeChat application will be used to disseminate relevant health information and monitor participants' adherence to their exercise plans through weekly reminders. The WeChat application is

Table 2 Description of the multicomponent exercise intervention programme

	Weeks 4–7	Weeks 8–11	Weeks 12–15
Aerobic exercise	Content: older adults choose an aerobic exercise based on their preferences and conditions, such as walking, jogging, dancing, etc Int: RPE 12–14 Time: 20 min	Content: Cf weeks 4–7 Int: RPE 12–14 Time: 25 min	Content: Cf weeks 4–7 Int: RPE 12–14 Time: 30 min
Resistance exercise	Content: elastic band resistance exercise includes seated chest push, elbow flexion, lateral body plank, seated knee lift and standing heel lift Sets: 2 Reps: 8–10 Time: 10 min	Content: Cf weeks 4–7 Sets: 2 Reps: 10–12 Time: 13 min	Content: Cf weeks 4–7 Sets: 3 Reps: 10–12 Time: 16 min
Balance exercise	Content: tandem stance, toe–heel stance and balanced stride walking Int: maximum intensity of tolerance Time: 5 min	Content: Cf weeks 4–7 Int: maximum intensity of tolerance Time: 7 min	Content: Cf weeks 4–7 Int: maximum intensity of tolerance Time: 9 min
Flexibility exercise	Content: shoulder stretching, back stretching and leg stretching Int: discomfort but not pain Time: 5 min	Content: Cf weeks 4–7 Int: discomfort but not pain Time: 5 min	Content: Cf weeks 4–7 Int: discomfort but not pain Time: 5 min

Cf, confer; Int, intensity; Reps, repetitions; RPE, Borg Rating of Perceived Exertion.

a mobile chat software that can quickly send messages, images and videos over the network. In cases where participants are unable to use the WeChat application, propaganda and supervision will be conducted via telephone follow-up.

The intervention programme is designed according to the principles of the COM-B model and is divided into six parts. (1) Psychological capacity: it refers to the knowledge to perform the behaviour. This study will hold health lectures to enhance participants' knowledge of exercise. (2) Physical capacity: it refers to the physical skills to perform the behaviour. This study will hold exercise instruction sessions to improve participants' exercise skills. (3) Physical opportunity: it refers to the physical conditions that support behaviour change. This study can facilitate participants' engagement by providing supportive materials and equipment (such as elastic bands). (4) Social opportunity: it refers to the interpersonal influences that support behaviour change. This study can create a favourable exercise atmosphere through multidimensional support including reminders from group leaders, encouragement from group members and supervision from researchers. (5) Automatic motivation: it refers to the processes that involve emotional reactions, desires and impulses. This study can encourage participants to be active and reinforce their motivation by setting goals, sharing experiences of role models and awarding medals. (6) Reflective motivation: it refers to the self-conscious planning and evaluation. This study can encourage participants to reflect on their behaviour through goal evaluation, exercise introspection and summary. Details of the exercise intervention based on the COM-B model are shown in [table 3](#).

Control group

Participants in the control group will receive usual diabetes care and will be invited to attend two 45-minute health lectures on the effects of exercise on frailty and general exercise instructions. They maintain their normal daily activities and will be recommended to participate in at least 150 min of moderate to high-intensity exercise per week. Additionally, telephone calls will be conducted on a monthly basis with participants for the purpose of monitoring their condition and responding to any queries they may have.

Assessments

Data collection will be performed at three time points during the study: T_0 (the baseline), T_1 (8 weeks) and T_2 (16 weeks). The assessment measures consist of socio-demographic and disease-related characteristics, frailty status, physical function, quality of life, depressive symptoms, self-efficacy for exercise and fasting blood glucose. The selection of outcome measurements in this study is informed by expert consultation. The sociodemographic and disease-related characteristics of the participants, such as age, gender, marital status, level of education, duration of diabetes, diabetes treatment programme and number of comorbidities, will be collected at baseline using a self-made questionnaire.

The primary outcome of the study is the frailty status, which will be measured by the FFP.⁴ It includes five components: reduced grip strength, slow walking speed, unintentional weight loss, self-reported exhaustion and low physical activity. Each component is classified as present (score of 1) or absent (score of 0), with a score of

Table 3 The exercise intervention based on the COM-B model

COM-B component	Theme	Target	Content	Time (weeks)
Capacity				
Psychological capacity	Health lecture	To strengthen older adults' understanding of prefrailty and to enhance their knowledge of exercise	Basic knowledge of prefrailty ▶ Explaining the basic knowledge of prefrailty, such as definition, risk factors and impact on diabetes ▶ Conducting quizzes on prefrailty knowledge and distributing a brochure	1
			Knowledge of exercise ▶ Explaining the benefits of exercise, pre-exercise assessment, recommended exercise modalities and the cautions of exercise for prefrail older adults with diabetes ▶ Conducting quizzes on exercise knowledge	2
Physical capacity	Exercise instruction	To enhance older adults' exercise skills and capacity	Teaching and demonstrating the multicomponent exercise programme, sharing exercise instructional videos, dividing exercise groups and choosing group leaders	3
			Guiding older adults to make appropriate transitions in exercise duration and intensity according to the principle of progressive exercise	3, 7, 11
Opportunity				
Physical opportunity	Provision of exercise resources	To facilitate the engagement of older adults in exercise with supportive materials and equipment	Distributing multicomponent exercise instructional atlases, exercise self-monitoring diaries and elastic bands	3
Social opportunity	Group support	To form a supportive behaviour environment for long-term exercise	Group leaders supervise group members, and group members remind each other to complete the 12-week multicomponent home-based exercise programme	4–16
	Professional supervision	To create a positive atmosphere for exercise and reduce barriers to behaviour change	On-line monitoring ▶ Reminding older adults to exercise and fill out self-monitoring diaries on time through WeChat ▶ Recognising the efforts of those who have completed their exercise plans and tracking the reasons for those who have not ▶ Summarising every week's exercise situation into a weekly exercise report and presenting it via WeChat	4– 16
			Off-line instruction ▶ Checking on the completion of self-monitoring diaries ▶ Identifying the obstacles that prevent those who do not perform well and proposing solutions	7, 11, 16
Motivation				
Automatic motivation	Goal setting	To reinforce older adults' exercise motivation	Assisting older adults in setting exercise goals for different exercise periods	3
	Experience sharing of role models	To enhance older adults' self-confidence and belief in exercise	Inviting older adults with good exercise adherence as role models to share their experiences of consistent exercise	7

Continued

Table 3 Continued

COM-B component	Theme	Target	Content	Time (weeks)
	Medals awarding	To stimulate older adults' exercise intentions and positive emotions	Giving medals and praise to older adults according to their exercise performance	7, 11, 16
Reflective motivation	Goal evaluation	To prompt reflection among older adults on their adherence to exercise	Instructing older adults to self-evaluate the accomplishment of exercise goals and dynamically adjusting exercise plans based on their feedback	7, 11, 16
	Exercise introspection	To optimise older adults' exercise behaviour	Encouraging older adults to talk about their shortcomings and problems in the exercise process and discuss ways to improve	11
	Summary	To encourage older adults to keep exercising	Guiding older adults to review their exercise process, summarise their feelings and experiences, and encouraging them to continue exercising	16

COM-B, Capacity, Opportunity and Motivation Behaviour.

0 considered robust, 1–2 as prefrailty and ≥ 3 as frailty.⁴ In this study, the detailed definition of the FFP is as follows:

- ▶ Reduced grip strength: this is measured by a hand dynamometer, with thresholds varying by Body Mass Index (BMI). For men, low grip strength is indicated by a measurement of less than 29 kg for a BMI ≤ 24 kg/m², ≤ 30 kg for a BMI between 24.1 and 28 kg/m² or ≤ 32 kg for a BMI > 28 kg/m². For women, thresholds are ≤ 17.1 kg for BMI ≤ 23 kg/m², ≤ 17.3 kg for BMI between 23.1 and 26 kg/m², ≤ 18 kg for BMI between 26.1 and 29 kg/m² or ≤ 21 kg for BMI > 29 kg/m².
- ▶ Slow walking speed: this criterion is met if participants' walking time of 4.57 m is lower than the corresponding standard based on different sexes and body heights (men: height ≤ 173 cm, ≥ 7 s; height > 173 cm, ≥ 6 s; women: height ≤ 159 cm, ≥ 7 s; height > 159 cm, ≥ 6 s).
- ▶ Unintentional weight loss: this criterion is met if participants lose 4.5 kg or 5% of their body weight unintentionally over the past year.
- ▶ Self-reported exhaustion: this criterion is met if participants report experiencing exhaustion or fatigue for 3 or more days during the week preceding the assessment.
- ▶ Low physical activity: participants meet this criterion if their weekly physical activity expenditure is below 383 kcal for men and 270 kcal for women, as assessed by the Chinese version of the International Physical Activity Questionnaire-Short Form.²²

The secondary outcomes include physical function, quality of life, depressive symptoms, self-efficacy for exercise and fasting blood glucose. Physical function will be assessed using the SPPB.²³ The SPPB has been shown to be a valid instrument for measuring physical function in community-dwelling older adults.²⁴ Quality of life will be determined by the Short Form-12 (SF-12).²⁵ The SF-12 has been validated for use in the Chinese elderly population,

demonstrating Cronbach's alpha of 0.91.²⁶ Depressive symptoms will be measured by the 15-item Geriatric Depression Scale (GDS-15).²⁷ The scale comprises 15 items, with a 'YES' or 'NO' response format. Its total scores range from 0 to 15, with higher scores indicating more depressive symptoms. A total score of ≥ 5 is defined as significant depressive symptoms.²⁸ The Chinese version of the GDS-15 has acceptable internal consistency, with a Cronbach's alpha of 0.74.²⁹ Self-efficacy for exercise will be assessed using the Self-Efficacy for Exercise scale (SEE).³⁰ It consists of 9 items, each rated on an 11-point Likert scale from 0 (not confident) to 10 (very confident). The total score ranges from 0 to 90, with higher scores indicating a stronger sense of exercise self-efficacy. The Chinese version of the SEE has an internal consistency of 0.75.³¹

In addition, adherence to the programme will be assessed through analysis of the activity diaries completed by the participants. Reasons for dropout, including adverse events, medical problems and participant decisions, will also be collected. Any adverse event, such as muscular soreness, falls or injuries, will also be recorded by the research team.

Data analysis

Data analysis will be performed by IBM SPSS V.25.0. Demographic data will be summarised and presented with appropriate descriptive statistics, including frequency distributions, means and SD, medians and interquartile ranges. Skewed variables will be appropriately transformed before inclusion in the inferential analysis. To compare baseline characteristics between the two groups, the t-test or Wilcoxon rank-sum test will be employed for continuous variables, and χ^2 or Fisher's exact test will be used for categorical variables. The intention-to-treat principle will be adopted in the outcome analysis, and the missing data will be imputed by the multiple imputation

method. The generalised estimating equations model will be used to compare the differential changes in each outcome between the two arms across time points. All statistical tests will be two-sided, with a significance level of 0.05.

Patient and public involvement

Patients or the public were not involved in planning the study design or leading the clinical trial.

Ethics and dissemination

The study protocol (registration number: ChiCTR2400082831; registration date: 9 April 2024) was reviewed and approved by the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University (approval number: K2023-320). This study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials guidelines. During the study, participants' information will be kept confidential and informed consent (online supplemental material) will be signed after participants have agreed to participate in this study. The entire process will be conducted in strict accordance with the principles of voluntariness, confidentiality and non-harm. All participants will be informed that they may refuse to participate in the study and may withdraw at any time without any penalty. Study results will be disseminated through publication in a peer-reviewed journal and presentation at conferences.

DISCUSSION

Affected by the progression of diabetes, prefrail older adults with diabetes are at risk of developing frailty.⁸ As prefrailty has great reversibility,⁹ it is crucial to develop effective exercise intervention strategies to delay frailty in prefrail older adults with diabetes. Nevertheless, the current evidence base for exercise intervention in this population remains neglected. To address this research gap, our study develops an exercise intervention based on the COM-B model to provide insight for a potentially beneficial strategy.

To the best of our knowledge, this study will be the first randomised controlled trial to assess the effectiveness of a theory-based exercise intervention among community-dwelling prefrail older adults with diabetes. This study is based on the COM-B model, which identifies the key components of behaviour change in relation to exercise. It also employs a range of behaviour change techniques that are consistent with this theoretical framework. This mapping process establishes a refined pathway linking behavioural change mechanisms to appropriate interventions. Additionally, the proposed exercise intervention programme, resulting from an evidence-based literature review, is individualised and takes into account the participants' needs and preferences.

If the intervention shows positive results, it will help to fill current knowledge gaps and contribute to clinical practice. Moreover, at the individual level, the

exercise intervention based on the COM-B model may help improve frailty status and other health outcomes in community-dwelling prefrail older adults with diabetes. At the organisational level, the findings will provide information on effective forms of exercise intervention for prefrail older adults with diabetes, enabling healthcare professionals to make evidence-based decisions about frailty prevention and management.

There are some limitations that need to be considered. First, due to the nature of the intervention, blinding of the participants and intervention providers will not be possible, which may introduce performance bias. However, outcome assessors will be blinded to reduce the amount of bias in the evaluation of the intervention's effects. Second, a reassessment will be conducted at 16 weeks when the intervention completes. Loss to follow-up may occur during this period, which will decrease the power of the study. To address this potential problem, a 20% attrition rate is considered in the sample size calculation. Intention-to-treat analysis will also be used in the data analysis.

In conclusion, this study protocol will provide insight into the effectiveness of an exercise intervention based on the COM-B model for community-dwelling prefrail older adults with diabetes. The proposed exercise intervention program has a strong theoretical base. The findings of this study are expected to contribute meaningful knowledge about the beneficial effects of exercise interventions based on the COM-B model, which will improve health outcomes in prefrail older adults with diabetes. If found to be effective, this exercise intervention based on the COM-B model will contribute to the refinement of subsequent steps in the design and procedures of exercise interventions for prefrail older adults with diabetes. It will also provide information on the feasibility of exercise intervention in primary healthcare clinical practice.

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Contributors WXW and JQ conceived and designed the study, wrote the first version of the manuscript and approved the final version of the manuscript. LNK participated in and supervised the study design, read and revised the manuscript, and approved the final version of the manuscript. JY reviewed the manuscript and approved the final version. LC revised the manuscript and approved the final version. YZ revised the manuscript and approved the final version. TTW revised the manuscript and approved the final version. LNK takes responsibility for the overall content as the guarantor.

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Competing interests WXW, JQ, LNK, LC, YZ and TTW are affiliated with Chongqing Medical University, which provided funding for this study. These authors declare that the funder had no influence on the study design and results interpretation. JY is affiliated with The First Affiliated Hospital of Chongqing Medical University and

declares no competing interests related to this study. All other authors have no competing interests to declare.

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